The Netherlands prepared a restriction report on manufacturing and industrial and professional uses of 1-methyl-2-pyrrolidone [1]

SUMMARY

The Dutch Member State Competent Authority has submitted a report proposing a restriction of the manufacturing and use of 1-methyl-2-pyrrolidone (N-methylpyrrolidone, NMP), unless the 8-hours average exposure of the workers (TWA) is below 5 mg/m^3, the 15-minutes peak exposure remains under 10 mg/m^3, and preventive measures are used for skin protection.

The substance is mainly used as a solvent and cleaning agent. It is used in a variety of industries, including petrochemical, agricultural, pharmaceutical, electronics and textile industries. The applications include use as a fuctional fluid, in wire- and non-wire coating, and as a cleaning agent.

1-methyl-2-pyrrolidone is classified as a category 1B reprotoxic substance. It also causes eye and skin iritation, and may cause irritation of the respiratory tract. The dossier submitter demonstrates that workers exposed to NMP in industrial and professional settings may be exposed above safe levels, i.e. the risks from exposure to the substance in these population groups are not adequately controlled. The focus of the restriction proposal is on the prenatal developmental toxicity, which is the potential effect of the substance on pregnant women and their unborn children.

It is estimated that, considering the potential health benefits of the proposed restriction, the costs related to its implementation are proportionate.

ECHA today starts the public consultation on the restriction report, which will end on 18 March 2014. However, ECHA encourages interested parties to provide their comments by 29 November 2013, to assist in the first discussion of the restriction proposal in committees meetings in December 2013.

SUGGESTED RESTRICTION

The Netherlands have submitted an Annex XV report proposing to restrict manufacture and use of 1-methyl-2-pyrrolidone (N-methylpyrrolidone, NMP).

In the report, it is proposed that: *1-methyl-2-pyrrolidone shall not be manufactured and used by professional or industrial worker, unless:*

- *the 8-hour TWA exposure will remain below 5 mg/m^3 and the 15 min peak exposure remains below 10 mg/m^3.*

and

- *dermal exposure is avoided by preventative measures.*

[1] The information note has been prepared on the basis of the Annex XV report prepared by the Netherlands.

The dossier submitter has proposed that the restriction should apply 60 months after the amendment of the REACH Annex XVII comes into force.

1-METHYL-2-PYRROLIDONE IN INDUSTRIAL AND PROFESSIONAL USES

1-methyl-2-pyrrolidone is manufactured in Europe in quantities over 18,000 tonnes per year. In addition, it is estimated that around 50% of the total tonnage used is imported into the EU as a pure substance or in a mixture. The use of the substance has decreased in recent years, particularly due to regulatory concerns following its classification as a reproductive toxicant 1B in 2010.

The substance is used as a solvent in various processes, in a wide variety of applications in industrial and professional settings. NMP may also be present in some consumer products. The uses can be described as: use in industrial chemical processes, charging and discharging of substances and mixtures, formulation of preparations, manufacturing of polymers, use in laboratories, use in construction chemicals, coating, cleaning agents, functional fluids, and agrochemicals. In industrial settings, NMP may be used under elevated temperatures up to 180 °C.

REASONS FOR ACTION

1-methyl-2-pyrrolidone is classified as a category 1B reprotoxic substance. It also causes eye and skin irritation, and may cause irritation of the respiratory tract. The dossier demonstrates that workers exposed to NMP in industrial and professional settings are exposed above safe levels, i.e. the risks from the substance in these population groups are not adequately controlled.

The developmental effects of exposure to NMP have mainly been investigated in animal studies. In humans decreased foetal growth and one case of stillbirth have been linked to NMP exposure. However, on the basis of available data it is not possible to estimate the health impact on the currently exposed population in a quantitative manner.

CONSEQUENCES OF THE ACTION

The Dossier submitter has assessed that the proposed restriction would result in a reduction of the health risks associated with the exposure to NMP of pregnant workers in industrial and professional settings. The proposed exposure limit would be particularly important in the reduction of risks of developmental effects occurring in those cases where early pregnancy is not known and/or has not been disclosed to the employer.

Alternative substances are available for some uses. Some of these substances are considered safer in relation to human health, whilst some have similar hazard profiles.

The costs to society from implementation of the restriction have been estimated. While the costs related to the implementation of the proposed restriction could be significant, they are nevertheless considered to be proportionate as implementation of the proposal would potentially lead to significant risk reduction.

COMMENTS PREFERABLY BY 29TH NOVEMBER

PUBLIC CONSULTATION

The opinion forming process of the ECHA Committees for Risk Assessment (RAC) and Socio-economic Analysis (SEAC) starts with a public consultation on 18 September 2013. Interested parties can comment on the proposal and the restriction report using the ECHA website. Although the public consultation concludes on 18 March 2014, the rapporteurs of RAC and SEAC would appreciate receiving comments by 29 November 2013 to assist them in the detailed discussion of the restriction proposal in December 2013.

The final opinions of both Committees are scheduled to be available by September 2014. ECHA will send these two opinions to the European Commission, which will take the decision whether to include the new restriction in Annex XVII of the REACH Regulation.

Please note that the public consultation process related to the proposal to change the harmonised classification of the substance is also in progress until 11 October 2013.