

Guide to the restriction process applying to diisocyanates







2. 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.



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.



. 1. © FSK e.V. . 2 . @ FSK e.V.





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 polyure-thane 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



Authorisation of



CHemicals

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.).

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.



Restriction

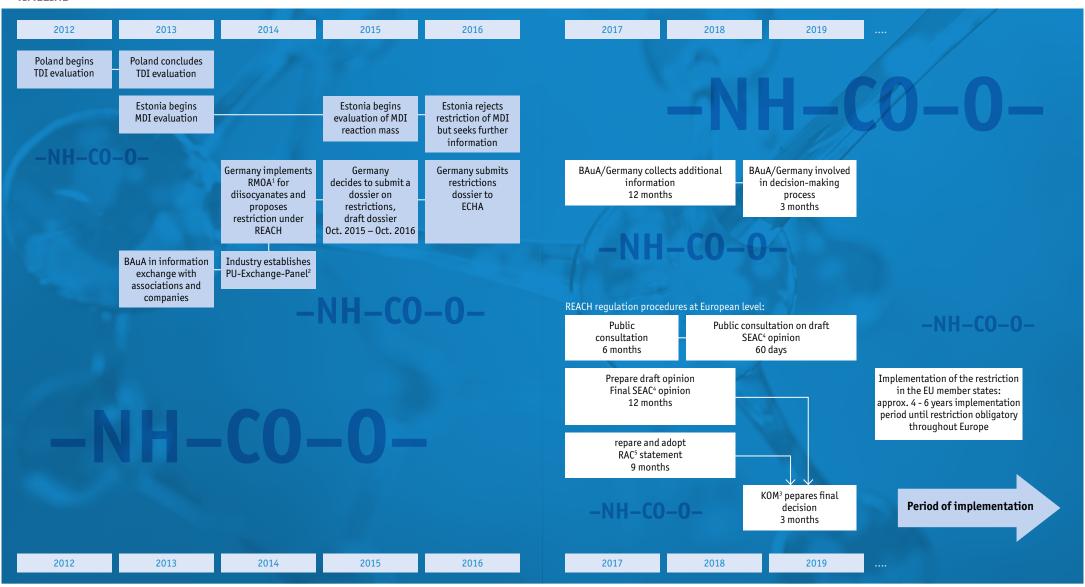
Restrictions are designed to protect human health and the environment from unacceptable hazards posed by chemicals. Restrictions may restrict or prohibit the production, marketing or use of a substance. In some specific cases, such as diisocyanates, where the product has an extremely wide range of applications, 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.



 GUIDE



TIMELINE



¹RMOA: Risk Management Option Analysis - helps to decide whether further regulatory risk management measures are required for a particular substance and to find the most appropriate instrument to address a problem.

²PU-Exchange-Panel: Interest Group of national and European associations, members see list on page 17.

3KOM: European Commission

⁴SEAC: Committee for Socio-economic Analysis (The Committee prepares ECHA opinions on the socio-economic impact of possible leaislation on substances in the REACH process.)

⁵RAC: Committee for Risk Assessment (The Committee prepares ECHA opinions on risks of possible substances to human health and the environment in the REACH process.)

.7. © FSK e.V. . .8. © FSK e.V.





Registration

Evaluation and

Authorisation of

CHemicals

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 measures in Germany

The BAuA (German Federal Institute for Occupational Safety and Health), the authority responsible for REACH in Germany, carried out an RMOA 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 proposal for a restriction was examined by RAC (Committee for Risk Assessment) and SEAC (Committee for Socio-economic Analysis - on the socio-economic impact of possible legislative measures on substances) and has been through two public consultation phases. The final draft of the restrictions dossier is in preparation, taking into account the opinions of RAC and SEAC as well as the contributions of the participants in the public consultation.

If the European Council or the European Parliament does not object to the restriction, the EU Commission will accept it. A decision by the EU Commission is expected in 2019. The restriction decision will be published in the Official Journal as Annex XVII of the REACH Regulation.

For the implementation of a corresponding catalogue of measures (training and certification system), a transition phase will be defined by the EU. The industry hopes for a period of up to six years until the substance restriction becomes mandatory throughout Europe and for all participants along the value-added chain.

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 17).

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.





Restriction Proposal and Exemptions

THE RESTRICTION PROPOSAL

Envisaged Annex XVII entry:

Diisocyanates ...

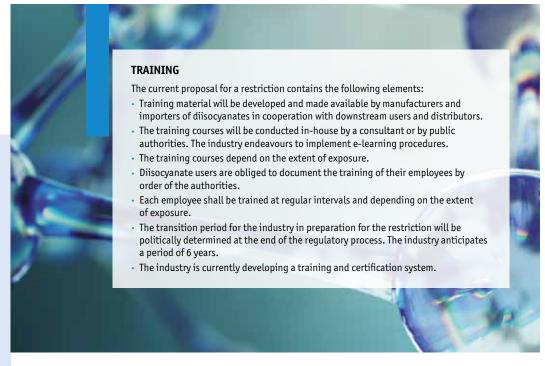
- 1. shall not be **used** as substances on their own, as a constituent in other substances or in mixtures for industrial and professional uses, unless
- a) the cumulative concentration of diisocyanates in the substance or mixture is less than 0,1 % by weight, or
- b) measurements under realistic conditions have demonstrated according to Appendix M that only an acceptable residual risk is present it the substance or mixture is used as described an intended or
- c) the substance or mixture is used in accordance with the provisions described in Appendix N.
- 2. shall not be **placed on the market** as substances on their own, as a constituent in other substances or in mixtures for industrial and professional uses, unless
- a) the cumulative concentration of diisocyanates in the substance or mixture is less than 0,1 % by weight, or
- b) measurements under realistic conditions have demonstrated according to Appendix M that only an acceptable residual risk is present if the substance or mixture is used as described an intended or
- c) the substance or mixture is supplied to a downstream user who uses the substance or mixture in accordance with the provisions described in Appendix N (1).
- (1) This can i.e. be assured if these persons have been trained by the person that placed this product on the market (product stewardship).

Appendix M and N will be developed in parallel to the Annex XV dossier.



The proposed restriction therefore prohibits the use of substances containing free diisocvanate (of any kind) in concentrations greater than 0.1% by weight, unless the company can clearly demonstrate that an operational process exists that ensures strict compliance with diisocyanate handling regulations.

This should also include requirements to safeguard against health risks for third parties (e.g. residents), in particular through spray foam applications. Compliance with this procedure (training system) must be documented by participation in a certification system prescribing the application of certain minimum conditions of use. Accordingly, products containing monomeric diisocyanates in concentrations of more than 0.1% by weight would be covered by this restriction.



Level 1 training (4 hours)*

- Loading/Unloading trucks
- Pumping/loading using closed systems
- Application of sealants and adhesives (including foam application from cans)
- composite materials after manufacturing
- Polyurethane processing elastomers
- Working in a laboratory

Level 2 training (4+4 hours)*

- Handling of cold fibres and
- with special closed machines such as foaming, adhesives, sealants,

Training level 1 can be done online

- · Handling of mixtures at ambient temperature (incl. foam tunnels)
- Handling of not fully cured parts (e.g. freshly cured, still warm)
- Spraying in a ventilation booth
- Spraying process
- Application by roller
- Application by brush
- Application by dipping and pouring
- Handling oligomers after manufacturing
- Foundry applications
- Mechanical post treatment (e.g. cutting) of not fully cured parts
- Cleaning and waste
- Maintenance and repairs with access equipment
- Change management

Level 3 training (4+4+8 hours)*

- Open handling of warm or hot product (45 °C and more)
- Spray application outdoors, with limited or exclusively natural ventilation (including large industrial halls) and spraying with high energy (e.g. foams, elastomers)

. 11 . @ FSK e.V. . 12 . @ FSK e.V.

^{*} The list is non-binding and not exhaustive. Further activities may be added.





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 are strongly committed to the safe use of diisocyanates and safety at the workplace at European and national levels.

For ISOPA, 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 been developing and promoting a series of measures for product stewardship.



Walk the Talk is a programme developed by the members of ISOPA with the aim of improving safety, health and environmental standards in the European polyurethanes industry. The Walk the Talk program focuses on the behavioural safety of industrial and commercial users through continuous exchange. The program includes detailed training on all phases of the industrial process: processing, maintenance, storage and disposal. From the arrival of chemicals to their disposal, which may require hazardous activities, ISOPA supports both users and logistics service providers. There are two information packages: A basic safety package and a package containing information on the European REACH and CLP regulations.



The **safe transport** of diisocyanates is important for both consumers and manufacturers. All those involved in the supply chain, the manufacturers, the transport companies and the recipients of the products play an important role in the prevention of accidents. ISOPA is committed to constantly raising standards in the loading, transport, unloading and storage of diisocyanates and polyols. The aim is to ensure maximum health and safety protection and a consistent, industry-wide approach. ISOPA has developed a set of guidelines that incorporate the common knowledge and best practices of ISOPA member companies' logistics personnel. They cover all aspects of the supply of chemicals.

alipasafeguard, ALIPA's **product safety program**, contains information packages as well as recommendations and measures for the safe handling of aliphatic isocyanates. The program focuses on the safe use of aliphatic diisocyanate monomers and the safe use of aliphatic polyisocyanates in spray applications.

alipasafeguard"

FREQUENTLY ASKED QUESTIONS ABOUT DIISOCYANATES

PRODUCTS

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

MDI stands for methylenediphenyl diisocyanate and TDI for toluene diisocyanate. Chemically, these substances belong to the aromatic diisocyanates and are organic compounds. Aliphatic diisocyanates include hexamethylene diisocyanate (HDI), methylenedicyclohexyl diisocyanate (HMDI) or hydrogenated MDI and isophorone diisocyanate (IPDI). Aliphatic diisocyanates are primarily used in the production of coatings, adhesives, sealants and elastomers. They are converted into polyisocyanates and used in smaller amounts than the aromatic diisocyanates. Aside from these most important diisocyanates, there are a number of other specialties.

Where are they used?

Together with polyols, the aromatic and aliphatic diisocyanates are the most important building blocks for the production of polyurethane. Polyurethane can be hard or soft and is used in a wide variety of applications, including building insulation, household appliances, adhesives, paints, automotive parts, sportswear, etc.

MARKET

Who are these chemicals sold to?

Diisocyanates and polyols are sold to downstream companies that use them in the production of flexible and rigid PUR foams, elastomers, binders or coatings. Further down the value chain are manufacturers of building insulation, household appliances, automotive parts, furniture, bedding, footwear, paints and adhesives, etc.

How many people does the industry employ?*

According to FSK surveys, more than 263,000 companies (most of them SMEs) are active in the polyurethane industry, creating over 1 million jobs in Europe.

Approx. 197,000 direct jobs (directly related to the production of PUR chemicals, including direct customers and downstream customers).

- Over 60,000 indirect jobs (suppliers/subcontractors)
- Nearly 732,000 jobs created by expenditure (i.e. the expenditure representing the economic contribution of the polyurethane industry to all non-PUR sectors of the 27 EU countries).
- * Source: FSK 2018

Which companies produce diisocyanates and polyols?

ISOPA represents the European producers of aromatic diisocyanates and polyols and has the following members: Covestro, BorsodChem, Dow, BASF, Huntsman and Shell.

ALIPA is the European professional association of manufacturers of aliphatic isocyanates. It was established by the largest European manufacturers BASF, Covestro, Evonik and Vencorex.

In which amounts are these substances produced in the EU?

In terms of raw material consumption, approximately 5 million metric tons of polyurethane were produced in the EMEA (Europe Middle East Africa) region in 2012. During the same period, global consumption of PUR raw materials was approximately 15.3 million tons.

What quantities of these substances are in circulation?

Based on figures from renowned market research and consulting companies for 2017, the FSK expects consumption of polyester raw materials in the EMEA region to be 6,015 kMT and 19,016 kMT globally. Acrylic polyols are approx. 454 kMT and aliphatic isocyanates 355 kMT.



SAFETY

Are diisocyanates safe?

Diisocyanates can be used safely at the workplace and in the production process if the chemicals are handled in accordance with the relevant risk management and safety measures. Since diisocyanates are exclusively reactive chemicals, the end products are also safe. After the chemical reaction, the products contain practically no free diisocyanates, i.e. consumers are not exposed to these substances and do not come into contact with them.

Do diisocyanates meet the criteria for classification as SVHCs?

Our industry is absolutely convinced that diisocyanates are not substances of very high concern according to the criteria set out in the REACH Regulation for the following three reasons:

- The limit value for triggering an inhalation allergy will never be reached provided the risk management
 measures are applied correctly. Our industry is thus convinced that the inclusion of diisocyanates as
 inhalation allergens in the SVHC list is not warranted and would not be justified and not appropriate to the risk.
- The effects of exposure to diisocyanates are reversible and not comparable to those of exposure to CMR (carcinogenic, mutagenic and reprotoxic) substances. As soon as the substance exposure ends most people experience significant improvement or complete elimination of the symptoms of sensitisation to diisocyanates.
- Over the last ten years, we have observed a significant decrease in cases of sensitisation by diisocyanates, with
 at the same time substantial growth of the PUR market, which has doubled since 1995. This confirms that
 new cases of sensitisation can be avoided through safe exposure limit values and appropriate controls.

What does sensitisation mean?

Sensitisation means that a person may develop an allergy to the substance after intensive exposure. When sensitised, the individual would exhibit a pronounced allergic reaction with consequences for the respiratory tract (e.g. asthma) with each new exposure to the substance (even at very low concentrations). Most people with diisocyanate-induced asthma experience improved symptoms or complete relief once substance exposure ends. It should also be emphasized that diisocyanates are used mainly in industrial or commercial applications. Health problems only occur if the person continues to be exposed to the substance after intensive exposure. These are intermediate products and not detectable in finished consumer goods. Sensitisation is therefore much more likely among employees than among consumers.

Are there alternatives to aromatic or aliphatic diisocyanates?

Polyurethane cannot be produced without aromatic or aliphatic diisocyanates. Therefore, there are no alternatives to MDI, TDI, HDI, IPDI or H12MDI. So far, no other chemical substances have been found that can replace their function in the manufacture of polyurethane products

Are there alternatives to polyurethane?

Polyurethane provides enormous advantages in many applications and contributes significantly to the sustainable development of society, e.g. through energy and resource efficiency. Alternative technologies are not available for all applications and alternative materials may not offer the same levels of durability and efficiency.

REGULATION STATUS

Why are restriction measures for diisocyanates being considered?

Restriction measures for diisocyanates are being considered because of the potential health consequences of sensitisation at the workplace exceeding a certain exposure limit value. A specific use restrictions is therefore intended. According to the conclusions of the risk management option analysis "The proposed restriction therefore prohibits the use of substances containing free diisocyanate (of any kind) in concentrations greater than 0.1% by weight, unless the company can clearly demonstrate that an operational process exists that ensures strict compliance with diisocyanate handling regulations. This should also include requirements to safeguard against health risks for third parties (e.g. residents), in particular through spray foam applications. Compliance with this procedure (training system) must be documented by participation in a certification

system prescribing the application of certain minimum conditions of use. Accordingly, products containing monomeric diisocyanates in concentrations of more than 0.1% by weight would be covered by this restriction.

Are diisocyanates still available on the European market and can they still be used legally?

Yes, diisocyanates will continue to be available on the European market. The training courses proposed by the German authorities will become compulsory as soon as the European Union has decided on the restriction.

What is the current status of the procedure?

The BAuA's proposal to limit the handling of diisocyanates exceeding 0.1% by weight to demonstrably trained persons is currently being examined at European level. The German proposal for a restriction was examined by RAC (Committee for Risk Assessment) and SEAC (Committee for Socio-economic Analysis - on the socio-economic impact of possible legislative measures on substances) and has been through two public consultation phases. The final draft of the restrictions dossier is in preparation, taking into account the opinions of RAC and SEAC as well as the contributions of the participants in the public consultation. Consultations are being held at European level between the member states, in which the PU Exchange Panel and the FSK are also involved. The industry is significantly involved in the process and can thus incorporate its position and numerous proposals into the restriction procedure.

What are the next steps?

The Commission is expected to adopt the draft unless the European Council or the European Parliament opposes the final draft of the restriction. A Commission decision is expected between summer 2018 and 2019. The restriction decision will be published in the Official Journal as Annex XVII of the REACH Regulation. The consequence is the introduction of a Europe-wide uniform and compulsory training and certification system.

Who is affected?

Every company dealing with diisocyanates is obliged to train its employees in the safe handling and use of the substances and to provide proof of this (certification). This applies to all companies along the value chain, from manufacturers/importers to system houses/formulators and downstream processors.

What are companies facing?

Training contents will be prepared uniformly throughout Europe. All companies are required to train all employees according to these contents, whereby the extent depends on the type of possible exposure. This also applies for the certification.

When will training and certification become compulsory?

The training and certification system will be implemented throughout Europe immediately following the Commission's decision. The contents and prerequisites for this are already in the development phase. A transition phase will be defined by the EU for the implementation of a corresponding catalogue of measures (training and certification system). The industry is hoping for a period of up to six years until the substance restriction becomes mandatory throughout Europe and for all participants along the value chain.





GLOSSARY

ALIPA European Aliphatic Isocyanates Producers Association German Federal Institute for Occupational Safety and Health BAuA

CEFIC Conseil Européen des Fédérations de l'Industrie Chimique - European Chemical Industry Council Classification, Labelling and Packaging - EU directive on classification, labelling and packaging CLP

of substances and mixtures

CMR-Stoffe Cancerogen, mutagen, reprotoxic substances - carcinogenic, mutagenic and fertility-endangering

substances

CoRAP Community Rolling Action Plan - a rolling community action plan defining the substances to

be evaluated under REACH over a three-year period

Diisocyanate Group of basic chemical building blocks mainly used in the manufacture of polyurethane products,

coatings, adhesives, sealants and elastomers. Aromatic diisocyanates are organic compounds (TDI and MDI), aliphatic diisocyanates include HDI, HMDI (hydrogenated MDI) and IPDI. In addition to

these most important diisocyanates, there are a number of other specialities.

ECHA European Chemicals Agency

EMEA Economic area Europe-Middle East-Africa

EU European Union

FSK Specialist Association Foamed Plastics and Polyurethanes

HDI Hexamethylene diisocyanate

Methylene dicyclohexyl diisocyanate or hydrogenerated MDI HMDI

4.4'-Methylene dicyclohexyl diisocyanate H12MDI

IPDI Isophorone diisocyanate

ISOPA European Diisocyanate and Polyol Producers Association

KMU Small and Medium Enterprises (EU-)KOM European Commission MDI Methylendiphenyl diisocyanate

PBT-Stoffe Persistent, bioaccumulative, and toxic substances

PUR/PU Polyurethane

RAC Committee for Risk Assessment of substances to human health and the environment REACH-VO

REACH Regulation - Registration, Evaluation and Authorisation of Chemicals

RMOA Risk management option analysis - helps to decide whether further regulatory risk management

measures are required for a particular substance and to find the most appropriate instrument

to address a concern.

SEAC Committee for Socio-economic Analysis - on the socio-economic impact of possible legislation

on substances

SVHC Substances of very high concern

TDI Toluolene diisocyanate

. 18 . © FSK e.V. . 17. © FSK e.V.



Brussels • Frankfurt • Stuttgart

Postal address: Stammheimer Straße 35 • D-70435 Stuttgart

Tel. +49 711 993 751-0 • www.fsk-vsv.de • fsk@fsk-vsv.de







Disclaimer of liability

This document is for information purposes only. All data and information in this document come from sources which the FSK considers reliable. In addition, the authors have taken the greatest possible care to ensure that the facts and opinions expressed are appropriate and accurate. Nevertheless, no guarantee or liability can be assumed for their correctness - either expressly or tacitly. In addition, all information may be incomplete or summarised. Neither the FSK e.V. nor the participating companies assume liability for damages arising from the use of this document or its contents or in any other way in this context.