

Helsinki, 22 June 2011 **Doc: MB/17/2011 final** 

# DECISION AMENDING DECISION MB/17/2008 ESTABLISHING REMEDIES FOR REVIEWING A PARTIAL OR FULL REJECTION OF A CONFIDENTIALITY REQUEST PURSUANT TO ARTICLE 118(3) OF REGULATION (EC) No 1907/2006

(Document adopted by the Management Board by written procedure on  $30\ May\ 2011)$ 

# THE MANAGEMENT BOARD OF THE EUROPEAN CHEMICALS AGENCY

Having regard to Article 24 of Regulation (EC) No 1272/2008 of the European Parliament and 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 (hereinafter the "CLP Regulation"),

# Whereas:

- (1) Article 24(4) of the CLP Regulation provides that the practical arrangements referred to in Article 118(3) of the REACH Regulation apply if the Agency does not accept a request for use of an alternative chemical name for a substance in a mixture on the label or in the safety data sheet.
- (2) Article 24(6) of the CLP Regulation provides that the practical arrangements referred to in Article 118(3) of the REACH Regulation apply if the Agency withdraws or amends its decision on the use of an alternative chemical name on the basis of new information.
- (3) It is necessary to amend the rules for implementing Article 118(3) of the REACH Regulation to include provisions referred to in Articles 24(4) and (6) of the CLP Regulation. These rules should be made publicly available.

# HAS ADOPTED THIS DECISION:

# Article 1

Decision of the Management Board of 23 April 2008 establishing remedies for reviewing a partial or full rejection of a confidentiality request pursuant to Article 118(3) of Regulation (EC) No 1907/2006 (MB/17/2008 final) is amended as follows.

The following paragraphs are added after the first paragraph in Article 1:

"Pursuant to Article 24 of the CLP Regulation, this Decision shall also prescribe the arrangements under which the manufacturer, importer or downstream user within the meaning of the CLP Regulation may seek redress in a situation where the Agency does not accept a request for use of an alternative chemical name or if the Agency withdraws or amends its decision on the use of an alternative chemical name on the basis of new information.

For the purposes of this Decision, the Decisions of the Agency to reject confidentiality requests and requests for use of an alternative chemical name, as well as decisions by the Agency to withdraw or amend its decision on the use of an alternative chemical name on the basis of new information shall be referred to as 'decisions to reject a confidentiality request', and the reference to "the registrant" shall cover also the manufacturer, importer or downstream user within the meaning of the CLP Regulation ";

# Article 2

This Decision shall enter into force on the date of its adoption.

### Article 3

This Decision shall be published on the Agency's website.

Done at Helsinki, 22 June 2011

signed
For the Management Board
Thomas JAKL