COMMISSION IMPLEMENTING DECISION (EU) 2016/2091

of 28 November 2016

not to identify hexamethylene diacrylate (hexane-1,6-diol diacrylate) (HDDA) as a substance of very high concern pursuant to Article 57(f) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council

(notified under document C(2016) 7524)

(Only the English text is authentic)

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ([1]), and in particular Article 59(9) thereof,

Whereas:

(1) In accordance with Article 59(3) of Regulation (EC) No 1907/2006, on 24 August 2015 Sweden submitted to the European Chemicals Agency ('the Agency') a dossier in accordance with Annex XV to that Regulation ('Annex XV dossier') for the identification of hexamethylene diacrylate (hexane-1,6-diol diacrylate) (HDDA) (EC No 235-921-9, CAS No 13048-33-4) as a substance of very high concern under Article 57(f) of that Regulation. The dossier submitter considered that there is scientific evidence of probable serious effects to human health due to the skin sensitising properties of HDDA giving rise to an equivalent level of concern to those of other substances listed in points (a) to (c) of Article 57; namely to substances which meet criteria for classification as carcinogenic category 1A or 1B, germ cell mutagenic category 1A or 1B, toxic to reproduction category 1A or 1B.

(2) On 10 December 2015 the Agency's Member State Committee (MSC) adopted its opinion ([2]) on the Annex XV dossier, following the Agency's general approach for the identification of substances of very high concern under Article 57(f) ([3]). In its opinion, MSC unanimously acknowledged there is scientific evidence suggesting that HDDA is a strong skin sensitiser. Although a majority of the MSC members considered that HDDA should be identified as a substance of very high concern in accordance with Article 57(f) of that Regulation, the MSC did not reach unanimous agreement. Three members abstained from a vote, while nine members did not agree that the information provided in the Annex XV dossier was sufficient to constitute an equivalent level of concern to those of other substances listed in points (a) to (e) of Article 57. Those nine members stated in their minority opinion that the effects of HDDA on human health cannot be considered as comparable to those substances which are carcinogenic, mutagenic or toxic for reproduction, in terms of both severity and irreversibility.

(3) On 15 January 2016, pursuant to Article 59(9) of Regulation (EC) No 1907/2006, the MSC referred its opinion to the Commission for a decision on the identification of HDDA as a substances for which there is scientific evidence of probable serious effects to human health which give rise to an equivalent level of concern to CMR substances (Category 1A or 1B) in accordance with Article 57(f) of that Regulation.

(4) The Commission notes that the classification of HDDA as skin sensitiser of category 1 in Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council ([4]) implies that HDDA and cross-reacting acrylates have the potential to cause severe adverse effects on the skin. The Commission also notes that the sensitisation of skin caused by HDDA is irreversible. However, although in the cases documented in the Annex XV dossier, moderate and occasionally severe adverse effects on the skin were reported, in all published

([1]) OJ L 396, 30.12.2006, p. 1.
([2]) http://echa.europa.eu/role-of-the-member-state-committee-in-the-authorisation-process/svhc-opinions-of-the-member-state-committee/-/substance-rev/12301/term
([3]) Identification of substances as SVHCs due to equivalent level of concern to CMRs (Article 57(f)) — sensitisers as an example
([4]) Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 (OJ L 353, 31.12.2008, p. 1).

case reports the skin damage disappeared completely after cessation of exposure and this happened in most cases in a relatively short time. The Commission therefore considers that the scientific evidence presented in the Annex XV dossier does not demonstrate that the probable serious health effects of HDDA are of equivalent concern to those of the substances that are classified as carcinogenic, mutagenic or toxic to reproduction.

(5) This decision is without prejudice to the outcome of any on-going or future assessment within the Agency or the Commission of skin sensitising substances in the context of Article 57(f) and it does not pre-empt the potential identification as SVHC.

(6) The measures provided for in this Decision are in accordance with the opinion of the Committee established under Article 133 of Regulation (EC) No 1907/2006,

HAS ADOPTED THIS DECISION:

Article 1

The substance hexamethylene diacrylate (hexane-1,6-diol diacrylate) (HDDA) (EC No 235-921-9, CAS No 13048-33-4) is not identified as a substance whose skin sensitising properties cause effects to human health that give rise to an equivalent level of concern pursuant to Article 57(f) of Regulation (EC) No 1907/2006.

Article 2

This Decision is addressed to the European Chemicals Agency.

Done at Brussels, 28 November 2016.

For the Commission
Elżbieta BIEŃKOWSKA
Member of the Commission