HSIA
halogenated
solvents
industry
alliance, inc.

February 28, 2012

Dr. Ruth Linn
Director
Office of the Report on Carcinogens
National Toxicology Program
National Institute of Environmental Health Sciences
P.O. Box 12233, MD K2-14
Research Triangle Park, NC 27709

Re: Request for Public Comment on Nominations to the RoC

Dear Dr. Linn:

The Halogenated Solvents Industry Alliance, Inc. (HSIA) offers these comments on substances that have been nominated for review in future editions of the Report on Carcinogens (RoC), 77 Fed. Reg. 2728 (January 19, 2012). HSIA did not nominate 1-bromopropane (n-propyl bromide or nPB) for listing, but we provide below available information on its production, use patterns, and human exposure and scientific issues important for assessing the carcinogenicity of the substance, as requested in the notice.

Use and Production of nPB

NPB is a brominated hydrocarbon with a strong odor. Its chemical formula is C_3H_7Br. NPB is used as a carrier solvent in aerosols and adhesives. Some brand names of products using nPB are: Abzol,® EnSolv,® and Solvon® cleaners; Pow-R-Wash® NR Contact Cleaner, Superkleen Flux Remover 2311, and LPS NoFlash NU Electro Contact Cleaner aerosols; and Whisper Spray and Fire Retardant Soft Seam 6460 adhesives. It also is used to remove wax, oil, and grease from electronics, metal, and other materials.[1] Specific applications include:[2]

[1] 72 Fed. Reg. 30168, 30171 (May 30, 2007).

[2] *Id.*

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Aerosol Solvents. NPB is used as an aerosol solvent in lubricants, coatings, or cleaning fluids for electrical or electronic equipment; lubricants, coatings, or cleaning fluids for aircraft maintenance; and spinnerrette lubricants and cleaning sprays used in the production of synthetic fibers.

Adhesives. NPB is used in adhesives for laminates, flexible foam, hardwood floors, tire patches, and metal to rubber adhesives. Of these applications, nPB-based adhesives have been used most widely in spray adhesives used in manufacture of foam cushions, and to a lesser degree in laminate adhesives.

Electronics, Metal, and Precision Cleaning. NPB is used in open vapor degreasing applications to remove processing lubricants such as oils, greases, and waxes which have been applied to aid manufacture but need to be removed before further processing of the manufactured substance.

Originally, nPB was used as a chemical intermediate in closed processes. It was nominated to the National Toxicology Program (NTP) for testing as a result of its introduction into the emissive applications described above:

> "In the early to mid 1990s, 1-bromopropane was used primarily as an intermediate in the production of pesticides, quaternary ammonium compounds, flavors and fragrances, pharmaceuticals, and other chemicals in well-controlled, closed processes. In the mid to late 1990s, it was introduced as a less toxic replacement for methylene chloride in emissive applications such as vapor and immersion degreasing operations and critical cleaning of electronics and metals. 1-Bromopropane was also introduced as a nonflammable, nontoxic, fast-drying, and inexpensive solvent for adhesive resins, and has been marketed as a replacement for ozone depleting refrigerants. 1-Bromopropane was nominated for study by the Occupational Safety and Health Administration based on the potential for widespread occupational and environmental exposure and a lack of toxicity and carcinogenicity data. Male and female F344/N rats and B6C3F1 mice were exposed to 1-bromopropane (99% or greater pure) by inhalation for 2 weeks, 3 months, or 2 years. Genetic toxicology studies were conducted in Salmonella typhimurium and Escherichia coli and mouse peripheral blood."[3]

As a result of the growing emissive use, global production of nPB was estimated to be 20,000-30,000 metric tonnes in 2007.[4] It is assumed to be produced in China, France, India,

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[3] NTP Technical Report 564, copy enclosed.

[4] Montreal Protocol On Substances that Deplete the Ozone Layer, Report of the UNEP Technology and Economic Assessment Panel (Progress Report, Volume 2, May 2010), 59. http://www.unep.org/ozone/teap/Reports/TEAP_Reports/. Because of its ozone depleting potential, the Parties to the Protocol have sought to limit nPB use to those situations where more economically feasible and environmentally friendly alternatives are not available (Decision XIII/7).

Israel, Japan, Jordan, and the United States. China is estimated to have produced around 20,000 metric tonnes in 2008, of which approximately 40% were exported. Use as a solvent was reported to be growing at a rate of 15-20% per year in the United States (5,000 metric tonnes) and Asian countries other than China. Solvent use in Japan was 1,100 - 1,200 metric tonnes in 2009. No information was available to the United Nations Environment Programme (UNEP) for other regions.[5]

Exposure to nPB

Enclosed is a summary of workplace exposure data for nPB collected by the EPA Significant New Alternatives Policy (SNAP) program from a variety of sources.[6] Given its use across a variety of applications, some of which are uncontrolled, it is not surprising that there is a wide range of exposures in the workplace, from a few parts per million ("ppm") up to 150 ppm or more.

A recently published study of exposure to nPB in New Jersey dry cleaning shops, attached, found exposures as high as 54 ppm.[7] The report states:

> "This study suggested that some green or organic alternative solvents in the dry cleaning industry intended to replace PERC may result in significant exposures above acceptable guidelines among some workers. One dry cleaning worker reported serious adverse health effects resulting in an emergency room visit. Careful consideration and study of potential exposures and health effects among workers using new chemicals or new processes must precede any regulatory attempt to facilitate substitution for environmental purposes."

Carcinogenicity

Perhaps the most significant recent information relevant to the health hazard of nPB is the results of 2-year carcinogenesis studies conducted and reviewed by NTP.[8] The enclosed report shows:

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[5] *Id.* UNEP reports that "Obtaining more complete and accurate data on production and uses of n-PB, as well as its emissions, continues to be difficult. No governmental records are available on emission or uses since n-PB is not classified or registered as a controlled chemical substance like CFCs, and HCFCs (ODS class I and II) nor designated as a hazardous air pollutant in the Clean Air Act in the USA or reportable compound for pollution release (emission) and transfer (PRTR) in Europe and Japan."

[6] EPA-HQ-OAR-2002-0064-0015.

[7] Blando, *et al.*, Preliminary Study of Propyl Exposure among New Jersey Dry Cleaners as a Result of a Pending Ban on Perchloroethylene, J. Air & Waste Manage. Assoc. 60(9): 1049-56 (2010).

[8] NTP Technical Report 564, Publication No 11-5906 (2011).

- Clear evidence of carcinogenicity in female F344 rats (adenomas in large intestine and equivocal evidence for skin tumors)

- Some evidence of carcinogenicity in male F344 rats (adenomas in large intestine, skin tumors, and equivocal findings for mesotheliomas and pancreatic adenomas)

- Clear evidence of carcinogenicity in female B6C3F1 mice (lung tumors)

- No evidence of carcinogenicity in male B6C3F1 mice

At this time, there are no reasons to assume that the mode, or modes, of action by which tumors are induced by nPB are not relevant to man and thus a linear, no-threshold dose-response relationship should be assumed. Using standard methodology for the calculation of cancer potency and risk estimation (the linearized multistage model) applied to the incidence of mouse lung tumors yields a q_1^* term. This value is the 95% confidence limit of the linear term resulting from the model. The cancer potency term for mouse lung tumors from the NTP bioassay is a risk of 1.95×10^{-3} per ppm (lifetime exposure). This potency value indicates that a lifetime risk of 1 in 1 million is potentially associated with an exposure of 0.5 ppb or 2.5 $\mu g/m^3$.

Exposure Recommendations

The American Conference of Governmental Industrial Hygienists (ACGIH) recommends Threshold Limit Values (TLVs®) for workplace exposure to many compounds. TLVs® refer to airborne concentrations of chemical substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed, day after day, over a working lifetime, without adverse health effects. The TLV® for nPB is 10 ppm as an 8-hour time-weighted average (TWA).

The current TLV® was set without regard to the recently reported NTP cancer bioassay results. The Notice of Intended Changes for 2012 recently published by ACGIH would dramatically lower the TLV® to 0.1 ppm and provides an A3 carcinogenicity classification. The documentation for this intended change is available from ACGIH for a nominal charge.

Very truly yours,

[Redacted]

Faye Graul
Executive Director

Enclosures