Octadecylamine

CAS No: 124-30-1
EINECS No: 204-695-3

ANNEX XV TRANSITIONAL REPORT

**Documentation of the
work done under
the Existing Substance Regulation (EEC) No 793/93
and
submitted to the European Chemicals Agency
according to
Article 136(3) of Regulation (EC) No 1907/2006**

2009

ANNEX XV TRANSITIONAL REPORT

This Annex XV transitional report has been submitted to ECHA according to the REACH Regulation (EC) No 1907/2006, Article 136(3). Octadecylamine was prioritised under the Existing Substance Regulation (ESR) (Regulation (EEC) No 793/93), however, the risk evaluation and/or risk management work for this substance was not finalised by 1 June 2008 (i.e. the date the ESR regulation was repealed and replaced by the REACH Regulation). As rapporteur of this substance according to the ESR, Germany was required to develop this Annex XV transitional report for this substance. This report contains information on hazard and risk, either documented in the Annex XV restriction report format or in the annexed risk assessment reports (RARs) following the structure used under the ESR. It also provides information on what possible actions the submitting Member State considers to be necessary in order to reduce the risks identified in the RARs.

According to the REACH Regulation the ECHA Secretariat or ECHA's Committees are neither required nor empowered to review these transitional dossiers. The Member States and the Commission are invited to use the information, as appropriate. For example:

- to initiate action under other Community legislation
- to take action at national level
- to develop when considered necessary an Annex XV dossier proposing restriction, identification of substances of very high concern (SVHC) under the REACH Regulation and/or harmonised classification and labelling under Regulation (EC) No 1272/2008.

In addition, industry should take into account the information in the Annex XV transitional report when preparing registration dossiers, including testing proposals, when implementing and recommending risk management measures prior to registration.

The table below describes whether discussions on one or several parts of the dossier (human health risk assessment report, human health risk reduction strategy, environmental risk assessment report, environmental risk reduction strategy) had already been finalised under the ESR:

Dossier status under Existing Substance Regulation

Status	Human Health (HH)	Environment (ENV)	Comments
Discussions on risk assessment report (RAR) at TC NES[1] concluded	Yes	Yes	HH RAR last discussed at TC NES April 2008 ENV RAR last discussed at TC NES June 2006
Strategy for limiting the risk endorsed at RRSM[2]	No	Not required	
Need for further information and/or testing identified[3]	Yes	No	Available data on the skin sensitisation potential is not sufficiently conclusive. The performance of a Local Lymph Node Assay (LLNA) is proposed with an appropriate substance of the category (primary alkyl amines).
Information requested according to Article 10(2) of Reg. 793/93	No	No	

[1] TC NES – Technical Committee for New and Existing Substances
[2] RRSM – Risk Reduction Strategy Meeting
[3] Conclusion (i) drawn in the risk assessment report by Member State/endorsed by TC NES, however, this further information need has not been included in a decision taken in accordance with Article 10(2) of Regulation (EEC) No 793/93.