

3rd edition

March 2021

SUCCESSFULLY NAVIGATING REACH



A guide to the REACH Restriction applying to diisocyanates

Isopa EUROPEAN DIISOCYANATE & POLYOL
PRODUCERS ASSOCIATION

ALIPA
EUROPEAN ALIPHATIC DIISOCYANATE PRODUCERS ASSOCIATION

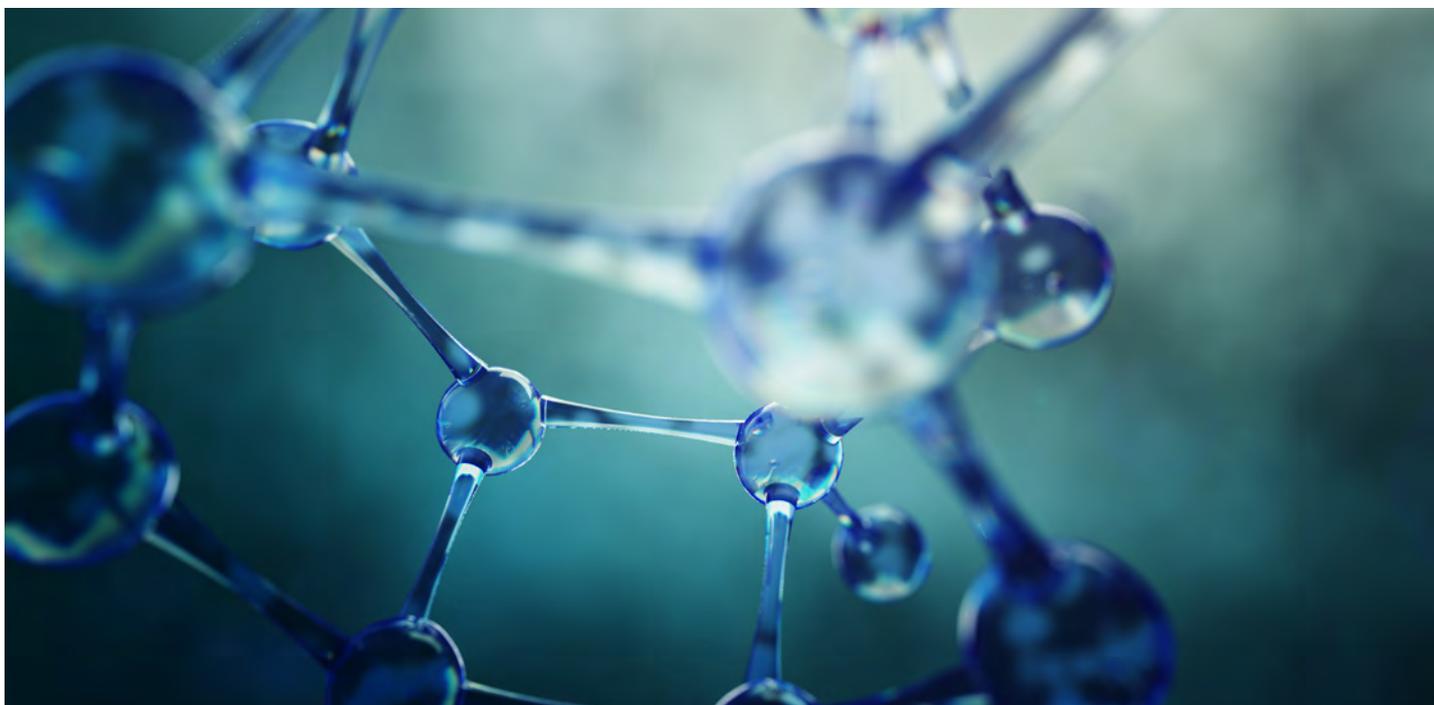
Introduction

Welcome to the ISOPA/ALIPA guide to the REACH Restriction applying to diisocyanates.

On 4 August 2020, the REACH Restriction on diisocyanates was published in the EU official journal applying after a transition period of three years. The Restriction will introduce mandatory training requirements for workers using diisocyanates.

With this document, we aim to answer some of the main questions that the polyurethanes value chain may have regarding the new REACH Restriction on diisocyanates by providing an overview on the adopted Restriction and its implications.

More broadly, this document elaborates on what REACH is all about, like other REACH processes with relevance on ISOPA/ALIPA's commitments and activities with the aim of ensuring the safe handling of diisocyanates throughout the value-chain in Europe and beyond.



Polyurethane

A product for the future

Polyurethanes are versatile, modern and safe. They are used in a wide range of applications to create a variety of consumer and industrial products that play a crucial role in making our lives more convenient, comfortable and sustainable.

Whether in rigid or flexible form, in elastomers, binders or coating materials, polyurethane has many uses and applications. Thanks to its versatility and unique properties, the list

of applications continues to grow with new, innovative applications coming on to the market all the time.

Polyurethane is a product for the future. It plays a central 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 high-tech polymer, which would not exist without diisocyanates and polyols. There are many types of diisocyanates, the foremost of which are: aromatic diisocyanates including methylene diphenyl diisocyanate (MDI) and Toluene diisocyanate (TDI); and hexamethylene diisocyanate (HDI), methylene dicyclohexyl diisocyanate or hydrogenated MDI (HMDI) and isophorone diisocyanate (IPDI), which are aliphatic isocyanates. Along with polyols, for example, alkoxyether chains, these chemicals form the building blocks of polyurethane.

Polyurethane is effectively derived from the chemical reaction between diisocyanates and polyols; when mixed together they polymerise.

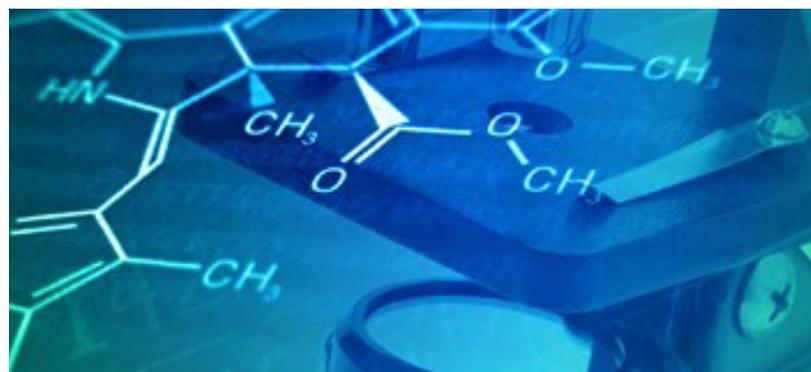
For polyurethane to meet quality standards and products' technical specifications, pigments and additives may be added to ensure the exact formulation of the product, be it foam, adhesives, elastomers or sealants and coatings. The range of possible densities is endless. As the molecule is adapted to provide different properties, polyurethane foam can display different levels of rigidity or flexibility.

For example, a comfortable sofa requires the use of carbon dioxide as a blowing agent for the production of soft foam. In rigid foams, a gas such as pentane is "trapped" in the foam's closed cells, optimising its insulation capacity.

In addition, the durability, corrosion resistance and weather resistance of polyurethanes makes them suitable for coating all kinds of surfaces. Polyurethane can also be used to safely bind together vastly different materials, such as wood, rubber, cardboard or glass.

For example, polyurethane adhesives enable the reuse of vehicle tyres in playgrounds, sports tracks or surfaces for sports stadiums after they are collected and shredded. Polyurethane coatings can furthermore protect substrates against corrosion and weathering, significantly increasing their durability and saving resources.

Further applications of diisocyanates include highly durable compact materials like thermoplastic polyurethane (TPU) and elastomers. Such materials are widely used for a variety of applications including wheels, ski boots and artificial leather.



Who are ISOPA and ALIPA?

ISOPA

ISOPA is the European trade association for producers of aromatic diisocyanates and polyols – the main building blocks of polyurethanes. ISOPA is a partner association of the European Chemical Industry Council (CEFIC) and the ISOPA 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.

ALIPA

Both associations are based in Brussels (BE) and encourage the safe and proper use of isocyanates and promote the highest level of best practices 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.

REACH and Diisocyanates

What is REACH all about?

Adopted in 2006, REACH stands for Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation. It is a European regulation that aims at improving the protection of human health and the environment from potential risks from chemical substances; whilst ensuring global competitiveness of the EU chemicals industry is maintained. As opposed to previous legislation, REACH places the burden of proof on 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 a substance can be safely used and communicate any risk management measures to their users.

To deliver on such ambitious objectives, the Regulation has put in place a number of processes that have required a huge response from the chemical industry and its value chains in recent years (more information on page 18).

Restriction

A restriction is used to protect human health and the environment from unacceptable risks posed by chemicals. Restrictions may limit or ban the manufacture, placing on the market, or use of a substance. In specific cases, like for diisocyanates, where the product is used in numerous applications, authorities may decide

to call for the development of targeted product stewardship initiatives. These will ensure that all workers who interact directly with the substances are both informed and trained in order to manage any risks associated with their handling and close contact.

REACH Restriction on diisocyanates

BAuA, the German REACH Competent Authority (CA), took a particular interest in the respiratory sensitising properties of diisocyanates at the workplace (if not handled properly).

In order to clarify the situation and identify the best policy tool, German authorities decided to conduct a Risk Management Option Analysis (RMOA). The exercise was completed in August 2014 and Germany recommended a more unique restriction route, by proposing mandatory training that would ensure safety in the workplace for workers handling diisocyanates.

In October 2015, BAuA formally registered its intention to prepare a restriction dossier. The dossier was formally sent to ECHA in October 2016 and was adopted by ECHA in December 2017. On 4 February 2020, the REACH Committee voted in favour of the European Commission's proposal for a REACH restriction on diisocyanates. The Restriction was published on 4 August 2020 applying from 24 August 2023 after a transition period of 3 years.

You will find below a summary of the requirements under the final legal text of the Restriction.

The Restriction introduces new minimum training requirements for workers handling diisocyanates and mixtures containing diisocyanates.

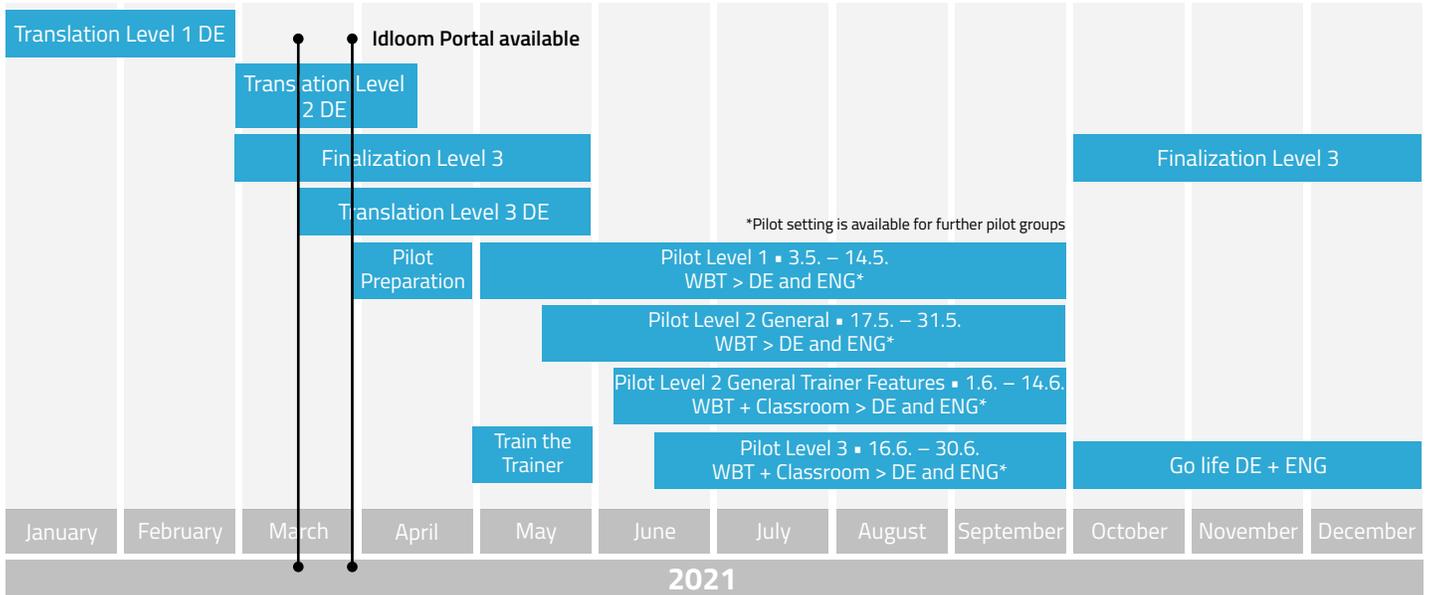
The following elements are set to be part of the restriction.

- The suppliers of diisocyanates shall ensure that the recipient is provided with training materials and courses in the official language(s) of the Member State(s) where the substance(s) or mixture(s) are supplied.
 - The training shall take into consideration the specificity of the products supplied, including composition, packaging, and design.
 - The training will be conducted either as classroom training/virtual, classroom training in house, by a consultant or by public authorities or as online training;
 - The trainings may be conducted through accredited trainers;
 - The user – either the employer of the user or the self-employed person - of diisocyanates must document the completion of the training;
 - Each employee will have to be trained once every five years, with the content and training duration depending on the use of diisocyanates in combination with the concrete task;
 - The transition period during which industry must prepare for the training requirements is 3 years as of publication in the official European Journal and applies from 24 August 2020.
 - The trainings must comply with provisions set by the relevant Member State in which the user operates. Member States may continue to apply their own requirements as long as the minimum requirements of the Restriction are met.
 - Training can be conducted in various ways, including off-site/on-site training courses, E-learning, integration of training into the product presentation;
 - The Member States must report on their established training requirements, the number of reported cases on occupational asthma and occupational respiratory and dermal disease, any national occupational exposure levels and information on enforcement activities.
- The member companies of ISOPA and ALIPA as well as trade associations (see page 12) of relevant downstream users are working closely together to develop the required set of training.

ISOPA and ALIPA's work moving forward

Diisocyanate manufacturers have invested in the development of a comprehensive package of training materials, which we are preparing for rollout following entry into force of the REACH Restriction.

ISOPA and ALIPA will work to educate the value-chain on the training requirements and the availability of training materials. We will also work with Member States to ensure that training materials meet their expectations and seek to promote a harmonised approach across the EU.



Trainings levels will depend on risk of exposure

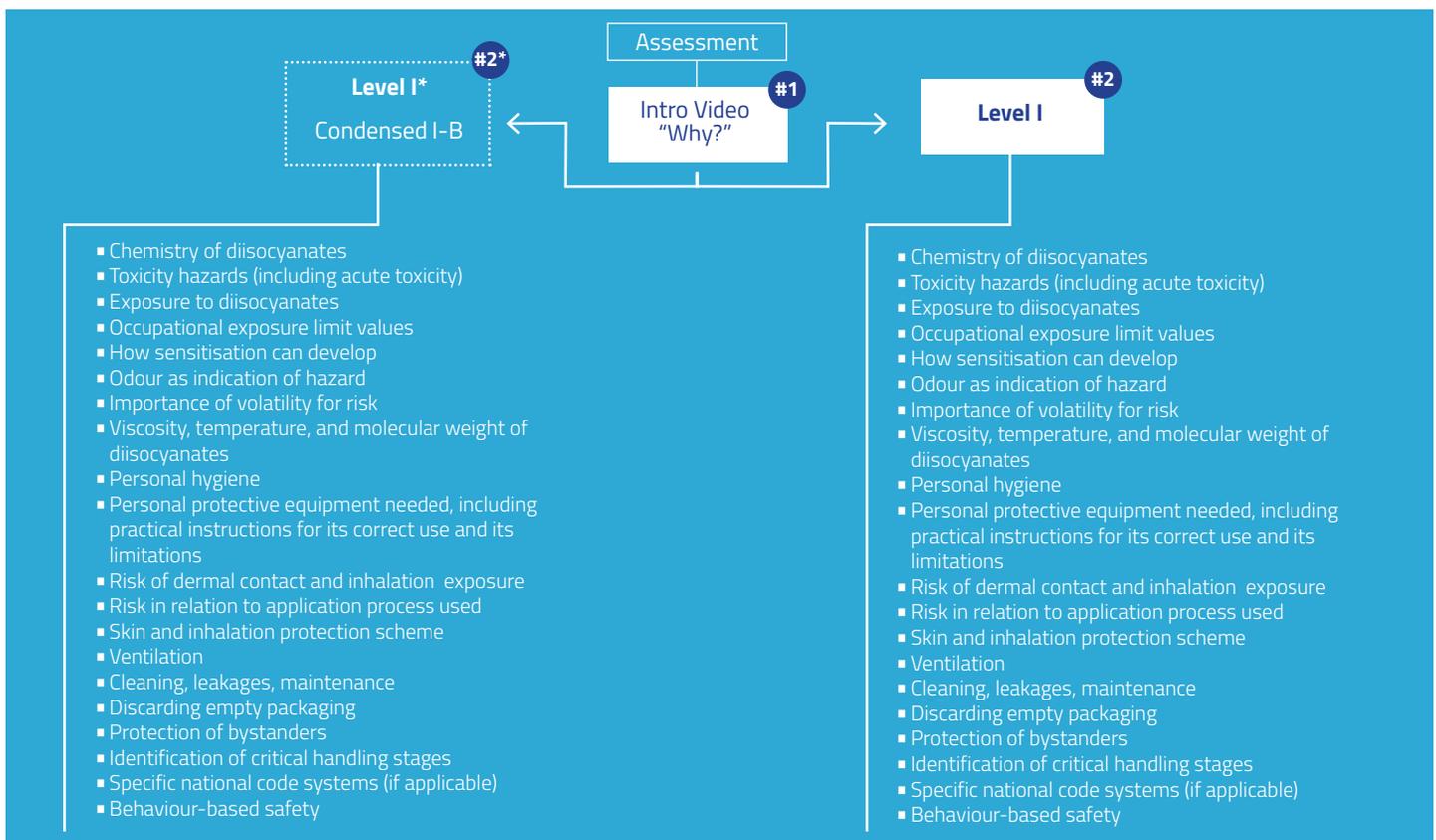
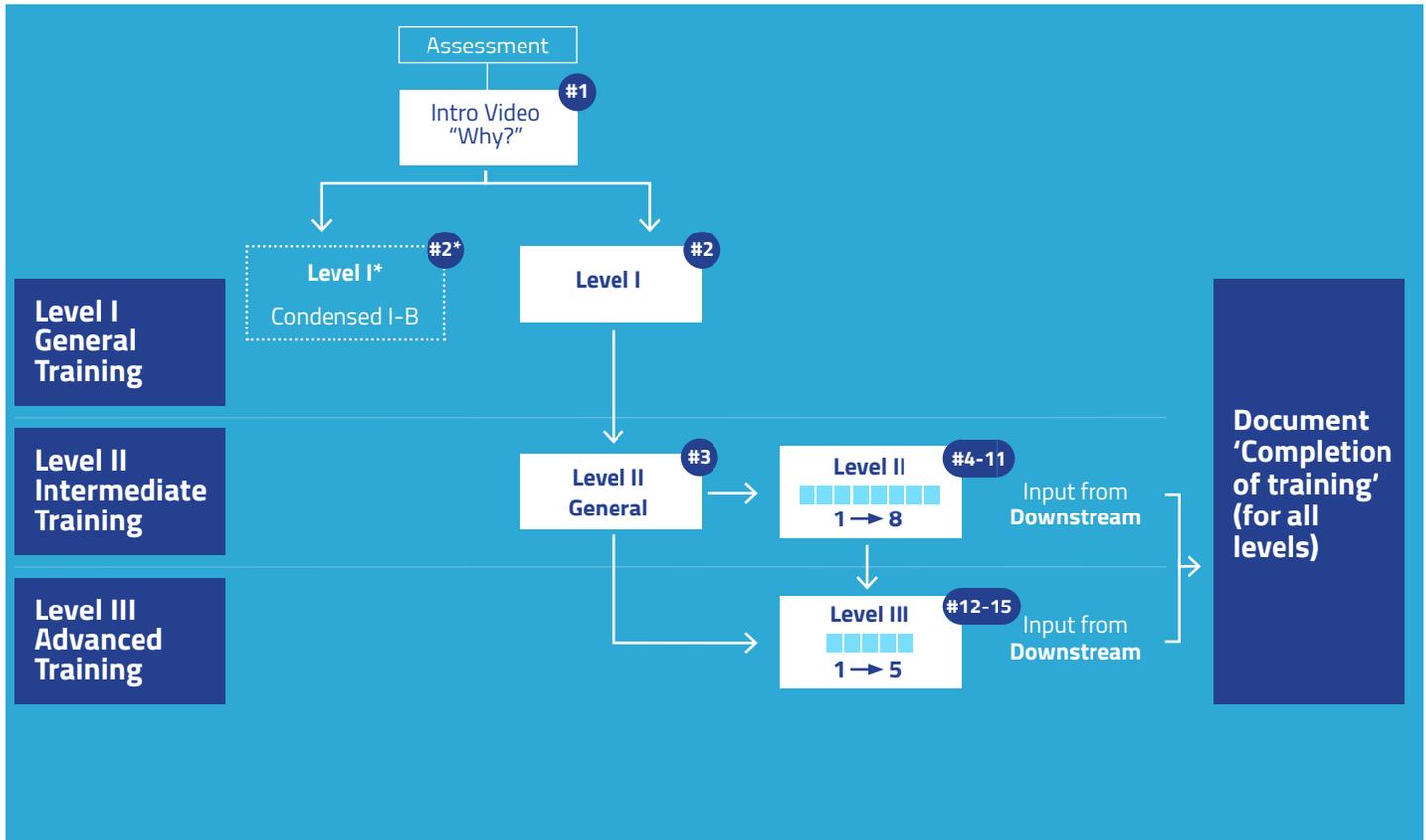
The Restriction specifies the level of training required for various uses of diisocyanates.

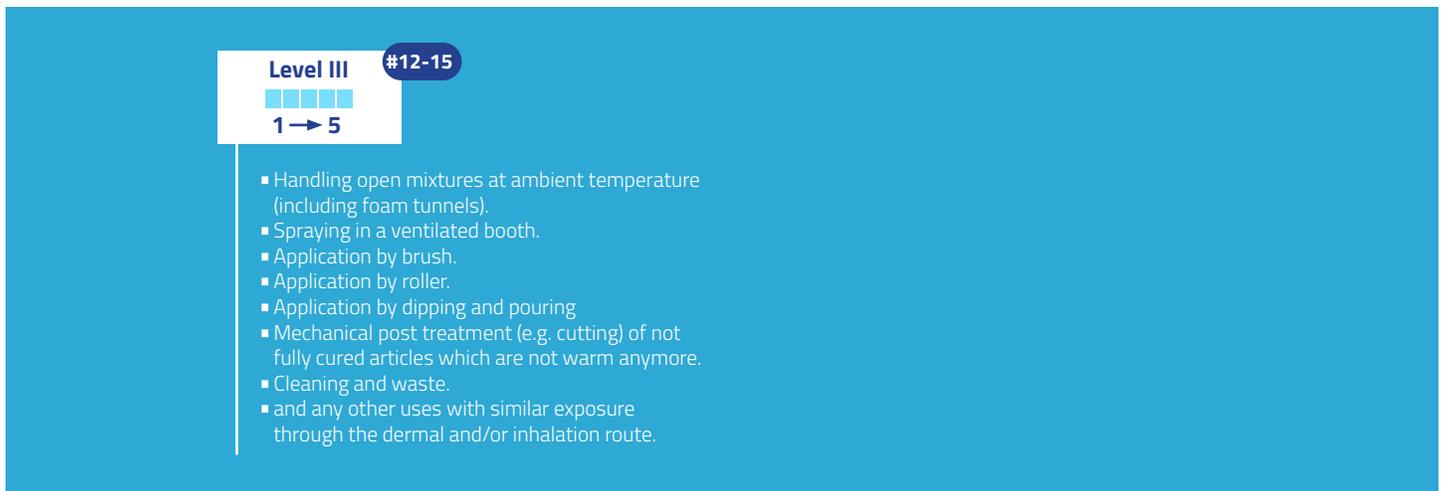
| Uses of diisocyanates requiring levels 1 training | Uses of diisocyanates requiring levels 1 and 2 training | Uses of diisocyanates requiring levels 1,2 and 3 training |
|--|--|--|
| <ul style="list-style-type: none"> all industrial and professional use(s) | <ul style="list-style-type: none"> handling open mixtures at ambient temperature (including foam tunnels); spraying in a ventilated booth; application by roller; application by brush; application by dipping and pouring; mechanical post treatment (e.g. cutting) of not fully cured articles which have cooled; cleaning and waste; any other uses with similar exposure through the dermal and/or inhalation route; | <ul style="list-style-type: none"> handling incompletely cured articles (e.g. freshly cured, still warm); foundry applications; maintenance and repair that needs access to equipment; open handling of warm or hot formulations (>45°C); spraying in open air, with limited or only natural ventilation (includes large industry working halls) and spraying with high energy (e.g. foams, elastomers); and any other uses with similar exposure through the dermal and/or inhalation route. |

| Level 1 training | Level 2 training | Level 3 training |
|--|--|---|
| <p>General training, including on-line training, on</p> <ul style="list-style-type: none"> ▪ chemistry of diisocyanates; ▪ toxicity hazards (including acute toxicity); ▪ exposure to diisocyanates; ▪ occupational exposure limit values; ▪ how sensitisation can develop; ▪ odour as indication of hazard; ▪ importance of volatility for risk; ▪ viscosity, temperature, and molecular weight of diisocyanates; ▪ personal hygiene; ▪ personal protective equipment needed, including practical instructions for its correct use and its limitations; ▪ risk of dermal contact and inhalation exposure; ▪ risk in relation to application process used; ▪ skin and inhalation protection scheme; ▪ ventilation; ▪ cleaning, leakages, maintenance; ▪ discarding empty packaging; ▪ protection of bystanders; ▪ identification of critical handling stages; ▪ specific national code systems (if applicable); ▪ behaviour-based safety. <p><i>General training can be e-learning or class room.</i></p> | <p>Intermediate Training</p> <ul style="list-style-type: none"> ▪ additional behaviour-based aspects; ▪ maintenance; ▪ management of change; ▪ evaluation of existing safety instructions; ▪ risk in relation to application process used; ▪ certification or documented proof that training has been successfully completed. <p><i>Intermediate training includes general training and can be either e-learning or class room.</i></p> | <p>Advanced Training</p> <ul style="list-style-type: none"> ▪ any additional certification needed for the specific uses covered; ▪ spraying outside a spraying booth; ▪ open handling of hot or warm formulations (>45 °C); ▪ certification or documented proof that training has been successfully completed. <p><i>Advanced training includes general and intermediate training and can be either e-learning or class room.</i></p> |

Training Structure

The training programme will reflect the three levels in the regulation intended for different users. Each level will have several modules with 15 foreseen in total.





Industry's commitment and dialogue with REACH authorities

The diisocyanates industry has been engaged in the regulatory process from the start in order to provide authorities with the most robust data and information, and to permit REACH regulators to have a pragmatic and harmonised approach, which could be applicable to all companies, including SMEs.

Following BAuA's RMOA on diisocyanates in 2014, ISOPA and ALIPA decided to further cooperate with downstream associations in the context of REACH-related issues. They actively provide relevant information to authorities by conducting research on diisocyanates in a newly created platform, the Polyurethane (PU) Exchange Panel.

The Panel's goal is to allow the entire value-chain to better participate in the process with all relevant REACH Competent Authorities in Europe. Several downstream associations of the PU Exchange Panel are joining efforts to develop teaching materials.

Associations Involved

List of panel members

EU

ALIPA
APPLIA
CEC (Footwear)
CEPE (Coatings & Paintings)
Cotance (Euroleather)
EFCC (Construction Chemicals)
EFIC (Furniture Industry)
EPF (Panel Federation)
EPDLA
ETRMA (Rubber)
Euratex
Euromoulders
Europur
Fecc (Chemical Distributors)
FEICA (Adhesives & Sealants)
FeRFA (Resin Flooring)
Icomia
ISOPA
PPA-Europe (Panels & Profiles)
PU Europe
RTP Resin
PDA Europe Polyurea Development Association

DE/BE

Deutsche Bauchemie

Fedustria

FSK

IVK (Adhesives)

IVPU (Rigid Foam Producers)

VdL (Coating industry)

ZVEI (Electric and Electronic Manufacturers)

Product stewardship programmes – Promoting the safe use of diisocyanates

The safe production, use, transport and selling of diisocyanates and polyols have always been one of ISOPA and ALIPA's core missions. ISOPA and ALIPA members as well as downstream users of diisocyanates at European and national levels are strongly committed to the safe use of diisocyanates and safety at the workplace.

For ISOPA and ALIPA, and the members of the PU Exchange Panel, behaviour at the workplace is key to ensuring the safe use of diisocyanates. For decades, the industry has therefore developed and promoted a number of product stewardship programmes.



Walk the Talk is a programme developed by the members of ISOPA with the aim of improving safety, health and environmental best practices across the European polyurethanes industry. The Walk the Talk programme focuses on the behavioural safety of industrial and professional users involved in the industry through an ongoing dialogue. The programme consists of detailed sets of training covering all the phases of the industrial process: processing, maintenance, warehousing and waste. From the arrival of chemicals to the discharge, which rely on potentially dangerous operations, ISOPA provides support to both users and logistics service providers. Two information packages are available: a Basic Safety Package and a package containing EU REACH & CLP information.



The safe transport of diisocyanates is essential for both people and manufacturers. All participants in the supply chain, manufacturers of MDI/TDI, transportation companies and receivers of the products play vital roles in ensuring that accidents are prevented. ISOPA is committed to the continuous improvement of best practices in the loading, transport, unloading and storage of diisocyanates and polyols. Our aim is to ensure maximum protection of health and safety and a consistent industry-wide approach. ISOPA has developed a series of guidelines that reflect the collective knowledge and best practice of the logistics personnel of the ISOPA member companies. They cover all aspects of the supply of chemicals.



ALIPA's Safeguard programme consists of information packages with recommendations and measures regarding safe handling of aliphatic isocyanates. The programme focuses on the safe use of aliphatic diisocyanate monomers and on safe use of aliphatic polyisocyanates in spray applications.

FAQ

on diisocyanates



Products

What are MDI, TDI, HDI, HMDI and IPDI?

MDI stands for Methylene diphenyl diisocyanate and TDI stands for Toluene diisocyanate. From a chemical point of view, they are aromatic diisocyanates and are considered organic compounds.

Aliphatic diisocyanates are hexamethylene diisocyanate (HDI), methylene dicyclohexyl diisocyanate or hydrogenated MDI (HMDI) and isophorone diisocyanate (IPDI).

Where are they used?

Together with polyols, MDI and TDI are the essential building blocks for the manufacturing of polyurethane. They can be tailored to be either rigid or flexible, and are the materials of choice for a broad range of applications such as insulation in buildings and white goods; and adhesives, coatings, automotive parts, sportswear, etc.

Aliphatic diisocyanates are light-resistant substances which are preferably reacted with polyester- and polyether-polyols and used for coatings, sealants and elastomers where colour-stability is required.



REACH RESTRICTION

Why did the EU adopt a Restriction on diisocyanates under REACH?

The REACH Restriction on Diisocyanates was adopted due to the occupational sensitisation health effect they could pose to workers above a certain level of exposure. It is therefore a specific use restriction that is envisaged. Restrictions will target products containing more than 0.1% by wt monomeric diisocyanates.

When will the Restriction apply?

After the publication in the official EU Journal on 4 August 2020, there will be a transition period of three years for companies placing diisocyanates on the market to give them adequate time to ensure compliance.

Can diisocyanates still be placed on the market in the EU and can I still legally use them?

Yes, diisocyanates remain available on the EU market but training is required for industrial and professional users. The Restriction intends to improve the behaviour of employees at the workplace with the aim of reducing the risk of developing occupational asthma.

Which steps do I need to take under the Restriction?

Industrial or professional users will be permitted use of diisocyanates if they complete a training course ensuring the control of dermal and inhalation exposure to reduce the risk of asthma before 24 August 2023.

ISOPA and ALIPA will keep stakeholders informed on the availability of the training materials and courses.

What will ISOPA and ALIPA do to support stakeholders?

Diisocyanate manufacturers have invested in the development of a comprehensive package of training materials, which we are preparing for rollout following the entry into force of the REACH Restriction.

ISOPA and ALIPA have successfully launched safety initiatives in the past which have already helped to reduce the number of sensitisation cases significantly. Campaigns like “Walk The Talk” (2006) and “We care that you care” (2010) raised the awareness of workers dealing with hazardous substances and refined measures to avoid contact with diisocyanates and polyurethane hardeners via skin and breathing systems.



Market

What are the supply chains for these chemicals?

Diisocyanates and polyols are sold to downstream companies producing flexible and rigid polyurethane foams as well as elastomers, binders or coating materials. Further down the value chain, we find manufacturers of building insulation, white goods, automotive, furniture and bedding, footwear, coatings and adhesives, etc.

How many people does the industry employ?

According to a survey conducted in 2018 by an external party, the polyurethane industry involves more than 244,000 companies (most of which are SMEs), providing almost five million jobs in Europe:

- 23 companies from the chemical industry are directly involved in the production of the main components for polyurethanes (polyols/diisocyanates) creating creates jobs for 13,500 employees across Europe.
- 350,000 employees directly contribute in terms of polyurethane production, including direct and downstream customers and their suppliers and subcontractors. Through its many applications, polyurethane is used by 4.7 million people throughout the EU in their work.

Which companies produce diisocyanates and polyols?

ISOPA represents the European manufacturers of aromatic diisocyanates and polyols, and its members are: Covestro, BorsodChem, Dow, BASF, 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.



Safety

Are diisocyanates safe?

Like any substance, the use of diisocyanates is safe when chemicals are handled according to relevant risk management and safety measures.

It is also important to stress that virtually no diisocyanates can be found in finished articles; hence, there is no consumer exposure. MDI and TDI do not migrate as they are only reactive chemicals.

Do MDI and TDI meet Substance of Very High Concern (SVHC) criteria?

Our industry firmly believes that MDI and TDI are not SVHC according to the criteria outlined under REACH, for the three following reasons:

- The threshold for respiratory sensitisation is never met when risk management measures are applied correctly. Our industry is therefore convinced that the inclusion of diisocyanates as sensitisers under the SVHC process would not be justified or proportionate to the risk.
- In case of exposure, the effects of MDI and TDI are reversible and not comparable to CMR (Carcinogenicity, Mutagenicity, Reproductive toxicity). When exposure ceases, the overwhelming majority of individuals with diisocyanate-related sensitisation show significant improvement or totally recovery.
- In the last decade, we have observed a significant decrease in cases of diisocyanate-related sensitisation against a growing polyurethane market that doubled since 1995; confirming that new sensitisation cases can be eliminated by implementing safe exposure limits and appropriate controls.

What is sensitisation?

Sensitisation means that after a high level of exposure, a person could become allergic to the substance. If sensitised, each time the person is in contact again with the substance (even at very low concentrations) the person would have a strong allergic reaction with respiratory impacts (e.g. asthma).

The majority of individuals with diisocyanates-related asthma show improvement over time or total recovery after exposure has ceased.

Furthermore, it is important to highlight that the majority of diisocyanates uses are industrial or professional applications. Health complaints only occur if the person is in contact with the substance at high levels of exposure.

Are there alternatives to polyurethanes?

Polyurethanes cannot be produced without aromatic or aliphatic diisocyanates. Therefore, there is no alternative for MDI, TDI, HDI, IPDI or H12MDI. To date, no other chemicals have been found to be able to replace their function in the production of polyurethane articles.

Are there alternatives to polyurethanes?

Polyurethanes provide outstanding benefits in many applications and contribute significantly to society's sustainable development, e.g. through energy and resource efficiency. Alternative technologies are not available for all applications and alternative materials might not provide the same performance in terms of durability and efficiency.

Further information on REACH and diisocyanates

Registration

First and foremost, companies are obliged to collect information on the properties and the uses of the substances they manufacture or import at or above one tonne per year. This includes an assessment of their hazards and potential risks.

Evaluation

ECHA and EU Member States will then evaluate the information submitted by companies, as well as the quality of the registration dossiers and testing proposals, in order to clarify if a given substance constitutes a risk to human health or the environment.

REACH Evaluation led by Poland and Estonia

Both TDI and MDI have been added to the ECHA Community Rolling Action Plan (CoRAP). TDI was evaluated in 2013 by the Polish Competent

Authority which concluded that no regulatory action was needed.

MDI has been evaluated since 2013 by Estonia which concluded that no regulatory follow-up action was needed. HDI was evaluated by Slovenia, which has also concluded that there was no need for further action.

Authorisation

The authorisation procedure aims to assure that the risks from Substances of Very High Concern (SVHC) are properly controlled, and that these substances are progressively replaced by suitable alternatives. SVHC substances are listed in the so-called 'Candidate list'. The list includes

Carcinogenic, Mutagenic, Reprotoxic (CMR) substances, Persistent Bio-accumulative Toxic (PBT) substances and substances of equivalent concern (endocrine disruptors, sensitisers, etc.).

Glossary

| | |
|-----------------------|---|
| ALIPA: | European Aliphatic Isocyanates Producers Association. |
| BAuA: | German Federal Institute for Occupational Safety and Health (BAuA). |
| CMR: | Substance classified in Part 3 of Annex VI to CLP Regulation as carcinogenic, mutagenic or toxic for reproduction. |
| CoRAP: | Community rolling action plan (CoRAP) – CoRAP specifies the substances that are to be evaluated under REACH over a period of three years. |
| Diisocyanates: | Family of chemical building blocks mainly used to make polyurethane products, such as rigid and flexible foams, coatings, adhesives, sealants and elastomers. Diisocyanates are divided into two types: aromatic diisocyanates and aliphatic diisocyanates. |
| ECHA: | European Chemicals Agency. |
| EU: | European Union |
| HDI: | Hexamethylene diisocyanate |
| HMDI: | Methylene dicyclohexyl diisocyanate or hydrogenated MDI |
| IPDI: | Isophorone diisocyanate |
| ISOPA: | European trade association for producers of diisocyanates and polyols. |
| MDI: | Methylenediphenyl diisocyanate |
| REACH: | Registration, Evaluation, Authorisation and Restriction of Chemicals |
| RMOa: | Risk management option analysis - helps decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern. |
| SVHC: | Substance of very high concern |
| TDI: | Toluene diisocyanate |

Isopa EUROPEAN DIISOCYANATE & POLYOL
PRODUCERS ASSOCIATION

ALIPA
EUROPEAN ALIPHATIC ISOCYANATES PRODUCERS ASSOCIATION

Jörg Palmersheim

ISOPA Aisbl

ALIPA Aisbl

Secretary General

Rue Belliard 65

B-1040 Brussels

Contact ISOPA:

Email: main@isopa.org

Visit us: www.isopa.org

Contact ALIPA:

Email: info@alipa.org

Visit us: www.alipa.org