BUREAU FOR CHEMICAL SUBSTANCES

SUBSTANCE EVALUATION

CONCLUSION DOCUMENT

as required by REACH Article 48

for

Tolylidene diisocyanate

EC No 247-722-4

CAS No 26471-62-5

Evaluating Member State(s): Poland

Dated: 12/11/2013

Evaluating Member State Competent Authority

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Year of evaluation in CoRAP: 2012

Member State concluded the evaluation without the need to ask further information from the registrants under Article 46(1) decision.

Please find (search for) further information on registered substances here:

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances

Foreword

Substance evaluation is an evaluation process under REACH Regulation (EC) No. 1907/2006. Under this process the Member States perform the evaluation and ECHA secretariat coordinates the work.

In order to ensure a harmonised approach, ECHA in cooperation with the Member States developed risk-based criteria for prioritising substances for substance evaluation. The list of substances subject to evaluation, the Community rolling action plan (CoRAP), is updated and published annually on the ECHA web site[1].

Substance evaluation is a concern driven process, which aims to clarify whether a substance constitutes a risk to human health or the environment. Member States evaluate assigned substances in the CoRAP with the objective to clarify the potential concern and, if necessary, to request further information from the registrant(s) concerning the substance. If the evaluating Member State concludes that no further information needs to be requested, the substance evaluation is completed. If additional information is required, this is sought by the evaluating Member State. The evaluating Member State then draws conclusions on how to use the existing and obtained information for the safe use of the substance.

This Conclusion document, as required by the Article 48 of the REACH Regulation, provides the final outcome of the Substance Evaluation carried out by the evaluating Member State. In this conclusion document, the evaluating Member State shall consider how the information on the substance can be used for the purposes of identification of substances of very high concern (SVHC), restriction and/or classification and labelling. With this Conclusion document the substance evaluation process is finished and the Commission, the registrants of the substance and the competent authorities of the other Member States are informed of the considerations of the evaluating Member State. Thus this conclusion document is not reflecting an official position of ECHA. In case the evaluating Member State proposes further regulatory risk management measures, this document shall not be considered initiating those other measures or processes.

[1] http://echa.europa.eu/regulations/reach/evaluation/substance-evaluation/community-rolling-action-plan

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1. CONCERN(S) SUBJECT TO EVALUATION

Tolylidene diisocyanate (TDI) was originally selected for substance evaluation in order to clarify suspected risks about:

- a respiratory and skin sensitizing properties,
- a potential carcinogenicity and
- a suspected PBT properties.
- wide dispersive use and high aggregated tonnage

According to human health TDI is classified regarding acute inhalation toxicity, as a skin, eye and respiratory irritant, skin and respiratory sensitizer, and suspected carcinogen because of its hydrolysis product – tolylidene diamine (TDA).
The TDI-induced health effects include development of occupational asthma due to its sensitization properties.

Regarding environmental hazard TDI is classified as harmful to aquatic life with long lasting effects.

TDI is very widely used in flexible polyurethanes to manufacture foams, elastomers, adhesives and sealants.
According to ECHA's database TDI is used in quantities of 100,000 - 1,000,000 tonnes per annum.

During the evaluation no further concerns to be clarified under substance evaluation process were identified.

2. CONCLUSION OF SUBSTANCE EVALUATION

The available information on the substance and the evaluation conducted has led the evaluating Member State to the following conclusions, as summarised in the table below.

Conclusions	**Tick box**
Need for follow up regulatory action at EU level *[if a specific regulatory action is already identified then, please, select one or more of the specific follow up actions mentioned below]*	
Need for Harmonised classification and labelling	
Need for Identification as SVHC (authorisation)	
Need for Restrictions	
Need for other Community-wide measures	
No need for regulatory follow-up action	X

3. JUSTIFICATION FOR THE CONCLUSION ON THE NEED OF REGULATORY RISK MANAGEMENT

3.1. NEED FOR FOLLOW UP REGULATORY ACTION AT EU LEVEL

3.1.1. Need for harmonised classification and labelling

-

3.1.2. Need for Identification as a substance of very high concern, SVHC (first step towards authorisation)

-

3.1.3. Need for restrictions

-

3.1.4. Proposal for other Community-wide regulatory risk management measures

-

3.2. NO FOLLOW-UP ACTION NEEDED

The concern could be removed because	**Tick box**
Hazard and /or exposure was verified to be not relevant and/or	
Hazard and /or exposure was verified to be under appropriate control and/or	*X*
The registrant modified the applied risk management measures.	
other: <Please specify>	

Human health

The existing information on TDI is sufficient to conclude that exposure to TDI has been linked with the development of asthma in workers. In animal exposure studies, the respiratory tract was the target organ for TDI. The substance causes skin, eye and lung irritation, impairment of lung function and is a respiratory and skin sensitizer.

Animal data indicate that TDI may be carcinogenic. IARC concluded that data were sufficient to show that TDI causes cancer in animals. WHO concluded that TDI should be treated as a potential human carcinogen.
Humans are not exposed to high levels of respiratory particles of TDI, concerns over the possible development of lung tumors should not be relevant. TDI is carcinogenic in animals following oral administration. No treatment-related tumor was observed in mice or rats following inhalation exposure. It is not clarified whether occupational exposure to such chemical is associated with an increased risk of cancer in humans. There is no known case of occupational cancer by TDI exposure.
On the basis of available information evaluated during the substance evaluation the current harmonised classification of TDI (CLP Annex VI, Index No 615-006-00-4) for human health as Carc. 2 (H351), Acute Tox. 2 (H330), Skin Irrit. 2 (H315), Eye Irrit. 2 (H319), Resp. Sens. 1 (H334), Skin Sens. 1 (H317) and STOT Single Exp. 3 (H335) is considered appropriate.

P, B and T Properties

The TDI compounds are not persistent in water, soil, or sediment. TDI is rapidly hydrolysed in aqueous solution, with a half-life less than one minute. The products of hydrolysis are the amines (TDAs), which itself reacts with another isocyanate group to yield an urea. This reaction of an amine with isocyanate is considerably faster than the reaction of water with the isocyanate and leads to polyureas, which are inert, insoluble solids. Polyureas have been identified as polymers of low ecological concern, both because of their inert characteristics, and based on the expectation that they are not bioavailable, and thus unlikely to accumulate in organisms and food chains in the environment.
Besides polyureas, however, there is also the potential for TDAs (2,4-toluene diisoamine (2,4-TDA) and 2,6-toluene diisoamine (2,6-TDA)) to form as a by-product of the hydrolysis of TDI, although the formation of TDA is generally considered negligible relative to the formation of polyureas in aqueous media. The scenarios which resulted in a significant, albeit low, concentration of TDA in the water column would occur under what would normally be considered unnaturally high dispersion/agitation, and therefore, are not likely to occur in nature.
It is expected that TDI isomers do not bioaccumulate because their tendency to hydrolyze rapidly makes their uptake and accumulation virtually impossible. The toluene diisocyanates were not categorized as bioaccumulative, and this decision was reaffirmed by the additional information provided by industry as well as additional literature searches performed. Log Kow predictions for TDA compounds are predicted to be very low (log Kow 0.16) which indicates that these substances are not likely to accumulate in organisms in the environment.
Ecotoxicological data for TDI and its degradation products indicate low to moderate toxicity to aquatic organisms. TDI does not fulfill the toxicity criteria (T) mentioned in the Guidance on information requirements and chemical safety assessment. Chapter R.11: PBT Assessment.
The data demonstrates that TDI and TDA substances do not meet the persistence criteria. TDI isomers do not bioaccumulate due to rapid hydrolysis.
Based on the available information, TDI and its degradation products are indicated as not potentially T.

Occupational exposure

As the identified uses of TDI include industrial and professional uses there is a potential for workplace exposure to the substance. Therefore the activities during manufacturing and transport of TDI are rigorously controlled. The Personal Protective Equipment (PPE) for effective protection of respiratory tract, skin and eyes includes filters with high efficiency for vapour, solid and liquid particles or self-contained breathing apparatus for higher concentration, protective gloves, safety shoes and safety glasses with side shields. PPE is in accordance with generally accepted standards. The exposure at workplace is also reduced by high quality ventilation and the use of closed systems.
European Diisocyanate & Polyol Producers Association has implemented the program and guidelines on the safe use of TDI for industrial and professional users to ensure worker's safety.
The effectiveness of protective devices in isocyanate exposure was confirmed in the study of spray painters. The researchers concluded that appropriate respirators (i.e. with sufficiently high airflow) provided reasonably effective protection if the workers were trained and fit tested (Heederik et al, 2012[i]).
The increase of analytical precision of the measurements of TDI in workplace, better practices in work places and development of risk management measures caused a significant reduction of asthma cases which is the most important health effect confirmed following TDI exposure.
The studies related to TDI exposure have shown a decrease of annual occupational asthma cases from 5% in the early years of the industry to less than 1% since 1980 (Diller, 2002[ii]).

These results are in agreement with the data on reduction of TDI concentration over the years. During the 1950s-1960s, TDI concentrations frequently exceeded 50 ppb in manufacturing and using facilities and since 1980 the concentration of TDI was below of 5 ppb (Ott at al, 2003[iii]).

It is concluded that where there is good control of exposures and compliance with current occupational exposure limits, then isocyanate asthma can be minimised. This is evidenced by the production site data where there is good training and surveillance and exposure control is rigorous.

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[i] Heederik D., Henneberger P.K. and Redlich C.A. Primary prevention: exposure reduction, skin exposure and respiratory protection. Eur. Respir. Rev. 2012; 21: 124, 112-124.

[ii] Diller W.F. Frequency and trends of occupational astma due to toluene diisocyanate: a critical review. Appl. Occup. Environ. Hyg. 2002, 17(12): 872-877.

[iii] Ott M.G., Diller W.F., Jolly A.T. Respiratory effects of toluene diisocyanate in the workplace: a discussion of the exposure-response relationship. Critical Reviews in Toxicology. 2003, 33(1):1-59.