National Tribal Toxics Council

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Irina Myers
USEPA Office of Pollution Prevention and Toxics (OPPT)
1200 Pennsylvania Avenue, NW
Mail Code: 7408M
Washington, DC 20460

RE: Proposed Rulemaking under the Toxic Substances Control Act for 1) Methylene Chloride and n-Methylpyrrolidone in Paint Removers and 2) Trichloroethylene in Certain Uses

Dear Ms. Myers,

Thank you for your continued support of the National Toxics Council's (NTTC) role in the Office of Pollution Prevention and Toxics (OPPT) programs on issues related to chemical safety, toxic chemicals, and pollution prevention. Among the key issues that the NTTC is focusing on are ways to reduce tribal exposure to toxic chemicals in Indian Country.

The NTTC appreciates the opportunity to participate in the recent Consultation and Coordination on the Proposed Rulemaking process for methylene chloride and n-methylpyrrolidone (NMP) in paint removers and trichloroethylene (TCE) in certain uses. Among the numerous areas of concern with these chemicals, the Council's priorities are the protection of tribal water resources, subsistence foods, and traditions. Addressed with supporting materials in the attached summary document, the NTTC recommends EPA's regulatory option 6(a)(1) under the Toxics Substance Control Act to prohibit the manufacture of methylene chloride and NMP in paint removers as described in EPA's Notification of Consultation and Coordination.[1] NTTC also recommends that EPA implement regulations on TCE that are no less stringent than the European Union's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals sunset on all uses of TCE after April 2016 without authorization (on closed systems only). The recommendations presented here are based on numerous examples of methylene chloride, NMP, and TCE having high volatility, easily transported through soil, groundwater, and air, and vapor intrusive when used in volume. Therefore, spills can generate vapor over years and affect entire communities depending on the environmental factors involved.

Sincerely,

Dianne C. Barton, National Tribal Toxics Council Chair

Note: The Members of the Council are offering their opinions on toxics issues and do not speak for individual tribes

The following recommendations are supported with the summaries presented below for each chemical:

> **Recommendation:** Methylene Chloride should be banned from all consumer products due to potential for serious health effects and availability of replacement products which are safer.
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> **Recommendation:** NMP should be banned from all consumer products due to the fetal effects on rats and rabbits in recent studies and the availability of a safer alternative. It is currently under consideration for such a ban by the World Health Organization as a result of their research.
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> **Recommendation:** EPA implement regulations on TCE that are no less stringent than the European Union's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals sunset on all uses of TCE after April 2016 without authorization (on closed systems only). The environmental exposure risk in addition to the use exposure risk far outweighs any beneficial use that may be claimed.

Methylene Chloride:

Recommendation: Methylene Chloride should be banned from all consumer products due to potential for serious health effects and availability of replacement products which are safer.

Numerous poisonings and deaths have been reported over several decades among workers and consumers using furniture strippers or other products containing methylene chloride in unventilated areas. Easily inhaled, methylene chloride converts to carbon monoxide once inside the body—making it especially dangerous for people with heart or lung disease, and pregnant women. Methylene chloride is used in many industrial and consumer applications; it does not occur naturally in the environment. The U.S. Department of Health and Human Services Household Products database lists 27 consumer products containing methylene chloride, most with concentrations greater than 50 percent. These include automotive cleaners, adhesive removers, paint strippers and graffiti removers.

Methylene chloride is toxic and can cause death. It can irritate the nose and throat and harm the nervous system. Symptoms may include headache, nausea, dizziness, drowsiness and confusion. Methylene chloride forms carbon monoxide in the body and can harm the blood (decreased ability to carry oxygen).

The effects of methylene chloride have not been studied in children, but they would likely experience the same health effects seen in adults exposed to the chemical. It is also not known if the way in which methylene chloride is absorbed, metabolized, and eliminated from the body is different in children than it is in adults. Therefore, adverse effects noted in animals and adult humans might also occur in children.[2]

Fortunately, there are readily available, safer alternatives. Water-based adhesives and cleaners can be substituted for products that contain methylene chloride. And soy-based strippers, mechanical methods, and benzyl alcohol are safer substitutes for methylene chloride-based paint strippers.[3] Replacement products such as n-Propyl bromide based solvent have proven to be a practical and effective replacement for methylene chloride in vapor degreasing, ultrasonic cleaning, cold immersion, wipe, carrier, deposition, and flush applications.

n-Methylpyrrolidone:

Recommendation: NMP should be banned from consumer products due to the fetal effects on rats and rabbits in recent studies and the availability of a safer alternative. It is currently under consideration for such a ban by the World Health Organization as a result of their research.

The World Health Organization has studied this chemical and indicates no identified safe level of this chemical in products and is investigating a ban on it. A number of studies that are not available in the open literature and

therefore are not usable as a basis for risk assessment in the Concise International Chemical Assessment Documents are reported below as supporting data for the developmental effects of NMP.[4]

N-Methyl-2-pyrrolidone (NMP) (CAS No. 872-50-4) is a water-miscible organic solvent. It is a hygroscopic colorless liquid with a mild amine odor. NMP is used in the petrochemical industry, in the microelectronics fabrication industry, and in the manufacture of various compounds, including pigments, cosmetics, drugs, insecticides, herbicides, and fungicides. An increasing use of NMP is as a substitute for chlorinated hydrocarbons. NMP is volatile, widely used as a solvent, and may enter the environment as emissions to the atmosphere, as the substance or it may be released to water as a component of municipal and industrial wastewaters. The substance is mobile in soil, and leaching from landfills is thus a possible route of contamination of groundwater.

In a multi-generation reproduction study, rats were exposed in the diet to NMP at doses of 50, 160, or500 mg/kg body weight per day. The first parental generation (P1) was exposed during a period prior to mating, gestation, lactation, and weaning of the litter (F1a) and during a period prior to a second mating, gestation, lactation, and weaning of the litter (F1b). The second parental generation (P2 = F1b) was exposed from day 21 postpartum as the P1 generation until the first litter (F2a) and the second litter (F2b) were delivered. The highest dose level caused decreased parental body weight and food consumption and a concomitant reduction in survival and growth rates in the offspring. The data from the 50 and 160 mg/kg body weight per day experiments with slightly lower male fertility and female fecundity indices do not clearly demonstrate a NOAEL (EXXON, 1991).

In a pre-test of developmental toxicity, five pregnant rabbits per dose level were exposed to 0, 300, 1000,or 2000 mg NMP/m3 (vapour/aerosol; MMAD 3.8–4.0 µm) for 6 h/day on days 7–19 post-insemination. Maternal toxicity was expressed as prolonged clotting time, decreased plasma protein content, and increased liver weight at both 1000 and 2000 mg/m3. In the main study, pregnant rabbits (15 per dose level) exposed head only for 6 h/day to 0, 200, 500, or 1000 mg NMP/m3 (vapour/aerosol; MMAD 2.7–3.5 µm) on days 7–19 post insemination showed no signs of maternal toxicity. At 1000 mg/m3, a slight fetal toxicity was seen as increased occurrence of skeletal variations (accessory 13th ribs) (BASF, 1993b).

The two studies show NOAELs for developmental and maternal toxicity of 500 mg/m3 (BASF, 1991). In a developmental study, pregnant rats (25 per dose level) were given daily NMP doses of 0, 40, 125, or400 mg/kg body weight by oral gavage on days 6–15 of gestation. Maternal and fetal toxicity were observed at the highest dose level compared with controls. The toxicity was indicated as maternal body weight gain decrement, reduced fetal body weights, and increased incidence of fetal stunting at 400 mg/kg body weight (EXXON, 1992).

In another developmental toxicity study (GAF, 1992), orally administered doses of 55, 175, or 540 mg NMP/kg body weight per day in pregnant rabbits (20 per dose level) on days 6–18 of gestation caused maternally decreased body weight gain at 175 and 540 mg/kg body weight per day. Developmental toxicity was shown as post-implantation loss, altered fetal morphology, and increased incidences of cardiovascular and skull malformations at 540 mg/kg body weight per day. An oral daily dose of 997 mg NMP/kg body weight administered to rats by gavage on days 6–15 of gestation showed no maternal toxicity but increased the incidence of resorptions (95%) and caused malformations in 8 out of 15 surviving fetuses. Other adverse effects observed were fetal mortality, reduced placental and fetal weights, and reduced fetal lengths. No adverse effect was observed at 332 mg NMP/kg body weight, but a minor decrease in placental weight was observed. Reported maternal toxicity data were unsatisfactory (US EPA, 1988).

Oral daily doses of 0, 1055, or 2637 mg/kg body weight on days 11–15 of gestation in mice caused an increase in resorption rate, increased incidence of runts, diminished fetal weight and length, and an increased rate of malformations such as cleft palate at the higher dose level. The lower dose level caused no observable embryo toxicity. Both developmental and maternal toxicity are insufficiently reported, and the exposure covers only a part of organogenesis (US EPA, 1988).

The maternal toxicity in rabbits after dermal application was studied in a range-finding study. Pregnant rabbits (15 per dose level) were exposed daily to dermal doses of 0, (as 40% aqueous solution). There was maternal toxicity, expressed as prolonged clotting time at 800 mg/kg bodyweight (BASF, 1993a).

DMSO is equally as effective as and considerably safer to use than NMP. Regardless of exposure type, DMSO has favorable safety data to support its use as a replacement for NMP, which has significant risk for pregnant females.

Trichloroethylene:

Recommendation: EPA implement regulations on TCE that are no less stringent than the European Union's Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals sunset on all uses of TCE after April 2016 without authorization (on closed systems only). The environmental exposure risk in addition to the use exposure risk far outweighs any beneficial use that may be claimed.

Based upon the current knowledge of TCE and its effects upon human health and the environment there is no justifiable reason to allow its continued use in products. TCE is so dangerous to consumer use that it should be totally banned in products. The mere fact that the OSHA requirements require external air respirators while using TCE indicates that it is a very high risk of inhalation poisoning. Its value in commercial solvents is outweighed by its environmental impacts. There are over 900 superfund sites that list TCE as a chemical of concern in the cleanups. Once in the groundwater, TCE is very difficult and expensive to remove, leaving the water unusable.

TCE has an effective and safer alternative, TCE Replacement, http://www.relspec.com/solutions/trichloroethylene-replacement.htm, last accessed June 9, 2015.

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[1] http://tcots.epa.gov/oita/tconsultation.nsf/ByUNID/9D6F3DC087B9B49885257E280067B7B9/$File/Notification+Letter+with+fact+sheet+Sec6.pdf?OpenElement last accessed June 8, 2015.

[2] Agency for Toxic Substances and Disease Registry (ATSDR). 2000. Toxicological profile for Methylene Chloride. Atlanta, GA: U.S. Department of Health and Human Services, Public Health Service.

[3] Methylene Chloride | Safer Chemicals Healthy Families *http://saferchemicals.org/get-the-facts/chemicals-of-concern/congress-must-expand-protections-against-widely-used-harmful-chemicals-methylene-chloride/* last accessed June 8, 2015.

[4] http://www.who.int/ipcs/publications/cicad/en/cicad35.pdf last accessed June 9, 2015.