

Directive 98/8/EC concerning the placing biocidal products on the market

Inclusion of active substances in Annex I or IA to Directive 98/8/EC

Assessment Report



Disodium octaborate tetrahydrate

Product-type 8

(Wood preservative)

20 February 2009

Annex I – the Netherlands

Disodium octaborate tetrahydrate (PT 8)**Assessment report**

Finalised in the Standing Committee on Biocidal Products at its meeting on 19 September 2008 in view of its inclusion in Annex I to Directive 98/8/EC

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1. STATEMENT OF SUBJECT MATTER AND PURPOSE

1.1. Procedure followed

This assessment report has been established as a result of the evaluation of Disodium octaborate tetrahydrate as product-type 8 (wood preservative), carried out in the context of the work programme for the review of existing active substances provided for in Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market¹, with a view to the possible inclusion of this substance into Annex I or IA to the Directive.

Disodium octaborate tetrahydrate (CAS no. 12280-03-4) was notified as an existing active substance, by Rio Tinto Minerals and Societa Chimica Larderello spa in a joined notification, hereafter referred to as the applicant, in product-type 8.

Commission Regulation (EC) No 1451/2007 of 4 December 2007² lays down the detailed rules for the evaluation of dossiers and for the decision-making process in order to include or not an existing active substance into Annex I or IA to the Directive.

In accordance with the provisions of Article 7(1) of that Regulation, the Netherlands was designated as Rapporteur Member State to carry out the assessment on the basis of the dossier submitted by the applicant. The deadline for submission of a complete dossier for Disodium octaborate tetrahydrate as an active substance in Product Type 8 was 28 March 2004, in accordance with Annex V of Regulation (EC) No 2032/2003.

On 27 March 2004, the Netherlands competent authorities received a dossier from the applicant. The Rapporteur Member State accepted the dossier as complete for the purpose of the evaluation on 24 September 2004.

On 7 July 2006, the Rapporteur Member State submitted, in accordance with the provisions of Article 14(4) and (6) of Regulation (EC) No 1451/2007, to the Commission and the applicant a copy of the evaluation report, hereafter referred to as the competent authority report. The Commission made the report available to all Member States by electronic means on 25 July 2006. The competent authority report included a recommendation for the inclusion of Disodium octaborate tetrahydrate in Annex I to the Directive for product-type 8.

In accordance with Article 16 of Regulation (EC) No 1451/2007, the Commission made the competent authority report publicly available by electronic means on 17 October 2006. This report did not include such information that was to be treated as confidential in accordance with Article 19 of Directive 98/8/EC.

In order to review the competent authority report and the comments received on it, consultations of technical experts from all Member States (peer review) were organised by the Commission. Revisions agreed upon were presented at technical and competent authority

1 Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. OJ L 123, 24.4.98, p.1

2 Commission Regulation (EC) No 1451/2007 of 4 December 2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. OJ L 325, 11.12.2007, p. 3

meetings and the competent authority report was amended accordingly.

On the basis of the final competent authority report, the Commission proposed the inclusion of Disodium octaborate tetrahydrate in Annex I to Directive 98/8/EC and consulted the Standing Committee on Biocidal Product on 20 February 2009.

In accordance with Article 15(4) of Regulation (EC) No 1451/2007, the present assessment report contains the conclusions of the Standing Committee on Biocidal Products, as finalised during its meeting held on 20 February 2009.

1.2. Purpose of the assessment report

This assessment report has been developed and finalised in support of the decision to include Disodium octaborate tetrahydrate in Annex I to Directive 98/8/EC for product-type 8. The aim of the assessment report is to facilitate the authorisation in Member States of individual biocidal products in product-type 8 that contain Disodium octaborate tetrahydrate. In their evaluation, Member States shall apply the provisions of Directive 98/8/EC, in particular the provisions of Article 5 as well as the common principles laid down in Annex VI.

For the implementation of the common principles of Annex VI, the content and conclusions of this assessment report, which is available at the Commission website³, shall be taken into account.

However, where conclusions of this assessment report are based on data protected under the provisions of Directive 98/8/EC, such conclusions may not be used to the benefit of another applicant, unless access to these data has been granted.

1.3. Overall conclusion in the context of Directive 98/8/EC

The overall conclusion from the evaluation is that it may be expected that there are products containing Disodium octaborate tetrahydrate for the product-type 8, which will fulfil the requirements laid down in Article 5 of Directive 98/8/EC. This conclusion is however subject to:

- i. compliance with the particular requirements in the following sections of this assessment report,
- ii. the implementation of the provisions of Article 5(1) of Directive 98/8/EC, and
- iii. the common principles laid down in Annex VI to Directive 98/8/EC.

Furthermore, these conclusions were reached within the framework of the uses that were proposed and supported by the applicant (see [Appendix II](#)). Extension of the use pattern beyond those described will require an evaluation at product authorisation level in order to establish whether the proposed extensions of use will satisfy the requirements of Article 5(1) and of the common principles laid down in Annex VI to Directive 98/8/EC.

³ <http://ec.europa.eu/comm/environment/biocides/index.htm>

2. OVERALL SUMMARY AND CONCLUSIONS

2.1. Presentation of the Active Substance

2.1.1. Identity, Physico-Chemical Properties & Methods of Analysis

Identity of the active substance

The CAS no. of Disodium octaborate tetrahydrate used in this CA-report is 12280-03-4.

The EC no. of Disodium octaborate tetrahydrate used in this CA-report is 234-541-0.

The minimum purity data presented by the notifier do not comply with impurity data and tests with the active substance. Based on impurity data and tests with the active substance, the minimum purity specification proposed by the RMS is 97.5% (w/w) expressed as $\text{Na}_2\text{B}_8\text{O}_{13}\cdot 4\text{H}_2\text{O}$ for both manufacturers.

There are no additives, no impurities > 1 g/kg and no (eco)toxicologically relevant impurities.

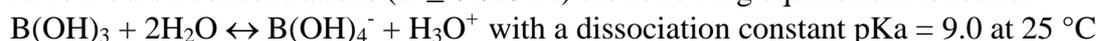
Physical and chemical properties of the active substance

Disodium octaborate tetrahydrate is a white, odourless solid. A melting point is found at 813/803 °C. A boiling point is not applicable.

The water solubility, dissociation constant, partition coefficient, and surface tension for disodium octaborate tetrahydrate as such cannot be determined because disodium octaborate tetrahydrate is converted into boric acid/borate upon dissolution in water: $\text{Na}_2\text{B}_8\text{O}_{13}\cdot 4\text{H}_2\text{O} + 9\text{H}_2\text{O} \leftrightarrow 2\text{NaB}(\text{OH})_4 + 6 \text{B}(\text{OH})_3$. The water solubility, dissociation constant, partition coefficient, and surface tension found will be the ones for an equivalent amount of boric acid in the presence of sodium ions.

Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donor). For this purpose the formula for boric acid is best written as $\text{B}(\text{OH})_3$.

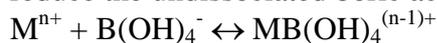
At low boron concentrations ($\text{B} \leq 0.025 \text{ M}$) the following equilibrium is found:



In dilute aqueous solutions ($\text{B} \leq 0.025 \text{ M}$) boric acid exists as undissociated boric acid $\text{B}(\text{OH})_3$ at $\text{pH} < 7$, at $\text{pH} > 11$ the metaborate ion $\text{B}(\text{OH})_4^-$ becomes the main species in solution. At in between values ($\text{pH} 7\text{-}11$) both species are present.

At higher boron concentrations ($\text{B} > 0.025 \text{ M}$) an equilibrium is formed between $\text{B}(\text{OH})_3$, polynuclear complexes of $\text{B}_3\text{O}_3(\text{OH})_4^-$, $\text{B}_4\text{O}_5(\text{OH})_4^{2-}$, $\text{B}_3\text{O}_3(\text{OH})_5^{2-}$, $\text{B}_5\text{O}_6(\text{OH})_4^-$ and $\text{B}(\text{OH})_4^-$. In short: $\text{B}(\text{OH})_3 \leftrightarrow \text{polynuclear anions} \leftrightarrow \text{B}(\text{OH})_4^-$. In acid solution at $\text{pH} < 5$, boron is mainly present as $\text{B}(\text{OH})_3$ and in alkaline solution at $\text{pH} > 12.5$, boron is mainly present as $\text{B}(\text{OH})_4^-$. At in between values ($\text{pH} 5\text{-}12$) polynuclear anions are found as well as $\text{B}(\text{OH})_3$ and $\text{B}(\text{OH})_4^-$.

In the presence of metal ions (e.g. Na, Mg, Ca) ion-pair complexes are formed, which further reduce the undissociated boric acid concentration:



These ion pair complexes are expected to be present in solutions of disodium tetraborate, disodium octaborate and buffered solutions of boric acid and boric oxide.

Vapour pressure and Henry's law constant are not applicable, because experimental data indicate that the vapour pressure is less than 10^{-5} Pa at ambient temperature. The water solubility for disodium octaborate tetrahydrate is 223.65 g/L (water solubility for boric acid in the presence of sodium ions). Disodium octaborate tetrahydrate is a non-flammable solid and

a flash point is not applicable. The active substance has no explosive and no oxidising properties.

Analysis of the active substance as manufactured

There are no methods to determine the active substance as manufactured or in the formulation. Instead, analytical methods are developed to determine the B₂O₃ and Na₂O content in boron based compounds.

Soil

Total boron can be extracted from soil by hot acid extraction with HNO₃ and HCl under reflux or by microwave digestion with HNO₃ and HF, with addition of HCl and H₂O₂ when needed. Several extraction methods are used to estimate the bioavailable boron fraction, of which the hot water soluble extraction is the most widely used.

Water

Boron can be detected in aqueous solutions by spectrophotometry after reaction with azomethine-H, or by ICP-AES.

Air

No data submitted. No data necessary.

Summary information on the identity and physico-chemical properties and analytical methods of Disodium octaborate tetrahydrate can be found in Appendix I to this document (List of Endpoints).

2.1.2. *Intended Uses and Efficacy*

Product type and field of use envisaged

Main group 2: preservatives

Product type 8: wood preservative

Disodium octaborate tetrahydrate is intended to be used as a preventive and curative wood preservative for wood and construction timbers in Use Classes 1, 2, 3 and 4a according to CEN 335-1 standard.

User

Industrial, Professional, Non-professional

Function

Fungicide and/or insecticide

Application

Products are applied by vacuum pressure, dipping, injection, spraying/deluge or brushing.

The assessment of the biocidal activity of the active substance demonstrates that it has a sufficient level of efficacy against the target organism(s) and the evaluation of the summary data provided in support of the efficacy of the accompanying product, establishes that the product may be expected to be efficacious.

In addition, in order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the intended uses of the substance, as identified during the evaluation process, are listed in [Appendix II](#).

2.1.3. Classification and Labelling

It is proposed to classify borates with reproduction category 2 and assign risk phrases R60-61. This is in line with the proposal of the EU commission working group of specialised experts in the field of reproduction toxicology (2004).

Proposed classification for the active substance Disodium octaborate tetrahydrate (identical to 67/548/EEC)

Class of danger	T
R phrases	R60-61

2.2. Summary of the Risk Assessment

2.2.1. Human Health Risk Assessment

The toxicokinetics and toxicological effects of boric acid, disodium tetraborate, boric oxide (B_2O_3) and disodium octaborate tetrahydrate are likely to be similar on a boron equivalents basis. Therefore, the data obtained from studies with different borates can be read across in the human health assessment for each individual substance.

2.2.1.1. Hazard assessment

Toxicokinetics

Absorption of borates via the oral route is nearly 100%. For the respiratory route also 100% absorption is assumed. Dermal absorption through intact skin is very low. For risk assessment of borates a dermal absorption of 0.5% is used as a reasonable worst case approach. In the blood boric acid is the main species present. Boric acid is not further metabolised. Boric acid is distributed rapidly and evenly through the body, with concentrations in bone 2-3 higher than in other tissues. Boron is excreted relatively rapidly with elimination half-lives of 1h in the mouse, 3h in the rat and 21h in humans, and has low potential for accumulation. Boric acid is mainly excreted in the urine.

Acute toxicity

Disodium octaborate tetrahydrate and other borates are of low acute toxicity: LD_{50} oral rat > 2000 mg/kg; LD_{50} dermal rat > 2000 mg/kg; LC_{50} inhalation rat > 2 mg/l (highest attainable concentration).

Irritation and Corrosivity

Disodium octaborate tetrahydrate is not a skin irritant or an eye irritant.

Sensitization

No signs of skin sensitization were observed in Buehler method skin sensitization tests with Disodium octaborate tetrahydrate or other borates and no evidence of skin sensitization in humans exposed occupationally to borates has been reported. Disodium octaborate tetrahydrate needs not to be classified as a skin sensitizer.

Repeated dose toxicity

In the repeated dose studies with mouse and rat (and dog although studies are not acceptable), consistently effects on the testes and on blood parameters were found. In the 90 days study in

the mouse and the 2 year study in the rat the animals appeared to be more sensitive to the effects on the haematopoietic system than on the testes. Similar results were obtained from studies with disodium tetraborates. The 2 years feeding study with boric acid in rats yielded an overall NOAEL (100 mg/kg bw, equal to 17.5 mg B/kg bw/day), based on reduction bodyweight, clinical sign of toxicity, in males testicular atrophy and reductions in red cell volume and Hb at a dose of 334 mg/kg bw/day (58.5 mgB/kg bw/day). This finding is supported by the study with disodium tetraborate decahydrate.

Genotoxicity

Disodium octaborate tetrahydrate has no genotoxic potential.

Carcinogenicity

In carcinogenicity studies in mice and rats no evidence of a carcinogenic effects of boric acid or sodium tetraborate decahydrate was observed. It is concluded that boric acid is unlikely to pose a carcinogenic risk.

Reproductive toxicity

Teratogenicity

The most sensitive species for developmental effects appears to be the rat. The NOAEL for embryotoxic/teratogenic effects of boric acid was 55 mg/kg bw/day (9.6 mg B/kg bw/day), based on a reduction in mean foetal body weight/litter and an increased incidence in short rib X111, which is considered a variation, at 76 mg/kg bw/day (13.3 mg B/kg bw/day). The relevance of the observed developmental effects for humans is not clear.

Fertility

In a multigeneration reproduction toxicity study in the rat with boric acid severely impaired reproductive potency was observed at 336 mg/kg bw/day. At this dose also marked reductions (70%) in relative testes weights were observed. At lower doses no reproductive effects or effects on testes weight were observed. These findings suggest that a reduction in testes weight will result in an impaired fertility. Since this study was seriously flawed, no definitive conclusions on the effects of boron on fertility in the rat can be drawn. Other repeated dose studies in several animal species have consistently demonstrated that the testis is a primary target organ for boron. Based on the data from the 2 years feeding study with boric acid in rats, the overall NOAEL for fertility is therefore 100 mg/kg bw/day, equal to 17.5 mg B/kg bw/day. This conclusion is supported by the study with disodium tetraborate decahydrate.

Neurotoxicity

No neurotoxic studies were available for the present evaluation. CNS depression was observed in poisoning cases in humans. Apart from the CNS effects that occur at these very high doses there are no indications that boric acid or other borates have neurotoxic properties. No neurotoxicity studies are required.

Human data

It has been suggested that the potential lethal oral dose of boric acid is 3-6g in children and 15-20 g for adults. However, lethal doses are not well documented. Acute effects may include nausea, vomiting, gastric discomfort, skin flushing, excitation, convulsions, depression and vascular collapse. Multiple exposure (high levels > 1g) results in various symptoms which may appear singly or together and include dermatitis, alopecia, loss of appetite, nausea, vomiting, diarrhoea, and focal or generalised central nervous system irritation or convulsions. Infants aged from 6 to 16 weeks who ingested sodium tetraborate at doses of about 0.98 g boric acid/day for periods of 4 to 12 weeks showed convulsions, generalised seizures and focal seizures.

Workers exposed occupationally to borax dust at concentrations of about 4 mg/m³ reported eye irritation, dry mouth, nose or throat, sore throat, acute and chronic respiratory irritation and productive cough.

Effects on human reproduction

In human epidemiological cohort study in Turkey no effects on reproduction were observed in populations exposed to high levels of boron through drinking water. However, this conclusion was based on the number of children born over a period of 15 years. Other endpoints such as time to pregnancy and number of miscarriages were not included. In a study in the USA, the fertility of male workers of a borax mine was studied. The study revealed that the workers exposed to low (<0.82 mg/m³) or high (>5.05 mg/m³) levels of boron in dust fathered more live births than was estimated on the basis of the data of the US general population. The extent to which the workers are comparable to the US general population however was not clear. Also in this study other endpoints such as time to pregnancy were not established.

2.2.1.2. Critical endpoints and assessment factors

Overall NOAEL

The toxicological data base reveals that the major targets for toxicity of borates are the testes and the blood. In the repeated dose studies with mouse, rat and dog, consistently effects on the testes and on blood parameters were found. In a 90 days study in the mouse the animals appeared to be more sensitive to the effects on the haematopoietic system than on the testes. In the rat effects on both the testes and on the blood were observed at dose levels of 334 mg boric acid/kg bw/day. The NOAEL in this study was 100 mg/kg bw/day (17.5 mg B/kg bw/day). Similar results were obtained from studies with disodium tetraborate decahydrate at equimolar doses of boron. Based on the NOAEL for embryotoxic/teratogenic effects of boric acid of 55 mg/kg bw/day (9.6 mg B/kg bw/day) the overall NOAEL is 9.6 mg B/kg bw/day.

Total assessment factor

The available information on kinetics and dynamics does not allow refinement of the standard assessment factors (10 for interspecies variation and 10 for intraspecies variation).

There are indications that the sensitivity for the effects on the testes does not differ markedly between subchronic and chronic exposure. Therefore the application of an additional assessment factor for extrapolation from subchronic to chronic exposure is not required.

ADI (acceptable daily intake) and ARfD (acute reference dose).

The borates will be used as wood preservatives. The borates are not used on wood products that are used for food preparation or feeding stuff. Furthermore finished wood products containing borates and manufactured for structural and building material are not appropriate to be used and would not be used to make products that would come in to contact with food or feeding stuff. Therefore the derivation of an ADI and ARfD is considered not necessary.

Drinking water limit

Based on the overall NOAEL (9.6 mg boron/kg bw/day), which was found in the developmental study in the rat and the overall assessment factor of 100, a tolerable daily intake (TDI) of $9.6/100 = 0.096$ mg/kg bw/day can be established. If 10% of the TDI is allocated to boron in drinking water, and assuming that an adult weighs 60 kg and consumes 2 litre drinking water per day, a drinking water guideline value 0.29 mg/L can be derived.

The WHO established in 1998 a drinking water guideline value of 0.5 mg/L, based on an overall NOAEL of 9.6 mg boron/kg bw per day from a developmental toxicity study in the rat, and a total assessment factor of 60. Drinking water on average contains 0.1-0.3 mg boron

per litre, while in some regions much higher concentrations have been measured (EHC 204, 1998). Boron in the soil and aquatic environment is predominantly originating from natural weathering of rock and sea water evaporation (EHC 204, 1998). Accordingly, human exposure to boron will probably not have changed significantly over time.

It is clear that a drinking water limit of 0.29 mg/L, as estimated on the basis of the present toxicological data set, will generally not be exceeded.

AOEL (acceptable operator exposure level).

Using the standard assessment factor of 100 (10 for interspecies- and 10 for intraspecies variation) an oral AOEL of 0.096 mg B/kg bw/day can be derived based on the NOAEL for embryotoxic/teratogenic effects of boric acid of 9.6 mg B/kg bw/day. Based on the NOAEL of 17,5 mg B/kg bw/day in a 2-year study in the rat and an assessment factor of 300 due to serious effects and based on the NOAEL of 21.8 mg B/kg bw/day in a teratogenicity study in the rabbit and an assessment factor of 300 due to serious effects AOEL values can be derived of 0.06 and 0.07 mg B/kg bw/day, respectively. For the risk assessment, a rounded (systemic) AOEL value of 0.1 mg B/kg bw/day was used for disodium octaborate tetrahydrate, even though values of 0.06 and 0.07 mg B/kg bw/day could be derived from the critical effects.

MOE (margin of exposure)

Professional users.

For the risk assessment of borates the systemic NOAEL of 9.6 mg/kg bw/day will be used. A MOE of 100 would be considered acceptable, on the basis of the standard assessment factors of 100 (10 x 10) for interspecies and intraspecies variability.

Non-professional users

The developmental studies are considered to be the most relevant for the risk characterization of non-professional users of borates. A MOE of 100 with respect to the NOAEL of 9.6 mg B/kg bw/day from the developmental toxicity study in the rat is considered acceptable.

2.2.1.3. Risk characterisation

Professional users

For calculating the exposure for the 7 processes of professional users, models in the TNsG on human exposure are used.

1. Vacuum pressure impregnation, normal treatment
2. Vacuum pressure impregnation, termite treatment
3. Double vacuum pressure, normal treatment
4. Double vacuum pressure, termite treatment
5. Dipping, normal treatment
6. Automatic spraying / deluge, normal treatment
7. Professional spraying on-site, normal treatment

Based on the AOEL approach and MOE approach it can be concluded that adverse health effects for the unprotected professional user due to the combined dermal and respiratory exposure of Disodium octaborate tetrahydrate, as a result of the 7 processes, cannot be excluded. Using standard protective gloves, coverall and dust masks for mixing and loading and protective gloves and coverall for application is sufficient enough to reduce the exposure to get the risk indices <1 and the MOE's >100 for all of the 7 processes.

Non-professional users.

For calculating the exposure for the 2 processes of non-professional users, models in the TNsG on human exposure are used.

1. Spraying
2. Brushing

Based on the AOEL approach and MOE approach it can be concluded that adverse health effects for the unprotected non-professional user due to the combined dermal and respiratory exposure of Disodium octaborate tetrahydrate, as a result of **spraying** and **brushing** can be excluded.

Indirect exposure as a result of use

For calculating the indirect exposure for 3 situations the reference scenarios in the user guidance TNsG (2002) are used.

1. Exposure during cutting and sanding by non-professionals, single exposure
2. Exposure during cutting and sanding by professionals, repeated, daily exposure
3. Exposure of a child playing on playground structure outdoors, repeated, daily exposure

Exposure due to chewing of wood chippings is considered negligible, as well as the exposure by inhaling volatilised residues indoor.

Based on the AOEL and MOE approach it can be concluded that no adverse health effects for the non-professional user and the professional user due to indirect exposure are expected.

For a child playing on a playground structure outdoors a health risk as a consequence of exposure to borates can be excluded.

2.2.2. Environmental Risk Assessment

Once borates are released to the environment, the predominant species is un-dissociated boric acid. For practical reasons boric acid and other borates are usually expressed on the basis of boron.

Boron is a naturally occurring element that is essential to a variety of organisms. Because of boron being present in natural environments, the background concentrations should be taken into account when deriving PNEC's. Boron concentrations in freshwater systems rarely exceed 1.0 mg B/L and are usually < 0.1 mg B/L. A recent review of European monitoring data report ranges of < 0.001 to 7.5 mg B/L, the mean 95-percentile concentration over 15 European countries ranges from 0.017 mg B/L in the United Kingdom to 0.632 mg B/L in Germany. Oceans have a natural level of boron of about 5 mg/L. Boron concentrations in soil are highly variable, ranges are 4 to 200 mg/kg, mostly as the *unavailable* earth mineral tourmaline and usual levels are 45-124 mg/kg dwt, based on observations in the United States. Boron levels in European groundwaters ranged for Italy and Spain from 0.5 to 1.5 mg/litre (mean boron concentrations); up to approximately 0.6 mg boron/litre in the Netherlands and United Kingdom, and levels in approximately 90% of samples in Denmark, France, and Germany were found to be below 0.3, 0.3, and 0.1 mg boron/litre, respectively. In the following sections, all data refer to added boron, unless stated otherwise.

2.2.2.1. PNEC derivation

The notifier proposed to base the Risk Assessment on total PNEC (i.e. including background concentrations). He argues that the background boron concentration influences a number of biological/ecological processes (e.g. optimal concentration ranges, acclimation/adaptation, and field community responses), and is crucial for the derivation of ecological relevant PNEC values.

The RMS partly agrees with this point of view but considers that other arguments have to be taken into account:

- In the added risk approach both the "Predicted Environmental Concentration" (PEC) and the "Predicted No Effect Concentration" (PNEC) are expressed as B added by man, resulting in an "added Predicted Environmental Concentration" (PEC_{add}) and "added Predicted No Effect Concentration" (PNEC_{add}), respectively. The use of the added risk approach (a method that in principle can be used for all naturally occurring substances) implies that only the anthropogenic amount of a substance, i.e. the amount added to the natural background concentration, is considered to be relevant for the effects assessment of that substance.
- There is inadequate knowledge of the natural Boron concentrations in water, sediment and soil.
- There is insufficient knowledge to incorporate bioavailability.
- No studies are available that indicate acclimatization and adaptation effects to the sensitivity of species to Boron - with the exception of deficiency occurring in some fish and plant studies.
- There is no information that Boron is essential to all biota.

The RMS therefore prefers to conduct the risk assessment on *added concentrations*.

Aquatic compartment

Based on the lowest NOEC of 1.8 mg B/L and an assessment factor of 10 the PNEC_{add,aquatic} for freshwater systems is set to **0.18 mg B/L**. Using equilibrium partitioning the PNEC_{add,sed} is set to **0.24 mg B/kg wwt**. As both PEC_{sed} and PNEC_{sed} values are based on equilibrium partitioning, no further assessment of the risk was performed.

Sewage treatment plants (STPs)

Based on a submitted microbial inhibition test with micro-organisms in activated sludge, a PNEC_{add,STP} of **1.8 mg B/L** was calculated, based on a NOEC of 17.5 mg B/L and applying an assessment factor of 10.

Air

No toxicity data for air were available. Therefore, a PNEC_{air} was not calculated.

Terrestrial compartment

The PNEC_{add,terrestrial} should be regarded as the concentration that may be *added* to the background without inducing adverse effects on the terrestrial ecosystem. It is implicitly assumed that the background concentration itself does not induce a toxic effect and that the background concentration is sufficient to meet the natural demands of the organisms and that there is no risk for deficiency.

The PNEC_{add,terrestrial} is set to **0.4 mg B/kg dwt soil**, equivalent to **0.35 mg B/kg wwt soil**. The applicability of a low PNEC_{add,terrestrial} should be judged in the light of sensitive plant species instead of being focussed solely on tolerant species.

Non compartment specific effects relevant to the food chain (secondary poisoning)

Boron is not bioconcentrated or bioaccumulated along the food chain in both aquatic and terrestrial ecosystems.

2.2.2.2. Exposure and risk characterisation

The environmental exposure assessments have been taken from the OECD Emission Scenario Document Number 1, 2 and 3, Emission Scenario Documents on Wood Preservatives (OECD,

2003) using boric acid as the representative boron compound. Boron is released into the environment during processing, from treated timber in storage after industrial treatment, during end use (in-service period) and during and after in-situ treatment of wood. Releases can enter the aquatic compartment (incl. sediment), soil (incl. groundwater) and to a lesser degree air, depending on the scenario. Applications involve the normal application and application against termites. Application against termites is only taken into account if it is considered relevant for certain scenarios.

The following applications and in-service uses are recognized:

- Processing/storage: Vacuum pressure¹; Double vacuum¹; Automated dipping/industrial deluge; Automated spraying
- In-situ applications: Noise barrier; Bridge; Fence; House; Transmission pole
- Wood in service¹: Noise barrier; Fence; House cladding; Transmission pole; Fence post

¹ scenarios relevant for applications against termites

No emissions to the environment are expected during service life for Use Class 1 (timber under cover including indoor joinery (preventive)) and Use Class 2 (timber under cover including indoor roofing timbers – risk of wetting (preventive)). Therefore Use Class 1 and 2 is considered not to lead to unacceptable risk to the environment.

The risk assessment for the industrial application phase (processing/storage), the *in-situ* treatment, and wood in service (Use class 3 and 4a) are considered below.

As to the waste stage the ESD states the following: “Waste treatment: at this stage the unused wood preservative products or the out-of-service treated wood is disposed of with waste. Waste treatment may consist of incineration or landfill dumping. Releases during these processes are considered through leaching models and release of non-degraded substances during incineration, especially heavy metal oxides. Disposal of wastes from treatment plants or disposal of treated wood after service do not fall under the scope of this ESD document. Waste wood, waste wood dust, protection foil, cleaning solvents, used cans and unused product should be disposed of according to national waste disposal regulations”.

Aquatic Environment (fresh water)

PEC/PNECs are > 1 (in the range of 7.9 to-79) for the in-situ treatments on and in service period of treated bridges over ponds, and a risk is expected. The other uses (processing, storage and wood in service, such as noise barriers) are considered as safe with respect to the risks for surface water.

Aquatic Environment (sediment)

As the $PNEC_{add, sed}$ and the $PEC_{add, sed}$ both are based on equilibrium partitioning, risks found in the aquatic risk assessment related to the bridge over pond scenario also will result in risks for the sediment. The other uses (processing, storage and wood in service, such as noise barriers) are considered as safe with respect to the risks for sediment.

Sewage treatment plants (STPs)

Industrial application and use of treated wood as a noise barrier may result in emission of boric acid to a STP. In all cases, a risk for micro-organisms in the STP is not expected ($PEC/PNEC < 1$).

Assessment of drinking water criterion

According to Directive 98/83/EC Annex I, part B, the limit value for boron in water is 1 mg/L. This value is exceeded in the scenario for *in-situ* treatment and treated wood in service

of a bridge over pond (UC3) (TIME2 PEC values ranging between 3.34 and 14.3 mg B/l) and the PEC/PNEC is also > 1. European monitoring data (Wyness et al. 2003) report ranges of < 0.001 to 7.5 mg B/L, the mean 95-percentile concentration over 15 European countries ranges from 0.017 mg B/L in the United Kingdom to 0.632 mg B/L in Germany. This means that disodium octaborate tetrahydrate (in situ applied and in service) in treated wood of bridges over ponds does **not** comply with the drinking water criteria.

Air

Because of the low vapour pressure, release of borates to air will be minimal. No $PEC_{add,air}$ and $PNEC_{add,air}$ were calculated.

Terrestrial environment

Storage of treated wood after industrial treatment, in-service and in-situ treatment of use class 3 and 4a treated wood will result in emission of boric acid to soil. PEC/PNEC ratios exceed 1 (range 5.1 – 600). Concerning the in-situ treatment of wood and storage of wood after industrial treatment and before shipment reasonable risk mitigation measures are available (see section 3.2 below). The in-service use of treated wood with boric acid for class 3 and 4a applications will lead to unacceptable risks.

Groundwater

The $PEC_{add,grw}$ is estimated from the $PEC_{add,terrestrial}$ using equilibrium partitioning. The calculated $PEC_{add,grw}$ is evaluated according to the criteria for water that will be used for production of drinking water. The limit value for boron is 1 mg B/L (Directive 98/83/EC Annex I, part B).

The $PEC_{add,grw}$ is above 1 mg B/L in all cases (range: 3.1 - 194) and the use of disodium octaborate tetrahydrate does **not** comply with the drinking water criterion.

Assessment of persistence in soil

Being an inorganic compound, boron does not comply with the persistence criteria of $DT_{90,field} < 1$ year and DT_{50} at 20°C < 6 months that are laid down in paragraph 85 of Annex VI to the Biocides Directive and in the TNsG on Annex I inclusion. According to the latter, the degradation triggers do not necessarily apply if the active substance is included in Annex I with regard to areas of use where a long lasting service-life of the treated material is essential and it is scientifically demonstrated that under field conditions there is no unacceptable accumulation in soil (e.g. that the $PEC/PNEC < 1$ in soil during the service-life of the treated article). The application as a wood preservative can be considered as such. It was shown above in Section 2.9.6 that for all Use Classes the PEC/PNEC ratio is far above 1 (range: 150 – 2244). Disodium octaborate tetrahydrate does not meet the criteria for persistence in soil, and is therefore considered persistent.

2.2.2.3. PBT assessment

Being an inorganic compound, boron does not biodegrade in marine or freshwater and sediments, and should therefore be considered as Very Persistent (VP).

Boron is not bioconcentrated, based on the available data the BCF is < 2000 L/kg wwt.

The chronic NOEC of boron for marine or freshwater organisms is > 0.01 mg B/L and boron is not considered to have endocrine disrupting effects. However, based on toxicological data, boron is classified with Toxic for Reproduction category 2 and assigned risk phrases R60 and R61. Therefore, boron should be considered as fulfilling the criteria for Persistence and Toxicity, but not for Bioaccumulation.

Boron does not fulfil the PBT-criteria. Therefore inclusion in Annex I is not restricted by these criteria.

2.2.3. *List of endpoints*

In order to facilitate the work of Member States in granting or reviewing authorisations, and to apply adequately the provisions of Article 5(1) of Directive 98/8/EC and the common principles laid down in Annex VI of that Directive, the most important endpoints, as identified during the evaluation process, are listed in [Appendix I](#).

3. DECISION

3.1. Background to the Decision

Disodium octaborate tetrahydrate is requested for inclusion in Annex I as a wood preservative to be used in Use Classes 1, 2, 3 and 4a by professional and non-professional users. Use Classes 4b and 5 are not included in the present assessment and no inclusion can be granted for these uses.

The unconditional inclusion of Disodium octaborate tetrahydrate in Annex I can only be granted in case efficacy can be demonstrated for all proposed uses and the proposed uses do not lead to an unacceptable risk for humans and the environment.

A conditional inclusion of Disodium octaborate tetrahydrate in Annex I can be granted in case efficacy can be demonstrated and at least one of the proposed uses do not lead to an unacceptable risk for humans or the environment.

The risk assessment for Disodium octaborate tetrahydrate is based on a fictitious model product containing 100% Disodium octaborate tetrahydrate. Actual products based on Disodium octaborate tetrahydrate contain less than 100% Disodium octaborate tetrahydrate, other active substances and additives. Therefore the assessment in this report is indicative. The risks of actual products should be assessed at the product authorisation level.

Inclusion of Disodium octaborate tetrahydrate in Annex I is feasible for the efficacy, human health and environmental aspect because efficacy is demonstrated for certain applications, a safe use is identified for human exposure when using PPE and for environmental exposure when the treated wood is used for Use Class 1 (wood under cover and fully protected from the weather) and Use Class 2 (wood under cover and fully protected from the weather but where high environmental humidity can lead to occasional but not persistent wetting for indoor use and/or incidentally getting wet).

For Use Class 3 and 4a the environmental risk assessment is performed according to the TGD and TNsG's, with high PEC:PNEC ratios ($PEC/PNEC \gg 1$) as a result.

At product authorisation level extra attention should be paid to potential risks for the environment for Use Classes 3 and 4a.

Methods of analysis:

All necessary methods of analysis for Disodium octaborate tetrahydrate are available.

Efficacy:

Pure Disodium octaborate tetrahydrate has shown to be effective against fungi (wet rot, dry rot), egg larvae of wood-boring insects and termites, however, the available data do not permit that final conclusions can be drawn concerning efficacy against all the target organisms to be controlled.

Leaching of most of the impregnated boric acid from treated wood can occur within days/months. No information is available about the influence of leaching on the efficacy of the Disodium octaborate tetrahydrate product.

Labelling and classification:

Disodium octaborate tetrahydrate has a proposed classification with: 'T' (Toxic), R60 (may impair fertility) and R61 (may cause harm to the unborn child). Products containing more than the specific concentration limit of 4.6% of boric acid will be classified with R60-61 and shall not be authorised for marketing to, or use by the general public.

Human health:

Adverse health effects due to the combined dermal and respiratory exposure to Disodium octaborate tetrahydrate can be excluded for the protected professional user using regular PPE, as a result of the proposed uses of the model product based on 100% Disodium octaborate tetrahydrate.

Because of the classification as toxic, products containing more than the specific concentration limit of 4.6% of disodium octaborate tetrahydrate cannot be used by non-professional users, although adverse health effects due to the combined dermal and respiratory exposure to disodium octaborate tetrahydrate can be excluded (see risk assessment).

No adverse health effects due to indirect exposure are expected for the non-professional user and the professional user.

For a child playing on a playground structure outdoors a health risk as a consequence of exposure to borates can be excluded.

Environment:

Storage:

Unacceptable emissions to soil during storage after industrial treatment are expected.

Emissions resulting from storage can for instance be prevented by covering the storage place and/or providing an impermeable storage floor. Under these conditions, the use of Disodium octaborate tetrahydrate is considered not to lead to unacceptable risk to the environment.

Service life of wood:

For Use Class 1 and 2, no emissions to the environment are expected during service life of the treated wood. Use Classes 3 and 4a are expected to lead to risks, resulting from emissions to soil (in-service treated fences and posts, noise barriers, transmission poles and wooden houses) and water (Bridge over pond scenario) during the service life (see table 3.1-1).

In-situ treatment:

Emissions to soil and water during *in-situ* treatment with Disodium octaborate tetrahydrate are expected to lead to risks. Prevention of losses to soil or water during treatment can be prescribed to reduce the PEC/PNEC ratios to below 1.

Table 3.1-1 Summary of environmental risk of Disodium octaborate tetrahydrate.

	Fresh water environment	Sediment	Sewage treatment plants	Drinking water criterion	Persistency in sediment	Air	Terrestrial environment	Groundwater	Persistency in soil
Industrial treatment	-	-	-	-	-	-	n.a.	n.a.	n.a.
Storage of industrial treated wood	-	-	-	-	-	-	+ ^a	+ ^a	+ ^a
Wood in service	-	-	n.a.	-	-	-	+	+	+
<i>In-situ</i> treatment	+ ^b	+	n.a.	+	-	-	+	+	+

- no risk expected
+ risk expected
n.a. not applicable
^a risk reduction possible, for instance storage on hard standing and collection of rainwater
^b only relevant for in-situ treatment of bridges over ponds

3.2. Decision regarding Inclusion in Annex I

The active substance Disodium octaborate tetrahydrate shall be included in Annex I to Directive 98/8/EC as an active substance for use in product-type 8 (wood preservative), subject to the following specific provisions:

The active substance Disodium octaborate tetrahydrate shall have a minimum purity of 975 g/kg expressed as $\text{Na}_2\text{B}_8\text{O}_{13}\cdot 4\text{H}_2\text{O}$.

Member States shall ensure that authorisations are subject to the following conditions:

- (1) Products authorised for industrial and professional use must be used with appropriate personal protective equipment, unless it can be demonstrated in the application for product authorisation that risks to industrial and/or professional users can be reduced to an acceptable level by other means.
- (2) In view of the risks identified for the soil and aquatic compartments appropriate risk mitigation measures must be taken to protect those compartments. In particular, labels and/or safety-data sheets of products authorised for industrial use shall indicate that freshly treated timber must be stored after treatment under shelter or on impermeable hard standing to prevent direct losses to soil or water and that any losses must be collected for reuse or disposal.

3.3. Elements to be taken into account by Member States when authorising products

The risk assessment based on the dummy product showed that the use of Disodium octaborate tetrahydrate in Use Class 1 and 2 is safe. For the use of that product in Use Class 3 and 4a unacceptable risks were identified in the soil and water compartment due to spills during in-

situ treatment and from the in-service leaching of boric acid to soil from treated wood. Disodium octaborate tetrahydrate shall not be authorized in wood preservative products for Use Class 3 and 4a if it has been concluded in the means of comparative assessment that there is a sufficient number of active substances for same use purposes for Use Class 3 and 4a with significantly lower risk and without unacceptable effects.

Disodium octaborate tetrahydrate was intended to be used by industrial, professional and non-professional users. However, Disodium octaborate tetrahydrate was found to be 'Toxic for reproduction category 2 (R60-61)'. Products containing more than the specific concentration limit of 4.6% disodium octaborate tetrahydrate will be classified with R60-61 and, according to article 5 (2) of the Directive, products with this classification shall not be authorised for marketing to, or use by the general public.

Health effects professional user: The risk characterization for human health is based on a 100% Disodium octaborate tetrahydrate product. Actual wood preservatives are based on less than 100% Disodium octaborate tetrahydrate and/or have more than one active substance. When authorising such products appropriate measures must be prescribed to protect professional users in such a way that risk indices are below 1.

Storage stage: The risk to the soil compartment following storage on site of industrial impregnated timber is unacceptable. Therefore emission reducing measures must be prescribed, for instance the storing of treated timber on hard impermeable standing and the collecting of rainwater from the storage area to prevent direct losses of boric acid to soil.

Handling and Storage

No special handling precautions are required, but dry indoor storage is recommended. Good housekeeping procedures should be followed to minimise dust generation and accumulation. No specific fire fighting measures are required since Disodium octaborate tetrahydrate is not flammable, combustible or explosive. The product is itself a flame retardant.

Suitable container material: paper, cardboard, plastic (polypropylene, high density polyethylene).

Unsuitable container material: base metals.

Polypropylene is not suitable for storage at low temperatures due to the brittleness of this material at low temperatures. Polyethylene should therefore be regarded as the preferred container material for Disodium octaborate tetrahydrate.

Emergency measures in case of accident

Inhalation: If symptoms such as nose or throat irritation are observed, remove to fresh air.

In case of contact with eyes: Rinse immediately with plenty of clean water or sterile saline solution for at least 15 minutes. If appropriate, remove contact lenses after 5 minutes rinsing. If symptoms persist, seek medical attention.

Skin contact: No treatment necessary because non-irritating.

Ingestion: Swallowing small quantities (one teaspoon) will cause no harm to healthy adults. If larger amounts are swallowed, give two glasses of water to drink and seek medical attention.

Avoid creation of dust. Use vacuum cleaners wherever possible.

Decontamination

Air: Borates are non-volatile. As a dust borates rapidly settle from the atmosphere.

Water: Borates are naturally occurring minerals and are present in surface and underground waters. Borates are rapidly dissolved in water and will disperse with dilution. Removal at low concentrations is unnecessary. Where water containing high levels of borates can be captured precipitation with lime can be used to reduce boron levels to the 100 ppm range. Treatments

with boron specific ion exchange resins and activated carbon are also possible.

Soil: Borates are naturally found in rocks and soil and are an essential micronutrient for all plant growth. Contaminated soil can be leached with water or acid to reduce boron levels.

Waste Management

Prevention of waste and unintended environmental releases is practiced by most, if not all operations. Storage of treated products is covered so as to prevent leaching and run-off. Small quantities can usually be disposed to landfill sites. No special disposal treatment is required, but local authorities should be consulted about any specific local requirements. Tonnage quantities of products are not considered appropriate for landfills. Such products should, if possible, be used for an appropriate application.

Unintended side effects

Borates are essential micronutrients for all plant life but at high levels they are phytotoxic.

Combustion Products

Fused borate, glass and water.

3.4. Requirement for further information

It is considered that the evaluation has shown that sufficient data have been provided to verify the outcome and conclusions, and permit the proposal for the inclusion of Disodium octaborate tetrahydrate in Annex 1 to Directive 98/8/EC.

3.5. Updating this Assessment Report

This assessment report may need to be updated periodically in order to take account of scientific developments and results from the examination of any of the information referred to in Articles 7, 10.4 and 14 of Directive 98/8/EC. Such adaptations will be examined and finalised in connection with any amendment of the conditions for the inclusion of Disodium octaborate tetrahydrate in Annex I to the Directive.

Appendix I: List of endpoints**Chapter 1: Identity, Physical and Chemical Properties, Classification and Labelling**

Active substance (ISO Common Name)	Disodium octaborate tetrahydrate
Function (<i>e.g.</i> fungicide)	Fungicide, insecticide

Rapporteur Member State	The Netherlands
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Identity (Annex IIA, point II.)

Chemical name (IUPAC)	disodium octaborate tetrahydrate
Chemical name (CA)	disodium octaborate tetrahydrate
CAS No.	Two CAS numbers exist for the same compound. <ul style="list-style-type: none"> • Disodium octaborate tetrahydrate, CAS no 12280-03-4 • Disodium octaborate anhydrous, CAS no 12008-41-2 For this CA-report, CAS no is 12280-03-4 is used (tetrahydrate form). CAS no 12008-41-2 is only used for the anhydrous form and is not assessed in this CA-report.
EC No.	234-541-0 This number is assigned to both disodium octaborate tetrahydrate and disodium octaborate anhydrous. In this CA-report only disodium octaborate tetrahydrate is assessed
Other substance No.	None
Minimum purity of the active substance as manufactured (g/kg or g/l)	The minimum purity data presented by the notifier do not comply with impurity data and tests with the active substance. Based on impurity data and tests with the active substance, the minimum purity specification proposed by the RMS is 97.5% (w/w) expressed as Na ₂ B ₈ O ₁₃ .4H ₂ O for both manufacturers.
Identity of relevant impurities and additives (substances of concern) in the active substance as manufactured (g/kg)	no additives no (eco)toxicologically relevant impurities
Molecular formula	Na ₂ B ₈ O ₁₃ .4H ₂ O
Molecular mass	412.52
Structural formula	Not applicable; the a.s. is an amorphous mixture of boric acid, disodium tetraborate decahydrate/pentahydrate.

Physical and chemical properties

Melting point (state purity)	813/803°C at atmospheric pressure (purity 98% (w/w) expressed as Na ₂ B ₈ O ₁₃ .4H ₂ O)
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Boiling point (state purity)	Not applicable
Temperature of decomposition	A phase transition is found at 567°C.
Appearance (state purity)	Solid white odourless powder (purity not stated)
Relative density (state purity)	1.874 at 22°C (purity 98% (w/w) expressed as Na ₂ B ₈ O ₁₃ ·4H ₂ O)
Surface tension	Not applicable
Vapour pressure (in Pa, state temperature)	Not applicable, because the melting point lies above 300 °C and experimental data indicate that the vapour pressure is less than 10 ⁻⁵ Pa at ambient temperature.
Henry's law constant (Pa m ³ mol ⁻¹)	Not applicable, because the melting point lies above 300 °C and experimental data indicate that the vapour pressure is less than 10 ⁻⁵ Pa at ambient temperature.
Solubility in water (g/l or mg/l, state temperature)	<p>pH_ 7.64: 223.65 g/L at 20.0°C for a super saturated solution (purity 98.0% (w/w) expressed as Na₂B₈O₁₃·4H₂O)</p> <p>-----</p> <p>The water solubility for disodium octaborate tetrahydrate as such cannot be determined because disodium octaborate tetrahydrate is converted into boric acid/borate upon dissolution in water.</p> <p>Water solubility studies at pH=5, 7, 9 are not possible, because of the strong buffering capacity of boric acid solutions and ion-pair formation in the presence of alkali-metal ions like Na, K.</p> <p>Temperature dependence of water solubility should be investigated</p> <p>Solubility measurements in the liquid, remaining after precipitation of an oversaturated solution are desirable. The effect of temperature on this solubility is also desirable.</p>
Solubility in organic solvents (in g/l or mg/l, state temperature) (Annex IIIA, point III.1)	Not required. The a.s. is not used in organic solvents nor would solubility data give any relevant information for the risk assessment.
Stability in organic solvents used in biocidal products including relevant breakdown products (IIIA, point III.2)	Not relevant.
Partition coefficient (log P _{ow}) (state temperature)	<p>pH_5: not investigated</p> <p>-----</p> <p>pH_7: not investigated</p> <p>-----</p> <p>pH_9: not investigated</p> <p>-----</p> <p>pH_7.5: -1.09 at 22°C in potassium/sodium phosphate buffer at a concentration of 0.0097 M boron (purity 99.0% w/w expressed as H₃BO₃).</p> <p>-----</p> <p>pH_unknown: -0.757 at 25 °C in water at concentration levels between 0.16 - 0.89 M boron (purity not indicated)</p> <p>-----</p> <p>pH_unknown: -0.74 in 2 M KCl at 25 °C</p> <p>pH_unknown: -0.56 in 3 M NaClO₄ at 25 °C</p>

Dissociation constant (not stated in Annex IIA or IIIA; additional data requirement from TNsG)

pH_unknown: -0.55 in 3 M NaClO₄ at 35 °C

The log P_{ow} for disodium octaborate tetrahydrate as such cannot be determined because disodium octaborate tetrahydrate is converted into boric acid/borate upon dissolution in water. The log Pow given is the log P_{ow} for boric acid.

The difference between log P_{ow} values obtained at different temperatures, different salinity, different concentration and different analysis, is only 0.5 log Pow unit. No further tests are required.

The dissociation constant for disodium octaborate tetrahydrate as such cannot be determined because disodium octaborate tetrahydrate is converted into boric acid/borate upon dissolution in water. The dissociation constant given is the dissociation constant for boric acid.

Boric acid is a Lewis acid (hydroxide ion acceptor) rather than a Brønsted acid (proton donator). For this purpose the formula for boric acid is best written as B(OH)₃.

pKa = 9.0 at 25°C for boric acid in dilute solutions only (B ≤ 0.025 M).

At higher boron concentrations, polynuclear complexes are formed and several dissociation/formation constants apply.

UV/VIS absorption (max.) (if absorption > 290 nm state ε at wavelength)

No absorption maximum or minimum found in neutral, basic or acidic medium in the range 190-500 nm. No absorption expected in the range 500-750 nm.

Flammability

Not highly flammable.

Explosive properties

Not explosive.

Classification and proposed labelling

with regard to physical/chemical data

None

with regard to toxicological data

Toxic, R60-61

with regard to fate and behaviour data

None

with regard to ecotoxicological data

None

Chapter 2: Methods of Analysis

Analytical methods for the active substance

Technical active substance (principle of method)
(Annex IIA, point 4.1)

Method BS 5688 : Part 8 :1979 ISO 2216-1972 [ISO title: Crude sodium borates for industrial use- Determination of sodium oxide and boric oxide contents- Volumetric method]. The ISO method has been withdrawn on 27 May 2002 and is not supported by ISO anymore. Because the method is still in use in Australia and the ISO method was withdrawn for the sole reason that the method was not verified anymore every 5 years, the method is considered acceptable by the RMS.

Impurities in technical active substance (principle of method) (Annex IIA, point 4.1)

Not required.

No impurities > 1 g/kg and no (eco)toxicologically relevant impurities.

Analytical methods for residues

Soil (principle of method and LOQ) (Annex IIA, point 4.2)

Total boron can be extracted from soil by hot acid extraction with HNO₃ and HCl under reflux or by microwave digestion with HNO₃ and HF, with addition of HCl and H₂O₂ when needed. Detection by ICP-AES (LOD ca. 4 µg B/L) or by photospectrometry after reaction with azomethine-H (LOD 0.01 – 1 mg B/L). LOQ depends on the extraction method

Air (principle of method and LOQ) (Annex IIA, point 4.2)

Not required.

Water (principle of method and LOQ) (Annex IIA, point 4.2)

Same methods as for soil

Body fluids and tissues (principle of method and LOQ) (Annex IIA, point 4.2)

Although classified as Toxic, no method is required. The same method as for soil can be used.

Food/feed of plant origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)

Not applicable

Food/feed of animal origin (principle of method and LOQ for methods for monitoring purposes) (Annex IIIA, point IV.1)

Not applicable

Chapter 3: Impact on Human Health

Absorption, distribution, metabolism and excretion in mammals (Annex IIA, point 6.2)

Rate and extent of oral absorption:

100%

Rate and extent of dermal absorption:

0.5%

Distribution:

Absorbed boron rapidly distributes throughout the body water in humans and animals.

Potential for accumulation:

Low

Rate and extent of excretion:

Excreted almost exclusively in the urine.

Toxicologically significant metabolite

Half-life < 24 hours.

Does not metabolise

Most of the simple inorganic borates such as boric acid; boric oxide; disodium tetraborate and disodium octaborate tetrahydrate exist predominantly as un-dissociated boric acid in dilute aqueous solution at physiological pH, leading to the conclusion that the main species in the plasma of mammals is un-dissociated boric acid. Since other borates dissociate to form boric acid in aqueous solutions, they too can be considered to exist as un-dissociated boric acid under physiological conditions. For example disodium octaborate tetrahydrate a solid solution of boric acid and disodium tetraborate decahydrate

Acute toxicity (Annex IIA, point 6.1)

Rat LD₅₀ oral

2550 mg/kg bw

Rat LD₅₀ dermal

> 2000 mg/kg bw

Rat LC₅₀ inhalation

> 2010 mg/m³

Skin irritation

Non Irritant

Eye irritation

Non Irritant

Skin sensitization (test method used and result)

Non Sensitiser – Buehler and Human

Repeated dose toxicity (Annex IIA, point 6.3)

Species/ target / critical effect

Testis, blood

Lowest relevant oral NOAEL / LOAEL

17.5 mg boron /kg bw/day

Lowest relevant dermal NOAEL / LOAEL

No data

Lowest relevant inhalation NOAEL / LOAEL

No data

Genotoxicity (Annex IIA, point 6.6)

Negative

Carcinogenicity (Annex IIA, point 6.4)

Species/type of tumour

Negative

lowest dose with tumours

Not relevant

Reproductive toxicity (Annex IIA, point 6.8)

Species/ Reproduction target / critical effect

Rat; mouse and dog testis; Testicular atrophy

Lowest relevant reproductive NOAEL / LOAEL

17.5 mg boron/kg bw/day

Species/Developmental target / critical effect

Rat: reduction in mean fetal body weight/litter, increased incidence in short rib X111)

Rabbit: increased incidence in major heart and/or great vessel malformations

Lowest relevant developmental NOAEL / LOAEL 9.6 mg boron/kg bw/day

Neurotoxicity / Delayed neurotoxicity (Annex IIIA, point VI.1)

Species/ target/critical effect Not relevant

Lowest relevant developmental NOAEL / LOAEL. Not relevant

Other toxicological studies (Annex IIIA, VI/XI)

Not relevant

Medical data (Annex IIA, point 6.9)

The human oral lethal dose is regularly quoted as 2-3 g boric acid for infants, 5-6 g boric acid for children and 15-30 g boric acid for adults. Acute effects of poisoning may include nausea, vomiting, gastric discomfort, skin flushing, excitation, convulsions, depression and vascular collapse. Multiple exposure to high levels of boron may result in dermatitis, alopecia, loss of appetite, nausea, vomiting, diarrhoea, and focal or generalised central nervous system irritation or convulsions.

Workers exposed to borax dust at about 4 mg/m³ reported eye irritation, dry mouth, nose or throat, sore throat, acute and chronic respiratory irritation and productive cough.

In human populations exposed to high boron levels in drinking water or male workers of a borax mine no effects on reproduction were observed.

Summary (Annex IIA, point 6.10)

ADI (if residues in food or feed)

AOEL (Operator/Worker Exposure)
acute/semi-chronic and chronic

Drinking water limit

ARfD (acute reference dose)

Value	Study	Safety factor
Not relevant		
Rounded 0,1* mg B/kg bw/day	developmental study rat	100
	EU Council Directive 98/83/EC. Quality of Water Intended for Human Consumption	
not relevant		

* A rounded (systemic) AOEL value of 0.1 mg B/kg bw/day was used for disodium octaborate tetrahydrate based on the NOAEL for embryotoxic/teratogenic effects of 9.6 mg B/kg bw/day and a standard assessment factor of 100 even though an AOEL value of 0.06 mg B/kg bw/day (based on a NOAEL of 17.5 mg B/kg bw/day in a 2-year study in the rat and an assessment factor of 300 due to serious effects) and an AOEL value of 0.07 mg B/kg bw/day (based on a NOAEL of 21.8 mg B/kg bw/day in a teratogenicity study in the rabbit and an assessment factor of 300 due to serious effects) could be derived from the critical effects.

Acceptable exposure scenarios (including method of calculation)

Professional users

Adverse health effects for the unprotected professional user due to the combined dermal and respiratory exposure of boric acid cannot be excluded. By using

Non-professional users	PPE sufficient reduction of the exposure can be achieved.
Indirect exposure as a result of use	Adverse health effects for the unprotected non-professional user due to the combined dermal and respiratory exposure of boric acid, as a result of spraying or brushing can be excluded. However, biocidal products containing more than 4.6% disodium octaborate tetrahydrate and classified with R60-61 shall not be authorised for marketing to, or use by the general public
	No adverse health effects for the non-professional user and the professional user due to indirect exposure are expected. For a child playing on a playground structure outdoors a health risk as a consequence of exposure to borates can be excluded.

Chapter 4: Fate and Behaviour in the Environment

Route and rate of degradation in water (Annex IIA, point 7.6, IIIA, point XII.2.1, 2.2)

Hydrolysis of active substance and relevant metabolites (DT ₅₀) (state pH and temperature)	hydrolytically stable
Photolytic / photo-oxidative degradation of active substance and resulting relevant metabolites	photolytically stable
Readily biodegradable (yes/no)	No
Biodegradation in seawater	not applicable
Non-extractable residues	Not applicable
Distribution in water / sediment systems (active substance)	no information supplied
Distribution in water / sediment systems (metabolites)	not applicable

Route and rate of degradation in soil (Annex IIIA, point VII.4, XII.1.1, XII.1.4; Annex VI, para. 85)

Mineralization (aerobic)	not applicable
Laboratory studies (range or median, with number of measurements, with regression coefficient)	DT _{50lab} (20°C, aerobic): not applicable
	DT _{90lab} (20°C, aerobic): not applicable
	DT _{50lab} (10°C, aerobic): not applicable
	DT _{50lab} (20°C, anaerobic): not applicable
	degradation in the saturated zone: not applicable
	Field studies (state location, range or median with number of measurements)
	DT _{90f} : not applicable
Anaerobic degradation	not applicable
Soil photolysis	not applicable
Non-extractable residues	not applicable
Relevant metabolites - name and/or code, % of applied a.i. (range and maximum)	not applicable
Soil accumulation and plateau concentration	not available

Adsorption/desorption (Annex IIA, point XII.7.7; Annex IIIA, point XII.1.2)

K _a , K _d	Average K _F 2.6 L/kg (range 0.4 – 8.41 L/kg; n = 9); average 1/n 0.83 (range 0.726 – 0.955)
K _{a_{oc}} , K _{d_{oc}}	no clear relationship with OC
pH dependence (yes / no) (if yes type of dependence)	no

Fate and behaviour in air (Annex IIIA, point VII.3, VII.5)

Direct photolysis in air	does not photolyse
Quantum yield of direct photolysis	not applicable
Photo-oxidative degradation in air	not applicable
Volatilization	Negligible – vapour pressure 9.9 x 10 ⁻⁶ Pa at 25°C

Monitoring data, if available (Annex VI, para. 44)

Soil (indicate location and type of study)	Range 45-124 mg/kg worldwide
Surface water (indicate location and type of study)	Range < 0.001 – 0.632 mg B/L in surface water (review of monitoring values for 15 EU countries)
Ground water (indicate location and type of study)	not available
Air (indicate location and type of study)	Estimated as 20 ng/m ³ (monitoring values near coastlines)

Chapter 5: Effects on Non-target Species

Toxicity data for aquatic species (most sensitive species of each group)

(Annex IIA, point 8.2, Annex IIIA, point 10.2)

Species	Time-scale	Endpoint	Toxicity
Fish			
<i>Catostomus latipinnis</i>	acute (96 h)	LC50	125 mg B/L
<i>Brachydanio rerio</i>	chronic (34 d)	NOEC	1.8 mg B/L
Invertebrates			
<i>Daphnia magna</i>	acute (48 h)	L(E)C50	141 mg B/L
<i>Daphnia magna</i>	chronic (21 d)	NOEC	10 mg B/L
Algae			
<i>Selenastrum capricornutum</i>	chronic (74.5 h)	NOEC (growth inhibition)	17.5 mg B/L
Microorganisms			
Activated sludge	chronic (3 h)	NOEC (respiration inhibition)	17.5 mg B/L
An assessment factor of 10 was applied to the lowest chronic NOEC of 1.8 mg B/l. Resulting in a PNEC _{add, aquatic} of 0.18 mg B/l.			

Effects on earthworms or other soil non-target organisms (most sensitive species for each group)

Acute toxicity for earthworms (Annex IIIA, point XIII.3.2)	14-days LC ₅₀ <i>Lumbricus terrestris</i> : 473 mg B/kg dwt (geomean of 501 and 447, test with H ₃ BO ₃)
Reproductive toxicity for earthworms (Annex IIIA, point XIII.3.2)	63-days NOEC <i>Eisenia andrei</i> : 54 mg B/kg dwt soil (geomean of 39, 79, 52, 52, test with H ₃ BO ₃)
Reproductive toxicity for springtails	28-days NOEC Juvenile reproduction <i>Folsomia candida</i> : 14 mg B/kg dwt soil (geomean of 14 and 14, test with H ₃ BO ₃)
Toxicity to plants	120-days NOEC root/shoot ratio <i>Hordeum vulgare</i> : 2 mg B/kg dwt soil
An assessment factor of 5 was applied to the lowest chronic NOEC of 2 mg B/kg dwt. Resulting in a PNEC _{add, soil} of 0.4 mg B/kg dwt or 0.35 mg B/kg wwt.	

Effects on soil micro-organisms (Annex IIA, point 7.4)

Nitrogen mineralization	20-days EC ₁₀ : 54 mg B/kg dwt soil (test with H ₃ BO ₃)
Carbon mineralization	no data available

Effects on terrestrial vertebrates

Acute toxicity to mammals (Annex IIIA, point XIII.3.3)	Oral LD ₅₀ Rat: 3450 mg/kg bw
Acute toxicity to birds (Annex IIIA, point XIII.1.1)	LD ₅₀ <i>Colinus virginianus</i> : > 527 mg B/kg bw (test with Na ₂ B ₄ O ₇ ·4H ₂ O)
Dietary toxicity to birds (Annex IIIA, point XIII.1.2)	5-days LC50 <i>Colinus virginianus</i> : > 983 mg B/kg fd; > 571 mg B/kg bw.d <i>Anas platyrhynchos</i> : > 2100 mg B/kg fd (test with Na ₂ B ₄ O ₇ ·4H ₂ O)
Reproductive toxicity to birds (Annex IIIA, point XIII.1.3)	no data available

Effects on honeybees (Annex IIIA, point XIII.3.1)

Acute oral toxicity	no data available
Acute contact toxicity	no data available

Effects on other beneficial arthropods (Annex IIIA, point XIII.3.1)

Acute oral toxicity	no data available
Acute contact toxicity	no data available
Acute toxicity to	no data available

Bioconcentration (Annex IIA, point 7.5)

Bioconcentration factor (BCF)	BAF < 10 L/kg (fish) BAF < 30 L/kg (plankton and invertebrates)
Depuration time (DT ₅₀) (DT ₉₀)	virtually all boron was eliminated within 24 days
Level of metabolites (%) in organisms accounting for > 10% of residues	no data available

Appendix II: List of Intended Uses

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount, assuming a wood density of 500 kg/m ³ (pine wood)			
				Type	Conc of as	Method kind	No	Interval between applications	kg/m ³ , BAE in wood	% (w/w), BAE in wood	% (w/v) BAE in treatment solution	kg/m ² , BAE on wood
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing DOT	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; vacuum pressure; closed mixing process; ambient temp	1	na	2.0	0.4	6-12 (a)	na
			Termites	powder; stand alone product	> 99.0%	industrial; vacuum pressure; closed mixing process; ambient temp	1	na	8.5	1.7	6-12 (a)	na
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing DOT	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; double vacuum pressure; closed mixing process; ambient temp	1	na	2.0	0.4	6-12 (a)	na
			Termites	powder; stand alone product	> 99.0%	industrial; double vacuum pressure; closed mixing process; ambient temp	1	na	8.5	1.7	6-12 (a)	na
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing DOT	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; automated dipping; closed mixing process temp 40-60 °C	1	na	n.a.	n.a.	12-35 (a)	0.05
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing DOT	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; deluge; closed mixing process temp 40-60 °C	1	na	n.a.	n.a.	12-35 (a)	0.05
Wood preservation (PT08) Preventive, UC 1,2,3	All Member States	model product containing DOT	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	industrial; automated spraying; closed mixing process temp 40-60 °C	1	na			12-35 (a)	0.05
Wood preservation (PT08)	All Member	model product	decay fungi; wood boring	powder; stand alone	> 99.0%	professional; in-situ injection;	1-10	1 hr to 1 yr	2.0	0.4	6-12 (a)	na

Object and/or situation	Member State or Country	Product name	Organisms controlled	Formulation		Application			Applied amount, assuming a wood density of 500 kg/m ³ (pine wood)			
				Type	Conc of as	Method kind	No	Interval between applications	kg/m ³ , BAE in wood	% (w/w), BAE in wood	% (w/v) BAE in treatment solution	kg/m ² , BAE on wood
Remedial, UC 4a	States	containing DOT	insects	product		on-site mixing; ambient temp						
Wood preservation (PT08) Remedial, UC 4a	All Member States	model product containing DOT	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	professional; in-situ brushing; on-site mixing; ambient temp	1-10	1 hr to 1 yr	n.a.	na	6-12 (a)	0.05
Wood preservation (PT08) Remedial, UC 4a	All Member States	model product containing DOT	decay fungi; wood boring insects	powder; stand alone product	> 99.0%	professional; in-situ spraying; on-site mixing; ambient temp	1-10	1 hr to 1 yr	n.a.	na	6-12 (a)	0.05
Wood preservation (PT08) Remedial, UC 4a	All Member States	model product containing DOT	decay fungi; wood boring insects	concentrated dilution; stand alone product	63	amateur; in-situ brushing; ambient temp	1	na	na	na	6-12 (a)	0.05
Wood preservation (PT08) Remedial, UC 4a	All Member States	model product containing DOT	decay fungi; wood boring insects	Concentrated dilution; stand alone product	63	amateur; in-situ spraying; ambient temp	1	na	n.a.	n.a.	6-12 (a)	0.05

na = not applicable

BAE = boric acid equivalents. For boric acid the conversion factor from boric acid weight units (e.g. gram) to boric acid equivalent weight units (e.g. gram) is 1. The conversion factor from BAE to boron equivalent is 0.175.

UC1• Use Class 1 timber under cover including indoor joinery (preventive)

UC2 Use Class 2 timber under cover including indoor roofing timbers – risk of wetting (preventive)

UC3 Use Class 3 exterior timbers out of ground contact, including joinery protected with a surface coating (preventive)

UC4a Use Class 4a remedial application to timbers in service in ground contact (curative).

(a) Solubility for boric acid is about 50 g/L, or 5% (w/v) BAE; therefore concentrations of 6-35% (w/v) for treatment solutions are not possible

Appendix III: List of studies

Data protection is claimed by the applicant in accordance with Article 12.1(c) (i) and (ii) of Council Directive 98/8/EC for all study reports marked "Y" in the "Data Protection Claimed" column of the table below. For studies marked Yes(i) data protection is claimed under Article 12.1(c) (i), for studies marked Yes(ii) data protection is claimed under Article 12.1(c) (ii). These claims are based on information from the applicant. It is assumed that the relevant studies are not already protected in any other Member State of the European Union under existing national rules relating to biocidal products. It was however not possible to confirm the accuracy of this information.

BEU = Borax Europe Limited

Reference list of studies on the active substance

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
A2.10/01	Smith, R.A, Ascherl, F.M	1999	Issues concerning the measurement of borate in occupational environments. Am. Ind. Hyg. Assoc. J., 60, No. 5, p.651-658. (September - October 1999) GLP Not relevant Published	No	
A3.1.1/01	Mellor's Comprehensive	1980	Supplement to Mellor's comprehensive treatise on inorganic and theoretical chemistry, Volume V, Boron, Part A: Boron-Oxygen Compounds, Longman London and New York, ISBN 0-582-46277-0, pp 170-213, pp 224-320, pp 343-344, pp 356-387, and pp 409-500. Non-GLP Published	No	
A3.1.1/02	Cordia JA, Bal EA, Mak WA, Wils ERJ	2003	Determination of some physico-chemical properties of Timbor, Rijswijk, The Netherlands, TNO Prins Maurits Laboratory, report PML 2002-C44rr, August 2003 Borax Europe Ltd GLP, provisional: unauthorised version Unpublished.	Yes	BEU
A3.1.3/01	Borax Consolidated Ltd	no date	Technical data sheet EC14, London, UK: Borax Consolidated Ltd. Non-GLP. Published	Yes	BEU
A3.1.3/02	Cordia JA, Bal EA, Mak WA, Wils ERJ	2003	Determination of some physico-chemical properties of Timbor, Rijswijk, The Netherlands, TNO Prins Maurits Laboratory, report PML 2002-C44rr, August 2003 Borax Europe Ltd GLP, provisional: unauthorised version Unpublished.	Yes	BEU
A3.2/01	Howarth R, Tremain SP, Bartlett AJ	1995	Disodium octaborate tetrahydrate determination of vapour pressure. Derby, UK: SafePharm Laboratories Ltd, Project number 801/010 Borax Consolidated Ltd. GLP Unpublished	Yes	BEU
A3.4/01	Cordia JA, Bal EA, Mak WA, Wils ERJ	2003	Determination of some physico-chemical properties of Timbor, Rijswijk, The Netherlands, TNO Prins Maurits Laboratory, report PML 2002-C44rr, August 2003	Yes	BEU

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Borax Europe Ltd GLP, provisional: unauthorised version Unpublished.		
A3.4/02	Spruit WET	2005	NMR of disodium octaborate tetrahydrate. Rijswijk, The Netherlands: TNO Defence, Security and Safety, report TNO-DV2 2005-PU004. Borax Europe Ltd. GLP. Unpublished	Yes	BEU
A3.5/01	Kirk-Othmer Encyclopedia of Chemical Technology	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A3.5/02	Cordia JA, Bal EA, Mak WA, Wils ERJ	2003	Determination of some physico-chemical properties of Timbor, Rijswijk, The Netherlands, TNO Prins Maurits Laboratory, report PML 2002-C44rr, August 2003 Borax Europe Ltd GLP, provisional: unauthorised version Unpublished.	Yes	BEU
A3.6/01	Bell RP, Edwards JO and Jones RB	1967	The structure and acidity of boric acid and their relation to reaction mechanisms. In: The chemistry of boron and its compounds. pp 209-221 Non GLP Published	No	
A3.6/02	Kankaanpera A and Salomaa P.	1969	The structure of boric acid in aqueous solution. Acta Chem. Scand. 23, No. 2, 712-713 Non-GLP Published	No	
A3.6/03	Jenkins HO	1945	Transactions of the Faraday Society 41, 138-140 Non-GLP Published	No	
A3.6/04	WHO.	1998	Guidelines for drinking water quality. 2nd Edition Addendum to Vol 2 Boron, page 15, World Health Organisation, Geneva. Non-GLP Published	No	
A3.6/05	Hahn FL and Klockmann R	1930	Die höheren Dissoziationsstufen der Phosphorsäure und der Borsäure Z physik. Chem., 151, 80-86. Non-GLP Published	No	
A3.6/06	Ingri N	1963	Equilibrium studies of polyanions containing B ^{III} , Si ^{IV} , Ge ^{IV} , and V ^V . Sven. Kem. Tidskr. 75(4):199-230. Non-GLP Published	No	
A3.6/07	Maeda M	1979	Raman spectra of polyborate ions in aqueous solution. J Inorg. Nucl. Chem. vol 41: 1217-1220 Non-GLP	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Published		
A3.6/08	Farmer J	1982	Structural chemistry in the borate industry, Chem and Ind Non-GLP Published	No	
A3.6/09	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A3.6/10	Holleman AF and Wiberg E and Wiberg N	1995	Lehrbuch der anorganischen Chemie. 101 st ed. De Gruyter, Berlin	No	
A3.6/11	De Vette HQM, Otto C, Schoonmade MA	2001	Hydrolysis as a function of pH and identification of breakdown products. A study on the identification and comparison of the dissociation products of Polybor tech, Borax Manufacturing grade and Boric acid manufacturing grade in aqueous solution using Raman spectroscopy. TNO report no v99-1153 (TX-2001-001)	Yes	BEU
A3.9/01	Barres M	1967	Contribution to the study of the isopolycondensation of alkaline borates by electrometry and partition Rev. Chim. Miner., 4, 803-838; Non-GLP Published	No	
A3.9/02	Cordia JA, Bal EA, Mak WA, Wils ERJ.	2003	Determination of some physico-chemical properties of Optibor EP. Rijswijk, The Netherlands: TNO Prins Maurits Laboratory. report PML 2002-C42rr, August 2003 Borax Europe Ltd. GLP, provisional: unauthorised version Unpublished	Yes	BEU
A3.13/01	Wurster ED	1963	Surface tension of aqueous 5-mol borax solutions. Ansheim, California, USA: US Borax Research Corporation, Technical Service Report No. 29A-1. Non-GLP Unpublished	Yes	BEU
A3.15/01	Mak WA	2004	Statement 014.16017/01.35. Rijswijk, The Netherlands: TNO Prins Maurits Laboratory Non-GLP Unpublished	Yes	BEU
A3.16/01	Mak WA	2004	Statement 014.16017/01.35. Rijswijk, The Netherlands: TNO Prins Maurits Laboratory Non-GLP Unpublished	Yes	BEU
A4.1/01	BSI	1979	BS 5688: Part 8: 1979, ISO 2216-1972 British standard methods of test for boric acid, boric oxide, disodium tetraborates, sodium perborates and crude sodium borates for industrial use. Part 8. Determination of sodium oxide and boric oxide contents of crude sodium borates (ISO title: Crude Sodium Borates For Industrial Use- Determination Of Sodium Oxide And Boric Oxide Contents- Volumetric Method)	No	BSI/ISO

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Non-GLP Published		
A5/01	Ingri N	1963	Equilibrium studies of polyanions containing B ^{III} , Si ^{IV} , Ge ^{IV} , and V ^V . Sven. Kem. Tidskr. 75(4):199-230. Non-GLP Published	No	
A5/02	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A5/03	De Vette HQM, Otto C, Schoonmade MA	2001	Hydrolysis as a function of pH and identification of breakdown products. A study on the identification and comparison of the dissociation products of Polybor tech, Borax Manufacturing grade and Boric acid manufacturing grade in aqueous solution using Raman spectroscopy. TNO report no v99-1153 (TX-2001-001)	Yes	BEU
A5/04	Maeda M	1979	Raman spectra of polyborate ions in aqueous solution. J Inorg. Nucl. Chem. vol 41: 1217-1220 Non-GLP Published	No	
A5/05	Lloyd JD	1993	The mechanisms of action of boron containing preservatives. Thesis submitted for degree of Doctor of Philosophy of the University of London and the Diploma of Membership of Imperial College (page 45 and 47 Tables 4 and 5) Non-GLP Published	No	
A5.3/01	Harrow KM	1950	Toxicity of water-soluble wood-preservatives to wood-destroying fungi. NZ Journal Sci. & Tech. Vol B 31, (5):14-19. Non-GLP Published	No	
A5.3/02	Baechler RH and Roth HG	1956	Laboratory leaching and decay tests on pine and oak blocks treated with several preservative salts. Amer. Wood Preserver's Assoc. Proc. Annu. Meet., 52:24-34 Non-GLP Published	No	
A5.3/03	Carr DR	1957	Toxicities of some water-borne wood preservatives to wood destroying fungi. New Zealand Forest Service, FRI report, VF 841.12:844.2 (931) CAR, 32 pages. Non-GLP Unpublished	No	
A5.3/04	Becker G, Hof T, Jacquot C, Lohwag K, Rennerfelt E and Walchli O	1966	Vergleichsversuche zur Laboratoriumsprüfung der pilzwidrigen Wirksamkeit von Holzschutzmitteln. Holz Roh-Werkst. 24 (2):53-58. Non-GLP Published	No	
A5.3/05	Gallagher LU	1968	Test of combined toxicity of Timbor and decay resistance of redwood heartwood.	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			UK: Ministry of Technology, Forest Products Research Laboratory, Experiment 504 Non-GLP Unpublished		
A5.3/06	Smith RS	1969	Wood preservative toxicity evaluation using wood weight loss and fungal respiration methods. Wood Science 2(1):44-53 Non-GLP Published	No	
A5.3/07	Bechgaard C, Borup L, Henningson B and Jermer J	1979	Remedial treatment of creosoted railway sleepers of redwood by selective application of boric acid. Stockholm, Sweden: Swedish Wood Preservation Institute, report no 135E, ISSN 0346-7090. Non-GLP Published	No	
A5.3/08	Doi S, Mori M and Mineki Y	1994	Preservative efficacy of boric acid triethanol amine solution against wood decay fungi. Stockholm, Sweden: The International Research Group on Wood Preservation, document IRG/WP 94-30050 Paper prepared for the 25th Annual Meeting, Bali, Indonesia, May-June, 1994 Non-GLP Published	No	
A5.3/09	Cookson LJ and Pham K	1996	Relative tolerance of twenty basidiomycetes to boric acid. Mat und Org 29 (3) 187-196. Non-GLP Published	No	CSIRO
A5.3/10	Cummins JE and Wilson HB	1936	The preservation of timber against the attacks of powder post borer (<i>Lyctus brunneus</i> Stephens) by impregnation with various chemicals. J. Counc. Sci. Ind. Res., 9(1):37-56. Non-GLP Published	No	
A5.3/11	Cummins JE	1939	The preservation of timber against the attacks of powder post borer (<i>Lyctus brunneus</i> Stephens) by impregnation with boric acid. J. Counc. Sci. Ind. Res., 12(1):30-49. Non-GLP Published	No	
A5.3/12	Spiller D	1948	Toxicity of boric acid to the common house borer, <i>Anobium punctatum</i> . Wellington, New Zealand: Department of Scientific and Industrial Research, Extract from the NZ Journal Sci. & Tech. Vol B 30 (20):22-30. Non-GLP Published	No	
A5.3/13	Taylor JM	1967	Toxicity of boron compounds to the common furniture beetle and house longhorn beetles. International Pest Control 9(1):14-17.	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Non-GLP Published		
A5.3/14	Mauldin JK and Kard BM	1996	Disodium octaborate tetrahydrate treatments to slash pine for protection against Formosan subterranean termite and eastern subterranean termite. J. of Economic Entomology 89:682-688. Non-GLP Published	No	
A5.3/15	Findlay WPK	1959	Boron compounds for the preservation of timber against fungi and insects. 6 th Wood Protection Congress of the German Society for Wood Research July, 1959 Reprinted in Pest Technology 2(6):124-127 Non-GLP Published	No	
A5.3/16	Becker G	1959	Beitrag zur Kenntnis der Wirksamkeit von Borverbindungen als Holzschutzmittel gegen Insekten und Pilze. Holz als Roh und Werkstoff 17(12):484-489. Non-GLP Published	No	
A5.3/17	Bravery AF and Carey JK	1983	A review of the data on the toxicity of boric acid to fungi and insects attacking wood. Building Research Advisory Service, Job no. P820648 Non-GLP Published	No	
A5.3/18	Borax Europe Ltd	2005	Explanatory note on efficacy assessment, application rates, environmental exposure assessment, boric acid. Borax Europe Ltd Non-GLP Unpublished	Yes	BEU
A5.4.1/01	Lloyd JD	1998	Borates and their biological applications. Stockholm, Sweden: The International Research Group on Wood Preservation. Doc no. IRG/WP98-30178. Paper prepared for the 29 th annual meeting , Maastricht, The Netherlands, June 1998 Non-GLP Published.	No	
A5.4.1/02	Lloyd JD and Dickinson DJ	1991	Comparison of the inhibitory effects of borate, germanate, tellurate, arsenite and arsenate on 6-phosphogluconate dehydrogenase. Stockholm, Sweden: The International Research Group on Wood Preservation. Doc no. IRG/WP1508 Paper prepared for the 22 nd annual meeting , Kyoto, Japan, May 1991. No GLP Published	No	
A5.4.1/03	Lloyd JD, Dickinson DJ and Murphy RJ	1990	The probable mechanisms of action of boric acid and borates as wood preservatives. Stockholm, Sweden: The International Research Group on	No	

Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
			Wood Preservation. Doc no. IRG/WP1450. Paper prepared for the 21 st annual meeting , Rotorua, New Zealand, May 1990 Non GLP Published		
A5.4.1/04	Lloyd JD, Dickinson DJ and Murphy RJ	1991	The effect of sorbitol on the decay of boric acid treated Scots pine. Stockholm, Sweden: The International Research Group on Wood Preservation. Doc no. IRG/WP1509. Paper prepared for the 22 nd annual meeting , Kyoto, Japan, May 1991 Non-GLP Published	No	
A6.2	Wester RC, Hui X, Hartway T, Maibach HI, Bell K, Schell MJ, Northington DJ, Strong P and Culver, BD	1998	In vivo percutaneous absorption of boric acid, Borax and disodium octaborate tetrahydrate in humans compared to in vitro absorption in human skin from infinite to finite doses. Toxicol Sciences 45 42-51 (1998) No GLP Unpublished	No	
A6.2-10/01	Farmer J	1982	Structural chemistry in the borate industry, Chem and Ind Non-GLP Published	No	
A6.2-10/02	Ingri, N	1963	Equilibrium studies of polyanions containing BIII, SiIV, GeIV, and VV. Sven. Kem. Tidskr. 75(4):199-230. Non-GLP Published	No	
A6.2-10/03	Kirk-Othmer Encyclopedia	1992	Kirk-Othmer Encyclopedia of Chemical Technology, John Wiley & Sons Inc., 4th Edition, Volume 4, pp 368-386. Non-GLP Published	No	
A6.2-10/04	Holleman AF and Wiberg E and Wiberg N	1995	Lehrbuch der anorganischen Chemie. 101st ed. De Gruyter, Berlin	No	
A6.2-10/05	De Vette HQM, Otto C, Schoonmade MA	2001	Hydrolysis as a function of pH and identification of breakdown products. A study on the identification and comparison of the dissociation products of Polybor tech, Borax Manufacturing grade and Boric acid manufacturing grade in aqueous solution using Raman spectroscopy. TNO report no v99-1153 (TX-2001-001)	Yes	BEU
A6.2-10/06	Maeda, M	1979	Raman spectra of polyborate ions in aqueous solution. J Inorg. Nucl. Chem. vol 41: 1217-1220 Non-GLP Published	No	
A6.2-10/07	Rickards, H and Arian, Z	2004	, Rate of Dissolution Study of Borax's Products, Borax Europe Limited Internal Technical Report. TR-2004-01 No GLP Unpublished	Yes	BEU
A7.1.1.1.1/01	De Vette	2001	Hydrolysis as a function of pH and identification of	Yes	BEU

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A7.1.1.1.1/03	Holleman AF and Wiberg E and Wiberg N	1995	Lehrbuch der anorganischen Chemie. 101 st ed. De Gruyter, Berlin	No	
A7.1.1.1.1/04	Kemp, P.H.	1956	"The Chemistry of Borates Part 1", copyright	No	
A7.1.1.1.1/05	Maeda M	1979	Raman spectra of polyborate ions in aqueous solution. J Inorg. Nucl. Chem. vol 41: 1217-1220 Non-GLP Published	No	
A7.1.1.1.1/06	Hanstveit A O	2004	Boric Acid (CAS No. 10043-35-3): Statement on Hydrolysis as a function of pH and identification of breakdown products TNO Report No V6004/05. Report to Borax Europe Limited Unpublished	Yes	BEU

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Section No / Reference No	Author(s)	Year	Title. Source (where different from company) Company, Report No. GLP (where relevant) / (Un)Published	Data Protection Claimed (Yes/No)	Owner
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Doc IIA	Adelhardt, M. and Fogh, A.	1983	Enquiries to a centre for information on poisoning during a period of 12 years (English translation). Boraks – er de farligt (12 ars forespørgsler til giftinformationscentralen) Ugeskr. Laeger. 145 3808 – 3810.	No	
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	AE	1998	Development of plant toxicity tests for assessment of contaminated soils. Orton, Canada: Aquaterra Environmental.	No	
Doc IIIA	Aitken, R.L. and McCallum, L.E.	1988	Boron toxicity in soil solution. Aust. J. Soil Res 26, 605-610.	No	
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	Beavers, J.B. and Fink, R.	1982b	Eight-day dietary LC50 of POLYBOR – Bobwhite quail. St. Michaels, USA: Wildlife International Ltd., project no. 135-103.	No	
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Doc IIA	Birge, W.J. and Black, J.A.	1977	Sensitivity of vertebrate embryos to boron compounds EPA-560/1-76-008, PB 267 085. Office of toxic substances, US EPA, Washington D.C. 20460, USA	No	
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Doc IIA	Brown, T.F., McCormick, M.E., Morris, D.R. and Zeringue, L.K.	1989	Effects of dietary boron on mineral balance in sheep. Nutr. Res. 9, 503-521.	No	
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Doc IIIA	Ciba, J. and Chrusciel, A.	1992	Spectrophotometric determination of boron in human hair with Azomethine H. Fresenius J. Anal. Chem. 342, 147-149	No	
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Doc IIIA	De Vette, H.Q.M., Otto, C. and Schoonmade, J.A.	2001	A study on the identification and comparison of the dissociation products of Polybor tech., Borax, Manufacturing grade and Boric Acid, Manufacturing grade in aqueous solutions using Raman spectrometry. Delft, The Netherlands: TNO Nutrition and Food Research. TNO study no. IMW-99-9050-01, report no. V99.1153. File: TX20000013.pdf	No	
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Appendix IV: List of standard terms and abbreviations

Stand. term / Abbreviation	Explanation
A	ampere
ACh	acetylcholine
AChE	acetylcholinesterase
ADI	acceptable daily intake
ADME	administration distribution metabolism and excretion
ADP	adenosine diphosphate
AE	acid equivalent
AF	assessment factor
AFID	alkali flame-ionisation detector or detection
A/G	albumin/globulin ratio
ai	active ingredient
ALD ₅₀	approximate median lethal dose, 50%
ALT	alanine aminotransferase (SGPT)
<i>Ann.</i>	Annex
AOEL	acceptable operator exposure level
AMD	automatic multiple development
ANOVA	analysis of variance
AP	alkaline phosphatase
approx	approximate
ARC	anticipated residue contribution
ARfD	acute reference dose
as	active substance
AST	aspartate aminotransferase (SGOT)
ASV	air saturation value
ATP	adenosine triphosphate
BAF	bioaccumulation factor
BCF	bioconcentration factor
bfa	body fluid assay
BOD	biological oxygen demand
bp	boiling point
BPD	Biocidal Products Directive
BSAF	biota-sediment accumulation factor
BSE	bovine spongiform encephalopathy

Stand. term / Abbreviation	Explanation
BSP	bromosulphophthalein
Bt	<i>Bacillus thuringiensis</i>
Bti	<i>Bacillus thuringiensis israelensis</i>
Btk	<i>Bacillus thuringiensis kurstaki</i>
Btt	<i>Bacillus thuringiensis tenebrionis</i>
BUN	blood urea nitrogen
bw	body weight
c	centi- (x 10 ⁻²)
°C	degrees Celsius (centigrade)
CA	controlled atmosphere
CAD	computer aided design
CADDY	computer aided dossier and data supply (an electronic dossier interchange and archiving format)
cd	candela
CDA	controlled drop(let) application
cDNA	complementary DANN
CEC	cation exchange capacity
<i>cf</i>	confer, compare to
CFU	colony forming units
ChE	cholinesterase
CI	confidence interval
CL	confidence limits
cm	centimetre
CNS	central nervous system
COD	chemical oxygen demand
CPK	creatinine phosphatase
cv	coefficient of variation
Cv	ceiling value
d	day(s)
DES	diethylstilboestrol
DIS	draft international standard (<i>ISO</i>)
DMSO	dimethylsulfoxide
DNA	deoxyribonucleic acid
dna	designated national authority

Stand. term / Abbreviation	Explanation
DO	dissolved oxygen
DOC	dissolved organic carbon
dpi	days post inoculation
DRP	detailed review paper (<i>OECD</i>)
DT _{50(tab)}	period required for 50 percent dissipation (under laboratory conditions) (define method of estimation)
DT _{90(field)}	period required for 90 percent dissipation (under field conditions) (define method of estimation)
dw	dry weight
DWQG	drinking water quality guidelines
ϵ	decadic molar extinction coefficient
EC ₅₀	median effective concentration
ECD	electron capture detector
ED ₅₀	median effective dose
EDI	estimated daily intake
EINECS	European inventory of existing commercial substances
ELINCS	European list of notified chemical substances
ELISA	enzyme linked immunosorbent assay
e-mail	electronic mail
EMDI	estimated maximum daily intake
EN	European norm
EPMA	electron probe micro-analysis
ERL	extraneous residue limit
ESPE46/51	evaluation system for pesticides
EUSES	European Union system for the evaluation of substances
F	field
F ₀	parental generation
F ₁	filial generation, first
F ₂	filial generation, second
FBS	full base set
FELS	fish early-life stage
FIA	fluorescence immuno-assay

Stand. term / Abbreviation	Explanation
FID	flame ionisation detector
F _{mot}	fractional equivalent of the metabolite's molecular weight compared to the active substance
FOB	functional observation battery
f _{oc}	organic carbon factor (compartment dependent)
fp	freezing point
FPD	flame photometric detector
FPLC	fast protein liquid chromatography
g	gram(s)
GAP	good agricultural practice
GC	gas chromatography
GC-EC	gas chromatography with electron capture detector
GC-FID	gas chromatography with flame ionisation detector
GC-MS	gas chromatography-mass spectrometry
GC-MSD	gas chromatography with mass-selective detection
GEP	good experimental practice
GFP	good field practice
GGT	gamma glutamyl transferase
GI	gastro-intestinal
GIT	gastro-intestinal tract
GL	guideline level
GLC	gas liquid chromatography
GLP	good laboratory practice
GM	geometric mean
GMO	genetically modified organism
GMM	genetically modified micro-organism
GPC	gel-permeation chromatography
GPS	global positioning system
GSH	glutathione
GV	granulosevirus
h	hour(s)
H	Henry's Law constant (calculated as a unitless value)

Stand. term / Abbreviation	Explanation
ha	hectare(s)
Hb	haemoglobin
HC5	concentration which will be harmless to at least 95 % of the species present with a given level of confidence (usually 95 %)
HCG	human chorionic gonadotropin
Hct	haematocrit
HDT	highest dose tested
hL	hectolitre
HEED	high energy electron diffraction
HID	helium ionisation detector
HPAEC	high performance anion exchange chromatography
HPLC	high pressure liquid chromatography or high performance liquid chromatography
HPLC-MS	high pressure liquid chromatography - mass spectrometry
HPPLC	high pressure planar liquid chromatography
HPTLC	high performance thin layer chromatography
HRGC	high resolution gas chromatography
H _s	Shannon-Weaver index
Ht	haematocrit
HUSS	human and use safety standard
I	indoor
I ₅₀	inhibitory dose, 50%
IC ₅₀	median immobilisation concentration or median inhibitory concentration 1
ICM	integrated crop management
ID	ionisation detector
IEDI	international estimated daily intake
IGR	insect growth regulator
im	intramuscular
inh	inhalation
INT	2-p-iodophenyl-3-p-nitrophenyl-5-phenyltetrazoliumchloride testing method

Stand. term / Abbreviation	Explanation
ip	intraperitoneal
IPM	integrated pest management
IR	infrared
ISBN	international standard book number
ISSN	international standard serial number
IUCLID	International Uniform Chemical Information Database
iv	intravenous
IVF	<i>in vitro</i> fertilisation
k (<i>in combination</i>)	kilo
k	rate constant for biodegradation
K	Kelvin
K _a	acid dissociation constant
K _b	base dissociation constant
K _{ads}	adsorption constant
K _{des}	apparent desorption coefficient
K _F	Freundlich distribution constant, indicating the relationship between de amount sorbed and equilibrium concentration in in water.
kg	kilogram
K _H	Henry's Law constant (in atmosphere per cubic metre per mole)
K _{oc}	organic carbon adsorption coefficient
K _{om}	organic matter adsorption coefficient
K _{ow}	octanol-water partition coefficient
K _p	solid-water partition coefficient
kPa	kilopascal(s)
l, L	litre
LAN	local area network
LASER	light amplification by stimulated emission of radiation
LBC	loosely bound capacity
LC	liquid chromatography
LC-MS	liquid chromatography- mass spectrometry
LC ₅₀	lethal concentration, median

Stand. term / Abbreviation	Explanation
LCA	life cycle analysis
LC-MS-MS	liquid chromatography with tandem mass spectrometry
LD ₅₀	lethal dose, median; dosis letalis media
LDH	lactate dehydrogenase
ln	natural logarithm
LOAEC	lowest observable adverse effect concentration
LOAEL	lowest observable adverse effect level
LOD	limit of detection
LOEC	lowest observable effect concentration
LOEL	lowest observable effect level
log	logarithm to the base 10
LOQ	limit of quantification (determination)
LPLC	low pressure liquid chromatography
LSC	liquid scintillation counting or counter
LSD	least squared denominator multiple range test
LSS	liquid scintillation spectrometry
LT	lethal threshold
m	metre
M	molar
µm	micrometre (micron)
MAC	maximum allowable concentration
MAK	maximum allowable concentration
MC	moisture content
MCH	mean corpuscular haemoglobin
MCHC	mean corpuscular haemoglobin concentration
MCV	mean corpuscular volume
MDL	method detection limit
MFO	mixed function oxidase
µg	microgram
mg	milligram
MHC	moisture holding capacity

Stand. term / Abbreviation	Explanation
MIC	minimum inhibitory concentration
min	minute(s)
MKC	minimum killing concentration
mL	millilitre
MLT	median lethal time
MLD	minimum lethal dose
mm	millimetre
MMAD	mass median aerodynamic diameter
mo	month(s)
MOE	margin of exposure
mol	mole(s)
MOS	margin of safety
mp	melting point
MRE	maximum residue expected
MRL	maximum residue level or limit
mRNA	messenger ribonucleic acid
MS	mass spectrometry
MSDS	material safety data sheet
MTD	maximum tolerated dose
MT	material test
MW	molecular weight
n.a.	not applicable
n-	normal (defining isomeric configuration)
n	number of observations
NAEL	no adverse effect level
nd	not detected
NEDI	national estimated daily intake
NEL	no effect level
NERL	no effect residue level
ng	nanogram
nm	nanometre
NMR	nuclear magnetic resonance
no, n ^o	number
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level

Stand. term / Abbreviation	Explanation
NOEC	no observed effect concentration
NOED	no observed effect dose
NOEL	no observed effect level
NOIS	notice of intent to suspend
NPD	nitrogen-phosphorus detector or detection
NPV	nuclear polyhedrosis virus
NR	not reported
NTE	neurotoxic target esterase
OC	organic carbon content
OCR	optical character recognition
ODP	ozone-depleting potential
ODS	ozone-depleting substances
OEL	occupational exposure limit
OH	hydroxide
OJ	Official Journal
OM	organic matter content
Pa	pascal
PAD	pulsed amperometric detection
2-PAM	2-pralidoxime
pc	paper chromatography
PC	personal computer
PCV	haematocrit (packed corpuscular volume)
PEC	predicted environmental concentration
PEC _A	predicted environmental concentration in air
PEC _S	predicted environmental concentration in soil
PEC _{SW}	predicted environmental concentration in surface water
PEC _{GW}	predicted environmental concentration in ground water
PED	plasma-emissions-detector
pH	pH-value
PHED	pesticide handler's exposure data
PIC	prior informed consent
pic	phage inhibitory capacity

Stand. term / Abbreviation	Explanation
PIXE	proton induced X-ray emission
pKa	negative logarithm (to the base 10) of the acid dissociation constant
pKb	negative logarithm (to the base 10) of the base dissociation constant
PNEC	predicted no effect concentration (compartment to be added as subscript)
po	by mouth
POP	persistent organic pollutants
ppb	parts per billion (10 ⁻⁹)
PPE	personal protective equipment
ppm	parts per million (10 ⁻⁶)
PPP	plant protection product
ppq	parts per quadrillion (10 ⁻²⁴)
ppt	parts per trillion (10 ⁻¹²)
PSP	phenolsulfophthalein
PrT	prothrombin time
PRL	practical residue limit
PT	product type
PT(CEN)	project team CEN
PTDI	provisional tolerable daily intake
PTT	partial thromboplastin time
QA	quality assurance
QAU	quality assurance unit
(Q)SAR	quantitative structure-activity relationship
r	correlation coefficient
r ²	coefficient of determination
RA	risk assessment
RBC	red blood cell
REI	restricted entry interval
RENI	Registry Nomenclature Information System
Rf	retardation factor
RfD	reference dose
RH	relative humidity
RL ₅₀	median residual lifetime

Stand. term / Abbreviation	Explanation
RNA	ribonucleic acid
RP	reversed phase
rpm	revolutions per minute
rRNA	ribosomal ribonucleic acid
RRT	relative retention time
RSD	relative standard deviation
s	second
S	solubility
SAC	strong adsorption capacity
SAP	serum alkaline phosphatase
SAR	structure/activity relationship
SBLC	shallow bed liquid chromatography
sc	subcutaneous
sce	sister chromatid exchange
SCAS	semi-continuous activated sludge
SCTER	smallest chronic toxicity exposure ratio (TER)
SD	standard deviation
se	standard error
SEM	standard error of the mean
SEP	standard evaluation procedure
SF	safety factor
SFC	supercritical fluid chromatography
SFE	supercritical fluid extraction
SIMS	secondary ion mass spectroscopy
S/L	short term to long term ratio
SMEs	small and medium sized enterprises
SOP	standard operating procedures
sp	species (only after a generic name)
SPE	solid phase extraction
SPF	specific pathogen free
spp	subspecies
SSD	sulphur specific detector
SSMS	spark source mass spectrometry
STEL	short term exposure limit
STER	smallest toxicity exposure ratio (TER)

Stand. term / Abbreviation	Explanation
STMR	supervised trials median residue
STP	sewage treatment plant
t	tonne(s) (metric ton)
t _½	half-life (define method of estimation)
T ₃	tri-iodothyroxine
T ₄	thyroxine
T ₂₅	tumorigenic dose that causes tumours in 25 % of the test animals
TADI	temporary acceptable daily intake
TBC	tightly bound capacity
TCD	thermal conductivity detector
TG	technical guideline, technical group
TGD	Technical guidance document
TID	thermionic detector, alkali flame detector
TDR	time domain reflectometry
TER	toxicity exposure ratio
TER _I	toxicity exposure ratio for initial exposure
TER _{ST}	toxicity exposure ratio following repeated exposure
TER _{LT}	toxicity exposure ratio following chronic exposure
tert	tertiary (in a chemical name)
TEP	typical end-use product
TGGE	temperature gradient gel electrophoresis
TIFF	tag image file format
TLC	thin layer chromatography
Tlm	median tolerance limit
TLV	threshold limit value
TMDI	theoretical maximum daily intake
TMRC	theoretical maximum residue contribution
TMRL	temporary maximum residue limit
TNsG	technical notes for guidance
TOC	total organic carbon
Tremcard	transport emergency card

Stand. term / Abbreviation	Explanation
tRNA	transfer ribonucleic acid
TSH	thyroid stimulating hormone (thyrotropin)
TTC	2,3,5-triphenylterazoliumchloride testing method
TWA	time weighted average
UDS	unscheduled DNA synthesis
UF	uncertainty factor (safety factor)
ULV	ultra low volume
UR	unit risk
UV	ultraviolet
UVC	unknown or variable composition, complex reaction products
UVCB	undefined or variable composition, complex reaction products in biological material

Stand. term / Abbreviation	Explanation
v/v	volume ratio (volume per volume)
vis	visible
WBC	white blood cell
wk	week
wt	weight
w/v	weight per volume
ww	wet weight
w/w	weight per weight
XRFA	X-ray fluorescence analysis
yr	year
<	less than
≤	less than or equal to
>	greater than
≥	greater than or equal to

Abbreviations of Organisations and Publications

Abbreviation	Explanation
ASTM	American Society for Testing and Materials
BA	Biological Abstracts (Philadelphia)
BART	Beneficial Arthropod Registration Testing Group
BBA	German Federal Agency of Agriculture and Forestry
CA(S)	Chemical Abstracts (System)
CAB	Centre for Agriculture and Biosciences International
CAC	Codex Alimentarius Commission
CAS	Chemical Abstracts Service
CCFAC	Codex Committee on Food Additives and Contaminants
CCGP	Codex Committee on General Principles
CCPR	Codex Committee on Pesticide Residues
CCRVDF	Codex Committee on Residues of Veterinary Drugs in Food

Abbreviation	Explanation
CE	Council of Europe
CEC	Commission of the European Communities
CEFIC	European Chemical Industry Council
CEN	European Committee for Normalisation
CEPE	European Committee for Paints and Inks
CIPAC	Collaborative International Pesticides Analytical Council Ltd
CMA	Chemicals Manufacturers Association
COREPER	Comite des Representants Permanents
COST	European Co-operation in the field of Scientific and Technical Research
DG	Directorate General
DIN	German Institute for Standardisation
EC	European Commission

Abbreviation	Explanation
ECB	European Chemicals Bureau
ECCO	European Commission Co-ordination
ECDIN	Environmental Chemicals Data and Information Network of the European Communities
ECDIS	European Environmental Chemicals Data and Information System
ECE	Economic Commission for Europe
ECETOC	European Chemical Industry Ecology and Toxicology Centre
EDEXIM	European Database on Export and Import of Dangerous Chemicals
EEC	European Economic Community
EHC	Environmental Health Criteria
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of New Chemical Substances
EMIC	Environmental Mutagens Information Centre
EPA	Environmental Protection Agency
EPAS	European Producers of Antimicrobial Substances
EPFP	European Producers of Formulated Preservatives
EPO	European Patent Office
EPPO	European and Mediterranean Plant Protection Organization
ESCORT	European Standard Characteristics of Beneficials Regulatory Testing
EU	European Union
EUPHIDS	European Pesticide Hazard Information and Decision Support System
EUROPOEM	European Predictive Operator Exposure Model
EWMP	European Wood Preservation Manufacturers
FAO	Food and Agriculture Organization of the UN
FOCUS	Forum for the Co-ordination of Pesticide Fate Models and their Use
FRAC	Fungicide Resistance Action Committee
GATT	General Agreement on Tariffs and

Abbreviation	Explanation
	Trade
GAW	Global Atmosphere Watch
GIFAP	Groupement International des Associations Nationales de Fabricants de Produits Agrochimiques (now known as GCPF)
GCOS	Global Climate Observing System
GCPF	Global Crop Protection Federation (formerly known as GIFAP)
GEDD	Global Environmental Data Directory
GEMS	Global Environmental Monitoring System
GRIN	Germplasm Resources Information Network
IARC	International Agency for Research on Cancer
IATS	International Academy of Toxicological Science
ICBP	International Council for Bird Preservation
ICCA	International Council of Chemical Associations
ICES	International Council for the Exploration of the Seas
ILO	International Labour Organization
IMO	International Maritime Organisation
IOBC	International Organization for Biological Control of Noxious Animals and Plants
IPCS	International Programme on Chemical Safety
IRAC	Insecticide Resistance Action Committee
ISCO	International Soil Conservation Organization
ISO	International Organization for Standardisation
IUPAC	International Union of Pure and Applied Chemistry
JECFA FAO/WHO	Joint Expert Committee on Food Additives
JFCMP	Joint FAO/WHO Food and Animal Feed Contamination Monitoring Programme
JMP	Joint Meeting on Pesticides

Abbreviation	Explanation
	(WHO/FAO)
JMPR	Joint Meeting of the FAO Panel of Experts on Pesticide Residues in Food and the Environment and the WHO Expert Group on Pesticide Residues (Joint Meeting on Pesticide Residues)
MITI	Ministry of International Trade and Industry, Japan
NATO	North Atlantic Treaty Organization
NAFTA	North American Free Trade Agreement
NCI	National Cancer Institute (USA)
NCTR	National Center for Toxicological Research (USA)
NGO	non-governmental organisation
NTP	National Toxicology Program (USA)
OECD	Organization for Economic Co-operation and Development
OLIS	On-line Information Service of OECD
OPPTS	Office of Prevention, Pesticides and Toxic Substances (US EPA)
OSPAR	Oslo Paris Convention (Convention for the Protection of the Marine Environment of the North-East Atlantic)
PAN	Pesticide Action Network
RIVM	Netherlands National Institute of Public Health and Environmental Protection
RNN	Re-registration Notification Network
RTECS	Registry of Toxic Effects of Chemical Substances (USA)
SETAC	Society of Environmental Toxicology and Chemistry
SI	Système International d'Unités
SITC	Standard International Trade Classification
TOXLINE	Toxicology Information On-line
UBA	German Environmental Protection Agency
UN	United Nations
UNEP	United Nations Environment Programme

Abbreviation	Explanation
WFP	World Food Programme
WHO	World Health Organization
WPRS	West Palearctic Regional Section
WTO	World Trade Organization
WWF	World Wildlife Fund