

TIMELINE FOR THE RE-CLASSIFICATION AND LABELLING OF MDI AS SUBSTANCE AND MIXTURES

Since January 2009, a new Regulation on Classification, Labelling and Packaging, the CLP Regulation, entered into force 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 (EC 2008/58/EC).

Via the 1st ATP of the CLP regulation the revised classification of 30th ATP of DSD was adopted under CLP in September 2009.

The requirements of the 1st ATP lead to the following consequences:

- **MDI – as substance** – will have to be classified and labelled with the new pictograms and hazard statements set by the CLP by 1st December 2010 at the latest.









Until 1 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 DPD as amended by the 30th and 31st ATP
 - **or** according to the new CLP regulation amended by its 1st ATP

The DPD classification and labelling can be used until 1 June 2015 at the latest. Then the CLP system becomes mandatory.

Year	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019 onwards	
CLP timeline	Substances		Classified, labelled and packaged under DSD. If CLP is applied in full, no DSD labelling and packaging required	Classified under both DSD and CLP; Labelled and packaged under CLP						Classified, labelled and packaged under CLP				
	Mixtures		Classified, labelled and packaged under DPD. If CLP is applied in full, no DPD labelling and packaging required						Classified, labelled and packaged under CLP					
			↑ CLP entry into force; repeal of annex I to DSD 20 January 2009	↑ Obligation to apply CLP to substances 1 December 2010					↑ Obligation to apply CLP to mixtures 1 June 2015					

The following table compares the MDI classification according to the DSD and the MDI classification according to the new CLP Regulation and when to apply them:

DSD (Dangerous Substances Directive, including 30 th and 31 st ATP)			CLP (Classification, Labeling and Packaging of Substances and Mixtures, including 1 st ATP)		
For substances: can be applied from 1 December 2010 (only in addition to CLP)			For substances: mandatory from 1 December 2010		
For mixtures* : mandatory from 1 December 2010 until end May 2015 (or replaced by CLP scheme)			For mixtures** : can be applied (alternative to DPD scheme), mandatory from 1 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.	 Warning	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.	 Warning	Skin Sens. 1	H317 : May cause an allergic skin reaction.

* under the DPD the classification and labelling of mixtures depends on the concentration level as specified here under

$C \geq 25\%$	Xn; R20-36/37/38-40-42/43-48/20
$10\% \leq C < 25\%$	Xn; R36/37/38-40-42/43-48/20
$5\% \leq C < 10\%$	Xn; R36/37/38-40-42/43
$1\% \leq C < 5\%$	Xn; R40-42/43
$0.1\% \leq C < 1\%$	Xn; R42

** under the CLP the classification and labelling of mixtures depends for some endpoints on the concentration level as specified here under

$C \geq 5\%$	Eye Irrit. 2; H319 Skin Irrit. 2; H315 STOT – SE 3; H335 Carc. 2; H351 Resp. Sens. 1; H334
$1\% \leq C < 5\%$	Carc. 2; H351 Resp. Sens. 1; H334
$0.1\% \leq C < 1\%$	Resp. Sens. 1; H334

The special rules for labelling and packaging of certain substances and mixtures are maintained and require that; unless already identified on the label of the packaging, mixtures containing isocyanates (as monomers, oligomers, prepolymers, etc., or as mixtures thereof) shall bear the following statement: EUH204 – ‘Contains isocyanates. May produce an allergic reaction.

For the acute toxicity endpoint (H 332) of a mixture the classification can be derived by :

- using toxicity data on the mixture itself, or in the absence of that information;
- applying bridging principles by using test data on similar mixtures and information on individual hazardous ingredient substances
- calculation of the acute toxicity estimate (ATE)

Details can be found in the CLP Regulation 1272/2008 section Part 3, section 3.1.3 and for guidance please contact your MDI supplier.

*** According the change of the classification and labelling system the current category 3 will become category 2 under the CLP Regulation. However, it should be pointed out that this change is not a stricter classification but it is merely a different approach.. The Category 2 Hazard Statement reads “H351: Suspected of causing cancer” (evidence may be derived either from limited evidence of carcinogenicity in human studies or from limited evidence of carcinogenicity in animal studies).

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. ISOPA members are committed to the highest standards in Health and Safety and are rolling out the 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 practise.

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.

ISOPA POSITION CONCERNING HAZARDS / RISKS OF MDI

It should be made clear that the new MDI classification reflects the hazards of this diisocyanate, but, it does not reflect the actual risks when MDI is handled and used properly. The new classification is based on tests performed on an artificial aerosol (see appendix) of MDI which is not the form of the substance placed on the market or will be encountered in normal handling and use.

Applications and uses as well as safe use will be part of the CSA/CSR (Chemical Safety Assessment/Report) under REACH.

November 2009

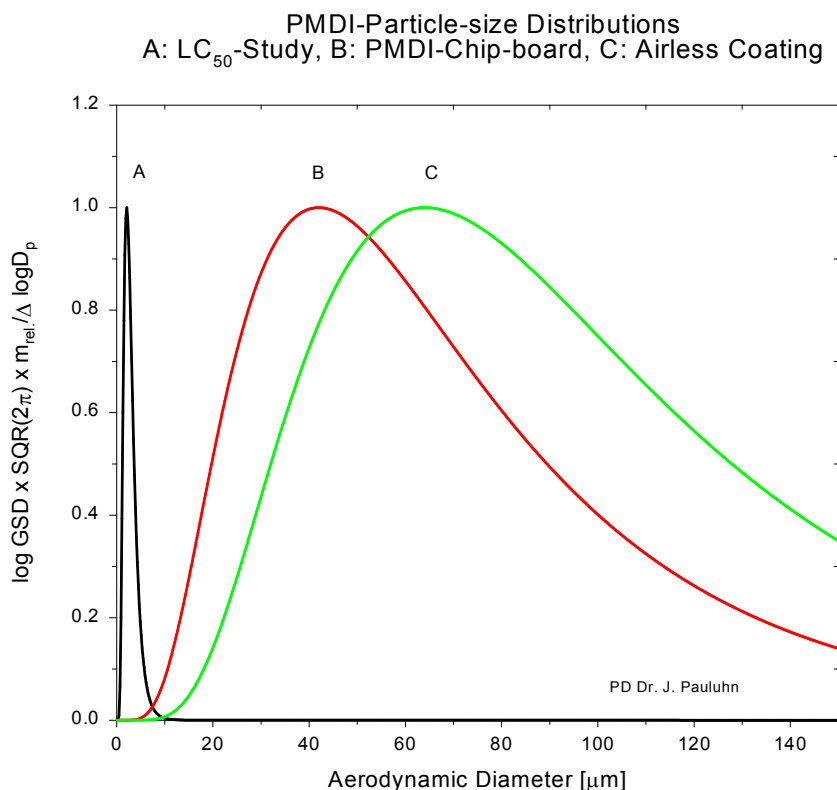
Appendix

Is MDI Really a Carcinogen?

An Aerosol Issue

The listing of MDI as a Carcinogen category 3 in the 30th ATP was the result of long discussions on a series of animal studies that were started in the 1980s and continued during the 1990s. In these studies animals were exposed to different types of MDI (monomeric and polymeric). A carcinogenic effect was only seen in long-term inhalation studies (two years) at high concentrations of specially prepared aerosols. The concentration required to cause tumours in the lungs of the test animals was 6 mg/m³, which is more than 100-times the MAK-value (0.05mg/m³). Even under these conditions only a few of the animals showed the formation of benign tumours.

These aerosols had to be respirable, what means that the droplets need to have a so-called aerodynamic diameter of $\leq 10 \mu\text{m}$. In the graph shown below the particle sizes for different MDI-aerosols are shown: Curve A is for a specially prepared respirable aerosol as used for such toxicological studies, curve B for an aerosol as used in chip-board production and curve C for an aerosol occurring in airless coating applications.



As can clearly be seen, the aerosols that emerge under practical working conditions are not respirable. The particles in these aerosols are simply too big to be able to access those (alveolar) parts of the lungs where the carcinogenic effect was

observed during the studies. Nevertheless, they may cause other effects such as irritation elsewhere in the respiratory tract or sensitisation.

Below the OEL levels there is no alveolar irritation, and without alveolar irritation there is no formation of such tumours; they occur only under continued conditions of irritation. For this reason, adhering to these OELs is the most important measure to avoid risk.

The fact that aerosols emerging under practical working conditions do not cause an increased risk for lung cancer is supported by epidemiological studies. Health surveillance programmes involving around 12,000 workers in the MDI processing industry did not show any increased risk of lung cancer.

.....

A detailed list of literature can be found in the EU Risk Assessment Report on MDI on the website of the European Chemicals Bureau:
<http://ecb.jrc.ec.europa.eu/esis/>
Please search for the CAS-number 26447-40-5.

W. Frank, November 2009