1. SECTION 1: Identification of the substance/mixture and of the company/undertaking

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.
Uses not recommended: Do not use for uses other than those indicated.

1.3. Details of the supplier of the safety data sheet

Leone s.p.a.
I – 50019 Sesto Fiorentino – Firenze - Via P. a Quaracchi, 48/50
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.
www.leone.it/emergency (EU and international telephone numbers).

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP].

Sezione	Classe di pericolo	Categoria	Classe categoria di pericolo	Indicazione di pericolo
3.3	Severe eye injury/eye irritation	2	Eye Irrit. 2	H319
3.7	Reproductive toxicity	1B	Repr. 1B	H360FD

For full text: see SECTION 16

2.2. Label elements

Pictograms: GHS08 GHS07

Hazard statements	H319	Causes serious eye irritation
	H360FD	May damage fertility. May damage the unborn child.
	P201	Obtain special instructions before use..
	P280	Wear protective gloves/protective clothing/eye protection/face protection
Precautionary Statement Prevention		
	P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
Precautionary Statement Response	P308+P313	IF exposed or concerned: Get medical advice/ attention.

2.3. Other hazards

PBT and vPvB assessment results
Based on its assessment results, this substance is not a PBT or vPvB.
Endocrine-disrupting properties
Does not contain an endocrine disruptor (ED) in a concentration of ≥0.1%.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name of the substance	CAS No.	EC No.	Index No.
di-Sodium tetraborate decahydrate	1330-43-4	215-540-4	005-001-00-4
Boric acid	10043-35-3	233-139-2	005-007-00-2

3.2. Mixtures

Not applicable.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation: Aerate the environment. Immediately remove the patient from the contaminated environment and keep the patient at rest in a well-ventilated room.

	In case of malaise, consult a doctor.
Skin contact	Wash thoroughly with soap and water.
Eye contact	Flush with running water for 10 minutes while holding the eyelids open. Do not use eye drops or ointments of any kind before examination or advice from ophthalmologist. In case of eye irritation, consult the ophthalmologist
Ingestion	Nonhazardous. You can administer activated charcoal in water or medicinal mineral vaseline oil. If you have an accident or feel unwell, consult your doctor immediately (if possible, show him the label)

4.2. Most important symptoms and effects, both acute and delayed
Irritation, nausea, vomiting, cramps, agitation, harmful effects on fertility.

4.3. Indication of any immediate medical attention and special treatment needed
In case of exposure or possible exposure, seek medical attention.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing Media	Water, foam, alcohol-resistant foam, dry extinguishing powder, chemical powders depending on the materials involved in the fire.
Unsuitable extinguishing Media	Water jet. Use water jets only to cool container surfaces exposed to fire.

5.2. Special hazards arising from the substance or mixture
Noncombustible.

5.3. Advice for firefighters
In case of fire and/or explosion, do not breathe fumes. Use respiratory protection.
Safety helmet and full protective clothing.
Water mist can be used to protect people engaged in extinguishment.
It is also advisable to use self-contained breathing apparatus, especially, if working in enclosed and poorly ventilated places and in any case if using halogenated extinguishing agents (fluobrene, solkane 123, naf etc.).
Cool containers with water jets.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel
Avoid contact with skin, eyes and clothing. Do not breathe in the dust. Move away from the area surrounding the spill or release. Do not smoke.
Wear mask, gloves and protective clothing.

6.1.2. For emergency responders

6.2. Environmental precautions
Wear mask, gloves and protective clothing.
Eliminate all open flames and possible sources of ignition. Do not smoke.
Arrange for adequate ventilation.
Evacuate the hazard area and, if necessary, consult an expert.

6.3. Methods and material for containment and cleaning up
Recommendations on how to contain a spill
Collect the product quickly while wearing a mask and protective clothing.
Collect the product for reuse, if possible, or for disposal.
Following collection, wash the affected area and materials with water.
Other information:
Store appropriate containers for disposal.

6.4. Reference to other sections
Section 8 and Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Precautions for safe handling
Wear gloves/protective clothing/eye/face protection.
Do not eat or drink while working.
Fire and aerosol/dust formation prevention measures
Eliminate dust deposits.
General occupational hygiene recommendations
Wash hands before breaks and at the end of work. Store away from food or feed and beverages.

7.2. Conditions for safe storage, including any incompatibilities
Keep in the original tightly closed container. Do not store in open or unlabeled containers.
Keep containers upright and secure, avoiding the possibility of dropping or knocking.
Store in a cool place, away from any source of heat and direct exposure to sunlight.

7.3 Specific end use(s)
There is no information available.

SECTION 8: Exposure controls/personal protection
8.1. Control parameters
- **BORAX:**

National limit values
Values related to human health

Relevant DNELs and other threshold levels				
Endpoint	**Threshold level**	**Protection target, route of exposure**	**Intended for**	**Exposure time**
DNEL	6,7 mg/m3	Human, by inhalation	Workers (industrial)	Chronic systemic effects
DNEL	316,4 mg/kg p.c/giorno	Human, dermal	Workers (industrial)	Chronic systemic effects

- **BORIC ACID**

Relevant DNELs and other threshold levels				
Endpoint	**Threshold level**	**Route of exposure**	**Intended for**	**Exposure time**
DNEL	8,3 mg/m³	Inhalation	Workers	Long-term sistermic
DNEL	392mg/kg p.c./giorno	Dermal	Workers	Long-term sistermic

8.2. Exposure controls
8.2.1. Appropriate engineering controls
Considering that the use of appropriate technical measures should always take priority over personal protective equipment, ensure good ventilation in the workplace through effective local exhaust ventilation.
When choosing personal protective equipment, seek advice from your chemical suppliers, if necessary.
Personal protective equipment should bear the CE marking attesting to its compliance with applicable standards.
Provide for emergency shower with eye wash.
8.2.2. Individual protection measures, such as personal protective equipment
Eye/faceprotection

Use the visor with side protection
We recommend wearing airtight goggles (ref. standard EN 166).

Skin Protection

Wear work clothes with long sleeves and safety footwear for professional category use.
Wash with soap and water after removing protective clothing.
Protect hands with category III work gloves. Compatibility, degradation, breakthrough time and permeability should be considered when making the final choice of work glove material. Gloves have a wear and tear that depends on the duration and mode of use.

Respiratory protection

It is recommended to wear a mask with type A filter whose class (1, 2 or 3). If gases or vapors of a different nature and/or gases or vapors with particles (aerosols, fumes, mists, etc.) are present, combined type filters should be provided. The use of respiratory protective means is necessary in case technical measures taken are not sufficient to limit the worker's exposure to the threshold values taken into consideration. However, the protection offered by masks is limited. Refer to EN 529 for the correct choice of respiratory protective equipment.
8.2.3. Environmental exposure controls
Keep away from drains, surface water and groundwater.
Emissions from production processes, including those from ventilation equipment, should be controlled for compliance with environmental protection regulations.

SECTION 9: Physical and chemical properties
9.1. Information on basic physical and chemical properties

	Boric acid	Tetraboron disodium decahydrate
Physical state	Solid	Solid
Colour	White.	White.
Odour	Odourless.	Odourless.
Melting point/freezing point	75°C (crystal water release)	no melting point can be defined in the 25-1000°C range because the substance decomposes above 10
Boiling point or initial boiling point and boiling range	Not determined	Not determined

Flammability	Not determined	Not determined
Lower and upper explosion limit	Not applicable.	Not applicable.
Flash point Auto-ignition temperature	Does not apply Not determined	Not determined The product is not self-heating
Decomposition temperature Ph	Irrelevant At 20°C: concentration 1g/l: 6.1; concentration 10g/l: 5.1; concentration 46.5g/l: 3.7	9.2 (in aqueous solution: 47g/l, 20°C)
Kinematic viscosity	Irrelevant	Not determined
Water solubility	49,74 g/l a 20°c	At 100°C: 379.9g/l
Partition coefficient n-octanol/water (log value)	-1,53 (valore pH: 7,5, 22°C)	Log Pow:--1.09 a 25°C
Vapour pressure	Not determined	Not determined
Density and/or relative density	1.49kg/dm3 at 23°C	1,73 g/cm3 at 20°C
Relative vapour density	/.	~750 kg/m3
Particle characteristics	the substance is not a nanoparticle	/.
Particle size	/.	Crystalline powder.

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Hazard classes according to GHS (physical hazards): insignificant

9.2.2. Other safety characteristics

There is no additional information

SECTION 10: Stability and reactivity

10.1. Reactivity

This material is not reactive under normal environmental conditions.

10.2. Chemical stability

The material is stable under normal environment and expected temperature and pressure conditions during storage and handling.

10.3. Possibility of hazardous reactions

Under normal use and storage conditions, no hazardous reactions are to be expected. Risk of explosion upon contact with acetic anhydride.

10.4. Conditions to avoid

Store away from heat.

10.5. Incompatible materials

None in particular. However, adhere to the usual cautions regarding chemicals.

10.6. Hazardous decomposition products

May develop boric anhydride and metaboric acid.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Boric Acid

Acute toxicity	Based on the available data, the classification criteria are not met.
Skin corrosion/irritation	Skin - Primary Skin Irritation Index (PDII) 0.1
Serious eye damage/irritation	Eyes - Corneal opacity <1
Respiratory or skin sensitisation	Skin: no skin sensitisation. Based on available data, the classification criteria are not met. Respiratory: no studies have been conducted on respiratory sensitisers. There are no data to suggest that boric acid is a respiratory sensitiser. Based on available data, the classification criteria are not met.
Germ cell mutagenicity	Based on the available data, the classification criteria are not met.
Carcinogenicity	No evidence of carcinogenicity.
Reproductive toxicity	Warning: the product may harm fertility and may harm the foetus.
STOT-single exposure	Based on the available data, the classification criteria are not met.
STOT-repeated exposure	Based on the available data, the classification criteria are not met.
Aspiration hazard	Based on the available data, the classification criteria are not met.

Tetraboron disodium decahydrate

Acute toxicity	It is not classified as acutely toxic.
Skin corrosion/irritation	It is not classified as corrosive/irritant to the skin.
Serious eye damage/irritation	Causes severe eye irritation.
Respiratory or skin sensitisation	It is not classified as a respiratory or skin sensitiser.
Germ cell mutagenicity	It is not classified as a germ cell mutagen.
Carcinogenicity	It is not classified as carcinogenic
Reproductive toxicity	It may harm the foetus. May harm fertility.
STOT-single exposure	Not classified as specific target organ toxicant (single exposure)
STOT-repeated exposure	Not classified as specific target organ toxicant (repeated exposure)
Aspiration hazard	It is not classified as hazardous in case of aspiration.

11.2 Information on other hazards

11.2.1. Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) in a concentration of ≥ 0.1%

11.2.2. Other information

Symptoms related to physical, chemical and toxicological characteristics

- On ingestion: vomiting, nausea, gastrointestinal disturbance
- In case of eye contact: causes severe eye irritation
- In case of inhalation: inhalation of dust may cause irritation of the respiratory tract.
- In case of skin contact: repeated and prolonged skin contact may cause irritation

Other adverse effects: cardiovascular system, cramps, agitation, adverse effects on fertility.

SECTION 12: Ecological information

12.1. Toxicity

Not classified as hazardous to the aquatic environment.

12.2. Persistence and degradability

Solubility in water: >10000mg/l.

12.3. Bioaccumulative potential

Not particularly concentrated in organisms

BORAX	n-octanol/water (log KOW)	-1.53 (pH value: 7.5, 22°C) (ECHA)
BORIC ACID	n-octanol/water (log KOW)	-1.09 (pH value: 7.5, 22°C) (ECHA)

12.4. Mobility in soil

The product is soluble in water and is leachable through normal soil.

12.5. Results of PBT and vPvB assessment

According to the available criteria, the product does not contain PBT and vPvB in ≥ 0.1%.

12.6. Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) in a concentration of ≥ 0.1%

12.7 Other adverse effects

Data is 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 including those of Decree-Law No. 153 of October 17, 2024.

13.1. Waste treatment methods

This material and its container must be disposed of as hazardous waste. Dispose of the product/container in accordance with local/regional/national/international regulations.

Disposal through sewage - relevant information

Do not dispose of residues into drains.

Waste treatment of containers/packaging

Handle contaminated packaging in the same way as the substance itself. Completely empty packaging can be recycled.

SECTION 14: Transport information

14.1. UN number or ID number

Not subject to transport regulations.

14.2. UN proper shipping name

None.

14.3. Transport hazard class(es)

None.

14.4. Packing group

None.

14.5. Environmental hazards

Not environmentally hazardous according to the Dangerous Goods Regulations.

14.6. Special precautions for user

There is no additional information.

14.7. Maritime transport in bulk according to IMO instruments

Bulk transport is not foreseen.

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).
This product is CE marked in accordance with the essential safety and performance requirements of Annex I of the European regulation on medical devices.

15.2. Chemical safety assessment

No chemical safety assessment has been conducted for this substance.

SECTION 16: Other information

This safety data sheet has been prepared in accordance with REACH Regulation (EC) 1907/2006 as amended by Regulation (EU) 2020/878.
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. R15/5E dated 31/01/2023 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.
Certain subsections of some sections are omitted because, as permitted by Annex II, Part B of Regulation (EU) 2020/878, they are not applicable.
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

H319	Causes serious eye irritation
H360FD	May damage fertility. May damage the unborn child.

Legend

CAS No.: Numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.
PBT: Persistent, Bioaccumulative and Toxic: Hazardous chemicals.
vPvB: Very Persistent Very Bioaccumulative.
CLP: Regulation (ec) no. 1275/2008 on classification, labelling and packaging.
DNEL: derived no-effect level.
EC Nr: The EC inventory (EINEC,ELINCS and the NPL list) is the resource for the seven-digit EC number that identifies commercially available substances within the EU (European Union).
Index Nr: The index number is the identification code assigned to the substance in Part 3 of Annex VI of Regulation (EC) No 1272/2008.
GHS: Globally Harmonized System of Classification and Labelling of Chemicals.
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals.
Repr.: Reproductive toxicity.
IMO: International Maritime Organization.
EN 166: Personal eye-protection – Specifications.
EN 529: Respiratory Protective Devices - Recommendations for Selection, Use, Care and Maintenance - Guidance Document.