CHEMICAL SAFETY REPORT

Substance Name: Diniobium Pentaoxide

EC Number: 215-213-6

CAS Number: 1313-96-8

Registrant's Identity: XXX

Table of Contents

Tables:

Part A

1. SUMMARY OF RISK MANAGEMENT MEASURES

As a result of the hazard assessment and PBT/vPvB assessment it is found that **Diniobium Pentaoxide (CAS# 1313-96-8)** does not meet the criteria for classification as hazardous (according to Directives 67/548/EEC and 1272/2008/EC) nor is it considered to be a PBT/vPvB. An exposure assessment and the subsequent step of risk characterization are not required. As a consequence there is no need to recommend specific operational conditions (OCs) and risk management measures (RMMs) for the manufacture and identified uses of the substance to demonstrate control of risk.

Nevertheless, general information on handling and storage of the substance as well as on exposure controls and personal protection are given below.

2. DECLARATION THAT RISK MANAGEMENT MEASURES ARE IMPLEMENTED

General information on handling and storage of the substance as well as on exposure controls and personal protection are given in the chemical safety report for the substance and is implemented at the site of use.

3. DECLARATION THAT RISK MANAGEMENT MEASURES ARE COMMUNICATED

The registrant declares that general information on handling and storage of the substance as well as on exposure controls and personal protection, including the risk management measures are communicated to distributors and direct customers by means of the extended Safety Data Sheet and other appropriate literature.

Part B

1. IDENTITY OF THE SUBSTANCE AND PHYSICAL AND CHEMICAL PROPERTIES

1.1. Name and other identifiers of the substance

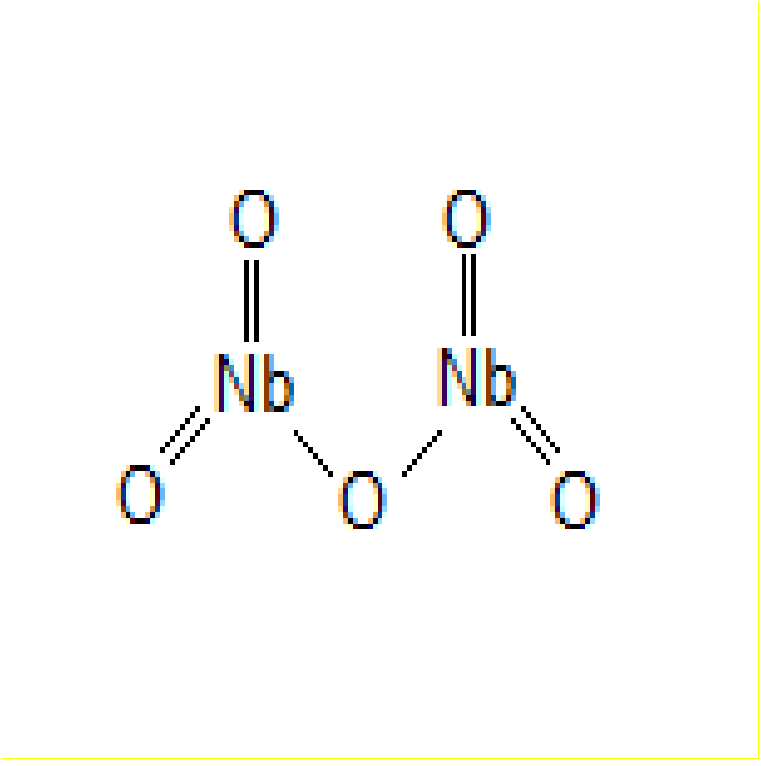
The substance **Diniobium Pentaoxide** is a mono constituent substance (origin: inorganic) having the following characteristics and physical–chemical properties (see the IUCLID dataset for further details).

The following public name is used: Niobium Pentoxide.

Table 1. Substance identity

EC number:	215-213-6
EC name:	diniobium pentaoxide
CAS number (EC inventory):	1313-96-8
CAS name:	Niobium(V) oxide
IUPAC name:	µ-oxido[tetrakis(oxido)]diniobium
Molecular formula:	Nb2O5
Molecular weight range:	265.8

Structural formula:



1.2. Composition of the substance

Overall information on composition:

Composition
Crystalline - Monoclinic Diniobium Pentaoxide_Boundary (boundary composition of the substance)
Crystalline - Monoclinic Diniobium Pentaoxide_LE (legal entity composition of the substance)
Crystalline - Orthorhombic Diniobium Pentaoxide_Boundary (boundary composition of the substance)
Crystalline - Orthorhombic Diniobium Pentaoxide_LE (legal entity composition of the substance)
Amorphous - Diniobium Pentaoxide_Boundary (boundary composition of the substance)
Amorphous - Diniobium Pentaoxide_LE (legal entity composition of the substance)

Name: Crystalline - Monoclinic Diniobium Pentaoxide_LE

State/form: solid: particulate/powder
Degree of purity: XXX % (w/w)
Description:

Table 4. Constituents (Crystalline - Monoclinic Diniobium Pentaoxide_LE)

Constituent	Typical concentration	Concentration range	Remarks
Diniobium Pentaoxide EC no.: 215-213-6			

Table 5. Impurities (Crystalline - Monoclinic Diniobium Pentaoxide_LE)

Constituent	Typical concentration	Concentration range	Remarks
tantalum EC no.: 231-135-5			
potassium EC no.: 231-119-8			
titanium EC no.: 231-142-3			
iron EC no.: 231-096-4			
silicon EC no.: 231-130-8			
nickel EC no.: 231-111-4			
tin EC no.: 231-141-8			
lead EC no.: 231-100-4			
phosphorus EC no.: 231-768-7			

Name: Crystalline - Orthorhombic Diniobium Pentaoxide_LE

State/form: solid: particulate/powder
Degree of purity: XXX % (w/w)
Description:

Table 8. Constituents (Crystalline - Orthorhombic Diniobium Pentaoxide_LE)

Constituent	Typical concentration	Concentration range	Remarks
Diniobium Pentaoxide EC no.: 215-213-6			

Table 9. Impurities (Crystalline - Orthorhombic Diniobium Pentaoxide_LE)

Constituent	Typical concentration	Concentration range	Remarks
tantalum EC no.: 231-135-5			
titanium EC no.: 231-142-3			
iron EC no.: 231-096-4			
sodium EC no.: 231-132-9			

Name: Amorphous - Diniobium Pentaoxide_LE

State/form: solid: particulate/powder
Degree of purity: XXX % (w/w)
Description:

Table 12. Constituents (Amorphous - Diniobium Pentaoxide_LE)

Constituent	Typical concentration	Concentration range	Remarks
Diniobium Pentaoxide EC no.: 215-213-6			

Table 13. Impurities (Amorphous - Diniobium Pentaoxide_LE)

Constituent	Typical concentration	Concentration range	Remarks
tantalum EC no.: 231-135-5			
titanium EC no.: 231-142-3			
iron EC no.: 231-096-4			
potassium EC no.: 231-119-8			
silicon EC no.: 231-130-8			
sodium EC no.: 231-132-9			
phosphorus EC no.: 231-768-7			
chlorine EC no.:			

1.3. Physicochemical properties

Table 14. Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state	The diniobium pentaoxide is a white powder.	**Value used for CSA:** solid at 20°C and 101.3 kPa The substance is a white/pale yellow powder.
Melting / freezing point	1512°C	**Value used for CSA:** 1512 °C at 101.3 kPa
Boiling point	not applicable	Substance is a solid which melts above 300°C.
Relative density	4,6 g/cm³ at 20 °C	
Granulometry	Substance marketed in powder form Range: 0.0400 µm to 2000 µm Mean value: 41.45 µm	Particle distribution test performed by laser diffraction according to OECD 110.
Vapour pressure	not applicable	The melting point is above 300°C.
Partition coefficient n-octanol/water (log Pow value)	not applicable	The substance is inorganic.
Water solubility	< 0,5 µg/L at 20 °C, pH = 8	**Value used for CSA:** 0.5 µg/L at 20 °C The solubility of Diniobium Pentaoxide was found to be clearly below 0.5 µg/L for the 7-day short term test as well as for the 28-day long term test in the given test medium at pH 8.
Surface tension	not applicable	The water solubility is below 1 mg/L at 20°C.
Flash point	not applicable	The substance is inorganic.
Autoflammability / self-ignition temperature	Substance shows no auto flammability.	The test substance does not undergo spontaneous combustion. Diniobium Pentaoxide is classified as not undergoing spontaneous combustion when tested according to EC Test Procedure A 16.
Flammability	not flammable	**Value used for CSA:** non flammable Non flammable solid. Based on chemical structure pyrophoric properties and flammability in contact with water are not to be expected.
Explosive properties	non explosive	There are no chemical groups associated with explosive properties present in the molecule.
Oxidising properties	no oxidising properties	**Value used for CSA:** Oxidising: no Diniobium Pentaoxideis not considered to be an oxidizing substance because there was no reaction zone which travelled along the pile for each tested mixture ofDiniobium Pentaoxideand cellulose.
Stability in organic solvents and identity of relevant degradation products	not applicable	The substance is inorganic.

Property	Description of key information	Value used for CSA / Discussion
Dissociation constant	not applicable	The substance is not soluble in water.
Viscosity	not applicable	The substance is a solid.

Data waiving

Information requirement: Boiling point

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the boiling point does not need to be determined as the melting point is above 300°C.

Information requirement: Vapour pressure

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the vapour pressure does not need to be determined as the melting point is above 300°C.

Information requirement: Partition coefficient n-octanol/water (log value)

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the partition coefficient does not need to be determined as the substance is inorganic.

Information requirement: Surface tension

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the surface activity does not need to be determined as the water solubility is below 1 mg/L at 20°C.

Information requirement: Flash point

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the flash point does not need to be determined as the substance is inorganic.

Information requirement: Flammability

Reason: study scientifically unjustified

Justification: In accordance with Regulation (EC) No 1907/2006, Annex XI, Section 1, the study does not need to be conducted as based on experience in handling and use and the chemical structure pyrophoric properties are not to be expected.

Information requirement: Flammability

Reason: study scientifically unjustified

Justification: In accordance with Regulation (EC) No 1907/2006, Annex XI, Section 1, the study does not need to be conducted as based on experience in handling and use and thechemical structure flammability on contact with water is not to be expected.

Information requirement: Explosive properties

Reason: other justification

Justification: In accordance with column 2 of REACH Annex VII, the explosiveness of the substance does not need to be tested, because there are no chemical groups associated with explosive properties in the molecule

Information requirement: Stability in organic solvents and identity of relevant degradation products

Reason: other justification

Justification: In accordance with Regulation (EC) No 1907/2006, Column 2 of Annex IX, Section 7.15, the study does not need to be conducted as the substance is inorganic.

Information requirement: Dissociation constant

Reason: study technically not feasible

Justification: In accordance with Regulation (EC) No 1907/2006, Annex XI, Section 2, the study does not need to be performed as the substance is not soluble in water.

Information requirement: Viscosity

Reason: study scientifically unjustified

Justification: In accordance with Regulation (EC) No 1907/2006, Annex XI, Section 1, the study does not need to be conducted as the test substance is a solid.

2. MANUFACTURE AND USES

Table 15. Quantities (in tonnes/year)

Year	Tonnages (tonnes per year)

2.1. Manufacture

2.2. Identified uses

3. CLASSIFICATION AND LABELLING

3.1. Classification and labelling according to CLP / GHS

Name: Diniobium Pentaoxide

Implementation: EU

State/form of the substance: powder

Related composition:
Amorphous - Diniobium Pentaoxide_LE; Crystalline - Monoclinic Diniobium Pentaoxide_LE; Crystalline - Orthorhombic Diniobium Pentaoxide_LE

Remarks: The classification and labelling are the same for the anhydrous and hydrated form.

Classification

The substance is not classified.

Table 26. Classification and labelling according to CLP / GHS for physicochemical properties

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Explosives:			conclusive but not sufficient for classification	6.1
Flammable gases:			conclusive but not sufficient for classification	6.2
Flammable aerosols:			conclusive but not sufficient for classification	6.2
Oxidising gases:			conclusive but not sufficient for	6.3

			classification	
Gases under pressure:			conclusive but not sufficient for classification	
Flammable liquids:			conclusive but not sufficient for classification	6.2
Flammable solids:			conclusive but not sufficient for classification	6.2
Self-reactive substances and mixtures:			conclusive but not sufficient for classification	
Pyrophoric liquids:			conclusive but not sufficient for classification	6.2
Pyrophoric solids:			conclusive but not sufficient for classification	6.2
Self-heating substances and mixtures:			conclusive but not sufficient for classification	
Substances and mixtures which in contact with water emit flammable gases:			conclusive but not sufficient for classification	6.2
Oxidising liquids:			conclusive but not sufficient for classification	6.3
Oxidising solids:			conclusive but not sufficient for classification	6.3
Organic peroxides:			conclusive but not sufficient for classification	
Corrosive to metals:			conclusive but not sufficient for classification	

*) Justification for (non) classification can be found in the CSR section indicated

Table 17. Classification and labelling according to CLP / GHS for health hazards

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Acute toxicity - oral:			conclusive but not sufficient for classification	5.2.3
Acute toxicity - dermal:			conclusive but not sufficient for classification	5.2.3
Acute toxicity -			conclusive but	5.2.3

inhalation:			not sufficient for classification	
Skin corrosion / irritation:			conclusive but not sufficient for classification	5.3.4 and 5.4.3
Serious damage / eye irritation:			conclusive but not sufficient for classification	5.3.4
Respiration sensitization:			conclusive but not sufficient for classification	5.5.3
Skin sensitation:			conclusive but not sufficient for classification	5.5.3
Aspiration hazard:			conclusive but not sufficient for classification	5.2.3
Reproductive Toxicity:			conclusive but not sufficient for classification	5.9.3
Reproductive Toxicity: Effects on or via lactation:			conclusive but not sufficient for classification	5.9.3
Germ cell mutagenicity:			conclusive but not sufficient for classification	5.7.3
Carcinogenicity:			conclusive but not sufficient for classification	5.8.3
Specific target organ toxicity - single:			conclusive but not sufficient for classification	5.2.3 and 5.3.4
Specific target organ toxicity - repeated:			conclusive but not sufficient for classification	5.6.3

*) Justification for (non) classification can be found in the CSR section indicated

Table 18. Classification and labelling according to CLP / GHS for environmental hazards

Endpoint	Hazard category	Hazard statement	Reason for no classification	CSR section*)
Hazards to the aquatic environment (acute/short-term):			conclusive but not sufficient for classification	7.6
Hazards to the aquatic environment (long-term):			conclusive but not sufficient for classification	7.6
Hazardous to the ozone layer:			conclusive but not sufficient for classification	7.6

*) Justification for (non) classification can be found in the CSR section indicated

Labelling

Signal word: No signal word

3.2. Classification and labelling according to DSD / DPD

3.2.1. Classification and labelling in Annex I of Directive 67/548/EEC

No relevant information available

3.2.2. Self classification(s)

Chemical name: Diniobium Pentaoxide

Related composition: Anhydrous form of Diniobium Pentaoxide

Remarks: The classification and labelling are the same for the anhydrous and hydrated form.

Table 19. Self classification according to Directive 67/548/EEC criteria

Endpoints	Classification	Reason for no classification	CSR section*)
Explosiveness		conclusive but not sufficient for classification	6.1
Oxidising properties		conclusive but not sufficient for classification	6.3
Flammability		conclusive but not sufficient for classification	6.2
Thermal stability		conclusive but not sufficient for classification	
Acute toxicity		conclusive but not sufficient for classification	5.2.3
Acute toxicity- irreversible damage after single exposure		conclusive but not sufficient for classification	5.2.3
Repeated dose toxicity		conclusive but not sufficient for classification	5.6.3
Irritation / Corrosion		conclusive but not sufficient for classification	5.3.4 and 5.4.3
Sensitisation		conclusive but not sufficient for classification	5.5.3
Carcinogenicity		conclusive but not sufficient for	5.8.3

Endpoints	Classification	Reason for no classification	CSR section*)
		classification	
Mutagenicity - Genetic Toxicity		conclusive but not sufficient for classification	5.7.3
Toxicity to reproduction-fertility		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction-development		conclusive but not sufficient for classification	5.9.3
Toxicity to reproduction - breastfed babies		conclusive but not sufficient for classification	5.9.3
Environment		conclusive but not sufficient for classification	7.6

*) Justification for (non) classification can be found in the CSR section indicated

3.2.3. Other classification(s)

The substance is not classified.

4. ENVIRONMENTAL FATE PROPERTIES

General discussion of environmental fate and pathways:

The defining characteristic of the inorganic diniobium pentaoxide is its insolubility in water. Diniobium pentaoxide remains stable in water and does not hydrolyse. It cannot be adsorbed and metabolised by living beings but would be excreted and thus does not bioaccumulate. Based on its intended uses (manufacture of superalloys, as a catalyst or to produce lenses) the substance is not expected to enter into the environment by any pathway. The oxide is not volatile and does not enter into the atmosphere. Biodegradation cannot be assessed since diniobium pentaoxide is inorganic. The substance is judged to be an inert, harmless substance which according to its uses does not enter the environment. Consequently, environmental effects have never been reported.

4.1. Degradation

4.1.1. Abiotic degradation

4.1.1.1. Hydrolysis

Data waiving

Information requirement: Hydrolysis

Reason: other justification

Justification: According to the Regulation (EC) No 1907/2006 (REACH) Annex VIII 9.2.2.1 column 2 studies on hydrolysis as a function of pH do not have to be conducted for substances highly insoluble in water. The water solubility of the test substance is with < 0.5 µg/L (highly insoluble).

Discussion

Substance is highly insoluble in water.

The following information is taken into account for any hazard / risk / persistency assessment:

Hydrolysis is not expected to occur since diniobium pentaoxide is insoluble in water.

4.1.1.2. Phototransformation/photolysis

4.1.1.2.1. Phototransformation in air

No relevant information available

4.1.1.2.2. Phototransformation in water

No relevant information available

4.1.1.2.3. Phototransformation in soil

No relevant information available

4.1.2. Biodegradation

4.1.2.1. Biodegradation in water

4.1.2.1.1. Screening tests

Data waiving

Information requirement: Biodegradation in water: screening test

Reason: other justification

Justification: In accordance with column 2 of the Annex VII (Regulation EC 1907/2006) performance of a biodegradation test is scientifically unjustified as the substance is inorganic.

4.1.2.1.2. Simulation tests (water and sediments)

Data waiving

Information requirement: Simulation testing for biodegradation in water and sediment

Reason: other justification

Justification: In accordance with column 2 of the Annex VII (Regulation EC 1907/2006) performance of a biodegradation test is scientifically unjustified as the substance is inorganic.

4.1.2.1.3. Summary and discussion of biodegradation in water and sediment

Discussion (screening testing)

Biodegradation cannot be assessed since diniobium pentaoxide is inorganic.

The following information is taken into account for any hazard / risk / persistency assessment:

Biodegradation cannot be assessed since diniobium pentaoxide is inorganic.

Discussion (simulation testing)

Biodegradation cannot be assessed since diniobium pentaoxide is inorganic.

The following information is taken into account for any hazard / risk / persistency assessment:

Diniobium pentaoxide is inorganic.

4.1.2.2. Biodegradation in soil

Data waiving

Information requirement: Soil simulation testing

Reason: other justification

Justification: In accordance with column 2 of the Annex VII (Regulation EC 1907/2006) performance of a biodegradation test is scientifically unjustified as the substance is inorganic.

Discussion

Biodegradation cannot be assessed since diniobium pentaoxide is inorganic.

The following information is taken into account for any hazard / risk / persistency assessment:

Diniobium pentaoxide is inorganic.

4.1.3. Summary and discussion of degradation

Abiotic degradation

No data is available and required under REACH on phototransformation of diniobium pentaoxide in air, water and soil. Hydrolysis does not need to be examined and is not expected to occur since diniobium pentaoxide is insoluble in water.

Biotic degradation

Biodegradation cannot be assessed since diniobium pentaoxide is inorganic.

4.2. Environmental distribution

4.2.1. Adsorption/desorption

Data waiving

Information requirement: Adsorption/desorption

Reason: study technically not feasible

Justification: The adsorption-desorption study according to OECD guideline 106 can not be performed with diniobium pentaoxide, due to following: 1) The oxide is highly insoluble in water. The water solubility of diniobium pentaoxide is < 0.5 µg/L (see study record water solubility). 2. Limit of quantification (LOQ) was determined to 0.5 µg niobium/L water (see study record water solubility). Thus, the concentration in the aqueous phase cannot be measured analytically with sufficient accuracy. According to OECD guideline 106 the concentration of the stock solution should be three orders of magnitude higher than the detection limit of the analytical method used to ensure accurate measurements.

Discussion

The adsorption-desorption study according to OECD TG 106 is technically not feasible. Due the insolubility of diniobium pentaoxide in water analytical measurements cannot be performed with sufficient accuracy.

The following information is taken into account for any environmental exposure assessment:

The adsorption-desorption behaviour cannot be tested due the insolubility of diniobium pentaoxide.

4.2.2. Volatilisation

No relevant information available

4.2.3. Distribution modelling

No relevant information available

4.2.4. Summary and discussion of environmental distribution

Experimental testing of adsorption/desorption behaviour of diniobium pentaoxide is technically not feasible since the test substance concentration in aqueous phase cannot be measured with sufficient accuracy due to insolubility in water. It is used mainly in the production of superalloys. Based on its uses a direct and indirect entry into the environment is very unlikely to occur. Diniobium pentaoxide is insoluble in water. It is considered to be harmless and not to accumulate in biota. Under environmental conditions diniobium pentaoxide is present as solid (melting point 1512 °C) and thus the substance is expected not to be volatile and not to enter into the atmosphere.

4.3. Bioaccumulation

Niobium is insoluble in water and not bioavailable to aquatic species. The substance cannot be absorbed via skin or gastrointestinal tract. Thus, there is no potential for bioaccumulation of niobium.

4.3.1. Aquatic bioaccumulation

Data waiving

Information requirement: Aquatic bioaccumulation

Reason: other justification

Justification: The defining characteristic of the inorganic diniobium pentaoxide is its insolubility in water. The Diniobium pentaoxide remains stable in water and does not hydrolyse. It cannot be adsorbed and

metabolised by living beings but would be excreted and thus does not bioaccumulate. Based on its intended uses (manufacture of superalloys, as a catalyst or to produce lenses) the substance is not expected to enter into the environment by any pathway. The substance is judged to be an inert, harmless substance which according to its uses does not enter the environment. Consequently, environmental effects have never been reported. Additionally, a bioaccumulation test is technically hardly feasible due to the highly insolubility of the substance and is not necessary due to the non-hazardous character of the substance.

4.3.2. Terrestrial bioaccumulation

No relevant information available

4.3.3. Summary and discussion of bioaccumulation

Aquatic bioaccumulation

The defining characteristic of the inorganic diniobium pentaoxide is its insolubility in water. The Diniobium pentaoxide remains stable in water and does not hydrolyse. It cannot be adsorbed and metabolised by living beings but would be excreted and thus does not bioaccumulate. Based on its intended uses (manufacture of superalloys, as a catalyst or to produce lenses) the substance is not expected to enter into the environment by any pathway. The substance is judged to be an inert, harmless substance which according to its uses does not enter the environment. Consequently, environmental effects have never been reported. Additionally, a bioaccumulation test is technically hardly feasible due to the highly insolubility of the substance and is not necessary due to the non-hazardous character of the substance.

The following information is taken into account for any hazard / risk / bioaccumulation assessment:

Niobium is insoluble in water and not bioavailable to aquatic species. The substance cannot be absorbed via skin or gastrointestinal tract. Thus, there is no potential for bioaccumulation of niobium.

4.4. Secondary poisoning

Interpretation of the available data with regard to the potential to bio-accumulate in the food chain:

Diniobium pentaoxide is harmless substance which is not metabolized. It is considered not to be bioaccumulative and thus not to be enriched in the food chain. Any adverse effect of Diniobium pentaoxide to species on higher trophic levels can be excluded.

5. HUMAN HEALTH HAZARD ASSESSMENT

5.1. Toxicokinetics (absorption, metabolism, distribution and elimination)

5.1.1. Non-human information

The results of studies on absorption, metabolism, distribution and elimination are summarised in the following table:

Table 20. Studies on absorption, metabolism, distribution and elimination

Method	Results	Remarks	Reference
Assessment of toxicological behaviour	Main ADME results: absorption: Nb2O5 is extremely inert and can only be dissolved under strongly oxidising conditions. Under physiological conditions, Nb oxide cannot be absorbed via skin or gastrointestinal tract. distribution: After oral administration, Nb pentoxide will remain in the GI tract until it is eventually excreted via faeces. metabolism: As an inorganic substance without any bioavailability, Nb2O5 cannot be metabolised. excretion: Diniobium Pentaoxide will not be absorbed via the oral route and ingested Nb2O5 will be eliminated via faeces without prior absorption. Evaluation of results: no bioaccumulation potential based on study results	1 (reliable without restriction) key study expert judgement **Test material (EC name): diniobium pentaoxide**	

5.1.2. Human information

No relevant information available

5.1.3. Summary and discussion of toxicokinetics

5.2. Acute toxicity

5.2.1. Non-human information

5.2.1.1. Acute toxicity: oral

The results of studies on acute toxicity after oral administration are summarised in the following table:

Table 21. Studies on acute toxicity after oral administration

Method	Results	Remarks	Reference
rat (Wistar) female oral: gavage	LD50: 5000 mg/kg bw (female)	1 (reliable without restriction) key study	Takawale, Dr. P. (2009)

Method	Results	Remarks	Reference
OECD Guideline 423 (Acute Oral toxicity - Acute Toxic Class Method)		experimental result **Test material (EC name): diniobium pentaoxide**	

5.2.1.2. Acute toxicity: inhalation

The results of studies on acute toxicity after inhalation exposure are summarised in the following table:

Table 22. Studies on acute toxicity after inhalation exposure

Method	Results	Remarks	Reference
rat (Sprague-Dawley) male/female inhalation: aerosol (nose only) OECD Guideline 403 (Acute Inhalation Toxicity)	LC50 (4 h): 5450 mg/m³ air (male/female)	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	Wilcox, S. (2001)

5.2.1.3. Acute toxicity: dermal

The results of studies on acute toxicity after dermal administration are summarised in the following table:

Table 23. Studies on acute toxicity after dermal administration

Method	Results	Remarks	Reference
rat (Wistar) male/female Coverage: occlusive Vehicle: water OECD Guideline 402 (Acute Dermal Toxicity)	LD50: > 2000 mg/kg bw (male/female)	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	Leoni, A.L. (2009)

5.2.1.4. Acute toxicity: other routes

No relevant information available

5.2.2. Human information

No relevant information available

5.2.3. Summary and discussion of acute toxicity

Acute dermal toxicity was tested in rats. The LD50 was greater than 2000 mg/kg bw. Due to the chemical properties of diniobium pentaoxide, it can be predicted that oral bioavailability of niobium metal is nil.

The oral LD50 is thus estimated to be greater than 5000 mg/kg bw and the inhalation LC50 is estimated to be greater than 5000 mg/m³ air.

Value used for CSA:

Acute oral toxicity: (LD50: 5000 mg/kg bw)

Acute dermal toxicity: (LD50: 2000 mg/kg bw)

Acute inhalation toxicity: (LC50: 5450 mg/m³)

Justification for classification or non classification

Dermal and oral LD50 values are greater than 2000 and 5000 mg/kg bw, respectively. Inhalation LC50 is greater than 5000 mg/m³ air. No classification for acute lethal effects is necessary.

5.3. Irritation

5.3.1. Skin

5.3.1.1. Non-human information

The results of studies on skin irritation are summarised in the following table:

Table 24. Studies on skin irritation

Method	Results	Remarks	Reference
rabbit (New Zealand White) Coverage: semiocclusive (clipped with electrical clipper) Vehicle: water OECD Guideline 404 (Acute Dermal Irritation / Corrosion)	not irritating Erythema score: 0 of max. 4 (Time point: 24/48/72 h) Reversibility: not applicable Edema score: 0 of max. 4 (Time point: 24/48/72 h) Reversibility: not applicable	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	Blanchard, E. L. (2000)
in vitro study human (not applicable) Coverage: semiocclusive (The EpiDerm TM tissues provided as kits) Vehicle: water OECD 431 (2004)	not corrosive tissue viability: 91 (mean) (Time point: 3 min) (value given as % of negative control) tissue viability: 66 (mean) (Time point: 60 min) (value given as % of negative control)	1 (reliable without restriction) supporting study experimental result **Test material (EC name): diniobium pentaoxide**	Stuhlmann, D. (2009)

Data waiving

Information requirement: Skin Irritation

Reason: study scientifically not necessary / other information available

Justification: an in vitro skin irritation study does not need to be conducted because adequate data from an in vivo skin irritation study are available [study scientifically not necessary / other information available]

5.3.1.2. Human information

No relevant information available

5.3.2. Eye

5.3.2.1. Non-human information

The results of studies on eye irritation are summarised in the following table:

Table 25. Studies on eye irritation

Method	Results	Remarks	Reference
rabbit (New Zealand White) Vehicle: unchanged (no vehicle) OECD Guideline 405 (Acute Eye Irritation / Corrosion)	not irritating Cornea score: (mean) 0 of max. 4 (Time point: 24/48/72 h) not applicableIris score: 0 of max. 2 (mean) (Time point: 24/48/72 h) Conjunctivae score: 0.3 of max. 3 (mean (mean of three animals and of three timepoints)) (Time point: 24/48/72 h) (fully reversible) Chemosis score: 0 of max. 4 (mean) (Time point: 24/48/72 h)	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	Blanchard, E. L. (2001)
in vitro study hen (White Leghorn) Vehicle: not applicable Chorioallantoic membrane (CAM) assay to screen the eye irritation potential of the test substance. Effects of the test item on the Choriallantoic membrane of 10 day bred chicken eggs are assessed within a treatment period of 5 minutes for the following effects: haemorrhage, lysis and coagulation. An irritation score is calculated and the test item is classified with this score.	not irritating	2 (reliable with restrictions) supporting study experimental result **Test material (EC name): diniobium pentaoxide**	Albrecht, A. (2009)

Data waiving

Information requirement: Eye Irritation

Reason: study scientifically not necessary / other information available

Justification: an in vitro eye irritation study does not need to be conducted because adequate data from an in vivo eye irritation study are available [study scientifically not necessary / other information available]

5.3.2.2. Human information

No relevant information available

5.3.3. Respiratory tract

5.3.3.1. Non-human information

5.3.3.2. Human information

No relevant information available

5.3.4. Summary and discussion of irritation

Diniobium pentaoxide was not corrosive to a human skin model in vitro. Subsequent in-vivo testing in rabbits demonstrated that the substance is also not irritating to skin. Diniobium pentaoxide was not irritating in an in-vitro HETCAM assay and in an in-vivo test in the eyes of rabbits.

The following information is taken into account for any hazard / risk assessment:

Diniobium pentaoxide is not irritating to skin or eyes.

Value used for CSA:

Skin irritation / corrosion: No adverse effect observed (not irritating)

Eye irritation / corrosion: No adverse effect observed (not irritating)

Justification for classification or non classification

The criteria for classification as skin or eye irritant of CLP or DSD are not fulfilled.

5.4. Corrosivity

5.4.1. Non-human information

5.4.2. Human information

5.4.3. Summary and discussion of corrosion

5.5. Sensitisation

5.5.1. Skin

5.5.1.1. Non-human information

The results of studies on skin sensitisation are summarised in the following table:

Table 26. Studies on skin sensitisation

Method	Results	Remarks	Reference
mouse (CBA) female Local lymph node assay OECD Guideline 429 (Skin Sensitisation: Local Lymph Node Assay)	not sensitising Stimulation index: The stimulation index at an extract concentration of 12.5% was 0.7 The stimulation index at an extract concentration of 25% was 1.3 The stimulation index at an extract concentration of 50% was 0.9	1 (reliable without restriction) key study experimental result **Test material**	Stelter, D. (2009)

Method	Results	Remarks	Reference
		(EC name): diniobium pentaoxide	

5.5.1.2. Human information

No relevant information available

5.5.2. Respiratory system

5.5.2.1. Non-human information

No relevant information available

5.5.2.2. Human information

No relevant information available

5.5.3. Summary and discussion of sensitisation

Skin sensitisation

Diniobium pentaoxide did not stimulate lymphocyte proliferation in a murine LLNA.

The following information is taken into account for any hazard / risk assessment:

Diniobium Pentaoxide was negative in the murine LLNA.

Value used for CSA: No adverse effect observed (not sensitising)

Justification for classification or non classification

Undiluted diniobium pentaoxide caused a maximum SI of 1.3 in the murine LLNA. No classification as skin sensitizer is warranted.

5.6. Repeated dose toxicity

5.6.1. Non-human information

5.6.1.1. Repeated dose toxicity: oral

The results of studies on repeated dose toxicity after oral administration are summarised in the following table:

Table 27. Studies on repeated dose toxicity after oral administration

Method	Results	Remarks	Reference
rat (Wistar) male/female combined repeated dose and reproduction / developmental screening (oral: gavage) Control: 0 mg/kg bw (nominal in water) LD: 250 mg/kg bw (nominal in water) MD: 500 mg/kg bw (nominal in water)	NOAEL: 1000 mg/kg bw (total dose) (male/female) No effects observed	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	Takawale, P. (2010a)

Method	Results	Remarks	Reference
HD: 1000 mg/kg bw (nominal in water) Vehicle: water Exposure: Males: 28-29 days. Females: maximum 54 days) (7 days per week) OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)			

Data waiving

Information requirement: sub-chronic toxicity study (90 days) (oral)

Reason: other justification

Justification: According to Regulation (EC) No 1907/2006, Annex IX, 8.6.2, column 2, a subchronic toxicity study (90 days) does not need to be conducted if the substance is unreactive, insoluble and not inhalable and there is no evidence of absorption and no evidence of toxicity in a 28-day 'limit test', particularly if such a pattern is coupled with limited human exposure. The physiochemical properties of the substance demonstrate no hazardous potential. Furthermore, the substance has a very low water solubility in buffered solution (< 0.0005 mg/L at 20 °C, at pH 8), being suggestive of very low absorption from the gastrointestinal tract subsequent to oral ingestion. Furthermore, data on the subacute (28-day) oral toxicity (combined repeated dose toxicity and reproduction/developmental screening tests according to OECD 422) conducted with the substance did not indicate any adverse systemic effects and any adverse findings in organs and tissues related to treatment in male and female rats up to the currently applied limit dose. Although the substance contains particles of inhalable size (> 90% with diameter of 69.4 µm), it is not considered to be absorbed in significant amounts, as it does not reach the thoracic or alveolar region due to their particle size higher than 50 and 10 µm, respectively. In addition, inhalable particles with poor water solubility are anticipated to deposit in nasopharyngeal region, were they could be coughed or sneezed out of the body or swallowed (ECHA, 2012). Therefore, under normal use and handling conditions, inhalation exposure and thus availability for respiratory absorption of the substance in the form of dusts is not significant. Although the molecular weight of the substance is suggestive of dermal uptake, the physical state in combination with the very low water solubility of the substance is suggestive of very low absorption through the skin. In addition, the fact that the substance is neither irritating nor sensitising to skin implies that dermal uptake of the substance in humans is considered as very limited (ECHA, 2012).

Therefore, a very low bioavailability in humans is anticipated for the substance after any route of exposure. As the substance is exclusively used at the industrial site, which assumes adequate protection measures for handling, exposure to humans, in general, is considered to be limited.

In summary, based on the physicochemical and toxicological properties, there is sufficient weight of evidence provided leading to the assumption/conclusion that the substance is not toxic after subchronic exposure. Therefore, in accordance with Annex XI, Section 1.2 of Regulation (EC) 1907/2006 further testing on vertebrate animals for that property shall be omitted and further testing not involving vertebrate animals may be omitted. Adequate and reliable documentation is provided in the technical dossier and the chemical safety report.

Reference:

ECHA (2012). Guidance on information requirements and chemical safety assessment, Chapter R.7c: Endpoint specific guidance.

5.6.1.2. Repeated dose toxicity: inhalation

No relevant information available

5.6.1.3. Repeated dose toxicity: dermal

No relevant information available

5.6.1.4. Repeated dose toxicity: other routes

No relevant information available

5.6.2. Human information

No relevant information available

5.6.3. Summary and discussion of repeated dose toxicity

Diniobium pentaoxide is insoluble in water. It is resistant to acids, including nitrohydrochloric acid (aqua regia), HCl, H2SO4, HNO3, and H3PO4 and to many organic and inorganic compounds. Diniobium pentaoxide is attacked by hot concentrated mineral acids, such as HF and HF/HNO3mixtures, but is resistant to fused alkali (Nowak & Ziolek, Chem. Rev. 1999,99, 3603-3624). I. e., diniobium pentaoxide is dissolved only under extremely oxidising conditions that are not compatible with administration to animals.

Due to its insolubility it can be assumed that diniobium pentaoxide even if applied as pure powder will not be absorbed in the stomach and intestinal tract. The negligible bioavailability after oral application allows the prediction that the NOAEL for toxicity after repeated oral exposure will be greater than 1000 mg/kg bw/day. This value was confirmed by the performed study.

This predictability makes repeated dose inhalation toxicity testing unnecessary. A similar rationale forbids the testing via the dermal route: since it is certainly predictable that diniobium pentaoxide as manufacured cannot penetrate the skin, any testing via this route is scientifically unjustified.

The following information is taken into account for any hazard / risk assessment:

Diniobium pentaoxide is not bioavailable. Repeated dose oral: NOAEL 1000mg/kg bw/day. Other routes tests are unnecessary.

Value used for CSA (via oral route - systemic effects):

(NOAEL: 1000 mg/kg bw/day) (rat)

Justification for classification or non classification

Repeated dose oral: NOAEL 1000mg/kg bw/day.

5.7. Mutagenicity

5.7.1. Non-human information

5.7.1.1. In vitro data

The results of in vitro genotoxicity studies are summarised in the following table:

Table 28. In vitro genotoxicity studies

Method	Results	Remarks	Reference
bacterial reverse mutation assay (e.g. Ames test) (gene mutation) S. typhimurium TA 1535, TA 1537, TA 98 and TA 100 (met. act.: with and without) E. coli WP2 uvr A pKM 101 (met. act.: with and without) Test concentrations: 5, 15, 50,	Evaluation of results: negative (with and without metabolic activation) Test results: negative for S. typhimurium TA 1535, TA 1537, TA 98 and TA 100(all strains/cell types tested) ; met. act.: with and without ; cytotoxicity: no ;	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	May, K. (2001)

Method	Results	Remarks	Reference
150, 500, 1500 and 5000ug/plate Positive control substance(s): benzo(a)pyrene (strains TA98, TA1537 and TA100 with S9) Positive control substance(s): 2-nitrofluorene (strain TA98 without S9) Positive control substance(s): sodium azide (strain TA100 and TA1535 without S9) Positive control substance(s): 2-aminoanthracene strains TA1535 and E.coli with S9 Positive control substance(s): 9-aminoacridine (strain TA1537 without S9) Positive control substance(s): AF-2 E.coli without S9 OECD Guideline 471 (Bacterial Reverse Mutation Assay)	vehicle controls valid: yes; negative controls valid: yes; positive controls valid: yes negative for E. coli WP2 uvr A pKM 101(all strains/cell types tested) ; met. act.: with and without ; cytotoxicity: no ; vehicle controls valid: yes; negative controls valid: yes; positive controls valid: yes		
mammalian cell gene mutation assay (gene mutation) mouse lymphoma L5178Y cells (met. act.: with and without) Test concentrations: Experiment I with and without metabolic activation: 39, 78, 156, 312, 625, 1250, 2500 and 5000 µg/mL Experiment II with metabolic activation: 60, 125, 250, 500, 1000, 2000, 3500 and 5000 µg/mL and without metabolic activation: 39, 78, 156, 312, 625, 1250, 2500 and 5000 µg/mL Positive control substance(s): ethylmethanesulphonate (without S9) Positive control substance(s): methylmethanesulfonate (without S9) Positive control substance(s): benzo(a)pyrene (with S9) OECD Guideline 476 (In vitro Mammalian Cell Gene Mutation	Evaluation of results: negative (with and without metabolic activation) Test results: negative for mouse lymphoma L5178Y cells(all strains/cell types tested) ; met. act.: with and without ; cytotoxicity: no ; vehicle controls valid: yes; negative controls valid: not examined; positive controls valid: yes	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	Kraft, M. (2009)

Method	Results	Remarks	Reference
Test)			
in vitro mammalian chromosome aberration test (chromosome aberration) Chinese hamster lung fibroblasts (V79) (met. act.: with and without) Test concentrations: See details given below. Positive control substance(s): ethylmethanesulphonate Positive control substance(s): cyclophosphamide OECD Guideline 473 (In vitro Mammalian Chromosome Aberration Test)	Evaluation of results: negative Test results: negative for Chinese hamster lung fibroblasts (V79)(all strains/cell types tested) ; met. act.: with and without ; cytotoxicity: no ; vehicle controls valid: yes; negative controls valid: yes; positive controls valid: yes	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	Singh, S. (2009)

5.7.1.2. In vivo data

No relevant information available

5.7.2. Human information

No relevant information available

5.7.3. Summary and discussion of mutagenicity

Diniobium pentaoxide was negative, with and without metabolic activation, in an Ames test, in an in-vitro chromosomal aberration assay and in a mouse lymphoma assay.

The following information is taken into account for any hazard / risk assessment:

Diniobium pentaoxide was negative, with and without metabolic activation, in a full battery of in-vitro genotoxicity tests.

Value used for CSA: Genetic toxicity: No adverse effect observed (negative)

Justification for classification or non classification

Diniobium pentaoxide was negative, with and without metabolic activation, in a full battery of in-vitro genotoxicity tests. No classification is warranted for this endpoint.

5.8. Carcinogenicity

5.8.1. Non-human information

5.8.1.1. Carcinogenicity: oral

No relevant information available

5.8.1.2. Carcinogenicity: inhalation

No relevant information available

5.8.1.3. Carcinogenicity: dermal

No relevant information available

5.8.1.4. Carcinogenicity: other routes

No relevant information available

5.8.2. Human information

No relevant information available

5.8.3. Summary and discussion of carcinogenicity

5.9. Toxicity for reproduction

5.9.1. Effects on fertility

5.9.1.1. Non-human information

The results of studies on fertility are summarised in the following table:

Table 29. Studies on fertility

Method	Results	Remarks	Reference
rat (Wistar) male/female combined repeated dose and reproduction / developmental screening oral: gavage Control: 0 mg/kg bw (nominal in water) LD: 250 mg/kg bw (nominal in water) MD: 500 mg/kg bw (nominal in water) HD: 1000 mg/kg bw (nominal in water) Vehicle: water Exposure: Males: 28-29 days. Females: maximum 54 days (7 days per week) OECD Guideline 422 (Combined Repeated Dose Toxicity Study with the Reproduction / Developmental Toxicity Screening Test)	**First parental generation (P0)** NOAEL - reproduction (PO) 1000 mg/kg bw/day) (male/female) based on: No adverse and treatment-related effects were observed **F1 generation** NOAEL - developmental toxicity (PO): 1000 mg/kg bw/day (nominal) (male/female) based on: No adverse and treatment-related effects were observed. **Overall reproductive toxicity** no	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	Takawale, P. (2010b)

Data waiving

Information requirement: Toxicity for reproduction / fertility

Reason: study scientifically unjustified

Justification: According to Regulation (EC) No 1907/2006, Annex IX, 8.7.3, column 1, an extended

one-generation reproductive toxicity study has to be performed in one species, male and female, using the most appropriate route of exposure, if the 28-day or 90-day studies indicate adverse effects on reproductive organs or tissues. Data on the subacute (28-day) oral toxicity (combined repeated dose toxicity and reproduction/developmental screening tests according to OECD 422) conducted with the substance did not indicate any adverse effects on gross and histopathology of reproductive organs or tissues related to treatment in male and female rats. Furthermore, no effects on reproductive performance, including copulation rate and fertility as well as delivery and viability of pups, were observed after treatment. Therefore, on behalf of animal welfare, the conduct of animal studies on the two-generation reproductive toxicity with the substance by any route of exposure is considered scientifically unjustified.

Toxicity to reproduction: other studies

No relevant information available

5.9.1.2. Human information

No relevant information available

5.9.2. Developmental toxicity

5.9.2.1. Non-human information

Data waiving

Information requirement: Developmental toxicity / teratogenicity

Reason: other justification

Justification: According to Regulation (EC) No 1907/2006, Annex IX, 8.7, column 2, a reproduction toxicity study is not indicated if the substance is of low toxicological activity (no evidence of toxicity seen in any of the tests available), it can be proven from toxicokinetic data that no systemic absorption occurs via relevant routes of exposure and there is no or no significant human exposure.

All available data show that the substance is of very low acute toxicity after oral, dermal and inhalation exposure. In addition, data on the repeated dose toxicity (combined repeated dose toxicity and reproduction/developmental screening tests according to OECD 422) of the substance demonstrate no adverse systemic effects after oral exposure and no effects on fertility and intrauterine development in rats up to the highest dose tested.

According to ECHA Guidance on information requirements and chemical safety assessment Chapter R.7c (ECHA, 2012), oral absorption via the gastrointestinal (GI) tract is favourable if the molecular weights is below 500, provided that the substance is sufficiently water soluble (> 1 mg/L), which is especially important for solids that have to dissolve into GI fluids before they can be absorbed. Although the molecular weight of the substance is below 500 g/mol, the very low water solubility of the substance in buffered solution (< 0.0005 mg/L at 20 °C, at pH 8) and the physical state (solid) are suggestive of very low absorption from the gastrointestinal tract subsequent to oral ingestion.

Determination of the particle size distribution demonstrated that the substance contains 90% of particles with a diameter of 69.4 µm, which may thus be inhaled, but may not reach the thoracic or alveolar region due to their particle size higher than 50 and 10 µm, respectively. If the poorly water soluble dusts deposit in nasopharyngeal region, they could be coughed or sneezed out of the body or swallowed (ECHA, 2012). Therefore, under normal use and handling conditions, inhalation exposure and thus availability for respiratory absorption of the substance in the form of dusts is not significant.

Although the molecular weight of the substance is suggestive of dermal uptake, the physical state in combination with the very low water solubility of the substance is suggestive of very low absorption through the skin. In addition, the fact that the substance is neither irritating nor sensitising to skin implies that dermal uptake of the substance in humans is considered as very limited (ECHA, 2012).

Therefore, a very low bioavailability in humans is anticipated for the substance after any route of exposure.

In summary, based on the physicochemical and toxicological properties, there is sufficient weight of evidence provided leading to the assumption/conclusion that the substance is not toxic to reproduction. Therefore, in accordance with Annex XI, Section 1.2 of Regulation (EC) 1907/2006 further testing on vertebrate animals for that property shall be omitted and further testing not involving vertebrate animals may be omitted. Adequate

and reliable documentation is provided in the technical dossier and the chemical safety report.

Reference:

ECHA (2012). Guidance on information requirements and chemical safety assessment, Chapter R.7c: Endpoint specific guidance.

5.9.2.2. Human information

No relevant information available

5.9.3. Summary and discussion of reproductive toxicity

Effects on fertility

The following information is taken into account for any hazard / risk assessment:

Diniobium pentaoxide is not bioavailable. Effect level for fertility/developmental toxicity (oral): NOAEL 1000mg/kg bw/day. Other routes tests are unnecessary.

Value used for CSA (route: oral):

NOAEL: 1000 mg/kg bw/day

Developmental toxicity

Diniobium pentaoxide is insoluble in water. It is resistant to acids, including nitrohydrochloric acid (aqua regia), HCl, H2SO4, HNO3, and H3PO4 and to many organic and inorganic compounds. Diniobium pentaoxide is attacked by hot concentrated mineral acids, such as HF and HF/HNO3mixtures, but is resistant to fused alkali (Nowak & Ziolek, Chem. Rev. 1999,99, 3603-3624). I. e., diniobium pentaoxide is dissolved only under extremely oxidising conditions that are not compatible with administration to animals.

Due to its insolubility it can be assumed that diniobium pentaoxide even if applied as pure powder will not be absorbed in the stomach and intestinal tract. The negligible bioavailability after oral application allows the prediction that the NOAEL for toxicity after repeated oral exposure will be greater than 1000 mg/kg bw/day. This value was confirmed by the combined repeated dose toxicity and reproduction/ developmental toxicity screening test performed study.

This predictability makes repeated dose inhalation toxicity testing unnecessary. A similar rationale forbids the testing via the dermal route: since it is certainly predictable that diniobium pentaoxide as manufactured cannot penetrate the skin, any testing via this route is scientifically unjustified.

Value used for CSA (route: oral)

NOAEL: 1000 mg/kg bw/day

Justification for classification or non classification

5.10. Other effects

5.10.1. Non-human information

5.10.1.1. Neurotoxicity

No relevant information available

5.10.1.2. Immunotoxicity

No relevant information available

5.10.1.3. Specific investigations: other studies

No relevant information available

5.10.2. Human information

No relevant information available

5.10.3. Summary and discussion of other effects

5.11. Derivation of DNEL(s) and other hazard conclusions

5.11.1. Overview of typical dose descriptors for all endpoints

Table 30. Available dose-descriptor(s) per endpoint as a result of its hazard assessment

Endpoint	Route	Dose descriptor or qualitative effect characterisation; test type	Reference to selected study (see footnotes for justification)
Acute toxicity	oral	LD50: 5000 mg/kg bw	
Acute toxicity	dermal	LD50: 2000 mg/kg bw	
Acute toxicity	inhalation	LC50: 5450 mg/m³	
Irritation / Corrosivity	skin	No adverse effect observed (not irritating)	
Irritation / Corrosivity	eye	No adverse effect observed (not irritating)	
Sensitisation	skin	No adverse effect observed (not sensitising)	
Repeated dose toxicity	oral	NOAEL: 1000 mg/kg bw/day (rat)	
Mutagenicity	in vitro / in vivo	No adverse effect observed (negative)	see section 5.7.1 / 5.7.2
Reproductive toxicity: effects on fertility	oral	(NOAEL): 1000mg/kg bw/day	
Reproductive toxicity: developmental toxicity	oral	(NOAEL): 1000mg/kg bw/day	

5.11.2. Selection of the DNEL(s) or other hazard conclusion for critical health effects

Table 31. Hazard conclusions for workers

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	no hazard identified	
Inhalation	Systemic effects - Acute	no hazard identified	
Inhalation	Local effects - Long-term	no hazard identified	
Inhalation	Local effects - Acute	no hazard identified	
Dermal	Systemic effects - Long-term	no hazard identified	
Dermal	Systemic	no hazard identified	

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
	effects - Acute		
Dermal	Local effects - Long-term	no hazard identified	
Dermal	Local effects - Acute	no hazard identified	
Eyes	Local effects	no hazard identified	

Further explanation on hazard conclusions:

- **Inhalation Systemic effects - Long-term:** Niobium is not bioavailable via this route. No DNEL is necessary for this route of exposure.
- **Inhalation Systemic effects - Acute:** Niobium is not bioavailable via the this route. No DNEL is necessary for this route of exposure.
- **Inhalation Local effects - Long-term:** Niobium is not bioavailable via this route. No DNEL is necessary for this route of exposure.
- **Inhalation Local effects - Acute:** Niobium is not bioavailable via this route. No DNEL is necessary for this route of exposure.
- **Dermal Systemic effects - Long-term:** Niobium is not bioavailable via the dermal route. No DNEL is necessary for this route of exposure.
- **Dermal Systemic effects - Acute:** Niobium is not bioavailable via the dermal route. No DNEL is necessary for this route of exposure.
- **Dermal Local effects - Long-term:** Niobium is not bioavailable via the dermal route. No DNEL is necessary for this route of exposure.
- **Dermal Local effects - Acute:** Niobium is not bioavailable via the dermal route. No DNEL is necessary for this route of exposure.

Discussion

Diniobium pentaoxide is not bioavailable via any foreseeable route of exposure. This entails a lack of toxicological hazards. Therefore, no toxicological threshold values have to be proposed for Diniobium Pentaoxide.

Table 32. Hazard conclusions for the general population

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
Inhalation	Systemic effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Inhalation	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Inhalation	Local effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Inhalation	Local effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Systemic	hazard unknown but no further hazard	

Route	Type of effect	Hazard conclusion	Most sensitive endpoint
	effects - Long-term	information necessary as no exposure expected	
Dermal	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Local effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Dermal	Local effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Oral	Systemic effects - Long-term	hazard unknown but no further hazard information necessary as no exposure expected	
Oral	Systemic effects - Acute	hazard unknown but no further hazard information necessary as no exposure expected	
Eyes	Local effects	hazard unknown but no further hazard information necessary as no exposure expected	

Further explanation on hazard conclusions:

- **Inhalation Systemic effects - Long-term:** There is no foreseeable exposure scenario for the general population for Nb2O5.
- **Inhalation Systemic effects - Acute:** There is no foreseeable exposure scenario for the general population for Nb2O5.
- **Inhalation Local effects - Long-term:** There is no foreseeable exposure scenario for the general population for Nb2O5.
- **Inhalation Local effects - Acute:** There is no foreseeable exposure scenario for the general population for Nb2O5.
- **Dermal Systemic effects - Long-term:** There is no foreseeable exposure scenario for the general population for Nb2O5.
- **Dermal Systemic effects - Acute:** There is no foreseeable exposure scenario for the general population for Nb2O5.
- **Dermal Local effects - Long-term:** There is no foreseeable exposure scenario for the general population for Nb2O5.
- **Dermal Local effects - Acute:** There is no foreseeable exposure scenario for the general population for Nb2O5.
- **Oral Systemic effects - Long-term:** There is no foreseeable exposure scenario for the general population for Nb2O5.
- **Oral Systemic effects - Acute:** There is no foreseeable exposure scenario for the general population for Nb2O5.

Discussion

There is no foreseeable exposure scenario for the general population for Nb2O5.

6. HUMAN HEALTH HAZARD ASSESSMENT OF PHYSICOCHEMICAL PROPERTIES

6.1. Explosivity

Data waiving: see CSR section 1.3 Physicochemical properties.

Discussion

There are no chemical groups associated with explosive properties present in the molecule.

The following information is taken into account for any hazard / risk assessment:

non explosive

Classification according to GHS

Name: Diniobium Pentaoxide

Related composition: Anhydrous form of Diniobium Pentaoxide

State/form of the substance: powder

Reason for no classification: conclusive but not sufficient for classification

Classification according to DSD / DPD

Classification status: 67/548/EEC self classification (Diniobium Pentaoxide)

Reason for no classification: conclusive but not sufficient for classification

Justification for classification or non-classification:

The available data on explosive properties of the test substance do not meet the criteria for classification according to Regulation (EC) 1272/2008 or Directive 67/548/EEC, and are therefore conclusive but not sufficient for classification: based on chemical structure the substance is not explosive.

6.2. Flammability

Flammability

The available information on flammability is summarised in the following table:

Table 33. Information on flammability

Method	Results	Remarks	Reference
EU Method A.10 (Flammability (Solids))	Evaluation of results: non flammable Study results: Ignition on contact with air: no (In contact with the flame the test item glowed. The glowing immediately extinguished after removal of the burner.) Remarks: The test was started by trying to ignite the pile at one end with a gas flame. During heating the test item glowed. During the ignition period of 5 minutes the test item	1 (reliable without restriction) key study experimental result **Test material (EC name): diniobium pentaoxide**	Walter, D. (2010a)

Method	Results	Remarks	Reference
	was not ignited. The flame immediately extinguished when the flame was removed. No burning or glowing spreaded over the length of the pile was observed. The test was repeated with the same results at the other end of the pile.		

Data waiving: see CSR section 1.3 Physicochemical properties.

Discussion

Non flammable solid. Based on chemical structure pyrophoric properties and flammability in contact with water are not to be expected.

The following information is taken into account for any hazard / risk assessment:

not flammable

Flash point

Data waiving: see CSR section 1.3 Physicochemical properties.

Discussion

The substance is inorganic.

The following information is taken into account for any hazard / risk assessment:

not applicable

Classification according to GHS

Name: Diniobium Pentaoxide

Related composition: Anhydrous form of Diniobium Pentaoxide

State/form of the substance: powder

Reason for no classification (Flammable gases): conclusive but not sufficient for classification

Reason for no classification (Flammable aerosols): conclusive but not sufficient for classification

Reason for no classification (Flammable liquids): conclusive but not sufficient for classification

Reason for no classification (Flammable solids): conclusive but not sufficient for classification

Classification according to DSD / DPD

Classification status: 67/548/EEC self classification (Diniobium Pentaoxide)

Reason for no classification: conclusive but not sufficient for classification

Justification for classification or non-classification:

The available data on flammability of the test substance do not meet the criteria for classification according to Regulation (EC) 1272/2008 or Directive 67/548/EEC, and are therefore conclusive, but not sufficient for classification:

No propagation of burning in a test according to EU Method A.10.

Based on the chemical structure and experience in handling and use, pyrophoricity and flammability on contact with water are not expected.

6.3. Oxidising potential

The available information on the oxidising potential is summarised in the following table:

Table 34. Information on oxidising potential

<table>
<tr><th>Method</th><th>Results</th><th>Remarks</th><th>Reference</th></tr>
<tr><td>Contact with: powdered cellulose

EU Method A.17 (Oxidising Properties (Solids))</td><td>Evaluation of results: no oxidising properties

maximum burning rate of test mixture: 0 mm/s (The flame went out immediately after removing the ignition source)

maximum burning rate of reference mixture: 0.43 mm/s

Remarks:

The mixture of test item and cellulose (2 portions of test item and 1 portion cellulose) was ignited at the tip of the cone. The vigour and duration of the resultant reaction was observed and recorded.

No vigorous reaction was observed. Grey smoke was observed during ignition with the flame. After removing of the ignition source no independent burning or glowing of the mixture of test item and cellulose was observed. After the test a residue of grey till brown colour was found on the top of the cone.

Main Test

The main test was performed with each one of the ranges of mixtures of the reference. The determined burning rates are given inTable1.

Table1:Burning rates of barium nitrate/cellulose-standard mixtures

<table>
<tr><th>Mixture of barium nitrate/ cellulose

(w/w)</th><th>Burning time after the reaction zone propagated an initial distance of 30 mm

[s]</th><th>Covered distance after the reaction zone propagated an initial distance of 30 mm [mm]</th><th>Burning rate

[mm/s]</th></tr>
<tr><td>6/4</td><td>462</td><td>200</td><td>0.43</td></tr>
<tr><td>6/4</td><td>471</td><td>200</td><td>0.42</td></tr>
</table>
</td><td>1 (reliable without restriction)

key study

experimental result

Test material (EC name): diniobium pentaoxide</td><td>Walter, D. (2010b)</td></tr>
</table>

Method	Results	Remarks	Reference

6/4	486	200	0.41
6/4	468	200	0.43
6/4	463	200	0.43
6/4	467	200	0.43
		Mean:	0.43
		RSD %:	1.9

RSD = relative standard deviation

The burning rates of the test item with cellulose are given inTable2.

Table2:Burning rates of test item/cellulose-mixtures containing 10 to 90 % of test item

Mixture of Test item/ cellulose (w/w)	**Burning time after the reaction zone propagated an initial distance of 30 mm [s]**	**Covered distance after the reaction zone propagated an initial distance of 30 mm [mm]**	**Burning rate [mm/s]**
9/1	0*	0	0
8/2	0*	0	0
7/3	0*	0	0
6/4	0*	0	0
5/5	0*	0	0
4/6	0*	0	0
3/7	0*	0	0
2/8	0*	0	0
1/9	0*	0	0

* the flame went out immediately after

Method	Results	Remarks	Reference
	removing the ignition source Because the burning rates of the single determinations (Table2) showed that there was no reaction zone which travelled along the pile the test item was not considered to be an oxidizing substance and no further testing was performed.		

Discussion

Diniobium Pentaoxide is not considered to be an oxidizing substance because there was no reaction zone which travelled along the pile for each tested mixture of Diniobium Pentaoxide and cellulose.

The following information is taken into account for any hazard / risk assessment:

no oxidising properties

Classification according to GHS

Name: Diniobium Pentaoxide

Related composition: Anhydrous form of Diniobium Pentaoxide

State/form of the substance: powder

Reason for no classification (Oxidising gases): conclusive but not sufficient for classification

Reason for no classification (Oxidising liquids): conclusive but not sufficient for classification

Reason for no classification (Oxidising solids): conclusive but not sufficient for classification

Classification according to DSD / DPD

Classification status: 67/548/EEC self classification (Diniobium Pentaoxide)

Reason for no classification: conclusive but not sufficient for classification

Justification for classification or non-classification:

The available data on oxidising properties of the test substance do not meet the criteria for classification according to Regulation (EC) 1272/2008 or Directive 67/548/EEC, and are therefore conclusive but not sufficient for classification: based on the test according to EU Method A.17 the substance is not oxidising.

7. ENVIRONMENTAL HAZARD ASSESSMENT

7.1. Aquatic compartment (including sediment)

No data is available on toxicity of diniobium pentaoxide to aquatic species.

In accordance with column 2 of Annex VII and VIII of Regulation (EC) No 1907/2006, short-term studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water. For diniobium pentaoxide a water solubility study has been performed resulting in a solubility <0.5 µg/L. An additionally performed oxide metal dissolution study came likewise to the result that the solubility is lower than 0.5 µg/L. Thus, diniobium pentaoxide is considered to be insoluble in water.

To prove whether a concentration of Diniobium pentaoxide lower than 0.5 µg/L, poses any potential risk to the aquatic environment, data from metals with a high toxicity to aquatic species can be considered for comparison. For example, Zinc is known to be very toxic to the aquatic environment (R50/53). For zinc a predicted no effect concentration (PNEC) of 7.8 µ/L was determined. This PNEC is still more than one order of magnitude above the water solubility of diniobium pentaoxide. Since this oxide cannot reasonably be considered to be more toxic than zinc, any adverse effect of diniobium pentaoxide can be excluded and testing is scientifically unjustified.

In column 2 of Annex IX of Regulation (EC) No 1907/2006, it is laid down that chronic toxicity tests shall be proposed by the registrant if the chemical safety assessment indicates the need to investigate further the effects on aquatic species. Since diniobium pentaoxide is not bioavailable, neither classified as dangerous to the environment nor it is a PBT or vPvB substance, there is no reason to perform long-term toxicity studies on aquatic species.

Diniobium pentaoxide is considered not to inhibit microorganisms in sewage treatment plants. Due to its insolubility in water the substance is assumed to be adsorbed and removed within the STP process.

7.1.1. Fish

7.1.1.1. Short-term toxicity to fish

Data waiving

Information requirement: Short-term toxicity testing on fish

Reason: other justification

Justification: In accordance with column 2 of Annex VII and VIII, studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water.

For diniobium pentaoxide, a water solubility study has been performed under GLP according to the OECD Guideline for the Testing of Chemicals No. 105 – Water Solubility. As a result, the water solubility was determined to be lower than the detection limit, which was 0.5 µg/L for the method used in this study.

Moreover, to take into account specific properties of metals, an additional study according to the OECD Guidance document No. 29 (transformation/dissolution of metals and metal compounds in aqueous media, OECD Series on Testing and Assessment) has been performed.

Consistent with the result obtained in the standard test, the water solubility was again determined to be lower than 0.5 µg/L.

In consequence of these results, the substance is considered to be insoluble in water. Even if we assume a very limited solubility lower than 0.5 µg/L, any adverse effect at this concentration can be excluded and testing – whether short-term or long-term – can be omitted.

To prove this assumption we considered for a comparison the aquatic ecotoxicity of Zinc, which is known to be very toxic to the aquatic environment and consequentially labelled as R50/53 according to regulation 67/548/EEC and as aquatic acute (and chronic) toxicity 1 according to regulation 1272/2008/EEC, respectively and thus can be seen as a “worst case scenario”. As published in the EU Risk Assessment Report

for Zinc metal (2008), the proposed predicted no effect concentration (PNEC) for dissolved Zinc in freshwater is 7.8 µg/L.

Thus, any adverse effect of diniobium pentaoxide at a concentration below 0.5 µg/L can be excluded and without reasonable doubt any testing is scientifically unjustified.

Discussion

The substance is not soluble in water.

The following information is taken into account for acute fish toxicity for the derivation of PNEC:

No toxic effect on fish is expected since diniobium pentaoxide is insoluble in water.

7.1.1.2. Long-term toxicity to fish

Data waiving

Information requirement: Long-term toxicity testing on fish

Reason: other justification

Justification: In accordance with column 2 of Annex VII and VIII, studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water.

For diniobium pentaoxide, a water solubility study has been performed under GLP according to the OECD Guideline for the Testing of Chemicals No. 105 – Water Solubility. As a result, the water solubility was determined to be lower than the detection limit, which was 0.5 µg/L for the method used in this study.

Moreover, to take into account specific properties of metals, an additional study according to the OECD Guidance document No. 29 (transformation/dissolution of metals and metal compounds in aqueous media, OECD Series on Testing and Assessment) has been performed.

Consistent with the result obtained in the standard test, the water solubility was again determined to be lower than 0.5 µg/L.

In consequence of these results, the substance is considered to be insoluble in water. Even if we assume a very limited solubility lower than 0.5 µg/L, any adverse effect at this concentration can be excluded and testing – whether short-term or long-term – can be omitted.

To prove this assumption we considered for a comparison the aquatic ecotoxicity of Zinc, which is known to be very toxic to the aquatic environment and consequentially labelled as R50/53 according to regulation 67/548/EEC and as aquatic acute (and chronic) toxicity 1 according to regulation 1272/2008/EEC, respectively and thus can be seen as a "worst case scenario". As published in the EU Risk Assessment Report for Zinc metal (2008), the proposed predicted no effect concentration (PNEC) for dissolved Zinc in freshwater is 7.8 µg/L.

Thus, any adverse effect of diniobium pentaoxide at a concentration below 0.5 µg/L can be excluded and without reasonable doubt any testing is scientifically unjustified.

Discussion

The substance is not soluble in water.

The following information is taken into account for long-term fish toxicity for the derivation of PNEC:

No toxic effect on fish is expected since diniobium pentaoxide is insoluble in water.

7.1.2. Aquatic invertebrates

7.1.2.1. Short-term toxicity to aquatic invertebrates

Data waiving

Information requirement: Short-term toxicity testing on aquatic invertebrates

Reason: other justification

Justification: In accordance with column 2 of Annex VII and VIII, studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water.

For diniobium pentaoxide a water solubility study has been performed under GLP according to the OECD Guideline for the Testing of Chemicals No. 105 – Water Solubility. As a result, the water solubility was determined to be lower than the detection limit, which was 0.5 µg/L for the method used in this study.

Moreover, to take into account specific properties of metals, an additional study according to the OECD Guidance document No. 29 (transformation/dissolution of metals and metal compounds in aqueous media, OECD Series on Testing and Assessment) has been performed. Consistent with the result obtained in the standard test, the water solubility was again determined to be lower than 0.5 µg/L.

In consequence of these results, the substance is considered to be insoluble in water. Even if we assume a very limited solubility lower than 0.5 µg/L, any adverse effect at this concentration can be excluded and testing – whether short-term or long-term – can be omitted.

To prove this assumption we considered for a comparison the aquatic ecotoxicity of Zinc, which is known to be very toxic to the aquatic environment and consequentially labelled as R50/53 according to regulation 67/548/EEC and as aquatic acute (and chronic) toxicity 1 according to regulation 1272/2008/EEC, respectively and thus can be seen as a "worst case scenario". As published in the EU Risk Assessment Report for Zinc metal (2008), the proposed predicted no effect concentration (PNEC) for dissolved Zinc in freshwater is 7.8 µg/L.

Thus, any adverse effect of diniobium pentaoxide at a concentration below 0.5 µg/L can be excluded and without reasonable doubt any testing is scientifically unjustified.

Discussion

The substance is not soluble in water.

The following information is taken into account for short-term toxicity to aquatic invertebrates for the derivation of PNEC:

No toxic effect is expected since diniobium pentaoxide is insoluble in water.

7.1.2.2. Long-term toxicity to aquatic invertebrates

Data waiving

Information requirement: Long-term toxicity testing on aquatic invertebrates

Reason: other justification

Justification: In accordance with column 2 of Annex VII and VIII, studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water.

For diniobium pentaoxide, a water solubility study has been performed under GLP according to the OECD Guideline for the Testing of Chemicals No. 105 – Water Solubility. As a result, the water solubility was determined to be lower than the detection limit, which was 0.5 µg/L for the method used in this study.

Moreover, to take into account specific properties of metals, an additional study according to the OECD Guidance document No. 29 (transformation/dissolution of metals and metal compounds in aqueous media, OECD Series on Testing and Assessment) has been performed.

Consistent with the result obtained in the standard test, the water solubility was again determined to be lower than 0.5 µg/L.

In consequence of these results, the substance is considered to be insoluble in water. Even if we assume a very limited solubility lower than 0.5 µg/L, any adverse effect at this concentration can be excluded and testing – whether short-term or long-term – can be omitted.

To prove this assumption we considered for a comparison the aquatic ecotoxicity of Zinc, which is known to

be very toxic to the aquatic environment and consequentially labelled as R50/53 according to regulation 67/548/EEC and as aquatic acute (and chronic) toxicity 1 according to regulation 1272/2008/EEC, respectively and thus can be seen as a "worst case scenario". As published in the EU Risk Assessment Report for Zinc metal (2008), the proposed predicted no effect concentration (PNEC) for dissolved Zinc in freshwater is 7.8 µg/L.

Thus, any adverse effect of diniobium pentaoxide at a concentration below 0.5 µg/L can be excluded and without reasonable doubt any testing is scientifically unjustified.

Discussion

The substance is not soluble in water.

The following information is taken into account for long-term toxicity to aquatic invertebrates for the derivation of PNEC:

No toxic effect is expected since diniobium pentaoxide is insoluble in water.

7.1.3. Algae and aquatic plants

Data waiving

Information requirement: Growth inhibition study with algae / cyanobacteria

Reason: other justification

Justification: In accordance with column 2 of Annex VII and VIII, studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water.

For diniobium pentaoxide a water solubility study has been performed under GLP according to the OECD Guideline for the Testing of Chemicals No. 105 – Water Solubility. As a result, the water solubility was determined to be lower than the detection limit, which was 0.5 µg/L for the method used in this study.

Moreover, to take into account specific properties of metals, an additional study according to the OECD Guidance document No. 29 (transformation/dissolution of metals and metal compounds in aqueous media, OECD Series on Testing and Assessment) has been performed. Consistent with the result obtained in the standard test, the water solubility was again determined to be lower than 0.5 µg/L.

In consequence of these results, the substance is considered to be insoluble in water. Even if we assume a very limited solubility lower than 0.5 µg/L, any adverse effect at this concentration can be excluded and testing – whether short-term or long-term – can be omitted.

To prove this assumption we considered for a comparison the aquatic ecotoxicity of Zinc, which is known to be very toxic to the aquatic environment and consequentially labelled as R50/53 according to regulation 67/548/EEC and as aquatic acute (and chronic) toxicity 1 according to regulation 1272/2008/EEC, respectively and thus can be seen as a "worst case scenario". As published in the EU Risk Assessment Report for Zinc metal (2008), the proposed predicted no effect concentration (PNEC) for dissolved Zinc in freshwater is 7.8 µg/L.

Thus, any adverse effect of diniobium pentaoxide at a concentration below 0.5 µg/L can be excluded and without reasonable doubt any testing is scientifically unjustified.

Discussion

Effects on algae / cyanobacteria

The substance is not soluble in water.

The following information is taken into account for effects on algae / cyanobacteria for the derivation of PNEC:

No toxic effect is expected since diniobium pentaoxide is insoluble in water.

7.1.4. Sediment organisms

No relevant information available

7.1.5. Other aquatic organisms

No relevant information available

7.2. Terrestrial compartment

Terrestrial data of diniobium pentaoxide are not available but due to the properties of diniobium pentaoxide a hazard to soil organisms is assumed to be low. In accordance with column 2 of EC 1970/2006 Annex IX the effects of terrestrial organisms need not to be tested if a direct and indirect exposure to the soil compartment is unlikely. For diniobium pentaoxide a water solubility study has been performed resulting in a solubility <0.5 µg/L. An additionally performed oxide metal dissolution study came likewise to the result that the solubility is lower than 0.5 µg/L. Thus, diniobium pentaoxide is considered to be insoluble in water. Due to its insolubility in water the substance is assumed to be adsorbed and removed within the STP process and an indirect exposure of soil organisms through sludge application can be ruled out. Regarding the insolubility (< 0.5 µg/L) it is not likely that the test substances can be found in the aquatic environment and therefore an application due to floods and irrigation can be ruled out.

The test substance is not classified and considering that diniobium pentaoxide is not bioavailable, neither classified as dangerous to the environment nor it is a PBT or vPvB substance, there is no reason to perform soil toxicity data.

7.2.1. Toxicity to soil macro-organisms

Data waiving

Information requirement: Toxicity to soil macro-organisms except arthropods

Reason: other justification

Justification: Terrestrial data of diniobium pentaoxide are not available but due to the properties of diniobium pentaoxide a hazard to soil organisms is assumed to be low. In accordance with column 2 of EC 1970/2006 Annex IX the effects of terrestrial organisms need not to be tested if a direct and indirect exposure to the soil compartment is unlikely. For diniobium pentaoxide a water solubility study has been performed resulting in a solubility <0.5 µg/L. An additionally performed oxide metal dissolution study came likewise to the result that the solubility is lower than 0.5 µg/L. Thus, diniobium pentaoxide is considered to be insoluble in water. Due to its insolubility in water the substance is assumed to be adsorbed and removed within the STP process and an indirect exposure of soil organisms through sludge application can be ruled out. Regarding the insolubility (< 0.5 µg/L) it is not likely that the test substances can be found in the aquatic environment and therefore an application due to floods and irrigation can be ruled out.

The test substance is not classified and considering that diniobium pentaoxide is not bioavailable, neither classified as dangerous to the environment nor it is a PBT or vPvB substance, there is no reason to perform soil toxicity data.

Information requirement: Toxicity to soil arthropods

Reason: other justification

Justification: Terrestrial data of diniobium pentaoxide are not available but due to the properties of diniobium pentaoxide a hazard to soil organisms is assumed to be low. In accordance with column 2 of EC 1970/2006 Annex IX the effects of terrestrial organisms need not to be tested if a direct and indirect exposure to the soil compartment is unlikely. For diniobium pentaoxide a water solubility study has been performed resulting in a solubility <0.5 µg/L. An additionally performed oxide metal dissolution study came likewise to the result that the solubility is lower than 0.5 µg/L. Thus, diniobium pentaoxide is considered to be insoluble in water. Due to its insolubility in water the substance is assumed to be adsorbed and removed within the STP process and an indirect exposure of soil organisms through sludge application can be ruled out. Regarding the insolubility (< 0.5 µg/L) it is not likely that the test substances can be found in the aquatic environment and therefore an application due to floods and irrigation can be ruled out.

The test substance is not classified and considering that diniobium pentaoxide is not bioavailable, neither classified as dangerous to the environment nor it is a PBT or vPvB substance, there is no reason to perform soil

toxicity data.

7.2.2. Toxicity to terrestrial plants

Data waiving

Reason: other justification

Justification: Terrestrial data of diniobium pentaoxide are not available but due to the properties of diniobium pentaoxide a hazard to soil organisms is assumed to be low. In accordance with column 2 of EC 1970/2006 Annex IX the effects of terrestrial organisms need not to be tested if a direct and indirect exposure to the soil compartment is unlikely. For diniobium pentaoxide a water solubility study has been performed resulting in a solubility <0.5 µg/L. An additionally performed oxide metal dissolution study came likewise to the result that the solubility is lower than 0.5 µg/L. Thus, diniobium pentaoxide is considered to be insoluble in water. Due to its insolubility in water the substance is assumed to be adsorbed and removed within the STP process and an indirect exposure of soil organisms through sludge application can be ruled out. Regarding the insolubility (< 0.5 µg/L) it is not likely that the test substances can be found in the aquatic environment and therefore an application due to floods and irrigation can be ruled out.

The test substance is not classified and considering that diniobium pentaoxide is not bioavailable, neither classified as dangerous to the environment nor it is a PBT or vPvB substance, there is no reason to perform soil toxicity data.

7.2.3. Toxicity to soil micro-organisms

Data waiving

Information requirement: Effects on soil micro-organisms

Reason: other justification

Justification: Terrestrial data of diniobium pentaoxide are not available but due to the properties of diniobium pentaoxide a hazard to soil organisms is assumed to be low. In accordance with column 2 of EC 1970/2006 Annex IX the effects of terrestrial organisms need not to be tested if a direct and indirect exposure to the soil compartment is unlikely. For diniobium pentaoxide a water solubility study has been performed resulting in a solubility <0.5 µg/L. An additionally performed oxide metal dissolution study came likewise to the result that the solubility is lower than 0.5 µg/L. Thus, diniobium pentaoxide is considered to be insoluble in water. Due to its insolubility in water the substance is assumed to be adsorbed and removed within the STP process and an indirect exposure of soil organisms through sludge application can be ruled out. Regarding the insolubility (< 0.5 µg/L) it is not likely that the test substances can be found in the aquatic environment and therefore an application due to floods and irrigation can be ruled out.

The test substance is not classified and considering that diniobium pentaoxide is not bioavailable, neither classified as dangerous to the environment nor it is a PBT or vPvB substance, there is no reason to perform soil toxicity data.

7.2.4. Toxicity to other terrestrial organisms

No relevant information available

7.3. Atmospheric compartment

Diniobium pentaoxide is not listed in Annex I of Regulation (EC) 2037/2000 on substances that deplete the ozone layer.

Diniobium pentaoxide is produced in massive compact form, which is not volatile and not released into the atmosphere.

7.4. Microbiological activity in sewage treatment systems

Data waiving

Information requirement: Effects on aquatic micro-organisms

Reason: other justification

Justification: According to the Regulation (EC) No 1907/2006 (REACH) Annex VIII 9.1.4 column 2, the toxicity to microorganisms in water does not need to be determined if the substance is highly insoluble in water. Tests on water solubility of diniobium pentaoxide have shown that the substance is insoluble (< 0.5 µg/L). For a substance being considered as insoluble, it can be assumed that it will be adsorbed and removed within the STP process.

Discussion

The substance is not soluble in water.

The following information is taken into account for effects on aquatic micro-organisms for the derivation of PNEC:

No toxic effect on microorganisms is expected since diniobium pentaoxide is insoluble in water.

7.5. Non compartment specific effects relevant for the food chain (secondary poisoning)

7.5.1. Toxicity to birds

No relevant information available

7.5.2. Toxicity to mammals

No relevant information available

7.6. PNEC derivation and other hazard conclusions

Table 35. Hazard assessment conclusion for the environment

Compartment	Hazard conclusion	Remarks/Justification
Freshwater		PNEC aqua (freshwater) can not be derived since no data is available on freshwater organisms. In accordance with column 2 of Annex VII and VIII, studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water. Since diniobium pentaoxide is considered to be insoluble in water (water solubility < 0.5 µg/L) and any adverse effect on aquatic organisms can be excluded, testing is scientifically unjustified.
Marine water		PNEC aqua (marine water) can not be derived since no data is available on freshwater or marine water organisms. In accordance with column 2 of Annex VII and VIII, studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water. Since diniobium pentaoxide is considered to be insoluble in water (water solubility < 0.5 µg/L) and any adverse effect on aquatic organisms can be excluded, testing is scientifically unjustified.
Intermittent releases to water		PNEC aqua (intermitten releases) can not be derived since no data is available on aquatic organisms. In accordance with column 2 of Annex VII and VIII, studies for the aquatic ecotoxicity do not need to be conducted if there are mitigating factors indicating that aquatic toxicity is unlikely to occur, for instance if the substance is highly insoluble in water.

Compartment	Hazard conclusion	Remarks/Justification
		Since diniobium pentaoxide is considered to be insoluble in water (water solubility < 0.5 µg/L) and any adverse effect on aquatic organisms can be excluded, testing is scientifically unjustified.
Sediments (freshwater)		PNEC sediment (freshwater) can not be derived since no data is available on aquatic or benthic organisms. For diniobium pentaoxide an entry into the environment is very unlikely to occur. Additionally, the substance is insoluble in water and thus not bioavailable. Due to the low bioavailability the bioaccumulation potential is negligible and diniobium pentaoxide is considered not to cause any hazardous effects. Thus, testing with sediment organisms is considered to be scientifically unjustified.
Sediments (marine water)		PNEC sediment (marine water) can not be derived since no data is available on aquatic or benthic organisms. For diniobium pentaoxide an entry into the environment is very unlikely to occur. Additionally, the substance is insoluble in water and thus not bioavailable. Due to the low bioavailability the bioaccumulation potential is negligible and diniobium pentaoxide is considered not to cause any hazardous effects. Thus, testing with sediment organisms is considered to be scientifically unjustified.
Sewage treatment plant		PNEC STP can not be derived since no data is available on microorganisms. According to the Regulation (EC) No 1907/2006 (REACH) Annex VIII 9.1.4 column 2, the toxicity to microorganisms in water does not need to be determined if the substance is highly insoluble in water. Tests on water solubility of diniobium pentaoxide have shown that the substance is insoluble (< 0.5 µg/L). For a substance being considered as insoluble, it can be assumed that it will be adsorbed and removed within the STP process.
Soil		PNEC soil can not be derived since no data is available on soil or aquatic organisms. According to column 2 of Annex X of the REACH regulation, studies on terrestrial organisms do not need to be conducted if direct and indirect exposure of the soil compartment is unlikely. Diniobium Pentaoxide is not supposed to be directly applied to soil. An indirect exposure to soil via sewage sludge transfer is also unlikely since diniobium pentaoxide is not water soluble and substances being considered as insoluble can be assumed to be adsorbed and removed within the STP process. Furthermore, no negative environmental effects have been reported. Since diniobium pentaoxide is not exposed to the soil and the substance is judged not to be hazardous to the environment, terrestrial testing is omitted.
Air		As no standardised biotic testing systems and guidelines are available at present for the air compartment, the derivation of a PNEC air is not feasible. Air is not a compartment of concern for diniobium pentaoxide as its volatility is low.
Secondary poisoning		PNEC oral can not be derived since no data is available on mammalian or on bird toxicity. As the test substance is not classified as toxic or harmful to mammals, the substance is also not considered to cause toxic effects in birds. Additionally, due to the low bioavailability (diniobium pentaoxide is insoluble in water) the bioaccumulation potential is negligible and thus the test substance is considered not to cause any hazardous effects to predators like birds. Since diniobium pentaoxide is not hazardous to mammals and the substance does not bioaccumulate, bird testing is scientifically unjustified.

Environmental classification justification

Diniobium Pentaoxide is judged not to be toxic to the environment.

Due to its insolubility in water, diniobium pentaoxide is considered not to cause any toxic effect on aquatic

species. Diniobium pentaoxide is inert and cannot be metabolised, thus it cannot be accumulated in living being and does not need to be classified and labelled as environmental hazardous according to the Regulation (EC) No 1272/2008 and the Regulation (EU) No 286/2011 (2nd ATP).

Due to its insolubility in water, diniobium pentaoxide is considered not to cause any toxic effect on aquatic species. Diniobium pentaoxide is inert and cannot be metabolised, thus it cannot be accumulated in living being and does not need to be classified and labelled as environmental hazardous according to Directive 67/548/EEC.

8. PBT AND vPvB ASSESSMENT

8.1. Assessment of PBT/vPvB Properties

8.1.1. Summary and overall conclusions on PBT or vPvB properties

Taking into account all available data on biotic and abiotic degradation, bioaccumulation and toxicity it can be stated that diniobium pentaoxide is neither toxic nor does it accumulate in living being, but it is judged to be very persistent in the environment. Since not all three criteria for persistence, bioaccumulation and toxicity are fulfilled, diniobium pentaoxide is judged not to be a PBT substance.

8.1.2. PBT/vPvB criteria and justification

Persistence Assessment

According to the "Guidance on information requirements and chemical safety assessment Chapter R.11: PBT Assessment" (ECHA, 2008) the screening assessment for persistence should be based on all available data from biodegradation studies, abiotic degradation studies and estimation models.

Since diniobium pentaoxide is an inorganic substance biodegradation cannot be assessed. Abiotic degradation is also not expected to occur. The substance is stable in water and does not hydrolyze. It is not volatile and does not enter into the atmosphere hence a reaction with atmospheric molecules, like OH radicals and a consequently degradation is impossible. Diniobium pentaoxide metal is considered to remain stable in nature and thus to be persistent (P).

Bioaccumulation Assessment

Diniobium pentaoxide is insoluble in water (< 0.5 µg/L) and not bioavailable to aquatic species. As an inorganic substance without any bioavailability, Nb2O5 cannot be metabolized. Under physiological conditions, diniobium pentaoxide cannot be absorbed via skin or gastrointestinal tract. Even in case of absorption via the oral route and ingested, Nb will be eliminated via faeces without prior absorption. Thus, there is no potential for bioaccumulation and diniobium pentaoxide is considered neither to be bioaccumulative (B) nor very bioaccumulative (vB).

Toxicity Assessment

According to the "Guidance on information requirements and chemical safety assessment Chapter R.11: PBT Assessment" (ECHA, 2008) the PBT assessment for toxicity must be based on NOEC values for marine or freshwater organisms, and on considerations of the classification of the substance as CMR and/or chronic toxic to humans.

No data is available on aquatic organisms, carcinogenicity and toxicity to reproduction. Since diniobium pentaoxide is insoluble in water and not bioavailable via any route it is not considered to cause any adverse effect neither to animals nor to humans. An acute dermal study with diniobium pentaoxide showed no effect, diniobium pentaoxide is neither irritant to skin nor to the eye and was found to be not sensitizing. Three studies on genetic toxicity showed that diniobium pentaoxide is not mutagenic. Based on these data diniobium pentaoxide is considered not to be toxic (T).

8.2. Emission Characterisation

Since diniobium pentaoxide does not fulfill the PBT and vPvB criteria, no emission characterization needs to be performed.

9. EXPOSURE ASSESSMENT (and related risk characterisation)

As a result of the hazard assessment and PBT/vPvB assessment it is found that diniobium pentaoxide does not meet the criteria for classification as hazardous (according to Directives 67/548/EEC and 1272/2008/EC) nor is it considered to be a PBT/vPvB. An exposure assessment and the subsequent step of risk characterization are not required.

10. RISK CHARACTERISATION RELATED TO COMBINED EXPOSURE

As a result of the hazard assessment and PBT/vPvB assessment it is found that diniobium pentaoxide does not meet the criteria for classification as hazardous (according to Directives 67/548/EEC and 1272/2008/EC) nor is it considered to be a PBT/vPvB. An exposure assessment and the subsequent step of risk characterization are not required.

Annex 1: References

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Annex 2: Information on Test Material

Test material: **Niobium Pentoxide; Niobium(V) oxide / 1313-96-8 / 215-213-6**
Form:

Composition type: Constituent	**Reference substance:** Diniobium Pentaoxide EC no.: 215-213-6 CAS no: 1313-96-8 IUPAC name: μ-oxido[tetrakis(oxido)]diniobium	**Concentration range:**

Test material: **Niobium Pentoxide; Niobium(V) oxide / 1313-96-8 / 215-213-6**
Form:

Composition type: Constituent	**Reference substance:** Diniobium Pentaoxide EC no.: 215-213-6 CAS no: 1313-96-8 IUPAC name: μ-oxido[tetrakis(oxido)]diniobium	**Concentration range:**

Test material: **Niobium(V) oxide / 1313-96-8 / 215-213-6**
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Composition type: Constituent	**Reference substance:** Diniobium Pentaoxide EC no.: 215-213-6 CAS no: 1313-96-8 IUPAC name: μ-oxido[tetrakis(oxido)]diniobium	**Concentration range:**

Test material: **Niobium Pentoxide; Niobium(V) oxide / 1313-96-8 / 215-213-6**
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Composition type: Constituent	**Reference substance:** Diniobium Pentaoxide EC no.: 215-213-6 CAS no: 1313-96-8 IUPAC name: μ-oxido[tetrakis(oxido)]diniobium	**Concentration range:**

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Test material: **Niobium Pentoxide; Niobium(V) oxide / 1313-96-8 / 215-213-6**
Form:

Composition type: Constituent	**Reference substance:** Diniobium Pentaoxide EC no.: 215-213-6 CAS no: 1313-96-8 IUPAC name: μ-oxido[tetrakis(oxido)]diniobium	**Concentration range:**