NMP

N-METHYLPYRROLIDONE PRODUCERS GROUP, INC.

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N-METHYL 2-PYRROLIDONE (NMP)
CONSIDERATIONS AGAINST USE IN COSMETICS, TOILETRIES, AND PERSONAL CARE PRODUCTS

NMP is a liquid under normal environmental conditions and is used in a wide range of industries because of its excellent solvent properties, its low vapor pressure, and its rapid degradation in the environment. Examples of products formulated with NMP include auto fuel system cleaners, paint removers, floor cleaners, and pesticides.

NMP is readily absorbed across all body surfaces. Due to its low vapor pressure, however, absorption through the skin represents the most likely and potentially the most significant route of exposure to NMP under most known consumer use conditions. This is particularly true with the use of NMP in cosmetics, toiletries, and other personal care products.[1] Consequently, the member companies of the NMP Producers Group have independently developed policies regarding the use of NMP in personal care products. NMP manufacturers should be consulted before considering such an application.

NMP has low acute toxicity and is potentially irritating to the skin and eyes. Exposure to high aerosol concentrations, but not NMP vapors, can cause respiratory tract irritation. NMP is negative in both *in vitro* and *in vivo* genotoxicity tests. Lifetime oral and inhalation exposures of rats to NMP did not result in an increased incidence of cancer. Lifetime oral exposures of mice to NMP resulted in an increased incidence of liver tumors, but only at the highest dose tested. These results are not considered biologically relevant to human exposures given the negative genotoxicity results in other test systems and the high doses (approaching lethal levels) required to produce effects in mice. NMP does not pose a reproductive hazard. Although some signs of systemic toxicity can be seen in chronic and multi-generation reproduction studies at relatively high doses, reproductive performance and reproductive organ histopathology are not affected.

The most sensitive health-related endpoint associated with NMP exposures in experimental animals is developmental toxicity (*e.g.,* decrements in fetal body weight) with oral exposures resulting in greater toxicity than comparable exposures via dermal contact. While whole body inhalation studies have also caused developmental effects in rodents, these effects occur only at NMP vapor concentrations approaching saturation and in the presence of maternal toxicity. Based on these developmental findings, various regulatory bodies have placed some restrictions on the commercial use of NMP.

In the European Union (EU), regulatory authorities have recently agreed to classify NMP as a Category 2 developmental toxicant. Once this classification is ratified, current EU legislation will preclude the intentional

[1] Cosmetics, toiletries, and personal care products are broadly defined to include those which are deliberately applied to the body but to exclude pharmaceuticals.

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addition of NMP to cosmetics at any level. In addition, the general public will be prohibited from using non-cosmetic products containing ≥5% NMP. Professionals will be able to use products containing ≥5% NMP, but their use will be subject to new requirements, including recordkeeping, worker protection precautions, as well as "marketing and use" regulations.

In addition, the California Office of Environmental Health Hazard Assessment identified NMP as a reproductive toxin for the developmental toxicity endpoint under Proposition 65 and established maximum allowable dose levels (MADLs) for NMP of 17,000 μg/day for dermal contact and 3,200 μg/day for inhalation exposures. Products that result in daily exposures exceeding these MADLs must carry an appropriate label under California law.

This information statement has been prepared by the NMP Producers Group. The Group was formed to promote the safe use of NMP and NMP derivatives through research, product stewardship, and outreach efforts within the framework of responsible chemical management. For more information, please contact the NMP Producers Group at the address above.