

COMMENTS FROM THE EUROPEAN UNION REGARDING NOTIFICATION

G/TBT/N/USA/1500

SIGNIFICANT NEW USE RULES ON CERTAIN CHEMICAL SUBSTANCES

The European Union (EU) would like to thank the US authorities for providing the opportunity to comment on the draft “Significant New Use Rules (SNURs) on Certain Chemical Substances” under the Toxic Substances Control Act (TSCA) for three chemical substances, which are the subject of premanufacture notices (PMN), notified as G/TBT/N/USA/1500.

The above-mentioned draft was notified to the TBT Committee on 12 July 2019, allowing only a 26-day commenting period, expiring on 7 August 2019. The EU takes this opportunity to recall that according to Article 2.9.4 of the TBT Agreement, Members shall, without discrimination, allow reasonable time for other Members to make comments on notified draft technical regulations. Furthermore, in its recommendation G/TBT/9 of 13 November 2000, the TBT Committee agreed that the normal time limit for comments on notifications should be at least 60 days and encouraged Members to provide, whenever possible, a time limit beyond 60 days, such as 90 days.

Having examined the notified draft, the EU would like to raise the following points and comments on one of the three PMN substances: Isocyanate terminated polyurethane resin (generic).

The EU shares the concern of the US authorities that certain isocyanate substances are the cause of sensitisation among consumers and / or workers.

Diisocyanates are used in many applications (foams, sealants, coatings) throughout the EU and most of them were registered under the REACH Regulation (EC) No 1907/2006¹. In their registration dossiers, manufacturers and importers in the EU have identified uses, which can be grouped as follows:

- manufacturing of diisocyanates;
- use in the production of polyurethanes and PU composite materials;
- use in production of foam;
- use in spray foam applications;
- use in coatings;
- use in adhesives.

The EU notes that the PMN states that the use of this PMN substance will be as an adhesive for open, non-dispersive use. In this regard, the EU would kindly ask the US authorities to clarify why other uses, which have the largest applications, such as the manufacture of polyurethanes, are not considered in the PMN.

¹ Please find a direct link here: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A02006R1907-20140410>

As the US action is based on the aim to assess, *inter alia*, consumer or commercial use (i.e. industrial use only), the EU would like to inform the US authorities of the following:

- Methylenediphenyl diisocyanate (MDI), including three specific isomers, is restricted under entry 56 of Annex XVII to the REACH Regulation when mixtures containing these substances are placed on the market for supply to the general public in concentrations equal to or greater than 0.1% by weight of MDI, unless suppliers ensure that the packaging of these products contains specific protective gloves and particular warnings and instructions for use. This restriction has applied in the EU since 27 December 2010.
- In accordance with the REACH Regulation, a Member State has prepared a dossier towards a restriction to tackle the industrial and professional uses of all diisocyanates. This dossier presents relevant information on the risk assessment, the analysis of alternatives and the socio economic analysis. In accordance with the REACH restriction procedure, the dossier was evaluated by the two Scientific Committees of the European Chemicals Agency (ECHA). The EU is now considering a Regulation under REACH to address the risk of diisocyanates accordingly. In this regard, the EU refers the US authorities to the following website, which can provide further useful information: <https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e180876053>

The EU would be grateful to receive any further information on the follow-up to this US activity, including the results of absorption and sensitisation testing to characterise the human health effects of the PMN substance.

The EU would be grateful if the above-mentioned points and comments could be taken into account and replied to before adoption of the notified draft.
