NATIONAL TOXICOLOGY PROGRAM **Technical Report Series** No. 269



(Technical-Grade 1,3-Dichloropropene [CAS No. 542-75-6] Containing 1.0% Epichlorohydrin as a Stabilizer)

IN F344/N RATS AND B6C3F1 MICE

(GAVAGE STUDIES)

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service National Institutes of Health

NATIONAL TOXICOLOGY PROGRAM

The National Toxicology Program (NTP), established in 1978, develops and evaluates scientific information about potentially toxic and hazardous chemicals. This knowledge can be used for protecting the health of the American people and for the primary prevention of disease. By bringing together the relevant programs, staff, and resources from the U.S. Public Health Service, DHHS, the National Toxicology Program has centralized and strengthened activities relating to toxicology research, testing and test development/validation efforts, and the dissemination of toxicological information to the public and scientific communities and to the research and regulatory agencies.

The NTP is made up of four charter DHHS agencies: the National Cancer Institute (NCI), National Institutes of Health; the National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health; the National Center for Toxicological Research, Food and Drug Administration; and the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control. In July 1981, the Carcinogenesis Bioassay Testing Program, NCI, was transferred to the NIEHS.

NTP TECHNICAL REPORT

ON THE

TOXICOLOGY AND CARCINOGENESIS STUDIES OF TELONE II•

(Technical-Grade 1,3-Dichloropropene [CAS No. 542-75-6] Containing 1.0% Epichlorohydrin as a Stabilizer)

IN F344/N RATS AND B6C3F1 MICE

(GAVAGE STUDIES)



NATIONAL TOXICOLOGY PROGRAM P.O. Box 12233 Research Triangle Park, NC 27709

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NOTE TO THE READER

These studies are designed and conducted to characterize and evaluate the toxicologic potential, including carcinogenic activity, of selected chemicals in laboratory animals (usually two species, rats and mice). Chemicals selected for testing in the NTP Carcinogenesis Program are chosen primarily on the bases of human exposure, level of production, and chemical structure. Selection per se is not an indicator of a chemical's carcinogenic potential. Negative results, in which the test animals do not have a greater incidence of cancer than control animals, do not necessarily mean that a test chemical is not a carcinogen, inasmuch as the experiments are conducted under a limited set of conditions. Positive results demonstrate that a test chemical is carcinogenic for animals under the conditions of the test and indicate that exposure to the chemical has the potential for hazard to humans. The determination of the risk to humans from chemicals found to be carcinogenic in animals requires a wider analysis which extends beyond the purview of this study.

Five categories of interpretative conclusions were adopted for use in June 1983 in the Technical Reports series to specifically emphasize consistency and the concept of actual evidence of carcinogenicity. For each definitive study result (male rats, female rats, male mice, female mice), one of the following quintet will be selected to describe the findings. These categories refer to the strength of the experimental evidence and not to either potency or mechanism.

- Clear Evidence of Carcinogenicity is demonstrated by studies that are interpreted as showing a chemically related increased incidence of malignant neoplasms, studies that exhibit a substantially increased incidence of benign neoplasms, or studies that exhibit an increased incidence of a combination of malignant and benign neoplasms where each increases with dose.
- Some Evidence of Carcinogenicity is demonstrated by studies that are interpreted as showing a chemically related increased incidence of benign neoplasms, studies that exhibit marginal increases in neoplasms of several organs/tissues, or studies that exhibit a slight increase in uncommon malignant or benign neoplasms.
- Equivocal Evidence of Carcinogenicity is demonstrated by studies that are interpreted as showing a chemically related marginal increase of neoplasms.
- No Evidence of Carcinogenicity is demonstrated by studies that are interpreted as showing no chemically related increases in malignant or benign neoplasms.
- Inadequate Study of Carcinogenicity demonstrates that because of major qualitative or quantitative limitations, the studies cannot be interpreted as valid for showing either the presence or absence of a carcinogenic effect.

Additionally, the following concepts (as patterned from the International Agency for Research on Cancer Monographs) have been adopted by the NTP to give further clarification of these issues:

The term *chemical carcinogenesis* generally means the induction by chemicals of neoplasms not usually observed, the earlier induction by chemicals of neoplasms that are commonly observed, or the induction by chemicals of more neoplasms than are generally found. Different mechanisms may be involved in these situations. Etymologically, the term *carcinogenesis* means induction of cancer, that is, of malignant neoplasms; however, the commonly accepted meaning is the induction of various types of neoplasms or of a combination of malignant and benign neoplasms. In the Technical Reports, the words *tumor* and *neoplasm* are used interchangeably.

This study was initiated by the National Cancer Institute's Carcinogenesis Bioassay Program, now part of the National Institute of Environmental Health Sciences, National Toxicology Program. The studies described in this Technical Report have been conducted in compliance with NTP chemical health and safety requirements and must meet or exceed all applicable Federal, state, and local health and safety regulations. All NTP toxicology and carcinogenesis studies are subjected to a data audit before being presented for peer review.

Although every effort is made to prepare the Technical Reports as accurately as possible, mistakes may occur. Readers are requested to identify any mistakes so that corrective action may be taken. Further, anyone who is aware of related ongoing or published studies not mentioned in this report is encouraged to make this information known to the NTP. Comments and questions about the National Toxicology Program Technical Reports on Toxicology and Carcinogenesis Studies should be directed to Dr. J.E. Huff, National Toxicology Program, P.O. Box 12233, Research Triangle Park, NC 27709 (919-541-3780).

These NTP Technical Reports are available for sale from the National Technical Information Service, U.S. Department of Commerce, 5285 Port Royal Road, Springfield, VA 22161 (703-487-4650). Single copies of this Technical Report are available without charge (and while supplies last) from the NTP Public Information Office, National Toxicology Program, P.O. Box 12233, Research Triangle Park, NC 27709.

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TELONE II[•]

$ClCH = CH - CH_2Cl$

(Technical-Grade 1,3-Dichloropropene [CAS No. 542-75-6] Containing 1.0% Epichlorohydrin as a Stabilizer)

C₃H₄Cl₂ Mol. Wt. 110.98

Synonyms: cis, trans-1,3-Dichloropropene; D-D^{*}Soil Fumigant; Telone^{*}Soil Fumigants; Vorlex^{*}Soil Fumigants

ABSTRACT

Toxicology and carcinogenesis studies of Telone II^{\circ} (a soil fumigant containing approximately 89% *cis-* and *trans-*1,3-dichloropropene, 2.5% 1,2-dichloropropane, 1.5% of a trichloropropene isomer, and 1.0% epichlorohydrin) were conducted by administering the commercial-grade formulation in corn oil by gavage to groups of 52 male and 52 female F344/N rats at doses of 0, 25, or 50 mg/kg and to groups of 50 male and 50 female B6C3F₁ mice at doses of 0, 50, or 100 mg/kg. Doses were administered three times per week for 104 weeks. Ancillary studies were conducted in which dose groups containing five male and five female rats were killed after receiving Telone II^{\circ} for 9, 16, 21, 24, or 27 months.

Mean body weights of high dose male rats were about 5% lower than those for the vehicle control and low dose male rats; no differences in body weights were observed among groups of female rats. Survival was comparable for the different groups of male and female rats. For male and female mice, the dosed groups initially weighed 6%-22% less than did the vehicle controls; the weight differential decreased to 5%-9% by the end of the studies. Twenty-five vehicle control male mice died during weeks 48-51 from suppurative inflammation of the heart (myocarditis). At the end of the studies, the survival of male mice was as follows: vehicle control, 8/50; low dose, 28/50; high dose, 31/50. Survival of female mice was lower (P < 0.05) in the high dose group than in the vehicle controls (46/50; 45/50; 36/50).

The primary organs affected were the forestomach (rats and mice), urinary bladder (mice), lung (mice), and liver (rats). Compound-related nonneoplastic lesions included basal cell or epithelial hyperplasia of the forestomach (rats and mice), epithelial hyperplasia of the urinary bladder (mice), and kidney hydronephrosis (mice). Neoplastic lesions associated with administration of Telone II^e included squamous cell papillomas of the forestomach (male rats: 1/52; 1/52; 9/52; female rats: 0/52; 2/52; 3/52; female mice: 0/50; 1/50; 2/50), squamous cell carcinomas of the forestomach (male rats: 0/52; 0/52; 4/52; female mice: 0/50; 0/50; 2/50), transitional cell carcinomas of the urinary bladder (female mice: 0/50; 8/50; 21/48), alveolar/bronchiolar adenomas (female mice: 0/50; 3/50; 8/50), and neoplastic nodules of the liver (male rats: 1/52; 6/52; 7/52).

Although the study in male mice was considered inadequate due to the deaths at weeks 48-51 of 25/50 vehicle control animals, 2/50 of the high dose males had transitional cell carcinomas of the urinary bladder. Furthermore, increases were seen in the incidences of alveolar/bronchiolar neoplasms of the lung (1/50; 13/50; 12/50) and of squamous cell papillomas of the forestomach (0/50; 2/50; 3/50). These findings plus the finding of nonneoplastic lesions in two of these organs (basal cell or epithelial hyperplasia of the forestomach: 0/50; 0/50; 4/50; epithelial hyperplasia of the urinary bladder: 0/50; 9/50; 18/50) suggest that Telone II[®] may have been responsible for the development of these lesions in male mice.

Development of lesions in the forestomach (basal cell hyperplasia and squamous cell papilloma) was observed to be time dependent. The results of the scheduled kills supported the findings of the carcinogenesis studies. When the results from the scheduled kills at all time points were pooled with those of the 24-month carcinogenesis studies, the incidences were as follows: basal cell or epithelial hyperplasia of the forestomach--male rats: 3/77; 13/77; 31/77; female rats: 1/75; 5/77; 35/77; squamous cell papilloma of the forestomach--male rats: 1/77; 1/77; 13/77; female rats: 0/75; 2/77; 8/77; neoplastic nodules of the liver--male rats: 1/77; 6/76; 8/77; female rats: 6/75; 8/77; 12/77.

cis- and trans-1,3-Dichloropropene are the principal components (89%) in Telone II[®], but the 1.0% epichlorohydrin, a direct-acting mutagen and carcinogen added as a stabilizer, may have influenced the development of forestomach lesions.

1,3-Dichloropropene was mutagenic in *Salmonella typhimurium* strains TA98, TA100, and TA1535 without metabolic activation and in TA100 and TA1535 with metabolic activation by Aroclor-induced male Sprague-Dawley rat and Syrian hamster liver S9. No mutagenic response was seen in TA1537. Sex-linked recessive lethal mutations were observed in *Drosophila melanogaster*, and 1,3-dichloropropene did not induce reciprocal translocations in *D. melanogaster*.

A data audit was conducted on the Telone II[•] 2-year carcinogenesis studies in rats and mice and the ancillary studies in rats. Except for the already known problem of survival of male vehicle control mice, no other discrepancies or problems that would compromise the validity of the findings or alter the interpretations of these studies were found.

Under the conditions of these gavage studies, there was *clear evidence of carcinogenicity*^{*} for male F344/N rats, as indicated by Telone II[•]-related increased incidences of squamous cell papillomas and carcinomas of the forestomach, as well as an increased incidence of neoplastic nodules of the liver. In female F344/N rats, there was some evidence of carcinogenicity because Telone II[•] caused an increased incidence of squamous cell papillomas of the forestomach. The experiment in male B6C3F1 mice was considered to be an *inadequate study of carcinogenicity* because of reduced survival in the vehicle control group. However, there was some indication in the male mice of Telone II[•]-related increases of transitional cell carcinomas of the urinary bladder, squamous cell papillomas of the forestomach, and alveolar/bronchiolar adenomas and carcinomas of the lung. There was *clear evidence of carcinogenicity* for female B6C3F1 mice, since Telone II[•] caused increased incidences of alveolar/bronchiolar adenomas of cell papillomas or carcinomas of the forestomach in the female mice. Telone II[•]-related nonneoplastic lesions included basal cell or epithelial cell hyperplasia in the forestomach of male and female rats and male and female mice and epithelial hyperplasia of the urinary bladder in male and female mice.

^{*}Categories of evidence of carcinogenicity are defined in the Note to the Reader on page 2.

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The NTP Technical Report on the Toxicology and Carcinogenesis Studies of Telone II[®] is based on 2year studies that began in February 1977 (rats) and July 1978 (mice) and ended in February 1979 (rats) and July 1980 (mice) at Frederick Cancer Research Center. Ancillary studies in rats were conducted between February 1977 and May 1979; the results are included in this Technical Report.

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The members of the Peer Review Panel who evaluated this Technical Report on July 27, 1984, are listed below. Panel members serve as independent scientists, not as representatives of any institution, company, or governmental agency. In this capacity, Panel members have five major responsibilities: (a) to ascertain that all relevant literature data have been adequately cited and interpreted, (b) to determine if the design and conditions of the NTP studies were appropriate, (c) to ensure that the Technical Report presents the experimental results and conclusions fully and clearly, (d) to judge the significance of the experimental results by scientific criteria, and (e) to assess the evaluation of the evidence of carcinogenicity and other observed toxic responses.

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^{*}Unable to attend meeting

SUMMARY OF PEER REVIEW COMMENTS ON THE TOXICOLOGY AND CARCINOGENESIS STUDIES OF TELONE II[®]

The review meeting for the Technical Report on the Toxicology and Carcinogenesis Studies of Telone II[®] began at 9 a.m., July 27, 1984, in the Conference Center, Building 101, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina. Members of the Subcommittee were: Drs. Jerry Hook (Chair), Curtis Harper, and James Swenberg. Members of the Panel of Experts were: Mr. Louis Belicksy and Drs. Devra Davis, Seymour Friess, Thomas Jones, Richard Kociba, David Kotelchuck, Tom Slaga, Steven Tannenbaum, Bruce Turnbull, and John Van Ryzin. Drs. Hook, Slaga, and Swenberg were unable to attend this meeting. Dr. Harper served as Acting Chair.

Dr. Turnbull, a principal reviewer, agreed with the conclusions of the Technical Report. He stated that although the design and conduct of the study were less than fully adequate, especially the lack of appropriate randomization and the delay of more than a month in carrying out a scheduled 15-month kill, these drawbacks were well documented and did not compromise the findings.

As a second principal reviewer, Dr. Jones agreed with the findings; however, he questioned the appropriateness of including in the conclusion mention of probable association of Telone II[®] with a number of tumors in male mice, since this study was considered inadequate because of markedly reduced survival in the vehicle controls.

As a third principal reviewer, Dr. Kotelchuck basically agreed with the conclusions. He said that the failure to randomize initial weights of the mice was an avoidable and potentially serious error, but he did not think it affected the carcinogenicity results. He shared Dr. Jones' concern about association of the chemical with increased incidences of tumors for male mice, since this was judged to be an inadequate study. However, since there were dose trends for some tumors, Dr. Kotelchuck proposed the following conclusion for male mice: "The experiment in male B6C3F1 mice was an inadequate study of carcinogenicity because of reduced survival in the vehicle control group. However, there was some indication in the male mice of Telone II®-related increases of squamous cell papillomas of the forestomach and transitional cell carcinomas of the urinary bladder." Dr. Jones and Mr. Beliczky thought that only the first sentence should be included; Dr. Tannenbaum said both sentences were appropriate because the carcinogenicity findings were consistent with those found in female mice and in rats of each sex. Dr. Kotelchuck also suggested not making a reference to the lung tumors, since their incidences fell within the range, albeit the upper limit, of historical control rates. Dr. J. Haseman, NIEHS, argued for retaining mention of the lung tumors based on their being at the upper limit of the historical control range, approximately double the mean historical control rate, and noted that a significant increase was seen in the incidence of lung tumors in female mice. Dr. Friess and Dr. Van Ryzin supported the recommendations, including the comment on the lung tumors.

Dr. Harper asked for a vote on the proposed single sentence conclusion statement for male mice: "The experiment in male B6C3F₁ mice was considered to be an *inadequate study of carcinogenicity* because of reduced survival in the vehicle control group." There were two affirmative votes (Drs. Jones and Kociba). Dr. Harper then requested a vote on the conclusion that would include this sentence followed by "However, there was some indication in the male mice of Telone II®-related increases of transitional cell carcinomas of the urinary bladder, squamous cell papillomas of the forestomach, and alveolar/bronchiolar adenomas and carcinomas of the lung." The two-sentence conclusion for the male mouse study was approved with seven affirmative votes.

Dr. Kociba and Dr. Davies asked that either an appendix that would include the hematology and clinical chemistry data or an availability statement be added. [A comment was added on page 34 that these data are available upon request.] The Panel discussed the possible carcinogenic effects of the 1.0% epichlorohydrin included as a stabilizer with the technical-grade 1,3-dichloropropene. Dr. B. Schwetz, NTP, noted that the 1,3-dichloropropene free of epichlorohydrin would not be stable enough to use in a study. Dr. Tannenbaum added that epichlorohydrin is an alkylating agent and a carcinogen in animals. Dr. Kotelchuck stated that the epichlorohydrin probably contributed to the stomach tumors; yet he felt it was important to test the chemical formulation to which humans are exposed. Dr. J. Huff, NTP, observed that the Telone II® formulation induced neoplasms at other sites in addition to those where epichlorohydrin has been reported to induce tumors, although an additive or enhancing interactive effect cannot be completely discounted.

Dr. Turnbull moved that the Technical Report on the toxicology and carcinogenesis studies of Telone II® be accepted with the revised conclusion for male mice and with other modifications as discussed. Dr. Kotelchuck seconded the motion, and the report was approved by eight affirmative votes. There was one abstention (Dr. Kociba).

I. INTRODUCTION

Chemical Background Production and Use Fate in Soil Residue Analysis of Well Water Metabolism and Disposition Toxicity of Telone II^o and 1,3-Dichloropropene in Animals Toxicity of D-D^o in Animals Toxicity and Exposure in Humans Mutagenicity Studies Carcinogenicity Studies Rationale for Testing

TELONE II[•]

$ClCH = CH - CH_2Cl$

(Technical-Grade 1,3-Dichloropropene [CAS No. 542-75-6] Containing 1.0% Epichlorohydrin as a Stabilizer)

C₃H₄Cl₂

Mol. Wt. 110.98

Synonyms: cis, trans-1,3-Dichloropropene; D-D[•]Soil Fumigant; Telone[•]Soil Fumigants; Vorlex[•]Soil Fumigants

Chemical Background

1,3-Dichloropropene, the main ingredient of Telone II^{\bullet}, was introduced as a commercial fumigant in 1955 by the Dow Chemical Company (Berry et al., 1980). A preparation containing 1,3-dichloropropene and 1,2-dichloropropane was marketed by Shell Oil Company under the name D-D^{\bullet} (Maddy et al., 1982; Parker et al., 1982).

1,3-Dichloropropene, a mixture of *cis* and *trans* isomers, is a clear, light straw-colored liquid with a penetrating, irritating, chloroform-like odor. The physical properties of a *cis/trans* mixture depend on the ratio of the isomers. 1,3-Dichloropropene is relatively insoluble in water (*trans* isomer, 0.28 g/100 ml water at 20° C; Metcalf, 1978) and is soluble in ether and benzene (Weast, 1976).

Production and Use

Telone II[•] is widely used in agriculture as a soil fumigant for parasitic plant nematodes (De Lorenzo et al., 1977; Maddy et al., 1982). Before 1978, about 25 million kilograms of 1,3-dichloropropene were produced annually in the United States (Flessel et al., 1978). In California, over one million kilograms of pesticides containing 1,3-dichloropropene were used in 1971 (De Lorenzo et al., 1977). In Italy, over 2 million kilograms were produced in 1972. Current production data are not available.

1,3-Dichloropropene formulations are usually applied undiluted to the soil around vegetable and tobacco crops to control nematodes (Flessel et al., 1978). 1,3-Dichloropropene is believed to act by chemically combining with some nucleophilic center (e.g., sulfhydryl, amine, or hydroxyl groups) in an essential enzyme in the nematode (Metcalf, 1978). As with other fumigants, the performance of 1,3-dichloropropene as a nematocide is dependent on the vapor pressure; diffusion coefficient; the distribution of the fumigant through air, water, and solid phases of the soil; and the temperature and moisture content of the soil.

Fate in Soil

1,3-Dichloropropene was reported to have a halflife in soil of about 10 days (Laskowski et al., 1982). In another study (Van Dijk, 1974), the estimated rates of disappearance of 1.3-dichloropropene isomers under various soil, temperature, and pH conditions differed widely depending on the methods of analyses. When the disappearance of the parent compounds was followed by gas chromatography, the estimated half-lives for cis- and trans-1,3-dichloropropene ranged from 3 to 37 days. When Cl⁻ release resulting from the degradation of 1,3-dichloropropene was followed by potentiometric titration, the estimated half-life for cis- and trans-1.3-dichloropropene was as long as 23 weeks. The cis- and trans-3-chloroallyl alcohols, presumed degradation products of the corresponding 1.3-dichloropropenes, were biodegraded more rapidly in soil. At 15° C in claycontaining soils, the average half-life for the 3chloroallyl alcohols was 1-2 days.

Since 1,3-dichloropropene is volatile and insoluble in water, losses are more likely to occur from volatilization than from leaching. The decomposition rate of 1,3-dichloropropene in loam soil was determined to be about 3.5% per day, whereas the decomposition rate in sandy and peat soils was less than 1% per day (Leistra, 1970). cis- and trans-1,3-Dichloropropene are hydrolyzed in wet soil to cis- and trans-3-chloroallyl alcohol (Castro and Belser, 1966). Studies under laboratory and outdoor conditions (Roberts and Stoydin, 1976) confirmed that 3chloroallyl alcohols were the major degradation products and showed that cis- and trans-3chloroacrylic acids were minor products.

Despite the volatility and degradability of 1.3dichloropropene, both the cis and trans isomers were detected several months after being applied to soils (Leistra, 1970; Williams, 1968). Twelve weeks after labeled cis- or trans-1.3dichloropropene was applied to soils and stored in sealed glass containers, 19% of the cis isomer and 18% of the trans isomer remained in sandy loam and 10% of the cis isomer and 22% of the trans isomer remained in medium loam (Roberts and Stoydin, 1976). After 20 weeks, 5% of the cis isomer and 4% of the trans isomer remained in sandy loam and 3% of the cis isomer and 14% of the trans isomer remained in medium loam. Eight months after D-D[•] soil fumigant was applied to a muck soil and to a sandy loam, cis- and trans-1,3-dichloropropene were detected in both soils (Williams, 1968).

Residue Analysis of Well Water

Fifty-four wells in certain communities in California where Telone[•] or D-D[•] had been applied for several years were selected for residue analysis of 1.3-dichloropropene and other pesticides (Maddy et al., 1982). No samples had measurable amounts of 1.3-dichloropropene at a minimum detectable level of 0.1 ppb. A similar study was conducted in which well water samples were taken from areas where 1,2-dibromo-3chloropropane (DBCP) had been applied. The samples were analyzed for DBCP, 1,3-dichloropropene, 1,2-dibromoethane (EDB), and other pesticides (Peoples et al., 1980). Although DBCP was found in 94 of 262 wells at concentrations ranging from 0.1 to 39 ppb, no detectable levels of 1,3-dichloropropene and/or EDB were found in the 72 well water samples analyzed. However, no data were given to indicate that either 1,3-dichloropropene or EDB was used near the wells.

Metabolism and Disposition

When 2.53-2.70 mg of cis- or trans-1.3dichloro[2-14C]propene was administered orally to Carworth Farm E rats, 80%-90% of the radiolabel was eliminated in the feces, urine, or expired air during the first 24 hours of the experiment (Hutson et al., 1971). Within 24 hours, 80.7% of the administered cis isomer and 56.5% of the administered trans isomer were eliminated in the urine. About 3.9% of the cis isomer and 23.6% of the trans isomer were recovered as [14C]carbon dioxide. A small amount (1%-4%) of 1,3-dichloropropene was exhaled directly. Rats apparently retain little ingested 1.3-dichloropropene. After 4 days, about 1% of the administered dose of either isomer was found in the carcass.

A glutathione-dependent biotransformation is on the major metabolic pathway of cis-1,3dichloro[14C]propene (Climie et al., 1979). An hepatic glutathione transferase catalyzes the conjugation of cis-1,3-dichloropropene with glutathione. The conjugate is further metabolized to a mercapturic acid and is excreted in the urine as N-acetyl-S-[(cis)-3-chloroprop-2-enyl]cysteine. This metabolite accounted for 92% of the 0- to 24-hour cumulative urinary radioactivity. In vitro metabolic studies using rat liver preparations (Climie et al., 1979) revealed that the cis isomer of 1,3-dichloropropene was degraded 4-5 times faster than the trans isomer.

The metabolic fate of 1,3-dichloropropene was studied in plants by using uniformly labeled $[^{14}C]$ -1,3-dichloropropene (60% trans isomer, 40% cis isomer) (Berry et al., 1980). 1,3-Dichloropropene was absorbed by the bush bean, tomato, or carrot from the solution culture (vermiculite and sand), rapidly translocated in the plants, and metabolized to 3-chloroallyl alcohol and then to 3-chloro-1-propanol and 3-chloroacrylic acid. The dichloropropene isomers and chloroallyl alcohol had short half-lives in the plant and were not detectable 120 hours after the administration of 1,3-dichloropropene.

With the exception of 3-chloro-1-propanol, metabolites similar to those present in the plant were also found in soil treated with 1,3-dichloropropene. Microbial metabolism by soil Pseudomonas sp. was responsible for this biotransformation (Castro and Belser, 1966; Belser and Castro, 1971). The overall metabolic pathway of 1,3-dichloropropene is illustrated in Figure 1.

In two recent abstracts (Dietz et al., 1984a, 1984b), the pharmacokinetics of macromolecular binding of 1,3-dichloropropene and its effects on nonprotein sulfhydryl content in the tissues were reported. When oral doses of 1 or 50 mg/kg 14C-cis-, trans-1,3-dichloropropene were administered to male F344 rats and 1 or 100 mg/kg to male B6C3F1 mice, urinary excretion was the predominant route of elimination in 48 hours, accounting for 51%-61% in rats and 63%-79% in mice. Feces and expired carbon dioxide contained approximately 18% and 6% of the administered dose in rats and 15% and 14% of the administered dose in mice, respectively. Only 2%-6% of the original dose remained in the carcasses at the end of 48 hours. The predominant metabolite was identified as N-acetyl-S-(3-chloroprop-2-enyl)cysteine, confirming the earlier findings of Climie et al. (1979). The sulfoxide or sulfone derivative of the above metabolite was tentatively identified as another major metabolite.

In the second study by Dietz et al. (1984b), the amount of nonprotein sulfhydryl (NPS) and covalent binding to macromolecules was measured in the forestomach, glandular stomach, liver, kidney, and urinary bladder in male F344 rats and male $B6C3F_1$ mice 2 hours following administration of a single oral dose of [14C]-1,3dichloropropene. The doses given were 0, 1, 5, 25, 50, or 100 mg/kg for NPS studies and 0, 1, 50, or 100 mg/kg for binding studies. Significant depletion of NPS levels was noted in the forestomach of rats and mice dosed with 25 mg/kg or above; the depletion ranged between 17% and 51% of the control values. Effects on NPS in the glandular stomach and liver were also dose dependent but less severe. Macromolecular covalent binding in the forestomach and glandular stomach was greatest at doses that caused the most depletion of tissue NPS. Limited binding was also noted in the liver, kidneys, or urinary bladders.

Toxicity of Telone II[®] and 1,3-Dichloropropene in Animals (Torkelson and Oyen, 1977)

The acute oral LD_{50} value for Telone II[®] was 713 mg/kg body weight in male and 470 mg/kg in female rats (strain unspecified). The liver and kidneys were the primary sites of acute toxicity. Telone II[®] formulations irritated the skin, causing edema, redness, and necrosis. When a 12.5% solution in propylene glycol was applied under a cuff and allowed to remain undisturbed for 24 hours, Telone II[®] was absorbed through the skin of rabbits (percent absorption was not reported); deaths occurred with doses of 0.125 and 0.25 g/kg. When undiluted Telone II[®] was applied in a similar manner to a group of rabbits (both sexes), the dermal LD₅₀ value was 504 mg/kg.

Twenty-four hours after a Telone II[®] formulation was instilled into the eyes of six rabbits for a 30second exposure period, four of the animals had severe conjunctival irritation and the remaining two rabbits exhibited slight-to-moderate corneal injury. These effects disappeared 8 days after instillation.

A single inhalation exposure of 7 hours at 400 ppm was lethal to male and female guinea pigs; under similar conditions, rats (strain unspecified) survived. Inhalation studies showed that 1,3-dichloropropene at vapor concentrations above 2,700 ppm was irritating to the eyes and nose of rats and caused severe lung, nasal, liver, and kidney injury. At concentrations of 1,000 ppm, it irritated the eyes and nose and was lethal to rats within 2 hours.

Inhalation exposure of rats (strain unspecified) and guinea pigs to 1,3-dichloropropene vapor (46% cis isomer, 53% trans isomer, and approximately 1% epichlorohydrin) at 11 or 50 ppm for 7 hours per day, 5 days per week for 1 month, produced kidney and liver injury. In another experiment, rats (strain unspecified), guinea pigs, rabbits, and dogs received 7-hour inhalation exposures to 1,3-dichloropropene at either 1 or 3 ppm, 5 days per week for 6 months. The only



(1,1,1,1)

FIGURE 1. METABOLIC PATHWAY OF 1,3-DICHLOROPROPENE

(Castro and Belser, 1966; Belser and Castro, 1971; Climie et al., 1979; Berry et al., 1980; Dietz et al., 1984a,b) effect attributable to exposure was a cloudy swelling of the renal tubular epithelium in male rats exposed at 3 ppm. Female rats exposed at 3 ppm had marginal increases in liver to body weight ratio.

Toxicity of D-D[•] in Animals (Parker et al., 1982)

D-D[•], a commercial preparation containing 25% cis-1,3-dichloropropene, 27% trans-1,3-dichloropropene, 29% 1,2-dichloropropane, and other related chlorinated hydrocarbons, was studied to examine inhalation toxicity in CD-1 mice and F344 rats. Exposure concentrations were 0, 5, 14, or 54 ppm, 6 hours per day, 5 days per week for 6 or 12 weeks. Body weights, organ weights, hematologic values, serum chemistry, urinalysis, and gross pathologic and histopathologic findings were evaluated. The only exposurerelated effects observed were increased liver-tobody weight ratios (male rats), increased kidneyto-body weight ratios (female rats), and slightto-moderate diffuse hepatocyte enlargement (male mice), all at the 54-ppm level.

Toxicity and Exposure in Humans

The most likely routes of human exposure to 1,3dichloropropene are through inhalation and the skin. Irritation of eyes and upper respiratory mucosa, accompanied by lacrimation, appears promptly after exposure to vapors (Gosselin et al., 1976). Inhalation by humans of air containing concentrations greater than 1,500 ppm produces headaches, mucous membrane irritation, dizziness, nausea, vomiting, gasping, coughing, substernal pain, and respiratory distress. Slightly elevated levels of serum glutamic oxaloacetic transaminase, serum glutamic pyruvic transaminase, or both were reported (Flessel et al., 1978; Gosselin et al., 1976). The chemical at vapor concentrations lower than 1,500 ppm produces central nervous system depression and moderate irritation of the respiratory system. Dermal exposure causes severe skin irritation with marked inflammatory response. Ingestion produces acute gastrointestinal distress, pulmonary congestion and edema, and central nervous system depression.

A human fatality occurred a few hours after the accidental ingestion of a D-D[•] mixture (Gosselin et al., 1976). The victim experienced abdominal pain and vomiting. He became semicomatose and exhibited muscle twitching. Death occurred in spite of gastric lavage and therapy for pulmonary edema. Markovitz and Crosby (1984) described three case reports of workers accidentally exposed to 1.3-dichloropropene. Nine firemen were treated for headache, neck pain, nausea, and breathing difficulty after cleaning up 1,3-dichloropropene that had spilled on a road in a tank truck accident. Six years later, two of the firemen developed lymphomas, and both died the following year. In another incident, a farmer injecting 1,3-dichloropropene into the soil was exposed to the chemical for about 1 month through a leaky hose, Within a year, he developed myelomonocytic leukemia and later died from pneumonia.

Torkelson and Oyen (1977) suggested that 7- to 8-hour daily occupational exposures to 1,3-dichloropropene not exceed time-weighted average concentrations of 1 ppm.

Mutagenicity Studies

Neudecker et al. (1977) found that the *cis* and trans isomers of 1.3-dichloropropene were mutagenic in strain TA1535 of Salmonella typhimurium and that the addition of rat liver S9 reduced the mutagenicity and cytotoxicity of both isomers. The cis- and trans-1,3-dichloropropene samples were 99.75% and 97.46% pure. The impurities in these samples were characterized as 3,3-dichloropropene and 1,2-dichloropropane. De Lorenzo et al. (1977) also found that cis- and trans-1,3-dichloropropene as well as Telone II[•] and D-D[•] soil fumigant (which contain both isomers of 1,3-dichloropropene) were mutagenic in strains TA1535, TA1978, and TA100 in the presence or absence of S9. Stolzenberg and Hine (1980) confirmed that 1,3-dichloropropene was a direct-acting mutagen in strain TA100 and that S9 reduced the mutagenicity. A mixture of the cis and trans isomers of 1.3-dichloropropene was mutagenic in strains TA1535 and TA100, was weakly mutagenic in strain TA98, and was not mutagenic in strain TA1537 (Appendix J). S9

reduced the mutagenicity of the isomer mixture, confirming the previous reports. These results suggest that 1,3-dichloropropene is a base-pair substitution mutagen that can be enzymatically detoxified by S9. In vitro studies by Climie et al. (1979) demonstrated that the glutathionedependent detoxification of the *trans* isomer is four- to fivefold less rapid than that of the *cis* isomer. In addition, a mixture of the two isomers induced sex-linked recessive lethal mutations in Drosophila but gave negative results when tested for its ability to induce reciprocal translocations in Drosophila (Appendix K).

Recently Talcott and King (1984) demonstrated that purification of four separate preparations of 1,3-dichloropropene by silicic acid chromatography, which removes polar impurities, eliminated the mutagenicity of the preparations in *S. typhimurium* strain TA100. Thus, the mutagenicity of 1,3-dichloropropene preparations observed in other studies may have been due to mutagenic polar impurities and not to 1,3-dichloropropene itself. Subsequent studies at NIEHS (Dr. E. Zeiger, unpublished data) with purified and unpurified samples of 1,3-dichloropropene confirmed that the purified 1,3-dichloropropene was not mutagenic in Salmonella TA100.

Carcinogenicity Studies

cis-1,3-Dichloropropene has been tested for carcinogenicity in mice by dermal and subcutaneous routes and in a mouse-skin initiation-promotion experiment (Van Duuren et al., 1979). The only chemical-related positive findings came from the subcutaneous injection experiment. Weekly injections of 3 mg cis-1,3-dichloropropene in 0.05 ml trioctanoin for 538 days produced fibrosarcomas at the injection site (left flank) in 6/30 female HA:ICR Swiss mice. Neither the trioctanoin vehicle controls nor the untreated controls had any fibrosarcomas.

Rationale for Testing

Telone II[•] was tested because of its widespread agricultural use, the structural similarity of 1,3dichloropropene to vinyl chloride (a known human and animal carcinogen), and the lack of conclusive carcinogenicity studies.

Telone II[®], NTP TR 269

II. MATERIALS AND METHODS

PROCUREMENT AND CHARACTERIZATION OF TELONE II[®] PREPARATION AND CHARACTERIZATION OF DOSE MIXTURES TWO-YEAR AND ANCILLARY STUDIES

Study Design Source and Specifications of Test Animals Animal Maintenance Clinical Examinations and Pathology Statistical Methods

PROCUREMENT AND CHARACTERIZATION OF TELONE II*

Telone II[•] was obtained from Dow Chemical USA (Freeport, TX) as a colorless liquid (Lot no. EXP-N-3993). According to the manufacturer, the 1983 specifications for Telone II[•] indicate that it contains 92% 1,3-dichloropropene (45% *cis*-isomer and 47% *trans*-isomer), 2% 1,2-dichloropropane, 1% epichlorohydrin, and a 5% mixture of chlorinated propenes and hexenes (Dow Chemical Co., 1983).

Purity and identity analyses of Telone II[®] were conducted at the Frederick Cancer Research Center. The boiling point was consistent with that for technical-grade 1,3-dichloropropene (CAS No. 542-75-6). The infrared and nuclear magnetic resonance spectra indicated that components other than cis- and trans-1,3-dichloropropene were present (Appendix H). Gas chromatographic analysis of the test material over the course of the 2-year studies indicated that it contained 88%-90% 1,3-dichloropropene. The two major components (approximately 42% and 46% of the total area by gas chromatographic analysis) were identified as cis- and trans-1,3dichloropropene by ¹³C nuclear magnetic resonance spectrometry and gas chromatography/mass spectrometry (Appendix H). The gas chromatographic/mass spectrometric analysis of the test material indicated that it contained 12 impurities with a combined area

that was approximately 12% of the total area. A peak with an area of 2.5% of the total area was identified as 1,2-dichloropropane; a peak with an area of 1.5% was identified as a trichloropropene isomer; and a second trichloropropene isomer was also identified. Epichlorohydrin was not quantitated at the Frederick Cancer Research Center. Reanalysis of Telone II[®] after 13 months of storage indicated that the composition of the compound was unchanged. The Telone II[®] preparation had the following composition:

1,3-Dichloropropene	88%-90%
cis-isomer	41.6%
trans-isomer	45.9%
1,2-Dichloropropane	2.5%
Trichloropropene isomer	1.5%
Epichlorohydrin	1.0%
Nine other impurities	Approximately 7.5%

PREPARATION AND CHARACTERIZATION OF DOSE MIXTURES

Telone II[•] and corn oil were mixed daily to yield the desired concentrations. Solutions were homogenized for 1-2 minutes in a Lourdes[•] blender. Dose solutions were analyzed periodically (Appendix I); because 52/68 of the samples were within \pm 10% of the target concentrations, it is estimated that the dose solutions were within specifications 76% of the time. Rarely did the dose solutions vary from the target concentration by as much as 20% (Table 1).

		Concentration of Telon for Target Concer		
		Rats	Mi	Ce
	5 mg/ml	10 mg /ml	10 mg/ml	20 mg/ml
Mean (mg/ml)	4.8	9.4	10.1	20.8
Standard deviation	0.50	0.54	1.3	2.14
Coefficient of variation (percent)	10.4	5.7	13.0	10.3
Range (mg/ml)	4.0-5.8	8.8-10.6	8.8-13.1	17.8-25.5
Number of samples	19	19	15	15

TABLE 1. ANALYSIS OF CHEMICAL/VEHICLE MIXTURES IN THE TWO-YEAR GAVAGE STUDIES OF TELONE II \bullet

(a) See Appendix I (Table I1) for results of individual analyses

TWO-YEAR AND ANCILLARY STUDIES

Study Design

In the 2-year carcinogenicity studies, groups of 52 F344/N rats of each sex were administered doses of 0, 25, or 50 mg/kg body weight Telone II^{\bullet} in corn oil 3 days per week for 104 weeks. Groups of 50 B6C3F₁ mice of each sex were administered 0, 50, or 100 mg/kg Telone II^{\bullet} on the same schedule. The gavage route was chosen as the simplest method to ensure systemic exposure of quantitated doses and because of the volatility and reactivity (in feed) of Telone II^{\bullet}. Dose selection was based on earlier short-term studies (primarily body weight reduction effects); data and records from these studies are not considered complete enough to report.

In the ancillary studies, the rats were from the same shipment as those in the 2-year studies, were kept in the same room, received the same doses, and were maintained and observed in the same manner.

Interim-Kill Studies: Groups of 28 rats of each sex were assigned to each dose group. At 9, 16, 21, 24, and 27 months of dosing, five rats of each sex in each dose group were killed and necropsies were performed. The three remaining rats of each sex in each dose group served as substitutes for any rats that died prematurely. Visible lesions were described and recorded. Tissues were preserved in 10% neutral buffered formalin. After the histopathologic evaluation of the 2-year carcinogenicity studies was complete, the liver, stomach, adrenal glands, thyroid gland, urinary bladder, kidneys, and mammary gland from interim-kill rats were examined microscopically to evaluate the development of lesions in these tissues with respect to time.

Hematologic and Clinical Chemistry Studies: Groups of 20 rats of each sex were assigned to each dose group. Twelve of the 20 rats were bled intraorbitally approximately once every 4 weeks, and samples were taken for clinical chemistry studies (1-ml samples); eight rats were bled for hematologic studies (0.25-ml samples). The following 18 hematologic and 25 clinical chemistry variables were measured:

<u>Hematology</u>

Red blood cell Hematocrit Hemoglobin Mean cell volume Mean cell hemoglobin Mean cell hemoglobin concentration White blood cell Differential-band neutrophils Differential-segmented neutrophils Differential lymphocytes Differential monocytes Differential eosinophils **Differential** basophils Absolute-band neutrophils Absolute-segmented neutrophils Absolute lymphocytes Absolute monocytes Absolute eosinophils

Clinical Chemistry

Calcium Inorganic phosphate Calcium/inorganic phosphate ratio Total protein Albumin Albumin/(protein-albumin) ratio Triglycerides Cholesterol Glucose Lactic acid dehydrogenase Creatinine phosphokinase Hydroxybutyrate dehydrogenase Phosphohexoisomerase Leucine aminopeptidase Cholinesterase Blood urea nitrogen Creatinine Uric acid Bilirubin--total Glutamic pyruvate transaminase Glutamic oxaloacetic transaminase Sorbitol dehydrogenase Isocitric dehydrogenase Gamma glutamyl transpeptidase Alkaline phosphatase

The test intervals for rats in the hematology subgroups were minus 1 week and plus 3, 7, 11, 15, 19, 23, 27, 31, 35, and 39 weeks. Those for rats in the clinical chemistry subgroups were minus 1 week and plus 1, 5, 9, 13, 17, 21, 25, 29, 33, 37, 39, and 69 weeks.

Source and Specifications of Test Animals

The male and female F344/N rats and B6C3F1 (C57BL/6N, female, \times C3H/HeN MTV⁻, male) mice used in this study were produced under barrier conditions at the Frederick Cancer Research Center under a contract to the Carcinogenesis Program. Breeding starts for the foundation colony at the production facility originated at the National Institutes of Health Repository. Animals used for testing were progeny of defined microflora-associated parents that were transferred from isolators to barrier-maintained rooms. Animals were transferred to the testing laboratory at 4-6 weeks of age. The animals were guarantined at the testing facility for 2-5 weeks. Thereafter, a complete necropsy was performed on five animals of each sex and species to assess their health status. The rodents were placed on study at 6-10 weeks of age.

Rats were assigned to cages so that average cage weights were approximately equal. Three shipments of mice were received at 2-week intervals. All vehicle control mice were from the first shipment; low dose mice were from the first and second shipments, and high dose mice were from the second and third shipments. As a result of this procedure, initial body weights of vehicle control mice were greater than those in the dosed groups.

Animal Maintenance

Rats were housed four per cage and mice five per cage. Feed and water were available ad libitum. Details of animal maintenance are summarized in Table 2.

Clinical Examinations and Pathology

All animals were observed twice daily for signs of moribundity or mortality. Clinical examinations and palpation for masses were performed weekly. Body weights by cage were recorded once per week. Mean body weights were calculated for each group. Moribund animals were killed, as were animals that survived to the end of the studies. Necropsies were performed on all animals, including those found dead unless they were excessively autolyzed or cannibalized. Thus, the number of animals from which particular organs or tissues were examined microscopically varies and is not necessarily equal to the number of animals that were placed on study in each group.

Examinations for grossly visible lesions were performed on major tissues or organs. Tissues were preserved in 10% neutral buffered formalin, embedded in paraffin, sectioned, and stained with hematoxylin and eosin. Tissues examined microscopically are listed in Table 2.

When the pathology examination was completed, the slides, individual animal data records, and summary tables were sent to an independent quality assurance laboratory. Individual animal records and tables were compared for accuracy, slides and tissue counts were verified, and histotechnique was evaluated. All tumor diagnoses, all target tissues, and all tissues from a randomly selected 10% of the animals

were evaluated by a quality assurance pathologist. Slides of all target tissues and those about which the original and quality assurance pathologists disagreed were submitted to the Chairperson of the Pathology Working Group (PWG) for evaluation. Representative coded slides selected by the Chairperson were reviewed by PWG pathologists, who reached a consensus and compared their findings with the original and quality assurance diagnoses. When diagnostic differences were found, the PWG sent the appropriate slides and comments to the original pathologist for review. This procedure has been described, in part, by Maronpot and Boorman (1982) and Boorman et al. (1985). The final diagnoses represent a consensus of contractor pathologists and the NTP Pathology Working Group.

Two PWG evaluations were held for these studies. The first PWG determined that the initial pathology report submitted by Frederick Cancer Research Center was inadequate and requested that all pathology records and slides be reread by a second pathologist. The second pathology report was approved with some modifications by the PWG.

Nonneoplastic lesions are not examined routinely by the quality assurance pathologist or PWG. Certain nonneoplastic findings are reviewed by the quality assurance pathologist and PWG if they are considered part of the toxic response to a chemical or if they are deemed of special interest.

Statistical Methods

Data Recording: Data on this experiment were recorded in the Carcinogenesis Bioassay Data System (Linhart et al., 1974). The data elements include descriptive information on the chemicals, animals, experimental design, survival, body weight, and individual pathologic results, as recommended by the International Union Against Cancer (Berenblum, 1969).

Survival Analyses: The probability of survival was estimated by the product-limit procedure of Kaplan and Meier (1958) and is presented in the form of graphs. Animals were censored from the survival analyses at the time they were found

TABLE 2. EXPERIMENTAL DESIGN AND MATERIALS AND METHODS IN THE TWO-YEAR GAVAGE STUDIES OF TELONE II* (a)

EXPERIMENTAL DESIGN	
Size of Test Groups	52 male and 52 female rats; 50 male and 50 female mice
Doses	Rats0, 25, or 50 mg/kg Telone II ^{\bullet} in corn oil via gavage 3 \times wk; mice0, 50, or 100 mg/kg; dose vol: 5.0 ml/kg for both species
Date of First Dose	Rats2/25/77; mice7/7/78
Date of Last Dose	Rats2/21/79; mice7/2/80
Duration of Dosing	104 wk; 3 × wk (M, W, F)
Type and Frequency of Observation	Observed 2 \times d for moribundity and mortality; clinical exam and palpation for masses 1 \times wk; weighed 1 \times wk
Necropsy and Histologic Examination	Necropsies, consisting of gross examination of major tissues, major organs and all gross lesions, performed on all animals. Tissues/organs examined histopathologically: gross lesions and tissue masses, blood smears, submandibular and mesenteric lymph nodes, salivary glands, femur (including marrow), thyroid gland, parathyroids, small intestine (one section), colon, liver, prostate/testes or ovaries/uterus, lungs and bronchi, mammary gland, skin, esophagus, stomach, brain (cerebellum and cerebrum), heart, thymus, trachea, pancreas, spleen, kidneys, adrenal glands, urinary bladder, pituitary, gallbladder (mice only)
ANIMALS AND ANIMAL MAINTENANCE	
Species	F344/N rats and B6C3F ₁ mice
Animal Source	Frederick Cancer Research Center (Frederick, MD)
Testing Laboratory	Frederick Cancer Research Center (Frederick, MD)
Time Held Before Start of Test	Rats3 wk; mice2-5 wk
Age When Placed on Study	Rats6 wk; mice6-10 wk
Age When Killed	Rats112-113 wk; mice111-117 wk
Necropsy Dates	Rats3/6/79-3/20/79; mice7/10/80-7/25/80
Method of Distribution	Ratsassigned to cages so that average cage weights were approximately equal; miceassigned to control (first shipment), low dose (first and second shipments), and high dose (second and third shipment) groups as animals arrived
Feed	Wayne Sterilizable Lab Meal [®] (Allied Mills, Chicago, IL) ad libitum in suspended stainless steel hoppers
Bedding	None; stainless steel wire grids (Lab Products, Rochelle Park, NJ) were placed in the bottom of the cages
Water	Acidified to pH 2.5 with HCl; available ad libitum from glass bottles; changed 2 $ imes$ wk

Cages	Polycarbonate (Lab Products, Inc., Garfield, NJ)
Cage Filters	Nonwoven polyester fiber (Hoeltge, Inc., Cincinnati, OH)
Animals per Cage	Rats4; mice5
Animal Room Environment	Ratstemp 22°-24° C; rel humidity about 45%-55%; 15 changes room air/h; fluorescent light 12 h/d; micesame as rats but 12-15 room air changes/h and 10 h light and 14 h dark cycles
Other Chemicals on Test in Same Room	None
CHEMISTRY	
Lot Numbers Used	EXP-N-3993
Supplier	Dow Chemical USA (Freeport, TX)
CHEMICAL/VEHICLE	
Preparation	Appropriate amounts of Telone II [®] and corn oil were mixed to give the desired concentrations. The solutions were homogenized for 1-2 minutes in a Lourdes [®] blender
Maximum Storage Time	Freshly prepared each day of dosing
Storage Conditions	Not stored

ANIMALS AND ANIMAL MAINTENANCE (Continued)

(a) Documentation not available for short-term studies; see text for the experimental design of the ancillary studies.

dead of other than natural causes or were found to be missing; animals dying from natural causes (including those killed while moribund) were not censored. Statistical analyses for a possible dose-related effect on survival used the method of Cox (1972) for testing two groups for equality and Tarone's (1975) life table test for a dose-related trend. All reported P values for the survival analysis are two-sided.

Calculation of Incidence Rates: The incidence of neoplastic or nonneoplastic lesions is given as the ratio of the number of animals bearing such lesions at a specific anatomic site to the number of animals in which that site was examined. In most instances, the denominators include only those animals for which the site was examined histologically. However, when macroscopic examination was required to detect lesions (e.g., skin or mammary tumors) prior to histologic sampling, or when lesions could have appeared at multiple sites (e.g., lymphomas), the denominators consist of the number of animals on which necropsies were performed.

Analysis of Tumor Incidence: Three statistical methods are used to analyze tumor incidence data. The two that adjust for intercurrent mortality employ the classical method for combining contingency tables developed by Mantel and Haenszel (1959). Tests of significance included pairwise comparisons of high dose and low dose groups with vehicle controls and tests for overall dose-response trends.

For studies in which compound administration has little effect on survival, the results of the three alternative analyses will generally be similar. When differing results are obtained by the three methods, the final interpretation of the data will depend on the extent to which the tumor under consideration is regarded as being the cause of death. All reported P values for tumor analyses are one-sided. Life Table Analyses--The first method of analysis assumed that all tumors of a given type observed in animals dving before the end of the study were "fatal"; i.e., they either directly or indirectly caused the death of the animal. According to this approach, the proportions of tumor-bearing animals in the dosed and vehicle control groups were compared at each point in time at which an animal died with a tumor of interest. The denominators of these proportions were the total number of animals at risk in each group. These results, including the data from animals killed at the end of the study, were then combined by the Mantel-Haenszel method to obtain an overall P value. This method of adjusting for intercurrent mortality is the life table method of Cox (1972) and of Tarone (1975).

Incidental Tumor Analyses--The second method of analysis assumed that all tumors of a given type observed in animals that died before the end of the study were "incidental"; i.e., they were merely observed at necropsy in animals dying of an unrelated cause. According to this approach, the proportions of tumor-bearing animals in dosed and vehicle control groups were compared in each of five time intervals: 0-52 weeks, 53-78 weeks, 79-92 weeks, week 93 to the week before the terminal-kill period, and the terminal-kill period. The denominators of these proportions were the number of animals on which necropsies were actually performed during the time interval. The individual time interval comparisons were then combined by the previously described method to obtain a single overall result. (See Haseman, 1984, for the computational details of both methods.)

All tumors observed in the ancillary study were considered to be incidental; hence the reported "life table analysis" is a combination of a life table analysis applied to tumors observed in animals dying during the course of the study and an incidental tumor test applied to tumors observed in scheduled-kill animals (Haseman, 1984); each scheduled-kill period (9, 16, 21, 24, and 27 months) was considered as a separate time interval. The 24-month data from the ancillary study were combined with the data from the terminal kill in the 2-year study.

Unadjusted Analyses--Primarily, survival-adjusted methods are used to evaluate tumor incidence. In addition, the results of the Fisher's exact test for pairwise comparisons and the Cochran-Armitage linear trend test (Armitage, 1971; Gart et al., 1979) are given in the appendix containing the analyses of primary tumor incidence. These two tests are based on the overall proportion of tumor-bearing animals and do not adjust for survival differences.

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III. RESULTS

RATS

TWO-YEAR STUDIES AND ANCILLARY STUDIES Body Weights and Clinical Signs Survival Ancillary Studies Pathology and Statistical Analyses of Results

MICE

TWO-YEAR STUDIES Body Weights and Clinical Signs Survival Pathology and Statistical Analyses of Results

Telone II[®], NTP TR 269

TWO-YEAR STUDIES AND ANCILLARY STUDIES*

Body Weights and Clinical Signs

Mean body weights of high dose male rats were approximately 5% lower than those of the vehicle controls after about week 28 (Table 3 and Figure 2). Mean body weights of dosed and vehicle control female rats were comparable. "he record of weekly clinical observations was incomplete for the first 18 months of the study. Other than a few instances of abnormal signs (e.g., convulsions, "wasting") for individual animals, no extraordinary clinical signs of toxicity were observed.

TABLE 3. MEAN BODY WEIGHTS AND SURVIVAL OF RATS IN THE TWO-YEAR GAVAGE STUDIES OF TELONE Π^\bullet

Weeks	Vehicle Control		Low Dose		High Dose			
on Study	Av. WL No. of		Av. WL	Wt. (percent	No. of	Av. Wt.	Wt. (percent	No. of
	(grams)	Survivors	(grams)	of controls)		(grams)	of controls)	Survivo
MALE			<u> </u>					
0	98	52	98	100.0	52	99	101.0	52
	160	51	160	100.0	52	162	101.3	52
2 4 6	211	51	211	100.0	48	210	99.5	52
6	244	51	247	101.2	48	244	100.0	52
8	269	51	274	101.9	48	271	100.7	52 52
10	290	50	291	100.3	48	283	97.6 98.4	52
12	306	50	311	101.6	48	301	97.0	51
16	328	50	332	101.2	48	318	97.4	51
20	344	50	346	100.6	48	335	95.3	51
24	362	50	363	100.3	48	345	94.9	51
28	372	50	375	100.8	48	353	93.5	51
32	386	50	387	100.3	48	361		50
36	394	50	400	101.5	48	375	95.2 95.3	50
40	400	50	409	102.3	48	381	95.4	50
44	409	50	421	102.9	48	390	94.2	50
48	411	50	426	103.6	48	387		50
52	417	49	428	102.6	48	391	93.8 92.9	49
60	420	49	423	100.7	48	390		49
68	431	49	441	102.3	47	403	93.5 91.5	49
76	433	49	440	101.6	47	396	91.5	49
84	428	47	437	102.1	46	390 408	95.6	45
92	427	47	438	102.6	45 42	393	94.0	41
100	418	44	423	101.2	42	383	74. U	-1
FEMALE								
0	88	52	89	101.1	52	90	102.3	52
2	124	51	125	100.8	52	129	104.0	52
4	145	51	146	100.7	52	149	102.8	52
6	162	51	162	100.0	52	166	102.5	52
8	174	51	174	100.0	52	179	102.9	52
10	182	51	182	100.0	52	189	103.8	52
12	189	51	189	100.0	52	197	104.2	52
16	197	51	198	100.5	50	202	102.5	52
20	202	51	202	100.0	50	209	103.5	52
24	214	51	213	99.5	50	217	101.4	52
28	219	51	219	100.0	50	224	102.3	52
32	227	51	225	99.1	50	233	102.6	52
36	234	51	234	100.0	49	239	102.1	52
40	239	51	241	100.8	49	246	102.9	52
44	245	51	248	101.2	49	252	102.9	52
48	249	51	252	101.2	49	257	103.2	52
52	255	50	258	101.2	49	261	102.4	52
60	262	50	268	102.3	48	267	101.9	52
68	290	49	285	98.3	48	285	98.3	52
76	291	48	301	103.4	47	294	101.0	52
84	303	47	311	102.6	45	301	99.3	48
92	305	45	321	105.2	39	316	103.6	46
100	305	38	324	106.2	39	314	103.0	40

*Unless otherwise stated, all data on body weights and survival were derived from the 2-year carcinogenicity studies; results from the ancillary studies were not used in these measurements and calculations.



FIGURE 2. GROWTH CURVES FOR RATS ADMINISTERED TELONE II* IN CORN OIL BY GAVAGE FOR TWO YEARS

Telone II®, NTP TR 269

Survival

Estimates of the probabilities of the survival of male and female rats administered Telone II[•] at the doses used in the 2-year studies and those of the vehicle controls are shown in Figure 3. No significant differences in survival were observed between any groups of either sex (Table 4).

Ancillary Studies

Initial analyses by Frederick Cancer Research Center of the hematologic and clinical chemistry data revealed certain statistically (*t*-test) significant changes in several analytes, including mean cell volume, cholinesterase, glucose, lactate dehydrogenase, triglycerides, and alpha-hydroxybutyrate dehydrogenase. Because these changes were neither consistent nor progressive over time and since there is a greater than normal variability in the data, these changes are not believed to be toxicologically significant. The data for serum cholinesterase, which had the most statistically significant changes and which also were the most variable, are listed in Appendix L (Table L1); all data for 18 hematologic and 25 clinical chemistry measurements are available from the NTP Archives.

The lesions observed in the rats in the interimkill groups are discussed along with those found in the 2-year carcinogenesis studies. Generally, the pathology data from the ancillary studies supported the results from the 2-year studies. The only instance in which the inclusion of data from the ancillary studies markedly affected the statistical significance of observed tumor increases was squamous cell papilloma of the forestomach in female rats.

	Vehicle Control	25 mg/kg	50 mg/kg
MALE (a)	· · · · · · · · · · · · · · · · · · ·	, ,, ,, ,, ,, ,, , , , ,, ,, ,, ,, ,	
Animals initially in study	52	52	52
Nonaccidental deaths before termination (b)	7	13	11
Accidentally killed	2	1	1
Killed at termination	42	37	40
Died during termination period	1	1	0
Survival P values (c)	0.414	0.222	0.459
FEMALE (a)			
Animals initially in study	52	52	52
Nonaccidental deaths before termination (b)	17	13	14
Accidentally killed	1	4	0
Killed at termination	34	35	38
Survival P values (c)	0.560	0.655	0.626

TABLE 4. SURVIVAL OF RATS IN THE TWO-YEAR GAVAGE STUDIES OF TELONE II*

(a) Terminal kill period: weeks 106-108

(b) Includes animals killed in a moribund condition

(c) The result of the life table trend test is in the vehicle control column, and those of the life table exact pairwise comparisons with the vehicle controls are in the dosed columns.


FIGURE 3. KAPLAN-MEIER SURVIVAL CURVES FOR RATS ADMINISTERED TELONE II[®] IN CORN OIL BY GAVAGE FOR TWO YEARS

Telone II[®], NTP TR 269

Pathology and Statistical Analyses of Results

This section describes the significant or noteworthy changes in the incidence of rats with neoplastic or nonneoplastic lesions in the forestomach, liver, adrenal gland, thyroid gland, urinary bladder, and kidney. Histopathologic findings on neoplasms in rats are summarized in Appendix A (Tables A1 and A2); the survival and tumor status for individual male and female rats also are summarized in Appendix A (Tables A3 and A4). Findings on nonneoplastic lesions are summarized in Appendix C (Tables C1 and C2). Appendix E (Tables E1, E2, and E3) gives the incidences of neoplasms and nonneoplastic lesions in rats in the interim-kill groups at 9, 16, 21, 24, and 27 months; the serum cholinesterase data are presented in Appendix L (Table L1). Appendix F (Tables F1 and F2) contains the statistical analyses of those primary tumors that occurred with an incidence of at least 5% in one of the three groups. The statistical analyses used are discussed in Chapter II (Statistical Methods) and Appendix F (footnotes). Historical incidences of tumors in corn oil vehicle control animals are listed in Appendix G.

Forestomach (reported as "stomach" or "forestomach" in the Carcinogenesis Bioassay Data System): Basal cell hyperplasia occurred at increased incidences in dosed male and female rats (Table 5). The pooling of data from the 2-year studies and the interim-kill studies reaffirmed the dose-related increases of basal cell hyperplasia in both sexes. Most hyperplastic lesions involved only the basal layer of the squamous epithelium and were diagnosed as basal cell hyperplasia rather than epithelial hyperplasia.

Squamous cell papillomas, squamous cell carcinomas, and squamous cell papillomas or carcinomas (combined) occurred with significant positive trends in male rats; the incidences of squamous cell papillomas and squamous cell papillomas or carcinomas in the high dose group were significantly greater than those in the vehicle controls (Table 5). When data from the 2-year and interim-kill studies were combined, the positive findings were reinforced. The increased incidences of squamous cell papillomas in female rats were not significant in the 2-year study, but the pooled results of the 2-year and interim-kill studies showed significant dose-related increases.

TABLE 5. ANALYSIS OF FORESTOMACH LESIONS IN RATS IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II^{*}(a)

	Vehi	cle Control	25 m	g/kg	50 n	ng/kg
	2-Year Study	2-Year and Ancillary Studies (b)	2-Year Study	2-Year and Ancillary Studies	2-Year Study	2-Year and Ancillary Studies
MALE						
Basal Cell or Epithelial Hype	rplasia					
Overall Rates	2/52 (4%)	3/77 (4%)	5/52 (10%)	13/77 (17%)	13/52 (25%)	31/77 (40%)
Squamous Cell Papilloma						
Overall Rates	1/52 (2%)	1/77 (1%)	1/52 (2%)	1/77 (1%)	9/52 (17%)	13/77 (17%)
Adjusted Rates	2.3%		2.4%		21.3%	
Terminal Rates	1/43 (2%)		0/38 (0%)		7/40 (18%)	
Life Table Tests	P = 0.002	P<0.001	P = 0.739	P = 0.742	P=0.008	P<0.001
Incidental Tumor Tests	P = 0.002	P<0.001	P = 0.702N	P=0.739N	P = 0.011	P<0.001
Squamous Cell Carcinoma						
Overall Rates	0/52 (0%)	0/77 (0%)	0/52 (0%)	0/77 (0%)	4/52 (8%)	4/77 (5%)
Adjusted Rates	0.0%	. ,	0.0%		10.0%	
Terminal Rates	0/43 (0%)		0/38 (0%)		4/40 (10%)	
Life Table Tests	P=0.014	P = 0.014	(c)	(c)	P = 0.054	P = 0.056
Incidental Tumor Tests	P = 0.014	P = 0.014	(c)	(c)	P = 0.054	P = 0.056
Squamous Cell Papilloma or	Carcinoma (d))				
Overall Rates	1/52 (2%)	1/77 (1%)	1/52 (2%)	1/77 (1%)	13/52 (25%)	17/77 (22%)
Adjusted Rates	2.3%		2.4%		30.8%	
Terminal Rates	1/43 (2%)		0/38 (0%)		11/40 (28%)	
Life Table Tests	P<0.001	P<0.001	P = 0.739	P = 0.742	P<0.001	P<0.001
Incidental Tumor Tests	P<0.001	P<0.001	P = 0.702N	P=0.739N	P<0.001	P<0.001
FEMALE						
Basal Cell or Epithelial Hype	rplasia					
Overall Rates	1/52 (2%)	1/75 (1%)	0/52 (0%)	5/77 (6%)	16/52 (31%)	35/77 (45%)
Squamous Cell Papilloma (e)						
Overall Rates	0/52 (0%)	0/75 (0%)	2/52 (4%)	2/77 (3%)	3/52 (6%)	8/77 (10%)
Adjusted Rates	0.0%		4.9%		7.4%	
Terminal Rates	0/34 (0%)		1/36 (3%)		2/38 (5%)	
Life Table Tests	P=0.097	P = 0.002	P = 0.241	P = 0.245	P = 0.138	P = 0.006
Incidental Tumor Tests	P=0.093	P = 0.002	P = 0.350	P = 0.309	P = 0.116	P = 0.005

(a) The statistical analyses used are discussed in Chapter II (Statistical Methods) and Appendix F (footnotes).
(b) Pooled results from the 2-year and the ancillary studies (9-, 16-, 21-, 24-, and 27-month kills)
(c) No P value is presented because no tumors were observed in the 25 mg/kg and vehicle control groups.

(d) Historical incidence in NTP studies: 6/1,114 (0.5%)
(e) Historical incidence of squamous cell papilloma or carcinoma in NTP studies: 5/1,125 (0.4%)

Liver: Neoplastic nodules were classified according to the recommendations of Squire and Levitt (1975) and the National Academy of Sciences (1980) with some modification; that is, small focal lesions causing only minimal compression, with little or no cytologic atypia in livers or with toxic or anoxic hepatic change (such as occurs with mononuclear cell leukemia), were classified in this study as nodular hyperplasia. Neoplastic nodules in male rats occurred with a significant positive trend, and the incidences in the dosed groups were significantly greater than that in the vehicle controls (Table 6). When the data from the 2-year and interim-kill studies were pooled, the significance of the increased incidences persisted. One other high dose male had an hepatocellular carcinoma. Incidences of neoplastic nodules in dosed female rats were not significantly increased in the 2-year study (vehicle control, 6/52, 12%; low dose, 6/52, 12%; high dose, 10/52, 19%) and in the pooled data from the 2-year and interim-kill studies (vehicle control, 6/75, 8%; low dose, 8/77, 10%; high dose, 12/77 16%).

TABLE 6. ANALYSIS OF LIVER TUMORS IN MALE RATS IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II[•]

	Vehicle Control		25 m	z/kg	50 mg/kg		
	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies	2-Year Study	2-Year and Ancillary Studies	
Neoplastic Nodule							
Overall Rates	1/52 (2%)	1/77 (1%)	6/52 (12%)	6/76 (8%)	7/52 (13%)	8/77 (10%)	
Adjusted Rates	2.3%		15.8%		17.5%		
Terminal Rates	1/43 (2%)		6/38 (16%)		7/40 (18%)		
Life Table Tests	P=0.023	P = 0.012	P=0.040	P = 0.043	P=0.025	P = 0.014	
Incidental Tumor Tests	P = 0.023	P = 0.012	P=0.040	P=0.043	P=0.025	P=0.014	
Neoplastic Nodule or Cs	rcinoma (b)						
Overall Rates	1/52 (2%)	1/77 (1%)	6/52 (12%)	6/76 (8%)	8/52 (15%)	9/77 (12%)	
Adjusted Rates	2.3%		15.8%		20.0%	•••••	
Terminal Rates	1/43 (2%)		6/38 (16%)		8/40 (20%)		
Life Table Tests	P=0.011	P = 0.006	P=0.040	P = 0.043	P=0.013	P = 0.007	
Incidental Tumor Tests	P=0.011	P = 0.006	P = 0.040	P = 0.043	P = 0.013	P = 0.007	

(a) Pooled results from the 2-year and the ancillary studies (9-, 16-, 21-, 24-, and 27-month kills)

(b) Historical incidence in NTP studies: $40/1,141(3.5\%) \pm 4\%$

Time-Dependent Development of Forestomach and Liver Lesions: The development of forestomach lesions (basal cell hyperplasia, squamous cell papilloma) in rats in the interim-kill groups followed a time-dependent trend in high dose males and females (Table 7). Basal cell hyperplasia of the forestomach was seen as early as 9-16 months after dosing began. The neoplasms of the forestomach and liver were not seen until 24 months after dosing began.

Adrenal Gland: Pheochromocytomas occurred in low dose males with a significantly increased incidence when compared with the vehicle controls (Table 8).

TABLE 7. INCIDENCE OF FORESTOMACH AND LIVER LESIONS IN RATS IN THE ANCILLARY STUDIES OF TELONE II*

	9	16	e Coi 21 hs on	24	27	9 (n	16	mg/k 21 ns on	24	27	9 (n	16	n <u>g/k</u> 21 15 on	g (a) 24 stuc	27 ly)
MALE															
Stomach: Basal Cell Hyperplasia Stomach: Squamous Cell Papilloma Liver: Neoplastic Nodule	0/5 0/5 0/5	0/5 0/5 0/5	1/5 0/5 0/5	0/5 0/5 0/5	0/5 0/5 0/5	0/5 0/5 0/5	1/5 0/5 0/5	3/5 0/5 0/4	3/5 0/5 0/5	1/5 0/5 0/5	1/5 0/5 0/5	5/5 0/5 0/5	4/5 0/5 0/5	4/5 2/5 1/5	4/5 2/5 0/5
FEMALE															
Stomach: Basal Cell Hyperplasia Stomach: Squamous Cell Papilloma Liver: Neoplastic Nodule	0/5 0/5 0/5	0/5 0/5 0/5	0/5 0/5 0/5	0/5 0/5 0/5	0/3 0/3 0/3	0/5 0/5 0/5	2/5 0/5 0/5	2/5 0/5 0/5	1/5 0/5 2/5	0/5 0/5 0/5	0/5 0/5 0/5	5/5 0/5 0/5	5/5 0/5 0/5	4/5 0/5 0/5	5/5 5/5 2/5

(a) Scheduled kills

TABLE 8. ANALYSIS OF ADRENAL GLAND TUMORS IN MALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II*

	Vehicle Control	25 mg/kg	50 mg/kg
Pheochromocytoma			
Overall Rates	2/52 (4%)	8/52 (15%)	6/52 (12%)
Adjusted Rates	4.7%	21.1%	13.6%
Terminal Rates	2/43 (5%)	8/38 (21%)	3/40 (7%)
Life Table Tests	P = 0.110	P=0.029	P=0.123
Incidental Tumor Tests	P = 0.141	P = 0.029	P = 0.192

Thyroid Gland: Follicular cell adenomas or carcinomas (combined) occurred in female rats with a significant positive trend; the incidences in the dosed groups were not significantly greater than that in the vehicle controls (Table 9). The increased incidences of follicular cell adenomas or carcinomas (combined) were not significant in dosed male rats.

Urinary Bladder: Edema of the submucosa of the urinary bladder was observed at increased

incidences in high dose males and high dose females (males: vehicle control, 0/52; low dose, 0/52; high dose, 9/52, 17%; females: vehicle control, 0/52; low dose, 0/52; high dose, 3/52, 6%).

Kidney: Nephropathy was increased in dosed female rats (vehicle control, 15/52, 29%; low dose 24/52, 46%; high dose, 25/52, 48%). No increases were observed in male rats (vehicle control, 38/52, 73%; low dose, 35/52, 67%; high dose, 42/52, 81%).

TABLE 9. ANALYSIS OF THYROID GLAND LESIONS IN RATS IN THE TWO-YEAR GAVAGE STUDIES OF TELONE II*

	Vehicle Control	25 mg/kg	50 mg/kg
MALE			<u></u>
Follicular Cell Adenoma or Carcinoma Overall Rates	0/52 (0%)	4/51 (8%)	1/51 (2%)
FEMALE			
Follicular Cell Hyperplasia Overall Rates	0/52 (0%)	0/52 (0%)	2/52 (4%)
Follicular Cell Adenoma Overall Rates	0/52 (0%)	1/52 (2%)	2/52 (4%)
Follicular Cell Carcinoma Overall Rates	0/52 (0%)	1/52 (2%)	2/52 (4%)
Follicular Cell Adenoma or Carcinoma			
Overall Rates	0/52 (0%)	2/52 (4%)	4/52 (8%)
Adjusted Rates	0.0%	5.6%	10.1%
Terminal Rates	0/34 (0%)	2/36 (6%)	3/38 (8%)
Life Table Tests	P=0.047	P = 0.251	P = 0.077
Incidental Tumor Tests	P=0.043	P = 0.251	P = 0.064

TWO-YEAR STUDIES

Body Weights and Clinical Signs

Initial mean body weights of dosed mice were 6%-22% lower than those of the vehicle controls; these differences were caused by failure to fully randomize the distribution of the animals. Three shipments of mice were received at 2-week intervals on 5/30/78, 6/13/78, and 6/27/78.

The mice were approximately 4-6 weeks of age when received. In most cases, weights of dosed

mice remained lower than those of the vehicle controls throughout the study (Table 10 and Figure 4); final body weights were 5% lower than those of the vehicle controls, except in low dose females (9% lower). The weekly clinical observation record was available from approximately 10 weeks after dosing began until the end of the study. No extraordinary clinical signs were observed.

TABLE 10.	MEAN BODY W	VEIGHTS AND	SURVIVAL	OF MICE	IN THE	TWO-YEAR	GAVAGE S	TUDIES
			OF TEL	ONE II				

Weeks		Control	-	Low Dose			High Dose	
oa Study	Av. WL	No. of	Av. Wt.	Wt. (percent		Av. Wt.	Wt. (percent	
	(grams)	Survivors	(grams)	of controls)	Survivors	(grams)	of controis)	Survivor
MALE								
0	23	50	20	87.0	50	20	87.0	50
2	27	50	26	96.3	50	25	92.6	50
4	29	50	28	96.6	49	27	93.1	49
8	31 32	50 50	30	96.8 93.8	49 49	29 30	93.5 93.8	49
10	33	50	30 31	93.9	49	31	93.9	49 49
12	35	50	33	94.3	49	32	91.4	49
16	33	50	34	103.0	49	31	93.9	49 49
20	37	50	36	97.3	49	35	94.6	49
24	39	50	36	92.3	49	35	89.7	49
28	39	50	36	92.3	49	34	87.2	49
32	40	50	37	92.5	49	36	90.0	49
36	40	50	37	92.5	49	36	90.0	49
40	41	50	37	90.2	48	36	87.8	49
44	40	48	37	92.5	46	36	90.0	49
48	42	48	39	92.9	48	35	83.3	49
52	40	23	38	95.0	47	37	92.5	47
60	41	23	39	95.1	42	38	92.7	46
68	41	22	37	90.2	40	36	87.8	46
76	43	22	39	90.7	40	37	86.0	44
84	41 -	21	39	95.1	39	37	90.2	42
92	. 40	15	38	95,0	38	37	92.5	40
100	40	12	38	95.0	35	38	95.0	38
FEMALE								
0	18	50	17	94,4	50	14	77.8	50
2	20	50	20	100.0	50	19	95.0	49
4	23	50	22	96.7	50	21	91.3	49
2 4 6 8	23	50	23	100.0	50	22	95.7	49
8	24	50	23	96.8	50	23	95.8	49
10	25	50	25	100.0	50	25	100.0	49
12	26	50	25	96.2	50	25	96,2	49
16	25	50	25	100.0	50	24	96.0	49
20 24	38	50 50	27	96.4	50	27 27	96.4	49
28	29 29	50 50	27 28	93.1	50 50	27	93.1 93.1	49
32	29	50 50	30	96.6 100.0	50 50	27 28	93,1 93,3	48 47
36	30	50	29	96.7	50	40 20	96.7	47
40	31	50	29	98.5	50	29 29	93.5	47
22	30	50	29	96.7	50	29	96.7	47
44 45	31	50	29	93.5	50	29	93.5	47
52	32	50	30	93.8	50	30	93.8	47
50	32	50	31	96.9	50	31	96.9	45
68	33	50	30	90.9	50	31	93.9	43
78	35	49	32	91.4	49	32	91.4	41
84	35	49	32	91.4	49	33	94.3	41
92	33	48	32	97.0	48	33	100.0	40
100	35	47	32	91.4	47	33	94.3	37



FIGURE 4. GROWTH CURVES FOR MICE ADMINISTERED TELONE II[•] IN CORN OIL BY GAVAGE FOR TWO YEARS

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Survival

Estimates of the probabilities of survival of male and female mice administered Telone II[®] at the doses used in the 2-year studies and those of the vehicle controls are shown in Figure 5. The survival of vehicle control male mice was significantly lower than that of either dose group (Table 11). The deaths of 39 male mice in the vehicle control group were attributed to suppurative inflammation of the heart (myocarditis); 25 of these mice died between weeks 48 and 51. In the survival analysis, these early deaths resulted in a precipitous drop in the Kaplan-Meier survival curve for the male control group (Figure 5). In male mice, myocarditis was diagnosed in 39 vehicle controls, 13 low dose animals, and 5 high dose animals: some of the same animals also had related heart lesions such as myocardial necrosis (Appendix D, Table D1). In female mice, the survival of the high dose group was significantly lower than that of the vehicle control group. None of the female mice had myocarditis.

Pathology and Statistical Analyses of Results

This section describes the significant or noteworthy changes in the incidence of animals with neoplastic or nonneoplastic lesions in the urinary bladder, lung, forestomach, and liver. Histopathologic findings on neoplasms in mice are summarized in Appendix B (Tables B1 and B2); the survival and tumor status for individual male and female mice also are summarized in Appendix B (Tables B3 and B4). Findings on nonneoplastic lesions are summarized in Appendix D (Tables D1 and D2). Appendix F (Tables F3 and F4) contains the statistical analyses of those primary tumors that occurred with an incidence of at least 5% in one of the three groups. The statistical analyses used are discussed in Chapter II (Statistical Methods) and Appendix F (footnotes). Historical incidences of tumors in corn oil vehicle control animals are listed in Appendix G. Since only eight vehicle control male mice lived to the end of the study, only analyses that account for differences in survival are considered for male mice.

~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	Vehicle Control	50 mg/kg	100 mg/kg
Animals initially in study Nonaccidental deaths before termination (b) Accidentally killed Died during termination period Killed at termination Survival P values (d)	50 (c) 42 0 4 4 <0.001	50 22 1 0 28 <0.001	50 19 0 2 29 <0.001
FEMALE (a)			
Animals initially in study Nonaccidental deaths before termination (b) Died during termination period Killed at termination Survival P values (d)	50 4 0 46 0.006	50 5 3 42 0.991	50 14 1 35 0.015

TABLE 11. SURVIVAL OF MICE IN THE TWO-YEAR GAVAGE STUDIES OF TELONE D	TABLE 11.	SURVIVAL OF MIC	E IN THE TWO-YEAR	GAVAGE STUDIES OF	TELONE II [•]
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(a) Terminal kill period: males--weeks 105-107; females--weeks 106-107

(b) Includes animals killed in a moribund condition

(c) Twenty-five male mice died between weeks 48 and 51; the cause was given as suppurative inflammation of the heart (myocarditis).

(d) The result of the life table trend test is in the vehicle control column, and the life table exact pairwise comparisons with the vehicle controls are in the dosed columns.



FIGURE 5. KAPLAN-MEIER SURVIVAL CURVES FOR MICE ADMINISTERED TELONE II[®] IN CORN OIL BY GAVAGE FOR TWO YEARS

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Urinary Bladder: Epithelial hyperplasia occurred at dose-related increased incidences in male and female mice (Table 12). The low survival rate of vehicle control male mice should be considered when the increases in dosed male mice are evaluated.

Transitional cell carcinomas in female mice occurred with a significant positive trend, and the incidences in the dosed groups were greater than that in the vehicle controls (Table 12). Two male mice in the high dose group had transitional cell carcinomas of the urinary bladder. Rather than proliferating outward as do papillomas, these neoplasms were characterized by solid or glandular growth that extended downward from the transitional epithelium into the submucosa and muscular layer and occasionally to the serosa of the bladder.

## TABLE 12. ANALYSIS OF URINARY BLADDER LESIONS IN MICE IN THE TWO-YEAR GAVAGE STUDIES OF TELONE II[•] (a)

	Vehicle Control	50 mg/kg	100 mg/kg
MALE			
Epithelial Hyperplasia Overall Rates	(b) 0/50 (0%)	9/50 (18%)	18/50 (36%)
<b>Transitional Cell Carcinoma</b> (c) Overall Rates	0/50 (0%)	0/50 (0%)	2/50 (4%)
FEMALE			
Epithelial Hyperplasia Overall Rates	2/50 (4%)	15/50 (30%)	19/48 (40%)
Transitional Cell Carcinoma (d) Overall Rates	0/50 (0%)	8/50 (16%)	21/48 (44%)
Adjusted Rates Terminal Rates Life Table Tests	0.0% 0/46 (0%) P<0.001	17.4% 7/45 (16%) P=0.005	56.5% 19/35 (54%) P<0.001
Incidental Tumor Tests	P<0.001	P = 0.006	P<0.001

(a) The statistical analyses used are discussed in Chapter II (Statistical Methods) and Appendix F (footnotes).

(b) At approximately 1 year of the study, 25 vehicle control male mice died from suppurative inflammation of the heart (myocarditis); only 8 mice in the group lived to the end of the study.

(c) Historical incidence in NTP studies: 0/1,033

(d) Historical incidence in NTP studies: 0/1,025

## **III. RESULTS: MICE**

Lung: Alveolar/bronchiolar adenomas occurred in female mice with significant positive trends (Table 13). The incidences of alveolar/bronchiolar adenomas in low dose male mice and high dose female mice were greater than those in the vehicle controls. Incidences of alveolar/ bronchiolar adenomas or carcinomas (combined) in dosed male mice and in high dose female mice were greater than those in the vehicle controls.

TABLE 13.	ANALYSIS OF LUNG TUMORS IN MICE IN THE TWO-YEAR GAVAGE STUDIES OF
	TELONE II [•]

	Vehicle Control	50 mg/kg	100 mg/kg
MALE			
Alveolar/Bronchiolar Adenoma			
Overall Rates	(a) 1/50 (2%)	11/50 (22%)	9/50 (18%)
Adjusted Rates	11.1%	33.4%	27.0%
Terminal Rates	0/8 (0%)	7/28 (25%)	7/31 (23%)
Life Table Tests	P=0.419	P = 0.147	P = 0.312
Incidental Tumor Tests	P=0.185	P = 0.026	P = 0.162
Alveolar/Bronchiolar Adenoma or Ca	rcinoma (b)		
Overall Rates	1/50 (2%)	13/50 (26%)	12/50 (24%)
Adjusted Rates	11.1%	39.8%	33.5%
Terminal Rates	0/8 (0%)	9/28 (32%)	8/31 (26%)
Life Table Tests	P = 0.264	P = 0.097	P = 0.166
Incidental Tumor Tests	P = 0.072	P=0.015	P = 0.040
FEMALE			
Alveolar/Bronchiolar Adenoma			
Overall Rates	0/50 (0%)	3/50 (6%)	8/50 (16%)
Adjusted Rates	0.0%	6.7%	21.3%
Terminal Rates	0/46 (0%)	3/45 (7%)	7/36 (19%)
Life Table Tests	P<0.001	P=0.118	P=0.002
Incidental Tumor Tests	P=0.001	P=0.118	P=0.003
Alveolar/Bronchiolar Adenoma or Ca	rcinoma (c)		
Overall Rates	2/50 (4%)	4/50 (8%)	8/50 (16%)
Adjusted Rates	4.3%	8.9%	21.3%
Terminal Rates	2/46 (4%)	4/45 (9%)	7/36 (19%)
Life Table Tests	P = 0.011	P = 0.327	P = 0.020
Incidental Tumor Tests	P = 0.019	P = 0.327	P = 0.032

(a) At approximately 1 year of the study, 25 vehicle control male mice died from suppurative inflammation of the heart (myoserditie); only 8 mice in the group lived to the and of the study.

(myocarditis); only 8 mice in the group lived to the end of the study. (b) Historical incidence in NTP studies: 155/1,082 (14%) ± 6%

(c) Historical incidence in NTP studies:  $52/1,103(5\%) \pm 3\%$ 

Forestomach (reported as "stomach" in the Carcinogenesis Bioassay Data System): Epithelial hyperplasia of the stomach was observed at increased incidences in high dose female mice (Table 14). Squamous cell papillomas or carcinomas (combined) occurred in female mice with a positive trend (Table 14). The incidences of high dose females with squamous cell papillomas or carcinomas (combined) and of high dose males with squamous cell papillomas were greater than those in the vehicle controls.

## TABLE 14. ANALYSIS OF FORESTOMACH LESIONS IN MICE IN THE TWO-YEAR GAVAGE STUDIES OF TELONE II•

	Vehicle Control	50 mg/kg	100 mg/kg
MALE			
Epithelial Hyperplasia			
	a) 0/50 (0%)	0/50 (0%)	4/50 (8%)
Squamous Cell Papilloma (b)			
Overall Rates	0/50 (0%)	2/50 (4%)	3/50 (6%)
Adjusted Rates	0.0%	6.7%	7.4%
Terminal Rates	0/8 (0%)	1/28 (4%)	1/31 (3%)
Life Table Tests	P = 0.234	P = 0.510	P = 0.280
Incidental Tumor Tests	P=0.051	P=0.403	P = 0.037
FEMALE			
Epithelial Hyperplasia			
Overall Rates	1/50 (2%)	1/50 (2%)	21/50 (42%)
Squamous Cell Papilloma or Carcinoma (	c)		
Overall Rates	0/50 (0%)	1/50 (2%)	(d) <b>4/50</b> (8%)
Adjusted Rates	0.0%	2.2%	10.6%
Terminal Rates	0/46 (0%)	1/45 (2%)	3/36 (8%)
Life Table Tests	P=0.014	P=0.496	P = 0.040
Incidental Tumor Tests	P = 0.021	P=0.496	P=0.059

(a) At approximately 1 year of the study, 25 vehicle control male mice died from suppurative inflammation of the heart (myocarditis); only 8 mice in the group lived to the end of the study.

(b) Historical incidence of squamous cell papillomas or carcinomas in NTP studies: 7/1,055 (0.7%)

(c) Historical incidence in NTP studies: 4/1,077 (0.4%)

(d) Two female mice had squamous cell papillomas, and two others had squamous cell carcinomas.

*Liver*: The incidences of hepatocellular adenomas and hepatocellular adenomas or carcinomas (combined) in low dose female mice were greater than those in the vehicle controls (Table 15). Incidences of these neoplasms in dosed males were not significantly increased (carcinoma: vehicle control, 4/50; low dose, 6/50; high dose, 10/50; adenoma or carcinoma: vehicle control, 5/50; low dose, 7/50; high dose, 13/50).

*Kidney*: Hydronephrosis occurred at increased incidences in dosed female mice (vehicle control, 0/50; low dose, 2/50, 4%; high dose, 14/50, 28%). One vehicle control male and no dosed males had this lesion. No renal tumors were observed.

#### TABLE 15. ANALYSIS OF LIVER TUMORS IN FEMALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II*

	Vehicle Control	50 mg/kg	100 mg/kg
FEMALE			
Hepatocellular Adenoma			,
Överall Rates	0/50 (0%)	5/50 (10%)	3/50 (6%)
Adjusted Rates	0.0%	10.8%	7.8%
Terminal Rates	0/46 (0%)	4/45 (9%)	2/36 (6%)
Life Table Tests	P = 0.082	P=0.033	P=0.088
Incidental Tumor Tests	P = 0.164	P = 0.040	P = 0.164
fepatocellular Carcinoma			
Overall Rates	1/50 (2%)	3/50 (6%)	0/50 (0%)
Hepatocellular Adenoma or Carcinoma (a)			
Överall Rates	1/50 (2%)	8/50 (16%)	3/50 (6%)
Adjusted Rates	2.2%	17.4%	7.8%
Terminal Rates	1/46 (2%)	7/45 (16%)	2/36 (6%)
Life Table Tests	P = 0.183	P = 0.018	P=0.232
Incidental Tumor Tests	P = 0.291	P = 0.021	P = 0.361

(a) Historical incidence in NTP studies:  $80/1,176(7\%) \pm 3\%$ 

## **IV. DISCUSSION AND CONCLUSIONS**

Body Weight and Survival Data Toxicity and Carcinogenesis The Potential Influencing Effects of 1,2-Dichloropropane and Epichlorohydrin Mutagenicity Structure/Activity Relationships Conclusions

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This report describes mainly the results of the 2year carcinogenesis studies of Telone II[®] in F344/N rats and B6C3F₁ mice. Ancillary studies were conducted in F344/N rats to follow the time-dependent development of certain lesions as well as to perform hematologic and clinical chemistry evaluations. Commercial-grade Telone II[•] containing approximately 89% cis- and trans-1,3-dichloropropene, 2.5% 1,2-dichloropropane, 1.5% of a trichloropropene isomer, and 1.0% epichlorohydrin was administered by gavage in corn oil three times a week to the rats at 0, 25, or 50 mg/kg and to the mice at 0, 50, or 100 mg/kg. Ancillary studies were conducted in which dose groups containing five male and five female rats were killed after receiving Telone II[®] for 9, 16, 21, 24, or 27 months. These studies were conducted by Frederick Cancer Research Center (FCRC; present name: Frederick Cancer **Research** Facility) under the National Cancer Institute (NCI) Bioassay Program. Short-term studies were conducted by FCRC in advance of these long-term studies, but the data and records were considered incomplete; consequently, no final reports were written and the results are not recorded in this Technical Report.

#### Body Weight and Survival Data

Administration of Telone II[•] did not have any significant effect on the body weights or survival of male or female rats. There was a marginal depression (5%-9%) of mean body weight in the high dose male rats during the study, beginning at about week 25.

The mice in the Telone II[®] carcinogenicity studies were from three different groups that were received at 2-week intervals: vehicle control mice were from the first group; low dose mice were from the first and second groups, and high dose mice were from the second and third groups. The lack of randomization and the age differential among the dosed and vehicle control groups led to lower initial mean body weights in the dosed groups, especially in high dose females, as compared with the vehicle control group (male: low dose, -13%; high dose, -13%; female: low dose, -6%; high dose, -22%). Mean body weights of dosed mice remained lower (5%-9%) than those of the vehicle controls throughout the study. This discrepancy in body

weight was not considered to be serious enough to compromise the conclusions of the study.

Survival of vehicle control male mice was low: only 8/50 (16%) were alive at the end of the study. Thirty-nine of the 42 early deaths were attributed to suppurative inflammation of the heart (myocarditis). The cause of this lesion is unknown. Although suppurative inflammation is most characteristic of a bacterial infection, the observed high incidence of myocarditis is not typical of common contagious bacterial infections of mice. The male mice study was considered inadequate because of the low survival in the vehicle control group. The female vehicle control (46/50) and low dose (45/50) groups had greater than usual survival rates at the end of the study, whereas 36/50 survived in the high dose group.

### **Toxicity and Carcinogenesis**

The forestomach (rat, mouse), liver (rat), urinary bladder (mouse), lung (mouse), and kidney (mouse) were the primary organs affected in the 2-year studies of Telone II[•]. A summary of the incidences of lesions in rats and mice is given in Table 16.

Stomach Lesions: Hyperplasia and benign and malignant neoplasms of the squamous epithelium of the forestomach were observed in both rats and mice. These lesions were probably the result of interaction between Telone II[®] and the epithelium of the forestomach. When the incidences of squamous cell papillomas of the forestomach in male rats in the 2-year and ancillary studies were combined, statistical evidence for a dose-related effect was strengthened (Tables 5 and 16). The incidence of squamous cell carcinoma of the forestomach showed a positive trend. No squamous cell carcinomas of the forestomach were observed in scheduled-kill rats.

Comparison of these findings with tumor incidence data from previous studies indicates that the observed incidence is well above the background level. The historical incidence for squamous cell papilloma or carcinoma of the forestomach in male F344/N rats is low (6/1,114, 0.5%, Appendix G, Table G9). In addition, a dose-response trend for basal cell hyperplasia of

		Male			Female	
	Vehicle	Low	High	Vehicle	Low	High
	Control	Dose	Dose	Control	Dose	Dose
RATS						
Forestomach						
Basal cell or epithelial						
hyperplasia	(a) 2/52	5/52	13/52	1/52	0/52	16/52
	(b) ( <b>3/77</b> )	(13/77)	(31/77)	(1/75)	(5/77)	(35/77)
Squamous cell papilloma	1/52	1/52	9/52	0/52	2/52	3/52
	(1/77)	(1/77)	(13/77)	(0/75)	(2/77)	(8/77)
Squamous cell carcinoma	0/52	0/52	4/52	0/52	0/52	0/52
-	(0/77)	(0/77)	(4/77)	(0/75)	(0/77)	(0/77)
Liver						
Neoplastic nodule	1/52	6/52	7/52	6/52	6/52	10/52
	(1/77)	(6/76)	(8/77)	(6/75)	(8/77)	(12/77)
Hepatocellular carcinoma	0/52	0/52	1/52	0/52	0/52	0/52
	(0/77)	(0/76)	(1/77)	(0/75)	(0/77)	(0/77)
MICE (c)						
Forestomach						
Epithelial hyperplasia	0/50	0/50	4/50	1/50	1/50	21/50
Squamous cell papilloma	0/50	2/50	3/50	0/50	1/50	2/50
Squamous cell carcinoma	0/50	0/50	0/50	0/50	0/50	2/50
Lung						
Alveolar/bronchiolar						
adenoma	1/50	11/50	9/50	0/50	3/50	8/50
carcinoma	0/50	2/50	3/50	2/50	1/50	0/50
Urinary Bladder						
Epithelial hyperplasia	0/50	9/50	18/50	2/50	15/50	19/48
Transitional cell						
carcinoma	0/50	0/50	2/50	0/50	8/50	21/48
Kidney						
Hydronephrosis	1/50	0/50	0/50	0/50	2/50	14/50

# TABLE 16. SUMMARY OF THE INCIDENCE OF SELECTED LESIONS IN RATS AND MICE IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II[•]

(a) Bold type indicates areas of probable biologic significance.
(b) Values in parentheses represent incidence rates for the pooled data of 2-year rat carcinogenesis and ancillary (five rats per dose per sex were killed at 9, 16, 21, 24, and 27 months) studies.
(c) At approximately 1 year of the study, 25 vehicle control male mice died from suppurative inflammation of the heart (myocarditis); only 8 mice in the group lived to the end of the study.

the stomach further supports the effects of Telone II[®] on the forestomach in the male rats.

In female rats, when the data from the 2-year studies were considered alone, an increasing trend (not statistically significant) appeared to be present for the squamous cell papilloma of the forestomach (vehicle control, 0/52; low dose, 2/52; high dose, 3/52). When the data from the ancillary studies were combined with those from the 2-year studies, the five tumors in the high strengthened the dose-response dose group trend (vehicle control, 0/75; low dose, 2/77; high dose, 8/77); a significant difference ( $P \le 0.006$ ) was present between the vehicle controls and the high dose groups. Since squamous cell papillomas or carcinomas are uncommon in female F344/N rats (5/1,125, 0.4%, Appendix G, Table G10) and a clear dose-response trend of basal cell hyperplasia of the forestomach was also observed, Telone II[®] is considered responsible for the effects in the forestomach in the female rats.

The study involving male  $B6C3F_1$  mice was considered inadequate because of the early deaths in the vehicle control group, which were probably due to myocarditis. Nonetheless, the squamous cell papillomas of the forestomach observed in the male mice (vehicle control, 0/50; low dose, 2/50; high dose, 3/50) are uncommon lesions (7/1,055, 0.7%, Appendix G, Table G11). Epithelial hyperplasia of the forestomach was also observed in 4/50 male mice in the high dose group.

In the female mice, the incidence of squamous cell papillomas or carcinomas of the forestomach (combined) was increased. The relatively low incidences of squamous cell papillomas of the forestomach in dosed female mice were greater than those normally seen in female B6C3F₁ mice (4/1,077, 0.4%, Appendix G, Table G12). In high dose female mice, epithelial hyperplasia of the forestomach was prevalent. The findings in mice suggest that the effects observed in the forestomach were related to administration of Telone II[•].

Liver lesions: Telone II[•]-related lesions in the liver were observed mainly in male rats. In the 2-year studies, a positive trend in the incidence of neoplastic nodules was observed in the male rats. When the data from the scheduled-kill studies were combined with those from the 2year studies, the dose-response trend of neoplastic nodules in the male rats remained significant. In the female mice, an increased incidence of hepatocellular adenoma or hepatocellular adenoma or carcinoma was seen in the low dose group (Table 15). Since no increase was observed in high dose females, this increase is not considered compound related.

Lung lesions: Telone  $II^{\bullet}$ -related lesions in the lung were observed mainly in female mice. The incidence of alveolar/bronchiolar adenomas in the high dose female mice was significantly increased; the significance was reduced when adenomas and carcinomas were combined (Table 15). The male mice showed a similar trend, but because of the early deaths in the vehicle controls and the late appearance of this tumor, a direct comparison of these rates might be misleading.

Urinary bladder lesions: The transitional cell carcinomas of the urinary bladder observed in the Telone II[®]-dosed mice are uncommon (0/1,033 for males and 0/1,025 for females. Appendix G, Table G13). The tumors did not proliferate outward in a papillary manner but were characterized by solid to glandular growths extending downward from the transitional epithelium into the submucosa and muscular laver and in a few cases to the serosa of the bladder. Urinary bladder tumors have often been associated with exposure to aromatic amines (Cohen et al., 1982; Hicks, 1983); however, the components of Telone II[®] are chemically and physically different from those of aromatic amines. No calculi were observed in the urinary bladder of the mice with transitional cell carcinomas. In the dosed female mice, epithelial hyperplasia of the urinary bladder was also increased. The prevalence of these neoplastic and nonneoplastic lesions in the dosed female mice indicates that the effects were related to administration of Telone II[•]. The increased incidence of epithelial hyperplasia and transitional cell carcinoma of the urinary bladder (2/50) in high dose males as compared with 0/50 in concurrent controls and 0/1,033 (for transitional cell carcinoma of the urinary bladder) in historical controls suggests that the effects are related to administration of

Telone II[®]. Lesions of the urinary bladder were not seen in rats.

Kidney lesions: Hydronephrosis was observed in dosed female mice. Since 8 of the 14 high dose females with hydronephrosis also had transitional cell carcinoma of the urinary bladder and 3 of the remaining 6 had hyperplasia of the urinary bladder, this lesion might have been a secondary effect of the urinary bladder lesions (i.e., restricted urine flow at the renal pelvis and/or ureter). Thirteen female mice had transitional cell carcinomas without hydronephrosis. The complete dilation of the pelvic area in the affected animals supports the possibility of hydronephrosis being secondary to the bladder lesions. Torkelson and Oyen (1977) reported that after male rats were exposed to 1,3-dichloropropene at a concentration of 3 ppm for 7 hours per day, 5 days per week for 6 months, only cloudy swelling of the renal tubular epithelium was found to be compound related.

Other organs: The incidence of pheochromocytomas of the adrenal gland (vehicle control, 2/52; low dose, 8/52; high dose, 6/52) was increased marginally (P < 0.05) in low dose male rats compared with that in the vehicle controls (Table 8). There was no dose-response relationship, and the mean historical incidence is 17% (Appendix G, Table G1). The combined incidence of follicular cell adenoma or carcinoma of the thyroid gland in female rats showed a marginal trend (vehicle control, 0/52; low dose, 2/52; high dose, 4/52). In both cases, the additional data from the ancillary studies strengthened the effects slightly (male--pheochromocytomas: vehicle control, 4/77; low dose, 14/77; high dose, 10/76; female--follicular cell adenomas or carcinomas: vehicle control, 0/75; low dose, 2/77; high dose, 5/77), but the increases remained marginal.

# The Potential Influencing Effects of 1,2-Dichloropropane and Epichlorohydrin

The material tested, Telone II[®], contains primarily isomers of 1,3-dichloropropene. The added stabilizer or impurities present in Telone II[®] are epichlorohydrin (1.0%) and 1,2-dichloropropane (2.5%). Both chemicals have been shown to be carcinogenic (Laskin et al., 1980; Konishi et al., 1980; NTP, 1985). These studies are described briefly below. An additional impurity, a trichloropropene isomer (1.5%), has not been tested for carcinogenicity.

1,2-Dichloropropane was administered in corn oil by gavage to F344/N rats and B6C3F1 mice (NTP, 1985). Doses of 0, 62, 125, or 250 mg/kg body weight were given five times per week for 103 weeks. Under these conditions, 1,2-dichloropropane caused an increased incidence of hepatocellular adenomas in male and female mice (male: vehicle control, 7/50; low dose, 10/49; high dose, 16/50; female: vehicle control, 0/50; low dose, 4/50; high dose, 5/50) and a marginally increased incidence of adenocarcinomas in the mammary gland in female rats (vehicle control, 1/50; low dose, 2/50; high dose, 5/50). These neoplasms are different from the principal neoplastic lesions observed in the Telone II[®] studies. Furthermore, the highest level of 1,2-dichloropropane that could be achieved with the dose regimen in the present studies is 2.5 mg/kg (i.e., 2.5% of the highest dose at 100 mg/kg) per administration. This level is approximately thirtyfold less than the dose levels used in the 1,2-dichloropropane study in which the dosing frequency was five times per week. Therefore, the 2.5% 1.2-dichloropropane in the Telone II[•] preparation was not considered to be responsible for any of the toxic responses.

Konishi et al. (1980) reported that male Wistar rats offered epichlorohydrin in drinking water at 0, 375, 750, or 1,500 ppm for 81 weeks developed forestomach hyperplasia (vehicle control, 0/10; low dose, 7/9; mid dose, 9/10; high dose, 12/12) and, at the two highest concentrations, forestomach papillomas (1/10, 7/12) and carcinomas (1/10, 2/12). Thus, forestomach hyperplasia was induced in male Wistar rats with long term intake of water containing as low as 0.375 mg epichlorohydrin/ml (i.e., 375 ppm), whereas forestomach papillomas and carcinomas were induced with 0.75-1.5 mg epichlorohydrin/ml water (750-1,500 ppm). In comparison, the present studies used 50 mg/kg Telone II[®] for rats and 100 mg/kg for mice as the high doses. Epichlorohydrin was present at a concentration of 1.0% in Telone II[®]; thus, the high dose rats or mice would have received epichlorohydrin at doses of 0.5 mg/kg or 1.0 mg/kg. Since the

gavage dose volume was 5 ml/kg, the epichlorohydrin concentrations for the high dose rats and mice would have been between 0.1 mg/ml or 0.2 mg/ml. Although these concentrations were several times lower than those calculated from the study by Konishi et al. (1980), the following factors suggest that epichlorohydrin, in addition to 1,3-dichloropropene, may have a role in the chronic toxicity (including carcinogenicity) in the present studies:

(1) The kinetics of a single gavage administration is such that the exposure to epichlorohydrin at the site of application is relatively brief but concentrated. In contrast, incorporation of epichlorohydrin in the drinking water means that the daily dose would be distributed throughout the day as the animals drink. The exposure, therefore, would be multiple and at lower epichlorohydrin concentrations. Thus, the gavage dosing in the Telone II[®] studies would probably produce epichlorohydrin concentrations at the site of application similar to those in the drinking water study by Konishi et al. (1980), albeit for much shorter periods.

(2) The same lesions (e.g., forestomach hyperplasia, papillomas, carcinomas) were seen in both the study by Konishi et al. (1980) and the present studies.

### Mutagenicity

Recently Talcott and King (1984) demonstrated that purification of four separate preparations of 1,3-dichloropropene by silicic acid chromatography (which removes polar impurities) eliminated the mutagenicity of the preparations in *Salmonella typhimurium* strain TA100. The authors showed that purified 1,3-dichloropropene was not mutagenic. The unpurified preparations contained a mixture of polar impurities that accounted for the mutagenic activity of three of the four preparations. Two oxidation products of 1,3-dichloropropene were tentatively identified in one of the mixtures of polar impurities: these were epichlorohydrin and 1,3-dichloro-2-propanol--both of which are mutagenic in Salmonella (McCann et al., 1975; Stolzenberg and Hine, 1980). These results suggest that mutagenic impurities rather than 1,3-dichloropropene itself account for the mutagenic activity of preparations of 1,3-dichloropropene. Nonetheless, Telone II[®] was mutagenic in Salmonella strains TA100, TA1535, and TA1978 in the presence or absence of S9 (De Lorenzo et al., 1977).

## Structure/Activity Relationships

Chu and Milman (1981) have reviewed the carcinogenesis data on vinyl chloride (a structural analog of 1,3-dichloropropene), vinylidine chloride, trichloroethylene, 1,2-dichloroethane, 1,2-dibromoethane, tetrachloroethylene, and epichlorohydrin. These compounds have been shown to be carcinogenic in at least one study. although controversy regarding carcinogenicity for some of these compounds may still exist. The structural formulae of these compounds are presented in Figure 6. These chemicals have two common features: they are all small molecules with a short carbon chain, and they are all chlorinated or brominated. Chu and Milman (1981) pointed out that direct-acting compounds such as 1,2-dibromoethane, 1,2-dichloroethane, and epichlorohydrin produced forestomach tumors when given by gavage or nasal cavity tumors when given by inhalation. 1,2-Dibromoethane and 1.2-dichloroethane also induced tumors distant from the site of application. 1.3-Dichloropropene has an allylic carbon that should be reactive and could account for the induction of tumors of the forestomach. In addition, metabolic activation is probable at the carbon-carbon double bond. The development of tumors at locations distant from the site of application may be related to the formation of reactive intermediates.







Vinyl Chloride

Vinylidine Chloride

Trichloroethylene







1,2-Dichloroethane

1,2-Dibromoethane (EDB)

Tetrachloroethylene



Epichlorohydrin



1,3-Dichloropropene (*cis*-form shown)

## FIGURE 6. STRUCTURES OF 1,3-DICHLOROPROPENE AND RELATED COMPOUNDS

#### Conclusions

Under the conditions of these gavage studies, there was clear evidence of carcinogenicity^{*} for male F344/N rats, as indicated by Telone II^{*}related increased incidences of squamous cell papillomas and carcinomas of the forestomach, as well as an increased incidence of neoplastic nodules of the liver. In female F344/N rats, there was some evidence of carcinogenicity because Telone II^{*} caused an increased incidence of squamous cell papillomas of the forestomach. The experiment in male B6C3F₁ mice was considered to be an *inadequate study of carcinogenicity* because of reduced survival in the vehicle control group. However, there was some indication in the male mice of Telone II^{*}-related

increases of transitional cell carcinomas of the urinary bladder, squamous cell papillomas of the forestomach, and alveolar/bronchiolar adenomas and carcinomas of the lung. There was clear evidence of carcinogenicity for female  $B6C3F_1$ mice, since Telone II[®] caused increased incidences of transitional cell carcinomas of the urinary bladder; Telone II[•] also increased the incidences of alveolar/bronchiolar adenomas of the lung and of squamous cell papillomas or carcinomas of the forestomach in the female mice. Telone II[®]-related nonneoplastic lesions included basal cell or epithelial cell hyperplasia in the forestomach of male and female rats and male and female mice and epithelial hyperplasia of the urinary bladder in male and female mice.

^{*}Categories of evidence of carcinogenicity are defined in the Note to the Reader on page 2.

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Telone II[®], NTP TR 269

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## **V. REFERENCES**

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## **APPENDIX** A

# SUMMARY OF THE INCIDENCE OF NEOPLASMS IN RATS IN THE TWO-YEAR GAVAGE STUDIES OF

## **TELONE II**•

	CONTR	ROL (VEH)	LOV	V DOSE	HIG	H DOS
ANIMALS INITIALLY IN STUDY	52		52		52	
ANIMALS NECROPSIED	52		52		52	
ANIMALS EXAMINED HISTOPATHOLOGICALLY	52		52	. <u></u>	52	
NTEGUMENTARY SYSTEM	(50)		(50)		(50)	
*ABDOMINAL CAVITY FIBROUS HISTIOCYTOMA, MALIGNANT	(52)		(52) 1	(2%)	(52)	
*SKIN	(52)		(52)	(270)	(52)	
SQUAMOUS CELL CARCINOMA			1	(2%)		
BASAL-CELL CARCINOMA TRICHOEPITHELIOMA	1	(2%)	1	(2%)	1	(2%) (2%)
*SUBCUT TISSUE	(52)		(52)	(270)	(52)	(470)
FIBROMA	Ĵ.	(6%)		(2%)		
FIBROUS HISTIOCYTOMA, MALIGNANT				(00)	1	(2%)
LEIOMYOSARCOMA NEURILEMOMA, MALIGNANT			T	(2%)	1	(2%)
ESPIRATORY SYSTEM						
#LUNG	(52)		(52)		(52)	
ALVEOLAR/BRONCHIOLAR ADENOMA	1		2	(4%)		
ALVEOLAR/BRONCHIOLAR CARCINOMA C-CELL CARCINOMA, METASTATIC	1	(2%)	2	(4%)		
IEMATOPOIETIC SYSTEM						
*MULTIPLE ORGANS	(52)		(52)		(52)	(8.41)
MALIGNANT LYMPHOMA, NOS MONOCYTIC LEUKEMIA	12	(23%)	12	(23%)	10	(2%) (19%)
#BONE MARROW	(52)	(20 %)	(52)	(20%)	(52)	(1070)
SARCOMA, NOS					1	(2%)
#SPLEEN MONOCYTIC LEUKEMIA	(52)	(00)	(52)		(52)	
#LYMPH NODE	(52)	(2%)	(52)		(52)	
C-CELL CARCINOMA, METASTATIC	(02)		ĩ	(2%)	(02)	
IRCULATORY SYSTEM NONE						
IGESTIVE SYSTEM	(70)		(70)		(70)	
*TONGUE SQUAMOUS CELL PAPILLOMA	(52)		(52)		(52)	(4%)
#LIVER	(52)		(52)		(52)	
	4	(2%)	0	(12%)	7	(13%)
NEOPLASTIC NODULE	1		6		4	(2%)
NEOPLASTIC NODULE HEPATOCELLULAR CARCINOMA	1		0		1	
NEOPLASTIC NODULE HEPATOCELLULAR CARCINOMA SARCOMA, NOS, METASTATIC	L		U		1 1 1	(2%)
NEOPLASTIC NODULE HEPATOCELLULAR CARCINOMA SARCOMA, NOS, METASTATIC FIBROUS HISTIOCYTOMA, METASTATIC #PANCREAS	(52)		(52)		ī (52)	(2%) (2%)
NEOPLASTIC NODULE HEPATOCELLULAR CARCINOMA SARCOMA, NOS, METASTATIC FIBROUS HISTIOCYTOMA, METASTATIC #PANCREAS ACINAR-CELL ADENOMA	(52) 2	(4%)	(52)		ī (52) 2	(2%)
NEOPLASTIC NODULE HEPATOCELLULAR CARCINOMA SARCOMA, NOS, METASTATIC FIBROUS HISTIOCYTOMA, METASTATIC #PANCREAS ACINAR-CELL ADENOMA #STOMACH	(52) 2 (52)	(4%)			1 (52) 2 (52)	(2%) (2%) (4%)
NEOPLASTIC NODULE HEPATOCELLULAR CARCINOMA SARCOMA, NOS, METASTATIC FIBROUS HISTIOCYTOMA, METASTATIC #PANCREAS ACINAR-CELL ADENOMA #STOMACH SQUAMOUS CELL PAPILLOMA	(52) 2 (52)		(52)		1 (52) 2 (52) 8	(2%) (2%) (4%) (15%)
NEOPLASTIC NODULE HEPATOCELLULAR CARCINOMA SARCOMA, NOS, METASTATIC FIBROUS HISTIOCYTOMA, METASTATIC #PANCREAS ACINAR-CELL ADENOMA #STOMACH	(52) 2 (52)	(4%)	(52) (52) (52)	(2%)	1 (52) 2 (52) 8 4 (52)	(2%) (2%) (4%)
NEOPLASTIC NODULE HEPATOCELLULAR CARCINOMA SARCOMA, NOS, METASTATIC FIBROUS HISTIOCYTOMA, METASTATIC #PANCREAS ACINAR-CELL ADENOMA #STOMACH SQUAMOUS CELL PAPILLOMA SQUAMOUS CELL CARCINOMA #FORESTOMACH SQUAMOUS CELL PAPILLOMA TRINARY SYSTEM	(52) 2 (52) 1 (52)	(4%)	(52) (52) (52) 1	(2%)	1 (52) 2 (52) 8 4 (52) 1	(2%) (2%) (4%) (15%) (8%)
NEOPLASTIC NODULE HEPATOCELLULAR CARCINOMA SARCOMA, NOS, METASTATIC FIBROUS HISTIOCYTOMA, METASTATIC #PANCREAS ACINAR-CELL ADENOMA #STOMACH SQUAMOUS CELL PAPILLOMA SQUAMOUS CELL CARCINOMA #FORESTOMACH SQUAMOUS CELL PAPILLOMA	(52) 2 (52) 1	(4%)	(52) (52) (52)	(2%)	1 (52) 2 (52) 8 4 (52) 1 (52)	(2%) (2%) (4%) (15%) (8%)

# TABLE A1. SUMMARY OF THE INCIDENCE OF NEOPLASMS IN MALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II®

## Telone II[®], NTP TR 269

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	CONTRO	L(VEH)	LOW	DOSE	HIG	H DOSI
ENDOCRINE SYSTEM		; — <u>, _ , _ , _ , _ , _ , _ , _ , _ , _ , </u>				
#PITUITARY	(52)		(50)		(50)	
CARCINOMA.NOS			(			(2%)
ADENOMA, NOS	1 (	2%)				•
CHROMOPHOBE ADENOMA	23 (		13	(26%)	16	(32%)
ACIDOPHIL ADENOMA	、			(2%)		
#ADRENAL	(52)		(52)	(=)	(52)	
CORTICAL ADENOMA		4%)	1	(2%)	,	
PHEOCHROMOCYTOMA	2 (			(13%)	6	(12%)
#ADRENAL MEDULLA	(52)		(52)		(52)	
PHEOCHROMOCYTOMA			1	(2%)		
#THYROID	(52)		(51)	• • •	(51)	
FOLLICULAR-CELL ADENOMA	·/		2	(4%)		
FOLLICULAR-CELL CARCINOMA			2	(4%)	1	(2%)
C-CELL ADENOMA	3 (	6%)			2	(4%)
C-CELL CARCINOMA	3 (	6%)	4	(8%)	2	(4%)
<b>#PARATHYROID</b>	(39)		(32)		(39)	
CARCINOMA,NOS					1	(3%)
ADENOMA, NOS	1 (3	3%)				
<b>#PANCREATIC ISLETS</b>	(52)		(52)		(52)	
ISLET-CELL ADENOMA	10 (	19%)		(13%)	9	(17%)
ISLET-CELL CARCINOMA	2 (4	<b>4%)</b> .	6	(12%)		
REPRODUCTIVE SYSTEM						
*MAMMARY GLAND	(52)		(52)		(52)	
FIBROADENOMA	í (	296)		(10%)	ĺ	(2%)
*PREPUTIAL GLAND	(52)		(52)	(	(52)	<b>x</b> =,
CARCINOMA,NOS	1 (5	296)				
ADENOMA, NOS					1	(2%)
ADENOCARCINOMA, NOS	2 (4	1%)				
#TESTIS	(52)		(52)		(52)	
INTERSTITIAL-CELL TUMOR	46 (8	38%)	46	(88%)	48	(92%)
NERVOUS SYSTEM						
#BRAIN	(52)		(52)		(52)	
GLIOMA, NOS	·		1	(2%)		
OLIGODÉNDROGLIOMA			1	(2%)		
SPECIAL SENSE ORGANS NONE						
MUSCULOSKELETAL SYSTEM		<u></u>				
*LUMBAR VERTEBRA	(52)		(52)		(52)	
OSTEOSARCOMA	(/		<b>、</b> /			(2%)
BODY CAVITIES						
*ABDOMINAL CAVITY	(52)		(52)		(52)	
RHABDOMYOSARCOMA				(2%)		
<b>*TUNICA VAGINALIS</b>	(52)		(52)		(52)	
MESOTHELIOMA, NOS		1%)	1	(2%)		(2%)
MESOTHELIOMA, MALIGNANT	1 (2	9 <b>6</b> ()			9	(4%)

#### TABLE A1. SUMMARY OF THE INCIDENCE OF NEOPLASMS IN MALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

#### TABLE A1. SUMMARY OF THE INCIDENCE OF NEOPLASMS IN MALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

	CONTROL (VEH)	LOW DOSE	HIGH DOSI
LL OTHER SYSTEMS	(20)	(70)	(10)
*MULTIPLE ORGANS ADENOCARCINOMA, NOS, METASTATIC	(52)	(52)	(52) 1 (2%)
MALIGNANT MELANOMA, METASTATIC	1 (2%)		1 (470)
FIBROUS HISTIOCYTOMA, METASTATIC	- (= %)	1 (2%)	
MESOTHELIOMA, MALIGNANT		1 (2%)	
OSTEOSARCOMA, METASTATIC		1 (2%)	1 (2%)
SITE UNKNOWN			
ADENOCARCINOMA, NOS			1
NUMBER OF ANIMALS WITH TISSUE EXAMIN	ED MICROSCOPICALLY	Y	
NUMBER OF ANIMALS NECROPSIED			·
NIMAL DISPOSITION SUMMARY		-	
ANIMALS INITIALLY IN STUDY NATURAL DEATH	52 8	52 12	52 10
MORIBUND SACRIFICE	0	2	10
SCHEDULED SACRIFICE		-	-
TERMINAL SACRIFICE	42	37	40
DOSING ACCIDENT	2	1	1
ACCIDENTALLY KILLED, NDA			
ACCIDENTALLY KILLED, NOS ANIMAL MISSING			
ANIMAL MISSING ANIMAL MISSEXED			
OTHER CASES			
			· · · · · · · · · · · · · · · · · · ·
UMOR SUMMARY TOTAL ANIMALS WITH PRIMARY TUMORS**	51	47	50
TOTAL PRIMARY TUMORS	123	127	135
TOTAL ANIMALS WITH BENIGN TUMORS	50	46	49
TOTAL BENIGN TUMORS TOTAL ANIMALS WITH MALIGNANT TUMOR	96 S 23	88	97 27
TOTAL MALIGNANT TUMORS	24	26 32	30
TOTAL ANIMALS WITH SECONDARY TUMOR		32 5	4
TOTAL SECONDARY TUMORS	1	5	4
TOTAL ANIMALS WITH TUMORS UNCERTAIN	۹-		
BENIGN OR MALIGNANT	3	7 '	8
TOTAL UNCERTAIN TUMORS	8	7	8
TOTAL ANIMALS WITH TUMORS UNCERTAIN	<b>i</b> -		
PRIMARY OR METASTATIC TOTAL UNCERTAIN TUMORS			
IUIAL UNGERTAIN TUMURS			

## SECONDARY TUMORS: METASTATIC TUMORS OR TUMORS INVASIVE INTO AN ADJACENT ORGAN

Telone II[®], NTP TR 269

## TABLE A2. SUMMARY OF THE INCIDENCE OF NEOPLASMS IN FEMALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II®

	CONTR	ol (veh)	LOW	DOSE	HIGH	i dose
ANIMALS INITIALLY IN STUDY ANIMALS NECROPSIED ANIMALS EXAMINED HISTOPATHOLOGICALLY	52 52 52 52		52 52 52		52 52 52	
INTEGUMENTARY SYSTEM *SKIN SQUAMOUS CELL CARCINOMA *SUBCUT TISSUE FIBROMA RHABDOMYOSARCOMA CARCINOSARCOMA	(52) (52) 1	(2%)	(52) (52) 1	(2%)	(52) 1 (52) 1	(2%) (2%)
RESPIRATORY SYSTEM #LUNG ALVEOLAR/BRONCHIOLAR ADENOMA ALVEOLAR/BRONCHIOLAR CARCINOMA GRANULOSA-CELL CARCINOMA, METAST	(52) 1	(2%)	(52)	(2%)	(52) 2 1 1	(4%) (2%) (2%)
HEMATOPOIETIC SYSTEM *MULTIPLE ORGANS MALIGNANT LYMPHOMA, NOS MONOCYTIC LEUKEMIA LEUKEMIA, MONONUCLEAR CELL #MANDIBULAR L. NODE CARCINOSARCOMA, INVASIVE #THYMUS THYMOMA	(52) 1 9 (52) (52)	(2%) (17%)	(52) 9 1 (52) (52) 1	(17%) (2%) (2%)	(52) 5 (52) 1 (50)	(10%) (2%)
CIRCULATORY SYSTEM #SPLEEN HEMANGIOSARCOMA	(52)		(51)		(52) 1	(2%)
DIGESTIVE SYSTEM *TONGUE SQUAMOUS CELL CARCINOMA #LIVER NEOPLASTIC NODULE #PANCREAS FIBROSARCOMA, METASTATIC #STOMACH SQUAMOUS CELL PAPILLOMA	(52) 1 (52) 6 (52) (52)	(2%) (12%)	(52) (52)	(12%) (4%)	(52) 1 (52)	(19%) (2%) (6%)
URINARY SYSTEM #URINARY BLADDER TRANSITIONAL-CELL CARCINOMA ADENOMATOUS POLYP, NOS	(52) 1	(2%)	( <b>52</b> ) 1	(2%)	(52)	

Telone II^o, NTP TR 269

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	CONTR	OL (VEH)	LOW	DOSE	HIG	H DOSI
INDOCRINE SYSTEM						
<b>#PITUITARY</b>	(50)		(51)		(52)	
CHROMOPHOBE ADENOMA		(56%)		(51%)		(58%)
CHROMOPHOBE CARCINOMA	2	(4%)		(2%)		(2%)
#ADRENAL	(52)		(52)		(52)	(00)
CORTICAL ADENOMA	2	(4%)		(00)	1	(2%)
CORTICAL CARCINOMA		(0.7)	1	(2%)		
PHEOCHROMOCYTOMA		(2%)		(4%)	(52)	
#THYROID	(52)		(52) 1	(2%)	(52)	(4%)
FOLLICULAR-CELL ADENOMA			1	(2%)	2	(4%)
FOLLICULAR-CELL CARCINOMA	4	(8%)		(12%)		(4%)
C-CELL ADENOMA	42		0	(4%)		(2%)
C-CELL CARCINOMA		(4%)	(52)	(4270)	(52)	(20)
<b>#PANCREATIC ISLETS</b>	(52) 3	(6%)		(2%)	(02)	
ISLET-CELL ADENOMA ISLET-CELL CARCINOMA	ა	(070)	1	(270)	1	(2%)
EPRODUCTIVE SYSTEM						
*MAMMARY GLAND	(52)		(52)		(52)	
ADENOMA, NOS	í	(2%)	(			
ADENOCARCINOMA, NOS	Ž	(4%)				(2%)
FIBROADENOMA	14	(27%)	20	(38%)		(46%)
*PREPUTIAL GLAND	(52)		(52)		(52)	
CARCINOMA,NOS			1	(2%)	2	(4%)
*CLITORAL GLAND	(52)		(52)		(52)	
CARCINOMA,NOS			1	(2%)		
ADENOMA, NOS			1	(2%)		
#UTERUS	(52)		(52)		(52)	
ADENOCARCINOMA, NOS					1	(2%)
LEIOMYOMA		(2%)				
ENDOMETRIAL STROMAL POLYP	16	(31%)	10	(19%)	12	(23%)
ENDOMETRIAL STROMAL SARCOMA	2	(4%)				
#OVARY	(52)		(52)		(52)	(0~)
GRANULOSA-CELL CARCINOMA						(2%)
FIBROSARCOMA					1	(2%)
IERVOUS SYSTEM NONE						
PECIAL SENSE ORGANS	<u>.                                    </u>					
*ZYMBAL GLAND	(52)		(52)		(52)	
CARCINOMA,NOS	(04)		(0-)		í	(2%)
IUSCULOSKELETAL SYSTEM NONE	<u></u>			<u></u>		
BODY CAVITIES NONE						
ALL OTHER SYSTEMS					/26	
*MULTIPLE ORGANS LEIOMYOSARCOMA, METASTATIC SITE UNKNOWN	(52)		(52)			(2%)
LEIOMYOSARCOMA					1	

### TABLE A2. SUMMARY OF THE INCIDENCE OF NEOPLASMS IN FEMALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

# NUMBER OF ANIMALS WITH TISSUE EXAMINED MICROSCOPICALLY • NUMBER OF ANIMALS NECROPSIED

52	52	52
16	13	13
1		1
0.4	QE	38
34		90
1	3	
	1	
	-	
98 38 70 S 18 22 S##	96 39 72 15 18	108 39 76 19 22 4 4
	e	10
		10
	<b>v</b>	A V
1-		
	16 1 34 1 45 98 38 38 70 25 18	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$

### TABLE A2. SUMMARY OF THE INCIDENCE OF NEOPLASMS IN FEMALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

ANIMAL NUMBER		00	003	0	007	0 0 9	0 1 1	0 1 3	0 1 5	0 1 7	019	0 2 1	0 2 3	0215	0 2 7	29	0 3 1	33	35	0 3 7	039	4	0 4 3	045	0 4 7	0 4 9
WEEKS ON STUDY		1 0 7	1 0 7	1 0 7	1 0 7	0 9 7	1 0 7	1 0 7	1 0 7	1 0 7	1 0 7	1 0 7	1 0 6	1 0 7	0 0 1	1 0 7	1 0 7	0 0 8	1 0 7	1 0 7	1 0 7	1 0 7	1 0 7	0 8 2	0 7 8	1 0 7
INTEGUMENTARY SYSTEM		1	+	+	+	+		+	 +	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
Basal cell carcinoma Subcutaneous tissue Fibroma		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
RESPIRATORY SYSTEM Lungs and bronchi Alveolar/bronchiolar adenoma Alveolar/bronchiolar carcinoma Trachea		+	+	+	++	+	+	+	++	+	+	+	+	+ X +	++	+	++	+	+	++	+	+	+	++	+	+
HEMATOPOIETIC SYSTEM Bone marrow Soleen Monocytic leukemia Lymph nodes Thymus		++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ +1	++ ++	++ + + 1	++ ++	++ ++	++ ++	++ ++	++ ++	++X++	+++++	++ ++	++ ++	++ ++	+++	+++++	++ ++	++ ++
CIRCULATORY SYSTEM Heart	-	+	+	÷	+	÷	÷	+	+	÷	+	+	+	+	÷	÷	+	+	+	+	+	+	+	+	+	+
DIGESTIVE SYSTEM Salivary gland Liver Neoplastic nodule Bila dust		++++	+++++	+++	++	++	++X+	++	++	+ + +	++	+ + -	++	++	+++	+ +	+++	+++	++	+++	++++	+++	+++	++++	+++	++
Bile duct Gailbladder & common bile duct Pancreas Acinar cell adenoma Esophagus		+N + +	+N + +	+ X + +	+X + +	+N + +	+ 2 + +	+ X + +	+ X + +	+N++	+N++	+ 1 + 2 +	+N++	+N+ +	+N+ +	+X+ +	+N++	+ X + +	+N++	+N +X +	+N + +	+ X + +	+N++	+ X + +	+ X + +	+ 2 + +
Stomach Squamous cell papilloma Small intestine Large intestine		+ +++	+ ++	+ ++	+ ++	+ +++	+ ++	+ ++	+ ++	+ ++	+ ++	+ ++	+ ++	+ ++	+ ++	+ ++	+ ++	+ ++	+ ++	+++	+ + +	+ ++	+ ++	++++	+ ++	+++
URINARY SYSTEM Kidney Urinary bladder		+ +	++	++	++	++	+++	+++	++	++	++	+++	+++	++	++	++	+++	++	++	++	++	++	++	+++	+++	++
ENDOCRINE SYSTEM Pituitary Adenoma, NOS Chromophobe adenoma Adrenai	- )	+	+	+	+	++	+	+ X +	+ X +	+ X +	+ x +	+	++	+ x	+	+ X +	+	+	+ X +	++	+	+ X +	+	+ X +	+ x +	- + x+
Cortical adenoma Pheochromocytoma Ihyroid C-cell adenoma		+	X +	X +	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	+
C-ceil cercinoma Parathyroid Adenoma, NOS		+	+	X +	+	÷ x	+	-	+	+	-	-	+	+	+	-	-	+	-	+	+	+	+	+	+	X
Pancreatic islets Islet cell adenoma Islet cell carcinoma		+	* X	+	+	+	+	+	*	+	*	+	+	+	+	+	+	+	+ X	+	+	+	*	+	+	+
REPRODUCTIVE SYSTEM Mammary gland Fibroadenoma	•	+	+	+	N	+	+	+	+	+	N	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
festis Interstitial cell tumor Prostate		+	+	* * *	+	+x +:	+x +:	+x +	+ ::	+	+	+x +:	**	+x +:	+ ::	+x +:	* * *	+ ::	+x +:	+ X + :	+ x +	***	** *:	*x +:	+ ::	*x +:
reputial/clitoral gland Carcinoma, NOS Adenocarcinoma, NOS		N	N	N X	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N X	N	N	N	N	N
ERVOUS SYSTEM	-	+	+	+	÷	+	+	+	÷	÷	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ODY CAVITIES Funica vaginalis Mesothelioma, NOS Mesothelioma, malignant	•	+	+	* x	+	+	+	+	+	+	+	*	+	+	+	+	+	+	+	+	+	+	+	+ X	+	+
ALL OTHER SYSTEMS Multiple organs NOS Malignant melanoma, metastatic Monocytic leukemia	1	N	N	N	N	N	N		N X	N	N	N	N X	N	N	N	N X	N	N	N	N	N X	N	N X	N	N

# TABLE A3. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE RATS IN THETWO-YEAR GAVAGE STUDY OF TELONE II*: VEHICLE CONTROL

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 + : Tissue Examined Microscopically

 - : Required Tissue Not Examined Microscopically

 X : Tumor Incidence

 N : Necropsy, No Autolysis, No Microscopic Examination

 S : Animal Missexed

No Tissue Information Submitted
 C : Necropsy, No Histology Due To Protocol
 A : Autolysis
 M : Animal Missing
 B : No Necropsy Performed

# TABLE A3. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE RATS: VEHICLE CONTROL (Continued)

| 0<br>5<br>1 | 0<br>5<br>3                            | 0<br>5<br>5                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                       | 0<br>5<br>7                                          | 0<br>5<br>9                                                                  | 0<br>6<br>1                                                                  | 0<br>6<br>3                                                        | 0<br>6<br>5                                                        | 0<br>6<br>7                                                        | 0<br>6<br>9                                                        | 0<br>7<br>1                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                 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      1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1 | ¹ / ₁ </td <td>¹/₁ ¹/₁ ¹/₁<!--</td--><td>1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1     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 1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1</td><td>1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1</td><td>Image: Amage: Amage:</td><td>Image: Second second</td></td> | ¹ / ₁ </td <td>1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1</td> <td>¹ ¹ ¹</td> <td>1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1</td> <td>1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1  
    1       1       1       1       1       1       1       1       1       1</td> <td>Image: Amage: Amage:</td> <td>Image: Second second</td> | 1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1 | ¹ | 1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1 | 1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1       1 | Image: Amage: | Image: Second |

* Animals Necropsied

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									_						-						_			-	
ANIMAL NUMBER	2 0 1	203	2 0 5	207	209	2 1 1	2 1 3	2 1 5	2 1 7	2 1 9	2 2 1	223	225	227	229	231	233	235	237	239	2 4 1	243	245	247	2 4 9
WEEKSON Study	1 0 6	1 0 2	0 6 3	1 0 6	0 0 3	002	104	1 0 6	1 0 6	1 0 6	1 0 6	106	1 0 6	1 0 6	104	1 0 6	106	106	0 94	106	1 0 6	1 0 6	100	1 0 6	0
INTEGUMENTARY SYSTEM Skin	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	. +	*	+	-
Squamous cell carcinoma Trichoepithelioma Subcutaneous tissue Fibroma Leiomyosarcoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	л + Х	+	+
RESPIRATORY SYSTEM . Lungs and bronchi Alveolar/bronchiolar adenoma C-cell carcinoma, metastatic Traches	+	+	++	·+ X +	+	+	++	+	+	+	+	* *	+	+	+	+	+	+	+	* *	+	+	+	+	++++
HEMATOPOIETIC SYSTEM Bone marrow Spleen Lymph nodes C-cell carcinoma, metastatic Thymus	+++++++++++++++++++++++++++++++++++++++	+++ +	+++++++++++++++++++++++++++++++++++++++	+++ +	+++ +	+++++++++++++++++++++++++++++++++++++++	+++++++++++++++++++++++++++++++++++++++	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	+++ +	- +++ +
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	 +
DIGESTIVE SYSTEM Selivary gland Liver	+	+++	++	++	+++	+	+	++	+++	++	++	+++	+++	+	+	++	‡	++;	+	++	++	+++	+	+++	-
Neoplastic nodule Bile duct Galibladder & common bile duct Pancreas Esophagus Stomach	+N+++	+ + + + + + + + + + + + + + + + + + + +	+2+++	+ + + z + + +	+z+++	+z++;	+2+1+	+ + + z + + +	+z+++	+2+++	+2+++	+ + + z + + +	+z+++	+N+++	+z+++	+2+++	+z++	X+X+++	+ Z + + +	+++2+++	+ 2 + + +	+z++	+N+++	+ + + + + +	+z++
Squamous ceil papilloma Small intestine Large intestine	‡	‡	++	+ +	+ +	‡	++	+ +	++	++	++	++	+ +	+ +	+ +	++	+	<b>+</b> +	+ +	<b>+</b> +	+ +	+ +	+ +	++	+
URINARY SYSTEM Kidney Liposarcoma Urinary bladder	+	+x +	+++	++	+ +	++	+ +	++	++	+	++	++	++	++	+ +	++	++	+++	++	++	+	+++	+ +	+++	+++++++++++++++++++++++++++++++++++++++
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma	+	+	-	+	+	+	+	*	+	+	*	*	*	+	*	+	+	+	+	+	+	+	+	+	+
Acidophìl adenoma Adrenal Cortical adenoma Pheochromocytoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+ X	+	+	+	+	+ x	+	+	+	+
Thyroid Follicular cell adenoma Follicular cell carcinoma C-cell carcinoma	+	+	+	+ X X	+	+	-	+	+	*	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Parathyroid Pancreatic islets Islet cell adenoma Islet cell carcinoma	<del>-</del>	+ * X	+	+ + X	++	+ +	+	+	++	++	+	+	+	++	+ + X	++	∓ x	+++	++	+ +	+ x	+++	+	++	+
REPRODUCTIVE SYSTEM Mammary gland Fibroadenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	÷ x	÷	+	+	+
Testis Interstitial cell tumor Prostate	× ×	÷	++	+ X +	+ +	+ +	* x +	+x+	+ X +	* *	** *	+x +	+ x +	+ x +	+ x +	+ x +	* *	+ x +	+ +	+ x +	+ X +	* *	+ X +	* *	* +
NERVOUS SYSTEM Brain Glioma, NOS Oligodendroglioma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
BODY CAVITIES Peritoneum Fibrous histiocytoma, malignant Rhabdomycearcoma	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N X	N	N	N	N	N	- N
Tunica vaginalis Mesothelioma, NOS	+	+	+	*	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ALL OTHER SYSTEMS Multiple organs NOS Fibrous histiocytoma, metastatic Mesothelioma, malignant	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N X	N	N	N	N	N	N
Osteosarcoma, metastatic Monocytic leukemia							x				x					x				x	<u>x</u>				x

# TABLE A3. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II*: LOW DOSE

 + : Tissue Examined Microscopically

 - : Required Tissue Not Examined Microscopically

 X : Tumor Incidence

 N : Necropsy, No Autolysis, No Microscopic Examination

 S : Animal Missezed

No Tissue Information Submitted
 C : Necropsy, No Histology Due To Protocol
 A : Autolysis
 M : Animal Missing
 B : No Necropsy Performed
### TABLE A3. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE RATS: LOW DOSE (Continued)

										_									_			_				-		
ANIMAL NUMBER	2 5 1	253	2 5 5	2 5 7	259	2 6 1	263	2 6 5	2 6 7	269	2 7 1	2 7 3	2 7 5	2 7 7	27	2 8 1	2 8 3	2 8 5	2 8 7	289	2 9 1	2 9 3	2 9 5	2 9 7	299	3 0 1	3 0 3	TOTAL
WEEKS ON STUDY	1 0 6	1 0 6	1 0 6	1 0 6	0 8 0	002	1 0 6	1 0 6	1 0 6	106	0 8 9	1 0 6	1 0 6	1 0 6	1 0 6	1 0 7	1 0 7	107	1 0 7	107	107	107	1 0 7	1 0 3	1 0 7	0 9 2	002	TISSUES TUMORS
INTEGUMENTARY SYSTEM	<u> </u>						-				1		-	+	-	-	+	+	+	-		+	+	+	+	+		•52
Skin Squamous cell carcinoma Trichoepithelioma Subcutaneous tissue Fibroma Leiomyosarcoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	× +	+	+	+	+ x	+	+	+	+	+	*52 1 1 1
RESPIRATORY SYSTEM Lungs and bronchi Alveolar/bronchiolar adenoma C-cell carcinoma, metastatic Trachea	+	+	++	++	+	+	+	++	+	+ x +	+	++	+	+	+	+	+	+	+	+	+	+	+	++	++	++	+++++++++++++++++++++++++++++++++++++++	52 2 2 52
HEMATOPOIETIC SYSTEM Bons marrow Spisen Lymph nodes C-ceil carcinoma, metastatic Thymus	+++++++	+++ +	+++ +	+++ +	+++ +	+++ +	+++++++++++++++++++++++++++++++++++++++	+++++++++++++++++++++++++++++++++++++++	+++++++++++++++++++++++++++++++++++++++	+++++++	+++ +	+++++++++++++++++++++++++++++++++++++++	++++++	++++++	+++++++++++++++++++++++++++++++++++++++	+ + + +	+++ +	+++ +	+++ +	++++++	+++ +	+++X+	+++ +	+++ +	+++ +	+++ +	++++ +	52 52 52 1 52
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	+	+	+	+	+	+	52
DIGESTIVE SYSTEM Salivary gland Liver Neoplastic nodule Bile duct Gallbladder & common bile duct Pancreas Esophagus Stomach Squamous cell papilloma Small intestine Large intestine	++ +N+++ ++	++ +2+++ ++	++ +z+++ ++	++x+z+++ ++	++ +Z+++ ++	++ +z+++ ++	++ +2+++ ++	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++x+z+++ ++	++ +Z+++ ++	++X+X+++ ++	++ +z+++ ++	+	++×+z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +Z+++X++	++ +Z+++ ++	++ +z+++ ++	++ +z+++ ++	52 52 6 52 •52 52 52 51 52 1 52 52 52				
URINARY SYSTEM Kidney Liposarcoma Urinary bladder	+	+	++	`+ +	+	+++	+	++	+++	+++	++	+++	+++	+	+++	+++	+++	+++	+++	+++	++	+ +	++	+++	++	++	+++++++++++++++++++++++++++++++++++++++	52 1 52
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Acidophil adenoma Adrenal Cortical adenoma Pheochromocytoma Thyroid Follicular cell adenoma Follicular cell cartinoma C-cell cartinoma	+ + *	++++	+ + +	++++	+ + +	++++	+x + +	+ + + X	+x + +	+x + + + + + + + + + + + + + + + + + +	+ x+ +	+ + + × +	*x + + *x	++++	+x + x +	+ + × +	- + +	+ + x+	+ + +	+ * *		+ x + + x	+ + × +	+ + + x	++++	+x + +	-++++	50 13 1 52 1 8 51 2 2 4
Parathyroid Pancreatic islets Islet cell adenoma Islet cell carcinoma	: ‡	+ + x	+++	- + x	+	Ŧ	Ŧ	+	++	~ + + +	++	+++	+ + x	+	+	++X	÷ x	+ + x	+++	<del>-</del> +	- + X	4++	++	+ + * X	++	Ŧ	‡	32 52 7 6
REPRODUCTIVE SYSTEM Mammary gland Fibroadenoma Testis Interstitial cell tumor Prostate	+ + * *	+ + + × +	+ + * * *	+X+X+	X	++++	+x + x +		+ + + x +			+ + + x +	+ + * *	+ + + × +		+ + * *		+ +x+		+x+x+	+ +x+	+ + + X +	+ + + × +		+ +x+	+ +x+	+ + +	*52 5 52 46 52
NERVOUS SYSTEM Brain Glioma, NOS Oligodendroglioma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+ X	+	+	*	+	+	+	.52 1 1
BODY CAVITIES Peritoneum Fibrous histiocytoms, malignant Rhabdomyosarcoma Tunics veginalis Mesothelioma, NOS	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N +	N X +	N +	*52 1 1 *52 1
ALL OTHER SYSTEMS Multiple organs NOS Fibrous histocytoma, metastatic Mesothelioma, malignant Osteosarcoma, metastatic			N		x	N	N	N			N	N	N	N			N	N X	N	N	N	N	N	N		N	N	*52 1 1 1
Monocytic leukemia	X			X						X					X	X									X			12

⁶ Animals Necropsied

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### TABLE AS. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II®: HIGH DOSE

ANIMAL Number	1	3	0	07	0	i	3	1	1	1	2	23	35	27	20	3	33	3	3	3	1	43	5	47
WEEKS ON Study		0	0	0	0	100	0 0	9	106	9	8	0	0	100	0	0 8 5	100	0	0	106	106	0	0	0 8 3
NTEGUMENTARY SYSTEM			• •	+	+	+	+	+	+	+	+	+	+	+	+	+	+	• •	+	+	+	+	+	+
Basal cell carcinoma Trichospithelioma Liboutaneous tissue Fibrous histiccytoma, malignant		+ 4	• +	+	+	+	+	+	÷	+	+	+	+	+	+	÷	+	+	+	+	+	+	+	+
Neurilemoma, malignant	_										X	-						-						
ESPIRATORY SYSTEM ungs and bronchi raches		+	+	++	+ +	<del>*</del> +	++	++	++	+	+	++	++	<b>+</b> +	+ +	++	++	+ +	++	++	+	++	++	+++
EMATOPOIETIC SYSTEM ne marrow largoma, NOS		• •	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	÷
ieen mph nodes lymus			+ + + +	++++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	+++	C+++	+++	+++	+++	+++	+++
RCULATORY SYSTEM			+	+		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
GESTIVE SYSTEM al cavity	-	N	N	N	N	N	N	N	N	N	N	N X	N	N	N	N	N	N	N	N	N	N	N	N
quamous cell papilloma livary giand ver		× + +	++	++	+ +	++;	++	+	++;	++x	++	X + +	+ + x	++	+ +	+ +	+ +	++	+ +	++	+++	++	+ +	+ +
ieopiastic nodule IepatocsIluiar carcinoma arcoma, NOS, metastatic Ibroua histiocytoma, metastatic						Ă			*	Å			~						x					
e duct libiadder & common bile duct ncreas	+ N + N +	* N	+ N +	+ N +	+ × +	+ z +	+ N +	+ 2 +	+ X +	+ N +	+ N +	+ z +	+ N + X	+ X +	+ N +	+ N +	+ N +	+ 2 +	+ N +	+ × +	+×+	+ X +	+ × +	+ N +
cinar cell adenoma pphagus imach	+	+++++++++++++++++++++++++++++++++++++++	++	++	+++	++	+ +	+ +	+ +	++	+ +	+ + +	+ +	+ +	+ +	++	++++	++	++	++	++	++	+ +	+ +
quamous cell papilloms quamous cell carcinoma iall intestine rge intestine	X	++	X + +	· + +	++	++	+ +	++	++	++	++++	× + +	+ +	++	X + +	++	++	++	++	++	x + +	+++	++	++
UNARY SYSTEM dney	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ubular cell adenocarcinoma inary bladder	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	+	+	÷	+	÷
DOCRINE SYSTEM witary arcinoma, NOS	-  +	+	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	+	+	+	+	+	+	+	_
hromophobe adenoma renai	+	+	X +	X +	+	X +	+	+	+	¥ +	+	•	+	X +	+	X +	+	+	+	+	+	+	+	+
heochromocytoma yroid olliqular cell carcinoma	+	× +	+	+	+	+	+	+	X +	+	× +	+	+	+	+	-	+	+	÷	+	+	+	+	+
-ceil adezoma -ceil carcinoma						X	,															X		
rathyroid arcinoma, NOS ncreatic ialeta let cell adenoma	+	+	*	+	+	+	+	+	+	- + X	+	+	+	+	+ X	+ ;	+ X	+	+	+	+ *	+	+	+
PRODUCTIVE SYSTEM	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ibroadénoma stis sterstitial cell tumor	x x	*	*	x+x	*	*	*	*	*	÷,	* :	÷.	, x	* :	+ K :	+ : X :	+ X	*	+ X	*	*	÷	+ X	+
ostate sputial/clitoral gland denoma, NOS	Ň	Ñ	+ N	+ N	+ N	* N	* N	ň	N N	+ N	× + N	+ N	Ň I	+ N 1	* i	Ň I	+ N	ň	+ N	ň	н N	ň	* N	+ N
RVOUS SYSTEM ain	-	+	+	+	+	+	+	+	+	+	+	+	+ -	+	÷	+ ·	+	+	+	÷	+	+	+	÷
ISCULOSKELETAL SYSTEM ne stocsercoma	N	N	N	N	N	N	N	N	N	N	N	N	NI	NI	N I	N I	N	N	N	N	N	N	N	NX
DY CAVITIES nice vaginalis esothelioma, NOS esothelioma, malignant	+	+	+	+	+	+	+	+	+	+	+	+ x	+	+	+	+ · x	+	+	+	+	+	+	+	+
L OTHER SYSTEMS ltiple organs NOS denocarcinoma, NOS, metastatic steosarcoma, metastatic	N	N	N	N	N	N	N .	N	N	N	N	N	N I X	N I	N I	N I	N .	N	N	N	N	N		N K
lalignant lymphoma, NOS Ionocytic leukemia	x			x					X :	x		:	x											
e unknown denocarcinoma, NOS												:	x											

 + :
 Tissue Examined Microscopically

 - :
 Required Tissue Not Examined Microscopically

 X :
 Tumor Incidence

 N :
 Necropsy. No Autolysis, No Microscopic Examination

 S :
 Animal Missexed

No Tissue information Submitted
 C : Necropsy, No Histology Due To Protocol
 A : Autolysis
 M : Animal Missing
 B : No Necropsy Performed

#### TABLE A3. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE RATS: HIGH DOSE (Continued)

,

ANIMAL Number	4 5 1	4 5 3	405	57	450	4 8 1	4 6 3	485	48	400	471	473	4 7 5	77	7	8	8	9.99	8	900	9	903	3 05 15	197	100	0 1	03	TOTAL
WEEKSON STUDY	0 6	0	1 0 6	0 8 8	100	0 2 8	000	0 9 7	0 8 6	1 0 1	1 0 6	1 0 6	106	1 0 6	06	0 1 2	106	106	106	106	1 0 6	0000	106	00	106	1 0 6	1 0 6	TISSUES
INTEGUMENTARY SYSTEM Skin	-	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+		•52
Basal cell carcinoma Trichoepithelioma		x													X													
Subcutaneous tissue Fibrous histiocytoms, malignant Neurilemoma, malignant	[‡]	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	*52 1 1
RESPIRATORY SYSTEM Lungs and bronchi Trachea	-	++	+++	+	+	+	+++	+++	+++	++	++++	+++	++	+++	+++	++	++	+++	++	++	++	++	++	+ +	++	++	+++	52 52
HEMATOPOIETIC SYSTEM Bone marrow		+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52
Sarcoma, NOS Spisen	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52
Lymph nodes Thymus	+	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	++	+++	++	++	++	++	++	++	+	52 52
CIRCULATORY SYSTEM	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52
DIGESTIVE SYSTEM Dral cavity	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	•52
Squamous cell papilloma Salivary gland Liver	+	+	+	+	+	+	+	+	+	+	+	+	+	++	+	+++	+	++	++	++	+++	++	+	+++	+	+++	<b>+</b>	2 52 52
Neoplastic nodule Hepatocellular carcinoma Sarcoma, NOS, metastatic	x	T	Ŧ	٢	x	T	Ŧ	Ŧ	F	F	T	F	*	r	ſ	ſ	F	r	r	x	F	T	F	F	f	x	۴	
Fibrous histiocytoms, metastatic Bile duct Galibladder & common bile duct	A + N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	* N	52 *52
Pancress Acinar cell adenoma	17	+	÷	+	+	+	+	+	+	+	÷	+	+	+	÷	+	÷	ž	+	+	x	+	+	+	÷	+	+	52
Esophagus Stomach	1	+ +	+ +	+ +	++	+	+	++	++	++	+++	++	+++	+++	<b>+</b> +	+ +	+++++++++++++++++++++++++++++++++++++++	++	++	+++	++	++	+++	++	++	+++	+. +	52 52
Squamous cell papilloma Squamous cell carcinoma					X					X							X					X	X		X	X	X	9
Small intestine Large intestine	‡	+	++	++	++	++	+	++	+	+	+	+	+	+	+	+	+	+	+	+	÷	÷	+	+	+	++	÷	52 52
URINARY SYSTEM Kidney Tubular cell adenocarcinoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	ž	+	+	+	+	+	+	+	+	52 1
Urinary bladder ENDOCRINE SYSTEM	-	+	+	+	_	_	+	+	+	+	+	<u>.</u>	+	+	+	+	+	+	+	+	+	+	+	+	-	+	-	52
Pitultary Caminoma, NOS	+	+	+	٠	+	+	÷	÷	÷	÷	+	÷	÷	÷	+	+	+	+	+	+	+	+	+	+	+	+	+	50
Chromophobe adenoma Adrenal	+	X +	+	¥	+	÷	X +	+	+	+	X +	+	¥ +	¥	÷	+	+	×	+	+	+	+	X +	÷	+	X +	¥	10 52
Pheochromocytoma Thyroid	+	+	÷	÷	+	+	¥	+	+	<u>+</u>	+	+	+	+	+	+	+	+	+	+	X +	¥	+	+	÷	÷	÷	6 81
Follicular cuil carcinoma C-cuil adenoma C-cuil carcinoma	ļ									X				v			v											22
Cicell Gardinoma Parathyrold Cardinoma, NOS	+	٠	÷	÷	-	٠	÷	÷	ŧ	÷	٠	-	÷	+	÷	-	Ŧ	-	÷	÷	٠	-	÷	÷	÷	+	-	39
Pancreatic islets Islet cell adenoma	x x	÷	+	+	+	+	+	ž	+	+	÷	+	٠	+	ŧ	÷	+	ż	+	+	+	+	+	+	+	÷	*	52 9
REPRODUCTIVE SYSTEM Mammary gland Fibroadenoma		+	+	÷	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	+	+	+	÷	+	+	+	+	+	*52
Testis Interstitial cell tumor	1 x	ż	ż	+	*	+	ż	*	‡	ż	÷X,	*	*	+×+×	*	*	+×+	****	÷X,	*	*	*	***	*	+x+N	*	*	46 59 51 •59
Prostate Proputia/clitoral gland Adesoma, NOS	Ň	* N		* N	* N	* N	Ň		* N	Ň	*N	X+N	* N	* N	X+N	* N	* N	Ň	X+N	X+N	¥ N	ŧ N	ŧ.	Ň	N,	¥ N	Ň	•52
NERVOUS SYSTEM Brain		+	+	+	+	+	+	+	+	+	+	+	+	+	ŧ	+	+	+	+	+	÷	+	+	÷	+	*	+	52
MUSCULOBKELETAL BYSTEM Bane Osteosarsoma	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Ń	N	N	N	N	•62
SODY CAVITIES Tunica vaginalis Mesothelioma, NOS Mesothelioma, malignant	•   •	+	÷	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	+ x	+	+	+	+	+	+	+	*52
ALL OTHER BYSTEMS Multiple organs NOS Adenocarcinoma, NOS, metastatio	N	N	N	N	N	'N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	*52
Osteosarcoma, metastatio Malignant lymphoma, NOS Monocytic leukemia Site unknown			x						X											x	x	x				x		10
Adenocarcinoma, NOS	1																											L

*Animula Necropsied

ANIMAL NUMBER	002	0	0 0 6	0 0 8	0 1 0	0 1 2	0 1 4	0 1 6	0 1 8	020	0 2 2	0 2 4	026	0 2 8	0 3 0	0 3 2	034	0 3 6	0 3 8	040	0 4 2	044	046	0 4 8	0 5 0
WEEKS ON STUDY	1 0 8	0 8 4	1 0 8	0 9 9	1 0 8	1 0 8	1 0 8	1 0 8	1 0 8	9	0 9 7	1 0 8	1 0 8	1 0 2	108	0 9 7	1 0 8	0 7 5	0 0 2	1 0 8	1 0 8	1 0 8	1 0 8	0 9 1	1 0 8
INTEGUMENTARY SYSTEM Subcutaneous tissue Rhabdomyosarcoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
RESPIRATORY SYSTEM Lungs and bronchi Alveolar/bronchiolar carcinoma Trachea	+	+	+	+	+ +	+ +	+	+++	+ +	++	++	+ +	+ +	+ +	++	+ +	+	++	+ +	+ +	++	+++	+	+++	++++
HEMATOPOIETIC SYSTEM Bone marrow Spieen Lymph nodes Thymus	+++++++++++++++++++++++++++++++++++++++	+ + + + +	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
DIGESTIVE SYSTEM Oral cavity Squamous cell carcinoma Salivary gland Liver Neoplastic nodule Bile duct	N ++	N ++ +	N ++ +	N ++ +	N ++ 4	N ++ +	N ++ 4	N ++X+	N ++	N ++++++++++++++++++++++++++++++++++++	NX++ +	N ++ H	N ++ +	N +++++++	N ++++++	N ++X+	N ++	N ++ +	N ++	++x	N ++++++	N ++X+	N ++ 4	N ++ +	++ + x
Galibiader & common bile duct Pancreas Esophagus Stomach Small intestine Large intestine	Z+++++	×++++	· z + + + + z	-Z+++++	·N+++++	·N+++++	· X + + + + + +	Z+++++	7.+++++	Z+++++	Z+++++	Z+++++	ž++++	Z+++++	·N+++++	·z+++++	Z+++++	·X+++++	2+++++	+z++++	Z+++++		· <b>X</b> + + + + +	N+++++	+2+++++
URINARY SYSTEM Kidney Urinary bladder Transitional cell carcinoma	+++	++	+++	++	+++	‡	+	‡	+++	++	‡	‡	+++	++	+++	++	++	+++	++	÷	++	+	+	+++	]
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Chromophobe carcinoma Adrenal Cortical adenoma Pheochromocytoma	+	+ X +	* *	+	+ +	* * +	+	* * +	* * +	+	+	* *	+ x +	* +	+	+ *	+	+	+	* *	* *	* +	* * +	++	- *
Thyroid C-cell adenoma C-cell carcinoma Parathyroid	+	+	* *	++	+ +	+	+	++	* * +	+ X +	+ +	+ +	+	+ +	+ +	+	++	++	+ +	+ +	+ -	+ +	+ +	+ +	*
Pancreatic islets Islet cell adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	*	+	+	*	+	+	+	+	+	+	+	+
REPRODUCTIVE SYSTEM Mammary gland Adenoma, NOS Adenocarcinoma, NOS	+	+	+	+	+	+	+	+	+	+	+	+	÷	÷	+	+	+	+	+	+	+	+	+	+	+
Fibroadenoma Uterus Leiomyoma Endometriai stromai polyp Endometriai stromai sarcoma	+	+	+	+	+ x	+	+ x	X + X	+ x	+ X X	+	+	*	+ x	+ x	X +	¥ +	+	+	× +	+ x	+ x	+	+ x	+
Ovary NERVOUS SYSTEM	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+   - (
Brain ALL OTHER SYSTEMS Multiple organs NOS Malignant lymphoma, NOS Monocytic leukemia	+ N	+ N	+ N	+ N	+ N	Ŧ N	+ N	+ N	+ N	+ N	+ N	+ N		+ N X	+ N		+ N X	+ 							

#### TABLE A4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELEONE II*: VEHICLE CONTROL

+ - X N S

Tissue Examined Microscopically Required Tissue Not Examined Microscopically Tumor Incidence Necropsy, No Autolysis, No Microscopic Examination Animal Missexed

No Tissue Information Submitted Necropsy, No Histology Due To Protocol Autolysis Animal Missing No Necropsy Performed :

C: A: M: B:

#### TABLE A4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE RATS: VEHICLE CONTROL (Continued)

ANIMAL NUMBER	0 5 2	054	0 5 6	0 5 8	000	0 6 2	0 6 4	0 6 6	0 6 8	0 7 0	0 7 2	074	0 7 6	078	080	0 8 2	0 8 4	0.00	0 8 8	0.00	0 9 2	004	006	98	100	1 0 2	1 0 4	TOTAL
WEEKSON STUDY	1 0 8	1 0 8	1 0 2	1 0 8	108	0 9 4	1( 0  8	1 0 8	1 0 8	090	1 0 8	108	108	1 0 1	100	0 4 9	1 0 8	1) 0 8	1 0 8	1 0 8	1 0 8	1 0 8	0 9 6	9	0 6 7	1 0 8	1 0 8	TISSUES
INTEGUMENTARY SYSTEM Subcutaneous tissue Rhabdomyosarcoma		_																									,	***
RESPIRATORY SYSTEM Lungs and bronchi Aiveolar/bronchiolar carcinoma Trachea	+	++	+ +	++	++	++	++	++	++	+++	++	+++	* *	+	++	+ +	+++	+ +	+++	+ +	++	+++	++	++	+ +	+ +	++	52 1 52
HEMATOPOIETIC SYSTEM Bone marrow Spleen Lymph nodes Thymus	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	-+++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	51 52 52 52
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52
DIGESTIVE SYSTEM Oral cavity Squamous cell carcinoma. Salivary gland	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N +	N	*52 1 52
Neoplastic nodule Bile duct	+	+	÷ .	+	÷	+++	+++++++++++++++++++++++++++++++++++++++	÷	+	÷	÷	÷	+	÷	+	÷	÷	÷	++ <b>X</b> +N	+ +	+ +;	+	+	÷	+ +	÷	++	52 6 52 *52
Gallbladder & common bile duct Pancreas Esophagus Stomach	2+++	Z+++.	2+++	N+++.	N+++	N+++.	N+++.	2+++	X+++.	2+++	Z+++.	N+++	z+++.	2+++	N+++	N+++.	N+++	++++	2+++.	N+++	2+++.	Z+++.	Z+++.	N+++	N+++.	N+++.	Z+++.	52 52 52
Small intestine Large intestine	÷	÷	+	+	-	+	+++	+	÷	+	÷	+	÷	+	+	++	+	++	+	+	÷	÷	+	÷	+	+	++	52 50
URINARY SYSTEM Kidney Urinary bladder Transitional cell carcinoma	++	++	+++	++	++	+	+	++	<b>+</b> +	+ + X	+	‡	++	+ +	+++	+++	+++	+ +	++	+++	++	++	++	++	++	+++	+++	52 52 1
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Chromophobe carcinoma	+	*	+	ź	ź	ź	ż	*	*	+	ż	+	+	*	<del>,</del>	-	*	*	+	*	+	*	ż	+	-	+	- *	50 28 2
Adrenal Cortical adenoma Pheochromocytoms	+	÷	÷	+	+	+	+	+	+	+	+	*	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52 2 1
Thyroid C-cell adenoma C-cell carcinoma	+	+	× X	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+ X	+	+	+	+	+	*	52 4 2
Parathyroid Pancreatic islets Islet cell adenoma	++	++	++	++	+	+	+ +	++	+ +	+ +	+	+ +	+ +	++	++	+	++	+ +	+ +	++	++	++ X	+	++	+	++	-	45 52 3
REPRODUCTIVE SYSTEM Mammary gland Adenoma, NOS	+	+	+	+	ż	+	+	+	+	+	+ x	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	*52
Adenocarcinoma, NOS Fibroadenoma Uterus Leiomyoma	+	¥	¥	X +	+	*	+	+	+	+	+	+	+	+	+	+	X X +	X +	+	+	+	¥ +	¥ +	¥ +	+	+	¥	14 52 1
Endometrial stromal polyp Endometrial stromal sarcoma Ovary	+	+	+	+	х +	+	÷	+	× +	+	х +	+	+	÷	x +	+	+	х +	÷	×. +	*	+	+	+	÷	+	+	16 2 52
NERVOUS SYSTEM Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-	52
ALL OTHER SYSTEMS Multiple organs NOS Malignant lymphoma, NOS Monocytic leukemia	N	N	N	N	N	N X		N		N X	N	N X	N		N X		N	N	N		N X	N	N	N X	N	N	א	*52 1 9

Animals Necropsied

#### TABLE A4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELEONE II*: LOW DOSE

ANIMAL NUMBER	2 0 2	2 0 4	2 0 6	2 0 8	2 1 0	2 1 2	2 1 4	2 1 6	2 1 8	2 2 0	2 2 2	2 2 4	226	2 2 8	2 3 0	2 3 2	2 3 4	2 3 6	2 3 8	2 4 0	2 4 2	2 4 4	2 4 6	2 4 8	2 5 0
WEEKS ON STUDY	1 0 7	1 0 7	0 8 7	1 0 7	1 0 7	1 0 7	1 0 7	1 0 7	1 0 3	0 8 7	1 0 7	1 0 7	1 0 7	1 0 7	1 0 7	1 0 2	1 0 7	0 1 2	1 0 7	1 0 7	0 8 3	0 7 5	1 0 7	1 0 7	1 0 6
INTEGUMENTARY SYSTEM Subcutaneous tissue Fibroma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
RESPIRATORY SYSTEM Lungs and bronchi Alveolar/bronchiolar carcinoma Trachea	+	++	+ +	+ +	++	+ +	+ +	++	++	++	++	* *	++	+++	+++	+	++	+	++	+ +	+ +	+ +	+++	++	+++
HEMATOPOIETIC SYSTEM Bone marrow Spieen Lymph nodes Thymus Thymoma	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	+++++	++++	++++	++++	++++
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
DIGESTIVE SYSTEM Selivary gland Liver Neoplastic nodule Bile duct Gallbladder & common bile duct Pancreas Esophagus Stomach Stomach Stomach Stall intestine Large intestine Large intestine	++ +z+++ ++	++ +++2+++ ++	++ +2+++×++	++ +z+++x++	++×+Z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +++z+++ ++	++ +++2+++ ++	++ +2+++ ++	++ +2+++ ++	++ +z+++ ++	++ +2+++ ++	++ +z+++ ++	++×+z+++ ++	++ +2+++ ++	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +2+++ ++	++ +z+++ ++	++ +++Z+++ ++	++ +z+++ ++	++ +z+++ ++
URINARY SYSTEM Kidney Urinary bladder Adenomatous polyp, NOS	+ +	+++	+++	++	++	++	++	++	+++	++	++	++	+ *	++	+++	++	+++	++++	++	+++	++	++	++	++++	- + +
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Chromophobe carcinoma Adrenal Cortical carcinoma Pheochromocytoma Thyroid	++++	++++	* + +	+ + +	+ + +	* + +	* + +	+ * *	* + +	+ + + +	+ + +	+ + +	* + +	* + +	+ + +	* + +	* + +	+ .+ +	+ + +	* + +	+ x + +	+++++	* + +	+ + X	- + +
Follicular cell adenoma Follicular cell carcinoma C-cell adenoma C-cell carcinoma Parathyroid Pancreatic ialets Ialet cell adenoma	++	-+	++	-+x	++	- +	+ +	x +	+++	++	++	x + +	x + +	++	++	-+	++	++	x + +	-+	++	++	++	-+	++
REPRODUCTIVE SYSTEM Mammary gland Fibroadenoma PreputiaVelitoral gland Carcinoma, NOS Adenoma, NOS Uterus	+ N +	+ N +	+ N +	+	+ x N +	+ x N +	+	+	+ x N +	+	+ N +	+ N +	+x n + x n +	+ N +	+x N + +	+x N + XN +	+x x x x +	+ N +	+x n +	+xn +	+ N +	+ N +	+xn +	+ x N +	- + + N +
Endometrial stromal polyp Ovary NERVOUS SYSTEM	+	+	+	+	+	+	X +	¥ +	+	+	X +	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ALL OTHER SYSTEMS	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Multiple organs NOS Monocytic leukemia Leukemia, mononuclear cell	N	N	N	N	N	N	N X	N X	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	X

Tissue Examined Microscopically Required Tissue Not Examined Microscopically Tumor Incidence Necropsy. No Autolysis, No Microscopic Examination Animal Missexed

: No Tissue Information Submitted C : Necropsy, No Histology Due To Protocol A : Autolysis M : Animal Missing B : No Necropsy Performed

#### TABLE A4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE RATS: LOW DOSE (Continued)

ANIMAL NUMBER	2 5 2	2 5 4	2 5 6	2 5 8	60	2 6 2	264	66	2 6 8	270	2 7 2	2 7 4	2 7 6	2 7 8	2 8 0	2 8 2	2 8 4	286	2 8 8	2 9 0	2 9 2	2 9 4	296	2 9 8	300	3 0 2	3 0 4	TOTAL
WEEKS ON STUDY	1	0 1 5	1 0 0	0 9 1	107	1 0 7	1 0 7	0 9 1	1 0 7	0 8 4	1 0 7	1 0 7	0 9 1	1 0 7	1 0 7	1 0 7	1 0 7	1 0 7	0 3 2	1 0 8	0 5 5	1 0 8	1 0 8	1 0 8	1 0 8	0 8 8	1 0 8	TISSUE
INTEGUMENTARY SYSTEM Subcutaneous tissue Fibroma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	*	+	+	+	+	+	+	+	+	+	+	+	+	*52 1
RESPIRATORY SYSTEM Lungs and broachi Alveolar/bronchiolar carcinoma Trachea	+++	+++	++	++	++	+++	++	+++	+++	++	++	+++	++	++	++	++	+++	++	++	+ + +	++	++	+++	+++	++	+++	+++	52 1 52
HEMATOPOIETIC SYSTEM Bone marrow Spieen Lymph nodes Thymus Thymoma	+++++++++++++++++++++++++++++++++++++++	++++	++++	++++	++++	++++	++++	+ - + +	++++X	-+++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	51 51 52 52 52 1
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52
DIGESTIVE SYSTEM Salivary gland Liver Neoplastic nodule Bile duct Gallbladder & common bile duct Pancress Esophagus Stomach Squamous cell papilloma Squamous cell papilloma Snall intestine	- + + x + N + + + + + + + + + + + + + + +	++ +z+++ ++	++×+Z+++ ++	++ ++	++ +2+++ +1	++ +Z+++ +1	++ +7,+++ +1	++ +Z+++ ++	++ +Z+++ ++	++ +2+++ ++	++ +z+++ ++	++ +2+++ +1	++ +++++ ++	++ +2+++ ++	++x+x+++ ++	++ +2+++ ++	++ +2+++ ++	++ +Z+++ ++	++X+X+++ ++	++ +7,+++ ++	++ +2+++ ++	++ +++Z+++ ++	52 52 6 52 *52 52 52 52 52 52 2 52 48					
JRINARY SYSTEM Kidney Jrinary bladder Adenomatous polyp, NOS	+	++	++	+++	+++	++++	+++	++++	+ +	+++	+++	+++	++++	+++	+++	+++	++	++	++	++	+	+++	+++	++	+ +	++	++	52 52 1
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Chromophobe carcinoma Adrenal Cortical carcinoma Pheochromocytoma	* *	+	+	* +	* +	* +	* +	* +	* *	* +	* +	* *	+	+	+ + X	* +	* *	* +	+	¥ +	+	+	+	* +	+	+	++	51 26 1 52 1 2
Thyroid Follicular ceil adenoma Follicular ceil carcinoma C-ceil adenoma C-ceil carcinoma Parathyroid Pancreatic isleta Islet ceil adenoma	++++	+ -+	+ + + +	+ + +	+ + +	+ ×∓	+ X ++	+ + +	+ X + +	+++	+ X ++	+x ++	+ ++	+++	+++	+ x + +	+ -+	+ -+	+ ++	+ -+	+ + +	+ -+	;+ + +	+ + +	+++	+++	+++	52 1 6 2 39 52 1
REPRODUCTIVE SYSTEM Mammary giand Fibroadenoma Preputiak/litoral giand Carcinoma, NOS Adsnoma, NOS Uterus Endometrial stromal polyp Ovary	+ N +	+ N + +	+ + + +	+ + + +	+x+ XX+	+ 12 + +	+ 77 + +	+ x + x +	+ + × N + +	+ x + x +	+ N + +	+ N + +	+ n + +	+ N + X +	+ x + +	+ N +X+	+xn +x+	+ + XX+ + +	+ N +	+xn + + +	+ 1 + + + +	+ N X + +	+ N + +	+ 12 + +	+xn +x+	+ x x + +	+ ×× + +	*52 20 *52 2 1 52 10 52
NERVOUS SYSTEM Brain			+	+	+	+	+	+	+	+	+	+	+ +	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52
ALL OTHER SYSTEMS Multiple organa NOS Monocytic leukemia Leukemia, mononuclear cell	- N	N	N	N X	N	N	N		N X	N	N	N	N X	N	N	N X	N	N	N	N	N	N X	N X	N	N	N X	N	*52 9 1

* Animals Necropsied

Telone II[®], NTP TR 269

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#### TABLE A4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II*: HIGH DOSE

ANIMAL	- 7	- 21	- 11			- 71	- 70	- 41	- 21	- 41	- 17	41	- 11	- 77		-70	- 71	- 11	- 77				-11	- 41	
NUMBER	02	04	0	0	10	12	1	1	1	20	22	24	426	2	30	32	34	36	3	40	4	44	446	48	5
WEEKSON STUDY	1 0 6	1 0 6	1 0 6	1 0 6	0 9 9	0 8 0	1 0 6	1 0 6	1 0 6	0 9 7	1 0 6	0 9 8	1 0 6	1 0 6	1 0 6	1 0 6	106	0 8 1	1 0 6	1 0 6	1 0 4	1 0 6	1 0 6	0  9  4	1 0 6
INTEGUMENTARY SYSTEM	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Squamous cell carcinoma Subcutaneous tissue Carcinosarcoma	+	: +	+	+	+	× +	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
RESPIRATORY SYSTEM Lungs and bronchi Alveolar/bronchiolar adenoma Alveolar/bronchiolar carcinoma Granulosa cell carcinoma, metas Traches	+	+	+	+	++	+	+	+ X +	* *	++	+	+	+	+	+	+++	+	+	++	+ +	+++	+	+ +	+	+ +
HEMATOPOIETIC SYSTEM Bone marrow	+	 +	-		-		<u>.</u>	+			-	-		+	-	-		-	+		-	_	-	_	-
Spleen Hemangiosarcoma	÷	÷	÷	÷	÷	÷	÷	÷	ż	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	+	+
Lymph nodes Carcinosarcoma, invasive Thymus	++	++	++	++	++	+++	+++	++	++	++	++	++	+++	++	++	++	++	++	++	++	++	++	++	++	+
CIRCULATORY SYSTEM . Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
DIGESTIVE SYSTEM Salivary gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	+	+
Liver Neoplastic nodule Bile duct	* *	+++++++++++++++++++++++++++++++++++++++	*	+	+	+	+	+	* *	+++++++++++++++++++++++++++++++++++++++	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Gailbladder & common bile duct Pancreas	- N +	Ň +	Ň +	Ň	Ň +	Ň	Ň +	Ň +	Ň ŧ	Ň +	Ň +	Ň +	Ň	Ň	Ň +	Ň	Ň	Ň +	Ň +	Ň +	Ň	Ň	Ň +	Ň	Ň
Fibrosarcoma, metastatic Esophagus	+	+	+	+	X +	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Stomach Squamous cell papilloma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	1
Small intestine Large intestine	÷	+	Ŧ	Ŧ	Ŧ	÷	++	+	÷	÷	+	+	+	Ŧ	÷	÷	÷	+	÷	÷	÷	+	÷	+	Ŧ
URINARY SYSTEM Kidney Urinary bladder	++	+++	+++	++	+	+++	+++	+++	+++	++	+++	+++	+++	++	++	++	++	++	++	+++	++	++	+	++	+
ENDOCRINE SYSTEM Pituitary	 						-	<u> </u>		-	 	-	_					-				_		-	-
Chromophobe adenoma Chromophobe carcinoma	,	ŗ	x		x	Ţ	r	•	x	•	Ŧ	x	x	'	,	ŕ	ŗ	,	x	x	x	x	x	x	x
Adrenal Cortical adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Thyroid Foilicuiar ceil adenoma Foilicuiar ceil carcinoma C-ceil adenoma	+	+	+	+	+	+ x	+	+	+	+	+	+ x	+	+	+	+	+	+	+	+	+	+	+	+	+
C-cell carcinoma Parathyroid	+	+	+	÷	-	+	_	+	+	_	+	_	_	-	-	+	+	+	+	¥ +	+	+	+	+	+
Pancreatic islets Islet cell carcinoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	*	+	+	+	+	+	+	+	+
REPRODUCTIVE SYSTEM Mammary gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
Adenocarcinoma, NOS Fibroadenoma Preputia/clitoral gland	X	X N	X N	X	N	N	X	X	X	N	N	N	N	N	N	N	N	X	X N	X	N	X	X	X N	N
Carcinoma, NOS Uterus	+	+	+	+	+	+	×	+	×	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
Adenocarcinoma, NOS Endometrial stromal polyp				x	X														x			x			
Ovary Granulosa cell carcinoma Fibrosarcoma	+	+	+	+	+ X	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
NERVOUS SYSTEM Brain	.+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	-
SPECIAL SENSE ORGANS Zymbal gland Carcinoma, NOS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
ALL OTHER SYSTEMS Multiple organs NOS Leiomyosarcoma, metastatic Monocytic leukemia	N	N	N	N	N	N	N	N	N	N X	N	N	N	N	N	N	N	N X	N	N X	N	N	N	N	- N
Site unknown Leiomyosarcoma				-														x							_

 + : Tissue Examined Microscopically

 - : Required Tissue Not Examined Microscopically

 X : Tumor Incidence

 N : Necropsy, No Autolysis, No Microscopic Examination

 S : Animal Missexed

:

No Tissue Information Submitted Necropsy, No Histology Due To Protocol Autolysis Animal Missing No Necropsy Performed

С: А: М: В:

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### TABLE A4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE RATS: HIGH DOSE (Continued)

ANIMAL NUMBER	4 5 2	454	4 5 6	4 5 8	46 6	4 6 2	464	4 6 6	4 6 8	470	4 7 2	774	7	7 8	80	482	784 4	4 8 6	8	90	4 9 2	4 9 4	496	4 9 8	999	5 0 2	0 4	TOTAL
WEEKSON Study	100	106	1 0 6	106	106	1 0 6	0 9 1	0 9 7	0 7 9	106	1 0 6	1 0 6	1 0 6	1 0 6	1 0 6	106	106	106	1 0 6	106	1 0 6	092	106	0 9 4	106	0 7 7	103	TISSUES
NTEGUMENTARY SYSTEM													-								_							
Skin Squamous cell carcinoma Subcutaneous tissue Carcinosarcoma	++	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+ + X	+	+	+	+	+	+	+	*52 1 *52 1
ESPIRATORY SYSTEM Jungs and bronchi Alveolar/bronchiolar adenoma Alveolar/bronchiolar carcinoma Granulosa cell carcinoma, metastatic	+	+	+	+	+	+	+	+	+	+	*	+	+	+	+	+	+	+	+	+	+	+	+	+	+ x	+	+	52 2 1 1
frachea	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52
HEMATOPOIETIC SYSTEM Sone marrow Solean Hemangiosarcoma Jymph nodes Carcinosarcoma, invasive Chymus	+++++++++++++++++++++++++++++++++++++++	++ +	++++++	++++++	+ + + +	++ + + +	++ + + +	+++++	++ + -	+++++	+++++	++ + +	++++++	+++ + +	++ ++ ++ +	+ + + +	++ + + +	+++++++++++++++++++++++++++++++++++++++	++++++	++ +X+	+++++	+++++	++ + +	-+ + +	++ + +	++ + -	+++++	50 52 1 52 1 50
CIRCULATORY SYSTEM	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52
DIGESTIVE SYSTEM salivary gland iver Neoplastic nodule Sile duct salibiadder & common bile duct "ancreas Fibrosaccoma, metastatic isophagus isophagus isomach Squamous cell papilloma mail intestine arge intestine	++x+N+ ++ ++	++X+Z+ ++ ++	++ +Z+ ++ ++	++ +Z+ ++ ++	++X+X+ ++ ++	++ +X+ ++X++	++ +z+ ++ ++	++ +Z+ ++X++	++ +Z+ ++ ++	++ +Z+ ++ ++	++ +Z+ ++ ++	++×+Z+ ++ ++	++ +Z+ ++ ++	++x+x+ ++ ++	++ +Z+ ++ ++	++ +Z+ ++ ++	++ +N+ ++X++	++×+Z+ ++ ++	++ +Z+ ++ ++	++ +Z+ ++ ++	++ +Z+ ++ ++	++ +Z+ ++ ++	++ +Z+ ++ ++	++ +Z+ ++ ++	++x+z+ ++ ++	++ +Z+ ++ ++	++ +z+ ++ ++	52 52 52 10 52 *52 52 52 52 3 52 52 52
IRINARY SYSTEM Lidney Jrinary bladder	+	++	++	++	·+	+++++++++++++++++++++++++++++++++++++++	+	+	++	+	++	++	++	+	 +	+	·++	+	+	+	+	++	++	++	++	++	- ++	52 52
NDOCRINE SYSTEM fituitary Chromophobe adenoma Chromophobe carcinoma drenal Cortical adenoma hyroid Follicular cell adenoma C-cell adenoma C-cell adenoma C-cell carcinoma arathyroid	+ x + + x	+x + +x +	+x + + +	+ + + x +	+x + + +	+x +x+ +	+ + +	** + + -	+ + +	+x + + -	+x + + +	+x + +	* + * * -	+x + + +	** + + +	+ + + -	+x + + -	+x + + +	+ + +	+ + +	+x + + +	+ x+ + +	+x + + +	+ + +	+x + + +	++++	- +x + + +	52 30 1 52 1 52 2 2 2 2 1 37
ancreatic islets Islet cell carcinoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52 .1
EPRODUCTIVE SYSTEM fammary giand Adenocarcinoma, NOS Fibrosdenoma reputiak/clitoral giand Carcinoma, NOS Juerus Adenocarcinoma, NOS Endometrial stromal polyp Mary	+ N + X+	+ N + +	+ xN + +	+ x + x+	+ xN + x+	+ x + +	+ 12 + +	+ XX + +	+ xN + +	+	+ xn + x+	+	+	+x N + +	+ XN + +	+ N + +	+ N + X+	+ XN + X+	+ N + +	+ x + +	+ XN + +	+ 7 + + +	+ N + +	+ x + +	+ XN + +;	+ x + +	+ N +	*52 1 24 *52 2 52 1 12 52
Granulosa cell carcinoma Fibrosarcoma									_																X		-	1
VERVOUS SYSTEM Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	52
PECIAL SENSE ORGANS ymbal gland Carcinoma, NOS	N	N	N	*	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	*52 1
LL OTHERSYSTEMS Aultiple organs NOS Leiomyosarcoma, metastatic Monocytic leukemia ite unknown Leiomyosarcoma	N	N	N	N	N X	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N		N X	N	N	N X	*52 1 5 1

*Animals Necropsied

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#### **APPENDIX B**

# SUMMARY OF THE INCIDENCE OF NEOPLASMS IN MICE IN THE TWO-YEAR GAVAGE STUDIES OF TELONE II•

	CONTR	OL (VEH)	LOW	DOSE	HIG	H DOS
ANIMALS INITIALLY IN STUDY	50	<u> </u>	50	<u> </u>	50	
NIMALS NECROPSIED	50		50		50	
ANIMALS EXAMINED HISTOPATHOLOGICALLY			50		50	
NTEGUMENTARY SYSTEM					(	
*SUBCUT TISSUE	(50)		(50)	(90)	(50)	
LEIOMYOSARCOMA			ł	(2%)		
RESPIRATORY SYSTEM			(= - )			
#LUNG ADENOCARCINOMA, NOS, UNC PRIM OR 1	(50) (FT		(50)		(50)	(2%)
HEPATOCELLULAR CARCINOMA, METAS	MEI T		1	(2%)	1	
ALVEOLAR/BRONCHIOLAR ADENOMA	<b>1</b>	(2%)		(22%)	9	
ALVEOLAR/BRONCHIOLAR CARCINOMA			2	(4%)	3	(6%)
IEMATOPOIETIC SYSTEM						
*MULTIPLE ORGANS	(50)		(50)		(50)	
MALIGNANT LYMPHOMA, NOS			2	(4%)	2	(4%)
#SPLEEN MALIGNANT LYMPHOMA, NOS	(50)		(49)	(4%)	(49)	(4%)
#LYMPH NODE	(50)		(50)	(370)	(50)	(**70)
MALIGNANT LYMPHOMA, NOS				(2%)	(00)	
ZIRCULATORY SYSTEM				····		
<b>#BONE MARROW</b>	(49)		(49)		(50)	
HEMANGIOSARCOMA	(20)		1	(2%)	(10)	
#SPLEEN HEMANGIOMA	(50)		(49) 3	(6%)	(49)	
HEMANGIOSARCOMA	1	(2%)	2	(4%)	1	(2%)
#THYMUS	(49)	(	(48)		(47)	<b>(</b>
HEMANGIOSARCOMA			1	(2%)		
DIGESTIVE SYSTEM						
#LIVER	(50)	(0.2.)	(50)	(0.2)	(50)	(00)
HEPATOCELLULAR ADENOMA HEPATOCELLULAR CARCINOMA	1 4	(2%) (8%)	16	(2%) (12%)	3	(6%) (20%)
#STOMACH	(50)	(070)	(50)	(1270)	(50)	(20%)
SQUAMOUS CELL PAPILLOMA	(00)			(4%)		(6%)
JRINARY SYSTEM	····					
<b>#URINARY BLADDER</b>	(50)		(50)		(50)	
TRANSITIONAL-CELL CARCINOMA					2	(4%)
NDOCRINE SYSTEM	(10)		/40		/ A P \	
<b>#PITUITARY</b> CHROMOPHOBE ADENOMA	(42)		( <b>48</b> ) 1	(2%)	(45)	
#ADRENAL	(50)		(50)	~~~/	(48)	
CORTICAL ADENOMA	1	(2%)			2	(4%)
<b>#PANCREATIC ISLETS</b>	(50)	(00)	(50)		(50)	
ISLET-CELL ADENOMA	1	(2%)				
EPRODUCTIVE SYSTEM NONE						

## TABLE B1. SUMMARY OF THE INCIDENCE OF NEOPLASMS IN MALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II®

## TABLE B1. SUMMARY OF THE INCIDENCE OF NEOPLASMS IN MALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

(50)	(50)	(50) 1 (2%) (50)
(50)	(50)	
(50)	(50)	
(50)	(50)	
		1 (2%)
MICROSCOPICALI	LY	
50 44 2	50 21	50 21
4	28 1	29
8 9 4 4 5 5	28 36 15 18 17 18 1 1 1	30 39 17 18 16 20 2 2 2
		1
	50 44 2 4 4 5 5 *	50 50 44 21 2 4 28 1 8 28 9 36 4 15 4 15 5 18 5 17 5 18 1 1

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C	CONTRO	OL (VEH)	LOW	DOSE	HIG	H DOSI
ANIMALS INITIALLY IN STUDY	50		50		50	
NIMALS NECROPSIED	50		50		50	
NIMALS EXAMINED HISTOPATHOLOGICALLY	50		50		50	
NTEGUMENTARY SYSTEM			(7.6)			
*SUBCUT TISSUE OSTEOSARCOMA	(50)	(2%)	(50)		(50)	
	1	(270)				
ESPIRATORY SYSTEM			(20)		(50)	
#LUNG ADENOCARCINOMA, NOS, METASTATIC	(50)		(50) 1	(2%)	(50) 1	(2%)
ALVEOLAR/BRONCHIOLAR ADENOMA				(6%)		(16%)
ALVEOLAR/BRONCHIOLAR CARCINOMA	2	(4%)		(2%)	·	(20.07
EMATOPOIETIC SYSTEM		_				
*MULTIPLE ORGANS	(50)		(50)		(50)	
MALIGNANT LYMPHOMA, NOS		(4.00)		(16%)	9	(18%)
MALIG. LYMPHOMA,HISTIOCYTIC TYPE #SPLEEN		(4%)	(50)		(50)	
#SPLEEN MALIGNANT LYMPHOMA, NOS	(50)		(00)	(2%)	(00)	
#LYMPH NODE	(50)		(50)		(50)	
LEIOMYOSARCOMA, METASTATIC			1	(2%)		
MALIGNANT LYMPHOMA, NOS		(4%)	1	(2%)	(50)	
#LIVER MALIG.LYMPHOMA, LYMPHOCYTIC TYPE	(50) 1	(2%)	(50)		(50)	
RCULATORY SYSTEM						- <u></u>
#SPLEEN	(50)		(50)		(50)	
HEMANGIOMA			ĺ	(2%)	(00)	
HEMANGIOSARCOMA		(2%)				(4%)
#LIVER	(50)	(10)	(50)	(00)	(50)	(2%)
HEMANGIOSARCOMA #UTERUS	(50)	(4%)	1 (50)	(2%)	1 (49)	(270)
HEMANGIOMA	(00)			(2%)		
#OVARY	(50)		(50)		(48)	
HEMANGIOMA			1	(2%)	1	(2%) (9%)
HEMANGIOSARCOMA		<del>.</del>			1	(2%)
IGESTIVE SYSTEM						
#LIVER HEPATOCELLULAR ADENOMA	(50)		(50) 5	(10%)	(50) 3	(6%)
HEPATOCELLULAR CARCINOMA	1	(2%)	š	(6%)	Ŭ	
SARCOMA, NOS, METASTATIC			•	(2.07)	1	(2%)
OSTEOSARCOMA, METASTATIC		(2%)	(		(70)	
#STOMACH SQUAMOUS CELL PAPILLOMA	(50)		(50)	(2%)	(50) 2	(4%)
SQUAMOUS CELL CARCINOMA			•	(470)		(4%)
RINARY SYSTEM						
#KIDNEY	(50)		(50)	(0.0)	(50)	
ADENOCARCINOMA, NOS, METASTATIC	(80)			(2%)	(48)	
#URINARY BLADDER TRANSITIONAL-CELL CARCINOMA	(50)		(50) 8	(16%)		(44%)
NDOCRINE SYSTEM						
#PITUITARY	(48)		(48)		(41)	
CHROMOPHOBE ADENOMA	4	(8%)		(13%)	2	(5%)
					(50)	
#ADRENAL CORTICAL ADENOMA	(50)		(50)	(2%)	(00)	

	CONTROL (VEH)	LOW DOSE	HIGH DOSE
REPRODUCTIVE SYSTEM *MAMMARY GLAND	(50)	(50)	(50)
ADENOCARCINOMA, NOS	2 (4%)	1 (2%) 2 (4%)	1 (2%)
FIBROADENOMA #UTERUS	(50)	(50)	(49)
SARCOMA, NOS LEIOMYOSARCOMA		1 (2%)	1 (2%)
#OVARY	(50)	(50)	(48)
ADENOCARCINOMA, NOS TERATOMA, NOS			1 (2%) 1 (2%)
VERVOUS SYSTEM NONE			
PECIAL SENSE ORGANS NONE			
AUSCULOSKELETAL SYSTEM NONE		<u></u>	
BODY CAVITIES NONE			<u></u>
ALL OTHER SYSTEMS NONE			
# NUMBER OF ANIMALS WITH TISSUE EXAMIN • NUMBER OF ANIMALS NECROPSIED	ED MICROSCOPICALI	.Y	
ANIMAL DISPOSITION SUMMARY	50	50	50
ANIMALS INITIALLY IN STUDY NATURAL DEATH	4	8	15
MORIBUND SACRIFICE			
SCHEDULED SACRIFICE TERMINAL SACRIFICE	46	42	35
DOSING ACCIDENT			
ACCIDENTALLY KILLED, NDA ACCIDENTALLY KILLED, NOS			
ANIMAL MISSING			
ANIMAL MISSEXED OTHER CASES			
TUMOR SUMMARY		33	34
TOTAL ANIMALS WITH PRIMARY TUMORS** TOTAL PRIMARY TUMORS	19	47	57
TOTAL ANIMALS WITH BENIGN TUMORS	5	17 22	13 17
TOTAL BENIGN TUMORS TOTAL ANIMALS WITH MALIGNANT TUMOR	5 NS 13	22	29
TOTAL MALIGNANT TUMORS	14	25	39 2
TOTAL ANIMALS WITH SECONDARY TUMOR TOTAL SECONDARY TUMORS	1 .	2 3	2
			1
TOTAL ANIMALS WITH TUMORS UNCERTAI			1
BENIGN OR MALIGNANT TOTAL UNCERTAIN TUMORS			
TOTAL ANIMALS WITH TUMORS UNCERTAL BENIGN OR MALIGNANT TOTAL UNCERTAIN TUMORS TOTAL ANIMALS WITH TUMORS UNCERTAL PRIMARY OR METASTATIC TOTAL UNCERTAIN TUMORS	N-		

#### TABLE B2. SUMMARY OF THE INCIDENCE OF NEOPLASMS IN FEMALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

### TABLE 53. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II⁴: VEHICLE CONTROL

ANIMAL NUMBER	0 0 1	003	005	007	09	0 1 1	0 1 3	0115	017	019	0 2 1	023	025	027	ON O	031	0 3 3	035	037	039	0 4 1	0 4 3	040	0 4 7	0 4 9
WEEKS ON STUDY	0 4 1	0 9 3	1 0 5	0 4 8	0 6 7	04	1. 0. 5.	049	1 0 3	049	0 5 1	0 5 1	040	0 5 1	0 5 1	096	090	082	1 0 5	049	0 5 1	1 0 5	0 5 1	0 5 1	0 8 8
RESPIRATORY SYSTEM Lungs and bronchi Alveolar/bronchiolar adenoma Trachea	+	++	+++	+++	++	++	+++	++	++	++	+++	+++	+++	+++	+	++	+++	+++	+	+++	++	+++	++	++	
HEMATOPOIETIC SYSTEM Bone marrow Spisen Hemangiosarcoma Lymph nodee Thymus	++ +-	++ ++	++ ++	++ ++	++ ++	+++++	++ ++	+++++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	1
CIRGULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+		+	+	+	+	+	+	+	+	+	-
DIGESTIVE SYSTEM Salivary gland Liver Hepatocellular adenoma Hepatocellular carcinoma Bile duct Gallbladder & common bile duct Pancreas	++ +z+	++ +z+	++ +2+	++ +z+	++ +z+	++ +z+	++ +z+	++ +z+	++ +z+	++ +2+	++ +z+	++ +2+	++ +2+	++ +z+	++ +z+	++ +z+	++ +×+	++x +x+	++ x+x+	++ +z+	++ +z+	++ +z+	++ +z+	+	++ x+x+
Esophagus Stomach Small intestine Large intestine	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++	++++
URINARY SYSTEM Kidney Urinary bladder	;	++	;	++	+++	+ +	+ +	+++	++++	+ +	++	+	++	+++	++	++	++	+++	+++	+	+	+	+	+	- { ‡
ENDOCRINE SYSTEM Pituitary Adrenai Cortical adenoma Thyroid Parathyroid Pancreatic islets islet cell adenoma	1+ +++	++ +++	++ +++	++ +++	+++++++++++++++++++++++++++++++++++++++	++ +-+	++ +++	-+ +++	-+ +++x	++ +++	++ +++	++ +-+	-+ +++	++ +++	++ +-+	++ +++	++ +++	++ +++	-+ +-+	-+ +-+	++ +-+	++ ++++++++++++++++++++++++++++++++++++	++ +++	++ +-+	- + + X + + +
REPRODUCTIVE SYSTEM Mammary gland Testis Prostate	++++	++++	++++	+++++	+ + + +	+ + +	+ + +	+ + +	+ + +	++++	+ + +	++++	+++	* <b>*</b> *	+++	+++	++++,	+++	+++++	+++	+++	++++	+++++	+ + +	 + + + +
NERVOUS SYSTEM Brain	+	+	+	+	+	+	÷	+	+	+	+	+	÷	÷	÷	+	÷	÷	÷	+	÷	+	+	+	+

No Tissue Information Submitted
 No Tissue Information Submitted
 Norropsy. No Histology Due Te Protocol
 A : Autolysis
 M : Animal Missing
 B : No Necropsy Performed

Tissue Examined Microscopically

 Required Tissue Not Examined Microscopically
 Tumor Incidence
 N : Necropsy, No Autolysis, No Microscopic Examination
 Animal Missezed

Telone II[®], NTP TR 269

#### TABLE B3. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE MICE: VEHICLE CONTROL (Continued)

ANIMAL	0	<u> </u>	g	o	ġ	ğ	0	g	g	0	2	<u>o</u>	2	2	Q,	9	9	0	<u>o</u>	9	0	<u>o</u>	0 9 5	0	9	1
NUMBER	1	53	55	5	5	6	6	65	6 7	69	7 1	7	75	7 7	579	8	8 3	85	8 7	089	9 1	9	5	9 7	9	TOTAL
WEEKS ON STUDY	104	1 0 5	048	103	080	105	0 9 1	0 5 0	0 4 8	088	0 4 8	0 5 1	050	1 0 5	049	050	0 4 8	0 9 2	0 4 9	0 9 8	0 5 0	0 4 9	000	1 0 2	1 0 5	TISSUES TUMORS
RESPIRATORY SYSTEM Lungs and bronchi Alveolar/bronchiolar adenoma Trachea	* * *	++	++	++	++	+ +	++	++	++	++	+ +	++	++	++	+ +	+	+	+ +	++	++	++	++	+ +	+	- + +	50 1 50
HEMATOPOIETIC SYSTEM Bone marrow Spleen Hemangiosarcoma Lymph nodes Thymus	++ ++	++ ++	++ ++	++ ++	++ ++	++x++	++ ++	++ ++	++ ++	+++++	+++++	+++++	++ ++ ++	+++++	+++++	+++++	++ ++	+++++	++ ++	+++++	++ ++	++ ++ ++	+++++	-+ ++	++ ++	49 50 1 50 49
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
DIGESTIVE SYSTEM Salivary gland Liver Hepatocellular sdenoma Hepatocellular carcinoma	+++	+++	+++	+++	++	++	+++	+++	+++	++	+++	+++	++	++	+ +	++	+++	+ + x	+ +	++	++	+++	+ + x	+++	++	50 50 1 4
Gallbladder & common bile duct Gallbladder & common bile duct Pancreas Esophagus Stomach Stomach Large intestine	+z++++	+2+++++	+ 2 + + + + + +	+z++++	+2+++++	+2+++++	+2+++++	+2+++++	+2+++++	+2+++++	+2+++++	+z++++	+2+++++	+2+++++	+N+++++	+2+++++	+2+++++	+2++++	+2++++++	+z++++	+z+++++	+z++++	(+z+++++	+z++++	+z++++	50 *50 50 50 50 50 50 50
CRINARY SYSTEM Kidney Urinary bladder	+++++	++	+ +	+++	++	+++	+++	+	+++	++	+++	++	+++	++	+++	+++	+++	+++	+	++	+++	+++	+++	++	++++	50 50
ENDOCRINE SYSTEM Pituitary Adrenal Cortical adenoma Thyroid Parathyroid Pancreatic ialeta Islet cell adenoma	++ +1+	1+ +1+	++ +++	++ +++	++ +-+	++ +++	++ + + + + + + + + + + + + + + + + + + +	++ +++	1+ +++	++ +++	++ +++	++ +++	++ +++	++ +++	++ +++	++ +++	++ +++	++ + - +	++ + + + + + + + + + + + + + + + + + + +	++ +++	++ + + + + + + + + + + + + + + + + + + +	++ +++	++ +++	++ +++	++ +++	42 50 1 50 33 50 1
REPRODUCTIVE SYSTEM Mammary gland Testis Prostate	+ + +	++++	+++	++++	+++	++++	+++	+++	+++	+++	+++	++++	++++	++++	++++	++++	++++	++++	+++	+++	+++	++++	+++	+++++	++++	*50 50 50
NERVOUS SYSTEM Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50

Animals Necropsied

ANIMAL Number	0 1	0	05	07	109	1	11	115	177	100	1 2 1	123	- 212	127	140	1 3 1	1 3 3	35	137	139	4	43	145	47	49
WEEKSON Study	0 6 7	1 0 5	1 0 5	1 0 5	105	1 0 5	104	105	1 0 5	1 0 5	0 5 3	1 0 5	05	1 0 5	1 0 5	105	1 0 5	105	1 0 3	1 0 5	079	1 0 5	105	1 0 1	1 0 5
INTEGUMENTARY SYSTEM Subcutaneous tissue Leiomycsaccoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
RESPIRATORY SYSTEM Lungs and bronchi Hepatoceliular carcinoma, metastatic Alveolar/bronchiolar adenoma Alveolar/bronchiolar carcinoma Trachea	+	+ x +	+ x +	+++	+ X +	+	+ x +	+	+	+	++	+ X +	+ X+	+	++	+ x +	++	+ x +	+	+ x +	+ x +	++	++	+	+ x +
HEMATOPOIETIC SYSTEM Bone marrow Hemangiosarcoma Spieen Hemangioma	+	+ +	++	++	+ +	+ + X	++	++	++	++	++	++	++	++	++	++	+ *	++	++	+ +	++	++	++	+++	- + +
Hemangiosarcoma Malignant lymphoma, NOS Lymph nodes Malignant lymphoma, NOS Thymus Hemangiosarcoma	+ +	+ +	+ +	+ +	+ +	л + +	+ +	+ +	+ +	X + +	+ +	+. +	+ -	+ +	+ +	+ +	++	+ +	* *	+ +	+ +	+ +	+ +	+ +	++
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	÷	+	+	.+	+	+	+	+	+	+	+	+	+	+	+	+
DIGESTIVE SYSTEM Salivary gland Liver Hepatocellular adenoma Hepatocellular carcinoma	+++++++++++++++++++++++++++++++++++++++	+++	+++	+ + x	++	+++	+++	++	++	++	+++	+ + x	++	++	++	++	++	‡ x	++	++	‡ * x	‡ *	++	++	++
Bile duct Galibladder & common bile duct Esophagus Stomach Squamous cell papilloma Small intestine Large intestine	+z+++ ++	+z+++ ++	++++++++	(+z+++ ++	+z+++ ++	+z+++ ++	+z+++ ++	+z+++ ++	+z+++ ++	+z+++ ++	+z+++ ++	(+z+++ ++	+z+++ ++	+z+++ ++	+z+++ ++	+z+++ ++	+z+++ ++	(+Z+++ ++	+2+++++++	+ 2 + + + + + + + + + 2 + + + + + + + +	(+z+++ ++	!+X+++ ++	+z+++ ++	+z+++ ++	+Z+++ ++
CRINARY SYSTEM Kidney Urinary bladder	+ +	‡	+ +	++	+	++	+	‡	+	++	+	++	+ +	++	+	++	+	++	++	+++	+ +	+	++	++	 + +
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Adrenal Thyroid Parathyroid	** + + + +	+ +++	+ ++ =	+ +++	+ +++	+ + + -	+ +++	+ ++=	+ + + + + + + + + + + + + + + + + + + +	+ +++	+ ++ -	+ +++	+ + + + + + + + + + + + + + + + + + + +	+ + + + + +	+ +++	+ +++	+ + + + + + + + + + + + + + + + + + + +	+ ++	+ ++ =	+ ++ -	+ + + + -	+ +++	+ +++	+ +++	+ + + -
REPRODUCTIVE SYSTEM Mammary gland Testis Prostate	+++	+++	+++	+++	+++		+++	+++	+++	++++	++++	+++	+++	+++	+++	+++	+++	++++	+++	+++	++++	+++	+++	+++	- +++
NERVOUS SYSTEM Brain	+	÷	÷	+	÷	+	÷	ŧ	ŧ	÷	÷	÷	+	+	÷	+	÷	+	÷	÷	÷	÷	+	÷	+
ALL OTHER SYSTEMS Multiple organs NOS Malignant lymphoma, NOS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	Ň	N

### TABLE B3. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II^o: LOW DOSE

Tissue Examined Microscopically
 Required Tissue Not Examined Microscopically
 X = Tumor incidence
 N = Necropsy, No Autolysis, No Microscopic Examination
 S = Animal Missexed

No Tissue Information Submitted
 C : Neeropsy, No Histology Due To Protocol
 A : Autolysis
 M : Animal Missing
 B :, No Neeropsy Performed

## TABLE B3. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE MICE: LOW DOSE (Continued)

ANIMAL Number	5	53	100	57	100	6	6	85	67	69	7	73	7	7	7	8	8	8	57	8	9	9	9	\$	9	TOTAL
WEEKS ON STUDY	102	00	00	103	105	105	0	9	0	000	9	084	000	0 8 8	8	040	100	100	102	102	054	100	030	105	105	TISSUE
INTEGUMENTARY SYSTEM Subcutaneous tissue Leiomyosarcoma	+	+	+	+	+	+	+	*	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	*50
RESPIRATORY SYSTEM Lungs and bronchi Hepatocsilular carcinoma, metastatic Alveolar/bronchiolar carcinoma Alveolar/bronchiolar carcinoma	+	+	+	+ x	+	+	+	+	+	+	+	+	+	+ X	+	+	+	+	+	+	+	ż	+	+	+	50 1 11 2 50
Traches HEMATOPOIETIC SYSTEM Bone marrow Kemangiosarcoma Spieen Hemangioma Hemangioma Hemangioma Malignant lymphoma, NOS Lymph nodes Malignant lymphoma, NOS Thymus	+++++++++++++++++++++++++++++++++++++++	+ + + + + +	+ + + + + + + + + + + + + + + + + + +	+ + + + +	+ + + * * * *	+ + + + +	+ + + +	+ + + -	+ + + +	+ + + + + +	+ + + + + +	+ + + ×+ +	+ + + + + +	+ + + + + +	+ + + + + +	+ + + + + + +	+ + + + +	+ + + + +	++++	++++	+ + + + +	+ + + + +	++++	++++	· · · · · · ·	48 1 40 3 2 2 50 1 45
Hemangioearcoma CIRCULATORY SYSTEM	+	+	+	+	+	+	+	+	+	+	+	- +	+	+	+	+	+	+	+	¥ +	+	+	+	+		50
DIGESTIVE SYSTEM Salivary gland Joer Hepatoceilular carcinoma Sile duct Callbladder & common bile duct Callbladder & common bile duct Sophagus Stomach Squamous cell papilloma Small intestine Large intestine	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++x +z+++ ++	++ +2+++ ++	++ +++	++ +2+++ ++	++ +2+++ ++	++ +2+++ ++	++ +z+++ ++	++ +z+++ ++	++ +2+++ ++	++ +2+++ ++	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +z+++ ++	++ +2+++ ++	++ x+z+++ ++	++ +2+++ ++	++ +2+++ ++	++ +×+× ++	50 50 1 6 50 50 50 50 50 50 50
JRINARY SYSTEM Gidney Jrinary bladder	‡	++	+ +	++	+ +	+ +	<b>+</b> +	+++	<b>+</b> +	+++	++	++	++	+ +	++	++	+ +	++	<b>+</b> +	+ +	++	++	+ +	+ +	+	50 50
NDOCRINE SYSTEM Vituitary Chromophobe adenoma drenai Aproid 'arathyroid	- + + -	- +++	+ ++ -	+ ++ -	+x + + +	+ +++	+ +++	+ +++	+ ++-	+ ++-	+ ++ -	+ +++	+ +	+ +++	+ +++	+ ++ -	+ +++	+ ++-	+ +++	+ ++ -	+ +++	+ +++	+ ++ 1	+ +++	+ + + +	48 1 50 49 27
REPRODUCTIVE SYSTEM Mammary gland Festis Prostate	++++	++++	+++	+++++	+++++	++++	+ + + + +	+ + + +	++++	+ + +	+ + +	++++	+++++	+++++	++++	+++++	+++++	+++++	++++	+++	++++	++++	+++	++++	+++	*50 50 50
NERVOUS SYSTEM	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
ALLO MS Multis Mali Ia, NOS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	NX	N	*50

* Animals Necropsied

TABLE B3.	INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE MICE IN THE
	TWO-YEAR GAVAGE STUDY OF TELONE II [®] : HIGH_DOSE

ANIMAL NUMBER	2 0 1	2 0 3	205	2 0 7	209	2 1 1	2 1 3	2 1 5	2 1 7	219	2 2 1	2 2 3	2225	2 2 7	229	2 3 1	2 3 3	235	2 3 7	239	2 4 1	2 4 3	245	2 4 7	2 4 9
WEEKS ON STUDY	0 9 5	1 0 5	1 0 4	002	0 5 0	0 8 0	0 8 7	1 0 5	1 0 5	1 0 5	1 0 5	1 0 5	1 0 5	1 0 3	104	1 0 5	1 0 1	1 0 5	1 0 5	1 0 5	1 0 3	1 0 5	1 0 5	1 0 5	0 7 5
RESPIRATORY SYSTEM Lungs and bronchi Adenoca, NOS unc prim/metastatic Hepatocellular carcinoma, metastatic Alveolar/bronchiolar adenoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+ x	+ x	+	+ x	+	+	+	+ x	+	+	+
Alveolar/bronchiolar carcinoma Trachea	+	+	+	+	+	+	X +	+	X +	+	+	+	+	+	+	+	X +	+	+	+	+	+	+	+	+
HEMATOPOIETIC SYSTEM Bone marrow Spleen Hemangiosarcoma	++++	++	++	++	+++	++	++	++	++	++	+	++	++	++ *	++	++	++	++ *	+++	++	++	++	+++	++	++
Malignant lymphoma, NOS Lymph nodes Thymus	+ -	+ +	+ +	+ +	+ +	+ +	+ +	+	+ +	+ +	+ +	+++	+ +	+++	++	+ +	++	A + + +	++	+ +	+-	++	+ +	++	<b>+</b> +
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
DIGESTIVE SYSTEM Salivary gland Liver Hepatoceilular adenoma	+	++	++	+ +	+++	+++	+ + x	+++	+++	++	++	+++	+++	++	+++	++	++	+++	++*x	++	++	+++	+++	+++	+.
Hepatocellular carcinoma Bile duct Gallbladder & common bile duct Pancreas	+ N +	+ z +	+ Z +	+ N +	+ z +	+ X +	+ N +	+ N +	+ N +	X + N +	+ X +	+ X +	X + N +	+ N +	+ N +	+ 2 +	X+N+	+ 2 +	+N+	+ 2 +	+ N +	+ N +	+ N +	+ 2 +	+ 2 +
Esophagus Stomach Squamous ceil papilloma Small intestine Large intestine	++++++	++ ++	++ ++	++ ++	++ ++	++x++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++x++	++ ++	++ ++	++++	++ ++	++ ++
URINARY SYSTEM Kidney Urinary bladder Transitional cell carcinoma	+	+++	++	+++	+++	++	+++	++	+ + X	+++	++	+++	++	++	++	++	++	++	++	+++	+ +	+++	+++	++	++++
ENDOCRINE SYSTEM Pituitary Adrenal Cortical adenoma	+	++	++	+	++	++	+	+++	+++	++	++	++ **	++++	+	Ŧ	++	++++	+++	++	+ + *	+++	++	++	+++	- + +
Thyroid Parathyroid	+	++	+	+	++	+++	+ +	+	+	+	+ +	++	+ +	++	+ +	++	++	+++	++	+ +	+ +	+ +	+	+	+
REPRODUCTIVE SYSTEM Mammary gland Testis Prostate	++++++	+++	++++	+++	+++	++++	+++	++++	+++++	+++	+++	+++	++++	++++	++++	++++	++++	+++	+++	++++	++++	+++	+++	++++	+++
NERVOUS SYSTEM Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	- +
SPECIAL SENSE ORGANS Lacrimal gland Adenoma, NOS	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N
ALL OTHER SYSTEMS Multiple organs NOS Hepatocellular carcinoma, metastatic Malignant lymphoma, NOS	N	N	N	N	N	N	N	N	N X	NX	N X	N	N	N	N	N	N	N	N	N	N	N	N	N	Ņ

 + :
 Tissue Examined Microscopically

 - :
 Required Tissue Not Examined Microscopically

 X :
 Tumor Incidence

 N :
 Necropsy, No Autolysis, No Microscopic Examination

 S :
 Animal Missezed

No Tissue Information Submitted
 Necropsy, No Histology Due To Protocol
 Autolysis
 Animal Missing
 B : No Necropsy Performed

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## TABLE B3. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF MALE MICE: HIGH DOSE (Continued)

ANIMAL NUMBER	2 5 1	253	255	257	200	2 6 1	2 6 3	265	26	269	2 7 1	273	275	277	279	2 8 1	283	285	2 8 7	2000	2 9 1	2 9 3	295	2 9 7	2 9 9	TOTAL
weeks on Study	0 5 0	105	1 0 5	105	103	1 0 5	1 0 5	103	0 7 5	100	0 5 3	100	105	0 8 3	105	0 9	1 0 6	1 0 6	106	106	1 0 5	106	106	1 0 6	1 0 6	TISSUES TUMORS
RESPIRATORY SYSTEM Lungs and bronchi Adsnoca. NOS unc prim/metastatic Hepatocellular carcinoma, metastatic Alveolar/bronchiolar adenoma Alveolar/bronchiolar carcinoma Trachea	+	+ X +	+	+	+	+	+	+ X +	+	+	+	+ X X +	+ x +	* *	+	++	+	+	+	+	+	+ x +	+	+	++	50 1 1 9 3 50
HEMATOPOIETIC SYSTEM Bone marrow Spleen Hemangiosarcoma Malignant lymphoma, NOS Lymph nodes Thymus	+ + + +	++ ++	++ ++	++ ++	++ ++	+ - ++	+++++	++ ++	++ ++	++ ++	++++	++ ++	+++++	++ ++	++ ++	++ ++	++ x++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	50 49 1 2 50 47
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
DICESTIVE SYSTEM Selivary gland Liver Hepatocellular adenoma Hepatocellular carcinoma Bile duct	++++++	+++++	++ +	+++++	+++++	+++++	+++ +	++ +	++ +	++ x+	++ +	++ x+N	++ +	+++++	++x +	++ x+	++ x+z	+++++	+++++	++ x+	++ x+:	++ +:	++ +:	÷	- ++ x+:	50 50 3 10 50
Galibladder & common bile duct Pancreas Esophagus Stomach Squamous ceil papilloma Small intestine Large intestine	Z+++X++	Z+++ ++	Z+++ ++	N+++ ++	2+++ ++	X+++ ++	N+++ ++	N+++ ++	N+++ ++	N+++ ++	N+++ ++	N+++ ++	N+++ ++	2+++ ++	X+++ +4	N+++ ++	X+++ +4	N+++ ++	X+++ ++	8+++ ++	X+++ ++	N+++ ++	N+++ ++	X+++ ++	2+++ ++	50 *50 50 50 50 50 50
URINARY SYSTEM Kidney Urinary bladder Transitional cell carcinoma	++	++	++	++	++	+++	++	++	+	++	+	+ +	+++	+ + X	+++	++	+++	+	+++	++	++	++	++	+++	+	50 50 2
ENDOCRINE SYSTEM Pituitary Adrenal Cortical adenoma Thyroid Parathyroid	-+++	+++++	** **	++++	++, + -	++ ++	++ ++	+++++	‡ ±	++++	+++	++ + + + + + + + + + + + + + + + + + + +	** **	++++	+ + + +	++++-	+++++++++++++++++++++++++++++++++++++++	++++1	+++++	++ +-	-+++	++++	-+ +-	++ ++	++++	45 48 2 50 28
REPRODUCTIVE SYSTEM Mammary giand Testis Prostate	++++	+++	+++	+++	++++	++++	+++	+++	+++	++++	+++	+++	+++	++++	+++	+++	+++	+++	. + + +	+++	+++	+++	+++	++++	+++	*50 50 50
NERVOUS SYSTEM Brain	+	+	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	+	+	÷	+	+	÷	+	+	+	50
SPECIAL SENSE ORGANS Lacrimal gland Adenoma, NOS	N	N	N	N	N X	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	*50 1
ALL OTHER SYSTEMS Muitiple organa NOS Hepatocellular carcinoma, metastatic Malignant lymphoma, NOS	Ň	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	*50 1 2

*Animals Necropsied

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ANIMAL NUMBER	0	004	006	00	010	0 1 2	0	0 1 6	0 1 8	0 2 0	22	0 2 4	0 2 6	0 2 8	0 3 0	0 3 2	34	036	0 3 8	040	042	0 4 4	046	048	0 5 0
WEEKS ON STUDY	106	1 0 6	1 0 6	1 0 6	1 0 6	106	1 0 6	106	1 0 6	106	106	1 0 6	106	1 0 6	1 0 6	106	1 0 6	106	1 0 4	106	071	1 0 6	106	1 0 6	1 0 6
INTEGUMENTARY SYSTEM Subcutaneous tissue Osteosarcoma	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	* x	+	+	+	
RESPIRATORY SYSTEM Lungs and bronchi Alveolar/bronchiolar carcinoma Trachea	++++	+++	+	+++	++	++	++	++	++	+++	++	++	++	++	++	++	++	++	++	++	++	++	++	+++	
HEMATOPOIETIC SYSTEM Bone marrow Spieen Hemangiosarcoma Lymph nodes Malignant lymphoma, NOS Thymus	+++++++++++++++++++++++++++++++++++++++	+++++	++ + +	++ + +	+++++	++ + +	+++++	++ + + +	+++++	++++++	+++++	++++++	++ + + +	++++++	++ + +	++ + + X+	++++++	+++++++++++++++++++++++++++++++++++++++	+++++	++ +x+	++++++	++ + + + +	++ + +	++ + +	++++
CIRCULATORY SYSTEM	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
DIGESTIVE SYSTEM Salivary gland Liver Hepatocellular carcinoma Hemangiosarcoma Osteosarcoma, metastatic Malig, iymphoma, lymphocytic type	++	++	+++	++	+++	+++	+++	+++	+++	++	++	++	+++	++x x	+++	++	+++	++	+ + x	+++	+ + X	++	++	++	+ + +
Bile duct Sailbisdder & common bile duct Pancreas Soophagus Stomach Smail intestine Arge intestine	+Z+++++	+ + + + + + + + + + + + + + + + + + + +	+z++++	+2+++++	+2+++++	+2+++++	+2+++++	+z++++	+z++++	+2+++++	+2++++	+2+++++	+z++++	+ Z + + + + + +	+z++++	+z++++	+z++++	+z++++	+2+++++	+2+++++	+z++++	+2+++++	+2+++++	+2+++++	*2*****
JRINARY SYSTEM Kidney Jrinary bladder	+	+++	++	++	+++	+	++	++	++	+++	++	++	++	+++	++	++	++	+++	++	++	++	++	+	++	1 + +
INDOCRINE SYSTEM Ituitary Chromophobe adenoma direnai Pheochromocytoma Thyroid arathyroid	++++	+ + ++	+ + + =	+ + + + + + + + + + + + + + + + + + + +	+ + + -	+ + + + + + + + + + + + + + + + + + + +	++++	++++	+ + ++	++++	+ + + -	+ + + + + + + + + + + + + + + + + + + +	++++	+ + + + + + + + + + + + + + + + + + + +	+ + + + + +	+ + + -	+ + ++	+ + + + + + + + + + + + + + + + + + + +	+++	+ + + -	+ + + + +	+++	++++	++++	
EPRODUCTIVE SYSTEM Mammary gland Adenocarcinoma, NOS Jucrus Vary	++++	+ ++	+ + + +	+ +	+ ++	+ + +	+ + +	+ ++	+ ++	+++	+ + + + + + + + + + + + + + + + + + + +	+	+ ++	+ ++	+ ++	+++	++++	++++	+ + + +	+ + +	+ ++	+ + + +	+ + +	+ + +	
NERVOUS SYSTEM Brain		+	+	+	+	+	+	+	• +	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	
ALL OTHER SYSTEMS Multiple organs NOS Malig. lymphoma, histiocytic type	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N

#### TABLE B4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II": VEHICLE CONTROL

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 + : Tissue Examined Microscopically

 - : Required Tissue Not Examined Microscopically

 X : Tumor Incidence

 N : Necropsy, No Autolysis, No Microscopic Examination

 S : Animal Missexed

No Tissue Information Submitted
 C : Necropsy, No Histology Due To Protocol
 A : Autolysis
 M : Animal Missing
 B : No Necropsy Performed

Telone II[®], NTP TR 269

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#### TABLE B4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE MICE: VEHICLE CONTROL (Continued)

ANIMAL NUMBER	0 5 2	0 5 4	056	0 5 8	060	0 6 2	064	066	0 6 8	070	0 7 2	074	076	0 7 8	080	082	0 8 4	0 8 6	0 8	0.00	092	0 9 4	096	0 9 8	1 0 0	TOTAL
WEEKS ON STUDY	1 0 6	1 0 6	106	1 0 6	098	1 0 6	1 0 6	106	1 0 6	1 0 6	1 0 6	1 0 6	106	1 0 6	106	0 8 8	1 0 6	106	106	106	1 0 6	106	106	106	I 0 6	TISSUES TUMORS
INTEGUMENTARY SYSTEM Subcutaneous tissue Osteosarcoma	.+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	*50 1
RESPIRATORY SYSTEM Lungs and bronchi Alveolar/bronchiolar carcinoma Trachea	+	+++	+++	+++	+++	+++	++	++	+++	+++	+++	+++	++	+++	+ * *	+++	* *	++	+++	+++	+++	+++	+++	+++	- + +	50 2 50
HEMATOPOIETIC SYSTEM Bone marrow Spieen Hemangiosarcoma Lymph nodes Malignant lymphoma, NOS Thymus	+++++	++++++	++ + +	++++++	++++++	+++++++++++++++++++++++++++++++++++++++	++ ++ +	++++++	++x+ +	++++++	+++++++++++++++++++++++++++++++++++++++	++ ++ +	+++++	+++++++	++ + +	+ + + +	++ + +	+++++	+++++++++++++++++++++++++++++++++++++++	++ + +	++ + +	++++++	+++++++++++++++++++++++++++++++++++++++	++ ++ +	++ + +	50 50 1 50 2 50
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
DIGESTIVE SYSTEM Salivary gland Liver Hepatocellular carcinoma Hemangiosarcoma Osteosarcoma, metastatic Malig, lymphoma, lymphocytic type	+ + x	++	+++	+	+++	+++	+	+++	+++	+++	+++	+++	++++	++	+++	+	+++	++++	+++	+++	+++	+++	++++	+++	++	48 50 1 2 1 1
Bile duct Galibladder & common bile duct Pancrees Esophagus Stomach Small intestine Large intestine	+z++++	+Z++++	+z++++	+z++++	+2+++++	+z++++	+2+++++	+z++++	+z++++	+z++++	+2+++++	+z++++	+z++++	+z++++	+z++++	+z++++	+2+++++	+ + + + + Z + + + + + + + + Z + + + + +	+z++++	+z++++	+z++++	+z++++	+z++++	+z++++	+z++++	50 *50 50 50 50 50 50 50
URINARY SYSTEM Kidney Urinary bladder	+++	+++	+++	++	++	++	++	+++	+++	++	+++	+++	+++	++	++	+++	++++	++	++	++	++	++	++	++	+++	50 50
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Adrenal Pheochromocytoma Thyroid Parathyroid	+x+ + -	+ + + + + + + + + + + + + + + + + + + +	+ + + + -	+ + ++	+++++	+ + ++	+ + ++	~ + ++	+ + ++	+x+++	+ + + + -	+ + + -	+ + + +	+ + + +	+ + + -	+ + + + + + + + + + + + + + + + + + + +	+++++	+ + + + + + + + + + + + + + + + + + + +	+x+ ++	- + +	++++	+ + + x + +	+ + + +	+++-	+++	48 4 50 1 50 29
REPRODUCTIVE SYSTEM Mammary gland Adenocarcinoma, NOS Uterus Ovary	++++	+ +	+ + ++	+x + +	+ ++	+ ++	+ + +	+ + +	+ ++	+ ++	+ ++	+ ‡	+ + +	+ + +	+ +	+ +	+ + +	++++	+ + +	+ ++	+ + + +	+ + +	+ * *	++++	+ ++	*50 2 50 50
NERVOUS SYSTEM Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	- +	50
ALL OTHER SYSTEMS Multiple organs NOS Malig. lymphoms, histiocytic type	N	N	N	N	N X	N	N	N	N	N X	N	N	N	N	N	N	N	N	N	N	N	N	N	N	- N	*50 2

* Animals Necropsied

ANIMAL NUMBER	1 0 2	104	106	108	1	12	1	16	18	120	122	124	26	128	130	32	1 3 4	36	1 3  8	40	142	44	46	4	1 5 0
WEEKSON STUDY	1 0 6	1 0 6	1 0 6	1 0 6	1 0 6	1 0 6	0 9 7	106	1 0 6	1 0 6	1 0 0	1 0 6	106	106	106	1 0 6	106	1 0 1	1 0 7	107	106	1 0 6	0 7 3	106	106
RESPIRATORY SYSTEM Lungs and bronchi Adenocarcinoma, NOS, metastatic Alveolar/bronchiolar sdenoma Alveolar/bronchiolar carcinoma Trachea	+ x +	+	+	+	+	+ +	++	+++	+	++	+	+	+++	+ +	+	+++	++	++	++	++	+ +	+ X +	+	+	+++
HEMATOPOIETIC SYSTEM Bone marrow Spieen Hemangioma Malignant lymphoma, NOS	;	++	+	++	+ * x	++	++	+++	++	++	++	++	++	++	+	++	++	++	++	++	++	++	++	++	++
Malignant lymphoma, NOS Lymph nodes Leiomyosarcoma, metastatic Malignant lymphoma, NOS Thymus	+	++	+	+	+ X	+ +	+	+ +	+ +	++	++	+ -	++	+ +	+ +	++	+ +	+ +	+	+	++	+ +	+	+	+
CIRCULATORY SYSTEM Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
DIGESTIVE SYSTEM Salivary gland Liver Hepatocellular adenoma Hepatocellular carcinoma	:	++	+	+++	++	++	+	+	‡ x	+++	++ *	++ x	+	++	++	++	+++	++	++	++	++	+ + * x	++ .	+++	++
Hemangiosarcoma Bile duct Gailbiadder & common bile duct Pancress Esophagus Stomach	+z+++	+ 2 + + +	+ + + + +	+ 2 + + +	+2+++	+2+++	+z++	+ 2 + + + 5	+ 2 + + +	+2+++	+2+++	+2+++	+2+++	+ 2 + + +	+2+++	+ 2 + + +	X+N+++	+2+++	+z+++	+2+++	+ 2 + + +	+2+++	+z+++	+z+++	+ 2 + + +
Squamous cell papilloma Small intestine Large intestine	‡	+	+	+ +	+ +	+ +	<b>+</b> +	* + +	+ +	+	+	+	+	+	+	+	‡	+	+	+	+	+ +	<b>+</b> +	‡	+
URINARY SYSTEM Kidney Adenocarcinoma, NOS, metastatic Urinary bladder Transitional cell carcinoma	++++	++	+ +	.+ +	+ +	+ +	+ +	+++	++	+++	+ +	++	+ +	+ +	+++	+ +	+ +	+ *	++	+ +	+ +	+ +	+ +	+ *	+ *
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Adrenai Cortical adenoma Pheochromocytoma Thyroid	++++++	+++	+ + + +	+x + +	++++	+++++++++++++++++++++++++++++++++++++++	++++	++++	+ + +	++++	+++++	+ + +	++++	+ + +	- + +	+++++	+++++	+++++	-+++++						
Parathyroid REPRODUCTIVE SYSTEM Mammary gland Adenocarcinoma, NOS	++	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
Fibroadenoma Uterus Leiomyosarcoma Hemangioma Ovary Hemangioma	+++	++	+	¥ +	+ +	+ +	+	+ +	+ +	+	× + +	+ +	+ *	+ +	+ +	+ +	+ +	+ +	+ +						
NERVOUS SYSTEM Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
ALL OTHER SYSTEMS Multiple organs NOS Malignant lymphoma, NOS	N	N	N	N	N	N	N	N	N	N	N X	N	N	N	N	N	N	N X	N	N	N	N	N	N	N

#### TABLE B4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II*: LOW DOSE

 + : Tissue Examined Microscopically

 - : Required Tissue Not Examined Microscopically

 X : Tumor Incidence

 N : .Necropsy, No Autolysis, No Microscopic Examination

 S : Animal Missezed

No Tissue Information Submitted
C : Necropsy, No Histology Due To Protocol
A : Autolysis
M : Animal Missing
B : No Necropsy Performed

### TABLE B4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE MICE: LOW DOSE (Continued)

ANIMAL	<u> </u>	Π	п	π	П	π	11	1	Π	π	π	ï	π	Π	π	Π	П	π	п	π	11	Π	U	π	2	T
NUMBER	5	5	5	5	6	62	6	6	6	7	72	7	76	7	8	82	8	8	8	ŝ	9	9	9	9	Õ	TOTAL
	4			-	- - -	41		ণ — স	9 	শ		-	м 		ন		ण - रा	भ ना	- 	ਯ -ਜ	. "	-11	ज -स	ज च	Ť	TISSUES
WEEKSON STUDY	0	07	88	1 0 7	07	0 7	0 7	0	0	07	97	0	07	97	07	07	97	07	97	07	0	07	0	07	07	TUMORS
RESPIRATORY SYSTEM									-										<u> </u>						-	50
Lungs and bronchi Adenocarcinoma, NOS, metastatic	+	+	+	+	+	+	+	+	+	+	+	+	+	+	*	+	+	-	Ŧ	T	-	٣	ž	T	т	1
Alveolar/bronchiolar adenoma Alveolar/bronchiolar carcinoma									X						x											3
Trachea	+	+	+	+	+	÷	÷	+	+	+	+	+	÷	+	+	+	+	+	+	+	+	+	+	+	+	50
HEMATOPOIETIC SYSTEM															·						<u> </u>			_		
Bone marrow Spieen	+++	+++	+++	+++	++	+	++	+	+	+++	+++	+++	++++	+++	++	+	++	÷	++	++	++	++	++	÷	÷	50 50
Hemangioma			-	v																						1
Malignant lymphoma, NOS Lymph nodes	+	+	+	<b>^</b>	+	+	+	÷	+	+	+	+	+	+	+	÷	+	+	+	+	+	+	+	÷	+	50
Leiomyosarcoma, metastatic Malignant lymphoma, NOS			х																							
Thymus	+	÷	÷	+	+	÷	+	+	+	÷	+	+	+	+	+	+	+	+	÷	÷	÷	+	-	÷	+	47
CIRCULATORY SYSTEM																			-			-			_	
Heart	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
DIGESTIVE SYSTEM	<u> </u>	<u> </u>					4		<u> </u>	<u> </u>								+	+	1	+		1	+	_	50
Salivary gland Liver	+	÷	Ŧ	+	Ŧ	÷	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	÷	Ŧ	Ŧ	Ŧ	÷	Ŧ	Ŧ	Ŧ	Ŧ	÷	Ŧ	÷	Ŧ	÷	50
Hepatoceilular adenoma Hepatoceilular carcinoma	}								x					x									X		x	5 3 1
Hemangiosarcoma	ļ								ĉ					•												i
Bile duct Gallbladder & common bile duct	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	+ N	* N	+ N	Ň.	+ N	*N	* N	+ N	+ N	* N	+ N	+ N	ň.	ň.	50 *50 50 50 50
Pancreas	+	÷	÷	÷	+	+	+	÷	÷	+	+	÷	++++	÷	+	+	+	÷	÷	÷	÷	÷	+	÷	÷	50
Esophagus Stomach	+++	Ŧ	Ŧ	Ŧ	++++	+++	÷	Ŧ	Ŧ	++	‡	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	Ŧ	50
Squamous cell papilloma Small intestine	L _	4	-	-		Ŧ	-	Ŧ	Ŧ	+	÷		1	1	+	+	1	+	+	+	+	+	+	+	+	50
Large intestine	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	÷	50 50
URINARY SYSTEM		-								-												-		_	-	
Kidney	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	+	50
Adenocarcinoma, NOS, metastatic Urinary bladder	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	+	+	+	÷	+	+	÷	+	÷	+	+	50
Transitional cell carcinoma	X	X								X					X				X							8
ENDOCRINE SYSTEM																					+				-	48
Pituitary Chromophobe adenoma	Ŧ	٣	+	-	x	+	+	Ŧ		Ŧ	-	Ŧ	Ŧ	T	x	T	-	x	T	*	T	x	x	Ŧ	Ŧ	6
Adrenal Cortical adenoma	+	+	+	+	+	+	+	+	+	+	+	+	*	+	+	+	+	+	+	+	+	+	+	+	+	50 1
Pheochromocytoma							X						<b>^</b>													1
Thyroid Parathyroid	+	++	+++	++	+	++	+	+	+++	+++	<u>+</u>	<u>+</u>	++	+++	t	+	<u>+</u>	-	+	-	÷	+	1	<u>+</u>	+	50 21
•										_	_			_	-				_			_				
REPRODUCTIVE SYSTEM Mammary gland	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	÷	÷	+	+	<u>+</u>	+	+	*50
Adenocarcinoma, NOS Fibroadenoma																							X			1 2
Uterus	+	+	<u>+</u>	+	+	+	+	+	+	+	÷	÷	÷	+	+	+	+	+	+	+	+	+	+	+	+	50
Leiomyosarcoma Hemangioma			X															x								
Ovary Hemangioma	+	+	+	+	+	+	+	+	+	+	+	÷	+	+	+	+	+	÷	+	+	+	+	+	÷	+	50 1
-																		_							-	
NERVOUS SYSTEM Brain	+	+	+	+	÷	+	÷	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
ALL OTHER SYSTEMS	.,			N		N7	<u>م</u> ر	N		N7	N	N	N	NT.	N	N	N	N	N	N	M	N	N	N	- N	*50
Multiple organs NOS Malignant lymphoma, NOS	N	N	N X	N	N	N X	<u>N</u>	N	N	N	X	X	N	N	^N	en l	14	X	1	<b>N</b>	14	N	14	X	1.4	-50
	L									_								-								L

* Animals Necropsied

ANIMAL NUMBER	202	204	N06	NOS	N-10	2	14	1	2 1 8	NNO	202	224	NNO		0 CP N	NCO	134	N 23 6	80 N	<b>4</b> 0	N 4 N	244	148	4	80
WEEKS ON STUDY	0 7	107	107	9	1 07	107	107	0 7	07	107	1 0 7	107	07	1 0 7	107	0240	107	107	1 07	107	107	1 07	107	0 8 7	1 0 7
REBPIRATORY SYSTEM Lungs and bronchi Adenocarcinoma, NOS, metastatic Alveolar/bronchiolar adenoma Trachea	+	+	+	+ x+	+	+	+ X	+	+	+	+ ×	+	+	* *	+	+	+ X	+	+	+	+	+	+	+ +	+ ×+
HEMATOPOIETIC SYSTEM Bone marrow Spisen Hemangiosarcoma Lymph nodes Thymus	++ ++	**	++x+1	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	+++++	<b>++</b> ++
CIRCULATORY SYSTEM Heart	. +	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+
DIOESTIVE SYSTEM Salivary gland Liver Hepatoceliular adenoma Sarcoma, NOB, metastatic	+	++	+	++	++	++	+++	+	++	++	++	++x	++	++	+++	+	+++	++	++	+	+	++	+++	+ x	+++
Hemanguoarcoma Bile duct Galiblacider & common bile duct Pancreas Esophagus Stomach Squamous ceil papilloma Squamous ceil carcinoma Squamous ceil carcinoma	+2+++ +	+X+++ X+	X+Z+++ +	+ x+++ x +	+2+++ +	+z+++ +	+z+++ +	+z+++ 4	+2+++ +	+2+++ +	+ X+++X +	+z+++ +	+2++2+	+z++ +	+z++ +	+2+++ +	+2+++ +	+z+++ +	+ ++ + +	+ +++ 2+	+2+++ +	+2+++ +	+2+++ +	+2+++ +	+2+++ +
Large intestine URINARY SYSTEM	+	+	÷	+	÷	÷	+	÷	÷	+	+	+	+	+	÷	+	+	+	÷	+	+	+	+	+	÷ 
Kidney Urinary bladder Transitional cell carcinoma	+	+ * x	+	++	++ *	++X	+++	+ + X	++	+ * X	++x	++ x	+ + x	+	* * X	+	+ *	++	+	++	+ * X	+	++	÷	++x
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Adrenal Pheochromocytoma Thyroid Parathyroid	- + + ++	- + + -	+ + + -	+ + +	+ + + + + + + + + + + + + + + + + + + +	++++	+ + + -	+ + + + + + + + + + + + + + + + + + + +	+ + +	+ + ++	+ + + + + + + + + + + + + + + + + + + +	+ +x++	** ++	+ + ++	+x+ ++	++++	+ + + =	++++	+++	+ + +	+ + ++	++++	- + ++	+ + + + 1	1 + + ++
REPRODUCTIVE SYSTEM Mammary gland Adenocarcinome, NOS Uterus	+	+	+	+	+	+	+	+	+	+	+	+	+	ż	+	+	+	+	+	+	+	+	+	+	 + +
Sarcoma, NOS Ovary Adenocarcinoma, NOS Teratoma, NOS Hemangioma Hemangiosarcoma	+	+	+	+	+	+	+	+	+	* *	+	+	+	+	+	+ X	+	+	+	+	+	+	+	×,	+
NERVOUS SYSTEM Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	÷	+	+
ALL OTHER SYSTEMS Multiple organs NOS Malignant lymphoma, NOS	N X	N	N	N	N	N X	N	N	N	Ŋ	N X	N X	N X	N	N X	N	N	N	N	N	N	N	N	N	N

### TABLE B4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II⁴: HIGH DOSE

Tissue Examined Microscopically
 Required Tissue Not Examined Microscopically
 X : Tumor Incidence
 N : Necropsy. No Autolysis, No Microscopic Examination
 S : Animal Missexed

No Tissue Information Submitted
C : Necropsy, No Histology Due To Protocol
A : Autolysis
M : Animal Missing
B : No Necropsy Performed

## TABLE B4. INDIVIDUAL ANIMAL TUMOR PATHOLOGY OF FEMALE MICE: HIGH DOSE (Continued)

ANIMAL NUMBER	2 5 2	2 5	256	258	260	262	264	26	26	217-0	2 7 2	274	276	2 7 8	280	282	2 8 4	286	200	2000	29	294	200	298	300	TOTAL
WEEKSON Study	070	107	107	107	107	0	104	107	0 9 3	000	107	0 6 1	107	9	107	107	107	097	0	030	107	107	0 7	0 7 5	0 6 1	TISSUES TUMORS
RESPIRATORY SYSTEM Lungs and bronchi Adenocarcinoma, NOS. metastatic Alveolar/bronchielar adenoma Traches	+ X +	+ x+	+	+	+	++	+	+	++	++	+	+	+	+	+	+	+	+	+	+	+	+	+ X +	+	++	50 1 8 50
HEMATOPOIETIC SYSTEM Bone marrow Spieen Hemangiosarcoma Lymph nodes Thymus	+ + + +	++ ++	++ ++	++X++	++ ++	++ ++	++ ++	++ ++	++ ++	++ + + -	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++	++ ++ ++	+++++	50 50 2 50 48
CIRCULATORY SYSTEM Heart	+	÷	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
DIGESTIVE SYSTEM Salivary gland Liver Hepatocellular adenoma Sartoma, NOS, metastatic Hemangiosarcoma	+++++	++	+++	‡	++	++	+	‡	+++	++	++++	+	++	‡	+++	++	++++	++	+++	+++	+	‡	+ *	+ + X	+	50 50 3 1
Bile duct Gallbladder & common bile duct Pancreas Esophagus Stomach Squamous cell papilloma	+z+++	+ X + + +	+z+++	+ 2 + + +	+ Z + + +	+z   + +	+ Z + + +	+ + + 7 + 7 + 7 + 7 + 7 + 7 + 7 + 7 + 7	+z+++	+ - + - + + +	+ z + + +	+ 2 + + +	+ 7 + + 7	+ z + + +	+ X + + +	+ 2 + + +	+ 2 + + + +	+ 2 + + +	+ 2 + + +	+ 2 + + +	+z+++	+ 2 + + +	+ 2 + + + +	+ z + + +	+z++	50 *50 49 50 50 2 2
Squamous cell carcinoma Small intestine Large intestine	<b>+</b> +	+++	+ +	++	<b>+</b> +	<b>+</b> +	+ +	+ +	<b>X + +</b>	+ +	+ +	++	++	<b>+</b> +	+ +	+ +	+ +	<b>+</b> +	+ +	+ +	<b>+</b> +	+ +	+ +	+ +	<b>+</b> +	2 50 50
URINARY SYSTEM Kidney Urinary bladder Transitional cell carcinoma	+ +	+ + * X	+ + * X	+	+	++	++	++ *	+	++	+ *	++	+ + X	+ *	+	+ *	+	++	++	++	+ + * x	++	++	+ *	++	50 48 21
ENDOCRINE SYSTEM Pituitary Chromophobe adenoma Adrenai Pheochromocytoma Thyroid	- + +	++++	++++	+++++	++++	-+	++++	+ + + +	+++++		++++	++++		- + +	++++	++++	++++	++++	+++	- + +	+ + +	+ + + + +	++++	+++++	+ + +	41 2 50 1 48
Parathyroid	-	-	+	÷	-	-	-	+	-	+	-	-	+	+	÷	+	-	-	-	+	+	-	+	+	+	31
REPRODUCTIVE SYSTEM Mammary gland Adenocarcinoma, NOS Uterus Sarcoma, NOS	+	+ +	+ +	+ +	+ +	+ +	+ +	+ +	+ -	+ +	+ +	+ +	+ +	+ +	+ +	+ +	+ +	+ +	+ +	+ +	+ +	++	+ +	+ +	+	*50 1 49 1
Ovary Adenocarcinoma, NOS Teratoma, NOS Hemangioma Hemangiosarcoma	+	+	+	+	+	-	+	+	-	+	+	+	+	+ x	+	+	+	+ x	+	+	+	+	+	+	+	48 1 1 1 1
NERVOUS SYSTEM Brain	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	+	50
ALL OTHER SYSTEMS Multiple organs NOS Malignant lymphoma, NOS	N	N	N	N	N	N	N X	N X	N	N	N	N	N	N X	N	N	N	N	N	N	N	N	N	N	N	*50 9

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#### **APPENDIX C**

# SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN RATS IN THE TWO-YEAR GAVAGE STUDIES OF TELONE II•

С	ONTRO	)L (VEH)	LOWD	OSE	HIGH I	OSE
ANIMALS INITIALLY IN STUDY	52	<u>i</u> in- <del>-</del>	52		52	
ANIMALS NECROPSIED	52		52		52	
ANIMALS EXAMINED HISTOPATHOLOGICALLY	52		52		52	
NTEGUMENTARY SYSTEM	(52)		(52)		(52)	
*SKIN EPIDERMAL INCLUSION CYST	(52)	(2%)	(82)		(52)	
INFLAMMATION, CHRONIC	1	(2%)	(70)		(50)	
*SUBCUT TISSUE CYST, NOS	(52)	(4%)	(52)		(52)	
ABSCESS, NOS		(2%)				
ESPIRATORY SYSTEM						
*LARYNX	(52)		(52)	(00)	(52)	
ABSCESS, NOS #TRACHEAL SUBMUCOSA	(52)		1 (52)	(2%)	(52)	
ABSCESS, NOS			1	(2%)		
#LUNG	(52)	(90)	(52)		(52)	
CONGESTION, NOS HEMORRHAGE	1	(2%) (2%)				
INFLAMMATION, INTERSTITIAL	-				1	(2%)
INFLAMMATION, SUPPURATIVE BRONCHOPNEUMONIA, ACUTE	1	(2%) (2%)	1	(2%)		
ABSCESS, NOS	1	(270)		(2%)		
PNEUMONIA INTERSTITIAL CHRONIC	3	(6%)		(2%)		(2%)
BRONCHOPNEUMONIA, CHRONIC		(40)			1	(2%)
GRANULOMA, NOS INFLAMMATION, FOCAL GRANULOMATOU		(4%) (2%)				
GRANULOMA, FÓREIGN BODY		• •			1	(2%)
HYPERPLASIA, ADENOMATOUS	1	(2%)	3	(6%)		
IEMATOPOIETIC SYSTEM						
#BONE MARROW HYPOPLASIA, NOS	(52) 1	(2%)	(52)		(52)	
#SPLEEN	(52)	(2,0)	(52)		(52)	
INFARCT, NOS	3	(6%)				(00)
INFARCT, HEALED HEMOSIDEROSIS	2	(4%)	2	(4%)		(2%) (4%)
#LYMPH NODE	(52)	(4%)	(52)	(=~)	(52)	(4,0)
HYPERPLASIA, LYMPHOID	1	(2%)	(70)		(50)	
#SUBMANDIBULAR L.NODE HYPERPLASIA, LYMPHOID	(52) 5	(10%)	(52)		(52)	
#MANDIBULAR L. NODE	(52)	(20,00)	(52)		(52)	
HYPERPLASIA, LYMPHOID	1	(2%)				
#MEDIASTINAL L.NODE HYPERPLASIA, LYMPHOID	(52)	(2%)	(52)		(52)	
#THYMUS	(49)	( <u> </u>	(52)		(52)	
ABSCESS, CHRONIC			1	(2%)		
IRCULATORY SYSTEM	(20)		(70)		(70)	
#LUNG PERIARTERITIS	(52)		(52)		(52) 1	(2%)
#HEART	(52)		(52)		(52)	
INFLAMMATION, CHRONIC	43	(83%)		(77%)		(75%)
INFLAMMATION WITH FIBROSIS FIBROSIS	2 43		36	(69%)	91	(60%)
#HEART/ATRIUM	(52)		(52)	(30 10)	(52)	
THEOMETS ODCANTERD			,			(2%)
THROMBUS, ORGANIZED #ENDOCARDIUM	(52)		(52)		(52)	(=)

## TABLE C1. SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN MALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II®

### TABLE C1. SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN MALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

	CONTRO	L (VEH)	LOWD	OSE	HIGH D	OSE
CIRCULATORY SYSTEM (Continued)			·····			n ¹
*VEIN	(52)		(52)		(52)	
THROMBOSIS, NOS			1	(2%)	(,	
#LIVER	(52)		(52)		(52)	
THROMBUS, ORGANIZED	(50)			(2%)		
#PANCREAS	(52)	(2%)	(52)	(170)	(52)	(150)
PERIARTERITIS #KIDNEY	1 (52)	(270)	(52)	(17%)	8 (52)	(15%)
PERIARTERITIS		(2%)	(02)		(02)	
DIGESTIVE SYSTEM	·····					
#LIVER	(52)		(52)		(52)	
HEPATITIS, TOXIC					1	(2%)
NECROSIS, FOCAL	1		1	(2%)	1	(2%)
NECROSIS, CENTRAL		(4%)				
METAMORPHOSIS FATTY		(8%)				
FOCAL CELLULAR CHANGE		(73%)	39	(75%)	34	(65%)
ANGIECTASIS REGENERATION, NOS	1	(2%)				(94)
#BILE DUCT	(52)		(52)		(52)	(2%)
HYPERPLASIA, NOS	(52)	(6%)	(02)			(4%)
#PANCREAS	(52)		(52)		(52)	
INFLAMMATION, CHRONIC	1	(2%)	()			
<b>#PANCREATIC ACINUS</b>	(52)		(52)		(52)	
ATROPHY, NOS		(46%)	20	(38%)	21	(40%)
#STOMACH	(52)	(87)	(52)	(07)	(52)	(05)
ULCER, NOS	1	(2%)		(2%)	1	(2%)
INFLAMMATION, CHRONIC	1	(994)	1	(2%)	1	(2%)
HYPERPLASIA, EPITHELIAL HYPERPLASIA, FOCAL	1	(2%)			1	(2%) (2%)
HYPERPLASIA, FOCAL HYPERPLASIA, BASAL CELL	1	(2%)	9	(6%)		(270) (17%)
#GASTRIC MUCOSA	(52)		(52)		(52)	(11,10)
ULCER, FOCAL	(01)			(2%)	(02)	
#GASTRIC SUBMUCOSA	(52)		(52)	(=)	(52)	
INFLAMMATION, CHRONIC		(2%)			(/	
INFLAMMATION, CHRONIC FOCAL				(2%)		
#FORESTOMACH HYPERPLASIA, BASAL CELL	(52)		(52) 2	(4%)	(52) 3	(6%)
JRINARY SYSTEM						
#KIDNEY	(52)		(52)		(52)	
CYST, NOS	• •				1	(2%)
NEPHROPATHY		(73%)		(67%)		(81%)
#U.BLADDER/SUBMUCOSA	(52)		(52)		(52)	
EDEMA, NOS		· · · · = =·····= · · · · · · · · · · ·	<u> </u>	<u> </u>	9	(17%)
NDOCRINE SYSTEM #PITUITARY	(52)		(50)		(50)	
CYST, NOS		(2%)	(00)		(00)	(2%)
MULTIPLE CYSTS		(2%)			•	
HYPERPLASIA, FOCAL		(2%)	1	(2%)	1	(2%)
#ADRENAL CORTEX	(52)		(52)	-	(52)	
DEGENERATION, LIPOID	-		-	( <b>a</b> )	1	(2%)
HYPERPLASIA, NOS	1 7	(2%) (12%)		(6%)	1	(2%)
HYPERPLASIA, FOCAL #ADRENAL MEDULLA		(13%)		(12%)		(4%)
#ADRENAL MEDULLA HYPERPLASIA, NOS	(52) 1	(2%)	(52) 1	(2%)	(52)	
HYPERPLASIA, FOCAL	. 3	(6%)		(4%)		
#THYROID	(52)		(51)		(51)	
CYSTIC FOLLICLES	(/		(/			(2%)
FOLLICULAR CYST, NOS		(4%)			_	••
INFLAMMATION, GRANULOMATOUS		(2%)				
HYPERPLASIA, C-CELL	3	(6%)				
<b>#PANCREATIC ISLETS</b>	(52)		(52)	( A M )	(52)	
HYPERPLASIA, NOS HYPERPLASIA, FOCAL	0	(6%)	2	(4%) (4%)	5	(10%)
		1011201	2	(4,70)		

(52)	(52)	(52)
(02)		1 (2%)
(52)		(51)
	(02)	(01)
	2 (496)	7 (14%)
= (4/4)		(52)
	(02)	(02)
	(52)	(52)
1 (24)	(02)	(02)
1 (2%)		
		· · · · · · · · · · · · · · · · · · ·
(52)	(52)	(52)
1 (2%)	1 (2%)	
	(52)	(52)
1 (2%)		(50)
(52)	(52)	(52)
		1 (2%)
	1 (2%)	
(52)	(52)	(52)
1 (2%)		
		()
(52)	(52)	(52)
		1 (2%)
		1 (2%)
(52)	(52)	(52)
		1 (2%)
		1 (2%)
(52)		(52)
······	4 (8%)	4 (8%)
1		
	1	
	$(52) \\ 1 (2\%)$ $(52) \\ 1 (2\%)$ $(52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52) \\ (52$	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$

### TABLE C1. SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN MALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

# NUMBER OF ANIMALS WITH TISSUE EXAMINED MICROSCOPICALLY • NUMBER OF ANIMALS NECROPSIED

TABLE C2.	SUMMARY	OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN FEMALE RATS IN	
		THE TWO-YEAR GAVAGE STUDY OF TELONE II®	

CC	)NTRC	OL (VEH)	LOWD	OSE	HIGH D	OSE
ANIMALS INITIALLY IN STUDY	52		52		52	
ANIMALS NECROPSIED	52		52		52	
ANIMALS EXAMINED HISTOPATHOLOGICALLY	52		52		52	
NTEGUMENTARY SYSTEM	(50)				(20)	
*SKIN EPIDERMAL INCLUSION CYST	(52)		(52)		(52)	(2%)
*SUBCUT TISSUE	(52)		(52)		(52)	(2,2)
CYST, NOS	1	(2%)				
ABSCESS, NOS			1	(2%)		,
ESPIRATORY SYSTEM						
#TRACHEA	(52)		(52)	(8.4)	(52)	
ASPIRATION, FOREIGN BODY	(50)			(2%)	(50)	
#LUNG	(52)		(52)		(52) 1	(2%)
INFLAMMATION, INTERSTITIAL BRONCHOPNEUMONIA, ACUTE	1	(2%)	1	(2%)		(4%)
ABSCESS, NOS		(2%)		(2%)		(4%)
PNEUMONIA INTERSTITIAL CHRONIC					-	
GRANULOMA, NOS	10		1	(2%)		
INFLAMMATION, FOCAL GRANULOMATOU HYPERPLASIA, ADENOMATOUS		(6%)		(2%) (10%)	1	(2%)
					•	
HEMATOPOIETIC SYSTEM *BLOOD	(52)		(52)		(52)	
LEUKOCYTOSIS, NEUTROPHILIC	(52)		(02)	(2%)	(02)	
#BONE MARROW	(51)		(51)	(2,2)	(50)	
HYPERPLASIA, NOS		(2%)	(0.07)			
#SPLEEN	(52)		(51)		(52)	(0.01)
FIBROSIS, FOCAL		(190)	~	(1 404)	1 8	(2%)
HEMOSIDEROSIS #MEDIASTINAL L.NODE	(52)	(13%)	(52)	(14%)	(52)	(15%)
GRANULOMA, PYOGENIC		(2%)	(02)		(02)	
#KIDNEY	(52)	(=,	(52)		(52)	
HEMATOPOIESIS			1	(2%)		
CIRCULATORY SYSTEM						
#HEART	(52)		(52)		(52)	
INFLAMMATION, CHRONIC			31	(60%)		(63%)
FIBROSIS	23 (52)	(44%)	19	(37%)	(52)	(23%)
#HEART/ATRIUM THROMBOSIS, NOS	(52)	(2%)	(52)		(52)	
THROMBUS, ORGANIZED	ī					
#PANCREAS	(52)		(52)		(52)	
PERIARTERITIS	/**		1	(2%)	120	
*MESENTERY PERIARTERITIS	(52)		(52) 1	(2%)	(52)	
DIGESTIVE SYSTEM #SALIVARY GLAND	(52)		(52)		(52)	
ATROPHY, NOS	(04)			(2%)		(2%)
#LIVER	(52)		(52)	.=,	(52)	,
ABSCESS, NOS		(2%)				
FIBROSIS, FOCAL			-	(00)	1	(2%)
	•	(40)		(2%) (2%)		
INFECTION, BACTERIAL		(4%) (6%)	1	(2%)		
NECROSIS, FOCAL			•	(4%)	1	(2%)
NECROSIS, FOCAL NECROSIS, CENTRAL			2	(4,70)		
NECROSIS, FOCAL	4	(8%) (67%)		(69%)		(77%)
NECROSIS, FOCAL NECROSIS, CENTRAL METAMORPHOSIS FATTY FOCAL CELLULAR CHANGE ANGIECTASIS	4	(8%)	36 1	(69%) (2%)		(77%)
NECROSIS, FOCAL NECROSIS, CENTRAL METAMORPHOSIS FATTY FOCAL CELLULAR CHANGE ANGIECTASIS REGENERATION, NOS	4 35	(8%)	36 1 1	(69%)	40	(77%)
NECROSIS, FOCAL NECROSIS, CENTRAL METAMORPHOSIS FATTY FOCAL CELLULAR CHANGE ANGIECTASIS REGENERATION, NOS #LIVER/CENTRILOBULAR	4 35 (52)	(8%) (67%)	36 1	(69%) (2%)		(77%)
NECROSIS, FOCAL NECROSIS, CENTRAL METAMORPHOSIS FATTY FOCAL CELLULAR CHANGE ANGIECTASIS REGENERATION, NOS	4 35 (52)	(8%)	36 1 1	(69%) (2%)	40	(77%)

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	CONTRO	L (VEH)	LOWD	OSE	HIGH I	OSE
DIGESTIVE SYSTEM (Continued)						
#PANCREAS	(52)		(52)		(52)	(00)
INFLAMMATION, CHRONIC FOCAL	(20)		(50)		1 (52)	(2%)
<b>#PANCREATIC ACINUS</b>	(52)	(90%)	(52)	(31%)	21	(40%)
ATROPHY, NOS	(52)	(29%)	(52)	(01 %)	(52)	(40 %)
#STOMACH EPIDERMAL INCLUSION CYST	1	(2%)	(0-)			
EDEMA, NOS	-		1	(2%)		
INFLAMMATION, CHRONIC	1		1	(2%)		(00)
ULCER, PERFORATED	1	(2%)	1	(2%)		(2%) (8%)
HYPERPLASIA, EPITHELIAL	1	(2%) (4%)	1	(2%)		(2%)
HYPERPLASIA, FOCAL HYPERPLASIA, BASAL CELL	2	(470)	•	(2 ~)		(23%)
HYPERKERATOSIS			1	(2%)		
#GASTRIC SUBMUCOSA	(52)		(52)		(52)	
EDEMA, NOS	1					
INFLAMMATION, NOS	1	(2%)				
JRINARY SYSTEM			(59)		(52)	
#KIDNEY	(52)	(906)	(52)		(02)	
ABSCESS, NOS	1	(2%) (29%)	24	(46%)	25	(48%)
NEPHROPATHY INFARCT, HEALED	10	(20 /0)		(2%)		
#U. BLADDER/SUBMUCOSA	(52)		(52)	· ·	(52)	
EDEMA, NOS					3	(6%)
NDOCRINE SYSTEM					(50)	
<b>#PITUITARY</b>	(50)	(00)	(51)	(40)	(52)	(2%)
CYST, NOS	4	(8%) (2%)	2	(4%)	. 1	(270)
MULTIPLE CYSTS HYPERPLASIA, FOCAL		(2%)				
#ADRENAL	(52)	(4,%)	(52)		(52)	
CONGESTION, NOS			2	(4%)		
ANGIECTASIS			1	(2%)	(50)	
#ADRENAL CORTEX	(52)		(52)		(52)	(2%)
DEGENERATION, LIPOID			10	(19%)	9	
HYPERPLASIA, NOS HYPERPLASIA, FOCAL	15	(29%)		(13%)	13	
#THYROID	(52)		(52)	(	(52)	
FOLLICULAR CYST, NOS	<b>v</b> /				1	(2%)
HYPERPLASIA, C-CELL	1	(2%)	1	(2%)	•	
HYPERPLASIA, FOLLICULAR-CELL			. (00)			(4%)
<b>#PARATHYROID</b>	(45)		(39)		(37)	(3%)
HYPERPLASIA, NOS	(52)		(52)		(52)	(0%)
#PANCREATIC ISLETS HYPERPLASIA, NOS	(04)		(02)			(4%)
REPRODUCTIVE SYSTEM						
*MAMMARY GLAND	(52)	(40)	(52)	(04)	(52)	
DILATATION/DUCTS	2	(4%)	1 (52)	(2%)	(52)	
*PREPUTIAL GLAND	(52)			(2%)	(02)	
HYPERPLASIA, NOS #UTERUS	(52)		(52)	(= -*/	(52)	
#UTERUS METAPLASIA, SQUAMOUS	1	(2%)	(			
#UTERUS/ENDOMETRIUM	(52)		(52)		(52)	
EMPYEMA			1	(2%)		100
HYPERPLASIA, CYSTIC		(10%)		(2%)	(52)	(2%)
#OVARY FOLLICULAR CYST, NOS	(52) 1	(2%)	(52) 2	(4%)	(02)	
NERVOUS SYSTEM			<u> </u>			
#BRAIN	(52)		(52)		(52)	
HYDROCEPHALUS, INTERNAL			1	(2%)		
HEMORRHAGE		(2%) (2%)				
HEMOSIDEROSIS						

# TABLE C2. SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN FEMALE RATS IN THE TWO-YEAR GAVAGE STUDY OF TELONE II® (Continued)

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TABLE C2.	SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN FEMALE RATS IN	
	THE TWO-YEAR GAVAGE STUDY OF TELONE II® (Continued)	

c	CONTROL (VEH)	LOW DOSE	HIGH DOSE
SPECIAL SENSE ORGANS *EYE/CONJUNCTIVA INFLAMMATION, SUPPURATIVE	(52)	(52)	(52) 1 (2%
MUSCULOSKELETAL SYSTEM NONE			
BODY CAVITIES			(2.8)
*THORACIC CAVITY ABSCESS, CHRONIC	(52)	(52) 1 (2%)	(52)
*MEDIASTINUM	(52)	(52)	(52)
INFLAMMATION, SUPPURATIVE	1 (2%)	1 (2%)	
ABSCESS, NOS *PERITONEUM	1 (2%) (52)	(52)	(52)
INFLAMMATION, NOS		1 (2%)	• • • • •
INFLAMMATION, FOCAL *EPICARDIUM	1 (2%) (52)	(52)	(52)
INFLAMMATION, CHRONIC SUPPURATIV	1 (2%)		• •
*MESENTERY	(52)	(52)	(52)
INFLAMMATION, GRANULOMATOUS NECROSIS, FAT	3 (6%)	3 (6%)	2 (4%) 2 (4%)
ALL OTHER SYSTEMS			
OMENTUM INFLAMMATION, GRANULOMATOUS	1		
SPECIAL MORPHOLOGY SUMMARY NO LESION REPORTED		1	

NUMBER OF ANIMALS WITH TISSUE I
 NUMBER OF ANIMALS NECROPSIED

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#### **APPENDIX D**

# SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN MICE IN THE TWO-YEAR GAVAGE STUDIES OF TELONE II[®]

c	ONTRO	L (VEH)	LOWD	OSE	HIGH D	OSE
ANIMALS INITIALLY IN STUDY	50		50		50	
ANIMALS NECROPSIED	50		50		50	
ANIMALS EXAMINED HISTOPATHOLOGICALLY	50	<del>-</del>	50		50	
NTEGUMENTARY SYSTEM					(	
*SKIN	(50)		(50)		(50)	(971)
ABSCESS, CHRONIC *SUBCUT TISSUE	(50)		(50)		(50)	(2%)
INFLAMMATION, SUPPURATIVE		(2%)	(00)			
INFLAMMATION, CHRONIC FOCAL	1	(2%)				
ESPIRATORY SYSTEM						
*NASAL CAVITY	(50)		(50)		(50)	(901)
HEMORRHAGE #LUNG	(50)		(50)		(50)	(2%)
EDEMA, NOS			í	(2%)	,	
HEMORRHAGE		(4%)	2	(4%)		(4%)
INFLAMMATION, INTERSTITIAL ABSCESS, NOS	1	(2%)	1	(2%)	1	(2%)
HEMOSIDEROSIS			1	(470)	1	(2%)
IEMATOPOIETIC SYSTEM						
#LYMPH NODE	(50)		(50)		(50)	
HEMORRHAGE			1	(2%)		(2%)
HEMOSIDEROSIS HYPERPLASIA, LYMPHOID			2	(4%)	1	(2%)
#MESENTERIC L. NODE	(50)		(50)	(4,0)	(50)	
HEMORRHAGE			2	(4%)		(14%)
#SMALL INTESTINE HYPERPLASIA, LYMPHOID	(50)		(50) 1	(2%)	(50)	
#THYMUS	(49)		(48)	(2,0)	(47)	
HEMORRHAGE		(4%)		(19%)		(4%)
CIRCULATORY SYSTEM						
#LUNG	(50)		(50)	(90)	(50)	
THROMBUS, ORGANIZED #HEART	(50)		1 (50)	(2%)	(50)	
HEMORRHAGE	4	(8%)		(14%)		(12%)
INFLAMMATION, SUPPURATIVE	39	(78%)	13	(26%)		(10%)
INFLAMMATION ACTIVE CHRONIC INFLAMMATION, CHRONIC			1	(2%)	1	(2%) (2%)
INFLAMMATION, CHRONIC FOCAL	1	(2%)	•	( <b>2</b> , <b>v</b> )	i	(2%)
FIBROSIS NECROSIS, NOS	1 91	(2%) (42%)	10	(20%)		(12%)
112010010,1100 		(======		(2070)		(1470)
DIGESTIVE SYSTEM #SALIVARY GLAND	(50)		(50)		(50)	
HEMORRHAGE			1	(2%)		
INFLAMMATION, CHRONIC		(28%)		(56%)		(42%)
#LIVER DILATATION, NOS	(50)		(50)		(50)	(2%)
INFLAMMATION, SUPPURATIVE	1	(2%)			1	(4 10)
NECROSIS, FOCAL	2	(4%)		(2%)		
NECROSIS, CENTRAL	22	(44%)		(18%) (9%)	5	(10%)
INFARCT, NOS METAMORPHOSIS FATTY	1	(2%)	1	(2%)		
FOCAL CELLULAR CHANGE	•		9	(4%)	3	(6%)
ANGIECTASIS		(2%)		(4170)		$(0, \mathbf{v})$

## TABLE D1. SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN MALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE 11 $^{\circ}$

	CONTROL (VEH)	LOWDOS	SE	HIGH D	OSE
DIGESTIVE SYSTEM (Continued)	<u></u>	<u></u>			
#BILE DUCT	(50)	(50)		(50)	
CYST. NOS		. ,		3	(6%
HYPERPLASIA, NOS				1	(2%)
<b>#PANCREAS</b>	(50)	(50)		(50)	
DILATATION/DUCTS		1 (2	<b>%</b> )		
INFLAMMATION, CHRONIC	(20)	2 (4	.%)	(50)	
<b>#PANCREATIC ACINUS</b>	(50)	(50)		(50)	(401)
ATROPHY, NOS	(50)	(50)			(4%)
#STOMACH	(50)	(50)		(50)	(8%)
HYPERPLASIA, EPITHELIAL					(0 %)
IRINARY SYSTEM					
#KIDNEY	(50)	(50)		(50)	
HYDRONEPHROSIS	1 (2%)				
INFLAMMATION, CHRONIC	1 (2%)	12 (2	<b>(4%</b> )	3	(6%)
INFLAMMATION, CHRONIC FOCAL	2 (4%)				(0~)
INFARCT, HEALED	(20)	/ <b># A</b> \			(2%)
#KIDNEY/PELVIS	(50)	(50)		(50)	(90)
INFLAMMATION, SUPPURATIVE	(50)	(50)			(2%)
<b>#URINARY BLADDER</b> INFLAMMATION, SUPPURATIVE	(50) 1 (2%)	(00)		(50)	(4%)
INFLAMMATION, SUPPORATIVE	1 (470)			_	(2%)
HYPERPLASIA, EPITHELIAL		9 (1	8%)		(36%)
NDOCRINE SYSTEM #ADRENAL CORTEX	(50)	(50)		(48)	
HYPERPLASIA, FOCAL	1 (2%)	1 (2	(96)	(40)	
#THYROID	(50)	(49)	,	(50)	
INFLAMMATION, CHRONIC	(00)		(%)	(,	
<b>#PANCREATIC ISLETS</b>	(50)	(50)	,	(50)	
HYPERPLASIA, NOS	2 (4%)				
EPRODUCTIVE SYSTEM					
*MAMMARY GLAND	(50)	(50)		(50)	
DILATATION/DUCTS	1 (2%)				
#TESTIS	(50)	(50)		(50)	
HEMORRHAGE	1 (2%)				
*EPIDIDYMIS	(50)	(50)	•	(50)	
INFLAMMATION, CHRONIC		1 (2	(%)	-	(0.01)
GRANULOMA, SPERMATIC				1	(2%)
ERVOUS SYSTEM					
#BRAIN/MENINGES	(50)	(50)		(50)	
INFLAMMATION, CHRONIC	1 (2%)	(EA)		/EA	
#BRAIN MINERALIZATION	(50) 8 (16%)	(50) 21 (4	296)	(50) 25	(50%)
HEMORRHAGE	11 (22%)	21 (4	<b>96</b> )		(2%)
CHOLESTEROL DEPOSIT	11 (22%) 1 (2%)	<i>4</i> (1		-	(~~~)
*SPINAL CORD	(50)	(50)		(50)	
HEMORRHAGE	1 (2%)	1 (2	<b>1%</b> )		
PECIAL SENSE ORGANS NONE		<u>,, , , , , , , , , , , , , , , , , , ,</u>			

## TABLE D1. SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN MALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II® (Continued)

NONE

## TABLE D1. SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN MALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

CONTROL (VEH)	LOW DOSE	HIGH DOSE
(50)		(50)
(50)		(50)
1 (2%)		
(50)	(50)	(50)
	1 (2%)	
1	1	1
	(50) (50) 1 (2%)	(50) (50) 1 (2%) (50) (50) 1 (2%)

# NUMBER OF ANIMALS WITH TISSUE EXAMINED MICROSCOPICALLY • NUMBER OF ANIMALS NECROPSIED

TABLE D2.	SUMMARY	OF THE	INCIDENCE	OF NONNEOPLA	ASTIC LI	ESIONS IN	FEMALE MICE IN
		THE	TWO-YEAR	GAVAGE STUDY	OF TEI	LONE II®	

CC	ONTRO	)L (VEH)	LOWD	DSE	HIGH D	OSE
ANIMALS INITIALLY IN STUDY	50	·	50		50	
ANIMALS NECROPSIED	50		50		50	
NIMALS EXAMINED HISTOPATHOLOGICALLY	50		50		50	
NTEGUMENTARY SYSTEM NONE						
ESPIRATORY SYSTEM						
#LUNG/BRONCHUS	(50)	(99)	(50)		(50)	
INFLAMMATION, CHRONIC #LUNG	(50)	(2%)	(50)		(50)	
HEMORRHAGE		(2%)	1	(2%)		
LYMPHOCYTIC INFLAMMATORY INFILTR	_	(=)		(2%)		
PNEUMONIA INTERSTITIAL CHRONIC	_				3	(6%)
INFLAMMATION, CHRONIC FOCAL	2	(4%)				(94)
ABSCESS, CHRONIC HYPERPLASIA, ADENOMATOUS	1	(2%)	2	(4%)		(2%) (2%)
					<u> </u>	
IEMATOPOIETIC SYSTEM #BONE MARROW	(50)		(50)		(50)	
MYELOFIBROSIS		(92%)		(96%)		(78%)
#SPLEEN	(50)	(02 %)	(50)		(50)	(,
HEMOSIDEROSIS		(2%)	1		1	
HYPERPLASIA, LYMPHOID		(2%)	3	(6%)	3	(6%)
<b>#SPLENIC FOLLICLES</b>	(50)	(0.0)	(50)		(50)	
HYPERPLASIA, FOCAL	1	(2%)	1	(2%)		
HYPERPLASIA, LYMPHOID #LYMPH NODE	(50)		(50)	(270)	(50)	
HEMOSIDEROSIS	(00)			(2%)		(2%)
HYPERPLASIA, LYMPHOID			3	(6%)		
CIRCULATORY SYSTEM						
#HEART	(50)		(50)		(50)	
ENDOCARDITIS, BACTERIAL			1	(2%)		
ABSCESS, NOS		(0.0)			1	(2%)
INFLAMMATION, CHRONIC		(2%)	(50)		(49)	
#UTERUS THROMBOSIS, NOS	(50) 1	(2%)	(50)		(43)	
DIGESTIVE SYSTEM						
#SALIVARY GLAND	(48)		(50)		(50)	
INFLAMMATION, CHRONIC		(65%)		(56%)	28	(56%)
ATROPHY, FOCAL	(20)			(2%)		
#LIVER	(50)		(50)	(90)	(50)	
HEMATOMA, NOS HEMATOMA, ORGANIZED	1	(2%)	1	(2%)		
INFLAMMATION, CHRONIC	3	(6%)	2	(4%)	3	(6%)
INFLAMMATION, CHRONIC FOCAL	š	(6%)	-		•	,
NECROSIS, FOCAL	ī	(2%)	3	(6%)		
NECROSIS, CENTRAL	1	(2%)		(007)		(2%)
FOCAL CELLULAR CHANGE		(16%)		(22%)	3	(6%)
<b>#PANCREAS</b> INFLAMMATION, CHRONIC	(50)	(69)	(50)	(8%)	(49)	
#PANCREATIC ACINUS	3 (50)	(6%)	(50)	(070)	(49)	
ATROPHY, NOS	4	(8%)		(8%)		(2%)
<b>#PERIPANCREATIC TISSUE</b>	(50)		(50)		(49)	
GRANULOMA, NOS					1	(2%)
#STOMACH	(50)		(50)		(50)	(90)
RUPTURE	1	(2%)	1	(2%)	21	(2%) (42%)
HYPERPLASIA, EPITHELIAL	1	4701	1	(470)	21	(4470)
<b>#SMALL INTESTINE</b>	(50)	()	(50)		(50)	

.

		(50)		(50)	
16				(80)	
			(4%)		(28%)
1	(32%)	9	(18%)	13	(26%)
4	(2%)				(001)
				1	(2%) (2%)
		9	(4%)	5	(10%)
		4	(470)	1	(2%)
(50)		(50)			(* ~)
(00)		(00)			(2%)
		1	(2%)	-	<b>,</b> ,
(50)			(=,	(48)	
(00)		1	(2%)	1	(2%)
		1	(2%)		
15	(30%)			1	(2%)
				19	(40%)
		(50)		(48)	
	(2%)	()			
-		1	(2%)		
				<u> </u>	<u></u>
(50)		(50)		(50)	
(		(			(2%)
			(2%)		
(50)		(50)	•	(50)	
		1	(2%)		
(50)		(50)			
		1	(2%)	-1	(2%)
1	(2%)			-	
					(4%)
(50)		(50)		(48)	
1	(2%)				
				(7.5)	
		(50)		(50)	
	(2%)	(= 4)		(10)	
(50)		(50)			(00)
		(20)			(2%)
· · · · ·	(0.0)	(50)		(49)	
		•	(00)	•	(100)
					(18%)
	(46%)		(00%)		(51%)
(50)			(4.01)		(104)
		2	(4%)	6	(13%)
1	(2%)		(00)		
/=-			(2170)	/40\	
(60)	(04)		(104)		(4%)
1	(470)		(1070)		
(EA)		(80)		(50)	
	(29)	(00)		(00)	
	(4)70 <i>)</i>	(50)		(50)	
	(60%)	18	(36%)		(34%)
			~~~/~/		(2%)
(50)		(50)			(- / * /
	(2%)	(00)		(
•					
-	$\begin{array}{c} 2\\ (50)\\ 1\\ (50)\\ (50)\\ (50)\\ 2\\ 1\\ (50)\\ 1\\ (50)\\ 1\\ (50)\\ 5\\ 1\\ (50)\\ 1\\ (50)\\ 1\\ (50)\\ 1\\ (50) \end{array}$	(50) $15 (30%)$ $2 (4%)$ (50) (50) (50) (50) (50) $(2%)$ (50) $(2%)$ (50) $1 (2%)$ (50) $1 (2%)$ (50) $1 (2%)$ (50) $1 (2%)$ $(46%)$ (50) $1 (2%)$ $(46%)$ (50) $1 (2%)$ $(10%)$ $1 (2%)$ (50) $(10%)$ $1 (2%)$ (50) $(10%)$ $(2%)$ (50) $(2%)$ (50) $(2%)$ (50) $(2%)$ (50) $(2%)$ (50) $(2%)$ (50) $(2%)$ (50) $(2%)$ (50) $(2%)$ (50)	$\begin{array}{cccccccccccccccccccccccccccccccccccc$	$ \begin{array}{cccccccccccccccccccccccccccccccccccc$	$\begin{array}{cccccccccccccccccccccccccccccccccccc$

TABLE D2. SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN FEMALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II® (Continued)

	CONTROL (VEH)	LOW DOSE	HIGH DOSE
MUSCULOSKELETAL SYSTEM *SKELETAL MUSCLE INFLAMMATION WITH FIBROSIS	(50) 1 (2%)	(50)	(50)
BODY CAVITIES *MEDIASTINUM	(50)	(50)	(50)
ABSCESS, NOS *PERITONEUM	(50)	(50)	1 (2%) (50)
INFLAMMATION, GRANULOMATOUS *MESENTERY	(50)	(50)	1 (2%) (50)
INFLAMMATION, CHRONIC NECROSIS, FAT		1 (2%) 1 (2%)	
ALL OTHER SYSTEMS *MULTIPLE ORGANS	(50)	(50)	(50)
INFLAMMATION, CHRONIC INFLAMMATION, CHRONIC FOCAL	4 (8%) 1 (2%)	3 (6%)	

TABLE D2. SUMMARY OF THE INCIDENCE OF NONNEOPLASTIC LESIONS IN FEMALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II[®] (Continued)

NUMBER OF ANIMALS WITH TISSUE EXAMINED MICROSCOPICALLY * NUMBER OF ANIMALS NECROPSIED

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APPENDIX E

SUMMARY OF THE INCIDENCE OF NEOPLASTIC AND NONNEOPLASTIC LESIONS IN RATS IN THE ANCILLARY GAVAGE STUDIES OF TELONE II^o

		Mor	nths	on St	tudy		Months on Study			Months on Study					
	9			24		- 9	16			27	- 9	10		24	27
	v	ehic	le Co	ontro	ol (a)		25	mg/	kg (a)		50	mg/l	(g (a)	
iver															
(No. examined)	5	5	5	5	5	5	5	4	5	5	5	5	5	5	5
Neoplastic Nodule	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0
Monocytic Leukemia	0	0	0	2	0	0	0	0	1	0	0	0	0	0	1
Focal Cellular Change	0	3	5	4	5	0	4	4	5	2	0	3	4	5	4
Hyperplasia, Focal	0	0	0	3	0	0	0	0	0	0	0	2	0	0	0
Inflammation,			_	-								_			
Acute and Chronic	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation, Focal	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
Metamorphosis, Fatty	0	2	0	0	1	U	0	0	0	1	0	0	0	0	0
Necrosis, Focal	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0
iver/Bile Duct															
(No. Examined)	5	5	5	5	5	5	5	4	5	5	5	5	5	5	5
Hyperplasia, Focal	0	0	0	2	0	0	0	0	0	0	1	0	0	1	2
idney															
(No. examined)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Abcess, Chronic	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Cyst, NOS	0	0	0	0	0	0	1	0	0	0	0	0	0	0	1
Inflammation, Chronic	1	1	0	0	0	1	2	0	0	0	0	1	0	0	0
Mineralization	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Nephropathy	0	1	5	5	5	0	0	4	5	5	1	0	4	5	5
drenal Cortex															
(No. examined)	5	5	5	5	5	5	5	5	5	5	5	4	5	5	5
Cortical Adenoma	0	0	0	0	0	0	0	1	0	1	0	0	0	0	0
Hyperplasia, Focal	0	1	0	4	0	0	0	0	3	0	0	0	0	0	0
drenal/Medulla															
(No. examined)	5	5	5	5	5	5	5	5	5	5	5	4	5	5	5
Pheochromocytoma	0	0	1	0	1	0	1	1	1	3	0	1	1	1	1
Hyperplasia, Focal	0	0	0	0	1	0	0	0	1	0	0	0	0	0	0
rinary Bladder															
(No. examined)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	4
Inflammation, Chronic	Ō	Ō	Ō	Ō	Ō	Ō	Ō	1	Ō	Ō	Ó	Ō	Ó	0	1
rinary Bladder/Submucosa															
(No. examined)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	4
Edema, NOS	Õ	Õ	Ō	1	1	ŏ	Õ	Ŏ	ĩ	ĭ	Ō	Ō	Ō	Ō	ĩ
orestomach															
(No. examined)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
Squamous Cell Papilloma	Ō	Ō	Ō	0	5 0	0	0	0	5 0	Ō	Ö	0	0	5 2 4	2
Hyperplasia, Basal Cell	Ó	Ó	1	0	0	0	1	3	3	1	1	5	4	4	4
Inflammation, Acute	0	0	0	0	0	0	0	0	0	1	0	0	0	0	0
Inflammation, Chronic	0	0	0	0	0	0	Ó	1	0	0	0	0	0	0	1
tomach															
(No. examined)	5	5	5	5	5	5	5	5	5	5	5	5	5	5	5
	ŏ	ŏ	2	ō	ŏ	ŏ	õ	1	ō	1	ŏ	ĩ	1	õ	Ō
Hemorrage			ō												ŏ

TABLE E1. SUMMARY OF THE INCIDENCE OF NEOPLASTIC AND NONNEOPLASTIC LESIONS IN MALE RATS IN THE ANCILLARY GAVAGE STUDY OF TELONE II[•]

		Mor	Months on Study				Months on Study					Months on Study					
	9 V	16	21	24 ontro	27	9	16		24	27	9	16	21		27		
Thyroid																	
(No. examined)	5	5	5	5	5	5	5	5	5	5	5	5	5	4	5		
C-Cell Carcinoma	0	0	0	1	0	0	0	0	0	0	0	0	0	0	Ó		
C-Cell Adenoma	0	0	1	1	1	0	0	1	1	0	0	0	0	0	1		
Follicular Cell Adenoma	0	0	0	0	1 0 0	0	0	0	0	0 0 0	0	0	0	0	1 0 1		
Follicular Cyst, NOS	0 0 0 0	0 0 0 0	0 0 0	0 0 1	0	0 0 0 0 0	0 0 0 0	1 0 1 0	1 0 0 0	0	0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	1		
Hyperplasia, C-Cell		0		1	1	0				1	0				1		
Hyperplasia, Follicular Cell	0	0	0	0	0	0	0	0	0	0	0	0	0	0	1		
Mammary Gland																	
(No. examined)	0	0	1	3	4	2	2	2	4	2	1	1	1	4	3		
Fibroadenoma	0	0	0 0	0	1	0	0	0	Û	0	0	0	0	1	1		
Adenoma, NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Dilatation/Ducts	0 0 0 0	0 0 0 0	0 0	0 0 0 0	0 0 0	0 0 0 0	0	0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0	0 0 0		
Hyperplasia, NOS	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0		
Fibroma	0	0	0	0	1	0	0	0	0	0	0	0	0	0	0		
Multiple Organs																	
Malignant Lymphoma,																	
Histiocytic Type	0	0	0	0	0	0	0	0	1	0	0	0	0	0	0		
Monocytic Leukemia	0 0	Ō	0	0	0 0	0	0	0	1 0	0 0	0	0 0	0	õ	1		

TABLE E1. SUMMARY OF THE INCIDENCE OF NEOPLASTIC AND NONNEOPLASTIC LESIONS IN MALE RATS IN THE ANCILLARY GAVAGE STUDY OF TELONE II* (Continued)

(a) Scheduled kill

	_			on St			Months on Study					<u>Months on Study</u>			
	9 V	16 ehic		24 ontro	27 l (a)	9	16 25	_	24 kg (a	27)	9		21 mg/k		27
Liver														<u> </u>	
(No. examined)	5	5	5	5	3	5	5	5	5	5	5	5	5	5	5
Neoplastic Nodule	ō	ō	ō	Ō	ō	ō	õ	ō	2	ō	ŏ	ō	ŏ	ō	2
Monocytic Leukemia	Ó	Ó	1	1	Ō	Ő	Ó	1	2	1	Ó	Ō	1	Ó	0
Focal Čellular Change	0	5	5	4	3	2	5	5	4	4	3	5	5	4	4
Hyperplasia, Focal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation,								_							
Acute and Chronic	0	0	1	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation, Focal	0	0 0	0	0 0	0 0	0	0	0	0	0	0	0	0	0	0
Metamorphosis, Fatty Necrosis, Focal	0 0	0	0 1	0	0	0 0	0 0	0 0	0 0	0 1	0 0	0 0	0 0	0 0	0 0
Liver/Bile Duct															
(No. examined)	5	5	5	5	3	5	5	5	5	5	5	5	5	5	5
Hyperplasia, Focal	0	0	0	0	0	0	0	Ó	0	0	0	0	0	0	0
(idney (No. examined)	5	5	5	5	3	5	5	5	5	5	5	5	5	5	5
Abcess, Chronic	ŏ	ŏ	ŏ	ĭ	ŏ	ŏ	ŏ	ŏ	ŏ	ŏ	ŏ	ŏ	ŏ	ŏ	ŏ
Cyst, NOS	õ	Õ	Ō	ō	õ	ō	ŏ	ō	ō	ō	ŏ	ŏ	ō	0	ŏ
Inflammation, Chronic	0	0	0	0	0	0	0	0	0	0	0	2	0	0	0
Mineralization	0	0	1	0	0	0	0	1	0	0	0	2	1	0	0
Nephropathy	0	0	2	2	3	0	0	1	4	5	0	0	2	5	5
Adrenal/Cortex	-	2	-	-	•	-	-	-	-	-	-	-	-		-
(No. examined)	5	5	5 0	5 0	3	5	5	5	5	5	5	5	5	5	5
Cortical Adenoma	0 0	0 3			0	0	0	0	0	0	0	0	0	0	0
Hyperplasia, Focal Hemorrhage	ő	0	2 1	1 0	0 0	0	0 0	2 0	1 0	3 0	0 0	1 0	1 0	3 0	1 0
drenal/Medulla															
(No. examined)	5	5	5	5	3	5	5	5	5	5	5	5	5	5	5
Pheochromocytoma	0	0	0	0	0	0	0	1	0	1	0	0	1	0	0
Hyperplasia, Focal	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Jrinary Bladder	_	-		-	•	-	-	_		-		-	-	-	-
(No. examined)	5	5	4	5	3	5	5	5	5	5	4	5	5	5	5
Inflammation, Chronic	1	0	2	0	1	0	1	3	0	1	0	1	1	0	1
rinary Bladder/Submucosa (No. examined)	5	Ę		F	3	ĸ	F	E	ĸ	5	A	g	r.	5	ĸ
Edema, NOS	0	5 0	4 0	5 0	3 0	5 0	5 0	5 0	5 0	5 0	4 0	5 0	5 1	5 1	5 1
`orestomach															
(No. examined)	5	5	5	5	3	5	5	5	5	5	5	5	5	5	5
Squamous Cell Papilloma	0	0	0	0	0	0	0	0	0	0	0	0	Õ	0	5
Hyperplasia, Basal Cell	0	0	0	0	0	0	2	2	1	0	0	5 0	5 0	4	5
Inflammation, Acute Inflammation, Chronic	0 0	0 0	0 0	0 0	0	0	0	0 0	0 0	0 0	0	0	0	0 0	0 0
tomach															
(No. examined)	5	5	5	5	3	5	5	5	5	5	5	5	5	5	5
Hemorrage	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
Inflammation, Chronic	0	0	1	1	0	0	0	2	3	0	0	0	2	0	1

TABLE E2. SUMMARY OF THE INCIDENCE OF NEOPLASTIC AND NONNEOPLASTIC LESIONS IN FEMALE RATS IN THE ANCILLARY GAVAGE STUDY OF TELONE II[•]

TABLE E2. SUMMARY OF THE INCIDENCE OF NEOPLASTIC AND NONNEOPLASTIC LESIONS IN FEMALE RATS IN THE ANCILLARY GAVAGE STUDY OF TELONE II* (Continued)

		Mor	ths o	on St	udy		Mon	ths g	n St	udy	<u>Months on Study</u>						
	9	16	21	24	27	9	16	21	24	27	- 9	16	21		27		
	V	ehic	le Co	ntro	l (a)		25	mg/h	(g (a)			50 1	ng/k	g (a)			
 Thyroid																	
(No. examined)	5	5	5	5	3	5	5	5	5	5	5	5	5	5	5		
C-Cell Carcinoma	0	0	Ō	0	0	0	0	0	0	0	0	0	5 0	0	0		
C-Cell Adenoma	0	0	0	0	0	0	0	0	0	2	0	0	0	0	0		
Follicular Cell Adenoma	0	0	0	0	0	0	0	0	0	0	0	0	0	1	0		
Follicular Cyst, NOS	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0	0 0 0	5 0 0 0 0 0	0 0 0 0	0 0 0 0	0 0 0 0 1	0 2 0 0	5 0 0 0 0 0	0 0 0 0	0 0 1 0	5 0 1 1 2 0	5 0 0 0 2 0		
Hyperplasia, C-Cell	0	1	0	0	0	0	0	0	1	1	0	0	0	2	2		
Hyperplasia, Follicular Cell	0	0	1	0	0	0	0	0	0	0	0	0	1	0	0		
Mammary Gland																	
(No. examined)	0	1	3	5	3	0	0	2	5	4	0	2	3	4	3		
Fibroadenoma	0	0	0	1	0	0	0	1	0	2	0	0	1	1	2		
Adenoma, NOS	Ó	Ó	1	0	0	Ō	Ó	0	0	0	0	0	0	0	0		
Dilatation/Ducts	0 0 0	0 0 0	0 1 1	1 0 0	0 0 0	0 0 0	0 0 0	1 0 0	0 0 1	2 0 0	0 0 0	2 0 0 0	0	1 0 1	3 2 0 0 0		
Hyperplasia, NOS	Ō	Ō	Ō	Ō	Ŏ	Ŏ	Õ	1	Ō	Ō	Ō	Č	Ō	1	Ō		
Multiple Organs																	
Malignant Lymphoma,																	
Histiocytic Type	0	0	0	0 1	0	0	0	0	0	0	0	0	0	0	0		
Monocytic Leukemia	Ó	0 0	0 0	1	0 1	0 0	0 0	0 0	0 0	0 2	ŏ	0 0	0 0	Ō	Ó		

(a) Scheduled kill

Telone II®, NTP TR 269

APPENDIX F

ANALYSES OF PRIMARY TUMORS IN RATS AND MICE IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II^o

TABLE F1. ANALYSIS OF PRIMARY TUMORS IN MALE RATS IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II*

		e Control	25 r	ng/kg		ng/kg
	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)
Subcutaneous Tissue: Fibroma						
Overall Rates (b)	3/52 (6%)		1/52 (2%)		0/52 (0%)	
Adjusted Rates (c)	7.0%		2.3%		0.0%	
Terminal Rates (d)	3/43 (7%)		0/38 (0%)		0/40 (0%)	
Life Table Tests (e)	P = 0.071 N		P = 0.342N		P=0.134N	
Incidental Tumor Tests (e)	P = 0.055N		P=0.278N		P=0.134N	
Cochran-Armitage Trend Test (e) Fisher Exact Tests	P=0.060N		P=0.309N		P=0.121N	
Hematopoietic System: Mononucle	ar Cell Leuke	emia				
Overall Rates (b)	13/52 (25%)		12/52 (23%))	10/52 (19%))
Adjusted Rates (c)	28.7%		30.7%		24.2%	
Terminal Rates (d)	11/43 (26%)	I	11/38 (29%))	9/40 (23%)	
Life Table Tests (e)	P = 0.351N		P = 0.545		P=0.387N	
Incidental Tumor Tests (e) Cochran-Armitage Trend Test (e)	P=0.315N P=0.279N		P=0.550N		P=0.355N	
Fisher Exact Tests			P=0.500N		P=0.319N	
Liver: Neoplastic Nodule						
Overall Rates (b)	1/52 (2%)	1/77 (1%)	6/52 (12%)	6/76 (8%)	7/52 (13%)	8/77 (10%)
Adjusted Rates (c)	2.3%		15.8%		17.1%	
Terminal Rates (d)	1/43 (2%)		6/38 (16%)	D	7/40 (18%)	
Life Table Tests (e)	P = 0.023	P=0.012	P = 0.040	P=0.043	P = 0.025	P=0.014
Incidental Tumor Tests (e)	P = 0.023	P = 0.012	P=0.040	P=0.043	P = 0.025	P=0.014
Cochran-Armitage Trend Test (e) Fisher Exact Tests	P=0.030	P=0.017	P=0.056	P = 0.056	P=0.030	P=0.017
Liver: Neoplastic Nodule or Carcin	oma					
Overall Rates (b)	1/52 (2%)	1/77 (1%)	6/52 (12%)	6/76 (8%)	8/52 (15%)	9/77 (12%)
Adjusted Rates (c)	2.3%		15.8%		20.0%	
Terminal Rates (d)	1/43 (2%)		6/38 (16%)		8/40 (20%)	
Life Table Tests (e)	P=0.011	P=0.006	P=0.040	P=0.043	P=0.013	P=0.007
Incidental Tumor Tests (e)	P=0.011	P=0.006	P=0.040	P=0.043	P=0.013	P=0.007
Cochran-Armitage Trend Test (e)	P = 0.015	P = 0.009				
Fisher Exact Tests			P = 0.056	P = 0.056	P=0.016	P=0.009
Stomach: Squamous Cell Papilloma						
Overall Rates (b)	1/52 (2%)	1/77 (1%)	1/52 (2%)	1/77 (1%)	9/52 (17%)	13/77 (17%)
Adjusted Rates (c)	2.3%		2.4%		21.3%	
Terminal Rates (d)	1/43 (2%)		0/38 (0%)		7/40 (18%)	
Life Table Tests (e)	P = 0.002	P<0.001	P=0.739	P=0.742	P=0.008	P<0.001
Incidental Tumor Tests (e)	P = 0.002	P<0.001	P=0.702N	P=0.739N	P=0.011	P<0.001
Cochran-Armitage Trend Test (e) Fisher Exact Tests	P = 0.002	P<0.001	P=0.752	P=0.752	P=0.008	P<0.001
Stamook Server Coll Court	_			-		-
Stomach: Squamous Cell Carcinom		0.000	0/59 (00)	0.007 (00)	AIEG (DAL)	AMTICAL
Overall Rates (b) Adjusted Rates (c)	0/52 (0%) 0.0%	0/77 (0%)	0/52 (0%) 0.0%	0/77 (0%)	4/52 (8%) 10.0%	4/17 (5%)
Adjusted Rates (c) Terminal Rates (d)	0.0% 0/43 (0%)		0.0% 0/38 (0%)		10.0% 4/40 (10%)	
Life Table Tests (e)	P = 0.014	P=0.014	0/38(0%) (f)	(f)	P = 0.054	P=0.056
Incidental Tumor Tests (e)	P = 0.014 P = 0.014	P = 0.014 P = 0.014	(f) (f)	(f)	P = 0.054 P = 0.054	P = 0.056 P = 0.056
Cochran-Armitage Trend Test (e)	P = 0.014 P = 0.015	P = 0.014 P = 0.015	(1)	(1)	£ - 0.009	1 -0.000
Fisher Exact Tests	2 - 0.010		(f)	(f)	P=0.059	P=0.060
			• *	••		

		e Control		ng/kg	<u>50 m</u>	
	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)
Stomach: Squamous Cell Papilloma	or Carcinon					
Overall Rates (b)	1/52 (2%)	1/77 (1%)	1/52 (2%)	1/77 (1%)		17/77 (22%)
Adjusted Rates (c)	2.3%		2.4%		30.8%	
Terminal Rates (d)	1/43 (2%)		0/38 (0%)		11/40 (28%)	
Life Table Tests (e)	P<0.001	P<0.001	P = 0.739	P = 0.742	P<0.001	P<0.001
Incidental Tumor Tests (e)	P<0.001	P<0.001	P = 0.702N	P=0.739N	P<0.001	P<0.001
Cochran-Armitage Trend Test (e) Fisher Exact Tests	P<0.001	P<0.001	P=0.752	P=0.752	P<0.001	P<0.001
Pituitary: Chromophobe Adenoma						
Overall Rates (b)	23/52 (44%)		13/50 (26%)		16/50 (32%)	
Adjusted Rates (c)	48.7%		33.0%		37.6%	
Terminal Rates (d)	19/43 (44%)		11/37 (30%)		13/39 (33%)	
Life Table Tests (e)	P = 0.159N		P = 0.093N		P = 0.196N	
Incidental Tumor Tests (e) Cochran-Armitage Trend Test (e)	P=0.128N P=0.112N		P = 0.074N		P = 0.157 N	
Fisher Exact Tests			P=0.042N		P = 0.143N	
Pituitary: Adenoma						
Overall Rates (b)	24/52 (46%)		14/50 (28%)		16/50 (32%)	
Adjusted Rates (c)	50.8%		34.5%		37.6%	
Terminal Rates (d)	20/43 (47%)		11/37 (30%)		13/39 (33%)	
Life Table Tests (e)	P = 0.121N		P = 0.101N		P = 0.150N	
Incidental Tumor Tests (e)	P = 0.083N		P = 0.069N		P = 0.116N	
Cochran-Armitage Trend Test (e) Fisher Exact Tests	P = 0.080N		P=0.045N		P = 0.104N	
Pituitary: Adenoma or Carcinoma						
Overall Rates (b)	24/52 (46%)		14/50 (28%)		17/50 (34%)	
Adjusted Rates (c)	50.8%		34.5%		40.0%	
Terminal Rates (d)	20/43 (47%)		11/37 (30%)		14/39 (36%)	
Life Table Tests (e)	P = 0.168N		P = 0.101 N		P = 0.203N	
Incidental Tumor Tests (e)	P=0.123N		P = 0.069 N		P = 0.164N	
Cochran-Armitage Trend Test (e)	P = 0.117 N					
Fisher Exact Tests			P = 0.045N		P = 0.147N	
Adrenal: Pheochromocytoma Overall Rates (b)	2/52 (4%)		Q/E9 (1 E0.)		6/59 / 1900	
	2/52 (4%) 4.7%		8/52 (15%)		6/52 (12%)	
Adjusted Rates (c) Terminal Rates (d)	4.7% 2/43(5%)		21.1% 8/38 (21%)		13.6%	
Life Table Tests (e)					3/40 (7%) P=0.123	
Incidental Tumor Tests (e)	P = 0.110 P = 0.141		P = 0.029 P = 0.029		P = 0.123 P = 0.192	
Cochran-Armitage Trend Test (e)	P = 0.141 P = 0.127		r — V.V47		F - 0.194	
Fisher Exact Tests	r -V.141		P=0.046		P=0.135	
Thyroid: Follicular Cell Adenoma or	Carcinoma					
Overall Rates (b)	0/52 (0%)		4/51 (8%)		1/51 (2%)	
Adjusted Rates (c)	0.0%		10.1%		2.4%	
Terminal Rates (d)	0/43 (0%)		3/38 (8%)		0/40 (0%)	
Life Table Tests (e)	P=0.361		P = 0.052		P=0.486	
Incidental Tumor Tests (e)	P = 0.435		P = 0.067		P = 0.602	
Cochran-Armitage Trend Test (e) Fisher Exact Tests	P = 0.379		P=0.057		P=0.495	

TABLE F1. ANALYSIS OF PRIMARY TUMORS IN MALE RATS IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II* (Continued)

	Vehicl	e Control	25 mg/kg		50 mg/kg	
	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)
Thyroid: C-Cell Adenoma		<u>-</u>				
Overall Rates (b)	3/52 (6%)		0/51 (0%)		2/51 (4%)	
Adjusted Rates (c)	7.0%		0.0%		5.0%	
Terminal Rates (d)	3/43 (7%)		0/38 (0%)		2/40 (5%)	
Life Table Tests (e)	P = 0.418N		P = 0.144N		P = 0.533	
Incidental Tumor Tests (e)	P = 0.418N		P = 0.144N		P=0.533N	
Cochran-Armitage Trend Test (e)	P=0.397N					
Fisher Exact Tests			P = 0.125N		P = 0.509N	
Thyroid: C-Cell Carcinoma						
Overall Rates (b)	3/52 (6%)		4/51 (8%)		2/51 (4%)	
Adjusted Rates (c)	7.0%		10.5%		5.0%	
Terminal Rates (d)	3/43 (7%)		4/38 (11%)		2/40 (5%)	
Life Table Tests (e)	P = 0.454N		P = 0.432		P = 0.533N	
Incidental Tumor Tests (e)	P = 0.454N		P = 0.432		P = 0.533N	
Cochran-Armitage Trend Test (e)	P = 0.426N					
Fisher Exact Tests			P = 0.489		P = 0.509N	
Thyroid: C-Cell Adenoma or Carcin	oma					
Overall Rates (b)	6/52 (12%)		4/51 (8%)		4/51 (8%)	
Adjusted Rates (c)	14.0%		10.5%		10.0%	
Terminal Rates (d)	6/43 (14%)		4/38 (11%)		4/40 (10%)	
Life Table Tests (e)	P = 0.347N		P = 0.449N		P = 0.415N	
Incidental Tumor Tests (e)	P = 0.347N		P = 0.449N		P = 0.415N	
Cochran-Armitage Trend Test (e)	P = 0.315N					
Fisher Exact Tests			P = 0.383N		P = 0.383N	
Pancreatic Islets: Islet Cell Adenom	a					
Overall Rates (b)	10/52 (19%)		7/52 (13%)		9/52 (17%)	
Adjusted Rates (c)	22.6%		17.3%		21.9%	
Terminal Rates (d)	9/43 (21%)		5/38 (13%)		8/40 (20%)	
Life Table Tests (e)	P = 0.513N		P=0.391N		P=0.566N	
Incidental Tumor Tests (e)	P = 0.435N		P = 0.298N		P = 0.503N	
Cochran-Armitage Trend Test (e)	P = 0.446N					
Fisher Exact Tests			P = 0.299N		P = 0.500N	
Pancreatic Islets: Islet Cell Carcino						
Overall Rates (b)	2/52 (4%)		6/52 (12%)		0/52 (0%)	
Adjusted Rates (c)	4.7%		15.3%		0.0%	
Terminal Rates (d)	2/43 (5%)		5/38 (13%)		0/40 (0%)	
Life Table Tests (e)	P = 0.293N		P = 0.101		P = 0.254N	
Incidental Tumor Tests (e)	P = 0.265N		P = 0.126		P = 0.254N	
Cochran-Armitage Trend Test (e)	P = 0.259N					
Fisher Exact Tests			P = 0.135		P = 0.248N	
Pancreatic Islets: Islet Cell Adenom		ma				
Overall Rates (b)	12/52 (23%)		13/52 (25%)		9/52 (17%)	
Adjusted Rates (c)	27.2%		31.6%		21.9%	
Terminal Rates (d)	11/43 (26%)		10/38 (26%)		8/40 (20%)	
Life Table Tests (e)	P = 0.353N		P = 0.374		P = 0.378N	
Incidental Tumor Tests (e) Cochran-Armitage Trend Test (e)	P = 0.272N P = 0.278N		P = 0.491		P = 0.321N	
Fisher Exact Tests			P = 0.500		P=0.313N	

TABLE F1. ANALYSIS OF PRIMARY TUMORS IN MALE RATS IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II* (Continued)

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TABLE F1. ANALYSIS OF PRIMARY TUMORS IN MALE RATS IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II* (Continued)

		e Control	25 mg/kg		50 mg/kg	
	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)
Mammary Gland: Fibroadenoma				, , , , , , , , , , , , , , , , , , ,		
Overall Rates (b)	1/52 (2%)		5/52 (10%	b)	1/52 (2%)	
Adjusted Rates (c)	2.3%		12.7%		2.5%	
Terminal Rates (d)	1/43 (2%)		4/38 (119	b)	1/40 (3%)	
Life Table Tests (e)	P = 0.554		P=0.081		P = 0.746	
Incidental Tumor Tests (e)	P = 0.587		P=0.105		P = 0.746	
Cochran-Armitage Trend Test (e)	P=0.589					
Fisher Exact Tests			P = 0.102		P = 0.752N	I
Testis: Interstitial Cell Tumor						
Overall Rates (b)	46/52 (88%)		46/52 (88	%)	48/52 (929	6)
Adjusted Rates (c)	97.9%		100.0%		100.0%	
Terminal Rates (d)	42/43 (98%)		38/38 (10	0%)	40/40 (100	%)
Life Table Tests (e)	P = 0.102		P = 0.117		P = 0.126	
Incidental Tumor Tests (e)	P = 0.243		P=0.390		P = 0.343	
Cochran-Armitage Trend Test (e)	P = 0.316					
Fisher Exact Tests			P = 0.620	N	P = 0.371	
Preputial Gland: Adenoma, Adenoc	arcinoma or	Carcinoma				
Överall Rates (b)	3/52 (6%)		0/52 (0%)		1/52 (2%)	
Adjusted Rates (c)	7.0%		0.0%		2.5%	
Terminal Rates (d)	3/43 (7%)		0/38 (0%)		1/40 (3%)	
Life Table Tests (e)	P = 0.196N		P=0.144	N	P = 0.331N	í
Incidental Tumor Tests (e)	P = 0.196N		P = 0.144	N	P = 0.331N	
Cochran-Armitage Trend Test (e)	P = 0.176N					
Fisher Exact Tests			P=0.121	N	P = 0.309 N	ſ
All Sites: Mesothelioma						
Overall Rates (b)	3/52 (6%)		2/52 (4%)		3/52 (6%)	
Adjusted Rates (c)	6.6%		5.3%		6.9%	
Terminal Rates (d)	2/43 (5%)		2/38 (5%)		2/40 (5%)	
Life Table Tests (e)	P = 0.566		P = 0.5491		P = 0.643	
Incidental Tumor Tests (e)	P = 0.536N		P=0.5091	N	P = 0.582N	
Cochran-Armitage Trend Test (e)	P = 0.588N					
Fisher Exact Tests			P = 0.500	N	P = 0.661 N	•

(a) Pooled results of the 2-year study and the ancillary study in which five rats per dose per sex were killed at 9, 16, 21, 24, and 27 months. Tumors observed in the ancillary studies are regarded as incidental rather than fatal in both the life table and incidental tumor tests.

(b) Number of tumor-bearing animals/number of animals examined at the site

(c) Kaplan-Meier estimated tumor incidence at the end of the study after adjusting for intercurrent mortality

(d) Observed tumor incidence at terminal kill

(e) Beneath the control incidence are the P values associated with the trend test. Beneath the dosed group incidence are the P values corresponding to pairwise comparisons between that dosed group and the vehicle controls. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death. The incidental tumor test regards these lesions as nonfatal. The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates. A negative trend or lower incidence in a dosed group is indicated by (N).

(f) No P value is presented because no tumors were observed in the 25 mg/kg and vehicle control groups.

TABLE F2. ANALYSIS OF PRIMARY TUMORS IN FEMALE RATS IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II[•]

		e Control	25 mg/kg		50 mg/kg	
	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)
Lung: Alveolar/Bronchiolar Adeno	ma or Carcin	oma				
Overall Rates (b)	1/52 (2%)		1/52 (2%)		3/52 (6%)	
Adjusted Rates (c)	2.9%		2.8%		7.9%	
Terminal Rates (d)	1/34 (3%)		1/36 (3%)		3/38 (8%)	
Life Table Tests (e)	P = 0.231		P = 0.749N	•	P = 0.345	
Incidental Tumor Tests (e)	P = 0.231		P = 0.749N	•	P = 0.345	
Cochran-Armitage Trend Test (e) Fisher Exact Tests	P = 0.202		P = 0.752		P=0.309	
Hematopoietic System: Mononucle	ar Cell Leuke	mia				
Overall Rates (b)	9/52 (17%)		10/52 (19%)	5/52 (10%)	
Adjusted Rates (c)	20.8%		25.1%		11.7%	
Terminal Rates (d)	3/34 (9%)		7/36 (19%)		2/38 (5%)	
Life Table Tests (e)	P = 0.147N		P = 0.500		P = 0.171 N	
Incidental Tumor Tests (e)	P = 0.179N		P = 0.602N		P = 0.286N	
Cochran-Armitage Trend Test (e)	P = 0.173N					
Fisher Exact Tests			P = 0.500		P = 0.195N	
Liver: Neoplastic Nodule						
Overall Rates (b)	6/52 (12%)	6/75 (8%)	6/52 (12%)	8/77 (10%)	10/52 (19%)	12/77 (16%)
Adjusted Rates (c)	16.7%		15.5%	26.3%		
Terminal Rates (d)	5/34 (15%)		4/36 (11%)		10/38 (26%)	
Life Table Tests (e)	P = 0.220	P = 0.134	P = 0.597N	P = 0.451	P = 0.275	P=0.166
Incidental Tumor Tests (e)	P = 0.204	P=0.111	P = 0.571	P = 0.319	P = 0.259	P = 0.157
Cochran-Armitage Trend Test (e)	P = 0.162	P=0.089				
Fisher Exact Tests			P = 0.620	P = 0.410	P = 0.208	P≈0.116
Stomach: Squamous Cell Papilloma						
Overall Rates (b)	0/52 (0%)	0/75 (0%)	2/52 (4%)	2/77 (3%)	3/52 (6%)	8/77 (10%)
Adjusted Rates (c)	0.0%		4.9%		7.4%	
Terminal Rates (d)	0/34 (0%)		1/36 (3%)		2/38 (5%)	
Life Table Tests (e)	P = 0.097	P = 0.002	P = 0.241	P = 0.245	P = 0.138	P≈0.006
Incidental Tumor Tests (e)	P = 0.093	P = 0.002	P = 0.350	P=0.309	P = 0.116	P=0.005
Cochran-Armitage Trend Test (e)	P = 0.082	P = 0.002				
Fisher Exact Tests			P = 0.248	P=0.255	P = 0.121	P=0.004
Pituitary: Chromophobe Adenoma						
Overall Rates (b)	28/50 (56%)		26/51 (51%))	30/52 (58%)	
Adjusted Rates (c)	71.5%		61.4%		68.1%	
Terminal Rates (d)	23/34 (68%)		19/35 (54%)	24/38 (63%)	
Life Table Tests (e)	P = 0.477N		P = 0.394N		P = 0.505N	
Incidental Tumor Tests (e)	P = 0.485		P = 0.510N		P = 0.489	
Cochran-Armitage Trend Test (e)	P = 0.468					
Fisher Exact Tests			P=0.380N		P = 0.511	
Pituitary: Chromophobe Adenoma						
Overall Rates (b)	30/50 (60%)	1	27/51 (53%))	31/52 (60%)	
Adjusted Rates (c)	72.9%		62.3%		68.8%	
Terminal Rates (d)	23/34 (68%)		19/35 (54%))	24/38 (63%)	
Life Table Tests (e)	P = 0.404N		P = 0.332N		P = 0.427N	
Incidental Tumor Tests (e)	P = 0.495N		P=0.396N		P = 0.565N	
Cochran-Armitage Trend Test (e)	P = 0.528N		D-0000			
Fisher Exact Tests			P = 0.304N		P = 0.565N	

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TABLE F2. ANALYSIS OF PRIMARY TUMORS IN FEMALE RATS IN THE TWO-YEAR AND ANCILARY GAVAGE STUDIES OF TELONE II* (Continued)

	Vehicl	e Control	25 mg/kg		50 mg/kg	
	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)
Thyroid: Follicular Cell Adenoma o	or Carcinoma					
Overall Rates (b)	0/52 (0%)		2/52 (4%)		4/52 (8	96)
Adjusted Rates (c)	0.0%		5.6%		10.1%	
Terminal Rates (d)	0/34 (0%)		2/36 (6%)		3/38 (8	%)
Life Table Tests (e)	P = 0.047		P=0.251		$P = 0.0^{\circ}$	77
Incidental Tumor Tests (e)	P = 0.043		P = 0.251		P = 0.0	64
Cochran-Armitage Trend Test (e)	P = 0.037					
Fisher Exact Tests			P=0.248		P = 0.0	59
Thyroid: C-Cell Adenoma						
Overall Rates (b)	4/52 (8%)		6/52 (12%)	2/52 (4)	96)
Adjusted Rates (c)	11.4%		16.7%		4.6%	
Terminal Rates (d)	3/34 (9%)		6/36 (17%)	1/38 (3)	%)
Life Table Tests (e)	P=0.244N		P = 0.405		P = 0.25	96N
Incidental Tumor Tests (e)	P = 0.251N		P=0.327		P = 0.23	92N
Cochran-Armitage Trend Test (e)	P=0.294N					
Fisher Exact Tests			P = 0.370		P=0.3	39N
Thyroid: C-Cell Adenoma or Carcin						
Overall Rates (b)	6/52 (12%)		8/52 (15%)	3/52 (64	Ж)
Adjusted Rates (c)	16.3%		22.2%		7.2%	
Terminal Rates (d)	4/34 (12%)		8/36 (22%)	2/38 (54	%)
Life Table Tests (e)	P = 0.170N		P=0.425		P=0.20)4N
Incidental Tumor Tests (e)	P=0.188N		P = 0.296		P = 0.21	16N
Cochran-Armitage Trend Test (e)	P=0.219N					
Fisher Exact Tests			P = 0.387		P=0.24	4N
Pancreatic Islets: Islet Cell Adenon						
Overall Rates (b)	3/52 (6%)		1/52 (2%)		0/52 (09	6)
Adjusted Rates (c)	8.5%		2.8%		0.0%	
Terminal Rates (d)	2/34 (6%)		1/36 (3%)		0/38 (09	6)
Life Table Tests (e)	P = 0.051N		P = 0.2871		P=0.10	
Incidental Tumor Tests (e)	P = 0.070N		P=0.3931	N	P = 0.12	27N
Cochran-Armitage Trend Test (e)	P = 0.060N					
Fisher Exact Tests			P = 0.309N	Ň	P = 0.12	1 N
Pancreatic Islets: Islet Cell Adenon		ma				
Overall Rates (b)	3/52 (6%)		1/52 (2%)		1/52 (29	6)
Adjusted Rates (c)	8.5%		2.8%		2.6%	
Terminal Rates (d)	2/34 (6%)		1/36 (3%)	_	1/38 (39	
Life Table Tests (e)	P = 0.175N		P = 0.287N	-	P=0.26	
Incidental Tumor Tests (e)	P = 0.207N		P=0.393N	١	P = 0.30	4N
Cochran-Armitage Trend Test (e) Fisher Exact Tests	P = 0.202N		P=0.3091	4	P=0.30	9N
Mammary Gland: Fibroadenoma	14/20 /000		00/20 /000	A	04/50/4	COL)
Overall Rates (b)	14/52 (27%)		20/52 (389	0)	24/52 (4	(970)
Adjusted Rates (c)	36.1%		51.2%	~	56.5%	00
Terminal Rates (d)	10/34 (29%)		17/36 (479	0)	20/38 (5	
Life Table Tests (e)	P = 0.066		P = 0.189		P=0.07	
Incidental Tumor Tests (e) Cochran-Armitage Trend Test (e)	P = 0.040 P = 0.027		P=0.054		P=0.05	
Fisher Exact Tests			P = 0.148		P=0.03	-

TABLE F2. ANALYSIS OF PRIMARY TUMORS IN FEMALE RATS IN THE TWO-YEAR AND ANCILLARY GAVAGE STUDIES OF TELONE II[•] (Continued)

	Vehicle Control		25 mg/kg			mg/kg
	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)	2-Year Study	2-Year and Ancillary Studies (a)
Mammary Gland: Adenoma or Fibr	oadenoma		// // // <u>// // // // // // // // // // // // //</u>			
Overall Rates (b)	15/52 (29%)	20/52 (38	96)	24/52 (46%)
Adjusted Rates (c)	38.8%		51.2%		56.5%	
Terminal Rates (d)	11/34 (32%)	17/36 (47	96)	20/38 (53%)
Life Table Tests (e)	P = 0.097		P = 0.252		P=0.1	14
Incidental Tumor Tests (e)	P = 0.063		P=0.085		P = 0.0	83
Cochran-Armitage Trend Test (e)	P = 0.043					
Fisher Exact Tests			P=0.203		P = 0.0	52
Preputial/Clitoral Gland: Adenoma	or Carcinor	na				
Överall Rates (b)	0/52 (0%)		3/52 (6%)		2/52 (4)	%)
Adjusted Rates (c)	0.0%		8.3%		5.3%	
Terminal Rates (d)	0/34 (0%)		3/36 (8%)		2/38 (5)	96)
Life Table Tests (e)	P = 0.231		P = 0.131		P = 0.20	63
Incidental Tumor Tests (e)	P = 0.231		P = 0.131		P = 0.20	
Cochran-Armitage Trend Test (e)	P = 0.202					
Fisher Exact Tests			P = 0.121		P = 0.24	48
Uterus: Endometrial Stromal Polyp)					
Overall Rates (b)	16/52 (31%)	10/52 (199	36)	12/52 (2	23%)
Adjusted Rates (c)	41.5%		25.7%		31.6%	
Terminal Rates (d)	12/34 (35%)	8/36 (22%)	12/38 (32%)
Life Table Tests (e)	P=0.136N	,	P = 0.1131		P = 0.16	
Incidental Tumor Tests (e)	P = 0.140N		P = 0.110		P = 0.1'	
Cochran-Armitage Trend Test (e)	P = 0.210N					
Fisher Exact Tests			P = 0.1291	N	P = 0.25	54N
Uterus: Endometrial Stromal Polyp	or Sarcoma					
Overall Rates (b)	17/52 (33%		10/52 (199	%)	12/52 (2	23%)
Adjusted Rates (c)	44.2%		25.7%		31.6%	
Terminal Rates (d)	13/34 (38%)	8/36 (22%)	12/38 (3	32%)
Life Table Tests (e)	P = 0.093N		P=0.0771	N	P = 0.11	2N
Incidental Tumor Tests (e)	P = 0.094N		P=0.0731	N	P=0.12	24N
Cochran-Armitage Trend Test (e)	P=0.152N					
Fisher Exact Tests			P=0.0901	Ń	P=0.19	91 N

(a) Pooled results of the 2-year study and the ancillary study in which five rats per dose per sex were killed at 9, 16, 21, 24, and 27 months. Tumors observed in the ancillary studies are regarded as incidental rather than fatal in both the life table and incidental tumor tests..

(b) Number of tumor-bearing animals/number of animals examined at the site

(b) Kaplan-Meier estimated tumor incidence at the end of the study after adjusting for intercurrent mortality

(d) Observed tumor incidence at terminal kill

(e) Beneath the control incidence are the P values associated with the trend test. Beneath the dosed group incidence are the P values corresponding to pairwise comparisons between that dosed group and the vehicle controls. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death. The incidental tumor test regards these lesions as nonfatal. The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates. A negative trend or lower incidence in a dosed group is indicated by (N).

TABLE F3. ANALYSIS OF PRIMARY TUMORS IN MALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II*

	Vehicle Control	50 mg/kg	100 mg/kg
Lung: Alveolar/Bronchiolar Adenoma			
Overall Rates (a)	1/50 (2%)	11/50 (22%)	9/50 (18%)
Adjusted Rates (b)	11.1%	33.4%	27.0%
Terminal Rates (c)	0/8 (0%)	7/28 (25%)	7/31 (23%)
Life Table Tests (d)	P = 0.419	P=0.147	P = 0.312
Incidental Tumor Tests (d)	P = 0.185	P=0.026	P = 0.162
war Alvesley/Prenchiolog Consinents			
Lung: Alveolar/Bronchiolar Carcinoma Overall Rates (a)	0/50 (0%)	2/50 (4%)	3/50 (6%)
	0.0%	7.1%	8.0%
Adjusted Rates (b)			
Terminal Rates (c)	0/8 (0%) D = 0.071	2/28 (7%)	1/31 (3%) B0.201
Life Table Tests (d)	P = 0.271	P = 0.538	P = 0.361
Incidental Tumor Tests (d)	P=0.165	P = 0.538	P=0.165
ung: Alveolar/Bronchiolar Adenoma o			
Overall Rates (a)	1/50 (2%)	13/50 (26%)	12/50 (24%)
Adjusted Rates (b)	11.1%	39.8%	33.5%
Terminal Rates (c)	0/8 (0%)	9/28 (32%)	8/31 (26%)
Life Table Tests (d)	P = 0.264	P=0.097	P = 0.166
Incidental Tumor Tests (d)	P=0.072	P=0.015	P=0.040
lematopoietic System: Lymphoma, All 1	Malignant		
Overall Rates (a)	0/50 (0%)	5/50 (10%)	4/50 (8%)
Adjusted Rates (b)	0.0%	14.6%	12.9%
Terminal Rates (c)	0/8 (0%)	2/28 (7%)	4/31 (13%)
Life Table Tests (d)	P = 0.383	P = 0.206	P = 0.340
Incidental Tumor Tests (d)	P=0.394	P = 0.200 P = 0.160	P = 0.340 P = 0.340
Circulatory System: Hemangioma	0(50(00)	0/20 (00)	0/50 (00)
Overall Rates (a)	0/50 (0%)	3/50 (6%)	0/50 (0%)
Adjusted Rates (b)	0.0%	10.7%	0.0%
Terminal Rates (c)	0/8 (0%)	3/28 (11%)	0/31 (0%)
Life Table Tests (d)	P = 0.324N	P = 0.406	(e)
Incidental Tumor Tests (d)	P=0.324N	P = 0.406	(e)
Circulatory System: Hemangiosarcoma			
Overall Rates (a)	1/50 (2%)	3/50 (6%)	1/50 (2%)
Adjusted Rates (b)	12.5%	9.9%	2.7%
Terminal Rates (c)	1/8 (13%)	2/28 (7%)	0/31 (0%)
Life Table Tests (d)	P = 0.225N	P = 0.698N	P = 0.455N
Incidental Tumor Tests (d)	P = 0.333N	P=0.678	P = 0.588N
Circulatory System: Hemangioma or He	mandiaeavaama		
Overall Rates (a)	1/50 (2%)	6/50 (12%)	1/50 (2%)
Adjusted Rates (b)	12.5%	20.3%	2,7%
Terminal Rates (c)	1/8 (13%)	5/28 (18%) D=0.464	0/31 (0%)
Life Table Tests (d)	P = 0.123N	P = 0.464	P = 0.455N
Incidental Tumor Tests (d)	P = 0.188N	P=0.400	P = 0.588N
iver: Adenoma			
Overall Rates (a)	1/50 (2%)	1/50 (2%)	3/50 (6%)
Adjusted Rates (b)	4.5%	3.6%	8.7%
Terminal Rates (c)	0/8 (0%)	1/28 (4%)	2/31 (6%)
Life Table Tests (d)	P = 0.487	P = 0.552N	P=0.689
Incidental Tumor Tests (d)	P=0.293	P = 0.753N	P=0.415

TABLE F3. ANALYSIS OF PRIMARY TUMORS IN MALE MICE IN THE TWO-YEAR GAVAGE STUDY OF TELONE II* (Continued)

	Vehicle Control	50 mg/kg	100 mg/kg	
Liver: Carcinoma		······		
Overall Rates (a)	4/50 (8%)	6/50 (12%)	10/50 (20%)	
Adjusted Rates (b)	25.8%	19.9%	28.3%	
Terminal Rates (c)	1/8 (13%)	5/28 (18%)	7/31 (23%)	
Life Table Tests (d)	P=0.539N	P=0.268N	P = 0.462N	
Incidental Tumor Tests (d)	P=0.255	P = 0.620	P=0.352	
Liver: Adenoma or Carcinoma				
Overall Rates (a)	5/50 (10%)	7/50 (14%)	13/50 (26%)	
Adjusted Rates (b)	29.2%	23.4%	35.9%	
Terminal Rates (c)	1/8 (13%)	6/28 (21%)	9/31 (29%)	
Life Table Tests (d)	P = 0.520	P=0.197N	P=0.483N	
Incidental Tumor Tests (d)	P = 0.142	P = 0.638	P=0.211	
Stomach: Squamous Cell Papilloma				
Overall Rates (a)	0/50 (0%)	2/50 (4%)	3/50 (6%)	
Adjusted Rates (b)	0.0%	6.7%	7.4%	
Terminal Rates (c)	0/8 (0%)	1/28 (4%)	1/31 (3%)	
Life Table Tests (d)	P=0.234	P = 0.510	P=0.280	
Incidental Tumor Tests (d)	P = 0.051	P = 0.403	P = 0.037	

(a) Number of tumor-bearing animals/number of animals examined at the site

(b) Kaplan-Meier estimated tumor incidence at the end of the study after adjusting for intercurrent mortality

(c) Observed tumor incidence at terminal kill

(d) Beneath the control incidence are the P values associated with the trend test. Beneath the dosed group incidence are the P values corresponding to pairwise comparisons between that dosed group and the vehicle controls. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death. The incidental tumor test regards these lesions as nonfatal. Because of the deaths of 25 vehicle controls during weeks 48-51, Cochran-Armitage and Fisher exact tests (which do not adjust for survival differences) were not carried out.

(e) No P value is presented because no tumors were observed in the 100 mg/kg and vehicle control groups.

TABLE F4. ANALYSIS OF PRIMARY TUMORS IN FEMALE MICE IN THE TWO-YEAR GAVAGESTUDY OF TELONE II*

	Vehicle Control	50 mg/kg	100 mg/kg
Lung: Alveolar/Bronchiolar Adenoma	<u></u>		
Overall Rates (a)	0/50 (0%)	3/50 (6%)	8/50 (16%)
Adjusted Rates (b)	0.0%	6.7%	21.3%
Terminal Rates (c)	0/46 (0%)	3/45 (7%)	7/36 (19%)
Life Table Tests (d)	P<0.001	P=0.118	P = 0.002
Incidental Tumor Tests (d)	P = 0.001	P = 0.118	P=0.003
Cochran-Armitage Trend Test (d)	P = 0.002		
Fisher Exact Tests		P = 0.121	P=0.003
ung: Alveolar/Bronchiolar Adenoma o	or Carcinoma		
Overall Rates (a)	2/50 (4%)	4/50 (8%)	8/50 (16%)
Adjusted Rates (b)	4.3%	8.9%	21.3%
Terminal Rates (c)	2/46 (4%)	4/45 (9%)	7/36 (19%)
Life Table Tests (d)	P = 0.011	P = 0.327	P = 0.020
Incidental Tumor Tests (d)	P = 0.019	P = 0.327	P = 0.032
Cochran-Armitage Trend Test (d)	P = 0.029		
Fisher Exact Tests		P=0.339	P=0.046
Hematopoietic System: Lymphoma, All	Malignant		
Overall Rates (a)	5/50 (10%)	10/50 (20%)	9/50 (18%)
Adjusted Rates (b)	10.6%	20.8%	23.6%
Terminal Rates (c)	4/46 (9%)	7/45 (16%)	7/36 (19%)
Life Table Tests (d)	P = 0.074	P = 0.132	P = 0.092
Incidental Tumor Tests (d)	P = 0.137	P=0.157	P = 0.158
Cochran-Armitage Trend Test (d)	P = 0.169	0.107	1 = 0.100
Fisher Exact Tests	1 - 0.100	P = 0.131	P=0.194
Circulatory System: Hemangioma			
Overall Rates (a)	0/50 (0%)	3/50 (6%)	1/50 (2%)
Adjusted Rates (b)	0.0%	6.7%	2.6%
Terminal Rates (c)	0/46 (0%)	3/45 (7%)	0/36 (0%)
Life Table Tests (d)	P=0.305	P=0.118	P = 0.459
Incidental Tumor Tests (d)	P=0.371	P = 0.118	P = 0.638
Cochran-Armitage Trend Test (d)	P = 0.376		1 - 41449
Fisher Exact Tests	0.070	P=0.121	P=0.500
Circulatory System: Hemangiosarcoma			
Overall Rates (a)	3/50 (6%)	1/50 (2%)	3/50 (6%)
Adjusted Rates (b)	6.4%	2.2%	8.0%
Terminal Rates (c)	2/46 (4%)	1/45 (2%)	2/36 (6%)
Life Table Tests (d)	P = 0.494	P = 0.317N	P=0.546
Incidental Tumor Tests (d)	P=0.586N	P = 0.317 N P = 0.277 N	
Cochran-Armitage Trend Test (d)	P=0.593N	F = 0.2 (/ IN	P = 0.640N
Fisher Exact Tests	L — A'AQ011	P=0.309N	P=0.661N
Janulatowy System, Howendows on Ho	mendiosensome		
Circulatory System: Hemangloma or He Overall Rates (a)	mangiosarcoma 3/50 (6%)	4/50 (8%)	4/80 (89L)
Adjusted Rates (b)	8.4%	a/50 (8%) 8.9%	4/50 (8%) 10.4%
Terminal Rates (c)	2/46 (4%)	4/45 (9%)	2/36 (6%)
Life Table Tests (d)	P = 0.302	P = 0.486	P = 0.375
Incidental Tumor Tests (d)	P = 0.302 P = 0.427	P = 0.480 P = 0.521	P=0.375 P=0.587
Cochran-Armitage Trend Test (d)	P = 0.424	4 - VIVA1	F = V.V0 (
	· - VITOT		

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TABLE F4. ANALYSIS OF PRIMARY TUMORS IN FEMALE MICE IN THE TWO-YEAR GAVAGESTUDY OF TELONE II* (Continued)

	Vehicle Control	50 mg/kg	100 mg/kg
Liver: Hepatocellular Adenoma			
Overall Rates (a)	0/50 (0%)	5/50 (10%)	3/50 (6%)
Adjusted Rates (b)	0.0%	10.8%	7.8%
Terminal Rates (c)	0/46 (0%)	4/45 (9%)	2/36 (6%)
Life Table Tests (d)	P = 0.082	P=0.033	P=0.088
Incidental Tumor Tests (d)	P = 0.164	P = 0.040	P = 0.164
Cochran-Armitage Trend Test (d)	P = 0.132		
Fisher Exact Tests		P = 0.028	P = 0.121
Liver: Hepatocellular Carcinoma			
Overall Rates (a)	1/50 (2%)	3/50 (6%)	0/50 (0%)
Adjusted Rates (b)	2.2%	6.7%	0.0%
Terminal Rates (c)	1/46 (2%)	3/45 (7%)	0/36 (0%)
Life Table Tests (d)	P = 0.457N	P = 0.298	P = 0.549N
Incidental Tumor Tests (d)	P = 0.457N	P = 0.298	P = 0.549N
Cochran-Armitage Trend Test (d)	P = 0.381N		
Fisher Exact Tests		P = 0.309	P = 0.500N
Liver: Hepatocellular Adenoma or Caro	cinoma		
Overall Rates (a)	1/50 (2%)	8/50 (16%)	3/50 (6%)
Adjusted Rates (b)	2.2%	17.4%	7.8%
Terminal Rates (c)	1/46 (2%)	7/45 (16%)	2/36 (6%)
Life Table Tests (d)	P=0.183	P=0.018	P = 0.232
Incidental Tumor Tests (d)	P = 0.291	P=0.021	P = 0.361
Cochran-Armitage Trend Test (d)	P = 0.287		1 * 0.001
Fisher Exact Tests	1 0.201	P = 0.015	P=0.309
Stomach: Squamous Cell Papilloma or (Carcinoma		
Overall Rates (a)	0/50 (0%)	1/50 (2%)	4/50 (8%)
Adjusted Rates (b)	0.0%	2.2%	10.6%
Terminal Rates (c)	0/46 (0%)	1/45 (2%)	3/36 (8%)
Life Table Tests (d)	P = 0.014	P=0.496	P = 0.040
Incidental Tumor Tests (d)	P = 0.021	P=0.496	P = 0.059
Cochran-Armitage Trend Test (d)	P = 0.026		
Fisher Exact Tests	1 - 0.020	P=0.500	P=0.059
Urinary Bladder: Transitional Cell Caro	rinoma		
Overall Rates (a)	0/50 (0%)	8/50 (16%)	21/48 (44%)
Adjusted Rates (b)	0.0%	17.4%	56.5%
Terminal Rates (c)	0/46 (0%)	7/45 (16%)	19/35 (54%)
Life Table Tests (d)	P<0.001	P = 0.005	P<0.001
Incidental Tumor Tests (d)	P<0.001	P = 0.000	P<0.001
Cochran-Armitage Trend Test (d)	P<0.001 P<0.001	0.000	1 < 0.001
Fisher Exact Tests	1 ~0.001	P=0.003	P<0.001
Pituitary: Chromophobe Adenoma			
Overall Rates (a)	4/48 (8%)	6/48 (13%)	2/41 (5%)
Adjusted Rates (b)	9.1%	14.0%	6.3%
Terminal Rates (c)	4/44 (9%)	6/43 (14%)	2/32 (6%)
Life Table Tests (d)	P = 0.456N	P = 0.355	P = 0.491N
Incidental Tumor Tests (d)	P = 0.456N	P = 0.355	P = 0.491N
Cochran-Armitage Trend Test (d)	P = 0.369N		
		P=0.370	

(a) Number of tumor-bearing animals/number of animals examined at the site

(b) Kaplan-Meier estimated tumor incidence at the end of the study after adjusting for intercurrent mortality

(c) Observed tumor incidence at terminal kill

(d) Beneath the control incidence are the P values associated with the trend test. Beneath the dosed group incidence are the P values corresponding to pairwise comparisons between that dosed group and the vehicle controls. The life table analysis regards tumors in animals dying prior to terminal kill as being (directly or indirectly) the cause of death. The incidental tumor test regards these lesions as nonfatal. The Cochran-Armitage and Fisher's exact test compare directly the overall incidence rates. A negative trend or lower incidence in a dosed group is indicated by (N).

APPENDIX G

HISTORICAL INCIDENCES OF TUMORS IN F344/N RATS

AND B6C3F1 MICE ADMINISTERED

CORN OIL BY GAVAGE

	Incidence in Vehicle Controls				
	Pheochromocytoma	Malignant Pheochromocytoma	All Pheochromocytomas		
Historical Incidence at Fre	ederick Cancer Research Center				
Telone II®	2/52	2/52	2/52		
Overall Historical Inciden	Ce				
TOTAL SD (b)	193/1,135 (17.0%) 10.20%	10/1,135 (0.9%) 1.51%	202/1,135 (17.8%) 10.13%		
Range (c)					
High Low	19/49 1/50	3/48 0/52	19/49 1/50		

TABLE G1. HISTORICAL INCIDENCE OF ADRENAL GLAND TUMORS IN MALE F344/N RATS ADMINISTERED CORN OIL BY GAVAGE (a)

(a) Data as of March 16, 1983, for studies of at least 104 weeks

(b) Standard deviation
(c) Range and SD are presented for groups of 35 or more animals.

TABLE G2. HISTORICAL INCIDENCE OF HEPATOCELLULAR TUMORS IN MALE F344/N RATS ADMINISTERED CORN OIL BY GAVAGE (a)

I	Incidence in Vehicle Controls			
Neoplastic Nodule	Carcinoma	Neoplastic Nodule or Carcinoma		
lerick Cancer Research Center				
1/52	0/52	1/52		
•				
31/1,141 (2.7%) 3.36%	9/1,141 (0.8%) 1.45%	40/1,141 (3.5%) 3.66%		
7/50 0/50	2/50 0/52	7/50 0/50		
	Neoplastic Nodule derick Cancer Research Center 1/52 e 31/1,141 (2.7%) 3.36% 7/50	Nodule Herick Cancer Research Center 1/52 0/52 e 31/1,141 (2.7%) 9/1,141 (0.8%) 3.36% 1.45% 7/50 2/50		

(a) Data as of March 16, 1983, for studies of at least 104 weeks
(b) Standard deviation
(c) Range and SD are presented for groups of 35 or more animals.

TABLE G3. HISTORICAL INCIDENCE OF THYROID GLAND FOLLICULAR CELL TUMORS IN FEMALE F344/N RATS ADMINISTERED CORN OIL BY GAVAGE (a)

	Ir	Incidence in Vehicle Controls		
	Adenoma	Carcinoma	Adenoma or Carcinoma	
Historical Incidence at F	Frederick Cancer Research Center	and an	<u>,</u>	
Telone II®	0/52	0/52	0/52	
Overall Historical Incide	ence			
TOTAL SD (c)	(b) 7/1,104 (0.6%) 1.46%	5/1,104 (0.5%) 0.87%	12/1,104 (1.1%) 1.51%	
Range (d) High	3/48	1/46	3/48	
Low	0/52	0/52	0/52	

(a) Data as of March 16, 1983, for studies of at least 104 weeks

(b) Includes three cystadenomas, NOS and one papillary cystadenoma, NOS

(c) Standard deviation

(d) Range and SD are presented for groups of 35 or more animals.

TABLE G4. HISTORICAL INCIDENCE OF HEPATOCELLULAR TUMORS IN MALE $B6C3F_1$ MICE ADMINISTERED CORN OIL BY GAVAGE (a)

	Incidence in Vehicle Controls		
	Adenoma	Carcinoma	Adenoma or Carcinoma
Historical Incidence at Frederick	Cancer Research Center		
Telone II®	1/50	4/50	5/50
Overall Historical Incidence			
TOTAL SD (c)	133/1,084 (12.3%) 6.72%	(b) 222/1,084 (20.5%) 7.90%	340/1,084 (31.4%) 10.30%
Range (d) High Low	13/50 0/50	18/50 4/50	25/50 5/50

(a) Data as of March 16, 1983 for studies of at least 104 weeks

(b) One hepatoblastoma was also observed.

(c) Standard deviation

(d) Range and SD are presented for groups of 35 or more animals.

	Incidence in Vehicle Controls		
	Leukemia	Lymphoma	Leukemia or Lymphoma
Historical Incidence at Freder	rick Cancer Research Center	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Telone II®	0/50	0/50	0/50
Overall Historical Incidence			
ТОТАL SD (b)	6/1,090 (0.6%) 2.24%	126/1,090 (11.6%) 5.63%	132/1,090 (12.1%) 6.35%
Range (c) High	5/48	11/50	13/48
Low	0/50	0/50	0/50

TABLE G5. HISTORICAL INCIDENCE OF HEMATOPOIETIC SYSTEM TUMORS IN MALE B6C3F₁ MICE ADMINISTERED CORN OIL BY GAVAGE (a)

(a) Data as of March 16, 1983, for studies of at least 104 weeks

(b) Standard deviation
(c) Range and SD are presented for groups of 35 or more animals.

TABLE G6. HISTORICAL INCIDENCE OF HEPATOCELLULAR TUMORS IN FEMALE B6C3F₁ MICE ADMINISTERED CORN OIL BY GAVAGE (a)

	Incidence in Vehicle Controls		
	Adenoma	Carcinoma	Adenoma or Carcinoma
Historical Incidence at Frederic	ck Cancer Research Center		
Telone II®	0/50	1/50	1/50
Overall Historical Incidence			
ТОТАL SD (b)	47/1,176 (4.0%) 2.55%	34/1,176 (2.9%) 2.18%	80/1,176 (6.8%) 3.37%
Range (c) High Low	5/50 0/50	4/50 0/50	7/50 1/50

(a) Data as of March 16, 1983, for studies of at least 104 weeks

(b) Standard deviation

(c) Range and SD are presented for groups of 35 or more animals.

TABLE G7. HISTORICAL INCIDENCE OF ALVEOLAR/BRONCHIOLAR TUMORS IN MALE B6C3F₁ MICE ADMINISTERED CORN OIL BY GAVAGE (a)

	Incidence in Vehicle Controls		
	Adenoma	Carcinoma	Adenoma or Carcinoma
Historical Incidence at Frederick	Cancer Research Center		
Telone II®	1/50	0/50	1/50
Overall Historical Incidence			
TOTAL SD (c)	99/1,082 (9.1%) 4,77%	(b) 58/1,082 (5.4%) 4.13%	(b) 155/1,082 (14.3%) 6.31%
Range (d) High Low	10/50 0/47	7/50 0/50	13/50 1/50

(a) Data as of March 16, 1983, for studies of at least 104 weeks
(b) Includes one adenocarcinoma, unclear primary or metastatic

(c) Standard deviation

(d) Range and SD are presented for groups of 35 or more animals.

TABLE G8. HISTORICAL INCIDENCE OF ALVEOLAR/BRONCHIOLAR TUMORS IN FEMALE B6C3F1 MICE ADMINISTERED CORN OIL BY GAVAGE (a)

	Incidence in Vehicle Controls		
	Adenoma	Carcinoma	Adenoma or Carcinoma
Historical Incidence at Frederic	Cancer Research Center		
Telone II®	0/50	2/50	2/50
Overall Historical Incidence			
TOTAL SD (b)	36/1,103 (3.3%) 2.81%	16/1,103 (1.5%) 1.61%	52/1,103 (4.7%) 3.46%
Range (c) High Low	5/50 0/50	2/49 0/50	6/50 0/50

(a) Data as of March 16, 1983, for studies of at least 104 weeks

(b) Standard deviation

(c) Range and SD are presented for groups of 35 or more animals.

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TABLE G9. HISTORICAL INCIDENCE OF STOMACH TUMORS IN MALE F344/N RATS ADMINISTERED CORN OIL BY GAVAGE (a)

	No. of Animals At Risk	No. of Tumors in Vehicle Controls	Site	Diagnosis
Historical Incid	ence at Frederick Canc	er Research Center		
Telone II®	52	1	Stomach, NOS	Squamous cell papilloma
Overall Historic	al Incidence			
	1,114	2	Stomach, NOS	Squameus cell papilloma
		1	Stomach, NOS	Squamous cell carcinoma
		2	Forestomach	Squamous cell papilloma
		1	Cardiac stomach	Squamous cell papilloma

(a) Data as of March 16, 1983, for studies of at least 104 weeks

TABLE G10. HISTORICAL INCIDENCE OF STOMACH TUMORS IN FEMALE F344/N RATS ADMINISTERED
CORN OIL BY GAVAGE (a)

	No. of Animals At Risk	No. of Tumors in Vehicle Controls	Site	Diagnosis
Historical Incide	ence at Frederick Canc	er Research Center	ин и станин соны Чайны жилтаг <u>соны сон</u> а соны так	
Telone II®	52	0		
Overall Historic	al Incidence			
	1,125	2	Stomach, NOS	Squamous cell papilloma
		1	Stomach, NOS	Squamous cell carcinoma
		1	Gastric mucosa	Squamous cell papilloma
		1	Forestomach	Squamous cell papilloma

(a) Data as of March 16, 1983, for studies of at least 104 weeks

TABLE G11. HISTORICAL INCIDENCE OF STOMACH TUMORS IN MALE B6C3F₁ MICE ADMINISTERED CORN OIL BY GAVAGE (a)

	No. of Animals At Risk	No. of Tumors in Vehicle Controls	Site	Diagnosis
Historical Incide	ence at Frederick Canc	er Research Center		<u> </u>
Telone II®	50	0		
Overall Historic	al Incidence			
	1,055	1	Stomach, NOS	Papilloma, NOS
		2	Stomach, NOS	Squamous cell papilloma
		2	Stomach, NOS	Squamous cell carcinoma
		1	Forestomach	Papilloma, NOS
		1	Forestomach	Squamous cell carcinoma

(a) Data as of March 16, 1983, for studies of at least 104 weeks

TABLE G12. HISTORICAL INCIDENCE OF STOMACH TUMORS IN FEMALE B6C3F1 MICEADMINISTERED CORN OIL BY GAVAGE (a)

	No. of Animals At Risk	No. of Tumors in Vehicle Controls	Site	Diagnosis
Historical Incid	ence at Frederick Canc	er Research Center		
Telone II®	50	0		
Overall Historic	al Incidence			
	1,077	2	Stomach, NOS	Squamous cell papilloma
		1	Stomach, NOS	Adenocarcinoma, NOS
		ī	Gastric mucosa	Squamous cell papilloma
		1	Gastric mucosa	Adenoma, NOS
		1	Gastric mucosa	Adenomatous polyp, NOS
		1	Forestomach	Squamous cell papilloma

(a) Data as of March 16, 1983, for studies of at least 104 weeks

TABLE G13. HISTORICAL INCIDENCE OF URINARY BLADDER TRANSITIONAL CELL TUMORS IN
B6C3F1 MICE ADMINISTERED CORN OIL BY GAVAGE (a)

	Male	Female			
Historical Incidence at Frederick Cancer Research Center					
Telone II®	0/50	0/50			
Overall Historical Incidence					
	0/1,033	0/1,025			

(a) Data as of March 16, 1983, for studies of at least 104 weeks

APPENDIX H

CHEMICAL CHARACTERIZATION OF TELONE II•

Telone II®, NTP TR 269

APPENDIX H. CHEMICAL CHARACTERIZATION

I. Identity and Purity Determinations of Lot No. EXP-N-3993

A. Physical Properties

1. Boiling Point:	Determined	Literature Values
	109° C	108°C (tech) 104°C (<i>trans</i>) 112°C (<i>cis</i>) (Merck, 1968)
2. Appearance: Colorless	liquid	
B. Spectral Data		
1. Infrared	Determined	Literature Values
a. Instrument:	Perkin-Elmer 467	
b. Cell:	Neat liquid film between sodium chloride plates	
c. Results:	3080, 3060, 2955, 1630, 1440, 1332, 1290, 1275, 1258, 1238, 1154, 1082, 1032, 938, 923, 855, 820, 760, 680 cm ⁻¹	<i>cis</i> -1,3-Dichloropropene: 3030, 2940, 1640, 1450, 1330, 1300, 1280, 1270, 1240, 1160, 1080, 940, 930, 860, 820, 780, 680 cm ⁻¹ <i>trans</i> -1,3-Dichloropropene: 3030, 2940, 1640, 1450, 1270, 1240, 1080, 940, 860, 780, 690 cm ⁻¹ (Graselli and Ritchy, 1975)
2. Illtraviolet/Visible	Determined	Literature Values

2. Ultraviolet/Visible	Determined	<u>Literature Values</u>
a. Instrument:	Cary 17 dual beam	
b. Solvent:	Hexane	
c. Results:	$\lambda_{\max} = 209 \text{nm}$ $\varepsilon_{\max} = 3395$	No reference found
3. Nuclear Magnetic Resonance

	Determined	Literature Values
Run 1: Proton spectrum		
a. Instrument:	Varian XL-100	
b. Solvent:	Deuterated chloroform with internal tetramethylsilane	
c. Results:	Unexplained resonances add up to approximately 16%-17% of total proton intensities	
Run 2: Carbon-13 spectrum		
a. Instrument:	Varian XL-100	
b. Solvent:	Deuterated chloroform with internal tetramethylsilane	
c. Results:	The ¹³ C spectrum for this 3-carbon compound showed six resonances. Off-resonance decoupling showed that the carbons resonating at $\delta = 42.0$ and 37.9 have two directly bonded protons, whereas the four olefinic carbons at $\delta = 129.1$, 127.3, and 122.3 each have one directly bonded proton. The ¹³ C spectrum indicates a mixture of <i>cis</i> - and <i>trans</i> -isomers	trans- (E) - 1,3-Dichloro- propene δ ¹³ C, ppm values are given as 41.8, 129.0, and 122.7 with 10% deuterated chloroform as internal reference (Chukovskaya et al., 1976)

C. Gas-Liquid Chromatographic Analyses

Assay 1:

Instrument: Hewlett-Packard 5710A Detector: Flame ionization Column: 3% SP-2250 on 100-120 mesh Supelcoport, 6 ft × 2 mm ID glass column Carrier gas: Nitrogen Carrier flow rate: 25 ml/min Column oven temperature program: 45°-80° C at 4° C/min Results: Two major and nine minor peaks

Retention <u>Time (min)</u>	Area (percent of <u>total)</u>		
3.64	3.1		
3.92	0.7		
4,27	0.9		
4.87	43.5		
	4.1		
5,96	44.9		
	0.7		
	0.3		
	18		
	0.2		
9.28	0.2		
	Total = 99.9		
	Time (min) 3.64 3.92 4.27 4.87 5.22 5.96 6.48 6.95 7.38 7.88		

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Assay 2:

Instrument: Hewlett-Packard 5710A Detector: Flame ionization Column: 10% Carbowax 20M on 100-120 mesh HP Chromosorb W, 6 ft × 2 mm ID, glass Carrier gas: Nitrogen Carrier flow rate: 20 ml/min Column oven temperature program: 50°-100° C at 4° C/min and held at 100° C for 8 min

Results: Two major peaks and 11 minor peaks

Peak	Retention <u>Time (min)</u>	Area (percent of <u>total)</u>
1	2.22	1.2
2	3.34	0.9
3	4.67	2.5
Ă	6.18	4.5
5	6.88	0.6
3 4 5 6 7 8 9 10	8.11	0.4
7	8.92	0.1
8	10.28	41.6
9	11.35	0.1
10	11.98	0.4
11	12.37	0.3
12	13.33	45.9
13	14.97	1.5
		Total = 100

D. Mass Spectrometry:

Instrument: Finnigan 3300 EI/MS with 6000 Finnigan data system Ionization mode: GLC/EI/MS Chromatograph: Varian 1400 GLC Column: 10% Carbowax 20M on 100-120 mesh HP Chromosorb W, 6 ft × 2 mm ID glass column Carrier gas: Helium Carrier flow rate: 25 ml/min Column temperature program: 50°-100° C at 4° C/min Results: Two major components plus 12 other components observed. Spectra were obtained on 12 of the 14 peaks. Five components were identified.

Peak	Computer Retention <u>Time (min)</u>	Identity
1	2.93	Not identified
2	8.88	Not identified
3	4.18	Not identified
4	4.87	Not identified
5	5.40	Not identified
ě	5,80 (2,5%)	1,2-Dichloropropane
8 7	6.27	Not identified
8	6.87	Not identified
8	8.40 (41.6%)	cis-1,3-Dichloropropene
10	9.80	Not identified
11	10.73 (45.9%)	trans-1,3-Dichloropropens
12	11.93 (1.5%)	Trichloropropene isomer
13	14.00	Not identified
14	16.70	Trichloropropene isomer

Note: The percentages in parentheses next to the retention times were taken from the gas-liquid chromatographic purity assay number 2 above.

II. Test Chemical Stability Study of Lot No. EXP-N-3993

A. Analytical Method:

Instrument: Hewlett-Packard 5710A Detector: Flame ionization Column: 3% SP-2250 on 100-120 mesh Supelcoport, 6 ft × 2 mm ID glass column Carrier gas: Nitrogen Carrier flow rate: 20 ml/min Column temperature program: Held at 45° C for 2 min; then increased to 100° C at 4° C/min and held at 100° C for 2 min

B. Results:

		Percentage			cis- and trans- 1,3-Dichloropropene	
Date	Isomer	Run 1	Run 2	Run 3	Total Percentage	
10/78	cis	43.0	43.2		an de la companya de	
	trans	46.8	46.6		89.8	
1/79	cis	42.0	42.0	43.2		
	trans	47.1	46.6	46.0	89.0	
4/79	cis	43.6	43.9			
	trans	45.9	46.6		90.0	
7/79	cis	43.7	43.5			
	trans	46.1	46.5		89.9	

APPENDIX I

CHEMICAL CHARACTERIZATION AND ANALYSIS OF DOSE MIXTURES: METHODS AND DATA

Studies Conducted at the Analytical Chemistry Laboratory

- I. Homogeneity: Telone II[•] in corn oil formed an isotropic solution of one phase. This conclusion was supported by the quality control program's data.
- II. Stability: Telone II[®]/corn oil dose mixtures were prepared fresh daily and were used immediately after preparation.

III. Quality Control Program Analysis:

- A. Assay method: Gas-liquid chromatography
- **B. Instrument:** Hewlett-Packard 5710A
- C. Column: 3% SP-2250 on 100-120 mesh Supelcoport, 6 ft \times 2 mm ID glass column
- **D. Detection:** ⁶³Ni electron capture
- E. Oven Temperature: Isothermal at 50°C.
- F. Carrier gas: Argon:methane (95:5)
- G. Flow rate: 20 ml/min
- H. Results: See Table I1

	for Target Concentrations (a) Rats Mice						
Date Mixed	Rats 5 mg/ml	10 mg/ml	10 mg/ml	20 mg/ml			
8/10/77	4.9	10.6					
9/12/77	5.3	10.4					
10/25/77	(b) 4.0	9.0					
11/23/77	5.2	10.0					
12/7/77	(b) 5.7	9.9					
1/9/78	(b) 5.8	9.2	••	••			
3/1/78	5.1	9.9	••				
4/25/78	4.3	9.1		**			
5/29/78	4.1	9.5					
7/1/78	4.8	9.1	**				
8/19/78	4.7	9.0	(b) 8.8	19.6			
9/5/78	4.8	(b) 8.8	(b) 8.9	19.6			
10/10/78	4.9	10.1	9.1	19.1			
11/8/78	(b) 4.1	9.1	9.3	18.8			
12/15/78	4.9	9.1	9.5	21.0			
1/17/79	4.8	9.3	9,5	18.6			
2/5/79	5.0	9.5					
3/26/79	4.8	9.1					
4/13/79	4.4	(b) 8.8					
5/25/79			(b) 11.1	21.1			
6/25/79			(b) 11.2	21.8			
7/9/79			10.2	19.4			
8/29/79			9.8	(b) 23.7			
9/7/79			(b) 13.1	(b) 25.5			
10/4/79			10.5	21.6			
12/12/79			9.4	(b) 23.0			
5/23/80			9.1	(b) 17.8			
6/24/80			(b) 12.5	22.0			
Mean (mg/ml)	4.8	9.4	10.1	20.8			
Standard deviation Coefficient of variation	0.50	0.54	1.31	2.14			
(percent)	10.4	5.7	13.0	10.3			
(percent) Range (mg/ml)	4.0-5.8	8.8-10.6	8.8-13.1	17.8-25.5			
Number of samples	4.0-5.8 19	19	15	15			

TABLE I1. ANALYSIS OF TELONE II[®]/CORN OIL MIXTURES IN THE TWO-YEAR GAVAGE STUDIES

(a) The data presented are the results of duplicate analyses.(b) Measured concentration differs from target concentration by more than 10%

Telone II[®], NTP TR 269

APPENDIX J

MUTAGENICITY OF 95% 1,3-DICHLOROPROPENE

IN SALMONELLA

Dose			
(µg/plate)	-59	+ S9 (rat)	+ S9 (hamster)
0	155 ± 1.3	165 ± 5.2	154 ± 9.6
3	165 ± 12.3	. 	
10			
33		197 ± 12.5	203 ± 7.1
100	$1,672 \pm 42.3$		249 ± 6.7
333	$2,327 \pm 171.6$		484 ± 22.7
1,000	•••	46 ± 46.3	155 ± 79.3
3,333	**	Toxic	Toxic
0	58 ± 3.5	47 ± 5.1	47 ± 1.7
	56 ± 5.4		
	83 ± 4.9		
33	136 ± 23.1	60 ± 3.7	63 ± 5.6
	586 ± 54.3		77 ± 6.1
	745 ± 26.4		135 ± 7.0
			Toxic
3,333	r	Toxic	Toxic
0	5 + 1.8	9 + 1.7	6 ± 1.5
	5 ± 0.9		· - ···
10	7 + 07		
33	8 + 1.5		
100	6 ± 1.5	10 ± 1.2	6 ± 0.7 4 ± 0.7
999	5 + 1.5	R + 12	7 ± 0.6
		K + 97	11 ± 3.3
		Torio	Toxic
0,000		A UAIC	L'UNIC
0	27 ± 0.6	35 ± 8.8	29 ± 4.5
3	35 ± 1.8	••	
10	31 ± 6.1	**	
33	46 ± 5.0		28 ± 0.9
	81 ± 7.8		35 ± 4.3
333	19 ± 11.3	31 ± 3.8	34 ± 5.9
			42 ± 4.9
			Toxic
	(µg/plate) 0 3 10 33 100 333 1,000 3,333 0 0 3 3 100 33 100 333 100 333 1,000	(µg/plate) -59 0 155 ± 1.3 3 165 ± 12.3 10 223 ± 24.7 33 510 ± 6.7 100 1,672 ± 42.3 333 2,327 ± 171.6 1,000 3,333 0 58 ± 3.5 3 56 ± 5.4 10 83 ± 4.9 33 136 ± 23.1 100 586 ± 54.3 33 136 ± 23.1 100 586 ± 54.3 333 745 ± 26.4 1,000 3333 745 ± 26.4 1,000 3333 745 ± 26.4 1,000 333 6 ± 1.5 10 7 ± 0.7 33 6 ± 1.5 100 6 ± 1.5 333 0 27 ± 0.6 3 35 ± 1.8 10 31 ± 6.1 33 46 ± 5.0 100 81 ± 7.8 333 19 ± 11.3	(µg/plate) -59 $+ 59 (rat)$ 0 155 ± 1.3 165 ± 5.2 3 165 ± 12.3 10 223 ± 24.7 33 510 ± 6.7 197 ± 12.5 100 1,672 ± 42.3 321 ± 19.1 333 2,327 ± 171.6 740 ± 18.2 1,000 46 ± 46.3 3,333 Toxic 0 58 ± 3.5 47 ± 5.1 3 56 ± 5.4 10 83 ± 4.9 33 136 ± 23.1 60 ± 3.7 100 596 ± 54.3 74 ± 7.0 333 745 ± 26.4 163 ± 19.5 1,000 126 ± 30.4 33 5 ± 0.9 10 7 ± 0.7 33 6 ± 1.5 10 ± 1.2 333 6 ± 1.5 10 ± 1.2 333 5 ± 1.5 6 ± 1.2 100 6 ± 1.5 10 ± 1.2 333

TABLE J1. MUTAGENICITY OF 95% 1,3-DICHLOROPROPENE IN SALMONELLA

(a) The S9 fractions were prepared from the livers of Aroclor 1254-induced animals (male Sprague-Dawley rats and male Syrian hamsters). Cells and test compound or solvent (DMSO) were incubated for 20 minutes at 37° C in the presence of either S9 or buffer (Yahagi et al., 1975). After the addition of soft agar, the contents of each tube were poured onto minimal medium, and the plates were incubated at 37° C for 48 hours (Ames et al., 1975). The experiment was performed twice, each in triplicate; because the results were similar, data from only one experiment are shown.

APPENDIX K

RESULTS OF TESTS IN DROSOPHILA

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TABLE K1. INDUCTION OF SEX-LINKED RECESSIVE LETHAL MUTATIONS IN DROSOPHILA BY 1,3-DICHLOROPROPENE

		Number of Lethals/Number of X Chromosomes Tested (a)				
Route of Exposure	Dose (ppm)	Mating 1	Mating 2	Mating 3	Total (percent)	
Feeding	0	3/1,200 3/1,159	1/1,200 0/1,119	0/1,171 1/1,069	4/3,571 <u>4/3,347</u> 8/6,918 (0.12)	
	5,750	7/1, 343 3/1,373	2/836 3/1,088	5/1, 106 0/838	14/3,285 <u>6/3,299</u> 20/6,584 (0.30)	

(a) The sex-linked recessive lethal assay was performed essentially as described by Abrahamson and Lewis (1971). Exposure by feeding was done by allowing 24-hr-old Canton-S males to feed for 3 days on a solution of the test chemical dissolved in 5% sucrose. Exposed males were mated to 3 *Basc* females for 3 days and given fresh females at 2-day intervals to produce 3 broods of 3, 2, and 2 days, after which the parents were discarded. F₁ heterozygous females were crossed to their siblings and placed in individual vials. F₁ daughters from the same parental males were kept together to identify clusters; none were found. After 17 days, presumptive lethals were identified as vials containing no wild-type males; these were retested. Comparisons were made with concurrent controls using the normal approximation to the Poisson distribution suggested by Margolin et al. (1983). The z value for the fed flies was 2.402, and it was significant at the 5% level of significance. Details on control frequencies of NTP-sponsored Drosophila studies can be found in Woodruff et al. (1984).

Route of			(Tran	Storage slocation	Total No. of	Total No. of	Total		
Exposure (a)	Dose (ppm)	1	2	3	4	5	Tests	Translocations	Translocations (percent)
Injection	5,750	0 1,401	1 1,267	0 1,478	0 1,414	0 1,405	6,965	1	0.01
Historical Control	0	0 4,563	0 4,335	0 4,373	0 3,623	0 2,743	19,637	0	0.00

TABLE K2. INDUCTION OF RECIPROCAL TRANSLOCATIONS IN DROSOPHILA BY 1,3-DICHLOROPROPENE

(a) The reciprocal translocations assay was performed essentially as described by Abrahamson and Lewis (1971). Exposed males were mated to 3 bw; st females for 3 days and discarded. The females were transferred to fresh medium every 3-4 days to produce a total of five cultures, and then they were discarded. In this manner, successive cultures sample sperm that were stored for increasing lengths of time. Individual F_1 males were backcrossed to bw; st females, and the F_2 were screened for pseudolinkage. This procedure allows the recovery of translocations involving the Y, second, or third chromosomes in any combination. Presumptive translocations were retested. Results were not significant at the 5% level of significance (Kastenbaum and Bowman, 1970).

APPENDIX L

SUMMARY OF SERUM CHOLINESTERASE DATA IN THE ANCILLARY GAVAGE STUDIES OF TELONE II^o

		Male Rats		F	emale Rats	
Weeks	Vehicle Contro	l 25 mg/kg	50 mg/kg	Vehicle Control	25 mg/kg	50 mg/kg
+1	86.9 ± 11.8	80.4 ± 5.1	78.9 ± 9.7	167.9 ± 28.5	155.0 ± 28.8	(b) 145.9 ± 13.0
5	80.7 ± 9.0	76.3 ± 19.3	76.8 ± 22.0	264.2 ± 48.0 (c)	340.0 ± 45.5	225.0 ± 34.1
9	87.5 ± 8.6	(b) 78.4 ± 9.5	77.3 ± 12.7	343.7 ± 65.6	344.1 ± 87.7	302.2 ± 56.9
13	82.9 ± 8.3	85.8 ± 13.7	74.3 ± 12.1	358.5 ± 79.5	392.1 ± 39.5	(c) 279.3 ± 49.0
17	96.5 ± 18.8	84.3 ± 9.7	87.9 ± 12.5	393.8 ± 56.1	328.2 ± 105.7	(c) 301.1 ± 51.9
21	91.9 ± 11.9	94.3 ± 25.7	82.1 ± 11.0	443.8 ± 97.7	365.3 ±110.0	(c) 328.1 ± 90.0
25	107.0 ± 12.5	(c) 89.5 ± 12.9	105.2 ± 12.8	548.3 ± 85.8	489.5 ± 28.1	(c) 341.8 ± 87.8
29	116.2 ± 23.7	102.2 ± 18.9	108.0 ± 12.5	485.3 ± 101.4 (c)	355.3 ± 87.3	(c) 274.0 ± 92.8
33	114.0 ± 8.8	103.3 ± 15.2	99.3 ± 16.7	442.3 ± 81.6	416.4 ± 77.8	(b) 343.7 ± 58.9
37	126.6 ± 22.7	108.8 ± 18.4	122.1 ± 14.8	507.1 ± 58.4	449.1 ± 94.7	(c) 298.5 ± 73.6
39	112.3 ± 10.6	95.2 ± 16.6	98.7 ± 11.3	496.7 ± 98.3	455.1 ± 97.8	392.5 ± 84.6
69	95.2 ± 11.6	96.2 ± 12.6	85.3 ± 4.7		358.7 ± 41.9	(c) 244.5 ± 46.4

TABLE L1. SUMMARY OF SERUM CHOLINESTERASE DATA IN THE ANCILLARY GAVAGE STUDIES OF TELONE II* (a)

(a) Values represent mean \pm standard deviation in milliunits per milliliter (N = 12). (b) Significant (t-test) changes at P ≤ 0.05 as compared with the vehicle control group (c) Significant (t-test) changes at P ≤ 0.01 as compared with the vehicle control group

APPENDIX M

DATA AUDIT SUMMARY

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APPENDIX M. DATA AUDIT SUMMARY

The data from the 2-year toxicology and carcinogenesis studies of Telone II[®] in F344/N rats and B6C3F₁ mice and the ancillary studies in F344/N rats were audited by the following persons from the National Toxicology Program (NTP) and Dynamac Corporation on January 10-20, 1984 (2-year carcinogenesis studies) and April 10-12, 1984 (ancillary studies): NTP--Ms. C. Davies, Dr. S. Eustis, Ms. A. Grant, Mr. M. Pielmier, Dr. C. Whitmire, and Dr. R. Yang; Dynamac Corporation--Dr. H. Appleton, Mr. C. Dippel, Dr. F. Garner, Mr. C. Lunchick, Mr. J. Plantz, Dr. R. Schueler, and Ms. C. Sunier.

The in-life phase of the studies was conducted from February 1977 to July 1980. The work was conducted by Frederick Cancer Research Center (FCRC) under a contract with the National Cancer Institute. These studies were initiated before NTP required Good Laboratory Practices compliance in October 1980.

The full audit reports (carcinogenicity and ancillary studies) are on file at the NTP Archives, National Institute of Environmental Health Sciences, Research Triangle Park, North Carolina. The audit consisted of examination of 10%-100% of the available toxicology, chemistry, and pathology data; this examination included the audit of 100% of clinical observation, mortality data, individual animal data records (IADR's), 100% of the slide/block matches of the high dose and vehicle control animals, and 10%-23% of the wet tissues.

One major problem unrelated to the audit was the early death in male mice, particularly in the vehicle control group. A technician's note implied gavage error; however, gross and microscopic examination did not uncover sufficient evidence to support the claim of gavage error. On the other hand, suppurative inflammation of the heart (myocarditis) was observed in all of these early deaths. The etiology of this lesion is not known. Because of the low survival rate of vehicle control male mice (8/50 alive at the termination of the study), the male mouse study was considered inadequate. The data indicated possible Telone II[®]-related neoplastic and nonneoplastic effects. Two lesser problems involved randomization of animals and body weight data. The rats were to have been randomized by body weight, and the body weights were indeed comparable among different groups at the start of the study; however, no record was available. In the mouse studies, three shipments of mice were received at 2-week intervals, and no record of randomization was available. The vehicle control male and female mice were from the first shipment, low dose males and females mostly from the second shipment, and the high dose groups mostly from the third shipment. Consequently, the body weights of the vehicle control mice groups were greater than those in the dosed groups. Any other discrepancies were generally related to poor recordkeeping (including loss of records) and undesirable laboratory practices. None of these problems was considered to have affected the final outcome of the study.

All chemical analyses were performed by the chemistry section of FCRC. The identity of the test material was confirmed, and the dose preparation was considered adequate. The chemical/vehicle analyses records were incomplete, but the available data provided sufficient information to suggest the accuracy of the dosing concentrations.

In the audit of IADR necropsy observations vs histopathology findings, discrepancies were found on the correlation of microscopic diagnoses with gross observations. Most of these were related to nontarget organs and are of minimal importance. The few items needing attention included some untrimmed lesions in the target organs (i.e., stomach and liver nodules or growths); these were subsequently recut, and microscopic examinations were carried out by the original pathologist. Subsequent diagnostic updates were made and incorporated into the Technical Report. An exception to the above was the stomach nodules observed in two low dose male mice and one high dose male mouse; they were not re-examined because (1) the male mouse study was considered inadequate and (2) if a conclusion were to be drawn from the incidence of forestomach neoplastic lesions in the male mice, the additional information from these three mice would not have changed the conclusion. Other

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problems and discrepancies concerning pathology data were minor and not considered of sufficient magnitude to affect the findings.

The ancillary studies were conducted concurrently with the 2-year rat carcinogenesis studies. Therefore, much of the above audit summary applies to the ancillary studies as well. Discrepancies were found between the protocol-designated interim-kill dates and the actual kill dates. As much as a 39-day difference was found. This particular discrepancy was rectified by designating the originally scheduled 15-month kill as the 16-month kill. A restricted pathology quality assessment/audit was conducted by Experimental Pathology Laboratory, Inc. As requested by NTP, this review was limited to three target tissues (liver, forestomach, and thyroid gland). Differences of opinion were noted in the diagnoses of neoplastic nodules in the liver and diagnoses of basal cell hyperplasia in the forestomach. No change was made in the Technical Report.

In conclusion, problems and discrepancies of varying magnitude were found; however, none was considered to be serious enough to preclude drawing conclusions from the data regarding the toxicity and carcinogenicity of Telone II[®] to F344/N rats and B6C3F₁ mice.