

EUROPEAN COMMISSION

> Brussels, 18.12.2014 C(2014) 9645 final

# COMMISSION IMPLEMENTING DECISION

# of 18.12.2014

# granting an authorisation for a use of dibutyl phthalate (DBP) under Regulation (EC) No 1907/2006 of the European Parliament and of the Council

(Text with EEA relevance)

[ONLY THE ENGLISH TEXT IS AUTHENTIC]

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### 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<sup>1</sup>, and in particular Article 64(8) thereof,

Whereas:

- (1) Dibutyl phthalate (DBP) (hereinafter referred to as "DBP") is listed in Annex XIV to Regulation (EC) No 1907/2006 and therefore subject to the authorisation requirement referred to in Article 56(1) of that Regulation.
- (2) An application for authorisation was submitted by Sasol-Huntsman GmbH & Co. KG on 29 July 2013 in accordance with Article 62 of Regulation (EC) No 1907/2006, for the use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride (MA).
- (3) On 15 April 2014 the European Chemicals Agency sent to the Commission the opinions of the Committee for Risk Assessment ("RAC") and the Committee for Socio-economic Analysis ("SEAC")<sup>2</sup> pursuant to the third subparagraph of Article 64(5) of Regulation (EC) No 1907/2006.
- (4) According to the RAC opinion, the risks to human health from the use of DBP applied for are adequately controlled in accordance with the provision of Article 60(2) of Regulation (EC) No 1907/2006, provided that the risk management measures and operational conditions as described in the application are adhered to.
- (5) It is therefore appropriate to authorise the use provided that the risk management measures and operational conditions described in the application, in particular in the chemical safety report, are fully applied.
- (6) In its opinion, the SEAC recommended the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 to be set at twelve years. This period was

<sup>&</sup>lt;sup>1</sup> OJ L 396, 30.12.2006, p. 1.

http://echa.europa.eu/documents/10162/7d4f4bc8-5e7c-48b6-a3e0-d08cc0a029e9

recommended taking into account the adequate control of the risks for workers arising from the use of the substance, the lack of suitable alternatives at present and the long time period required to transition to a suitable alternative, the long investment cycle in the sector as well as the considerable socio-economic implications for the applicant and its supply chain in the event of no authorisation. The length of the recommended review period also takes into account the applicant's efforts to search for suitable alternative substances, the time necessary to identify and implement such alternatives in a research and development program to be undertaken by the applicant with a time-frame of 18 years. The recommended review period also takes into account the fact that the immediate transition to an alternative technology after the sunset date would place substantial financial burden on the applicant and would have consequences to the applicant's supply chain. SEAC recommended that the merit of continued use of the substance applied for is re-evaluated in 12 years.

- (7) It is therefore appropriate to set the review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 at twelve years.
- (8) A full application of the risk management measures and operational conditions described in the application, in particular in the chemical safety report, to ensure adequate control of risks for the use applied for is a necessary condition for the authorisation. In their opinions, the RAC and SEAC did not recommend any additional conditions or additional monitoring arrangements. However, in order to facilitate the enforcement of the decision, it is appropriate to include a monitoring arrangement requiring the holder of the authorisation to submit, upon request, to the competent authority of the Member State where the use takes place a succinct summary of the risk management measures and operational conditions of the relevant parts of the above mentioned chemical safety report in an official language of that Member State.
- (9) 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

An authorisation is granted in accordance with Article 60(2) of Regulation (EC) No 1907/2006 for the following use of dibutyl phthalate (DBP) (EC No. 201-557-4, CAS No. 84-74-2), subject to full application of the risk management measures and operational conditions described in the chemical safety report submitted pursuant to Article 62(4)(d) of that Regulation<sup>3</sup>. The authorised use is identified by the following authorisation number:

[REACH/14/2/0]

Use: The use of DBP as an absorption solvent in a closed system in the manufacture of maleic anhydride (MA)

### Article 2

The review period referred to in Article 60(9)(e) of Regulation (EC) No 1907/2006 shall expire on 21 February 2027.

### Article 3

The following monitoring arrangements referred to in Article 60(9)(f) shall apply:

<sup>3</sup> 

 $<sup>\</sup>underline{http://ec.europa.eu/DocsRoom/documents/5550/attachments/1/translations/en/renditions/native}$ 

on request of the competent authority of the Member State, where the authorised use takes place, the holder of the authorisation shall submit to that authority a succinct summary of the applicable risk management measures and operational conditions referred to in Article 1, in an official language of the Member State.

## Article 4

This Decision is addressed to Sasol-Huntsman GmbH & Co. KG, Römerstrasse 733, D-47443 Moers, Germany.

Done at Brussels, 18.12.2014

For the Commission Elżbieta BIEŃKOWSKA Member of the Commission

> CERTIFIED COPY For the Secretary-General,

Jordi AYET PUIGARNAU Director of the Registry EUROPEAN COMMISSION