BACKGROUND INFORMATION

MDI

CLP REGULATION

CHANGEOVER TO THE NEW EU CLASSIFICATION AND LABELLING SCHEME

November 2011

INTRODUCTION

The new EU law on Classification, Labelling and Packaging, the CLP Regulation, entered into force January 2009 in order to align existing EU legislation to the United Nations Globally Harmonised System (GHS).

This CLP Regulation will, after a transitional period, replace the current rules on classification, labelling and packaging of substances (Directive 67/548/EEC) and preparations (Directive 1999/45/EC), known as the Dangerous Substances Directive (DSD) and the Dangerous Preparations Directive (DPD) respectively.

Just before the entry in force of the CLP, the classification of MDI had been revised under the DSD via the 30th Adaptation to the Technical Progress (2008/58/EC). The 30th ATP of DSD was then adopted in the form of the 1st ATP of the CLP (Commission Regulation (EC) No 790/2009) in September 2009 and thus came into effect in all EU Member States simultaneously.

THE REQUIREMENTS OF THE 1ST ATP:

- **MDI – as substance** – has to be classified and labelled with the new pictograms and hazard statements set by the CLP since 1st December 2010. Until 1st June 2015 MDI has to be classified following both the DSD **and** the CLP. Both classifications will appear on the Product Safety Data Sheet.

- **MDI containing mixtures** will have to be classified and labelled from 1st December 2010
  - **either** according to the pictograms and phrases set by the 1st ATP (Annex I)
  - **or** according to the 1st ATP (Annex IV)
    The old classification and labelling system (Annex I) can be used until End of May 2015 at the latest, then the CLP system becomes mandatory.

EFFECT ON HEALTH AND SAFETY IN THE WORKPLACE

There will be no impact on workplace health and safety from this change beyond what is good practice today. We would like to refer to ISOPA's Walk the Talk programme (www.isopa.org/walkthetalk). This programme is designed to build on the existing knowledge of users of MDI and gives practical guidance to safe working practice.

MDI, along with other diisocyanates, is already subject to stringent Occupational Exposure Limits (OELs, such as the German MAK-value) and observance of these limits is a top priority. OELs control exposure and, hence, risk.
As a result of the change in classification, there will be no further restrictions regarding the handling and use of MDI and MDI-based preparations (mixtures) in the workplace and no changes in the OEL values.

The following table compares the MDI classification according to Annex I and IV of the 1st ATP of the CLP Regulation:

Annex I **For substances:** can be applied until end May 2015 (see right column) **For mixtures: mandatory from 1st December 2010** until end May 2015			**Annex IV** **For substances: mandatory from 1st December 2010** **For mixtures**: can be applied, **mandatory from 1st June 2015**		
	Carc. Cat. 3	R40: Limited evidence of a carcinogenic effect.	 Warning	Carc. Cat. 2*	H351: Suspected of causing cancer by inhalation.
	Damage to health by prolonged exposure	R48/20: Danger of serious damage to health by prolonged exposure.		STOT RE** 2	H373: May cause damage to respiratory system through prolonged or repeated exposure.
	Harmful	R20: Harmful by inhalation.	 Warning	Acute tox. 4	H332: Harmful if inhaled.
	Inh. Sens.	R42: May cause sensitization by inhalation.	 Danger	Resp. Sens.1	H334 : May cause allergy or asthma symptoms or breathing difficulties if inhaled
	Irritant	R36/37/38: Irritating to eyes, respiratory system and skin.	 Warning	Eye Irrit. 2	H319: Causes serious eye irritation.
				Skin Irrit. 2	H315: Causes skin irritation.
				STOT SE*** 3	H335: Respiratory tract irritation.
	Skin Sens.	R43: May cause sensitization by skin contact.		Skin Sens. 1	H317: May cause an allergic skin reaction.

*This is not a stricter classification but merely a renaming. The current category 3 will become category 2.
**Specific Target Organ Toxicity (Repeated Exposure)
*** Specific Target Organ Toxicity (Single Exposure)

Classification of MDI-containing mixtures, as specified in the 1st ATP CLP-Regulation (Annex I), to be applied at 1st December 2010 at the latest:

Classification of MDI-containing mixtures, based on concentration of MDI	
Concentration Limits	
C ≥ 25%	Xn; R20-36/37/38-40-42/43-48/20
10% ≤ C<25%	Xn; R36/37/38-40-42/43-48/20
5% ≤ C<10%	Xn; R36/37/38-40-42/43
1% ≤ C<5%	Xn; R40-42/43
0.1% ≤ C<1%	Xn; R42

Classification of MDI-containing mixtures, as specified in the 1st ATP CLP-Regulation (Annex IV), to be applied at 1st June 2015 at the latest, but, can be applied voluntarily before. Nevertheless, either R or H classification can be used, not both.

C ≥ 10%	H373, May cause damage to organs, cat. 4 H319, Eye Irrit. cat. 2 H315, Skin Irrit. cat. 2 H335, STOT – SE. cat. 3 H351, Carc. cat. 2 H334, Resp. Sens. cat.1 H317: May cause an allergic skin reaction
C ≥ 5%	H319, Eye Irrit. cat. 2 H315, Skin Irrit. cat. 2 H335, STOT – SE. cat. 3 H351, Carc. cat. 2 H334, Resp. Sens. cat.1 H317: May cause an allergic skin reaction
1% ≤ C<5%	H351, Carc. cat. 2 H334, Resp. Sens. cat.1 H317: May cause an allergic skin reaction
0,1% ≤ C < 1%	H334, Resp. Sens. cat.1

WHICH MDI PRODUCTS ARE AFFECTED?

The new classification of MDI is listed in the 1st ATP of the CLP Regulation under Index No 615-005-00-9 which stands for isomers of MDI (corresponding CAS Nos given), but, it does not refer to MDI homologues (CAS No 9016-87-9 is missing). The question of whether the co-called PMDI (mixture of isomers and homologues of MDI) falls under this Regulation can be answered as follows:

MDI and PMDI have comparable properties and the official MDI Risk Assessment Report from the EU Commission contains in Chapter 1.1 “Identification of the Substance” under “Synonyms” among others the chemicals names: “Methylene bisphenyl isocyanate, Crude MDI, Polymeric MDI, PMDI, Generic MDI and non-isomer specific MDI”. Therefore, it is recommended to treat PMDI the same as MDI and to apply the classification and labelling rules accordingly.

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