

3-Dimethylaminopropyl Methacrylamide

5205-93-6

OVERVIEW

Prepared for the National Cancer Institute (NCI) for consideration by the Chemical Selection Working Group (CSWG) by Technical Resources International, Inc. under contract no. N02-07007.

2-Propenamide, N-[3-(dimethylamino)propyl]-2-methyl-, more commonly known as 3-dimethylaminopropyl methacrylamide (DMAPMA) came to the attention of the National Cancer Institute (NCI) Division of Cancer Biology as the result of a review of high production chemicals in commerce that do not meet the criteria for inclusion in the United States (U.S.) Environmental Protection Agency (EPA) HPV Challenge Program.

DMAPMA is used for the synthesis of polymers that have many uses, including paint resins, dispersions/emulsions, performance products, paper and water products, hair care products, and reactive systems. The result is that there is potential worker exposure in multiple industries that have different degrees of process enclosure and worker protection. Some uses, e.g., automotive coatings, weather-resistant house paints, and textiles, might result in extensive worker exposure and widespread consumer use. In addition, the monomer may be found in food contact substances.

The available information on DMAPMA is insufficient to define a toxicological profile for this chemical. Repeat dose studies in rats showed an increase in spleen weight in females, increases in liver and kidney weights in males, and tubular atrophy in the testes of males. No information was found in the available literature regarding cancer or chemical disposition. The test compound was negative with and without metabolic activation in the following genetic toxicity tests: cytogenetic assay in V79 Chinese hamster cells; HPRT locus activity in V79 Chinese hamster cells; and reverse mutation assay in *S. typhimurium* TA98, TA100, TA102, TA1535, and TA1537.

Several related compounds are currently under review for toxicity testing or are already in testing:

- 3-Dimethylaminopropylamine (CAS No. 109-55-7) was recently nominated by the NCI to the National Testing Program (NTP) for the following tests: genetic toxicology in *Salmonella typhimurium* with a nitrosating agent and disposition and nitrosation in rodents.
- *t*-Butylacrylamide (CAS No.107-58-4) is being reviewed by the CSWG.
- Acrylamide (CAS No.79-06-1) was nominated to NTP by the Food and Drug Administration (FDA) and is on test at the National Center for Toxicological Research (NCTR) for toxicological characterization, toxicokinetics, mechanistic (hemoglobin adducts), carcinogenicity, and bioavailability (NTP, 2003).

NOMINATION OF 3-DIMETHYLAMINOPROPYL METHACRYLAMIDE TO THE NTP

Based on a review of the available literature and the recommendations of the Chemical Selection Working Group (CSWG) on December 15, 2004, NCI nominates this chemical for testing by the National Toxicology Program (NTP) and forwards the following information:

- The attached Summary of Data for Chemical Selection
- Copies of references cited in the Summary of Data for Chemical Selection
- CSWG recommendations to:
 - (1) Characterize the toxicity of DMAPMA in a 90-day study, including histopathology, especially of the liver, spleen, and kidneys.
 - (2) Conduct metabolic and disposition studies to characterize the metabolites of DMAPMA.
 - (3) Depending on the metabolites identified, the issue of appropriate assays to characterize the genotoxicity of this chemical should be revisited.

PRIORITY

The CSWG suggested that the recommended testing be conducted with moderate priority.

COMMENTS

The testing of DMAPMA is justified based on the high potential for human exposure, particularly in the workplace, and concerns raised about the carcinogenic potential of acrylamides in general.

Concerns about possible nitrosation were raised at the meeting.

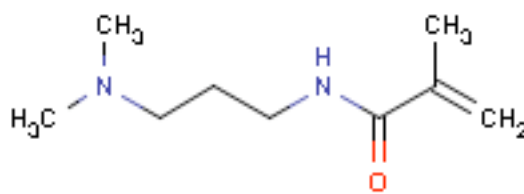
The studies selected should be designed in conjunction with ongoing and anticipated tests of related chemicals.

SUMMARY OF DATA FOR CHEMICAL SELECTION

CHEMICAL IDENTIFICATION

| | |
|--------------------------|--|
| <u>CAS Registry No.:</u> | 5205-93-6 |
| <u>CAS Name:</u> | 2-Propenamide, N-[3-(dimethylamino)propyl]-2-methyl- (9CI) |
| <u>Synonyms:</u> | 3-Dimethylaminopropyl methacrylamide; N-(3- (dimethylamino)propyl)methacrylamide; dimethylamino propyl methacrylamide; EINECS No. 226-002-3 (4) |

Structure, Molecular Formula



C₉H₁₈N₂O

Mol. wt. 170.25

Structural Class: N-substituted methacrylamide

Chemical and Physical Properties:

| | |
|----------------------------------|---|
| <u>Description:</u> | Clear to yellowish liquid with amine-like odor (Lewis, 2002; Röhm America LLC, 2002) |
| <u>Melting point:</u> | < -60 degrees °C (Röhm America LLC, 2002) |
| <u>Boiling point:</u> | >150 degrees C at 1013 mbar (European Commission, 2000a; Röhm America LLC, 2002) 134 degrees C at 2 mm Hg (Sigma-Aldrich, 2004a) |
| <u>Solubility:</u> | Miscible with water (European Commission, 2000a; Sigma-Aldrich, 2004a) |
| <u>Density/Specific gravity:</u> | 0.94 g/cm ³ (Röhm America LLC, 2002; Sigma-Aldrich, 2004a) |

Flash Point: 128 degrees C (DIN 51758) (Röhm America LLC, 2002)
235 degrees F (113 degrees C) (closed cup) (Sigma-Aldrich, 2004a)
140 degrees C (closed cup) (Lewis, 2002)

Reactivity: Shelf life of standard stabilized product: 3 months at a maximum temperature of 30 degrees C (Röhm America LLC, 2002)

Flammable; polymerization may be initiated by contamination with peroxides, azo compounds, heavy metal ions, or sulfur containing compounds (European Commission, 2000a)

Store only in original container at a temperature not greater than 30 °C; keep out of light; fill container to 90% of capacity or less, since oxygen is required for stability (European Commission, 2000a)

O/W Partition Coefficient: Log $K_{O/W}$ = 0.08 (European Commission, 2000a)

Technical Products and Impurities:

2-Propenamide, N-[3-(dimethylamino)propyl]-2-methyl- is available from Röhm America LLC, a subsidiary of Degussa Corp., at a purity of at least 98.5 % and water content less than 0.10% (Röhm America LLC, 2002).

N-[3-(Dimethylamino)propyl]methacrylamide (99%) is available in smaller quantities from Sigma-Aldrich (Sigma-Aldrich, 2004b).

EXPOSURE INFORMATION

Production and Producers:

N-alkyl derivatives of acrylamide are prepared by the reaction of acryloyl chloride with the corresponding amine. Thus, N-dimethyl(propyl)amine would be used to synthesize DMAPMA. Acrylamide itself is prepared from acrylonitrile either by homogeneous sulfuric acid hydration or by heterogeneous catalytic hydration (Ohara *et al.*, 2003).

Production/import Levels:

Annual production ranges, supplied as nonconfidential information to the U.S. Environmental Protection Agency (EPA) under the Inventory Update Rule (IUR) are presented in Table 1.

Table 1. Production Levels of DMAPMA

| Year | Pounds |
|-------------|-------------------------|
| 1986 | 10,000 - 500,000 |
| 1990 | 10,000 - 500,000 |
| 1994 | 500,000 - 1,000,000 |
| 1998 | >1,000,000 - 10,000,000 |
| 2002 | >1,000,000 – 10,000,000 |

Source: EPA, 2005

For the 14-month period from April 2003 to June 2004, the Port Import/Export Reporting Service (PIERS) database reported DMAPMA imports with a cargo weight of 175,601 pounds (Dialog Information Services, 2004).

In the European Union, DMAPMA is listed as an HPV chemical, meaning that >1,000 metric tons was produced or imported from 1990-1994 (ESIS, 2004).

Producers and Importers:

According to Chemical Sources International, there are 4 U.S. suppliers of DMAPMA (Chemical Sources International, 2004).

According to recent issues of chemical directories, DMAPMA is manufactured or distributed by ICN, Monomer-Polymer & Dajac Labs, Röhm America, L.L.C. (a subsidiary of Degussa Corporation), San Esters Corp. (a subsidiary of Mitsubishi Rayon), and TCI (ChemACX, 2004; Chemical Week Associates, 2004; Tilton, 2004).

DMAPMA may be stabilized with MEHQ (mequinol) which is negative in the Ames assay but produced forestomach tumors in rats following oral administration (Asakawa et al., 1994, as cited in CCRIS, 2004; Chemfinder, 2004).

Use Pattern:

DMAPMA is widely used for the synthesis of many different polymers and copolymers. Examples of these uses include:

- *Paint resins:* Tailor made binder molecules are used in a variety of automotive coatings (Röhm America LLC, 2004).
- *Dispersions/emulsions:* DMAPMA monomer is incorporated into paints and coatings to improve their weatherability (Röhm America LLC, 2004)
- *Performance products:* DMAPMA is used in textile finishing to achieve various effects on fabrics (Röhm America LLC, 2004).
- *Paper and water:* DMAPMA polymers and copolymers are used in paper and ink, particularly in inkjet printers (Johnson, 2003; Röhm America LLC, 2004).
- *Reactive systems:* Many reactive adhesives contain DMAPMA polymers and copolymers (Röhm America LLC, 2004).
- *Hair care products:* DMAPMA-based polymers and copolymers, including Styleze and Aquaflex, are used in a variety of hair care products (ISP Japan, 2004; Röhm America LLC, 2004; Walgreens, 2004).

- *Food contact substances:* In 1995, DMAPMA monomer was authorized by legislation in the United Kingdom (U.K.) for use for one year as a constituent of plastic materials and articles in contact with food (Her Majesty's Stationery Office, 1995). No later references to this use in the U.K. or to a similar use in the United States were found in the available literature.

As of June 2004, a total of 629 patents containing reference to dimethylaminopropyl methacrylamide or dimethylamino propyl methacrylamide were filed with the U.S. Patent and Trademark Office since 1976 (U.S. Patent and Trademark Office, 2004).

Human Exposure:

There is very little information available on exposure to DMAPMA. Exposure to DMAPMA from polymers and copolymers made from DMAPMA has been examined for the polymer Styleze upon its importation into Australia. Analysis of Styleze by gas chromatography showed no low molecular weight species present, but the limit of detection was not stated (Australian Government, Department of Health and Ageing, NICNAS, 2003).

Available data on the monomer and polymers and their logical implications are discussed below.

Occupational Exposure. Worker exposure would be expected to occur from emissions during production of DMAPMA and polymers or copolymers produced from DMAPMA and from any residual monomer content in polymerized products. Spillage of DMAPMA or products containing DMAPMA could result in dermal contact.

The National Occupational Exposure Survey (NOES), which was conducted by the National Institute for Occupational Safety and Health (NIOSH) between 1981 and 1983, estimated that 595 employees (chemists, male and female) were potentially exposed to DMAPMA in the workplace (NOES, 2004). These figures do not reflect recent usage of DMAPMA.

Environmental Exposure. There are no data directly addressing environmental exposure to DMAPMA, but some information can be gleaned from a document on Styleze (Australian Government, Department of Health and Ageing, NICNAS, 2003). During the reformulation of Styleze into hair care products, approximately 4.5% was expected to be wasted through spill, container residues, and equipment washing. Approximately one third of the wasted material would probably go to on-site or public sewage treatment plants, where 80% of the polymer was expected to be removed. The remaining two thirds of the material would probably go to landfill. For a worst case scenario in which a full reformulation batch would be released to sewers, the resulting concentration of the polymer in receiving waters was calculated to be 0.04 mg/l. The resulting concentration of monomer would be expected to be much lower.

Consumer Exposure. Consumer exposure would be expected to occur from migration of residual DMAPMA monomer from polymers and copolymers made from DMAPMA. These articles are used in many products with high consumer exposure, including automotive coatings, weather-resistant house paints, textiles, paper for ink jet printers, reactive adhesives, and hair care products. The quantities of DMAPMA monomer present in these products are expected to be low, based on the very limited data available for Styleze.

If DMAPMA is present as a residue in substances that come into contact with food, widespread, low-level consumer exposure from migration of residual DMAPMA monomer would be predicted to occur. Although DMAPMA was authorized for use in food contact substances in the U.K. in 1995 for one year, no information was identified in the available literature on its presence in food.

Environmental Occurrence:

DMAPMA is a synthetic chemical not found in nature. In concentrated form, DMAPMA polymerizes spontaneously, but it is much less reactive in dilute solution. Accordingly, the production and use of DMAPMA could result in its release to the environment through various waste streams.

Regulatory Status:

No standards or guidelines have been set by the National Institute for Occupational Safety and Health (NIOSH) or the Occupational Safety and Health Administration (OSHA) for occupational exposure to or workplace allowable levels of DMAPMA. DMAPMA is not on the American Conference of Governmental Industrial Hygienists (ACGIH) list of compounds for which recommendations for a threshold limit value (TLV) or biological exposure index (BEI) are made.

No information was found on DMAPMA in a search of regulatory documents from the EPA or FDA.

TOXICOLOGICAL INFORMATION

Human Data:

No epidemiological studies or case reports investigating the association of exposure to DMAPMA and cancer risks in humans were identified in the available literature.

Animal Data:

Acute Studies. Lethal doses of DMAPMA in laboratory animals are listed in Table 2 below.

Table 2. LD₅₀ (mg/kg) Values for DMAPMA

| Species (route) | LD ₅₀ (mg/kg) |
|-----------------|--------------------------|
| Rat (oral) | 3,334 |
| Rabbit (dermal) | 2,355 |

Source: European Commission (2000a)

DMAPMA was irritating to rabbit skin and highly irritating to rabbit eyes (European Commission, 2000a).

Subchronic Studies. The toxicity of DMAPMA when given daily by oral administration to rats for two weeks before mating, during mating, and until the day before sacrifice (at least 4 weeks of treatment for males and day 3 post-partum for females) was examined. Four groups of 10 male and 10 female Sprague Dawley rats received DMAPMA by gavage at 50, 100, 200, or 400 mg/kg/day. A fifth group served as controls (Degussa Corporation, 2002).

No signs of DMAPMA toxicity were noted, and body weight was unaffected. A statistically significant increase in absolute and relative spleen weight was observed in high-dose females with an increase in relative spleen weight noted in 200 mg/kg/day females. A dose-related increase, statistically significant at the highest dose, was observed in relative liver and kidney weights in the males. Unilateral, slight to moderate tubular atrophy in the testes was reported in 3 of 5 high-dose males and a unilateral sperm granuloma and

reduction in sperm were described in 2 high-dose males. The study was conducted in accordance with OECD 422 (Degussa Corporation, 2002).

Carcinogenicity Studies. No 2-year carcinogenicity studies of DMAPMA in animals were identified in the available literature.

Short-term Tests:

A limited number of short-term assays have been conducted using DMAPMA.

- In a cytogenetic assay using V79 Chinese hamster cells without metabolic activation, DMAPMA (98.78% stabilized with 643 ppm hydroquinone monomethylether) at concentrations of 100 :g/ml (18 hr treatment) or 300 :g/ml (28 hr treatment) tested negative. Higher concentrations could not be tested due to toxic effects. With S-9 mix, the OECD guideline 473 maximum recommended concentration of 10 mM was attained, and was also negative (European Commission, 2000a).
- In the mammalian cell gene mutation assay testing the HPRT locus in V79 cells, concentrations of 100-1,700 :g/ml of DMAPMA (98.78% stabilized with 643 ppm hydroquinone monomethylether) were negative both with and without metabolic activation. The test was conducted in accordance with OECD guideline 471 (European Commission, 2000a).
- DMAPMA (98.78% stabilized with 643 ppm hydroquinone monomethylether) tested negative for genotoxicity in *Salmonella typhimurium* TA98, TA100, and TA102, TA1535, and TA1537 at concentrations of 33.3 to 5000 :g/plate with and without metabolic activation. The test was conducted in accordance with OECD guideline 471 (European Commission, 2000a).

Metabolism: No information on DMAPMA metabolism was found in the available literature.

Other Biological Effects: No information on other biological effects was found in the available literature.

Structure/Activity Relationships:

The following chemical was selected for structural similarity to DMAPMA: N-(dimethylaminopropyl)acrylamide; CAS No. 3845-76-9 (ChemID, 2004). Two additional

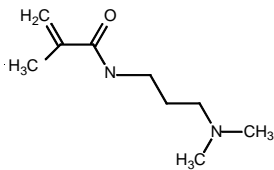
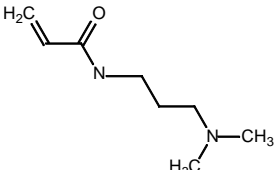
chemicals, methacrylamide (CAS No. 79-39-0) and 3-dimethylaminopropylamine (CAS No. 109-55-7) were considered since they are structural fragments of DMAPMA.

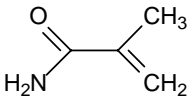
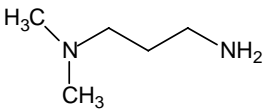
N-(Dimethylaminopropyl)acrylamide is an HPV chemical in the European Union. An IUCLID Dataset on this chemical describes it as negative in the Ames test. The strains of *S. typhimurium* used and the issue of metabolic activation were not addressed in the report (European Commission, 2000b).

N-(Dimethylaminopropyl)acrylamide is covered by the Significant New Use Rule (SNUR) provision of TSCA (EPA, 1991a). In 1991, EPA published findings that (1) this compound (PMN No. P-86-1602) has been shown to cause neurotoxicity in test animals, and (2) similar substances have been shown to cause carcinogenicity, genotoxicity, reproductive toxicity, and developmental toxicity in test animals. Accordingly, EPA recommended the following toxicity testing should the manufacturer increase the production volume: (1) glove permeability, (2) 90 day subchronic toxicity, and (3) dominant lethal assay (EPA, 1991b). No follow up material has been found in the available literature.

Information on the toxicities of structurally related chemicals is presented in Table 3 below.

Table 3. Structure-Activity Analysis of Chemicals Related to DMAPMA

| Chemical/CAS No. | Structure | Toxicity | Reference |
|---|---|--|-----------------------------|
| 3-Dimethylaminopropyl methacrylamide 5205-93-6 |  | Negative for mutagenicity in <i>S. typhimurium</i> and in cytogenetics assays in Chinese hamster V-79 cells | European Commission (2000a) |
| N-(Dimethylaminopropyl) acrylamide 3845-76-9 |  | Described as negative for mutagenicity in <i>S. typhimurium</i> and for clastogenicity in the <i>in vivo</i> micronucleus assay in Sprague-Dawley rats fed 4,069 mg/kg for 16, 48, or 72 hr. | European Commission (2000b) |

| | | | |
|---|---|--|---|
| <p>Methacrylamide 79-39-0</p> |  | <p>Neurotoxicity observed in sub-chronic studies in rats, cats, and mice; morphological changes in nerves sometimes described.</p> <p>In subchronic studies in rabbits, kidney damage observed as well as neurotoxicity.</p> <p>Convulsions and unique neurotoxic effects in dogs in 6.5-14-month oral studies with follow-up to 8 yrs.</p> <p>In a 4, 8, & 12-month study in Wistar rats given 200-1,200 ppm in drinking water, peripheral neuropathy and atrophy of the gastrocnemius muscle detected at highest doses.</p> <p>Not mutagenic in <i>S. typhimurium</i> TA98, TA100, TA1535, TA1537, & TA1538 with & without S-9.</p> <p>Negative in mouse dominant lethal assay.</p> <p>Not a tumor initiator in CD-1 mice gavaged at 25-100 mg/kg 6 times with or without TPA; 28 week post observation period.</p> <p>Lung adenomas in ddY mice given 5 intraperitoneal injections of 200 mg/kg with a 6-month post-observation period.</p> | <p>European Commission (2000c)</p> |
| <p>3-Dimethylaminopropyl amine 109-55-7</p> |  | <p>Not mutagenic in <i>S. typhimurium</i> TA98, TA100, TA1535, TA1537, TA1538, TA1950, and his G46 with and without rat liver S-9.</p> <p>Did not induce micronuclei in mouse bone marrow cells.</p> | <p>Zeiger <i>et al.</i>, 1987, as cited in CCRIS, 2004 OECD, 2004</p> |

In addition to the studies described in Table 3, the reproductive and developmental toxicity of methacrylamide in mice has been examined by the NTP. Using the Continuous Breeding protocol in Swiss CD-1 mice, the NTP determined that methacrylamide at 24-240 ppm

administered in the drinking water for up to 27 weeks was without effect on F₀ body weights, neurotoxicity, or reproduction, and had only transient effects on body weight and grip strength in F₁ mice, with no alterations in their fertility. In a developmental toxicity study of methacrylamide in CD-1 Swiss mice, 60 mg/kg/day as an oral dose was described as the No-Observed-Adverse-Effect Level for both maternal and developmental toxicity. At the highest dose, 180 mg/kg/day, methacrylamide produced mild maternal effects and clear evidence of developmental toxicity because of an increased proportion of nonlive implants per litter (NTP, 1991; NTP, 1992).

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