

1 June 2009

## Background document for bis(tributyltin) oxide (TBTO)

Document developed in the context of ECHA's first Recommendation for the inclusion of substances in Annex XIV

### 1. Identity of the substance

Chemical name: bis(tributyltin) oxide  
EC Number: 200-268-0  
CAS Number: 56-35-9  
IUPAC Name: hexa-n-butyldistannoxan

### 2. Background information

#### 2.1. Intrinsic properties

Bis(tributyltin) oxide was identified as a Substance of Very High Concern (SVHC) meeting the criteria of a PBT substance pursuant to Article 57 (d) and was therefore included in the candidate list for authorisation following ECHA's decision ED/67/2008 on 28 October 2008.

#### 2.2. Imports, exports, manufacture and uses

##### 2.2.1. *Volume(s), imports/exports*

In 2007 there was one manufacturer left in the EU producing Tributyltin compounds (EC, 2007). Estimations based on information from the industry gave the following quantities of TBTs manufactured and sold in the EU in 2007: 500 tonnes/year as intermediate for synthesis and less than 100 tonnes/year of TBTO (probably around 30 tonnes/year, EC, 2007) are exported outside the EU for production of biocidal products. In general the volumes of TBT compounds have been reduced due to phasing out and prohibition of their use as biocide (EC, 2007).

Manufacturing of mono- and di-substituted organotin compounds have been increasing and were in 2007 around 20 000 tonnes/year (EC, 2007). TBTO can be found as an impurity of up to 1 % in these compounds (RCOM, 2008), resulting in a total quantity of up to 200 tonnes/year.

The amounts of TBTO manufactured for intermediate use (synthesis) and unintentionally formed as an impurity of mono- and di-substituted organotin compounds are not in the scope of Title 7 and will not be considered in this document.

In conclusion, the amount of TBTO manufactured for non intermediate use is assumed to be around 30 t/y, which are exported from the EU. According to the information available, there is currently no known non-intermediate use of TBTO in the EU.

### 2.2.2. *Manufacture and uses*

#### 2.2.2.1. Manufacture and releases from manufacture

In 2007 there was one manufacturer left in the EU producing tributyltin compounds (EC 2007). No data for releases from manufacturing of TBTO are available.

#### 2.2.2.2. Uses and releases from uses

TBTO is currently only used in the EU as an intermediate for manufacture of other chemicals.

One of the former uses of TBTO in Europe was for biocidal application; however this use is now prohibited in the EU as it has not been notified under the Biocidal Products Directive. However, as both these uses are not in the scope of authorisation they are not further discussed.

Presently, there is no known non-intermediate use of TBTO in the EU. Consequently, no releases from uses covered by the authorisation requirement are anticipated.

In 2001, TBT concentrations in water and sediment were 3.62 mg/L and 10.8 mg/kg respectively, with maximum concentration of 53 mg/kg TBT in harbours (Norwegian Competent Authority, 2008). However, due to strongly reduced uses of TBT, also declining trends in sediment TBT concentrations were identified, e.g. in many German rivers, TBT sediment concentrations were already below 0.005 mg/kg in 2003 (Norwegian Competent Authority, 2008).

#### 2.2.2.3. Geographical distribution and conclusions in terms of (organisation and communication in) supply chain

Presently there is only one company manufacturing TBTO in the EU/EEA and a total number of seven companies manufacturing various organostannic compounds, located in Germany (3), the Netherlands, Italy (2) and Switzerland (EC, 2007).

The actors directly associated with the TBTO supply chain and potentially affected by a possible authorisation requirement include only one manufacturer. The supply chain for TBTO is therefore rather simple as it is only used as intermediate or exported.

### 2.3. Availability of information on alternatives<sup>1</sup>

No data available.

### 2.4. Existing specific Community legislation relevant for possible exemption

It is noted that TBTO is restricted in accordance with entry 20 of Annex I to Directive 76/769/EEC and entry 20 of Annex XVII<sup>2</sup> of REACH Regulation.

### 2.5. Any other relevant information (e.g. for priority setting)

Members of the European Disposables and Nonwovens Association (EDANA) have voluntarily agreed to ensure that from 2000, raw materials that come into contact with the user contain less than 2 ppb of TBT and <10 ppb for each species of organotin individually. These limits refer to the organotin concentration in the raw materials used for absorbent hygiene products and are indicated to be the current detection limit for the analytical methods adopted (EC, 2007).

## 3. **Conclusions and justification**

### 3.1. Prioritisation

The amount of TBTO manufactured for non intermediate use is assumed to be around 30 t/y, which are exported from the EU. According to the information available, there is currently no known non-intermediate use of TBTO in the EU.

Although TBTO is a PBT substance,, ECHA recommends not to prioritise bis(tributyltin)oxide (TBTO) for inclusion in Annex XIV as there are no known uses of TBTO within the EU.

### 3.2. Recommendation for Annex XIV entry.

As the substance was not prioritised for inclusion in Annex XIV no recommendation for its Annex XIV entry has been developed.

## 4. **References**

EC (2007): Impact assessment of potential restrictions on the marketing and use of certain organotin compounds. Final report prepared for European Commission Directorate-General Enterprise and Industry.

Norwegian Competent Authority (2008): Annex XV Dossier. Proposal for identification of a substance as a PBT substance. Substance name: Bis(tributyltin)oxide).

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<sup>1</sup> Please note that this information was not used for the prioritisation.

<sup>2</sup> Annex XVII shall apply from 1 June 2009, until that Directive 76/769/EEC applies.

RCOM (2008): *“Responses to comments”* document. Document compiled from the commenting period 14.01-14.04.2009.