ESMA Information Note:
New classification and labelling for N-Vinyl Caprolactam

A classification and labelling change has recently been advised by the lead REACH registrant of N-vinyl caprolactam (NVC, CAS number 2235-00-9), which is a key substance widely used by ink manufacturers in both analogue and digital ink formulations.

The previous classification varied amongst suppliers of the substance, but generally included the following hazard[1] statements:
H302 Harmful if swallowed;
H319 Causes serious eye irritation.

The new classification advised by the lead registrant is as follows:
H302 Harmful if swallowed;
H317 May cause an allergic skin reaction;
H319 Causes serious eye irritation;
H372 Causes damage to organs through prolonged or repeated exposure.

The additional hazard statement H317 will apply to mixtures when present in concentrations of 1% or more and H372 in concentrations of 10% and above.

The REACH Regulation requires manufacturers to set derived no effect levels (DNEL), as part of the chemical safety assessment that is required for substances supplied in quantities of 10 tonnes per annum.

The DNEL for NVC has been set as follows:

Workers[2]
Long term exposure, local effects inhalation (LTLI): 0.17 mg/m^3
Long term exposure, systemic effects, inhalation (LTSI): 4.9 mg/m^3
Long term exposure, systemic effects, dermal (LTSD): 0.7 mg/kg

Exposures at or below the DNEL are considered to be safe:

"The risk to humans can be considered to be controlled if the exposure levels estimated do not exceed the appropriate DNEL" [3]

Substances manufacturers are also required to provide an Exposure Scenario for supported uses of their substances, to include the recommended risk management measures to comply with a DNEL (where one is set) and control exposure during the life

ESMA vzw
Sint-Jorisveld 44, B-3390 Tielt-Winge Belgium
Tel: +32 16 894353, Fax: +32 16 434971
Website: http:/www.esma.com

VAT Number BE 0887.979.075

cycle of use. For NVC, this includes the various ink manufacturing stages and printing applications.

Suppliers of mixtures must also communicate relevant information to their customers regarding DNELs and risk management measures in relation to the constituents of their products.

All users of NVC containing materials have to ensure that their risk management measures control exposure below the DNEL.

The new labelling that must be applied to products containing NVC is currently being processed (along with revisions to safety data sheets to include the DNEL and recommended risk management measures) and will be enacted by ESMA companies by 01 May 2014 i.e. within the 6 months recommended by industry trade associations, including ESMA, following notification of the reclassification.

[1] In accordance with the Classification, Labelling and Packaging Regulation (CLP), currently applicable to substances and which must be used to classify mixtures by mid 2015 at the latest. The new classification and labelling scheme is currently being implemented by most mixture manufacturers to meet the 2015 deadline and is therefore used as the classification criteria for the purposes of this communication (see separate ESMA Information Note for Customers on CLP).

[2] DNELs must be derived by REACH registrants for the most likely routes of exposure (inhalation, dermal and oral). A value must be established for each relevant population e.g. workers, consumers. Several DNEL values may therefore be established for the same substance.

Local effects: The effect upon health that may be observed directly at the point of contact;

Systemic effects: The effects that may occur in more remote organs.

[3] 'Guidance on information requirements and chemical safety assessment
Chapter R.8: Characterisation of dose [concentration]-response for human health',
European Chemicals Agency, http://echa.europa.eu/"