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FEICA Fact Sheet on the classification and labelling of one-component moisture curing polyurethane foams containing medium-chained chlorinated paraffins (MCCP)

Background

Classification and labelling of MCCP as a substance and mixtures containing MCCP

MCCP, medium-chained chlorinated paraffins, are chlorinated paraffins with a carbon chain length from C14 to C17, CAS 85535-85-9.

MCCPs were re-classified and thus re-labelled according to the CLP Regulation, the Regulation on Classification, Labelling and Packaging (1272/2008/EC) of substances and mixtures. The CLP Regulation aligns existing EU legislation with the United Nations Global Harmonised System (GHS).

The requirements of the 1st and 2nd ATP of CLP lead to the following consequences:

- Since 1 December 2010, MCCP (as a substance) is labelled with the new pictogram and hazard statements set by the CLP (H400 H410).
- Since 1 December 2012, the chronic ecotoxicity data (No Observed Effect Concentration = NOEC) for MCCP triggers a specific concentration limit of H410 by implementing the Mc-factor (chronic) of 10 in product classification and labelling.

New classification and labelling of MCCP according to the 1st ATP of the CLP

Classification		Labelling		
Hazard Class	Hazard Statement	Pictogram Signal Word	Hazard Statement	Supplemental H.-Statement
Lact	H362	GHS09	H362	EUH066
Aquatic Acute 1	H400 (M _α -factor 1)	Warning	H410	
Aquatic Chronic 1	H410 (M _c -factor 10)			

Classification of MCCP in mixtures

Under CLP, the labelling of mixtures depends on the concentration levels as specified hereunder:

Pure substance	H410 – H066-H362
C ≥ 25%	H410 - H362
C ≥ 2.5%	H410 - H362
C ≥ 1%	H411 - H362
C ≥ 0.25%	H411
C ≥ 0.025%	H412

Classification of one-component PU foam mixtures containing MCCP

One-component PU foams represent complex polymeric mixtures that are virtually insoluble in aqueous media. Typical one-component PU foams contain up to 30% MCCP and would need to be labelled as Aquatic Chronic 1 (H410) by the conventional summation method for classification and labelling. According to CLP, mixtures have to be preferably classified for acute and long-term aquatic environmental hazards when there is test data available on the mixture as a whole (CLP, 4.1.3.3).

According to Article 12 of CLP, the classification scheme requires further evaluation where the bioavailability of the substance or mixture is in question. Further to that, a substance or mixture need not be classified where it can be shown by conclusive experimental data from internationally acceptable test methods, that the substance or mixture is not biologically available. Biological availability involves both, the release from a medium (if present) and the absorption by an organism, respectively. The approach taken by FEICA follows the principles outlined in Annex IV of the CLP guidance for metals. By this methodology a dissolution/transformation test over a relevant period of time (28 days) and under environmentally realistic conditions can prove that the dissolved concentration of the substance of concern is below the Ecotoxicity Reference Values (i.e. NOEC), and hence, the classification for long-term hazards can be dismissed. Conclusively, for MCCP, if there is adequate experimental data available for the one-component PU foam mixture at 1mg/l that shows that MCCP is not released (i.e. NOEC values are >1mg/l) there is no need to classify the mixture for long-term aquatic hazard (chronic 1, 2, or 3).

Acute effect on aquatic life in one-component PU foam mixtures containing MCCP

The European producers of one-component PU foams, participating in the "FEICA OCF Working Group", instructed BMG Engineering AG (Zürich), an independent Swiss Institute, to execute suitable tests in order to investigate the influence of MCCP (in a typical one-component PU foam formulation) on the acute aquatic ecotoxicity of the product. These tests were commissioned to determine the effect of MCCP in one-component PU foam mixtures but are valid for two component foam systems too.

Two tests were performed:

- a 48-hour Acute Toxicity to *Daphnia magna*
- a fresh water algal growth inhibition test with *Desmodesmus subspicatus*

Both tests were carried out with a generic one-component PU foam formulation, containing 30 % of MCCP (in the prepolymer).

In the presence of water or humidity, the foam reacts quickly and forms a skin in ca. 10 minutes and cures in about 1 hour. It is understood that (hydrophobic) MCCP will not be able to diffuse into water once the skin has formed and even less so when the foam is totally cured as the MCCP is captured in the formed structure. Therefore, it can be assumed that these tests represent the worst-case scenario as the freshly sprayed and thus uncured foam comes into contact with water without having formed a skin.

The test reports of BMG study no. A10-00856 and BMG study no. A10-00857 respectively, showed no negative acute effects on the *Daphnia magna* and algal growth. Even for freshly sprayed one-component PU foam containing 30% of MCCP in the prepolymer.

Thus, the results imply that acute labelling of one-component PU foam formulations containing up to 30 % MCCP in the prepolymer with H400 under CLP is not necessary.

Chronic effect on aquatic life of one-component PU foam mixtures containing MCCP

The Association of European Producers of one-component PU foams, participating in the "FEICA OCF Working Group", have instructed NOACK Laboratories (Sarstedt), an independent German Institute, to execute suitable tests to investigate the potential influence of MCCP (in a typical one-component PU foam formulation) on aquatic life. These tests were commissioned to determine the bioavailability of MCCP in one-component PU foam mixtures but are also valid for two component foam systems.

Tests performed:

- a 28-day leaching test in aqueous media on the relevant limit concentration for chronic effects (1mg/l)

The test was carried out with a generic one-component PU foam formulation, containing 30 % of MCCP in the prepolymer.

In the presence of water or humidity the foam reacts quickly and forms a skin in ca. 10 minutes and cures in about 1 hour. It is understood that (hydrophobic) MCCP will not be able to diffuse into water once the skin has formed and even less so when the foam is totally cured as the MCCP is captured in the formed structure. In order to enhance the leaching potential of this structure, the foam was deep-frozen and milled to a powder prior to exposure to water.

The test report of study no. 140306HW_CLW15930 indicated that, at a sample concentration of 1 mg/L of dispersed one-component PU foam polymer, containing 30 % MCCP, no dissolved MCCP could be detected in the media during the 28-day test period. The limit of detection (LOD) was < 0.2 micrograms per litre.

Because the LOD is well below the lowest reported NOEC values for MCCP of 10 µg/l, the test provides sufficient scientific evidence that no chronic effects are to be expected.

Thus, the results imply that the classification of one-component PU foam formulations containing up to 30 % MCCP with Aquatic Acute 1 and Aquatic Chronic 1, and therefore their labelling with H410 under CLP is not necessary.

Despite the positive results and the clear toxicological interpretation, the OCF Working Group has decided to retain H413 ("May cause long lasting effects to aquatic life not hazardous for the environment"). The hazard symbols H400 and H410 for CLP are to be removed. The classification with aquatic chronic 4, H413 (CLP) was selected according to table 4.1.0 of the Regulation (EU) No. 286/2011 ("safety net").

Conclusion

Based on the above rationale and test results, FEICA has adopted the following additional classification and labelling for one-component PU foam formulations containing max. 30% of MCCP in the prepolymer:

CLP	
30 % ≥ C ≥ 1.0 %	H413 H066-H362
1,0 % ≥ C ≥ 0.25 %	H413

Note: Formulations not containing MCCPs are exempt from this additional classification.

Contacts for more info

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