AGREEMENT OF THE MEMBER STATE COMMITTEE

ON IDENTIFICATION OF HEXABROMOCYCLODODECANE (HBCDD)

AND ALL MAJOR DIASTEREOISOMERS IDENTIFIED

AS A SUBSTANCE OF VERY HIGH CONCERN

According to Articles 57 and 59 of
Regulation (EC) No 1907/2006[1]

Adopted on 8 October 2008

This agreement concerns

Substance name: Hexabromocyclododecane and all major diastereoisomers identified

EC number: 247-148-4 and 221-695-9
CAS number: 25637-99-4 and 3194-55-6

Names of major diastereoisomers identified

Alpha (α) – hexabromocyclododecane (CAS No 134237-50-6)

Beta (β) – hexabromocyclododecane (CAS No 134237-51-7)

Gamma (γ) – hexabromocyclododecane (CAS No 134237-52-8)

Molecular formula: $C_{12}H_{18}Br_6$

[1] 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

Sweden presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (30 June 2008, submission number AJ018587-40) on identification of hexabromocyclododecane (and all major identified diastereoisomers) as a substance of very high concern because of its PBT properties.

The Annex XV dossier was circulated to Member States on 30 June 2008 and the Annex XV report was made available to Interested Parties on the ECHA website on the same date according to Articles 59(3) and 59(4).

Comments were received from both Member States and Interested Parties on the proposal.

The dossier was referred to the Member State Committee on 15 September 2008 and discussed in the meeting of the Committee on 7 – 8 October 2008.

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

Hexabromocyclododecane (and all major identified diastereoisomers) is identified as a substance of very high concern because it fulfils the criteria of Article 57 (d) of Regulation (EC) No 1907/2006 (REACH).

UNDERLYING ARGUMENTATION
FOR IDENTIFICATION OF SUBSTANCE OF VERY HIGH CONCERN

Persistence: There are two degradation simulation studies in soil. In the first one the half-life for the γ-HBCDD diastereomer was of 119 days when recalculated to 12°C. In the other study no transformation was observed after 112 days of incubation. Based on the two studies hexabromocyclododecane (HBCDD) fulfils the P-criterion in soil.

In addition, there are two degradation sediment simulation tests available. For α-HBCDD, which seems to be the least degradable diastereomer, an aerobic DT_{50} of approximately 210 days in sediment recalculated at 12°C was determined, which is above the P-criterion of 120 days in sediment. For γ-HBCDD the available studies indicate very different half-lives. In the first study, using very low concentrations of γ-HBCDD, the parent compound disappeared with a half-life of 21 and 61 days (recalculated to 12°C) in two different sediments and in the second study, where a concentration similar to what is measured close to polluted areas was tested, the DT_{50} for γ-HBCDD was 197 days (recalculated to 12°C) in aerobic sediment.

The measured data available from dated sediment cores indicate slow degradation rates of HBCDD and support the results of the second study. It is therefore considered that the P criterion is also fulfilled in sediment.

Furthermore, HBCDD is found to be ubiquitously present in remote areas in abiotic samples and biota, providing evidence that the substance is persistent in the environment. Also the temporally increasing concentrations found in biota support the picture of HBCDD as a persistent substance.

Bioaccumulation: HBCDD meets the vB criterion based on reliable experimental BCFs from two flow-through bioconcentration tests with fish. A BCF of 18 100 was chosen as a representative value in the EU risk assessment. Furthermore, a large set of measured data in biota in the field indicate, that HBCDD is biomagnified in the environment. No diastereomer specific BCFs are available. However, the concentration of α-HBCDD in biota is generally much higher than the concentration of the other two main diastereomers despite it being present in commercial HBCDD in a relatively low concentration.

Toxicity: HBCDD fulfils the T criterion. A 21d-NOEC of 3.1 µg l^{-1} has been derived for *Daphnia magna* in a flow-through test. It is noted, that ecotoxicity testing of HBCDD is highly complicated due to its very low water solubility.

Other: HBCDD has a high potential for long-range environmental transport. Its half-life in the atmosphere is > 2 days and it has been found in remote areas in abiotic samples (air, deposition, sediment) and biota (polar bears, bird eggs, seals) in the majority of samples in recent years. Additionally, a study comparing the long-range transport potential of “existing” POPs and HBCDD with the help of tuna fish samples, found HBCDD to have a very high potential for long-range environmental transport.

Conclusion:

Hexabromocyclododecane (HBCDD) fulfils both the B and the vB-criteria based on experimental data (BCF=18100) and measured data from biota. With a NOEC of 3.1 µg/l for *Daphnia* the T-criterion is also met. The available soil degradation simulation data show that the half-life of HBCDD in aerobic soil is > 120 d and thus the P-criterion in soil is met. In addition, degradation sediment simulation tests and dated sediment cores are available indicating slow degradation rates of HBCDD thus supporting the P criterion in sediment.

Furthermore, HBCDD is found to be ubiquitously present in remote areas in abiotic samples and biota providing evidence that the substance is persistent in the environment and undergoes long-range environmental transport. **It is therefore concluded that HBCDD is a PBT substance**.

Reference:

1. Support Document Hexabromocyclododecane (Member State Committee, 8 October 2008)