

Consultation Plan: Proposed Rulemaking Under TSCA Section 6(a) for N-Methylpyrrolidone and Methylene Chloride

Background Information on this Initiative

The EPA is developing proposed regulations under Section 6(a) of the Toxic Substances Control Act (TSCA) for methylene chloride and n-methylpyrrolidone (NMP) when used in paint or coating removal products.

The EPA identified and chose these chemicals for risk evaluation as part of EPA's TSCA Work Plan for Chemical Assessment. Developmental toxicity effects are associated with certain uses of NMP. Methylene chloride is a volatile compound that is classified as a human carcinogen. NMP and methylene chloride are used in commercial processes and in consumer products in residential settings.

Section 6(a) of TSCA provides authority for EPA to address risks resulting from the manufacture (including import), processing, distribution in commerce, use, and disposal of chemicals. Specifically, the EPA will determine whether the continued use of NMP and methylene chloride in paint and coating removers presents or will present an unreasonable risk to human health and the environment. During this rulemaking, the EPA will consider several approaches under TSCA Section 6(a) to determine which option(s) will be the least burdensome and still adequately address the risks associated with NMP and methylene chloride in paint removers used commercially and by consumers.

1. Background on Methylene Chloride and NMP

Methylene chloride is a volatile, colorless liquid with a sweet odor. It has a low boiling point, is non-flammable, non-explosive, and non-corrosive to most materials. It has been the subject of regulations by the EPA, the Occupational Safety and Health Administration, the Consumer Product Safety Commission, and the European Commission. Methylene chloride is used in paint removers, adhesives, metal cleaning, chemical processors, polyurethane foam, and pharmaceuticals.

NMP is a mildly volatile, colorless liquid. It is subject to regulations by the EPA as an inert ingredient in some pesticides, and currently is on the candidate list of substances of very high concern for authorization in the European Commission. In paint removers, it is often used instead of the more volatile methylene chloride. NMP is also used in petrochemical processing, engineering plastics, coatings, electronic cleaning, and agricultural chemicals.

The EPA's final risk assessments for NMP (released in March 2015)¹ and methylene chloride (released in August 2014)² evaluated human health risks to consumers and workers, including

¹ NMP final risk assessment http://www.epa.gov/oppt/existingchemicals/pubs/nmp_ra_3_23_15_final.pdf

² Methylene chloride final risk assessment: http://www.epa.gov/oppt/existingchemicals/pubs/TSCA_Workplan_Chemical_Risk_Assessment_of_DCM.pdf

bystanders, from exposures to these chemicals when used in a variety of paint removal scenarios. Table 1 below summarizes the findings of these two risk assessments.

Table 1: Summary of Risk Assessments

Chemical in Paint Removers	NMP	Methylene Chloride
Exposure	Exposure through dermal, vapor-through-skin, and inhalation	Exposure through inhalation
Acute effects and risks	Acute effects: Fetal mortality (developmental effects). Concern is for women of child-bearing age	Acute effects: Confusion, incapacitation, and death
	Acute risks if used on a single day, for 8 hours, with or without gloves or for 4 hours without gloves	Acute risks in most exposure scenarios including when respiratory protection is worn
Chronic effects and risks	Chronic effects: Reduced fetal body weight (developmental effects). Concern is for women of child-bearing age.	Chronic effects: Cancer and liver toxicity
	Chronic risks if used for more than 5 consecutive days, 8 hours per day, with or without gloves or 4 hours per day, without gloves	Risks from chronic (lifetime) exposure in all except lowest exposure levels and PPE is worn
Bystander risk	No risks to bystanders	Risks to bystanders except in lowest-exposure scenarios

2. Reason for This Action

The EPA’s final risk assessments on NMP and methylene chloride when used in paint removers found the risks described earlier. EPA is undertaking various regulatory and voluntary actions, including this action under TSCA Section 6(a), to adequately protect against these risks.

The EPA’s rationale for this rulemaking includes an assessment of the risks to human health, the availability of substitutes for these chemicals, and a need for regulation.

- Risks to human health:** The EPA’s risk assessments found acute and chronic risks when paint removal products containing these chemicals are used in consumer and occupational scenarios. These risks are not theoretical; as cited in the risk assessment for methylene chloride, more than 13 deaths since 2000 have been caused by paint removers containing methylene chloride when used for bathtub refinishing³. Regarding NMP, in addition to the animal studies cited in the risk assessment, Solomon et al. (1996) presents a case report of a pregnant woman whose fetus died in utero at week 31 of pregnancy. She was exposed throughout pregnancy to NMP by inhalation and dermal exposure; during week 16 of the pregnancy she cleaned up a spill of NMP using latex gloves that dissolved in the NMP. She was ill for the next 4 days and experienced malaise, headache,

³ CDC 2012. Centers for Disease Control and Prevention. “Fatal Exposure to Methylene Chloride Among Bathtub Refinishers — United States, 2000–2011” Morbidity and Mortality Weekly Report. February 24, 2012. 61(07); 119 – 122. http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6107a2.htm?s_cid=mm6107a2_w

nausea and vomiting. This case-report is well-documented, ruled out reasonable complicating factors and provides some evidence that NMP may be fetotoxic⁴.

- **Availability of substitutes:** The EPA’s research to date indicates that effective and economically feasible substitute products for paint removers containing methylene chloride or NMP are currently available. Though methylene chloride and NMP may have in the past been the preferred methods of removing paint or other coatings, there currently are practical alternative products for all situations in which a paint remover containing methylene chloride or NMP is used.
- **Need for regulation:** Despite widespread acknowledgement of the hazards of methylene chloride in paint stripping products, consumers and businesses continue to use products containing these chemicals. Recent fatalities and injuries following exposure to paint strippers containing this chemical highlight the inability of warnings, existing worker protection regulations, and most personal protective equipment to reduce risks to human health from this use of methylene chloride. Though less widely used and presenting a different toxicological hazard, paint stripping products containing NMP also present the public with significant health risks. Effectively marketed as “biodegradable” and “low VOC”, individual and consumer users of these products are not likely to realize the potential hazards nor the need for specialized personal protection when using these products.

4. The Proposed Regulation

Uses being considered for regulation under TSCA Section 6(a) are commercial and consumer uses of paint removal products that contain methylene chloride or NMP. The EPA is currently in the early stages of the rulemaking process, and interested in receiving information from Tribes to inform the development of regulatory options.

Table 2 below summarizes regulatory options available under TSCA Section 6(a).

⁴ Solomon et al. 1996.

Table 2: Options under TSCA Section 6(a)

TSCA Section	Option	Summary
6(a)(1)	A requirement (A) prohibiting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.	Prohibit or limit manufacture
6(a)(2)	A requirement (A) prohibiting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.	Prohibit or limit for particular use or above a set concentration
6(a)(3)	A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such warnings and instructions shall be prescribed by the Administrator.	Require warnings and instructions
6(a)(4)	A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture and monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.	Require recordkeeping and testing
6(a)(5)	A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.	Prohibit or regulate manner or method of commercial use
6(a)(6)	(A) A requirement prohibiting or otherwise regulating any manner or method of disposal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes. ⁵	Prohibit or regulate manner or method of disposal
6(a)(7)	A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such unreasonable risk of injury to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such risk of injury, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.	Direct manufacturers/processors to give notice of risk and replace or repurchase

⁵ A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

Potential Impact to Tribes

The EPA recognizes that decisions concerning TSCA Section 6(a) regulations have consequences for Tribes. Tribes may be affected to the extent that tribal populations are exposed to methylene chloride or NMP when using paint removers occupationally or as part of do-it-yourself projects and repairs, or when they are used in residences as part of renovation projects. Additionally, businesses in Indian Country using these products may be affected by any finalized regulations under TSCA Section 6(a).

In addition to general comments, EPA requests input on any disproportionate public health or economic impacts that methylene chloride and NMP used in paint removers may have on tribal populations.

Opportunity for Tribes to Participate

The tribal consultation process establishes a timeline for government-to-government consultation and coordination. After the conclusion of the tribal consultation process, tribes may also participate in any public review and comment process.

Tribes may access related consultation information on the EPA Tribal Portal under Tribal Consultation Opportunities, located at: yosemite.epa.gov/oita/TConsultation.nsf/TC?OpenView.

More information on methylene chloride and NMP is located at: www.epa.gov/iaq/formalde.html.

The combined goal of all these efforts is to ensure there is sufficient information for tribal officials to make an informed decision about the desire to continue with consultation and to understand how to provide informed input.

Additional Information

CDC 2012. Centers for Disease Control and Prevention. “Fatal Exposure to Methylene Chloride Among Bathtub Refinishers — United States, 2000–2011” *Morbidity and Mortality Weekly Report*. February 24, 2012. 61(07); 119 – 122.

http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6107a2.htm?s_cid=mm6107a2_w

CPSC 2013. U.S. Consumer Product Safety Commission. *What You Should Know About Using Paint Strippers*. April 20, 2013.

<http://www.cpsc.gov/Global/Safety%20Education/Home-Appliances-Maintenance-Structure/423%20Paint%20Stripper%20Publication.pdf>

NIOSH Hazard alert

https://www.osha.gov/dts/hazardalerts/methylene_chloride_hazard_alert.html

US EPA Methylene chloride final risk assessment

http://www.epa.gov/oppt/existingchemicals/pubs/DCM_OPPTWorkplanRA_final%208_26_14.pdf

US EPA NMP final risk assessment

http://www.epa.gov/oppt/existingchemicals/pubs/nmp_ra_3_23_15_final.pdf