

DIANTIMONY TRIOXIDE

CAS-No.:1309-64-4

EINECS-No.: 215-175-0

SUMMARY RISK ASSESSMENT REPORT

Final Report 2008

Sweden

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PREFACE

The report provides a summary of the risk assessment of the substance diantimony trioxide. It has been prepared by Sweden in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances. For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references, the reader is referred to the original risk assessment report that can be obtained from European Chemicals Bureau¹. The present summary report should preferably not be used for citation purposes.

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¹ European chemicals Bureau – Existing Chemicals - <http://ecb.jrc.ec.europa.eu/>

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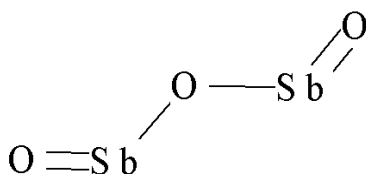
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1 GENERAL SUBSTANCE INFORMATION

1.1 Identification of the substance

Antimony is a metalloid that belongs to group 15, period 5 of the periodic table of the elements. Oxidation states of antimony include - 3, 0, + 3, and + 5, where the two latter, i.e. +3 and +5, are the two predominant environmental ones.

CAS No: 1309-64-4
EINECS No: 215-175-0
IUPAC Name: Diantimony trioxide
Molecular formula: Sb_2O_3
Structural formula:



Molecular weight: 291.52
Synonyms: Antimony (III) oxide
Antimony (3+) oxide
Antimony oxide (Sb_2O_3)
Antimony peroxide
Antimony trioxide
Antimony oxide
Antimony sesquioxide
Antimony white
Flowers of antimony
Senarmontite
Valentinite
Sesquioxide
C.I. Pigment White 11
C.I. 77052

1.2 Purity/impurities, additives

The purity of commercial grades of diantimony trioxide on the EU market has been reported to be 99.3 to 99.5 % (with the exception of wetted forms, for which a lower specification limit of 95 % was given). The only two relevant impurities are arsenic and lead. As of June 2006 all diantimony trioxide used within the EU will contain less than 0.1 % As (before this date approximately 3.6 % of the diantimony trioxide used in the EU contained between 0.1 and < 0.2 % As, the rest < 0.1 % As). The range given by EU producers is 0.0040 to 0.0860 % As. The content of lead in diantimony trioxide used in the EU is less than 0.25 % Pb.

Other impurities occurring in trace amounts: Cu, Fe, Ni, SO_4^{2-} , Si, Mn, Mg, Sn, Al, Ag, Cd, Bi, V, and Se.

The impurities present primarily depend on the geographical mineralogy from which the raw material is derived.

1.3 Physico-chemical properties

Diantimony trioxide is solid and is commercialized as a white, odourless, crystalline powder. Based on handbook data the melting point is 655 °C and the boiling point is 1550 °C, vapour pressure at ambient temperature is considered to be negligible. The solubility in reconstituted standard water (= ISO 6341 medium; temperature 22.2 °C) is 2.76 mg Sb/L. Dissolution of the substance in reconstituted standard water decreases constantly from pH 1 to pH 7. Above pH 7 the trend changes and the solubility of diantimony trioxide increases rapidly to pH 8, where a new equilibrium is established and the increase in solubility becomes much slower. The octanol-water partition coefficient ($\log K_{OW}$) is not relevant for this type of substance.

Diantimony trioxide has two molecular arrangements, Senarmontite (CAS 12412-52-1) and Valentinite (CAS 1317-98-2). Since diantimony trioxide can and will exist in both these modifications at environmental conditions and no data are available to differentiate between the two as regards exposure and effects, the intention is to cover both with the CAS Number for diantimony trioxide, i.e. 1309-64-4.

1.4 Classification and labelling

1.4.1 Current classification

Diantimony trioxide is classified as a dangerous substance within the meaning of Directive 67/548/EEC and is listed in Annex 1 of this Directive (21st ATP), being assigned the following risk and safety phrases:

Category 3 carcinogen

Xn Harmful

R40 Limited evidence of a carcinogenic effect

S36/37 Wear suitable protective clothing and gloves

S2 Keep out of reach of children

S22 Do not breathe dust

1.4.2 Proposed classification

In addition to the current classification the Rapporteur proposes:

Xi; R38 (Irritating to skin)

Rationale for the proposed classification:

The classification proposal is based on practical experience in humans.

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GENERAL INFORMATION ON EXPOSURE

Diantimony is produced from minerals. The most important mineral source of the metal is stibnite (antimony trisulfide, Sb_2S_3), but it is also found in trace amounts in silver, copper and lead ores.

Diantimony trioxide is commercially produced at four sites in the EU (2006). The annual production volume in year 2005 was 24250 tonnes in the EU and approximately 120 000 tonnes worldwide. Diantimony trioxide is mainly produced by re-volatilizing of crude stibnite or oxidation of antimony metal, with the latter process dominating in the EU.

In the EU in 2005, diantimony trioxide was used as flame-retardant in plastics (38%), PVC (36%), rubber (9%) and textiles (7%), as a catalyst in polyethylene terephthalate production (4%), additive in glass manufacture (1%) and in pigments in paint and ceramics (5%).

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3 ENVIRONMENT

3.1 EXPOSURE

Predicted environmental concentrations are shown together with risk characterisation ratios in Table 3-4 - Table 3-8.

3.1.1 General Discussion

Diantimony trioxide is released to the environment via emissions to air, waste water, surface water and soil from manufacture, formulation, processing, use and disposal of diantimony trioxide, but also via coal combustion and refuse incineration, non-ferrous metal production (e.g. Cu), and road traffic.

3.1.1.1 Environmental releases

Total estimated emissions of antimony into the environment in the EU from production of diantimony trioxide are 1.36 tonnes per annum (tpa) to air, 0.006 tpa to surface water, 1.79 tpa to industrial urban soil. Total antimony emissions from formulation/industrial use/service life (of flame-retardants in plastic and rubber, flame-retardants in textiles, use as catalyst in PET-industry, use in paint and use in glass), were estimated to be 0.434 tpa to air, 1.75 tpa to surface water, 29.7 tpa to waste water and 34.5 tpa to industrial urban soil. Antimony emissions from disposal either assuming 100% incineration or 100% landfill were calculated to be 4.5 or 0 tpa to air, 5.4 or 0.378 tpa to waste water and 0 or 0.047 tpa to surface water, respectively. Total estimated emissions of antimony from unintentional sources are 16.67 tpa to air, 0.8 tpa to surface water and 2.5 tpa to industrial urban soil.

Realistic Worst Case (RWC) ambient concentrations were calculated as the median of the country specific 90th percentile values using available ambient measured data from EU countries (and Norway). RWC ambient concentrations were derived for fresh water (0.72 µg Sb/L; dissolved), freshwater sediment (3 mg Sb/kg dw), soil (1.7 mg Sb/kg dw), air (2.6 ng Sb/m³), marine water (0.20 µg Sb/L; dissolved) and marine sediment (3 mg Sb/kg dw).

RWC-ambient concentrations were used instead of the calculated PEC_{regional} as background concentrations in the calculations of local PECs. See tables in chapter 3.3 for local PECs.

3.1.1.1.1 Environmental fate

In the environment diantimony trioxide will slowly dissolve and transform into $Sb(OH)_3$, which is oxidized to $Sb(OH)_6^-$ under oxic conditions. Antimony, being a natural element, cannot by definition be degraded. However, it can be transformed between different binding/speciation forms and oxidation states.

Combustion/incineration processes transform antimony compounds to diantimony trioxide regardless of the pre-incinerated form of antimony. There are indications that diantimony

trioxide may dissolve in the atmosphere and that the trivalent form will oxidize to the pentavalent form. Antimony is deposited from the atmosphere predominantly dissolved in rain, but also as particulate matter in wet and dry deposition.

In natural waters dissolved antimony exists almost exclusively in the two valency states +3 and +5 as Sb(OH)_3 and Sb(OH)_6^- , respectively. According to thermodynamic calculations, antimony should almost exclusively be present as Sb(V) in oxic systems, and as Sb(III) in anoxic systems. Even though the dominant species in oxic waters is Sb(V), Sb(III) has been detected in concentrations much above what is predicted, and the reverse is true for Sb(V) in anoxic systems.

After slow dissolution and subsequent oxidation of Sb_2O_3 in soil, its fate is controlled by sorption of Sb(OH)_6^- on soil constituents and precipitation of $\text{Ca[Sb(OH)}_6\text{]}_2$. The solubility of antimony compounds depends on the soil conditions (Eh/pH) and the time given to dissolve. The most important soil characteristic as regards the mobility of antimony in soil (and sediments) appear to be pH and the presence of hydrous oxides of iron, manganese, and aluminium, to which antimony may adsorb with decreasing sorption at increasing pH. In addition, hydrous oxides seem to oxidise dissolved trivalent antimonite (Sb(OH)_3) to the pentavalent antimonate (Sb(OH)_6^-). Due to the anionic character of the dissolved species (Sb(OH)_6^-), antimony is expected to have a low affinity for organic carbon. However, there exist results that indicate that the sorption of Sb(V) by humic acid in acid soils with high proportions of organic matter may be more important than previously suspected, although the strong Sb(V) scavenging potential of Fe(OH)_3 probably results in a diminished role of organic matter binding in soils with high amounts of non-crystalline hydroxides. The cationic exchange reactions, which are the main sorption reactions on clay minerals, are not expected to be important for the anionic antimony.

Antimony released to the environment will eventually end up in either of the two compartments soil or sediment, depending on the release, the form of antimony, meteorological conditions, etc. The distribution of antimony between aqueous phase and soil/sediment/suspended matter is described using the partitioning coefficients $\log K_{p_{\text{soil}}} = 1.98 \text{ L/kg}$, $\log K_{p_{\text{suspended matter}}} = 3.65 \text{ L/kg}$ and $\log K_{p_{\text{sediment}}} = 3.4 \text{ L/kg}$, which are the median values of the available reliable partitioning coefficients for the respective compartments.

The bioaccumulation potential seems to be low to moderate. No reliable bioaccumulation studies are available and measured data from different aquatic organisms have been used to calculate tentative BCF values. For marine fish the BCFs vary between 40 and 15000 whereas for freshwater fish the BCF values are lower, the highest being 14. For invertebrates tentative BCFs below 1 up to 4000-5000 have been calculated. It should be noted that there is a considerable uncertainty in these BCF values. The BCF value finally used in the risk characterisation is 40.

3.2 EFFECTS

The toxicity of antimony is expected to be exerted through its ions. Since environmental conditions (e.g. pH and redox potential) control the speciation of dissolved antimony in water, sediment and soil, regardless of the antimony compound added, toxicity data for all antimony compounds were considered useful for deriving toxicity thresholds for diantimony trioxide. It should be noted that when using an antimony compound other than diantimony trioxide as a

source of antimony in toxicity testing, an increase in counter ions and protons will occur which may influence the interpretation of the observed responses. How much protons that are produced, and whether this will affect the pH or not, depends on the conditions in the test system, the type of antimony compound used, and the amount of the antimony compound added. The effect of counter ions and pH, and hence the relevance of the toxicity data for diantimony trioxide was evaluated on a case-by-case basis.

The majority of the available toxicity data are for Sb(III) compounds and only a few data for Sb(V) compounds are available. There are however at present no toxicity studies available which also include redox speciation measurements. Since the results of toxicity studies using a trivalent antimony compound are probably due to exposure to a mixture of trivalent and pentavalent antimony ions, and since there is no conclusive evidence supporting a significant difference in toxicity between the two valences, it is decided not to differentiate between relevant and reliable results originating from toxicity studies with tri- or pentavalent antimony compounds.

3.2.1 Aquatic compartment

The lowest reliable acute and chronic toxicity data for different aquatic organisms are presented below in Table 3-1 and Table 3-2. Except for the marine fish *Pargus major*, for which the source of antimony was $K[Sb(OH)_6]$, all these data were obtained using $SbCl_3$. The reported aquatic toxicity values are above the solubility limits of antimony when using diantimony trioxide at the pH levels used in these studies.

Table 3-1 Acute aquatic toxicity test results

Marine fish [<i>Pargus major</i>]	96 h LC50	6.9 mg Sb/L (measured total)
Freshwater fish [<i>Pimephales promelas</i>]	96 h LC50	14.4 mg Sb/L (measured filtered)
Invertebrates [<i>Chlorohydra viridissimus</i>]	96 h LC50	1.77 mg Sb/L (measured filtered)
Algae [<i>Raphidocelis subcapitata</i>]	72 h ErC50 (growth rate)	> 36.6 mg Sb/L (measured total)

Table 3-2 Chronic aquatic toxicity test results

Fish [<i>Pimephales promelas</i>]	28 d NOEC / LOEC (growth; length)	1.13 / 2.31 mg Sb/L (measured total)
Invertebrates [<i>Daphnia magna</i>]	21 d NOEC / LOEC (reproduction)	1.74 / 3.13 mg Sb/L (measured total)
Algae [<i>Raphidocelis subcapitata</i>]	72 h NOEC / LOEC (growth rate)	2.11 / 4.00 mg Sb/L (measured total)

Freshwater

There are reliable and relevant short-term toxicity data available for a number of species including fish, daphnia and algae. However, the most sensitive species in the acute toxicity tests was the green hydra *Chlorohydra viridissimus*, with an LC_{50} value of 1.77 mg Sb/l.

Relevant and reliable long-term toxicity studies are available for fish, daphnia and algae. The most sensitive organisms in the long-term toxicity tests seem to be fish. The lowest NOEC (1.13 mg Sb/l) has been derived in a study on the fish *Pimephales promelas*. According to the TGD, an assessment factor of 10 shall be applied on the lowest NOEC when NOECs from three trophic levels are available.

However, according to a footnote c in the TGD, when deriving a $PNEC_{\text{freshwater}}$, it says that an assessment factor of 50 should be used on the lowest of three NOECs covering three trophic levels when such NOECs have not been generated from that trophic level showing the lowest L(E)C50 in the short term test. According to Appendix IV in the TGD, fish (lowest NOEC) and hydra (lowest L(E)C50) both belong to the trophic level “Secondary consumers”. As a consequence of that this footnote does not apply on this dataset, and an assessment factor of 10 should be used. Using the assessment 10 on the lowest NOEC results in a $PNEC_{\text{freshwater}} = 0.113$ mg Sb/l.

Marine water

The only reliable and relevant toxicity study of antimony available for the marine environment is an acute toxicity study on the marine fish *Pagrus major*, which resulted in a LC_{50} (96 h) of 6.9 mg Sb/l. Therefore, toxicity data from tests on freshwater organisms are used to derive a $PNEC_{\text{marine water}}$. Relevant and reliable long-term toxicity studies are available from three trophic levels. The lowest NOEC (28d)(1.13 mg Sb/l) has been derived in a study on the fish *Pimephales promelas*.

According to the TGD, an assessment factor of 100 should be applied to the lowest of three long-term NOECs from three freshwater or saltwater species (normally algae and/or crustaceans and/or fish) representing three trophic levels. There is however a footnote (Notes: c) in the TGD, when deriving a $PNEC_{\text{marine water}}$, that says that an assessment factor of 500 should be applied to the lowest NOEC when the lowest NOEC has not been derived from the taxonomic group showing the lowest EC_{50} -value. This should apply to the available data since the hydra (lowest L(E)C₅₀) belongs to a different taxonomic group than the fish (lowest NOEC). But since the same freshwater data set is used for both the freshwater and marine water assessment, and the “default” difference between freshwater and marine water is a factor of 10, it would be inconsistent to use an assessment factor of 10 for freshwater and an assessment factor of 500 for marine water.

Based on the above, it is decided to use an assessment factor of 100 on the lowest of the three available freshwater NOECs, which results in a $PNEC_{\text{marine water}} = 11.3$ µg Sb/l.

3.2.1.1 Effects on microorganisms

There is one relevant and reliable study available on microorganisms that can be used to derive the $PNEC_{\text{microorganisms}}$. Based on inhibition of nitrification and measured Sb concentrations a NOEC of 2.55 mg Sb/l and an EC_{50} of 27 mg Sb/l was derived.

According to the TGD, the $PNEC_{\text{microorganisms}}$ can be calculated from the EC_{50} from a test performed with nitrifying bacteria by dividing the EC_{50} by 10 or can be set equal to the NOEC

from such a test. This would result in a $PNEC_{\text{microorganisms}}$ of 2.55 or 2.7 mg Sb/l. Selecting the lowest results in a $PNEC_{\text{micro-organisms}} = 2.55$ mg Sb/l.

3.2.1.2 Effects assessment for the sediment

Freshwater

Reliable and relevant chronic NOEC values are available for three species with different living and feeding conditions. According to the TGD (2003) the $PNEC_{\text{sediment}}$ shall be derived from the lowest NOEC divided by an assessment factor of 10. The lowest NOEC (78 mg Sb/kg ww or 112 mg Sb/kg dw) has been derived for the midge *Chironomus riparius* and the oligochaete *Lumbriculus variegatus*. This results in a $PNEC_{\text{freshwater sediment}} = 11.2$ mg Sb/ kg dw (7.8 mg Sb/kg ww.).

Marine water

As no studies on marine sediment organisms are available the $PNEC_{\text{marine sediment}}$ is derived from studies on freshwater sediment species. Reliable and relevant chronic NOEC values are available for three freshwater sediment species with different living and feeding conditions. The freshwater NOEC is 78 mg Sb/kg ww or 112 mg Sb/kg dw. According to the TGD, the assessment factor used should be 50, which results a $PNEC_{\text{marine sediment}} = 2.24$ mg Sb/kg dw (1.6 mg Sb/kg ww).

3.2.2 Atmosphere

No data is available on atmospheric toxicity of antimony.

3.2.3 Terrestrial compartment

The lowest reliable terrestrial toxicity data were determined in a soil spiked with Sb_2O_3 and aged for 31 weeks before testing (see Table 3-3).

Table 3-3 Lowest chronic toxicity test results for terrestrial species

Plants [<i>Hordeum vulgare</i>]	5 d NOEC (root elongation)	= 370 mg Sb/kg dw (measured*)
Invertebrates [<i>Folsomia candida</i>]	28 d NOEC (reproduction)	= 370 mg Sb/kg dw (measured*)
Microorganisms	7 d NOEC (nitrification)	= 710 mg Sb/kg dw (measured*)

*Recalculated in order to represent toxicity data in fully equilibrated diantimony trioxide amended soil (see below).

Valid bounded chronic NOECs are available for plants (999 mg Sb/kg dw), invertebrates (999 mg Sb/kg dw), and microorganisms (2930 mg Sb/kg dw). The $PNEC_{\text{soil}}$ is based on the porewater concentration measured at NOEC (9.7 mg Sb/l), divided with an assessment factor of 10 (Standard TGD procedures) which is multiplied with the equilibrium solid:liquid distribution coefficient (K_d) for Sb in this soil. The K_d value for the soil used in the present studies is 38 l/kg,

which is the value observed for the Sb_2O_3 amended soil aged for five years and for the soluble SbCl_3 added to soil. The resulting $\text{PNEC}_{\text{soil}}$ after having performed this calculation is 37 mg Sb/kg dw corresponding to 32.6 mg Sb/kg ww.

3.2.4 Non compartment specific effects relevant to the food chain

The reproduction and developmental toxicity studies available for diantimony trioxide are, all except one, inhalation exposure studies. Even though the inhalation exposure studies reveal effects they are not considered relevant to use in the assessment of secondary poisoning. It can be discussed if the effects on liver seen in the two repeated dose oral studies are relevant on a population level. However, it is decided to use these data, i.e. a NOAEL of 1686 mg/kg bw/day for female rats from a 90 day repeated dose study in the derivation of a $\text{PNEC}_{\text{oral}}$ for secondary poisoning. Using the conversion factor 20 (rats >6 weeks) for the NOAEL to NOEC conversion and an assessment factor of 90 as suggested in the TGD results in a $\text{PNEC}_{\text{sec poisoning}}$ of 375 mg Sb/kg food. This value is also used for the assessment of secondary poisoning in the marine environment.

3.3 RISK CHARACTERISATION

The risk assessment has considered all the main stages during which antimony may be released into the environment due to production, use and waste disposal of diantimony trioxide. The regional background concentrations used in the modelling are based on measured RWC ambient levels of antimony in Europe.

3.3.1 Aquatic compartment (incl. sediment)

3.3.1.1 Freshwater

The risk characterisation ratios for surface water are shown in Table 3-4 below. Predicted PECs have only been included for the reasonable worst cases, not for all sites giving emission information. The reason is that all reasonable worst case predicted PECs are below the PNEC.

Table 3-4 PEC/PNEC ratios for the aquatic compartment

	PEC _{water} (µg Sb/l)	RCR (PEC/PNEC)
Production, site P1	39.5	0.35
Production, site P5	0.88	0.008
Formulation as flame-retardant in plastics and rubber	4.7	0.06
Formulation as flame-retardant in plastics and rubber, assuming releases to air	0.72	0.04
Processing as flame-retardant in plastics and rubber	2.12	0.02
Formulation as flame-retardant in textiles, generic site	28.5 (14.6)*	0.25 (0.13)*
Formulation as flame-retardant in textiles, site AM19U	4.71	0.04

Formulation/application of back coating as flame-retardant in textiles, site FT-2	2.17	0.02
Formulation as flame-retardant in textiles, site 96	3.06	0.03
Application of textile back-coating, generic site	69.4	0.62
Application of textile back-coating, site RC74U	2.38	0.02
Production of PET polymer – i.e. formulation	4.0	0.041
Production of PET articles – i.e. industrial use	0.75	0.007
Use as flame-retardant in paint– formulation	1.32	0.011
Use in paint, pigment production	1.47	0.012
Use in paint, site AMI 3G - formulation,	3.19	0.03
Formulation in glass	0.72	0.006
Glass-manufacturing, ProcGlass 2	3.1	0.03
Glass-manufacturing, ProcGlass 3	0.90	0.008
Regional	0.72	0.006

*The PEC_{water} is calculated assuming that the waste water is not treated in a municipal STP. The figures within brackets represent the PEC and RCR if STP treatment is assumed.

All risk characterization ratios are below 1, which indicates that the risk to surface water is low both from regional and local sources.

Conclusions to the risk assessment for surface water:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are already being applied.

Conclusion (ii) applies to all scenarios.

3.3.1.2 Freshwater sediment

The risk characterisation ratios for sediment are shown in Table 3-5. Predicted PECs have only been included for the reasonable worst cases and if these give $PEC > PNEC$ also for other sites in the same use pattern, but not for all sites giving emission information.

Table 3-5 PEC/PNEC ratios for sediment

	$PEC_{\text{local, sediment}}$ (mg Sb/kg ww)	RCR (PEC/PNEC)
Production, site P1	38.33	4.9
Production, site P5	0.80	0.10
Formulation as flame-retardant in plastics and rubber	4.51	0.58
Formulation as flame-retardant in plastics and rubber, assuming releases to air	0.65	0.083
Processing as flame-retardant in plastics and rubber	2.01	0.26

	PEC _{local, sediment} (mg Sb/kg ww)	RCR (PEC/PNEC)
Formulation as flame-retardant in textiles, generic site	27.65	3.54
Formulation as flame-retardant in textiles, site AMI19U	4.52	0.58
Formulation/application of back-coating as flame-retardant in textiles, site FT-2	2.06	0.26
Formulation as flame-retardant in textiles, site 96	2.92	0.38
Application of textile back-coating, generic site	67.36	8.64
Application of textile back-coating, site RC74U	2.26	0.29
Production of PET polymer – i.e. formulation	3.84	0.49
Production of PET articles – i.e. industrial use	0.68	0.087
Use in paint flame-retardant – formulation	1.23	0.16
Use in paint, pigment production	1.38	0.18
Use in paint, site AMI 3G - formulation,	3.05	0.39
Formulation in glass	0.65	0.083
Glass-manufacturing ProcGlass 2	2.93	0.38
Glass-manufacturing ProcGlass 3	0.83	0.11
Regional (PEC based on monitoring data)	0.65	0.083

The PEC/PNEC ratio is well below 1 for the regional risk characterisation, but above 1 in some local scenarios. The risk characterisation is conservative in the way that the bioavailability is assumed to be 100 %. There is, however, no information available that makes it possible to take bioavailability into account.

Four sites producing diantimony trioxide have reported information on releases making it possible to make a completely site-specific prediction of PEC. Of these, one (site P1) had a PEC/PNEC ratio >1 which is also supported by measured concentrations of antimony in sediment near the site, whereas the other three had PEC/PNEC ratios <1.

For the use areas formulation and industrial processing of flame-retardant textile back-coatings, the PEC/PNEC ratios are above 1 only for the generic (formulation and processing) sites. The PEC calculation for the generic textile formulation site is performed assuming no municipal STP treatment. The reason for this is that the emission factor used represents emissions after on-site treatment and it is not considered to be a reasonable worst case to assume both on site and off site sewage treatment. However, even if it was assumed that the waste water from the generic site was treated off site the PEC would be 14.2 mg/kg ww giving a PEC/PNEC ratio of 1.82. Nine sites using diantimony trioxide in textiles have reported information on releases making it possible to make a completely site-specific prediction of PEC. Of these all had PEC/PNEC ratios <1. Ten sites gave enough information on releases (to either water or air but not both) to make a site-specific prediction of PEC based partly on reported and partly on default values. All of these gave PEC/PNEC ratios <1. Six sites gave some information, but not enough to make a prediction of a site-specific PEC.

Conclusions to the risk assessment for the sediment compartment:

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to the generic scenarios for formulation and application of flame-retardant textile back-coating and to one production site (site P1).

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are already being applied.

Conclusion (ii) applies to all other scenarios, including nineteen sites using diantimony trioxide in textile applications and three production sites, that all report releases.

3.3.2 Atmosphere

No PNEC can be derived for the atmosphere and so only a qualitative assessment can be made for this compartment. Neither biotic nor abiotic effects are considered likely due to the atmospheric release of antimony resulting from production and use of products containing diantimony trioxide, nor are any effects considered likely due to releases of antimony from unintentional sources.

Available information indicates a potential for antimony to be transported over long distances via the atmosphere.

Conclusions to the risk assessment for the atmosphere:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

3.3.3 Terrestrial compartment

The risk characterisation ratios for agricultural soil are shown in Table 3-6. Predicted PECs have only been included for the reasonable worst cases, not for all sites giving emission information. The reason is that all reasonable worst case predicted PECs are below the PNEC.

Table 3-6 PEC/PNEC ratios for agricultural soil (30 d average)

	PEC (mg Sb/kg w w)	RCR (PEC/PNEC)
Production, site P1	1.51	0.046
Production, site P5	1.56	0.048
Formulation as flame-retardant in plastics and rubber	3.04	0.093
Formulation as flame-retardant in plastics and rubber, assuming releases to air	1.5	0.046
Processing as flame-retardant in plastics and rubber	2.04	0.063

Formulation as flame-retardant in textiles, generic site	1.5 (6.86)*	0.046 (0.21)*
Formulation as flame-retardant in textiles, site AMI19U	4.75	0.15
Formulation/application of back-coating as flame-retardant in textiles, site FT-2	2.06	0.06
Formulation as flame-retardant in textiles, site 96	2.4	0.074
Application of textile back-coating, generic site	28	0.86
Application of textile back-coating, site RC74U	2.14	0.07
Production of PET polymer – i.e. formulation	2.77	0.08
Production of PET articles – i.e. industrial use	1.51	0.046
Use in paint flame-retardant – formulation	1.62	0.050
Use in paint, pigment production	1.65	0.050
Use in paint, site AMI 3G - formulation,	5.12	0.16
Formulation in glass	1.5	0.046
Glass-manufacturing Proc Glass 2	1.5	0.046
Glass-manufacturing Proc Glass 3	1.5	0.046
Regional	1.5	0.046

*The PEC_{soil} is calculated assuming that the waste water is not treated in a municipal STP and consequently no sewage sludge is spread on agricultural soil. The figures within brackets represent the PEC and RCR if STP treatment and spreading of sewage sludge on agricultural soil is assumed.

All risk characterisation ratios are below 1, which indicates that the risk to soil is low.

Conclusions to the risk assessment for the terrestrial compartment:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are already being applied.

Conclusion (ii) applies to all scenarios.

3.3.4 Non compartment specific effects relevant to the food chain

The resulting PEC/PNEC ratios for the fish food chain are shown in Table 3-7 and for the earthworm food chain in Table 3-8. Predicted PECs have only been included for the reasonable worst cases, not for all sites giving emission information. The reason is that all reasonable worst case predicted PECs are below the PNEC.

Table 3-7 PEC/PNEC ratios for secondary poisoning via the fish food chain

	BCF=40	
	PEC (mg Sb/kg)	RCR (PEC/PNEC)
Production, site P1	0.18	0.0005

Production, site P5	0.031	0.00008
Formulation as flame-retardant in plastics and rubber	0.094	0.0003
Formulation as flame-retardant in plastics and rubber, assuming releases to air	0.029	0.0000827
Processing as flame-retardant in plastics and rubber	0.052	0.0001
Formulation as flame-retardant in textiles, generic site	0.46	0.001
Formulation as flame-retardant in textiles, site AMI19U	0.083	0.0002
Formulation/application of back-coating as flame-retardant in textiles, site FT-2	0.050	0.0001
Formulation as flame-retardant in textiles, site 96	0.057	0.0002
Application of textile back-coating, generic site	1.2	0.003
Application of textile back-coating, site RC74U	0.045	0.0001
Production of PET polymer – i.e. formulation	0.083	0.0002
Production of PET articles – i.e. industrial use	0.029	0.0001
Use in paint flame-retardant – formulation	0.039	0.0001
Use in paint, pigment production	0.041	0.0001
Use in paint, site AMI 3G - formulation,	0.076	0.0002
Formulation in glass	0.029	0.0001
Glass-manufacturing Proc Glass 2	0.045	0.0001
Glass-manufacturing Proc Glass 3	0.030	0.0001

Table 3-8 PEC/PNEC ratios for secondary poisoning via the earthworm food chain

	PEC (mg Sb/kg)	RCR (PEC/PNEC)
Production, P1	0.17	0.0005
Production, P5	0.17	0.0005
Formulation as flame-retardant in plastics and rubber	0.25	0.0007
Formulation as flame-retardant in plastics and rubber, assuming releases to air	0.17	0.0005
Processing as flame-retardant in plastics and rubber	0.20	0.0005
Formulation as flame-retardant in textiles, generic site	0.47	0.001
Formulation as flame-retardant in textiles, site AMI19U	0.35	0.0009
Formulation/application of back-coating as flame-retardant in textiles, site FT-2	0.20	0.0005
Formulation as flame-retardant in textiles, site 96	0.22	0.0006
Application of textile back-coating, generic site	1.7	0.004
Application of textile back-coating, site RC74U	0.20	0.0005
Production of PET polymer – i.e. formulation	0.24	0.0006
Production of PET articles – i.e. industrial use	0.17	0.0005
Use as flame-retardant in paint– formulation	0.17	0.0005
Use in paint, pigment production	0.18	0.0005
Use in paint, site AMI 3G - formulation,	0.37	0.001
Formulation in glass	0.17	0.0005

	PEC (mg Sb/kg)	RCR (PEC/PNEC)
Glass-manufacturing, ProcGlass 2	0.17	0.0005
Glass-manufacturing, ProcGlass 3	0.17	0.0005

All risk characterization ratios are far below 1, for both the fish and the earthworm food chains. This indicates that the risk of secondary poisoning from the use of diantimony trioxide is low.

Conclusions to the risk assessment for secondary poisoning:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

3.3.5 Marine risk assessment

3.3.5.1 PBT-assessment

There is currently no agreed approach to perform a PBT assessment of a metal, therefore a PBT assessment will not be performed.

3.3.5.2 Risk characterisation for the marine environment

3.3.5.2.1 Marine water

The PEC/PNEC ratios for marine surface water are given in Table 3-9. Predicted PECs have only been included for the reasonable worst cases and if these give $PEC > PNEC$ also for other sites in the same use pattern, but not for all sites giving emission information. In this case there are no reporting sites known to be located by the sea.

Table 3-9 PEC/PNEC ratios for marine surface water

	PEC ($\mu\text{g Sb/l}$)	RCR (PEC/PNEC)
Production, P1**	-	-
Production, P5*	0.23	0.02
Formulation as flame-retardant in plastics and rubber	1.00	0.09
Formulation as flame-retardant in plastics and rubber, assuming releases to air	0.20	0.02
Processing as flame-retardant in plastics and rubber	0.48	0.04
Formulation as flame-retardant in textiles, generic site	2.98	0.26

Formulation as flame-retardant in textiles, site AMI19U**	-	-
Formulation/processing as flame-retardant in textiles, site FT-2**	-	-
Formulation as flame-retardant in textiles, site 96**	-	-
Application of textile back-coating, generic site	13.9	1.23
Application of textile back-coating, site RC74U**	-	-
Production of PET polymer – i.e. formulation	0.9	0.08
Production of PET articles – i.e. industrial use	0.20	0.02
Use as flame-retardant in paint– formulation	0.26	0.02
Use in paint, pigment production	0.27	0.02
Use in paint, site AMI 3G - formulation**,	-	-
Formulation in glass	0.20	0.02
Glass-manufacturing Proc Glass 2***	0.44	0.04
Glass-manufacturing Proc Glass 3**	-	-
Regional (PEC based on monitoring data)	0.20	0.02

* not known whether the releases are to freshwater or marine water

**not located by the sea

*** not located by the sea, included as a theoretical reasonable worst case

The risk characterization for marine water indicates concern locally for the application of textile back-coating generic site.

Conclusions to the risk assessment for marine surface water:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are already being applied.

Conclusion (ii) applies to all scenarios.

Despite having RCR >1 conclusion iii) is not drawn for application of flame-retardant back-coating. The reason for this is that, according to information from IAOIA, none of the sites covered by the survey IAOIA performed to collect exposure data from all their customers is located by the sea. However, it has to be pointed out that the coverage of this survey regarding textile backcoating sites was rather low. Therefore, it cannot be ruled out that textile backcoating sites located at the sea having emissions to the marine environment may exist.

3.3.5.2.2 Marine sediment

The PEC/PNEC ratios for marine sediment are given in Table 3-10. Predicted PECs have only been included for the reasonable worst cases and if these give PEC > PNEC also for other sites in the same use pattern, but not for all sites giving emission information.

It is the PEC derived using the median of the available partition coefficients of suspended matter that has been used for the risk characterisation.

Table 3-10 PEC/PNEC ratios for marine sediment

	PEC _{local, sed} (mg/kg wet wt.)	RCR (PEC/PNEC)
Production, P1**	-	-
Production, P5*	0.68	0.44
Formulation as flame-retardant in plastics and rubber	1.42	0.91
Formulation as flame-retardant in plastics and rubber, assuming releases to air	0.65	0.42
Processing as flame-retardant in plastics and rubber	0.92	0.59
Formulation as flame-retardant in textiles, generic site	3.35	2.15
Formulation as flame-retardant in textiles, site AMI19U**	-	-
Formulation/application of back-coating as flame-retardant in textiles, site FT-2**	-	-
Formulation as flame-retardant in textiles, site 96**	-	-
Application of textile back-coating, generic site	13.95	8.9
Application of textile back-coating, site RC74U**	-	-
Production of PET polymer – i.e. formulation	1.29	0.83
Production of PET articles – i.e. industrial use	0.66	0.42
Use in paint flame-retardant – formulation	0.71	0.45
Use in paint, pigment production	0.72	0.46
Use in paint, site AMI 3G - formulation**	-	-
Formulation in glass	0.65	0.42
Glass-manufacturing ProcGlass 2***	0.67	0.43
Glass-manufacturing ProcGlass 3**	-	-
Regional (PEC based on monitoring data)	0.65	0.42

*not known whether the releases are to freshwater or marine water

** not located by the sea

*** not located by the sea, included as a theoretical reasonable worst case

Similar to freshwater sediment, the PEC/PNEC ratio is below 1 for the regional risk characterisation, but above 1 in the local scenarios for certain use areas. An assessment factor of 50 has been used to derive the PNEC. The assessment factor could be lowered to 10 if two additional tests on marine sediment living species are performed. Furthermore, the risk characterisation is conservative in the way that the bioavailability is assumed to be 100 %. There is, however, no information available that makes it possible to take bioavailability into account

Conclusions to the risk assessment for the marine sediment compartment:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those that are already being applied.

Conclusion (ii) applies to all scenarios.

Despite having $RCR > 1$ conclusion iii) is not drawn for formulation and application of flame-retardant back-coating. The reason for this is that, according to information from IAOIA, none of the sites covered by the survey IAOIA performed to collect exposure data from all their customers is located by the sea. For the formulation of flame-retardant in textiles the coverage of this survey is high and there is a high probability that for this use area the marine scenario may not be relevant. For application of textile back-coating on the other hand the coverage of the survey is lower and it cannot be ruled out that sites located at the sea having emissions to the marine environment may exist.

3.3.5.2.3 Secondary poisoning in the marine environment

The PEC/PNEC ratios for marine secondary poisoning are given in Table 3-11, and Table 3-12.

Predicted PECs have only been included for the reasonable worst cases and if these give $PEC > PNEC$ also for other sites in the same use pattern, but not for all sites giving emission information.

Table 3-11 PEC/PNEC ratios in fish for secondary poisoning in the marine environment

	BCF=40	
	PEC (mg Sb/kg)	RCR (PEC/PNEC)
Production P1**	-	-
Production P5*	0.0084	0.00002
Formulation as flame-retardant in plastics and rubber	0.021	0.00006
Formulation as flame-retardant in plastics and rubber, assuming releases to air	0.0080	0.00002
Processing as flame-retardant in plastics and rubber	0.013	0.00003
Formulation as flame-retardant in textiles, generic site	0.051	0.0001
Formulation as flame-retardant in textiles, site AMI19U**	-	-
Formulation/application of back-coating as flame-retardant in textiles, site FT-2**	-	-
Formulation as flame-retardant in textiles, site 96**	-	-
Application of textile back-coating, generic site	0.23	0.0006
Application of textile back-coating, site RC74U**	-	-
Production of PET polymer – i.e. formulation	0.019	0.00005
Production of PET articles – i.e. industrial use	0.0080	0.00002
Use as flame-retardant in paint– formulation	0.0090	0.00002
Use in paint, pigment production	0.0092	0.00002
Use in paint, site AMI 3G - formulation**	-	-
Formulation in glass	0.0080	0.00002
Glass-manufacturing, ProcGlass 2***	0.0096	0.00003
Glass-manufacturing, ProcGlass 3**	-	-

* not known whether the releases are to freshwater or marine water

** not located by the sea

*** not located by the sea, included as a theoretical reasonable worst case

Table 3-12 PEC/PNEC ratios in fish-eating marine top predators for secondary poisoning in the marine environment

	BCF=40	
	PEC (mg Sb/kg)	RCR (PEC/PNEC)
Production, P1**	-	-
Production, P5*	0.0081	0.00002
Formulation as flame-retardant in plastics and rubber	0.010	0.00003
Formulation as flame-retardant in plastics and rubber, assuming releases to air	0.0080	0.00002
Processing as flame-retardant in plastics and rubber	0.0089	0.00002
Formulation as flame-retardant in textiles, generic site	0.017	0.00004
Formulation as flame-retardant in textiles, site AMI19U**	-	-
Formulation/application of back-coating as flame-retardant in textiles, site FT-2**	-	-
Formulation as flame-retardant in textiles, site 96**	-	-
Application of textile back-coating, generic site	0.053	0.0001
Application of textile back-coating, site RC74U**	-	-
Production of PET polymer – i.e. formulation	0.010	0.00003
Production of PET articles – i.e. industrial use	0.0080	0.00002
Use as flame-retardant in paint– formulation	0.0082	0.00002
Use in paint, pigment production	0.0083	0.00002
Use in paint, site AMI 3G - formulation**	-	-
Formulation in glass	0.0080	0.00002
Glass-manufacturing, ProcGlass 2***	0.0083	0.00002
Formulation in glass, ProcGlass 3**	-	-

* not known whether the releases are to freshwater or marine water

** not located by the sea

*** not located by the sea, included as a theoretical reasonable worst case

All risk characterization ratios are far below 1, both for predators and top predators.

Conclusions to the risk assessment for marine secondary poisoning:

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

3.3.6 Areas of uncertainty in the environmental risk assessment

As with any “generic” risk assessment, there are uncertainties inherent in the approach taken.

For most of the scenarios considered, the best information available to the specific industries has been used in preference to the default values. There is however not a complete set of data. This necessarily introduces uncertainties into the estimates.

The RCW-ambient PEC for water, sediment and soil is based on 90th percentiles from the available data. However, not all of the original data points are available, i.e. some studies only report median or mean values, whereas other report ranges, etc. This makes it very difficult to calculate a true 90th percentile value (which would need all of the individual data points from each study).

A consequence of taking the regional concentration to be the median of the country specific 90th percentile values is that, for a number of countries, the country-specific 90th percentile is actually higher than the concentration used for the regional concentration.

The selection of a value for the partition coefficient suspended matter – water, has a major impact on the conclusions on risk for both freshwater and marine sediments. Furthermore the bioavailability has been set to 100 % in the absence of other information.

4 HUMAN HEALTH

4.1 EXPOSURE

The human population may be exposed to diantimony trioxide at the workplace, from use of consumer products containing diantimony trioxide and indirectly via the environment through contact with contaminated air. Humans may also be exposed indirectly via the environment through consumption of food, water and soil. However, the exposure will then be to the antimony ion. Since there is a continuous exposure to diantimony trioxide via the environment, humans may be exposed during their entire lifetime. In addition, there might be combined exposure to humans from more than one of these sources.

4.1.1 Occupational exposure

There are several industries in which diantimony trioxide is produced or used, and the life cycle stages where occupational exposure may occur are; production, formulation, i.e. industrial use of diantimony trioxide as an additive, and processing, i.e. industrial and professional use of semi- or end-products containing diantimony trioxide. At some sites, both formulation and processing may take place. In addition, exposure might occur during recycling and disposal of articles containing diantimony trioxide, but there is no available information about this. It is assumed that exposure during recycling and disposal is limited compared to the exposure from production, formulation and industrial and professional use, and therefore this scenario is not considered further in this exposure assessment.

In addition to production of diantimony trioxide, the following uses have been identified:

- Use as catalyst in production of PET.
- Use as flame-retardant in production of plastics.
- Use as flame-retardant in treated textiles.
- Use in pigments, paints, coatings and ceramics.
- Use as flame-retardant in production of rubber.
- Use in production of crystal glass.

Occupational exposure scenarios where diantimony trioxide is formed but not used, such as in battery production, have not been included in this assessment.

The following data were used for the occupational exposure assessments of diantimony trioxide:

- Measured workplace data from production and uses of diantimony trioxide.
- Physico-chemical data of diantimony trioxide.
- Qualitative data, such as process description and use pattern of the product, and quantitative data regarding frequency and duration of handling of diantimony trioxide.
- Concentrations of diantimony trioxide used in the different products.

The main routes of occupational exposure to diantimony trioxide are inhalation of airborne solid dust and dermal exposure to solid diantimony trioxide, either by contamination of skin surfaces during direct handling or by dermal deposition of airborne dust.

The exposure values for the different scenarios for workers are summarised in the table below. For inhalation, the values shown are 8 h-TWA (time weighted average) air concentrations and

for dermal exposure the values are given as mg per kg body weight and day. Typical and reasonable worst case (RWC) values were assessed. For production, values with and without use of respiratory protection devices (RPE) are given.

Table 4-1. Summary of external exposure of diantimony trioxide for workers.

Inhalation exposure	Typical (mg Sb ₂ O ₃ /m ³)	RWC (mg Sb ₂ O ₃ /m ³)	Remarks
1. Production of diantimony trioxide			
- Conversion	0.027 with RPE	2.9 without RPE 0.15 with RPE	Measured data
- Refuming	0.012 with RPE	0.94 without RPE 0.047 with RPE	Measured data
- Final handing	0.040 with RPE	2.1 without RPE 0.11 with RPE	Measured data
2. Use as a catalyst in production of PET			
- Powder handling	0.002	0.026	Measured data
3. Use as a flame-retardant in production of plastics			
- Raw material handling	0.13	0.57	Measured data
4. Use as a flame-retardant in treated textiles			
- Formulation	0.13	0.57	Analogous data
- Processing	<0.001	0.001	Measured data
- Further handling	negligible	negligible	Industry information
5. Use in pigments, paints, coatings and ceramics			
- Loading and mixing	0.036	0.16	Analogous data
6. Use as a flame-retardant in production of rubber			
- Formulation	0.051	0.22	Analogous data
- Processing	0.064	0.14	Analogous data
7. Use in production of crystal glass			
- Cutting	0.003	0.015	Analogous data
Dermal exposure	Typical (mg Sb ₂ O ₃ /kg/day)	RWC (mg Sb ₂ O ₃ /kg/day)	Remarks
1. Production of diantimony trioxide			
- Conversion	0.23	0.72	Measured data
- Refuming	0.54	0.99	Measured data
- Final handing	0.81	1.4	Measured data
2. Use as a catalyst in production of PET			
- Powder handling	0.10	0.17	Analogous data
3. Use as a flame-retardant in production of plastics			

- Raw material handling	0.19	0.34	Analogous data
4. Use as a flame-retardant in treated textiles			
- Formulation	0.13	0.22	Analogous data
- Processing	0.13	0.86	Modelled data
- Further handling	0.0023	0.010	Measured data
5. Use in pigments, paints, coatings and ceramics			
- Loading and mixing	0.066	0.11	Analogous data
6. Use as a flame-retardant in production of rubber			
- Formulation	0.066	0.11	Analogous data
- Processing	0.051	0.089	Analogous data
7. Use in production of crystal glass			
- Cutting	0.086	0.31	Analogous data

4.1.2 Consumer exposure

There is no known direct private use of diantimony trioxide as such. However, diantimony trioxide is used in several products, some of which are available to consumers. Some examples of end products containing diantimony trioxide or antimony are: PET, cuddly toys, flat and pile upholstered furniture (residential and commercial furniture), upholstery seating and interior textiles in private and public transportation, textiles, wall coverings, electrical and electronic equipment e.g. distribution boxes for electrical lines, polyvinyl chloride wire and cable. Due to wear and tear of the diantimony trioxide containing materials, the material will partly be abraded into small particles. These particles will become a part of the in-house dust. Consequently, exposure of consumers to diantimony trioxide may occur via the inhalation and dermal route. Although originating from the use of diantimony trioxide the actual oral exposure via PET-bottles and cuddly toys is not to diantimony trioxide itself but to antimony. To calculate the concentration of diantimony trioxide, the measured levels of antimony are adjusted with a factor of 1.2 (correction for molecular weight). This approach is taken in order to enable comparison between exposure values and effect data, which are based on diantimony trioxide. The specific hand-to-mouth behaviour of small children may play a particular role for their exposure. Therefore oral exposure to diantimony trioxide for children via sucking on cuddly toys and ingestion of dust has been estimated.

Four scenarios for consumer exposure were evaluated. The values are based on measured data.

- PET-bottle: The reasonable worst-case *oral exposure* is 0.035 µg/kg bw/day for *an adult* drinking from a PET bottle.
- Fabrics: The reasonable worst-case *dermal exposure* is 1.8 µg/kg bw/day for *an adult* sitting on upholstery fabric.
- Cuddly toys: For *a child* sucking on cuddly toys the reasonable worst-case *oral exposure* is 0.25 µg/kg bw/day.
- Indoor air: The reasonable worst-case exposure of diantimony trioxide via indoor air is $3.15 \cdot 10^{-6}$ mg/m³. For *a child* the reasonable worst-case *oral exposure*, via ingestion of dust from indoor air, is 0.60 µg/kg bw/day.

4.1.3 Man exposed indirectly via the environment

Humans may be exposed via the environment by inhalation of particles in air or ingestion of contaminated food and water. Diantimony trioxide is released to the environment through air effluents and wastewater from manufacture, formulation, processing, use and disposal of diantimony trioxide containing products. In the environment, diantimony trioxide originating from production/use of diantimony trioxide will dissolve to the trivalent and predominantly pentavalent ions. As a consequence, the actual exposure from drinking water, food and breast milk will be to the antimony ions. Antimony is also a naturally occurring element. Therefore, its presence in the environment, and thereby also indirectly in water and in food and beverages produced from agricultural goods, may also be attributed to natural sources. To calculate the concentration of diantimony trioxide, the measured levels of antimony are adjusted with a factor of 1.2 (correction for molecular weight). This approach is taken in order to enable comparison between exposure values and effect data, which are based on diantimony trioxide.

Four *regional* scenarios for human exposure to diantimony trioxide via the environment are presented. The exposure values are based on measured data.

- Food: The reasonable worst-case *oral* exposure via food is 0.096 µg/kg bw/day for *adults*.
- Breast milk: The reasonable worst-case *oral* exposure via breast milk is 0.087 µg/kg bw/day for *infants* during the first 0-3 months.
- Drinking water: A reasonable worst-case *oral* exposure via drinking water is estimated to 0.029 µg/kg bw/day.
- Outdoor air: The reasonable worst case concentration in outdoor air is 3.12 ng/m³.

Local exposure: The maximum local concentration in air is 1 µg/m³. The maximum local exposure via water is 2.8 µg/kg/day. It should however be noticed that this exposure is a gross overestimate as it is based on untreated surface water which is not representative for drinking water in the EU.

4.2 EFFECTS

Toxicokinetics

In a rat study, the oral absorption was 0.3 % and 0.05 % at 100 mg/kg bw and 1000 mg/kg bw, respectively. However, at relevant human exposure levels, which are lower, an oral absorption of 1 % is assumed. Dermal absorption of diantimony trioxide is considered negligible based on an *in vitro* human skin percutaneous study which showed 0.26 % absorption. Based on particle size, the deposition of inhaled diantimony trioxide in the airways is calculated by the MPPD model resulting in an estimated total absorption via inhalation of 6.82 %.

After oral exposure of rats to diantimony trioxide suspension, antimony is distributed to most organs with the highest concentrations found in whole blood, thyroid and bone marrow. After repeated inhalation exposure to diantimony trioxide, antimony accumulates in lung tissue and is retained in the lungs for long periods of time (the biological elimination half time in humans has been estimated to 600-3700 days). Antimony has also been detected in low amounts in human foetal liver as well as in human breast milk, placenta, amniotic fluid and umbilical cord blood, indicating that antimony can be distributed to the foetus and excreted in breast milk; thus exposure may occur both *in utero* and during breast-feeding. After oral

exposure most of the antimony is excreted in the faeces, due to low oral absorption. Absorbed antimony is excreted both in faeces and in urine, biliary excretion being higher than urinary excretion.

Acute toxicity

There is one acute inhalation toxicity OECD guideline study with 4 hours (nose-only) exposure of male and female rats, which shows no signs of toxicity for diantimony trioxide, indicating a 4-hour $LC_{50} > 5200 \text{ mg/m}^3$. The animal studies on acute oral exposure do not comply with current standards. Still, they indicate that the oral LD_{50} is in excess of 20 000 mg/kg bw in rats. There is one study on dermal exposure in rabbits that indicates that the LD_{50} for dermal exposure is higher than 8300 mg/kg bw. The overall conclusion is that, despite the poor quality of the available acute oral and dermal toxicity studies with diantimony trioxide in laboratory animals, they indicate that diantimony trioxide is of low acute inhalation, oral and dermal toxicity.

Irritation

Although no reliable data are available for skin irritation to diantimony trioxide the weight-of-evidence suggests that diantimony trioxide is irritating to human skin. Several human case report studies indicate that diantimony trioxide may cause dermatitis on skin damp with perspiration and the lesions appear to be closely associated with sweat ducts. Diantimony trioxide should therefore be regarded as a skin irritant in humans under conditions that evoke sweating. The lack of dermal irritation in rabbits may be explained by the fact that rabbits lack sweat glands. Two eye irritation studies in rabbits show that diantimony trioxide causes reversible symptoms of mild eye irritation. There is one acute inhalation toxicity animal study available, which has also assessed the irritation potential of diantimony trioxide to the respiratory tract, indicating that diantimony trioxide is not irritating to the respiratory system.

Sensitisation

A skin sensitisation study on diantimony trioxide, performed according to TG 406, shows that diantimony trioxide is not skin sensitising in guinea pigs.

Repeated dose toxicity

The repeated dose toxicity of diantimony trioxide has been investigated in several animal studies via the inhalation and oral routes of exposure. The majority of these studies are considered inconclusive because they do not comply with current test guidelines. The conclusive studies show that diantimony trioxide is toxic to lung. In an inhalation repeated dose toxicity study in rats (not following OECD test guideline), the substance was administered via whole body inhalation to 65 animals/sex/dose at 0, 0.06, 0.51 and 4.50 mg/m^3 , for 5 days/week for 12 months followed by a 12-month observation period. Interstitial fibrosis, granulomatous inflammation and bronchiolar/alveolar hyperplasia occurred in a number of animals during the observation period, most pronounced in the high-dose group. Increased numbers of alveolar/intraalveolar macrophages and particulate material in alveolar/intraalveolar macrophages were seen in all dose groups during both the exposure and the observation periods. The diantimony trioxide lung burden data showed a lung burden-dependent effect on the diantimony trioxide clearance rate in the high-dose group. It was calculated that with a lung containing approximately 2 mg of diantimony trioxide after 52 weeks of exposure, pulmonary clearance was decreased by 80 % with an increase in the clearance half time from 2 to 10 months. Thus, the clearance mechanism was significantly impaired at this exposure level and was interpreted as an intrinsic toxic effect of diantimony trioxide rather than a general effect due to particle overload. Absolute and

relative lung weights were unaffected in all exposure groups. Based on impaired lung clearance the LOAEC and NOAEC for repeated dose inhalation toxicity were considered to be 4.50 mg/m^3 and 0.51 mg/m^3 , respectively. The NOAEC was determined in a study with a high background incidence of lung inflammation in controls, therefore there is some uncertainty regarding the reliability of the numerical values. In an OECD guideline 90-day oral study, diantimony trioxide did not cause systemic toxicity at doses up to 1686 and 1879 mg/kg/day in male and female rats, respectively.

Genotoxicity

Diantimony trioxide is not considered to induce gene mutations *in vitro*, but induces structural chromosome aberrations in cultured mammalian cells *in vitro*. Oral *in vivo* studies on the induction of chromosome aberrations and micronuclei in the bone marrow (involving 21-day administration at the limit dose of 1000 mg/kg bw/day) and unscheduled DNA synthesis in the liver have produced negative results. It can be concluded that diantimony trioxide does not cause systemic genotoxicity *in vivo* after oral administration in rats and mice. Further, the available *in vivo* data might suggest that a possible genotoxic potency of diantimony trioxide would be low and it is believed that a possible local genotoxic effect of diantimony trioxide would only be biologically relevant at concentration levels that also cause particle overload. Therefore, there is also no concern for local genotoxicity of diantimony trioxide in the lung.

Carcinogenicity

Three chronic toxicity/carcinogenicity studies in rats with inhalation exposure to diantimony trioxide are available. The exposure duration in all three animal studies is 12 months and thus all studies deviate from the OECD guideline on chronic toxicity/carcinogenicity, which states an exposure period of 24 months for rats. In the study by Watt, inhalation of $5.0 \text{ mg Sb}_2\text{O}_3/\text{m}^3$ produced lung neoplasms in 44 % of the animals tested (only females were exposed). In the study by Groth et al., $45 \text{ mg Sb}_2\text{O}_3/\text{m}^3$ produced pulmonary neoplasms in 32 % of the female rats exposed but none in the male rats. The study by Newton et al. showed no lung tumours at any dose level up to 4.5 mg/m^3 . A comparison of the histopathology tissue sections from the Watt- and the Newton-studies indicated higher lung deposition of antimony and more severe lung damage in exposed rats in the Watt-study than in the Newton-study, which allegedly were conducted at similar exposure levels ($1.9\text{-}5.0$ and $0.06\text{-}4.50 \text{ mg/m}^3$, respectively). This suggests that the exposure levels in the Watt study were likely higher (5-fold) than those reported, and consequently make the study unsuitable for derivation of a NOAEC.

Based on these data it is concluded that diantimony trioxide induces tumours in rat lung. The most likely mechanism for the lung carcinogenicity is impaired lung clearance and particle overload followed by an inflammatory response, fibrosis and tumours. Consequently, diantimony trioxide can be regarded as a threshold carcinogen and the NOAEC of 0.51 mg/m^3 , derived for local repeated dose toxicity and based on impaired clearance of particles, is also used for carcinogenicity. The NOAEC was determined in a study with a high background incidence of lung inflammation in controls, therefore there is some uncertainty regarding the reliability of the numerical value.

Toxicity for reproduction

No reproductive toxicity studies have been conducted for diantimony trioxide. However, detailed examination of male and female reproductive organs from repeated-dose toxicity studies via the oral route of exposure has been done. Testicular toxicity of diantimony

trioxide has been investigated in male mice and male rats. In this 4-week study, diantimony trioxide was administered via gavage to 10 mice and 8 rats per dose at 0, 12.0 and 1200 mg/kg bw/day for 5 and 3 days/week, respectively. An oral NOAEL > 1200 mg/kg bw for testicular toxicity was derived. In a rat 90-day oral feeding study performed according to OECD TG 408, no histopathological changes were observed in testes up to a dose of 1686 mg/kg/d or in ovaries and uterus up to a dose of 1879 mg/kg. Based on these results, diantimony trioxide is not toxic to male or female reproductive tissues.

The developmental toxicity of diantimony trioxide has been investigated, following a test protocol based on TG 414. However, some alterations in the conduct of the study were made. 26 mated rats per group were exposed (nose-only) from day 0 to day 19 of gestation at concentrations of 0, 2.6 (SD±2.43), 4.4 (SD±3.88) and 6.3 (SD±4.18) mg diantimony trioxide/m³. No evidence of developmental toxicity was observed in rats at doses up to 6.3 mg diantimony trioxide/m³, which suggests that the NOAEC for developmental toxicity is 6.3 mg/m³, the highest exposure level tested. The LOAEC for maternal toxicity (acute pneumonia and significantly increased absolute and relative lung weights relative to controls) in this study was 2.6 mg/m³. However, body weight and food intake were not affected at any dose level.

4.3 RISK CHARACTERISATION

The key toxicological endpoints for diantimony trioxide are skin irritation, repeated dose toxicity (lung effects) and local lung carcinogenicity. The critical effect measures are summarised in the table below (Table 4-2). NOAEL/NOAEC values are given for repeated dose and developmental toxicity. For acute toxicity LD₅₀ values are given. The absence or presence of irritating, sensitising or genotoxic properties are indicated by a – or a + sign, respectively.

As the dermal absorption of diantimony trioxide is considered negligible no risk characterisation of dermal exposure to diantimony trioxide is performed.

For risk assessment the MOS approach as outlined in the TGD (Human health Risk Characterisation, Final draft) is applied.

Table 4-2. Summary of critical effect measures.

Endpoint	In vitro	Inhalation measure	Dermal measure	Oral measure
Acute toxicity		5200 mg/m ³	8300 mg/kg bw	20 000 mg/kg bw
Irritation / corrosivity		-	+	
Sensitisation			-	
Repeated dose toxicity		0.51 mg/m ³		1686 mg/kg/d
Mutagenicity	+			-
Carcinogenicity		0.51 mg/m ³		
Fertility impairment				1686 mg/kg bw
Developmental toxicity		6.3 mg/m ³		

4.3.1 Workplace

Irritation

Diantimony trioxide is considered irritating to skin. Given the skin irritating potential of diantimony trioxide it is concluded that the substance is of concern for workers with regard to skin irritation and conclusion (iii) is reached to indicate the need for classification. Once classified the conclusion (iii) will be changed to conclusion (ii).

Repeated dose toxicity

Repeated inhalation exposure to diantimony trioxide gives local toxic effects in the lung and a NOAEC of 0.51 mg/m^3 is derived from a 12 month inhalation exposure study in rat, supported by observations of acute pneumonia in a 19 days inhalation developmental toxicity study. No systemic toxicity is observed after repeated exposure; therefore no quantitative risk characterisation is performed for systemic repeated dose toxicity.

To calculate MOS-values for local pulmonary toxicity the exposure levels (see Table 4-1) should be compared with a corrected NOAEC of 0.26 mg/m^3 calculated as follows: The experimental NOAEC of 0.51 mg/m^3 adapted by a factor of $6/8$ to account for differences between the experimental inhalation duration of 6 h per day and the average working day of 8 h per day and then multiplied by a factor of $6.7/10$ for activity driven differences of respiratory volumes in workers ($0.51 \text{ mg/m}^3 \cdot 6/8 \cdot 6.7/10$). The achieved MOS-values are then compared with a reference MOS of 12.5 (see Table 4-3 below).

The following assessment factors are applied in the setting of a reference MOS to a local effect in the lung:

- a factor of 2.5 for interspecies differences
- a factor of 5 for intraspecies differences; this covers the variation in sensitivity expected between workers

Table 4-3 Occupational risk assessment for repeated dose toxicity (local effects) and carcinogenicity in the lung. The NOAEC value is compared with typical and reasonable worst-case (RWC) exposures to calculate MOS values.

	Inhalation (local effects)							
	Typical exposure* (mg/m ³)	Corrected NOAEC (mg/m ³)	MOS	Conclusion	RWC exposure* (mg/m ³)	Corrected NOAEC (mg/m ³)	MOS	Conclusion
Production of diantimony trioxide								
Conversion, with RPE	0.027	0.26	9.6	(iii)	0.15	0.26	1.7	(iii)
Refuming, with RPE	0.012	0.26	22	(ii)	0.047	0.26	5.5	(iii)
Final handling, with RPE	0.040	0.26	6.5	(iii)	0.11	0.26	2.4	(iii)
Conversion, without RPE					2.9	0.26	0.09	(iii)
Refuming, without RPE					0.94	0.26	0.28	(iii)
Final handling, without RPE					2.1	0.26	0.12	(iii)
Use as a catalyst in production of PET								
Powder handling	0.002	0.26	130	(ii)	0.026	0.26	10	(iii)

Use as flame-retardant in production of plastics								
Raw material handling	0.13	0.26	2	(iii)	0.57	0.26	0.46	(iii)
Use as flame-retardant in treated textiles								
Formulation	0.13	0.26	2	(iii)	0.57	0.26	0.46	(iii)
Processing	<0.001	0.26	-		0.001	0.26	260	(ii)
Further handling	negl.	0.26	-		negl.	0.26	-	
Use in pigments, paints, coatings and ceramics								
Loading and mixing	0.036	0.26	7.2	(iii)	0.16	0.26	1.6	(iii)
Use as flame-retardant in production of rubber								
Formulation	0.051	0.26	5.1	(iii)	0.22	0.26	1.2	(iii)
Processing	0.064	0.26	4	(iii)	0.14	0.26	1.9	(iii)
Use in production of crystal glass								
Cutting	0.003	0.26	87	(ii)	0.015	0.26	17	(ii)

Mutagenicity and carcinogenicity

It is concluded that diantimony trioxide does not cause systemic genotoxicity *in vivo* after oral administration in rats and mice. However, it is not possible to conclude on mutagenicity in specific site of contact tissues (local mutagenicity), as no such tests have been performed, and thus whether the results are relevant for the situation in the lung after inhalation exposure, which is the site where tumours have been found in the carcinogenicity studies. However, the overall expert judgement by TC NES is that the most likely mechanism for diantimony trioxide induced lung carcinogenicity appears to be impaired clearance and particle overload followed by an inflammatory response, fibrosis and tumours. Further, it is believed that a possible local genotoxic effect of diantimony trioxide would only be biologically relevant at concentration levels that also cause particle overload. Therefore, there is also no concern for local mutagenicity of diantimony trioxide. In conclusion, there is no concern for genotoxicity and conclusion (ii) is reached.

Diantimony trioxide is classified for carcinogenicity. Although the mechanism for pulmonary tumour formation is still unclear it may be assumed that particle deposition followed by macrophage infiltration, pulmonary inflammation and impaired clearance are pivotal initial steps in the process. Consequently, diantimony trioxide can be regarded as a threshold carcinogen and as a starting point for a quantitative risk characterisation the NOAEC of 0.51 mg/m³ derived for local repeated dose toxicity is also used for carcinogenicity (see Table 4-3). MOS values and reference MOS values are the same as for local lung toxicity (see above).

In summary

When considering the risks to human health arising from occupational exposure to diantimony trioxide, the key areas are for local pulmonary toxicity and carcinogenicity. Therefore it is considered that risk reduction measures are required and conclusion (iii) applies to most exposure scenarios. Although control measures are available in these industry sectors, there is no

evidence that the appropriate equipment is in place in all EU workplaces, and that it is used in the correct manner. Furthermore, in the diantimony trioxide production industry, where the risk was assessed both with and without use of RPE, conclusion (iii) is reached even when RPE is taken into account. In addition, there is concern for skin irritation and conclusion (iii) is reached to indicate the need for classification.

4.3.2 Consumers

Consumer exposure may occur through inhalation, ingestion and dermal contact with articles containing diantimony trioxide or through inhalation or ingestion (children only) of domestic dust. Considering the low exposure levels for consumers reported in the exposure assessment part (~60.000 times lower than the NOAEC established in long-term repeated dose inhalation study), consumers are not expected to be exposed to dianimony trioxide in the range of hazardous doses and conclusion (ii) is reached for all end-points.

4.3.3 Man indirectly exposed via the environment

Diantimony trioxide is released to the environment via emissions to air, waste water, surface water and soil from manufacture, formulation, processing, use and disposal of diantimony trioxide, but also via coal combustion and refuse incineration, non-ferrous metal production (e.g. Cu), and road traffic. Humans may be exposed via the environment by inhalation of particles in air or ingestion of contaminated food and water, but the exposure levels are low (~120.000 times lower than the NOAEC established in long-term repeated dose inhalation study) and conclusion (ii) is therefore reached for all end-points.

5 OVERALL RESULTS OF THE RISK ASSESSMENT

5.1 ENVIRONMENT

The compartments of concern are: fresh water sediment (generic scenarios for formulation and application of flameretardant textile back-coating and one production site), marine water (generic scenario only) and marine sediment (generic scenario only).

5.1.1 Aquatic compartment

5.1.1.1 Surface water

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

5.1.1.2 Sediment

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to the generic scenarios for formulation and application of flameretardant textile back-coating and to one production site (site P1).

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all other scenarios, including nineteen sites using diantimony trioxide in textile applications and three production sites, that all report releases.

5.1.1.3 Waste water treatment plants

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

5.1.2 Terrestrial compartment

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

5.1.3 Atmosphere

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

5.1.4 Secondary poisoning

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

5.1.5 Marine compartment

5.1.5.1 PBT-assessment

There is currently no agreed approach to perform a PBT-assessment of a metal, therefore a PBT-assessment will not be performed.

5.1.5.2 Marine water

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

Despite having $RCR > 1$ conclusion iii) is not drawn for application of flame-retardant back-coating. The reason for this is that, according to information from IAOIA, none of the sites covered by the survey IAOIA performed to collect exposure data from all their customers is located by the sea. However, it has to be pointed out that the coverage of this survey regarding textile backcoating sites was rather low. Therefore, it cannot be ruled out that textile backcoating sites located at the sea having emissions to the marine environment may exist.

5.1.5.3 Marine sediment

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

Despite having $RCR > 1$ conclusion iii) is not drawn for formulation and application of flame-retardant back-coating. The reason for this is that, according to information from IAOIA, none of the sites covered by the survey IAOIA performed to collect exposure data from all their customers is located by the sea. For the formulation of flame-retardant in textiles, the coverage of this survey is high and there is a high probability that for this use area the marine scenario may not be relevant. For application of textile back-coating on the other hand the coverage of the survey is lower and it cannot be ruled out that sites located at the sea having emissions to the marine environment may exist.

5.1.5.4 Secondary poisoning in the marine environment

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios.

5.2 HUMAN HEALTH

5.2.1 Human health (toxicity)

Human populations exposed to diantimony trioxide include workers, consumers and humans exposed via the environment. Indirect exposure via the environment to the antimony ion may also occur as diantimony trioxide is dissolved to trivalent antimony which is further oxidised to pentavalent antimony in the environment. For exposure assessment, measured data, analogues data, calculations and modelling have been used.

The endpoints of concern are: skin irritation, local pulmonary toxicity and carcinogenicity.

Repeated inhalation exposure to diantimony trioxide gives local toxic effects in the lung and a NOAEC of 0.51 mg/m³ is derived from a 12 month inhalation exposure study in rat, supported by observations of acute pneumonia in a 19 days inhalation developmental toxicity study. No systemic toxicity was observed after repeated exposure.

Diantimony trioxide is considered to be a carcinogenic substance and is classified for carcinogenicity. Although the mechanism for pulmonary tumour formation is still unclear it may be assumed that particle deposition followed by macrophage infiltration, pulmonary inflammation and impaired clearance are pivotal initial steps in the process. Consequently, diantimony trioxide can be regarded as a threshold carcinogen and as a starting point for a quantitative risk characterisation the NOAEC of 0.51 mg/m³ derived for local repeated dose toxicity is also used for carcinogenicity.

5.2.1.1 Workers

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to skin irritation for all scenarios to indicate the need for classification. Once classified, conclusion (iii) will be changed to conclusion (ii).

Conclusion (iii) also applies to repeated dose toxicity (local pulmonary toxicity after inhalation) and carcinogenicity (pulmonary carcinogenicity) for the following scenarios:

- Production of diantimony trioxide: Conversion, Refuming and Final handling with and without RPE
- Use as a catalyst in production of PET: Powder handling
- Use as flame-retardant in production of plastics: Raw material handling
- Use as flame-retardant in treated textiles: Formulation
- Use in pigments, paints, coatings and ceramics: Loading and mixing
- Use as flame-retardant in production of rubber: Formulation and Processing.

5.2.1.2 Consumers

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios

5.2.1.3 Humans exposed via the environment

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to all scenarios

5.2.1.4 Combined exposure

The most important sources of human exposure to diantimony trioxide are probably identified. Additions of individual scenarios are not considered to change any of the conclusions, and no calculation on combined exposure has therefore been performed.

Conclusion (iii) There is a need for limiting the risks; risk reduction measures which are already being applied shall be taken into account.

Conclusion (iii) applies to workers (see workers above).

5.2.2 Human health (risks from physico-chemical properties)

Conclusion (ii) There is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already.

Conclusion (ii) applies to flammability and explosive and oxidising properties. These properties are not considered to form a hazard; hence further risk characterisation has not been undertaken. In addition, there is no need for further information and/or testing with regard to physico-chemical properties.

GLOSSARY

Standard term / Abbreviation	Explanation/Remarks and Alternative Abbreviation(s)
<i>Ann.</i>	Annex
AF	assessment factor
BCF	bioconcentration factor
bw	body weight / <i>Bw, b.w.</i>
°C	degrees Celsius (centigrade)
CAS	Chemical Abstract System
CEC	Commission of the European Communities
CEN	European Committee for Normalisation
CEPE	European Council of the Paint, Printing Ink and Artists' Colours Industry
d	day(s)
d.wt	dry weight / dw
DG	Directorate General
DT ₅₀	period required for 50 percent dissipation (define method of estimation)
DT _{50lab}	period required for 50 percent dissipation under laboratory conditions (define method of estimation)
DT ₉₀	period required for 90 percent dissipation (define method of estimation)
DT _{90field}	period required for 90 percent dissipation under field conditions (define method of estimation)
EC	European Communities
EC	European Commission
EC ₅₀	median effective concentration
EEC	European Economic Community
EINECS	European Inventory of Existing Commercial Chemical Substances
EU	European Union
EUSES	European Union System for the Evaluation of Substances
f _{oc}	Fraction of organic carbon
G	gram(s)

PNEC(s)	Predicted No Effect Concentration(s)
PNEC _{water}	Predicted No Effect Concentration in Water
(Q)SAR	Quantitative Structure Activity Relationship
STP	Sewage Treatment Plant
TGD	Technical Guidance Document ²
UV	Ultraviolet Region of Spectrum
UVCB	Unknown or Variable composition, Complex reaction products or Biological material
v/v	volume per volume ratio
w/w	weight per weight ratio
w	gram weight
GLP	Good Laboratory Practice
h	hour(s)
ha	Hectares / <i>h</i>
HPLC	High Pressure Liquid Chromatography
IARC	International Agency for Research on Cancer
C ₅₀	median immobilisation concentration or median inhibitory concentration 1 / <i>explained by a footnote if necessary</i>
ISO	International Standards Organisation
IUPAC	International Union for Pure Applied Chemistry
kg	kilogram(s)
kPa	kilo Pascals
K _{oc}	organic carbon adsorption coefficient
K _{ow}	octanol-water partition coefficient
K _p	Solids water partition coefficient
l	litre(s)
log	logarithm to the basis 10
L(E)C ₅₀	Lethal Concentration, Median
LEV	Local Exhaust Ventilation
m	Meter
µg	microgram(s)

² Commission of the European Communities, 1996. Technical Guidance Documents in Support of the Commission Directive 93/67/EEC on risk assessment for new substances and the Commission Regulation (EC) No 1488/94 on risk assessment for existing substances. Commission of the European Communities, Brussels, Belgium. ISBN 92-827-801[1234]

mg	milligram(s)
MAC	Maximum Accessibility Concentration
MOS	Margins Of Safety
NOAEL	No Observed Adverse Effect Level
NOEC	No Observed Effect Concentration
NOEL	No Observed Effect Level
OEL	Occupational Exposure Limit
OECD	Organisation for Economic Co-operation and Development
OJ	Official Journal
pH	potential hydrogen <i>-logarithm</i> (to the base 10) of the hydrogen ion concentration {H ⁺ }
pKa	<i>-logarithm</i> (to the base 10) of the acid dissociation constant
pKb	<i>-logarithm</i> (to the base 10) of the base dissociation constant
Pa	Pascal unit(s)
PEC	Predicted Environmental Concentration
STP	Sewage Treatment Plant
WWTP	Waste Water Treatment Plant