

**AGREEMENT OF THE MEMBER STATE COMMITTEE
ON IDENTIFICATION OF
BIS(TRIBUTYLTIN) OXIDE (TBTO)
AS A SUBSTANCE OF VERY HIGH CONCERN**

**According to Articles 57 and 59 of
Regulation (EC) No 1907/2006¹**

Adopted on 1 October 2008

This agreement concerns

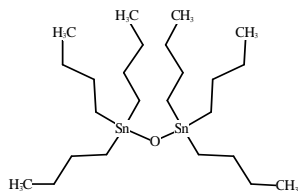
Substance name: Bis(tributyltin) oxide (TBTO)

EC number: 200-268-0

CAS number: 56-35-9

Molecular formula: C₂₄H₅₄OSn₂

Structural formula:



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

Norway presented a proposal in accordance with Article 59(3) and Annex XV of the REACH Regulation (30 June 2008, submission number AK009127-53) on identification of bis(tributyltin) oxide 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 and agreed in the written procedure of the Member State Committee with closing date of 1 October 2008.

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

Bis(tributyltin) oxide 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: Bis(tributyltin) oxide (TBTO) transforms in aqueous solution to tributyltin (TBT). The form in which TBT is present in the environment, depends much on pH, but also on other abiotic conditions. Various degradation studies in water show half-lives between few days to several months. Half-lives of > 1- 15 years have been observed in sediment degradation experiments. In a soil degradation study an aerobic half-life of 114 d at 25 °C was estimated corresponding to 323 d at 12 °C. Based on the available data it is concluded that TBT meets the P/vP criterion.

Bioaccumulation: The bioaccumulation potential is expected to be dependent on the pH of the exposure medium. Due to the dissociation behaviour, a higher bioaccumulation potential is generally expected at pH > 6.5, whereas in the acidic range a lower bioaccumulation potential can be anticipated due to the predominance of the ionised, more hydrophilic form of tributyltin.

Experimental BCFs in whole fish > 2000 were determined in studies with appropriately low test concentrations and long exposure periods in several marine fish species. Accumulation of TBT compounds to invertebrates has been observed in various studies. The accumulation/concentration factors in certain molluscs have been observed in a range of 10 000 to 100 000. Experimental reliable BCFs are available for four marine fish species and they all are > 2000; TBT meets therefore the bioaccumulation criterion (B).

Toxicity: A large data set on standard and non-standard long-term effect studies is available for TBT compounds. The lowest reliable chronic NOEC for TBT was identified to be 0.06 µg Sn l⁻¹, corresponding to ca. 0.15 µg TBT l⁻¹, for *Daphnia magna*. In addition to the very high toxicity in relation to conventional toxicity endpoints, TBT compounds elicit effects in the endocrine systems of aquatic organisms. The mollusc species *Nucella lapillus* (dog whelk) is the most sensitive species to tributyltin compounds. A LOEC of 0.002 µg l⁻¹ was obtained in a 360-d study looking at imposex (NOEC < 0.002 µg l⁻¹). TBT compounds are considered to fulfil the T criterion for ecotoxicity.

Moreover tributyltin compounds are classified as toxic; danger of serious damage to health by prolonged exposure through inhalation and if swallowed (T; 48/23/25) and TBTO therefore fulfils also the T criterion for human health.

In the impact assessment of potential restrictions on the marketing and use of certain

organotin compounds it is concluded that, in relation to the marine environment, TBT is likely to be classified as both PBT and vPvB substance.

Conclusion: Tributyltin, the aqueous transformation product of bis(tributyltin) oxide, fulfils the P, B and T criteria. Furthermore, bis(tributyltin) oxide fulfils the T criterion for human health due to the hazard classification of tributyltin compounds. Bis(tributyltin) oxide is considered to be a PBT substance.

Reference:

1. Support Document Bis(tributyltin) oxide (Member State Committee, 1 October 2008)