

### AGREEMENT OF THE MEMBER STATE COMMITTEE

## ON IDENTIFICATION OF DIISOBUTYL PHTHALATE (DIBP) AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of Regulation (EC) No 1907/2006<sup>1</sup>

Adopted on 27 November 2009

## This agreement concerns

**Substance name: Diisobutyl phthalate (DIBP)** 

EC number: 201-553-2 CAS number: 84-69-5

Molecular formula: C<sub>16</sub>H<sub>22</sub>O<sub>4</sub>

Structural formula:

iPr 0 iPr

<sup>1</sup> 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

Germany presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (28 August 2009, submission number CC017711-68) on identification of *disobutyl phthalate* as a substance of very high concern because of its toxic to reproduction properties.

The Annex XV dossier was circulated to Member States on 31 August 2009 and the Annex XV report was made available to interested parties on the ECHA website on the same day according to Articles 59(3) and 59(4).

Comments were received by both Member States and interested parties on the proposal.

The dossier was referred to the Member State Committee on 16 November 2009 and agreed in the written procedure of the Committee with a closing date of 27 November 2009.

Agreement of the Member State Committee in accordance with Article 59(8):

Diisobutyl phthalate (DIBP) is identified as a substance of very high concern because it fulfils the criteria of Article 57 (c) of Regulation (EC) No 1907/2006 (REACH).

# UNDERLYING ARGUMENTATION FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

## **Toxicity for reproduction:**

Pursuant to Annex V of Commission Regulation (EC) No 790/2009<sup>2</sup> diisobutyl phthalate (DIBP) will as of 1 December 2010 be listed in Table 3.2 (the list of harmonised classification and labelling of hazardous substances from Annex I to Directive 67/548/EEC) of Annex VI, part 3, of Regulation (EC) No 1272/2008<sup>3</sup> as toxic to reproduction category 2; R61 (May cause harm to the unborn child).<sup>4</sup>

Therefore, this classification of the substance in Commission Regulation (EC) No 790/2009 shows that the substance meets the criteria for classification as toxic to reproduction in accordance with Article 57 (c) of REACH.

#### **Reference:**

1. Support Document *Diisobutyl phthalate* (DIBP) (Member State Committee, 27 November 2009)

<sup>&</sup>lt;sup>2</sup> Commission Regulation (EC) No 790/2009 of 10 August 2009 amending, for the purposes of its adaptation to technical and scientific progress, Regulation (EC) No 1272/2008 of the of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures (1<sup>st</sup> ATP)

<sup>&</sup>lt;sup>3</sup> 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.

<sup>&</sup>lt;sup>4</sup> Pursuant to the 1<sup>st</sup> ATP, the classification according to Table 3.1 (list of harmonised classification and labelling of hazardous substances) of Annex VI, part 3, of Regulation (EC) No 1272/2008 will as of 1 December 2010 be toxic to reproduction category 1B, H360Df (May damage the unborn child. Suspected of damaging fertility).