

Regulatory Alert

REACH Regulation Annex XVII - Entry 74 (diisocyanates)

Entered into Force 24 August 2020

Country: European Union Countries

Please see the disclaimer at the end of the alert

INTENDED AUDIENCE

This Regulatory Alert is intended for IAEG members who use substances and mixtures that contain diisocyanates for A&D product applications.

EXECUTIVE SUMMARY

Background on Regulation:

On 4 August 2020, Entry 74 was added to EU REACH Annex XVII per Commission Regulation (EU) 2020/1149, restricting the use and placing on the market of diisocyanates.

Diisocyanates commonly have a harmonized classification as respiratory sensitizers category 1, and as skin sensitizers category 1, according to Annex VI of Regulation (EC) No 1272/2008 (Classification, Labelling and Packaging Regulation, or CLP). The Annex XV dossier submitted in support of the restriction indicated that respiratory sensitization, due to both dermal and inhalation exposure to diisocyanates, leads to occupational asthma in workers, which has been identified as a significant occupational health problem in the European Union (EU). The annual number of new occupational diseases caused by diisocyanates was considered to be unacceptably high. The Annex XV dossier demonstrated that action on a Union-wide basis was necessary, and proposed to restrict industrial and professional use, as well as the placing on the market of diisocyanates on their own, and as constituent of other substances and in mixtures.

APPLICABILITY

Diisocyanates are mainly used to make polyurethane products, such as rigid and flexible foams, coatings, adhesives, sealants and elastomers and are commonly used in aircraft coatings.

The restriction concerns the use and placing on the market of diisocyanates in substances and mixtures for industrial and professional uses*, unless:

- the cumulative concentration of diisocyanates in the substance or mixture is less than 0.1% by weight; or
- the employer or self-employer has ensured that the industrial or professional user(s) have successfully completed training on the safe use of diisocyanates prior to the use of the substance(s) or mixture(s);

Further, suppliers must ensure that the recipient of such substance(s) or mixture(s) is provided with information on the training requirements and includes this information on the packaging.

See the 'Regulatory Obligation' section below for exact timescales.

*In this case, industrial and professional users means any worker or self-employed worker handling diisocyanates on their own, as a constituent in other substances or in mixtures for industrial and professional use(s) or supervising these tasks.

RELEVANT DATES

- ❖ **Entry 74 published:** 4 August 2020
- ❖ **Entry 74 in force:** 24 August 2020
- ❖ **In force date of first restriction:** 25 February 2022
- ❖ **In force date of second restriction:** 25 August 2023

- ❖ Adequate training required before industrial or professional use: 24 Aug 2023
- ❖ Training completion must be documented and refreshed every five (5) years.

REGULATORY OBLIGATIONS

The timing of the requirements is as follows:

- Substances or mixtures may not be placed on the EU market for industrial or professional use after **24 February 2022** unless the concentration of diisocyanates is < 0.1% by weight, or the supplier provides the recipient with information on the safety training requirements and labels the packaging to indicate the need for such training requirements, i.e. "As from 24 August 2023 adequate training is required before industrial or professional use." Note that this labeling requirement is in advance of the training requirement date;
- Diisocyanates may not be used in the EU for industrial or professional uses as from **24 August 2023** unless the concentration of diisocyanates is < 0.1% by weight, or it has been ensured that the users have completed specific training on the safe use of diisocyanates prior to commencing use.

Specific, required training topics include the instructions for the control of dermal and inhalation exposure to diisocyanates at the workplace, and comply with any additional applicable local requirements. Further, specific required training topics depend on the type of work being done. Training elements are included within three categories: 1) General level, 2) Intermediate Level, and 3) Advanced Level Training. For example, "spraying outside a spraying booth" requires "Advanced Level" training. Training completion must be documented and refreshed every five (5) years. Training materials must be provided by the diisocyanate supplier, and must be delivered by an expert on occupational health and safety with competence acquired by relevant vocational training.

- Suppliers of diisocyanates must ensure that the recipient of such substance(s) or mixture(s) is provided with information on the training requirements and include this information on the packaging.

RISKS TO AEROSPACE AND DEFENSE

EU based users of substances and mixtures that contain diisocyanates for A&D product applications are required to comply with Entry 74 and either limit use concentrations, or provide proof of adequate training for workers using diisocyanates.

Risks include:

- Enforcement due to failure to comply with training requirements for use of restricted diisocyanate materials.
- Potential to disrupt A&D supply chain, i.e. the supply or import (“placing on EU market”) of diisocyanate materials.

IAEG ACTIONS RELATED TO THIS RISK

Encourage IAEG members using substances or mixtures containing diisocyanates in the EU to provide the required training to their workers.

Encourage IAEG members purchasing chemical products being placed on the market in the EU that contain diisocyanates to ensure that the products are placed on the market in accordance with the requirements in Entry 74.

IAEG members should be encouraged to contact their suppliers for support according to their individual use in a timely manner. Awareness training should be initiated by a dialogue between supplier and user.

USEFUL LINKS

Regulation (EC) No 1907/2006 (REACH Regulation):

<https://eur-lex.europa.eu/eli/reg/2006/1907>

Regulation (EU) 2020/1149 (Entry 74 - Diisocyanates):

<https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=uriserv:OJ.L .2020.252.01.0024.01.ENG&toc=OJ:L:2020:252:TOC>

Diisocyanate info – including relevant CAS & EC numbers listed in Annex XVII

https://echa.europa.eu/substances-restricted-under-reach?p_p_id=disslists_WAR_disslistsportlet&p_p_lifecycle=0&p_p_state=normal&p_p_mode=view&p_p_col_id=column-1&p_p_col_pos=1&p_p_col_count=2&disslists_WAR_disslistsportlet_keywords=&disslists_WAR_disslistsportlet_orderByCol=prc_entry_no&disslists_WAR_disslistsportlet_substance_identifier_field_key=&disslists_WAR_disslistsportlet_advancedSearch=false&disslists_WAR_disslistsportlet_delta=50&disslists_WAR_disslistsportlet_orderByType=asc&disslists_WAR_disslistsportlet_doSearch=&disslists_WAR_disslistsportlet_prc_entry_no=&disslists_WAR_disslistsportlet_deltaParamValue=50&disslists_WAR_disslistsportlet_andOperator=true&disslists_WAR_disslistsportlet_resetCur=false&disslists_WAR_disslistsportlet_cur=2

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