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

1.1. Product identifier

Product description: Brazing flux type Flux A4, supplied in powder or paste form.

UFI: 3500-X0XH-X009-Y9T5

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

Identified Use Professional use: flux for orthodontic soldering.

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

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

Reproductive toxicity, cat. 2 H361

Additional information concerning health and/or environmental hazards can be found in sections 11 and 12 of this sheet.

2.2. Label elements

Programs GHS: GHS08
Signal word: Danger
Hazard statements: H361: Suspected of damaging fertility or the unborn child.
Precautionary statements: P280: Wear protective gloves/protective clothing/eye protection/face protection.
P201: Obtain special instructions before use.
P308+P313 IF exposed or concerned: Get medical advice/ attention.

Containing potassium metaborate.

2.3. Other hazards

According to the available data the product does not contain PBT or vPvB substances in a percentage greater than 0.1%.
Not classified as SVHC.
Not classified as substances with endocrine disrupting properties in concentrations >=0,1%.
Avoid inhaling fumes that develop during brazing operations, using extractor hoods, and/or protective masks.
Worker must use and carefully preserve the individual means of protections made available to them or provided by the employer and comply with the safety provisions.
Before starting welding and brazing operations, workers must be aware of the safety rules and must respect these rules.
Workers' bodies must be protected with suitable clothing.
Welding and brazing operations can present a danger of developing dangerous metal oxides and metal fumes (fine particles on the order of millimeters in size).

SECTION 3: Composition/information on ingredients

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

Hazardous ingredients	Product identifier	%W/W	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Potassium metaborate	CAS no. 13709-94-9 EC-No.: 201-297-1	50-60	Reproductive toxicity cat. 2, H361
Potassium tetrafluoroborate	CAS no. 14075-53-7 EC-No.: 237-928-2	40-50	

The full text of the hazard statements (H) is given in section 16 of the sheet.

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation	Remove the person from the danger area and let the breathe fresh air. If symptoms persist, consult a doctor. If the person is unconscious keep him in a stable position on his side during the transport.
Skin contact	Wash thoroughly with plenty of water for a few minutes.
Eye contact	Irritating to eyes. Rinse eyes for a few minutes with water, keeping the eyelids wide open.
Ingestion	Rinse your mouth thoroughly. Call a doctor immediately.

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

No information available.

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

No information available.

SECTION 5: Firefighting measures

The product is not flammable.

5.1. Extinguishing media

Suitable extinguishing Media	General means: chemical powder, CO_2, etc... Water spray can be used to disperse flammable substances and protect people involved in the fire.
Unsuitable extinguishing Media	None.

5.2. Special hazards arising from the substance or mixture

Fire or explosion hazards. In the event of a fire, dangerous substances may be released: potassium oxides, hydrogen fluoride, boron trifluoride.

5.3. Advice for firefighters

General information:

Cool the product with water jets to prevent decomposition and the development of substances potentially hazardous to health.

Collect extinguishing water which must not be discharged into drains. Dispose of contaminated water used for extinguishing and the residue of the fire according to current regulations.

Equipment:

Always wear full fire protection equipment, complete with breathing masks.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear a suitable respiratory mask for dust.

6.2. Environmental precautions

Prevent the product from entering sewers, surface water and groundwater.

6.3. Methods and material for containment and cleaning up

Powder flux:

Leave the area and wait for the product to settle on the ground. Ventilate the area and carefully collect any dust. Dispose of collected dust in accordance with local laws and regulations.

Flux paste:

Rinse thoroughly with water, avoiding water entering drainage systems. Dispose of the collected liquid (water and flux) in accordance with local laws and regulations.

6.4. Reference to other sections

For information on safe handling, refer to Section 7.

For information on personal protective equipment, refer to Section 8.

For information on disposal, refer to Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

The product must be handled by qualified personnel equipped with adequate personal protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Store in the original packaging, in a dry and well-ventilated area.

7.3. Specific end use(s)

When brazing, keep the workplace well-ventilated or use appropriate mechanical air extraction methods. If necessary, wear a suitable respiratory mask.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Potassium Metaborate

CAS: 13709-94-9
ACGIH 6 mg/m^3
ACGIH 2 mg/m^3
Potassium tetrafluoroborate
CAS: 14075-53-7
ACGIH 10 mg/m^3

DNEL
Potassium tetrafluoroborate

	Effects on consumers	Effects on workers
Route of exposure	Long systemic	Long systemic
Cutaneous	3,7 mg/kg bw/day	20,5 mg/kg bw/day
Inhalation	1,13 mg/mc	4,54 mg/mc
Oral	67 µg/kg bw/d	

PNEC
Potassium tetrafluoroborate
Fresh water: 2 mg/1.
Sea water: 0,2 mg/1.
Microorganisms STP: 55 mg/1.

8.2. Exposure controls

8.2.2. Individual protection measures, such as personal protective equipment

Eye protection	It is recommended to wear sealed safety glasses with side shields (ref. EN 166).
Hand protection	It is advisable to protect your hands with work gloves.
Respiratory protection	Ensure a well-ventilated workplace using mechanical air extraction and/or stale air exhaust system. If these measures are not sufficient to keep the concentration of the product below the exposure limit values, wear a suitable respirator.
Skin protection	We recommend wearing waterproof safety footwear and professional, long-sleeved, waterproof work clothes (ref. EN 344). After removing your work clothes, wash them with soap and water.
General hygiene measures	No information available.

8.2.3. Environmental exposure controls

No information available.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	Solid, dust or paste.
Colour	White
Odour	Slight
Odour threshold	Not applicable
Melting point/Freezing point	>550°C
Boiling point or initial boiling point and boiling range	Not applicable
Flammability	Not applicable
Lower and upper explosion limit	Not applicable
Flash point	Not applicable
Auto-ignition temperature	Not applicable
Decomposition temperature	Not applicable
pH	Approximately 8
Kinematic viscosity	Not applicable
Solubility	Not applicable
Partition coefficient n-octanol/water (log value)	Not applicable
Vapour pressure	Not applicable
Density and/or relative density	Not applicable
Relative vapour density	Not applicable
Particle characteristics	Not applicable

9.2. Other information

No information available.

9.2.2. Other safety characteristics

Explosive properties	Not applicable
Oxidising properties	Not applicable

SECTION 10: Stability and reactivity

10.1. Reactivity
Information not available.

10.2. Chemical stability
The product is stable under normal conditions of use and storage.

10.3. Possibility of hazardous reactions
Information not available.

10.4. Conditions to avoid
Avoid exposure to high temperatures.
Avoid exposure to humidity.

10.5. Incompatible materials
Keep away from: acids, strong bases, strong reducing agents.

10.6. Hazardous decomposition products
In case of decomposition, vapors of potassium fluoride and boron trifluoride may occur.

SECTION 11: Toxicological information

In the absence of experimental toxicological data on the product itself any product health hazards have been assessed based on the properties of the substances contained, according to the criteria laid down by the relevant regulations for the classification. Therefore, the concentrations for the individual dangerous substances listed in Section 3, to assess toxicological effects resulting from exposure to the product.

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

Metabolism, kinetics, mechanism of action and other information
Information not available.
Information on probable routes of exposure
Information not available.
Immediate, delayed and chronic effects resulting from short and long-term exposures.
Information not available.
Interactive effects
Information not available.
Acute toxicity

Substance	CAS	Method	Value	Unit of measure / Notes
Flux AG1		LD50-oral LC50-inhalation LD50-dermal	Not classified Not classified Not classified	(no significant component) (no significant component) (no significant component)
Potassium metaborate	13709-94-9	LD50-oral LC50-inhalation LD50-dermal	>3800 >2500	Mg/kg – Rat Mg/kg - Rabbit
Potassium tetrafluoroborate	14075-53-7	LD50-oral LC50-inhalation LD50-dermal	>2000 5,3	Mg/kg – Rat Mg/1/4h - Rat

Skin corrosion / skin irritation
It does not meet the classification criteria for this hazard class.
Serious eye damage / eye irritation
It does not meet the classification criteria for this hazard class.
Respiratory or skin sensitization
It does not meet the classification criteria for this hazard class.
Mutagenicity on germ cells
It does not meet the classification criteria for this hazard class.
Carcinogenicity
It does not meet the classification criteria for this hazard class.
Reproductive toxicity
Suspected of damaging fertility or the unborn child.
Specific target organ toxicity (STOT) – Single exposure
It does not meet the classification criteria for this hazard class.
Specific target organ toxicity (STOT) – Repeated exposure
It does not meet the classification criteria for this hazard class.
Danger in case of aspiration
It does not meet the classification criteria for this hazard class.

11.2 Information on other hazard

11.2.1. Endocrine disrupting properties
Based on available data, the product does not contain substances present in the main European lists of potential or suspected endocrine disruptors with effects on human health currently being evaluated.

SECTION 12: Ecological information

12.1. Toxicity

Substance	CAS	Method	Value	Unit of measure	Notes
Potassium metaborate	13709-94-9	LC10-Fish LC50-Fish EC10-Crustaceas EC50-Crustaceas EC10 Algae/Aquatic Plants EC50 Algae/Aquatic Plants NOEC-Fish NOEC-Crustaceans NOEC- Algae/Aquatic Plants			
Potassium tetrafluoroborate	14075-53-7	LC10- Fish LC50- Fish EC10-Crustaceas EC50- Crustaceans EC10 Algae/Aquatic Plants EC50 Algae/Aquatic Plants NOEC-Fish NOEC-Crustaceans NOEC- Algae/Aquatic Plants	 >760 >100 >100	 Mg/1/96h Mg/1/48h Mg/1	 Leuciscus idus Daphnia magna Pseudokirchneriella subcapitata

12.2. Persistence and degradability
Information not available.

12.3. Bioaccumulative potential
Information not available.

12.4. Mobility in soil
Information not available.

12.5. Results of PBT and vPvB assessment
N/A

12.6. Endocrine disrupting properties
Based on available data, the substance is not listed in the main European lists of potential or suspected endocrine disruptors with effects on the environment being evaluated.

12.7. Other adverse effects
Information 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 17 October 2024.

13.1. Waste treatment methods
Reuse if possible. Product residues are to be considered hazardous special waste. The dangerousness of waste that partly contains this product must be assessed based on current legislative provisions. Disposal must be entrusted to a company authorized to manage waste, in compliance with national and possibly local regulations.

Contaminated packaging

Contaminated packaging must be recovered or disposed of in compliance with national waste management.

SECTION 14: Transport information
The product is not to be considered dangerous according to current transportation regulations of dangerous goods by road (A.D.R.), by rail (RID), by sea (IMDG Code) and by air (IATA).

14.1. UN number or ID 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. Maritime transport in bulk according to IMO instruments
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
A chemical safety assessment has not been developed for the mixture and the substances it contains.

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 odonatological 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. R16-7E dated 14/09/2023 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
H361 Suspected of damaging fertility or the unborn child.

Legend
ACGIH: American Conference of Governmental Industrial Hygienists.
ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS No.: numerical identifier that uniquely identifies a chemical substance, assigned by the Chemical Abstract Service.
CLP: Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008.
DNEL: Derived-No Effect Level.
EC-Number: EINECS and ELINCS Number (see also EINECS and ELINCS).
EC10: Effect concentration for 10% of the sample.
EC50: 50 % effective concentration. Corresponds to the concentration of a tested substance capable of causing 50 % effect changes (e.g. on growth) during a specified time interval.
EN 166: Personal eye-protection – Specifications.
EN 344: Safety, protective and occupational footwear for professional use - Additional requirements and test methods.
GHS: Globally Harmonized System of Classification and Labelling of Chemicals.
IATA: International Air Transport Association.
IMDG Code: International Maritime Dangerous Goods Code.
IMO: International Maritime Organization.
LC10: Lethal concentration for 10% of the sample.
LC50: Lethal Concentration 50: lethal concentration of substance for 50% of organisms of a certain population during a certain exposure period.
LD50 Lethal Dose 50: the dose required to kill half the members of a tested population after a specified test duration.
NOEC: No-Observed Effect Concentration.
PBT: Persistent, Bioaccumulative And Toxic Substances.
PNEC: Predicted No-Effect Concentration.
REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
RID: Regulations concerning the International Carriage of Dangerous Goods by Rail.
STP: Waste water treatment plant.

SVHC: Substances of Very High Concern.
UFI: Unique Formula Identifier.
vPvB: Very Persistent And Very Bioaccumulative Substances.