



**Disodium tetraborate anhydrous**

**CAS No: 1330-43-4**  
**EINECS No: 215-540-4**

**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). Disodium tetraborate anhydrous 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and/or risk management work for this substance was not finalised by 1 June 2008 (i.e. the date the ESR regulation was repealed and replaced by the REACH Regulation).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, Austria 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 <sup>1</sup> concluded	No	No	HH RAR last discussed at TC NES December 2007 ENV RAR last discussed at Technical Meeting December 2003
Strategy for limiting the risk endorsed at RRSM <sup>2</sup>	No	No	
Need for further information and/or testing identified <sup>3</sup>	Yes	Yes	HH: Information on occupational exposure for producing/importing processing sites, downstream uses and consumer applications. ENV: Information on environmental exposure for all compartments. Based on the results from of the marine exposure evaluations it might become necessary to carry out ecotoxicity tests with marine species. Further ecotoxicity tests might be advisable to improve PNECs for the STP, the freshwater and the terrestrial compartments.
Information requested according to Article 10(2) of Reg. 793/93	No	No	

<sup>1</sup> TC NES – Technical Committee for New and Existing Substances

<sup>2</sup> RRSM – Risk Reduction Strategy Meeting

<sup>3</sup> 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.