

SECTION 1: Identification of the substance or mixture and of the company**1.1. Product identifier**

Product description: Deoxidizer.

1.2. Relevant identified uses of the substance or mixture and uses advised against

Identified Use Professional use: Product for the adhesion of stainless steel solders to orthodontic products.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.

I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 50

e-mail: research@leone.it – <http://www.leone.it>

Tel. +39 055.30.44.1 – Fax +39 055 374808.

1.4. Emergency telephone number

+39 055.30.44.1. An answering machine is on during closing time.

SECTION 2: Hazards identification**2.1. Classification of the substance or mixture**

According to Regulation (EC) no. 1272/2008 [CLP].

Repr. 1B

H360FD

2.2. Label elements

Signal word

Danger

Hazard statements:

H360

May damage fertility or the unborn child.

Precautionary statements

P201
P308+P313Obtain special instructions before use.
If exposed or concerned: Get medical advice/attention.**2.3. Other hazards**

Not classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients**3.1. Substances**

This product is a mixture.

3.2. Mixtures

Substances in the product which may present a health or environmental hazard, or which have been assigned occupational exposure limits, are detailed below.

According to Regulation (EC) no. 1272/2008 [CLP].

Hazardous ingredient(s)	% W/W	ECS no.	CAS no.	Hazard Class and Category Code(s)	Hazard statement Code (s)
Boric acid	75	233-139-2	10043-35-3	Repr. 1B	H360
Tetraboron disodium decahydrate	25	235-541-3*	12267-73-1*	Repr. 1B	H360

SECTION 4: First aid measures**4.1. Description of first aid measures**

Inhalation IF INHALED: ventilate the working place. Move to a good ventilated area and take a rest. If you feel unwell seek for medical advice.

Skin contact IF ON SKIN (or hair): wash with plenty of water and soap.

Eye contact IF IN EYES: Rinse opened eye for at least 10 minutes.

Ingestion induce vomiting; drink a lot of water or milk; seek immediately for medical advice showing this safety data sheet. It is possible to give activated carbon suspended in water or medicinal white mineral oil.

4.2. Most important symptoms and effects, both acute and delayed

Ingestion may cause nausea, vomiting, diarrhoea and delayed redness of the skin.

4.3. Indication of any immediate medical attention and special treatment needed

Show this safety data sheet to the doctor in attendance.



SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media In case of fire, use water CO₂, chemical powder depending on the employed material.

Unsuitable extinguishing Media None in particular.

5.2. Special hazards arising from the substance or mixture

(Borace)none. (boric acid) the product develops Formation of toxic gases is possible during heating or in case of fire.

5.3. Advice for firefighters

In case of fire is recommended to wear a MSHA/NIOSH-approved self-contained breathing apparatus operating in the pressure demand mode.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Use respiratory protective device against the effects of fumes/aerosol.

6.2. Environmental precautions

Contain leaks with earth or sand. If the product is in liquid form, do not allow to enter drainage system, surface or ground water.

6.3. Methods and material for containment and cleaning up

For fine dusts use a vacuum cleaner.

Wash the area with water by taking appropriate measures in order to avoid environmental pollution problems . Dispose of contaminated material in accordance with Section 13.

6.4. Reference to other sections

Section 7, Section 8 and Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Safety advice Avoid contact and inhalation of fumes (Section 8). Do not smoke at work place.

Technical protective measures Ensure good aeration, ventilation and dust extraction system (boric acid). Use safety eyewear.

Fire and explosion protection information No special measures.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage in rooms and containers Keep container well closed. Store in a dry and well- ventilated place.

Joint storage Keep away from strong reducing; no other special precautions are required. (Borax).

Additional details regarding storage None.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

	Boric acid	Tetraboron disodium decahydrate
TLV-TWA	STEL: 6mg/m ³ . LTEL: 2 mg/m ³ .	5 mg/m ³ .

8.2. Exposure controls

Do not eat, drink, smoke or sneeze at the workplace.

Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection Operate with adequate protection, according to good working practices.

Body protection Operate with adequate protection, according to good working practices.

Hand protection The selected protective gloves have to satisfy the specifications of EU Directive 89/89 EEC and the standard EN 347 derived.

Material: PVC o PE Mat. thickness nd Penetration time ask to the supplier (EN 374).

Respiratory protection Wear suitable respiratory protective equipment with filter P3.

Industrial hygiene (Boric acid) Keep away from foodstuffs , beverages and feed . Immediately remove contaminated clothing.

Wash your hands before break or at the end of work. Keep protective clothing separately.

Women who are pregnant should strictly avoid inhalation or skin contact.



Environmental exposure controls

Precautionary measures: ensure adequate ventilation to the premises where the product is stored and / or handled.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

	<u>Boric acid</u>	<u>Tetraboron disodium decahydrate</u>
Appearance	Crystalline powder.	Granular powder.
Colour	White.	White.
Odour	Odourless.	Odourless.
pH:	Not applicable.	48.9 g/l at 20°C: 9.32 (sat. Sol.).
Melting point	169 (Zers.)°C.	62°C (anhydrous salt 742 °C).
Boiling point	300°C.	Not applicable.
Flash point	Not applicable.	Not applicable.
Decomposition Temperature	Not defined.	Not defined.
Vapour Tension	0 hPa at 20°C.	Not applicable.
Auto ignition temperature	Not defined.	Not defined.
Explosive properties	Not explosive.	Not applicable.
Density	1.453 g/cm ³ .	1.73 g/cm ³ (water=1).
Bulk density at 20°C	500 kg/m ³ .	Non defined.
Relative density	Non defined.	Non defined.
Vapour density	Not applicable.	Non defined.
Solubility (Water)	300 g/l a 20°C.	51.4 g/l a 20° 1910 g/l a 100 °C.
Solubility (other)	Soluble in trichloromethane.	Ethylene glycol, glycerin, alcohol (slight solubility).
Partition coefficient n-Octanol/ water	Non defined.	Non defined.
Dynamic viscosity	Not applicable.	Not applicable.
Cinematic viscosity	Not applicable.	Not applicable.

9.2. Other information

No further details as regards the safety-relevant parameters are required.

SECTION 10: Stability and reactivity

10.1. Reactivity

Information not available.

10.2. Chemical stability

The product is stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known.

10.4. Conditions to avoid

No data available.

10.5. Incompatible materials

It reacts with strong reducing (metal hydrides, alkaline metals, acetic anhydride) , the development of hydrogen which could cause explosions.

10.6. Hazardous decomposition product(s)

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Boric Acid

Acute toxicity

Irritability

On skin: Not irritant.

In eyes: Not irritant.

Ingestion

May be harmful if swallowed.

Inhalation

May be harmful if inhaled.

Sensitisation

No sensitizing effects known.

Other data(experimental toxicity)

No other relevant data available.

Other toxicological data

It can cause foetal malformation.

CMR effects (carcinogenesis, Mutagenesis, Teratogenesis)

Repr. Cat. 1B.

Tetraboron disodium decahydrate

Acute toxicity Oral LD50 > 2000 mg/kg (rat).

Irritability In eyes: slightly irritant.

On skin: irritant for skin and mucous membranes.



Inhalation	Slightly irritant for the first part of the respiratory tract.
Sensitisation	No reported evidence of that effect.
Chronic toxicity	very rare chronic poisoning can cause digestive disorders and skin lesions.
CMR effects	Carcinogenesis: No reported evidence of that effect. Mutagenesis: No reported evidence of that effect. Teratogenesis: Animal studies have shown that large doses, administered by ingestion, can cause atrophy in the male reproductive apparatus.

SECTION 12: Ecological information

12.1. Toxicity

Boric acid

Not applicable.

Tetraboron disodium decahydrate

Aquatic toxicity

- LC50: 27 mg B/l/4 days in fresh water (trout).
- LC50: 54 mg B/l/4 days in fresh water (trout).
- LC50: 155 mg B/l/4 days in fresh water (catfish).
- LC50: 71 mg B/l/4 days in hard water (catfish).
- LC50: 65 mg B/l/4 days in fresh water (gold fish).
- LC50: 59 mg B/l/4 days in hard water (gold fish).

Note: Boron is the reference to characterize the ecological effect of the product.

phytotoxicity: Boron is an essential element for the plants growth, but can be dangerous for high quantities. Avoid environmental contamination.

12.2. Persistence and degradability

Information not available.

12.3. Bioaccumulative potential

Not available.

12.4. Mobility in soil

Not available.

12.5. Results of PBT and vPvB assessment

Not available.

12.6. Other adverse effects

Not available.

SECTION 13: Disposal considerations

Dispose of in accordance with local and national regulations. In Italy dispose of according to Legislative Decree of April 3 2006 no. 152 "Regulations on environmental subject", application of European Directives on environmental protection, and subsequent modifications and integrations.

13.1. Waste treatment methods

Advice: not be disposed together with household garbage . Do not empty into drains . Recycle if possible or contact a waste company to ensure proper disposal.

Uncleaned packaging:

Contaminated containers and packaging of dangerous substances or preparations, have the same treatment as products.

European Parliament and Council Directive 94/62/EC of 20 December 1994 on packaging and packaging waste.

Uncleaned Packagings are to be disposed in the same manner as the product . Wash with water to be treated before disposal.

SECTION 14: Transport information

Not dangerous according to current transportation regulations.

14.1. UN-number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

Not applicable.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Not applicable.

14.6. Special precautions for user

Not applicable.



14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Not applicable.

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Regulation (EC) no. 1272/2008 (Classification, labeling and packaging of substances and mixtures) and subsequent amendments, amending and repealing Directive 67/548/EEC and 1999/45/EC, and amending Regulation (EC) no. 1907/2006.

Directive 2009/161/EU (third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC).

15.2. Chemical safety assessment

Not applicable.

SECTION 16: Other information

This Safety data sheet was prepared in accordance with the Commission Regulation (EU) no. 453/2010 and Commission Regulation (EU) no. 2015/830.

The safety data sheet has been written according to relevant European provisions, on the basis of information received by the supplier of the mixture.

The product is intended for orthodontic and odontological use only. The use of the product has to be restricted to skilled and licensed professionals. The information relates only to specific product designated and is not intended as a warranty of quality.

Leone disclaims any responsibility arising out of the use of the information here furnished, or of the handling, the application or the manufacture of the product here described. The final user is called to verify the application and completeness of the information herein in relationship to the specific use and reliability of the rules and local applicable dispositions.

The present information does not imply any liberty to break patent rights.

Previous safety data sheet no. R15/4E dated 16/01/2017 is to be considered obsolete. In comparison to the preceding revision, meaningful changes have not been effected but only adjustments to the European provisions which regulate the compilation of safety data sheets.

This safety data sheet is subject to revision. Visit our web site www.leone.it for an updated version of the present sheet.

Hazard statements

H360: May damage fertility or the unborn child.

P201: Obtain special instructions before use.

P308+P313: If exposed or concerned: Get medical advice/attention.

Legend

CAS No.: Chemical Abstract Service Registry number.

EC-No.: European Inventory of Existing Commercial Chemical Substances.

EN 374: Gloves Giving Protection from Chemicals and Micro-Organisms.

IBC Code: International Bulk Chemicals Code.

LD50: Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.

LTEL: Long Term Exposure Limit.

MSHA: Mine Safety and Health Administration.

NIOSH: National Institute for Occupational Safety and Health.

PBT: Persistent, Bioaccumulative And Toxic Substances.

STEL: Short Term Exposure Limit.

TLV: Threshold Limit Value.

TWA: Time Weighted Average.

vPvB: Very Persistent And Very Bioaccumulative Substances.

*referred to $\text{Na}_2\text{B}_4\text{O}_7 \cdot x\text{XH}_2\text{O}$