

# BDO & Derivatives Sector Group

## Position Statement Regarding the EU Classification and Labeling for N-Methylpyrrolidone (NMP)

June 2nd, 2009

The Cefic BDO and Derivatives Sector Group would like to inform you about the formal European Union (EU) review of the classification and labeling of N-methylpyrrolidone (NMP) (Chemical Abstract Service Number 872-50-4; EC No. 212-828-1) for health effects, and of a specific concentration limit for preparations containing NMP.

On January 15, 2009, revisions to NMP's classification, labeling, and specific concentration limits were published in the EU Official Journal. According to Commission Directive 2009/2/EC -- commonly known as the 31st Adaptation to Technical Progress to the Dangerous Substances Directive (the 31st ATP) -- Annex 1 of the Dangerous Substances Directive (67/548/EEC) will be amended with regard to NMP as follows:

### Classification:

Repr. Cat. 2; R61: May cause harm to the unborn child  
(Category 2: for substances that should be regarded as if they cause developmental toxicity in humans)  
Xi; R36/37/38: Irritating to eyes, respiratory system, and skin

### Labeling:

T: Toxic  
R: 61-36/37/38: May cause harm to the unborn child  
Irritating to eyes, respiratory system, and skin  
S: 53-45: Avoid exposure - obtain special instruction before use.  
In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).



Substances classified as Category 2 developmental toxicants (T: R61) carry the “Toxic” symbol and trigger classification of preparations containing the substance at the “specific concentration limit.” These materials are also subject in the EU to increased worker protection, recordkeeping, storage provisions, and “marketing and use” regulations which typically limit usage to professional users and prohibit use in products placed on the market for sale to the general public.

**Specific Concentration Limit:**

$C \geq 10\% \text{ T; R61-36/37/38}$

$5\% \leq C < 10\% \text{ T; R61}$

The result is that the R61 classification and labeling will apply when NMP is present in a preparation at greater than or equal to 5%. Furthermore, it has been agreed that a 10% concentration limit should apply to the irritating properties of NMP, meaning that the R36/37/38 classification and labeling will apply when NMP is present in a preparation at greater than or equal to 10%.

As stated in the EU Official Journal, “Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 June 2009 at the latest.”

However, due to the recent publication of Regulation 1272/2008/EC (also known as the CLP Regulation), Annex I of Directive 67/548/EEC has been replaced by Annex VI of the CLP Regulation. The content of ATP 30<sup>th</sup> and 31<sup>st</sup> are not yet implemented in Annex VI of the CLP. Hence, a new ATP 1<sup>st</sup> to Annex VI of the CLP has to come into effect. This enforcement is expected by mid 2009 with a potential transition period until Dec 1<sup>st</sup>, 2010.

In this complex regulatory situation the members of the Cefic BDO and Derivatives Group have decided to provide the market with a clear and consistent hazard communication for NMP and to implement re-classification, labeling, and specific concentration limits between June 1<sup>st</sup> and September 1<sup>st</sup>, 2009.

If you have any questions about the content of this statement, please contact the Cefic BDO and Derivatives Sector Group manager Walter Cremers ([wcr@cefic.be](mailto:wcr@cefic.be)) or your NMP supplier.