



**B&C CONSORTIA
MANAGEMENT**

NMP Producers Group Meeting with the Office of Management and Budget

Washington, D.C.
December 5, 2016

Kathleen M. Roberts
B&C Consortiumia Management
Washington, D.C.
www.bc-cm.com

Lynn L. Bergeson
Bergeson & Campbell, P.C.
Washington, D.C.
www.lawbc.com

N-Methylpyrrolidone Producers Group, Inc.

- **The N-Methylpyrrolidone (NMP) Producers Group, Inc. includes domestic manufacturers of NMP**
 - **Member companies are BASF Corporation, Lyondell Chemical Company, and Ashland Inc.**
- **The Group promotes the responsible use of NMP and NMP derivatives through research, product stewardship, and advocacy efforts**
- **NMP is used as an intermediate or a solvent in electronics, agricultural chemical, pharmaceutical, coating, petrochemical processing, and industrial and consumer cleaner sectors**

NMP Producers Group's Concern

- **Proposed Toxic Substances Control Act (TSCA) Section 6 rulemaking is not consistent with March 2015 final NMP risk assessment**
 - **U.S. Environmental Protection Agency (EPA) concluded staff has stated the proposed Section 6 actions will be based on “supplemental risk assessment analyses”**
- **This approach conflicts with amended TSCA Section 26(l)(4)**


TSCA Section 26(l)(4)

- With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments *for which the Administrator has published a completed risk assessment prior to June 22, 2016*, the Administrator may publish *proposed and final rules under section 2605(a) of this title that are consistent with the scope of the completed risk assessment* for the chemical substance and consistent with other applicable requirements of section 2605 of this title (***emphasis added***)

NMP Risk Assessment -- Prior to Enactment

■ Published in March 2015

➤ 15 months prior to enactment of Lautenberg



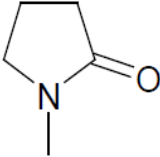
United States
Environmental Protection Agency

EPA Document# 740-R1-5002
March 2015
Office of Chemical Safety and
Pollution Prevention

TSCA Work Plan Chemical Risk Assessment

N-Methylpyrrolidone:
Paint Stripper Use

CASRN: 872-50-4



March 2015

Scope of Completed March 2015 NMP Risk Assessment

- **Paint stripping applications**
 - **Occupational -- acute exposure**
 - **Occupational -- chronic exposure**
 - **Occupational -- other workers that may be nearby**
 - **Consumer -- acute exposure**
 - **Consumer -- other residents that may be nearby**
- **Scope did not include chronic exposures to consumers**

Scope of Completed NMP Risk Assessment

■ 1.2.2 Scope of the Assessment (page 23 of 281)

This assessment also examined consumer exposures to NMP-based paint strippers in consumer use scenarios. EPA/OPPT also evaluated exposures to other residents who did not use the product, but may be indirectly exposed in the home while located nearby while the product is being used (i.e., nearby residents). The consumer exposures were assumed to be of short duration (acute), based on a single project (e.g., strip paint off of a coffee table, chest of drawers or bathtub) and that NMP is readily eliminated from the body, mainly by extensive metabolism and rapid excretion in the urine (Akesson and Paulsson, 1997; Jonsson and Akesson, 2003; Payan, 2002).

NMP Risk Assessment Conclusions for Consumer Use

- **Margin of Exposure (MOE) estimates calculated for acute exposure consumer scenarios**
- **Presence of risk was defined as MOE < benchmark of 30**
 - **All consumer scenarios except one yield MOE > 30**
 - **One scenario, designed as upper bound exposure, yielded MOE of 29.5**
 - **EPA states 29.5 MOE to be equivalent to 30**
- **EPA found all consumer applications low or no risk (at or above the MOE of 30 threshold for risk)**

NMP Risk Assessment Conclusions for Consumer Use

■ 4.1.2 Risk Estimates for Acute Consumer Exposure to NMP (page 87 of 281)

The results of the risk calculations for all exposure scenarios indicates that one scenario in particular, brush application on a bathtub, in a bathroom, upper-end parameters, with higher air saturation and in the absence of gloves, yields an MOE of 29.5 for woman of childbearing age. EPA/OPPT considers this value to be equivalent to the benchmark MOE of 30, indicating low risk. EPA/OPPT designed this scenario to represent an upper bound exposure scenario based on assumptions from a reported fatality using a DCM-based paint stripper and is thus considered an upper bounding estimate of exposure for surface area treated (and hence mass of product used), volume of room of use and ventilation rate for both the room of use and the entire house. The shape of the bathtub contributed to the production of a “source cloud”, consisting of higher NMP concentrations above the tub. These factors combined to result in the highest airborne concentrations of NMP in the room of use. The only difference between the two scenarios, 4 and 5, is the choice of saturation concentration for the NMP, with the higher saturation concentration leading to larger exposures. The brush on product was used in the bathroom scenario because it was the only product that had measured emission rates (there are no measured emission data for NMP spray products), it is also possible that dermal exposure would be more likely from a brush on product.

EPA Statements in Conflict with Consumer Findings

- **The March 2015 final NMP risk assessment did not identify risk with consumer use scenarios evaluated**
- **In contrast, EPA stated in presentations from March and June 2016 small business consultations that:**
 - **NMP risk assessment showed risks were identified for a number of worker and consumer exposure scenarios; and**
 - **Section 6 risk management needed to reduce risks to workers and consumers**

EPA “Supplemental” Risk Assessment

- **In late June 2016, EPA informed the NMP Producers Group that the “supplemental” risk assessment showed potential consumer risk**
- **The supplemental risk assessment cannot be viewed as “completed” per TSCA Section 26(l)(4) because it:**
 - **Is not posted on EPA’s website or in EPA’s docket**
 - **Was not subject to:**
 - **Public review and comment**
 - **Small business review**
 - **Peer review process**

EPA “Supplemental” Risk Assessment (cont’d)

- **No publicly available information on consumer scenarios that warrant Section 6 action**
 - **EPA had worst-case acute exposure in initial March 2015 risk assessment**
 - **If supplemental risk assessment includes consumer chronic exposure, it is not consistent with the initial scope**

NMP Section 6 Proposed Rulemaking Must Be Consistent with NMP Risk Assessment

- **Scope of completed NMP risk assessment for consumer applications = acute exposures**
- **Finding of completed NMP risk assessment = no risk identified for consumer applications**
- **Proposed Section 6 rulemaking should not include actions related to potential consumer risk**
 - **If it does, the Office of Management and Budget must direct EPA**
 - **To withdraw the proposed Section 6 rulemaking and**
 - **Issue an updated NMP risk assessment for public review and comment**

Thank You

Kathleen M. Roberts
Manager
NMP Producers Group, Inc.
B&C Consortia Management, L.L.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037
[kroberts@bc-cm.com](mailto: kroberts@bc-cm.com)

Lynn L. Bergeson
BERGESON & CAMPBELL, P.C.
2200 Pennsylvania Avenue, N.W.
Suite 100W
Washington, D.C. 20037
[lbergeson@lawbc.com](mailto: lbergeson@lawbc.com)