



Guide to the restriction process applying to diisocyanates



3. revised edition

Dear FSK Members,

We have revised and updated this guide on the use and handling of diisocyanates with regard to the REACH process.

Together with our partner associations ISOPA/ALIPA and EUROPUR, we have reviewed questions relating to diisocyanates and their safe handling in the PUR value chain.

This document outlines in particular the processes and regulatory measures under REACH which could have an impact on the production and use of diisocyanates in the future. We have sought to reflect the current status of the regulatory process. We do not rule out further changes at EU level and will keep you informed – especially on individual diisocyanate substances – and will keep you up to date.

POLYURETHANE – a product for the future

Polyurethanes are versatile, modern and safe. They are used to produce a wide variety of consumer and industrial products that make a decisive contribution to making our lives more convenient, comfortable and environmentally friendly. Whether in rigid or flexible form, elastomers, binders or coating materials, polyurethane is used in a wide variety of applications. Thanks to its versatility and unique properties, the list of applications is long and getting longer with new innovative applications coming on to the market all the time.

Polyurethane is a product for the future. It plays a crucial role in our evolving needs, allowing us to do things that a generation ago would have seemed impossible.

DIISOCYANATES and POLYOLS – the building blocks of polyurethane

Polyurethane is a plastic (a polymer), which would not exist without diisocyanates and polyols. Together with polyols, which consist of long alkoxyether chains, diisocyanates such as methylene diphenyl diisocyanates (MDI) and toluene diisocyanates (TDI) form the basic building blocks of polyurethane. Polyurethane is formed by the chemical reaction between diisocyanates and polyols when they are mixed with each other. Foam is produced by adding water, acid or the use of physical blowing agents.

For polyurethane to meet high quality expectations and technical product specifications, dyes and additives are added to ensure the correct composition of the foam. This enables an almost endless variety of foam densities. The molecule is adapted to allow for various properties, PUR materials can be made more rigid or more flexible. Carbon dioxide for example is used as a blowing agent to produce flexible foam for a comfortable sofa. All blocks of foam are tested for compliance with European safety standards.

In rigid foam, a cell gas, e.g. pentane, can be trapped in the closed cells of the foam to optimise its insulating properties. Water can also be used as an alternative blowing agent. With their durability, corrosion and weather resistance, polyurethanes are also suitable for coating a wide variety of surfaces. Polyurethane can also be used to securely bond different materials such as wood, rubber, metal, cardboard or glass.

Polyurethane adhesives make it possible to use end-of-life tyres on children's playgrounds, sports fields or in sports stadiums after collection and shredding. Polyurethane coatings protect substrates from corrosion and weather influences and thus significantly increase their durability while at the same time conserving resources.

The FSK – Specialist Association Foamed Plastics and Polyurethanes

Successful industries need strong specialist organisations as a platform for exchange and contacts and to represent their interests. The FSK is one of the most important specialist associations in its sector in Europe and, in its 50-year tradition, is the largest national association of the foam plastics and polyurethane processing industry.

The Specialist Association Foamed Plastics and Polyurethanes (FSK) is an association of the plastics processing industry, representing a total volume of around 10 billion euros in the polyurethanes and foamed plastics industry. The FSK is part of a network of several associations, e.g. the ARGE (specialist associations of chemicals, plastics and textiles).

The FSK is also the supporting association of the German Association of Plastics Converters (GKV). The members of the FSK include raw material companies, machine manufacturers, system houses/formulators and above all processing companies from the material sectors polyurethane, polypropylene, polyethylene, rubber foams, melamine resin foam, PVC foam, etc.

Who are ISOPA/ALIPA and EUROPUR?

ISOPA is the European trade association of manufacturers of aromatic diisocyanates and polyols – the main building blocks of polyurethane. ISOPA promotes the highest level of best practice in the distribution and use of diisocyanates and polyols in Europe and ensures that all stakeholders can easily access accurate and up-to-date information on these substances. ISOPA is based in Brussels, Belgium, and is an affiliated organisation of the European Chemical Industry Council (CEFIC). ISOPA's members include BASF, BorsodChem, Covestro, Dow, Huntsman and Shell Chemicals

ALIPA is the European Aliphatic Isocyanates Producers Association. It was created by the major European producers BASF, Covestro, Evonik and Vencorex in order to encourage the safe and proper use of aliphatic isocyanates.

EUROPUR is the European association of flexible polyurethane foam blocks manufacturers. Polyurethane foams make our daily lives safer and more comfortable. They are vital to applications that we take for granted. Mattresses, furniture cushions and car seats are just some examples. As part of the global chemical industry, EUROPUR is committed to Responsible Care®. This notably means that we seek to continuously improve the environmental, health and safety knowledge and performance of our technologies, processes and products over their life cycles.



Registration



Evaluation and



Authorisation of



CHemicals

Registration

Since 1 June 2007 companies are obliged to collect information on the properties and uses of substances they manufacture or import in quantities of more than one tonne per year. They must also assess the hazards and potential risks posed by these substances.



REACH & DIISOCYANATES

As important building blocks for polyurethane production, diisocyanates are subject to the REACH regulation. (Registration, Evaluation and Authorization of Chemicals).

WHAT IS REACH ALL ABOUT?

The REACH Regulation was adopted by the European Union in 2006 to improve the protection of human health and the environment against possible risks from chemicals while maintaining the global competitiveness of the European chemical industry.

As opposed to previous legislation, REACH places the burden of proof on the industry. To comply with the Regulation, companies must correctly identify and manage risks. In turn, chemical producers must demonstrate to the European Chemicals Agency (ECHA) how the substance can be used safely and communicate the risk management measures to their users.

To achieve these objectives, a number of procedures were introduced by the Regulation. The chemical industry and its associated value chains have already implemented a considerable part of this in recent years.

Evaluation

The information provided by the companies and the quality of the registration dossiers and testing proposals are then evaluated by ECHA and the member states to determine whether a particular substance poses a risk to human health or the environment.



Authorisation

The authorisation procedure is intended to ensure that the risks arising from substances of very high concern (SVHC) are adequately controlled and that these substances be gradually replaced by suitable alternatives. Substances of very high concern are listed in the so-called „candidate list“.

This list includes carcinogenic, mutagenic and reprotoxic (CMR) substances, persistent, bioaccumulative and toxic (PBT) substances and substances of similar concern (endocrine disruptors), inhalation allergens etc.).

Restriction

Restrictions are designed to protect human health and the environment from unacceptable hazards posed by chemicals. Restrictions may restrict or prohibit the production, marketing or use of a substance. In some specific cases, such as diisocyanates, where the product has an extremely wide range of applications, the authorities may require the development of targeted measures for product stewardship. This ensures that all employees exposed to these substances are both informed and trained to control possible risks in handling these substances.



Registration

Evaluation
and

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Analysis of diisocyanates under REACH

Regulatory processes for diisocyanates since 2012

Diisocyanates have been subject to regulatory processes since 2012. TDI, MDI and aliphatic isocyanates have been included in the Community Rolling Action Plan (CoRAP) of ECHA. The Polish authorities assessed TDI in 2013 and concluded that no regulatory measures were required.

In Estonia MDI underwent assessments between 2013 and 2016, indicating that although a restriction was not appropriate, further information needed to be obtained.

Restriction proposal from Germany

The BAuA (German Federal Institute for Occupational Safety and Health), the authority responsible for REACH in Germany, carried out an RMOA (Risk Management Option Analysis) on diisocyanates in 2014. In doing so, it examined in particular the properties of diisocyanates and a possible connection to inhalation allergies due to improper handling in the workplace. After the RMOA, Germany pleaded for a more innovative method of restriction in the form of compulsory training to ensure the safety of employees in the workplace when handling diisocyanates. In October 2015, the BAuA announced its intention to prepare a dossier on restrictions and officially submitted the dossier to ECHA in October 2016.

Restriction measures at European level

The German restriction proposal has been examined by the Committee for Risk Assessment (RAC) and the Committee for Socio-economic Analysis (SEAC) and has undergone two phases of public consultation.

In February 2020, the REACH Regulatory Committee agreed to the restriction of the use of diisocyanates. The EU Council and the EU Commission did not have any substantive objections to the restriction proposal and the introduction of training. On 04 Aug. 2020 the restriction of diisocyanates was published in the Official Journal of the EU. The restrictions are to be implemented on a mandatory basis after a three-year transitional period, from 24 Aug. 2023.

Industry's commitment and dialogue with REACH regulatory authorities

The diisocyanate industry (manufacturers), processors, formulators/system-houses and machine manufacturers have been involved in the process from the very beginning in order to provide authorities with the most reliable data and information possible and to enable REACH regulatory authorities to adopt an appropriate and uniform approach that could be applicable to all companies, including SMEs (small and medium-sized enterprises).

Following the BAuA's RMOA for diisocyanates in 2014, ISOPA and ALIPA decided to seek further cooperation with downstream associations on REACH relevant issues. They also decided to actively provide the authorities conducting research on diisocyanates with relevant information within the framework of a newly created platform, the PU Exchange Panel (see page 21).

The aim of this specialist committee is to enable better participation of the entire value chain in the process with BAuA and all other authorities responsible for REACH in Europe. It supports the BAuA, ECHA and the Commission in the development of appropriate and reliable measures.

The federation of associations is jointly developing the training material on the safe handling of diisocyanates in order to ensure comprehensive occupational health and safety throughout Europe.

The Europe-wide restriction of diisocyanates

The Regulation stipulates that the marketing, distribution and further use of products containing diisocyanate is only allowed after successful training. Industrial or professional users must be trained in occupational safety, handling, control of exposure at the workplace and personal protective equipment before handling diisocyanate products. This means that the permitted products can still be sold and used if appropriate measures are taken to implement occupational health and safety.

After the end of the transitional phase, from 24 Aug. 2023, diisocyanates may only be used as a substance, as a component of a substance or in a mixture if the concentration is less than 0.1% by weight or if it is ensured that the user has successfully completed training in the use of diisocyanates before using them

DIISOCYANATES

1. May not be used after 24 August 2023, either as a substance or as a constituent of other substances or in mixtures, for industrial or commercial purposes, unless,

(a) the concentration of diisocyanates, individually and in combination, is less than 0.1% by weight; or

(b) the employer or self-employed person ensures that industrial or commercial users have successfully completed training in the safe use of diisocyanates before using the substance(s) or mixture(s).

2. May not be placed on the market after 24 February 2022, either as a substance or as a constituent of other substances or mixtures, for industrial or professional use, unless ,

(a) the concentration of diisocyanates, individually and in combination, is less than 0.1% by weight; or

the supplier ensures that the recipient of the substance(s) or mixture(s) is aware of the requirements referred to in paragraph 1(b) and that the following declaration is clearly marked on the packaging in such a way that it is clearly distinguishable from the other information on the label: from 24 August 2023, appropriate training must be provided before industrial or commercial use.

3. For the purposes of this entry, 'industrial or commercial user(s)' means any employee or self-employed person who handles or supervises the handling of diisocyanates as substances or as components of other substances or in mixtures for industrial and commercial use.

COURSES/TRAINING

The courses/training are divided into three levels based on the handling of diisocyanates and the extent of exposure. They thus provide the basis for the safe handling of diisocyanates. Experts in occupational safety and health are responsible for implementation.

According to the REACH Regulation, the courses/training must provide guidance on how to control workplace exposure through skin contact and inhalation. The rules of the Member State in which the industrial or commercial user(s) is (are) operating must be considered. National requirements for the use of the substance(s) can still be implemented or applied provided that the minimum requirements under REACH are met.

Suppliers of the substance(s) or mixture must also ensure that training materials and courses/training are available to the recipient in the official language of the Member State(s) to which the substance(s) or mixture(s) is/are supplied. The specifics of the products supplied, including composition, packaging and design, must also be considered.

Documentation/certification is required upon successful completion of the training(s). The courses/training must be repeated every 5 years.

The training content is derived from material already developed and then made available by manufacturers and importers of diisocyanates in cooperation with downstream users and distributors.

For more information on the training content, please refer to the relevant sections of this guide.

LEVEL 1 Basics

How will training be provided?

- online or in person

Who will be trained?

- all industry and commercial users

What will be trained?

- Chemical properties of diisocyanates
- Toxicity (including acute toxicity)
- Exposure to diisocyanates
- Workplace limit values
- Causes of sensitisation
- Odour as an indication for danger
- Risk relevance of volatility
- Viscosity, temperature and molecular weight of diisocyanates
- Personal hygiene
- Necessary personal protective equipment including practical instructions concerning their proper use and their limitations
- Risk of exposure through skin contact and inhalation
- Risk regarding application process used
- Measures to protect the skin and respiratory protection
- Ventilation
- Cleaning, leakage, maintenance
- Disposal of empty packaging
- Disposal of waste products
- Identification of new handling stages

LEVEL 2 Follow-up training

How will training be provided?

- online or in person

Who will be trained?

Persons using diisocyanates in the following applications:

- Handling of open mixtures at room temperature (including in foam tunnels)
- Spraying in a ventilated spray booth Application with a roller
- Application with a brush
- Application by dipping and pouring Mechanical post-treatment (e.g. cutting) of not completely dried cooled products
- Cleaning and waste disposal
- Any other application where a similar exposure by skin contact and/or inhalation exists

What will be trained?

- All contents of level 1
- Other behaviour-related aspects
- Maintenance
- Change Management
- Evaluation of existing safety instructions
- Risk regarding application process used

How will training be provided?

- Successful participation
- Certificate of completion
- Certificate of successful completion

LEVEL 3 Advanced training – Intense training

How will training be provided?

- online or in person

Who will be trained?

Persons using diisocyanates in the following applications:

- Handling of not completely dried products (e.g. freshly dried, still warm)
- Foundry applications
- Maintenance and repair work, for which access to equipment is required
- Open handling of warm or hot formulations (> 45 °C)
- Spraying in outdoor areas, with limited or exclusively natural ventilation (also in large industrial work halls) and spraying with high energy (e.g. foam, elastomers)
- Any other application where a similar exposure by skin contact and/or inhalation exists

What will be trained?

- All contents of level 1 and 2
- Any other certification required for the specific application
- Spraying outside a spray booth
- Open handling of warm or hot formulations (> 45 °C)

How will training be provided?

- Successful participation
- Certificate of completion
- Certificate of successful completion