EuPIA information note for members

N-vinyl caprolactam

Recent communications from registrants, in particular the lead registrant, have advised users of a change in the Derived No Effect Level (DNEL) and the classification and labelling of N-vinyl caprolactam (NVC), CAS No. [2235-00-9]. EuPIA wishes to ensure that all members using this material are aware of the changes and their responsibilities.

The critical worker DNEL[1] is 0.17 mg/m^3 for local effects via inhalation. EuPIA members are expected to review their risk assessments to ensure that NVC can still be used safely within their own handling and formulating operations. Please also consider the risk control measures described in the supplier Safety Data Sheet. Members are also recommended to review the uses of their products which contain NVC, to ensure that such uses are safe, and thereby permit the continuation of supply to their customers.

In addition to the changes in DNELs, the classification of NVC has changed to the following:

Acute Toxicity Cat. 4 (oral) — H302 - Harmful if swallowed.

Skin Sensitizer Cat. 1B — H317 - May cause an allergic skin reaction.

Eye Damage/Irritation Cat. 2 — H319 - Causes serious eye irritation.

Specific Target Organ Toxicity - Repeated Exposure Cat. 1 — **H372 - Causes damage to organs (Liver, Respiratory system) through prolonged or repeated exposure.**

DANGER

This means that NVC now falls within the criteria of the EuPIA Exclusion List, and as such members are expected to find a replacement. Normally six months would be recommended for this; however, since no technical equivalent appears to be currently available for NVC, EuPIA TC is exceptionally setting a timeframe of **twelve months** for its substitution, i.e. until November 2014 (subject to review at the EuPIA TC meetings in March and October 2014). Members are requested to inform the Secretariat of any difficulties or to highlight areas of specific concern.

The new DNELs, control measures and classification should be incorporated into revised Safety Data Sheets, and the labelling update of members' products containing NVC should be implemented as soon as practicable, and certainly within six months (i.e. by May 2014).

In addition, members should be aware that the corresponding re-classification according to the EU Dangerous Substances Directive includes **T;R48/23 Toxic: danger of serious damage to health by prolonged exposure through inhalation.** This brings NVC within the scope of the 'Seveso II' Directive on control of major accident hazards (96/82/EC), although it is not in scope of the revised 'Seveso III' Directive 2012/18/EU which will apply from 1 June 2015. In the intervening period members should check their inventory, as NVC will count towards the qualifying quantities for the lower- and higher-tier requirements.

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[1] Other DNELs are described in the SDS. Consumer DNELs are lower, but NVC is expected to be cured in prints that may be handled by the public. See the supplier SDS for more information.

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