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Toxicology and Chemical Substance (TCS)
European Chemicals Bureau
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PERBORIC ACID, SODIUM SALT

CAS No: 11138-47-9

EINECS No: 234-390-0

Summary Risk Assessment Report

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European Union Risk Assessment Report

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CAS No: 11138-47-9

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SUMMARY RISK ASSESSMENT REPORT

Final report, 2007

Austria

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PREFACE

This report provides a summary, with conclusions, of the risk assessment report of the substance perboric acid, sodium salt (sodium perborate) that has been prepared by Austria in the context of Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances.

For detailed information on the risk assessment principles and procedures followed, the underlying data and the literature references, the reader is referred to the comprehensive Final Risk Assessment Report (Final RAR) that can be obtained from the European Chemicals Bureau¹. The Final RAR should be used for citation purposes rather than this present Summary Report.

Please note

The environment part of the risk assessment on sodium perborate was finalised in July 2003 with **Conclusion (iii)** - “there is a need for limiting the risks” - drawn for the following scenarios:

Risk for the aquatic compartment - for two production and for two formulation sites;

Risk for microorganisms in STP - for two production sites.

During the preparatory work for the development of a risk-reduction-strategy Industry submitted new information on the production and formulation sites at risk that led to a change of the conclusions: The **conclusion (ii)** – “there is at present no need for further information and/or testing and no need for risk reduction measures beyond those which are being applied already” applies to all production and formulation sites for the aquatic compartment as well as for microorganisms in STP.

Reasoning:

Regarding the sites at risk for the aquatic compartment, both production sites ceased the production of sodium perborate and both formulation sites stopped its production of detergents. One of the two production sites at risk for microorganisms in STP ceased the production of sodium perborate. At the other site, according to information from Industry, there is no biological waste water treatment plant as the production process is an inorganic process. Therefore, there is no risk for microorganisms at this production site.

Since the environment part of the RAR on sodium perborate had already been finalised at that time, the changes in the text of the relevant sections of the RAR were given in the form of an addendum. Please note that the present summary report includes the information given in the addendum.

¹ European Chemicals Bureau – Existing Chemicals – <http://ecb.jrc.it>

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1

GENERAL SUBSTANCE INFORMATION

1.1

IDENTIFICATION OF THE SUBSTANCE

Table 1.1 Substance identification

CAS No.	11138-47-9 ^{a)}	
EINECS No.	234-390-0 ^{a)}	
EC name	Perboric acid, sodium salt	
CAS name	Perboric acid, sodium salt	
IUPAC name	Sodium perborate	
Sub-groups sodium perborates		
Synonyms:	sodium perborate monohydrate ^{b)} sodium peroxoborate monohydrate, PBS1; PBSM "anhydrous sodium perborate" ^{c)}	sodium perborate tetrahydrate ^{b)} sodium peroxoborate tetrahydrate PBS4; PBST "sodium perborate hexahydrate" ^{c)}
EINECS no:	239-172-9 [1]	not available
EC name:	Sodium perborate [1]	
CAS no:	15120-21-5 [1] 10332-33-9 [2]	10486-00-7 [3] 13517-20-9 [4]
CAS name:	Perboric acid (H3BO2(O2)), monosodium salt [1] Perboric acid (HBO(O2)), sodium salt, monohydrate [2]	Perboric acid (HBO(O2)), sodium salt, tetrahydrate [3] Perboric acid (H3BO2(O2)), monosodium salt, trihydrate [4]
Molecular formula according to CAS ^{d)} :	BH ₃ O ₄ .Na [1] BHO ₃ .H ₂ O.Na [2]	BHO ₃ .4H ₂ O.Na [3] BH ₃ O ₄ .3H ₂ O.Na [4]
Structural formula of the salts:	$\begin{array}{c} \text{OH} \\ \\ \text{HO}-\text{B}-\text{O}-\text{O}^- \text{Na}^+ \quad [1] \\ \\ \text{O}=\text{B}-\text{O}-\text{O}^- \\ \\ \text{Na}^+ * \text{H}_2\text{O} \quad [2] \end{array}$	$\begin{array}{c} \text{O}=\text{B}-\text{O}-\text{O}^- \\ \\ \text{Na}^+ * 4 \text{H}_2\text{O} \quad [3] \\ \\ \text{OH} \\ \\ \text{HO}-\text{B}-\text{O}-\text{O}^- \\ \\ \text{Na}^+ * 3 \text{H}_2\text{O} \quad [4] \end{array}$
Molecular weights g/mol:	99.8 [1/2] ^{e)}	153.9 [3,4] ^{e)}

Table 1.1 continued overleaf

Table 1.1 continued Substance identification

Sub-groups sodium perborates		
Revised structural formulas:	$\left[\begin{array}{c} \text{HO} \quad \text{O}-\text{O} \quad \text{OH} \\ \diagdown \quad \diagup \\ \text{B} \quad \quad \text{B} \\ \diagup \quad \diagdown \\ \text{HO} \quad \text{O}-\text{O} \quad \text{OH} \end{array} \right]^{2-} \cdot 2 \text{Na}^+$	$\left[\begin{array}{c} \text{HO} \quad \text{O}-\text{O} \quad \text{OH} \\ \diagdown \quad \diagup \\ \text{B} \quad \quad \text{B} \\ \diagup \quad \diagdown \\ \text{HO} \quad \text{O}-\text{O} \quad \text{OH} \end{array} \right]^{2-} \cdot 2 \text{Na}^+ \cdot 6 \text{H}_2\text{O}$
	anhydrous sodium perborate ^{c)}	sodium perborate hexahydrate ^{c)}

- Collective CAS/EINECS Number for the mono- and the tetrahydrate of sodium perborate;
- Common, but "old" nomenclature of the sodium perborates;
- Correct term and formula according to Xray diffraction studies (Koberstein et al., 1970);
- According to the "multicomponent molecular formula" as used in the CAS registry system
- Since for exposure calculations and read-across between the monohydrate and the tetrahydrate boron equivalents were used, the differences in the molecular weight can be neglected because the relative boron content of the different formulas the same.

Anhydrous sodium perborate (CAS No. 90568-23-3) and sodium perborate hexahydrate (CAS No. 125022-34-6) (see revised structural formulas above), are in accordance with today's knowledge on the dimeric nature of the peroxoboron anions, i.e. dimers of CAS No.s 10332-33-9 and 10486-00-7, respectively, which are the commonly used "old" formulas. Since it is still customary to use these "old" formulas and nomenclature of the perborates, which disregards the dimeric structure of the molecules, the terms "sodium perborate monohydrate" and "sodium perborate tetrahydrate" are used throughout this assessment report.

Two additional sodium perborates are described in the literature: dehydrated sodium perborate (dexol, oxoborate; CAS No. 7632-04-4) and sodium perborate trihydrate ("old" nomenclature: sodium peroxoborate trihydrate, correct term: "sodium perborate tetrahydrate"; CAS No.s 28962-65-4 and 28108-09-0). The trihydrate is not of commercial importance. Dehydrated sodium perborate is a not well defined compound liberating the releasable oxygen spontaneously as elemental oxygen when coming into contact with water. It is supposed to consist of sodium borate and a boron oxygen radical.

As far as available, data on the trihydrate was included as the environmental behaviour of a substance in general can be stated independent of its water content in the crystalline form. In addition, sodium peroxoborate tetrahydrate turns into the trihydrate and the monohydrate during dehydration. However, the dehydrated compound is not considered further as it has a completely different decomposition behaviour due to its radical structure.

1.2 PURITY/IMPURITIES, ADDITIVES

In the scientific literature the addition of silicates (sodium and magnesium) or other magnesium salts in a concentration range of 0.1 to 10% is described to avoid the decomposition of the technical product.

Table 1.2 Purity, impurities and additives of sodium perborate monohydrate / tetrahydrate

Parameter	CAS-No.	Name	Value	Comment
Purity	10332-33-9	Sodium perborate monohydrate	≥ 94%	-
	10486-00-7	Sodium perborate tetrahydrate	≥ 96%	-
Impurities	1303-96-4 (x 10 H ₂ O) 1330-43-4 (without water)	Borax	< 2%	-
	7732-18-5	Water	≤ 1%	-
	-	several metals	< 200 ppm total metal content	-
Additives	7487-88-9	MgSO ₄	≤ 1.2%	Stabilizer The concentrations in the monohydrate are somewhat higher than in the tetrahydrate; one product contains additionally an unknown stabilizer

The generation of active oxygen in aqueous solutions is the basis for the use of sodium perborate as bleaching component in detergent products and bleaching agents. Therefore, the purity of the technical products is furthermore characterised by their active oxygen content. Pure sodium perborate monohydrate contains a maximum of 16.0% active oxygen, pure tetrahydrate maximum 10.38% (calculated from the empirical formula assuming that the peroxy bridges in the molecules are completely degraded with oxygen emerging). The following data are available for the commercial products:

Monohydrate: approximately 15% w/w
Tetrahydrate: approximately 10% w/w

1.3 PHYSICO-CHEMICAL PROPERTIES

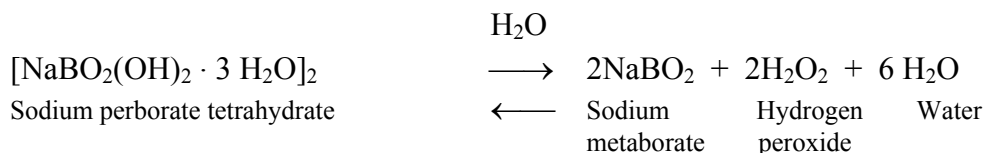
Table 1.3 Summary of physico-chemical properties

Parameter	Sodium perborate monohydrate		Sodium perborate tetrahydrate	
	Value	Comment	Value	Comment
Physical state	Solid			
Melting point (°C)	-	decomposition (only few data available: > 50 - > 180°C)	Approximately 60-65.5	melting in its own crystallization water; beginning decomposition
Boiling point (°C)	-	Decomposition	-	decomposition
Density (20°C)	0.4-0.65	relative density	0.65-0.9	relative density
Vapour pressure (hPa, 20°C)	-	not applicable due to ionic hydrated structure; deliberation of crystallization water at reduced pressure	-	not applicable due to ionic hydrated structure; deliberation of crystallization water at reduced pressure
Surface tension (mN/m, 20°C)	-	it can be assumed that the surface tension of both hydrates is equal	64.6	aqueous solution of 1 g perborate/l
Water solubility (g/l, 20°C)	Approximately 15-16	-	Approximately 23	-
Dissociation constant pKa	-	not applicable due to decomposition	-	not applicable due to decomposition
Partition coefficient log K _{ow}	-	not applicable (analytical difficulties); see also derogation statement and Chapter 1.3	-	not applicable (analytical difficulties); see also derogation statement and Chapter 1.3
Particle size of the technical product (mm)	> 0.1-0.16 (98 %)	details on particle size distribution especially for the fraction below 0.1 mm not available	> 0.1 (95 %)	details on particle size distribution especially for the fraction below 0.1 mm not available
Conversion factor	dose (monohydrate) x 0.108 = equivalent dose (boron) dose (monohydrate) x 0.341 = equivalent dose (hydrogen peroxide)	-	dose (tetrahydrate) x 0.07 = equivalent dose (boron) dose (tetrahydrate) x 0.221 = equivalent dose (hydrogen peroxide)	-

The sodium perborates are white, odorless crystalline powders (20°C, 1013 hPa). The molecular crystalline structure consists of dimeric [(HO)₂(BOO)]- units which form symmetric cyclic hexagonal anions with two peroxo bridges each. In its crystalline form the substances are stable under dry conditions. Sodium perborate tetrahydrate dehydrates at elevated temperatures (starting at temperatures of about 50°C) via the trihydrate towards the monohydrate which then decomposes to the metaborate.

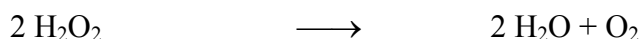
Aqueous solutions of sodium perborate react like alkaline solutions of hydrogen peroxide. As far as the technical relevant concentrations are concerned the pH of 10.1 to 10.4 is practically not dependent on the concentration of the substance in water. However, at low concentrations in the mg/l range pH values of 8 to 9 are to be expected. Considering the use of the perborate in detergent products and bleaching agents furthermore the rate of dissolution in water is of technical relevance. The dissolution of the monohydrate in water proceeds much more rapidly than that of the tetrahydrate.

In aqueous solutions at room temperature an equilibrium between sodium perborate and hydrogen peroxide/sodium metaborate is instantly established:



At low concentrations (about ≤ 2 g/l, i.e. also in the environmentally relevant concentration range) the equilibrium is largely on the side of the hydrolysis products whereas at higher concentrations (about ≥ 12 g/l) the undissociated molecule is present in aqueous solutions.

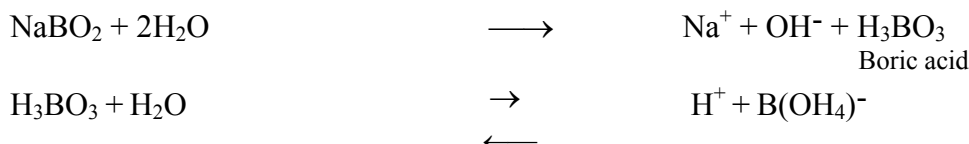
Via degradation to (active) oxygen and water the hydrogen peroxide can be removed from the equilibrium leading to an irreversible shift of the equilibrium (equation above) to the degradation products sodium metaborate and water:



This reaction is the basis of the bleaching effect of the sodium perborate in the washing process.

The active oxygen concentration in the aqueous solutions of sodium perborate serves as a measure of the degree of their decomposition. It can be determined via titration of the hydrogen peroxide or potentiometrically. Unfortunately, these methods are shifting the equilibrium reaction towards the end products and therefore may be afflicted with considerable uncertainties. From the measurement of the boron content of the solutions the degradation rate of the perborates cannot be determined either as it cannot be decided whether sodium perborate or sodium metaborate/boric acid, respectively, are the underlying sources. The analytical determination of the perborate anion itself is not possible.

The degradation product sodium metaborate is the salt of a strong base (sodium hydroxide) and a weak acid (boric acid). Therefore, the substance is expected to be present in aqueous solutions at environmental temperature and pH mainly as the weakly dissociated boric acid (pKa value at room temperature 9.25):



Further considerations on degradation products of sodium perborate e.g. in the hazard part of this risk assessment will therefore focus on boric acid as the predominant species.

1.4 CLASSIFICATION

Current classification

The provisional classification by manufacturer (see IUCLID data sheet of 27th of May, 1999) is:

Table 1.4 Provisional classification by manufacturer

Classification	Sodium perborate monohydrate	Sodium perborate tetrahydrate
Class of danger	O, Xn, Xi	Xi
R phrases	R8, R22, R36/38	R36

Proposed classification

Environment: The EU Working Group on Classification and Labelling of Dangerous Substances has agreed not to classify Sodium perborate as dangerous for the environment (C&L meeting in June 2003).

Sodium perborate is instable in water. The hydrolysis respectively degradation products hydrogen peroxide and boric acid (i.e. boron) have been taken into account for classification.

The EU Working Group on Classification and Labelling has decided to classify neither hydrogen peroxide nor boric acid as dangerous for the environment.

Human health: The EU Working Group on Classification and Labelling of Dangerous Substances has agreed on split-entries dependent on particle size as follows (C&L meeting in March 2006):

Sodium perborate monohydrate:

- containing < 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm: O; R8 - Repr. Cat.2; R61 - Repr. Cat.3; R62 - Xn; R22 - Xi; R37-41 (with Specific Concentration Limits for eye irritation and reproductive toxicity)
- containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm: O; R8 - Repr.Cat.2; R61 - Repr.Cat.3; R62 - T; R23 - Xn; R22 - Xi; R37-41 (with Specific Concentration Limits for eye irritation and reproductive toxicity)

Sodium perborate tetrahydrate:

- containing < 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm: Repr.Cat.2; R61 - Repr.Cat.3; R62 - Xi; R37-41 (with Specific Concentration Limits for eye irritation and reproductive toxicity)
- containing ≥ 0.1% (w/w) of particles with an aerodynamic diameter of below 50 µm: Repr.Cat.2; R61 - Repr.Cat.3; R62 - Xn; R20 - Xi; R37-41 (with Specific Concentration Limits for eye irritation and reproductive toxicity).

2

GENERAL INFORMATION ON EXPOSURE

Production

In the EU member states, 12 production sites of 7 producers were identified. At four of these sites the production was ceased recently. The remaining are located in Austria, Belgium, Germany, Italy, Portugal and Spain.

Sodium perborate tetrahydrate is commercially the by far more important compound compared to the monohydrate. Sodium perborate monohydrate is produced at most of the sites but the produced quantities of the monohydrate amount only to about 10 to 20% of the tetrahydrate. In a total, the consumption ratio of sodium perborate monohydrate versus tetrahydrate is estimated to 15:85.

The perborate quantities for the European market are almost exclusively produced in the EU member states. A production of ca. 570 000 tonnes/year is reported for 1997, with 1% of the production quantity (approximately 5,000 tonnes/year) being imported, and 27% of the production quantity exported (153,000 tonnes/year).

Uses

Sodium perborate mono- and tetrahydrate are used as oxidising and bleaching agents mainly in detergents (approximately 96%; household detergents as well as detergents for institutional uses) and also in cleaning (e.g. automatic dishwashers, stain removers in form of bleach booster tablets) and cosmetic preparations (denture cleansers) (approximately 4%). In the laundry washing perborates are applied in regular and compact heavy-duty powders. Additional minor uses are detergents in hospital cleaning and as preservative in artificial tears (see the Human Health part of the RAR).

Due to their slow rate of degradation at low temperatures (leading to slow deliberation of active oxygen in the washing process), in the past the substances were used in heavy-duty detergents only for washings that can be boiled. Since about 20 years bleaching activators are added to the washing powders which accelerate the degradation rate already at temperatures between 30 and 40°C.

Trends

There is no clear trend concerning the production quantities of sodium perborate in the past ten years. Whereas in mid- and Northern Europe the consumption of washing powders is decreasing since 1989 with an increasing use of compact powders (market share > 50%) the countries of Southern Europe show an increasing tendency in the consumption of washing powders with a decrease in the application of compact powders (market share 10-20%). The increased use of compact powders will not necessarily lead to a decrease in the consumption of bleaching agents per washing cycle, on the contrary there may be a slight increase.

There is some evidence, however, that perborate was partly substituted by percarbonate in the last years and that the importance of percarbonate as a bleaching agent will increase further. In Germany the number of perborate containing laundry detergents for domestic and institutional uses has decreased significantly within the last four years. From investigations in the frame of the German Washing and Cleaning Agents Act, the quantities of sodium perborate and sodium percarbonate in laundry detergents can be estimated to be about the same in 2000, sodium percarbonate quantities being slightly higher. However, in dish washing detergents sodium

perborate is the bleaching agent with the highest used amount, sodium percarbonate having only a share of 20%.

3 ENVIRONMENT

3.1 ENVIRONMENTAL EXPOSURE

Environmental releases

Sodium perborate may be released into the environment during its production, formulation, use and disposal. Releases from processing are considered to be negligible. Emissions may occur into the atmosphere, the hydrosphere and as solid wastes with the hydrosphere being by far the most important target compartment for releases from the wide dispersive use of detergent products and bleaching agents.

From the degradation behavior of sodium perborate it is concluded that in most cases boric acid is the relevant compound in the aquatic environment. Only at production and formulation sites without STP hydrogen peroxide releases into surface water can occur which were already evaluated in the EU Risk Assessment on Hydrogen Peroxide. Consequently, concentrations in the receiving environmental compartments are given in relation to the summary term “boron” being the parameter which is determined in chemical analyses. However, it has to be kept in mind that, besides the perborates, there are numerous other sources for the occurrence of boron compounds in the environment including natural sources.

During the use of consumer products containing sodium perborate for cleaning and bleaching purposes the perborate is intentioned to be decomposed to hydrogen peroxide which is the acting agent in the bleaching and cleaning process and to sodium metaborate which is mainly available as boric acid under environmental conditions.

From this it can be assumed that apart from the releases of sodium perborate during the industrial production and the formulation of detergent products and bleaching agents the aquatic environment will be mainly exposed to its degradation products.

Environmental fate

Whereas in sterile and in pure water no degradation of sodium perborate could be observed, a rapid primary degradation in industrial and municipal STP as well as in domestic waste water can be expected. Hence, for the exposure assessment concerning the elimination of sodium perborate in STPs complete biodegradation of the compound is assumed. Degradation was also observed in natural surface waters, exhibiting a half-life of 59 hours.

No experimental results are available for the decomposition of sodium perborate by direct and indirect photochemical reactions in water and air and for the degradation in soil.

Studies on the environmental distribution behaviour of sodium perborate are not available. From the ionic structure of the substances a significant volatilisation from water is not to be expected. Due to the intended decomposition during use and the degradation in the aquatic environment an assessment of the adsorption behaviour should be derived from the data on the degradation products, where water-soluble borates have a slight tendency for adsorption to soil, sediment particles and sewage sludge, depending e.g. on pH, organic matter content and the number of active adsorption sites. However, boric acid, the predominant borate species present at acidic pH levels, was found to be mobile in soil and sediment. At relevant environmental pH values of ≤ 7 no significant adsorption of boron compounds in soil and the aquatic compartments are to be expected.

Experimental data on the bioaccumulation of sodium perborate is not available. Due to the ionic nature of sodium perborate and its degradation products a potential for bioaccumulation is not to be expected. Bioconcentration factors (BCF) calculated from borate concentrations in field collections of several fish were in the range of 0.1 - 1.25 indicating no significant potential for bioaccumulation which should also be true for boric acid. Hydrogen peroxide generated from sodium perborate will be rapidly degraded by abiotic and biotic processes.

Environmental concentrations

Monitoring data on the sodium perborates themselves were not identified as only indirect methods are available for the analytical determination. The hydrogen peroxide emerging during degradation of the sodium perborate can be assumed to be rapidly degraded to water and oxygen, whereas the remaining boric acid is stable in the aqueous phase. Boron in form of borate is furthermore released by the weathering of rocks so that also surface waters in remote areas may contain small amounts of boron from natural sources. From measurements in several German rivers, the detergents based fraction of the boron concentrations in surface waters was estimated to be between 50 and 70% for the 70's and early 80's.

3.1.1 Aquatic environment

Due to the wide dispersive use of detergent products and bleaching agents the hydrosphere is by far the most important target compartment for releases. Predicted Environmental Concentrations (PEC) on the basis of boron are calculated for the local aquatic environments of the production and formulation sites using all site specific information available. In case of missing site-specific information, the default values of the TGD were used.

Table 3.1 Summary of PEC_{local} for the aquatic environment

	PEC _{local} _{water} (mg boron/l)	PEC _{STP} (mg boron/l)
Production	0.18 - 0.7 *	0.1 - 1526 *
Formulation	0.18 - 0.5 *	0 - 3.2 *
consumer use of detergent products and bleaching agents	0.6 #	4.29 #
institutional use of detergent products and bleaching agents	0.4 #	1.71 #

* Based on site specific data;

EUSES calculations

Significant releases of hydrogen peroxide into surface water from consumer and institutional use can be excluded as the substance is completely degraded during the washing process and in domestic waste water.

The PEC_{regional}_{water} was calculated to be 0.18 mg boron/l, the PEC_{continental}_{water} 0.06 mg boron/l (using EUSES).

From their inorganic structure it can be concluded that boron compounds will not adsorb to organic matter. PEC_{local}_{sediment} cannot be calculated with the estimation method given in the TGD as this method is based on the adsorption of substances to the organic matter of the sediment. From the scientific literature, however, there is no evidence for a significant adsorption of the substances to soil or sediment under environmentally relevant conditions. An

accumulation of any of the borate salts in the sediment is not to be expected and the quantification of $PEC_{local, sediment}$ seems to be of minor importance.

3.1.2 Atmosphere

The PEC_{local} for the atmosphere are summarised in **Table 3.2**.

Table 3.2 Summary of PEC_{local} for the atmosphere

	$PEC_{local, air}$ (mg/m ³)
Production	0.3 – 11.4 *
Formulation	0.03 #
consumer use of detergent products and bleaching agents	no significant releases expected
institutional use of detergent products and bleaching agents	no significant releases expected

* Based on site specific data;

EUSES calculations

For the calculation of the regional exposure 10% of the estimated emission from production, formulation and use is used as input for the calculation of the $PEC_{regional, air}$. Data on atmospheric emissions for the formulation of sodium perborate containing products are not available. From the use of the respective consumer products no relevant emissions into the atmosphere are to be expected. With the basic data of the regional system an atmospheric concentration of $> 25 \text{ ng boron/m}^3$ ($= 338 \text{ ng sodium perborate/m}^3$) can be calculated. This is a maximum concentration for the boron content of the gaseous phase as wet and dry deposition processes, leading to a removal of the substances from air, were not considered. Due to the high water solubility of the sodium perborate and borate salts these deposition processes are considered to reduce the atmospheric concentrations considerably.

Concerning the total tropospheric burden for gas-phase and particulate boron, a contribution of 0.002–0.009% to the natural atmospheric boron burden from the use of detergents can be estimated. Hydrogen peroxide which may emerge from the degradation of airborne sodium perborate is also considered to be of minor importance due to the numerous other sources of atmospheric hydrogen peroxide from photo-oxidative processes (see EU Risk Assessment Report on Hydrogen Peroxide).

3.1.3 Terrestrial compartment

The possible emissions into the terrestrial compartment e.g. via waste from production cannot be quantified as data on the treatment of waste are lacking.

Releases from the application of sodium perborate or borate containing activated sludge appear to be of minor importance as no significant adsorption of sodium perborate or boric acid onto activated sludge from STPs is to be expected under environmentally relevant conditions. Also hydrogen peroxide generated from sodium perborate will degrade rapidly in the sludge and therefore no hydrogen peroxide emissions to soil from the application of sludge will be assumed.

For the deposition of sodium perborate from emissions into the atmosphere (e.g. from production sites), it can be assumed that sodium perborate is solely emitted with dust and further completely adsorbed onto the airborne aerosol. The total aerial deposition flux/kg soil and day calculated

according to TGD for the production sites is then in the range of some nanograms to $\leq 3 \mu\text{g}/\text{kg}$ soil and day. The estimated releases from formulation are even lower. Aerial deposition of sodium perborate is therefore assumed to be of minor importance.

3.2 EFFECTS ASSESSMENT

3.2.1 Aquatic compartment (incl. sediment)

Decomposition behaviour of sodium perborate in aqueous solution together with the analytical problems concerning the determination of perborates in water do not allow conclusions on the nature of the substance or degradation products, to which test species were exposed during exposure in laboratory tests on aquatic toxicity. In aqueous solutions, sodium perborate is in equilibrium with hydrogen peroxide with the equilibrium being largely on the side of hydrogen peroxide in the environmentally relevant concentration range. So it can be concluded that short-term effects are dominated by the presence of hydrogen peroxide (active oxygen) in the aqueous solutions.

For the evaluation of short-term effects in aquatic compartments, therefore the Predicted No Effect Concentration for H_2O_2 was used ($\text{PNEC}_{\text{aquatic}} = 10 \mu\text{g}/\text{l}$) (see EU RAR on Hydrogen Peroxide).

After degradation of hydrogen peroxide the remaining borate species should be the sole toxicologically relevant substances with sodium metaborate being the first degradation product and boric acid assumed to be the relevant long-term degradation product. Undissociated boric acid is expected to be the predominant boron species in natural fresh water with a pH of 6-9 and should be responsible for possible aquatic toxicity in this compartment. An extensive evaluation of the effect data available for boric acid will be performed within the risk assessment of the priority substances boric acid and the sodium tetraborates.

For sediment dwelling organisms, no experimental results are available and the application of the estimation method given in the TGD is not assumed to be adequate for ionic substances. So a PNEC for sediment dwelling organisms cannot be calculated. However, due to the rapid decomposition in natural water containing viable microorganisms together with the insignificant adsorption potential, benthic organisms in surface waters are expected to be sufficiently covered by the PNEC derived for aquatic organisms of the water-phase.

For the derivation of a $\text{PNEC}_{\text{microorganisms}}$, the slight inhibitory effect (treated here as LOEC) of sodium perborate trihydrate on activated sludge activity observed at 500 mg sodium perborate/l was considered. In this test, the effect on two different parameters was determined both indicative for microbial activity/degradation potential of activated sludge. As the measured endpoints are directly related to the protection of the microbial degradation activity in STP, an assessment factor of 1 was applied leading to a $\text{PNEC}_{\text{microorganisms}}$ of 500 mg sodium perborate/l.

3.2.2 Terrestrial compartment

Experimental studies on the effects of sodium perborate on terrestrial organisms are not available. As for the assessment of effects on sediment dwelling organisms, the application of the estimation method given in the TGD is not assumed to be adequate for ionic substances.

3.2.3 Atmosphere

Experimental studies on the effects of sodium perborate in the atmosphere were not available.

3.2.4 Secondary poisoning

Due to the ionic nature of sodium perborate and their degradation products a potential for bioaccumulation is not to be expected. Furthermore, the emerging hydrogen peroxide will be reduced rapidly.

3.3 RISK CHARACTERISATION

Water is the main target compartment of sodium perborate due to its physico-chemical properties and its use pattern. As the substance is instable in water the hydrolysis and degradation products, hydrogen peroxide and boric acid (i.e. boron), respectively, have to be considered for risk assessment.

The risk assessment on hand assesses the risk arising from sodium perborate and its degradation product hydrogen peroxide. The conclusions drawn solely refer to the risk arising from these substances.

The degradation product boric acid will be assessed in the future EU Risk Assessment on boric acid and sodium tetraborates.

3.3.1 Aquatic compartment (incl. sediment)

3.3.1.1 Production

Hydrogen peroxide: For production sites with STP it is assumed that hydrogen peroxide is completely degraded in the STP or that there are no emissions. 6 out of 9 production sites of sodium perborate were already assessed in the EU Risk Assessment Report on Hydrogen Peroxide as these are also production sites for hydrogen peroxide. There is one production site with sole production of sodium perborate. This site has no STP, but it has changed the production process in July 2001 so that sodium perborate is no longer emitted. Therefore, it is assumed that no hydrogen peroxide is emitted either and **conclusion (ii)** can be derived for this site. For two production sites (C, F) producing sodium perborate as well as hydrogen peroxide – having no STP and being already assessed in the EU Risk Assessment Report on hydrogen peroxide - **conclusion (ii)** applies as production of sodium perborate ceased in 2003 at both sites.

3.3.1.2 Formulation

Hydrogen peroxide: For those formulation sites with STP it is assumed that hydrogen peroxide is completely degraded in the STP. The two remaining formulation sites stopped detergent formulation. Thus, **conclusion (ii)** applies to all formulation sites.

3.3.1.3 Processing

Only very small amounts of the production quantity are used in organic synthesis. A significant additional risk from possible releases into the aquatic compartment is not to be expected.

Conclusion (ii).

3.3.1.4 Consumer use of detergents and bleaching agents

It is assumed that hydrogen peroxide is completely degraded during the washing process and in domestic waste water. This has therefore not to be considered further in the risk characterisation.

Conclusion (ii).

3.3.1.5 Institutional use of detergents and bleaching agents

It is assumed that hydrogen peroxide is completely degraded during the washing process and in domestic waste water. This has therefore not to be considered further in the risk characterisation.

Conclusion (ii).

Microorganisms in STP

For all production sites and all formulation sites **conclusion (ii)** can be derived.

Only very small quantities of sodium perborate are processed in chemical synthesis – a quantification of PEC_{stp} seems therefore not to be necessary.

Due to its rapid degradation in the washing process and in domestic waste water it is not to be expected that significant amounts of sodium perborate are released to STPs from the consumer and institutional use of detergents and bleaching agents.

Information on the $PEC/PNEC_{stp}$ for the degradation product hydrogen peroxide can be found in the EU Risk Assessment Report on Hydrogen Peroxide.

Sediments

It is not to be expected that sodium perborate or its degradation product boric acid adsorb significantly onto the sediment. Therefore, a risk characterisation for this compartment is not deemed necessary.

3.3.2 Terrestrial compartment

Data on the treatment of waste from production and formulation are lacking. Emissions into the terrestrial compartment from sewage sludge or via atmospheric deposition are assumed to play a minor role. Studies on the effects of sodium perborate on terrestrial organisms are not available.

As it is to be assumed that sodium perborate will degrade rapidly in soils, terrestrial organisms may further be exposed to the degradation product boric acid. An effects evaluation for these compounds will be carried out in a EU Risk Assessment Report on boric acid and sodium tetraborates.

3.3.3 Atmosphere

Under dry conditions no degradation of sodium perborate will occur. An effects assessment for airborne sodium perborate seems not of high priority as the atmosphere is not the main target compartment of the substance. It is furthermore to be expected that airborne sodium perborate will be rapidly washed out of the atmosphere by wet deposition due to its high water solubility.

Conclusion (ii) applies to all life cycle steps as there are no significant releases to be expected.

3.3.4 Secondary poisoning

From the ionic structure of sodium perborate and its degradation product boric acid it can be concluded that a significant accumulation of these substances in the biota is not to be expected. Also the bioaccumulation potential of hydrogen peroxide emerging during degradation is low (see EU RAR on Hydrogen Peroxide). A risk characterisation of non-compartment specific effects relevant to the food chain is therefore not necessary.

4 HUMAN HEALTH

4.1 HUMAN HEALTH (TOXICITY)

4.1.1 Exposure assessment

4.1.1.1 Occupational exposure

Production

Production of sodium perborate is essentially a continuous process conducted in closed systems. The process itself is automated and all operations are fully located within a closed building.

Dust exposure may occur during filling operations and maintenance. Since there were no significant differences in concentrations measured during individual workplace operations, these operations will not be considered separately in the risk assessment. The medians of measurements range from 0.43 to 2.14 mg/m³. The more recent measurements at workplaces with presumed high exposure show that exposure concentrations may be in the order of 1 mg/m³, which is chosen as typical value for the risk assessment. The highest 90th percentile value of 12.1 mg/m³ is used for the reasonable worst case.

The possibility of dermal exposure to perborate containing solutions (3-10%) during cleaning and maintenance operations is reported. Skin contact to sodium perborate containing dust or respective solutions may occur during weighing/mixing, transport of bags and laboratory operations as far as these processes are carried out semi-automated or manual. Measured data on dermal exposure are not available. Based on EASE calculations, the value of 12 mg/kg bw/day was taken forward for risk assessment.

Formulation

Most operations during formulation are continuous automated processes. Intermittent exposure only occurs in semi-automated filling, emptying, transferring, weighing and mixing operations and in maintenance and disposal/waste management operations.

Dust measurements from detergent factories show that in general exposure to sodium perborate by inhalation is lower than in the perborate production. 90th percentiles of the overall exposure concentrations ranged from 0.18 to 0.93 mg/m³. Data on the concentrations of respirable dust and on the size distribution of the dust particles are lacking. The perborate concentrations in commercial detergent products are generally between 5 and 25%, and at a maximum 50%. As data on the perborate content of the dust are lacking, the worst case is assumed that dust concentrations are solely caused by sodium perborates.

For dermal exposure measured data were not available. Based on EASE calculations, the value of 12 mg/kg bw/day was taken forward for risk assessment.

Occupational exposure from end uses

Exposure from professional use of detergents may occur in laundries, canteens or restaurants and from the use of detergents for hospital cleaning. In professional laundries, the powder is

dispensed and prediluted in a closed dosing system. Exposure occurs only very occasionally during maintenance or troubleshooting. The exposure in laundries can vary from 4 to 12 times per day for the person who doses powder (up to 20% w/w sodium perborate) in the washing machine dispenser. Occupational exposure from the use of the end products is considered as negligible.

4.1.1.2 Consumer exposure

Use of detergent products

For the risk assessment, it was assumed that the exposure from detergent products (such as laundry detergents and dishwashing detergents) occurs only to sodium perborate tetrahydrate because this compound is commercially more important.

Since detergents containing sodium perborate are either granulated or in tablet form, dust release is low. Considering the maximum estimated exposure concentration of less than $0.008 \mu\text{g}/\text{m}^3$ and the very low exposure duration, exposure by inhalation is negligible.

Dermal exposure to sodium perborate may occur during handling of these products, i.e. during machine filling operations. Furthermore, although sodium perborate is only in heavy duty laundry detergents for machine washing, it might be possible that these detergents are used also for handwashing. For this scenario, a maximum exposure to sodium perborate of less than 1 mg/kg bw per day is calculated (for a bw of 70 kg), which is negligible.

Use of bleaching agents

The estimations for the exposure to bleaching agents (such as denture cleansers and stain removers) are related to sodium perborate monohydrate as this substance appears to be commercially more relevant in these products than the tetrahydrate. Consumer exposure from the use of denture cleansers may occur either by absorption from the mucous membranes or by swallowing of the solution. Assuming 100% absorption, an internal dose of 0.17 mg/kg bw per day is estimated. Exposure by handling of denture cleanser or bleach booster tablets is considered to be negligible. Due to the tablet form of the preparation, release of powder from tablets is not to be expected.

Use as preservative in artificial tears

The content of sodium perborate in artificial tears is 0.28 mg/g. Assuming that 20 mg of the artificial tears are applied 10 times per day and that absorption is 100%, the resulting dose would be 0.0008 mg/kg bw per day (for a body weight of 70 kg), which is negligible.

Use in mouthwash solutions

According to recent information some smaller companies may sell mouth wash solutions containing sodium perborate. After mouthwashing, the 3% of the dose remaining in the mouth is swallowed and nearly completely absorbed in the gastrointestinal tract. Assuming two mouthwashes per day, the daily dose would be 72 mg sodium perborate per person or 1 mg/kg bw per day (for a body weight of 70 kg).

4.1.1.3 Humans exposed via the environment

Possible sources for an indirect exposure of the general public to sodium perborate are inhalation of ambient air and, as the hydrosphere is the main target compartment of the substance, consumption of drinking water and skin contact with water.

Indirect exposure by inhalation is not to be expected for sodium perborate and boric acid. Significant quantities of airborne dust will not emerge from the use pattern and the physico-chemical properties of these substances. From the use of detergents, a contribution of 0.002-0.009% to the natural atmospheric boron burden (releases from oceans, burning of coal and refuse, volcanic activities) was estimated. Therefore, production, formulation and use of sodium perborate are of minor importance for indirect exposure via inhalation and will not be considered further in this risk assessment.

An oral uptake of sodium perborate itself via drinking water is not to be expected due to hydrolysis. Also the emerging hydrogen peroxide should not reach the drinking water due to degradation. The uptake of boron (in the form of boric acid) via drinking water is reported in the literature without specifying the underlying sources. In a worldwide data compilation of the WHO it was found that the most values were clearly below 0.4 mg/l. In contrast, bottled mineral water of different origin showed in a number of cases significantly higher concentrations up to 4 mg/l, which perhaps is due to the geological surroundings of the various springs. Assuming a maximum value of 0.4 mg boron/l drinking water and a contribution of 50 to 70% to the boron content of the fresh water from the use of sodium perborate containing detergents and bleaching agents, a maximum of about 0.2 mg boron/l drinking water may be caused by the use of sodium perborate.

No quantification is possible for dermal exposure to borate or hydrogen peroxide during swimming and bathing in natural waters. However, this exposure path is regarded as minor important and will not be considered further in this risk assessment.

4.1.1.4 Combined exposure

Exposure at the workplace has been identified to be by far the most important source of human exposure to sodium perborate. Therefore combined exposure is not considered relevant.

4.1.2 Effects assessment

4.1.2.1 Toxicokinetics, metabolism and distribution

From a study with human volunteers using mouthwash solutions it can be concluded that oral absorption is 100%. The blood boron concentrations reached the maximum 2 hours after administration and returned to the initial level within 1-2 days after single mouthwash as well as after prolonged treatment. Sodium perborate is degraded to boric acid and H₂O₂ and is excreted as boric acid via the urine.

No information is available on absorption via inhalation. Since the lung is rather effective in the degradation of H₂O₂ due to the presence of catalase, the equilibrium between perborate and its degradation products is shifted towards the degradation products, leading to further degradation of sodium perborate. The absorption via inhalation of sodium perborate hydrates is assumed to be 100%.

There are no valid quantitative data on the absorption of sodium perborate following dermal exposure. Absorption from the mucous membranes of the mouth seems to be low. Dermal absorption of H₂O₂ is negligible. A thorough investigation showed that dermal absorption of other boron compounds is very low. Therefore for the risk assessment dermal absorption of 1% was assumed.

No data are available on the metabolism and the distribution of sodium perborate within the body. From investigations with other boron compounds, it may be suspected that elevated boron concentrations are found in the bones.

4.1.2.2 Acute toxicity

In animal experiments, after oral intake typical findings were hyperaemia and necrosis of the stomach. Dogs showed a strong vomiting reflex due to the pressure resulting from H₂O₂ production and subsequent oxygen release. Based on studies performed according to current guidelines, sodium perborate monohydrate should be classified as “Harmful if swallowed” (Xn; R22) due to the oral LD₅₀ in rats of 1,800 mg/kg bw. No classification is required for the perborate tetrahydrate with an oral LD₅₀ in rats of 2,567 mg/kg bw.

According to an acute inhalation study showing an LC₅₀ of 1,164 mg/m³ sodium perborate tetrahydrate (thoracic fraction of dust particles) should be classified as “Harmful by inhalation” (Xn; R20). Based on read across and the knowledge from acute oral studies, the thoracic particle fraction of sodium perborate monohydrate should also be classified as T; R23.

For the dermal route, due to the LD₅₀ of more than 2,000 mg/kg bw for the monohydrate no classification is required and it is assumed that the same holds for the tetrahydrate, which was less toxic via the oral route due to the higher water content.

4.1.2.3 Irritation

Skin irritation: Both, sodium perborate monohydrate and tetrahydrate tested as a solid substance according to the criteria for classification should not be classified as skin irritants.

However, in some studies with the monohydrate after prolonged exposure very mild irritating effects were observed which were not completely reversible in some cases. Solutions of 10% sodium perborate tetrahydrate are mildly irritating.

Eye irritation: Sodium perborate caused strong eye irritation in animal studies, the effects being not reversible in most of the animals tested. Although the scores for irritation are not sufficient for classification with R41, due to the irreversibility of the effect both sodium perborate monohydrate and tetrahydrate are proposed to be classified with Xi; R41, “Risk of serious damage to eyes”.

4.1.2.4 Corrosivity

Sodium perborate is not to be classified as corrosive to skin.

4.1.2.5 Sensitisation

Sodium perborate is not to be regarded as a skin sensitising substance. Furthermore, there is no concern for respiratory sensitisation.

4.1.2.6 Repeated dose toxicity

Oral: Effects after oral application of sodium perborate can be attributed to the degradation products. In a 28-day study the only dose investigated was 1,000 mg/kg bw which showed effects on the stomach, spleen and the haematopoietic system. Thus the LOAEL is 1,000 mg sodium perborate tetrahydrate/kg bw (70 mg boron/kg bw) and no NOAEL can be derived.

Inhalation: For sodium perborate no animal studies are available for repeated dose toxicity by inhalation. From a rat inhalation study with H₂O₂ a NAEC of 13.1 mg/m³ can be calculated for sodium perborate. However, the target of intoxication and consequently the NOAEC for sodium perborate particles may be different from H₂O₂ gas.

Although no clear NOAEC can be derived for repeated dose lung effects in workers, the health surveillance data that have been obtained over up to 20 years from a high proportion of the workplaces with the highest potential exposure levels suggest that there is no concern with regard to possible obstructive lung effects such as asthma or chronic bronchitis.

Slight and temporary reversible irritating effects have been found in the eyes and in the nose. These effects may be attributed to peak exposures, as they were reported only incidentally. Assuming that all sodium perborate is deposited in the upper airways and is degraded to H₂O₂, the NOAECs from H₂O₂ can be applied: The provisional human NOAEC of 1.4 mg/m³ for irritating effects of H₂O₂ on the upper airways corresponds to a NAEC of 6.3 mg/m³ for sodium perborate tetrahydrate.

Dermal: Bearing in mind the results from the oral studies and that sodium perborate is not taken up very efficiently by the skin, the NOAEL of the dermal repeated dose toxicity study of 200 mg/kg bw, which was the highest dose tested, may be too low.

4.1.2.7 Mutagenicity

In vitro studies without metabolic activation show a genotoxic potential of sodium perborate, which may be due to the generation of H₂O₂. Since the effects of H₂O₂ are reduced in the presence of catalase, the genotoxic potential of sodium perborate may not be relevant in vivo. Furthermore and in contrast to H₂O₂, due to its ionisation sodium perborate itself should be taken up less easily by cells than H₂O₂.

4.1.2.8 Carcinogenicity

No animal data on carcinogenicity of sodium perborate is available. In the 28-day test, 1,000 mg/kg bw sodium perborate tetrahydrate led to hyperplasia of the fundic mucosa of the stomach in rats. It may be speculated that, in analogy to H₂O₂, prolonged exposure to high irritating concentrations of sodium perborate may cause tumours as a consequence of increased cell proliferation. From the reversibility of the effects on the stomach with sodium perborate as well as with H₂O₂, it can be argued, that doses, which would not lead to irritation, also would not lead to tumour formation.

4.1.2.9 Toxicity for reproduction

Fertility

The testes are target organs of toxicity of boron compounds. In the 28-day study after oral application of 1,000 mg sodium perborate tetrahydrate/kg bw a decrease in absolute testes weights was recorded, which could be an early sign of testicular toxicity, however without a reduction in relative testis weight. Histological examinations of the testes did not reveal any signs of toxicity at 1,000 mg/kg bw, whereby testes were fixed with formalin, a method which allows only detection of major effects as it leads to cellular shrinkage.

At the meeting in October 2004, the Specialised Experts declared that the 28-day study of Degussa (1989) alone was very limited and insufficient for classification. Since boric acid as a metabolite of sodium perborate is systemically available, a NAEL of 249 mg/kg bw was deduced for sodium perborate tetrahydrate based on read across from the boron content. The dose level of 1,000 mg/kg bw is considered a LOAEL and is taken forward to Risk Characterisation.

Developmental toxicity

In a study on developmental effects of sodium perborate tetrahydrate according to OECD Guideline 414, 100 mg/kg bw of sodium perborate tetrahydrate was regarded by the authors of the study as the NOAEL for both maternal and developmental toxicity.

External malformations observed at 100 mg/kg bw were statistically significant but considered incidental due to lack of dose response. Therefore, these effects were not taken into consideration for deriving the NOAEL.

4.1.3 Risk characterisation

The risk assessment is carried out on sodium perborate tetrahydrate, as more data are available on this compound than on sodium perborate monohydrate. Sodium perborate tetrahydrate is less toxic than the monohydrate, as can be seen from acute toxicity data. This is in agreement with its higher water content. However the differences are considered as minor, compared to other uncertainties in the evaluation of the database.

For some consumer exposure scenarios, exposure will be to the degradation products boric acid and hydrogen peroxide and not to sodium perborate. For these exposure scenarios the risk for hydrogen peroxide is evaluated based on the EU Risk Assessment for Hydrogen Peroxide. For boric acid the risk will be evaluated in the future EU Risk Assessment Report on Boron Compounds.

4.1.3.1 Workers

Inhalation: There is no concern for acute toxicity, irritation, sensitisation, mutagenicity and carcinogenicity for workers exposed in production and formulation of sodium perborate and from exposure to the end product. **Conclusion (ii).**

The risk from repeated exposure has been assessed for 3 effects: Systemic effects, lung effects (by using spirometric investigations from workplace surveillance data) and effects on the upper airways (NAEC extrapolated from data with H₂O₂).

Systemic effects were assessed by applying route to route extrapolation from the oral route (LOAEL_{oral rat} of 1,000 mg/kg bw → LAEC_{inhalation worker} of 1,736 mg/m³). There is no concern for systemic effects for any exposure scenario. **Conclusion (ii)**.

For the lung effects no definitive NOAEL could be derived, as corresponding exposure measurements are not available for the health surveillance data. Nevertheless, due to the complete absence of effects in workforces of several production plants **conclusion (ii)** can be drawn for workers in production, and consequently also for workers in formulation or the use of the end product, who are exposed to lower exposure concentrations than the production workers.

The situation is different for effects on the upper airways. Assuming that all sodium perborate is deposited in the upper airways and decomposed to H₂O₂, the NOAEC for H₂O₂ can be applied. Both derived NAECs for sodium perborate, either extrapolated from a rat study (13.1 mg/m³) or from human experience (6.3 mg/m³), show that, for the reasonable worst-case concentration, there is concern for irritative effects, during the production of 12 mg/m³. This fits very well to the actual experience with sodium perborate, that accidentally effects have been reported which probably can be related to high exposure concentrations. Therefore, **conclusion (iii)** is drawn for this scenario. No concern is derived for the typical exposure in production plants of 1 mg/m³ and for all other worker exposure scenarios.

For the assessment of developmental effects, route to route extrapolation was performed (NOAEL_{oral rat} of 100 mg/kg bw → NAEC_{inhalation worker} of 174 mg/m³). Taking into consideration the interindividual differences and the type of effect, a MOS of 14 leads to the conclusion that there is concern for production workers at reasonable worst case exposure i.e. **Conclusion (iii)**. In contrast, the MOS is sufficient for the reasonable worst-case exposure in formulation and use of the end product, for typical exposure in all worker scenarios as well as for effects on fertility i.e. **Conclusion (ii)**.

Dermal exposure: The risk characterisation for dermal exposure concludes that there is no concern for all endpoints and exposure scenarios. **Conclusion (ii)**.

Combined exposure: From the highest exposure value of 12.1 mg/m³ a body dose of about 2 mg/kg bw/day can be derived assuming 10 m³ respired per workday, 100% absorption in the lung and 70 kg bw. The maximum dermal dose would be 0.12 mg/kg bw assuming 1% absorption, which is negligible compared to the uptake via inhalation. Therefore the conclusions derived for uptake via inhalation also hold for combined exposure.

4.1.3.2 Consumers

Inhalation: As the exposure by inhalation is negligible during handling of detergents, there is no risk for all endpoints.

Dermal: There is no concern for systemic toxicity of sodium perborate hydrates for any endpoint from the handling of detergent products either as solution or as powder, since the exposure is negligible and the absorption is very low. This includes also irritation/corrosivity because the concentration of sodium perborate in detergents is only approximately 0.3%. For comparison, 10% solutions of sodium perborate are only mildly irritating. Furthermore, there is no concern for eye irritation from the use of sodium perborate in artificial tears, which contain very low concentrations (0.028%), presumably below any irritation threshold.

Oral: The use of sodium perborate in mouthwash solutions is a very minor use. However it leads to the highest exposure concentrations of all consumer exposure scenarios of 1 mg/kg bw/day.

Therefore a risk characterisation was performed: **conclusion (ii)** applies to all endpoints. Lower exposure concentrations were derived for the use of sodium perborate in denture cleansers and in artificial tears. Therefore also for these exposure scenarios there is no concern for all endpoints.

4.1.3.3 Humans exposed via the environment

Indirect exposure to sodium perborate is not to be expected due to the degradation of the compound. Also no exposure to H_2O_2 is expected due to the hydrolysis.

For boric acid the consumption of drinking water was identified as the only relevant boron source resulting from the commercial use of sodium perborate hydrates in detergent products and bleaching agents. A drinking water concentration of about 0.2 mg boron/l at a maximum would correspond to a body dose of 6 μ g boron/kg bw/day, assuming a consumption of 2 l drinking water/d and a body weight of 70 kg. This corresponds to 25% of the background exposure of 24 μ g boron/kg bw/day via food in Germany. This exposure scenario will be discussed in the foreseen EU risk assessment on the boric acid and sodium tetraborates.

4.1.3.4 Combined exposure

Exposure to sodium perborate at the workplace by inhalation is by far higher than consumer exposure. Therefore combined exposure is not relevant.

For H_2O_2 , the exposure to the compound itself is by far more important than exposure from the degradation of sodium perborate. The combined exposure to boric acid from different sources will be addressed in the planned EU risk assessment on the boric acid and sodium tetraborates.

4.2 HUMAN HEALTH (PHYSICO-CHEMICAL PROPERTIES)

From the physico-chemical properties of sodium perborate hydrates no adverse effects on human health are to be expected for workers and consumers. The substances are not flammable or explosive. Sodium perborate monohydrate is classified as oxidising. Involved in fire both perborate hydrates may decompose yielding oxygen which supports combustion.

5 RESULTS

5.1 ENVIRONMENT

5.1.1.1 Aquatic compartment (incl. sediment)

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

This conclusion applies to all production and formulation sites, for processing as well as the consumer and institutional use of detergents and bleaching agents for the aquatic compartment (water). Furthermore, this conclusion applies to all production and formulation sites for microorganisms in STP.

5.1.1.2 Terrestrial compartment

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

A risk characterisation for this compartment is not deemed necessary.

5.1.1.3 Atmosphere

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

This conclusion applies to all life cycle steps.

5.1.1.4 Secondary poisoning

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

A risk characterisation for non-compartment specific effects relevant for the food chain is not deemed necessary.

5.2 HUMAN HEALTH

5.2.1 Human health (toxicity)

5.2.1.1 Workers

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

This conclusion applies to highly exposed workers in the production of sodium perborate via inhalation of dust. There is concern for effects on the upper airways and for developmental effects.

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

This conclusion applies to all other scenarios and endpoints.

5.2.1.2 Consumers

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

This conclusion applies to all scenarios and endpoints.

5.2.1.3 Humans exposed via the environment

Indirect exposure to sodium perborate is not to be expected due to the degradation of the compound. Therefore, a risk characterisation is not deemed necessary.

5.2.1.4 Combined exposure

Exposure to sodium perborate at the workplace by inhalation is by far higher than consumer exposure. Therefore combined exposure is not deemed to be relevant.

5.2.2 Human health (risks from physico-chemical properties)

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

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perboric acid, sodium salt

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The report provides the comprehensive summary of the risk assessment of the substance sodium perborate (sodium perborate monohydrate and sodium perborate tetrahydrate). It has been prepared by Austria in the frame of Council Regulation (EEC) No. 793/93 on the evaluation and control of the risks of existing substances, following the principles for assessment of the risks to humans and the environment, laid down in Commission Regulation (EC) No. 1488/94.

Part I - Environment

This part of the evaluation considers the emissions and the resulting exposure to the environment in all life cycle steps. Following the exposure assessment, the environmental risk characterisation for each protection goal in the aquatic, terrestrial and atmospheric compartment has been determined.

The environmental risk assessment concludes that there is no concern for any compartment arising from the use of the substance.

Part II – Human Health

This part of the evaluation considers the emissions and the resulting exposure to human populations in all life cycle steps. The scenarios for occupational exposure, consumer exposure and humans exposed via the environment have been examined and the possible risks have been identified.

The human health risk assessment concludes that there is no concern for the endpoints acute toxicity, irritation, sensitisation, mutagenicity, carcinogenicity, and fertility for workers in production. No concern for any endpoints also applies to workers during formulation and contact to end products, as well as to consumers and humans exposed via the environment.

For workers in the production of sodium perborate, there is concern for effects on the upper airways and for developmental effects after high inhalation exposure to sodium perborate dust.

The conclusions of this report will lead to risk reduction measures to be proposed by the Commission's committee on risk reduction strategies set up in support of Council Regulation (EEC) N. 793/93.

