

# SAFETY DATA SHEET

(in accordance with Regulation (EU) 2020/878)



## RAYKAT BRIX

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### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING.

#### 1.1 Product identifier.

Product Name: **RAYKAT BRIX**

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

Use: Fertilizer (professional use)

#### 1.3 Details of the supplier of the safety data sheet.

Company: **ATLANTICA AGRICOLA SA**  
Address: C/ CORREDERA Nº33 ENTLO  
City: VILLENA  
Province: ALICANTE  
Telephone: +34 96 5800358  
Fax: +34 96 5804309  
E-mail: sds@atlanticaagricola.com

#### 1.4 Emergency telephone number:

The Cyprus Poison Center Number is **1401** (currently operating 24 hrs/day, 7 days/week)

### SECTION 2: HAZARDS IDENTIFICATION.

#### 2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008:

- Eye Irrit. 2 : Causes serious eye irritation.
- Repr. 1B : May damage fertility or the unborn child.
- STOT SE 3 : May cause respiratory irritation.
- Skin Irrit. 2 : Causes skin irritation.

#### 2.2 Label elements.

##### Labelling in accordance with Regulation (EC) No 1272/2008:

Pictograms:



Signal Word:

**Danger**

Hazard statements:

- H315 Causes skin irritation.
- H319 Causes serious eye irritation.
- H335 May cause respiratory irritation.
- H360FD May damage fertility. May damage the unborn child.

Precautionary statements:

- P102 Keep out of reach of children.
- P270 Do not eat, drink or smoke when using this product.
- P280 Wear protective gloves/protective clothing/eye protection/face protection.
- P501 Dispose of contents/container to collection point for special waste.

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P303+P361+P353 +P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower. Immediately call a POISON CENTER or doctor/physician.  
P305+P351+P338+P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER or doctor/physician.

Contains:  
boric acid  
potassium carbonate

### 2.3 Other hazards.

The mixture does not contain substances classified as PBT.  
The mixture does not contain substances classified as vPvB.  
The mixture does not contain any endocrine disrupting properties substances.

In normal use conditions and in its original form, the product itself does not involve any other risk for health and the environment.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS.

### 3.1 Substances.

Not Applicable.

### 3.2 Mixtures.

Substances posing a danger to health or the environment in accordance with the Regulation (EC) No. 1272/2008, assigned a Community exposure limit in the workplace, and classified as PBT/vPvB or included in the Candidate List:

Identifiers	Name	Concentrate	(*)Classification - Regulation (EC) No 1272/2008	
			Classification	Specifics concentration limits and Acute toxicity estimate
CAS No: 584-08-7 EC No: 209-529-3 Registration No: 01-2119532646-36	potassium carbonate	20 - 50 %	Eye Irrit. 2, H319 - STOT SE 3, H335 - Skin Irrit. 2, H315	-
Index No: 005-007-00-2 CAS No: 10043-35-3 EC No: 233-139-2 Registration No: 01-2119486683-25	[1] boric acid	0.3 - 2.5 %	Repr. 1B, H360FD	-

(\*) The complete text of the H phrases is given in section 16 of this Safety Data Sheet.

[1] Substance included in the list established under Article 59, paragraph 1, REACH (Candidate substance).

## SECTION 4: FIRST AID MEASURES.

IRRITANT MIXTURE. Its repeated or prolonged contact with the skin or mucous membranes can cause irritant symptoms such as reddening of the skin, blisters, or dermatitis. Some of the symptoms may not be immediate. They can cause allergic reactions on the skin.

### 4.1 Description of first aid measures.

Delayed effects may occur after the exposure to the product.

#### Inhalation.

Take the victim into open air; keep them warm and calm. If breathing is irregular or stops, perform artificial respiration. Do not administer anything orally. If unconscious, place them in a suitable position and seek medical assistance.

#### Eye contact.

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Remove contact lenses, if present and if it is easy to do. Wash eyes with plenty of clean and cool water for at least 10 minutes while pulling eyelids up, and seek medical assistance. Don't let the person to rub the affected eye.

**Skin contact.**

Remove contaminated clothing. Wash skin vigorously with water and soap or a suitable skin cleaner. NEVER use solvents or thinners.

**Ingestion.**

If accidentally ingested, seek immediate medical attention. Keep calm. NEVER induce vomiting.

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

Irritant Product, repeated or prolonged contact with skin or mucous membranes can cause redness, blisters or dermatitis, inhalation of spray mist or particles in suspension may cause irritation of the respiratory tract, some symptoms may not be immediate.

Long-term chronic exposure may result in injury to certain organs or tissues.

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

In case of doubt or when symptoms of feeling unwell persist, get medical attention. Never administer anything orally to persons who are unconscious. Keep the person comfortable. Turn him/her over to the left side and stay there while waiting for medical care.

## SECTION 5: FIREFIGHTING MEASURES.

The product is NOT classified as flammable, in case of fire the following measures should be taken:

**5.1 Extinguishing media.**

**Suitable extinguishing media:**

Extinguisher powder or CO<sub>2</sub>. In case of more serious fires, also alcohol-resistant foam and water spray.

**Unsuitable extinguishing media:**

Do not use a direct stream of water to extinguish. In the presence of electrical voltage, you cannot use water or foam as extinguishing media.

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

**Special risks.**

Exposure to combustion or decomposition products can be harmful to your health.

**5.3 Advice for firefighters.**

Use water to cool tanks, cisterns, or containers close to the heat source or fire. Take wind direction into account. Prevent the products used to fight the fire from going into drains, sewers, or waterways.

**Fire protection equipment.**

According to the size of the fire, it may be necessary to use protective suits against the heat, individual breathing equipment, gloves, protective goggles or facemasks, and boots.

## SECTION 6: ACCIDENTAL RELEASE MEASURES.

**6.1 Personal precautions, protective equipment and emergency procedures.**

For exposure control and individual protection measures, see section 8.

**6.2 Environmental precautions.**

Product not classified as hazardous for the environment, avoid spillage as much as possible.

**6.3 Methods and material for containment and cleaning up.**

Contain and collect spillage with inert absorbent material (earth, sand, vermiculite, Kieselguhr...) and clean the area immediately with a suitable decontaminant.

Deposit waste in closed and suitable containers for disposal, in compliance with local and national regulations (see section 13).

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### 6.4 Reference to other sections.

For exposure control and individual protection measures, see section 8.

For later elimination of waste, follow the recommendations under section 13.

## SECTION 7: HANDLING AND STORAGE.

### 7.1 Precautions for safe handling.

For personal protection, see section 8.

In the application area, smoking, eating, and drinking must be prohibited.

Follow legislation on occupational health and safety.

Never use pressure to empty the containers. They are not pressure-resistant containers. Keep the product in containers made of a material identical to the original.

### 7.2 Conditions for safe storage, including any incompatibilities.

Store according to local legislation. Observe indications on the label. Store the containers between 5 and 25 ° C, in a dry and well-ventilated place, far from sources of heat and direct solar light. Keep far away from ignition points. Keep away from oxidising agents and from highly acidic or alkaline materials. Do not smoke. Prevent the entry of non-authorized persons. Once the containers are open, they must be carefully closed and placed vertically to prevent spills.

The product is not affected by Directive 2012/18/EU (SEVESO III).

### 7.3 Specific end use(s).

Fertilizer.

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

### 8.1 Control parameters.

The product does NOT contain substances with Professional Exposure Environmental Limit Values. The product does NOT contain substances with Biological Limit Values.

Concentration levels DNEL/DMEL:

Name	DNEL/DMEL	Type	Value
boric acid CAS No: 10043-35-3 EC No: 233-139-2	DNEL (Workers)	Inhalation, Chronic, Systemic effects	8,3 (mg/m <sup>3</sup> )

### **POTASSIUM CARBONATE (CAS N°: 584-08-7)**

**VLA-ED-PNCOF** (insoluble particles not classified in other ways)

Breathable fraction: 10 mg / m<sup>3</sup>

Inhalable fraction: 3 mg / m<sup>3</sup> (INSHT)

**TLV-TWA-PNCOF** (insoluble particles not classified in other ways)

Breathable fraction: 10 mg/m<sup>3</sup>

Inhalable fraction: 3 mg/m<sup>3</sup> (ACGIH)

Human exposure:

For workers

DNEL (inhalation, local long-term effects): 10 mg / m<sup>3</sup>

For the population:

DNEL (inhalation, local long-term effects): 10 mg / m<sup>3</sup>

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.

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DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

### 8.2 Exposure controls.

#### Measures of a technical nature:

Provide adequate ventilation, which can be achieved by using good local exhaust-ventilation and a good general exhaust system.

<b>Concentration:</b>	<b>100 %</b>		
<b>Breathing protection:</b>			
If the recommended technical measures are observed, no individual protection equipment is necessary.			
<b>Hand protection:</b>			
PPE:	Non-disposable protective gloves against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals for which the glove has been tested.		
CEN standards:	EN 374-1, EN 374-2, EN 374-3, EN 420		
Maintenance:	A schedule for the periodical replacement of gloves should be established in order to guarantee their replacement before pollutants permeate them. The use of contaminated gloves could be more dangerous than not using gloves, since the pollutant can gradually accumulate in the glove's material.		
Observations:	They are to be replaced whenever tears, cracks or deformations are observed or when exterior dirt could reduce their strength.		
Material:	PVC (polyvinyl chloride)	Breakthrough time (min.): > 480	Material thickness (mm): 0,35
<b>Eye protection:</b>			
PPE:	Protective goggles with built-in frame.		
Characteristics:	«CE» marking, category II. Eye protector with built-in frame for protection against dust, smoke, fog and vapour.		
CEN standards:	EN 165, EN 166, EN 167, EN 168		
Maintenance:	Visibility through lenses should be ideal. Therefore, these parts should be cleaned daily. Protectors should be disinfected periodically following the manufacturer's instructions.		
Observations:	Some signs of wear and tear include: yellow colouring of the lenses, superficial scratching of the lenses, scraping etc.		
<b>Skin protection:</b>			
PPE:	Chemical protective clothing		
Characteristics:	«CE» marking, category III. Clothing should fit properly. The level of protection must be set according to a test parameter called BT (Breakthrough Time), which indicates how long it takes for the chemical to pass through the material.		
CEN standards:	EN 464, EN 340, EN 943-1, EN 943-2, EN ISO 6529, EN ISO 6530, EN 13034		
Maintenance:	In order to guarantee uniform protection, follow the washing and maintenance instructions provided by the manufacturer.		
Observations:	The protective clothing's design should facilitate correct positioning, staying in place without moving for the period of use expected, bearing in mind environmental factors as well as any movement or position the user might adopt while carrying out the activity.		
PPE:	Anti-static safety footwear against chemicals.		
Characteristics:	«CE» marking, category III. Check the list of chemicals against which the footwear is resistant.		
CEN standards:	EN ISO 13287, EN 13832-1, EN 13832-2, EN 13832-3, EN ISO 20344, EN ISO 20345		
Maintenance:	For correct maintenance of this kind of safety footwear, it is necessary to observe the instructions specified by the manufacturer. The footwear should be replaced as soon as any sign of damage is observed.		
Observations:	The footwear should be cleaned regularly and dried when damp, although it should not be placed too close to a source of heat in order to avoid any sharp changes in temperature.		

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES.

### 9.1 Information on basic physical and chemical properties.

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Physical state: Liquid  
Colour: dark brown.  
Odour: N.A./N.A.  
Odour threshold: N.A./N.A.  
Melting point: N.A./N.A.  
Freezing point: N.A./N.A.  
Boiling point or initial boiling point and boiling range: N.A./N.A.  
Flammability: N.A./N.A.  
Lower explosion limit: N.A./N.A.  
Upper explosion limit: N.A./N.A.  
Flash point: N.A./N.A.  
Auto-ignition temperature: N.A./N.A.  
Decomposition temperature: N.A./N.A.  
pH: 11 - 11.5 (100%).  
Kinematic viscosity: N.A./N.A.  
Solubility: N.A./N.A.  
Hydrosolubility: N.A./N.A.  
Liposolubility: N.A./N.A.  
Partition coefficient n-octanol/water (log value): N.A./N.A.  
Vapour pressure: N.A./N.A.  
Absolute density: N.A./N.A.  
Relative density: 1.37 g/cc.  
Relative vapour density: N.A./N.A.  
Particle characteristics: N.A./N.A.

N.A./N.A. = Not applicable/Not available due to the nature/properties of the product

### 9.2 Other information

Viscosity: N.A./N.A.  
Explosive properties: N.A./N.A.  
Oxidizing properties: N.A./N.A.  
Dropping point: N.A./N.A.  
Blink: N.A./N.A.

N.A./N.A. = Not applicable/Not available due to the nature/properties of the product

## SECTION 10: STABILITY AND REACTIVITY.

### 10.1 Reactivity.

The product does not present hazards by their reactivity.

### 10.2 Chemical stability.

Unstable in contact with:  
- Acids.

### 10.3 Possibility of hazardous reactions.

Neutralization can occur on contact with acids.

### 10.4 Conditions to avoid.

- Avoid contact with acids.

### 10.5 Incompatible materials.

Avoid the following materials:  
- Acids.

### 10.6 Hazardous decomposition products.

Depending on conditions of use, can be generated the following products:  
- Corrosive vapors or gases.

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### SECTION 11: TOXICOLOGICAL INFORMATION.

IRRITANT MIXTURE. Splashes in the eyes can cause irritation.

IRRITANT MIXTURE. The inhalation of spray mist or suspended particulates can irritate the respiratory tract. It can also cause serious respiratory difficulties, central nervous system disorders, and in extreme cases, unconsciousness.

IRRITANT MIXTURE. Its repeated or prolonged contact with the skin or mucous membranes can cause irritant symptoms such as reddening of the skin, blisters, or dermatitis. Some of the symptoms may not be immediate. They can cause allergic reactions on the skin.

#### 11.1 Information on hazard classes as defined in Regulation (EC) N° 1272/2008.

There are no tested data available on the product.

Repeated or prolonged contact with the product can cause the elimination of oil from the skin, giving rise to non-allergic contact dermatitis and absorption of the product through the skin.

a) acute toxicity;

Not conclusive data for classification.

b) skin corrosion/irritation;

Product classified:

Skin irritant, Category 2: Causes skin irritation.

c) serious eye damage/irritation;

Product classified:

Eye irritation, Category 2: Causes serious eye irritation.

d) respiratory or skin sensitisation;

Not conclusive data for classification.

e) germ cell mutagenicity;

Not conclusive data for classification.

f) carcinogenicity;

Not conclusive data for classification.

g) reproductive toxicity;

Product classified:

Reproductive toxicant, Category 1B: May damage fertility or the unborn child.

h) STOT-single exposure;

Product classified:

Specific target organ toxicity following a single exposure, Category 3: May cause respiratory irritation.

i) STOT-repeated exposure;

Not conclusive data for classification.

j) aspiration hazard;

Not conclusive data for classification.

#### Toxicological information about the substances present in the composition:

##### POTASSIUM CARBONATE (CAS N° 584-08-7)

Acute Toxicity			
Type	Assay	Specie	Result
Oral	LD50	Rat	>2000 mg/kg
Cutaneous	DL50	Rabbit	>2000 mg/kg bw
Inhalation	CL50	Rat	>4,6 mg/L air (4,5h)

#### Corrosion / irritation of the skin:

Irritating to the skin: Category 2: causes skin irritation.

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studies with rabbits show no skin irritation. Accidental exposure (man 50 years) deep dermal lesions. If irritant effects are intensified in the case of the mixture with cleaning agents or other unidentified substances.

### Serious eye injuries:

Eye Irritation: Category 2: Causes severe eye irritation (rabbit).

### Specific toxicity target organs (single exposure).

Category 3: can irritate the airways.

### Sensitization:

Respiratory Sensitization: No data available

Skin Sensitization: not sensitizing (guinea pig).

### Repeated dose toxicity:

Specific toxicity in target organ (repeated exposure): In view of the available data, the classification criteria are not met.

Oral route of exposure (rat):

NOAEL: 2667 mg / kg bw / day (actual dose received, male)

NOAEL: 3331 mg / kg bw / day (actual dose received; female)

(Test conducted with Potassium Bicarbonate. Study of 18 months).

Inhalation exposure:

NOAEC (local): 0.062 mg / L air

(Equivalent to OECD Method 412)

### CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction):

**Carcinogenicity:** In view of the available data, the classification criteria are not met.

Oral exposure in rats:

NOAEL: 2667 mg / kg bw / day (actual dose received, male)

NOAEL: 3331 mg / kg bw / day (actual dose received; female)

(Test conducted with Potassium Bicarbonate. Study of 30 months).

**Germ cell mutagenicity:** A view of the available data, the classification criteria are met.

Negative in tests in vitro mutations in bacteria (equivalent to OECD 471 method), in vitro assays of mutations in mammalian cells (equivalent method OECD 476) and in vitro chromosomal aberration test (OECD 473 method equivalent).

**Reproductive toxicity:** In view of the available data, the classification criteria are not met.

Oral exposure in rats:

NOEL (maternal toxicity, teratogenicity, fetotoxicity): 180 mg / kg bw / day (maximum dose, no effects are observed)

(Equivalent to OECD Method 414).

**Reproductive toxicity, effects on or via lactation:** No information available

### Aspiration hazard:

In view of the available data, the classification criteria are not met.

### BORIC ACID (CAS Nº 10043-35-3)

#### - Acute toxicity:

Acute toxicity	Oral LD50	>2000mg/kg	Rat	Test method: OECD 401
Acute toxicity	Dermal DL50	>2000mg/kg	Rabbit	Test method: FIFRA (40 CFR 163)
Acute toxicity	Inhalation CL50	>2,03 mg/l (polvo/niebla)	Rat 4 hours	Test method: OECD 403

#### - Skin corrosion or irritation.

Method: primary skin irritation study - FIFRA (EPA, 40 CFR 163).

Species: New Zealand white rabbit.

Dose: 0.5 g moistened with saline solution.

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Routes of exposure: skin.

Results: no skin irritation was observed. Primary irritation average rating: 0.1. According to available data, the classification criteria are not met.

- **Irritation Serious eye damage.**

Methods: eye irritation study - similar to OECD Guideline 405.

Species: New Zealand white rabbit.

Dose: 0.1 g.

Routes of exposure: eyes.

Result: non-irritant, corneal involvement or irritation disappear in 7 days.

Classification: According to the average scores of <1 and taking into account the effects completely disappeared in seven days, the classification criteria are not met. No adverse effects were seen in the eye after many years of occupational exposure

- **Respiratory or skin sensitization.**

Method: Buehler test - OECD Guideline 406.

Species: guinea pig.

Dose: 0.4 g 95% w / w / boric acid.

Routes of exposure: skin.

Result: not cause skin sensitization. No studies have been conducted on respiratory sensitization. There are no data to indicate that boric acid cause respiratory sensitization. Based on existing data, the classification criteria are not met.

- **Germ cell mutagenicity.**

Method: we have conducted several in vitro mutagenicity studies in boric acid, including genetic mutation mammalian cells, the unscheduled DNA synthesis, chromosomal aberration and sister chromatid exchange in mammalian cells.

Species: mouse lymphoma L5178Y, V79 Chinese hamster cells, C3H / 10T1 / 2 cells, hepatocytes, Chinese Hamster Ovary (CHO cells).

Dose: 1.0 - 10.0 mg / ml (1000-10000 ppm) of boric acid.

Routes of exposure: in vitro.

Result: not mutagenic. According to available data, the classification criteria are not met.

- **Carcinogenicity**

Method: Equivalent to OECD Guideline 451.

Species: B6C3F1 mice.

Dose: 446; 1150 mg boric acid / kg bw / day

Routes of exposure: study of oral feeding.

Results: no evidence of carcinogenicity was observed. According to available data, the classification criteria are not met.

- **Reproductive toxicity.**

Method: feeding study three generations, similar to the study of two generations of the OECD Guideline 416.

Species: rat

Dose: 0; 34 (5.9); 100 (17.5) and 336 (58.5) mg of boric acid (mg B) / kg bw / day.

Routes of exposure: study of oral feeding.

Results: The NOAEL in rats with respect to effects on fertility in males is 100 mg boric acid / kg bw acid, equivalent to 17.5 mg B / kg bw.

Method: Toxicity study of boric acid for prenatal development - OECD Guideline 414.

Species: rat.

Dose: 0; 19 (3.3); 36 (6.3); 55 (9.6); 76 (13.3) and 143 (25) mg of boric acid (B mg) / kg bw.

Routes of exposure: study of oral feeding.

Results: the NOAEL in rats in regard to the effects on fetal development, including fetal weight loss and minor skeletal variations, is 55 mg of boric / kg bw acid or 9.6 mg B / kg.

Rating: Reproductive toxicity Category 1B (Hazard: H360FD: May damage fertility can harm the fetus.).

Method: occupational assessment studies sensitive sperm parameters of workers subjected to intense exposure to borates.

Epidemiological studies have been conducted to evaluate the high levels of environmental exposure to boron and its effects on human development.

Species: Human

Dose: a subset of workers underwent B 125 mg / day.

Routes of exposure: combined oral ingestion and inhalation

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Results: no adverse effects were seen on fertility of male workers. Epidemiological studies on the effects on the development of human indicate no effects in workers exposed to borates and the population living in areas with high environmental levels of boron

### Summary assessment of CMR properties:

Boric acid is not mutagenic and, according to the negative results of bioassays of 2 years duration, is not carcinogenic. Therefore, a classification of these parameters to the disodium tetraborate is not required, under Directive (EC) 67/548 / EEC or Regulation (EC) No 1272/2008 (CLP) with. A study of several generations of rats established a NOAEL for fertility in males of 17.5 mg B / kg / day. Effects have been observed in the development of laboratory animals, the most sensitive species rat whose NOAEL is 9.6 mg B / kg bw / day. Disodium tetraborate is classified in the 1st ATP to the CLP as Repr. 1B; H360FD. Although it has been shown that boron affects male reproduction under studies with laboratory animals they have not been found clear evidence of effects attributable to boron in male reproduction of workers subject to intense exposure to such substance.

#### - STOT- single exposure:

Method: Standard Test Method for calculating the sensory irritation from chemicals in the atmosphere - ASTM E981-04 (2004).  
Species: mouse.

Dose: 221 - 1096 mg of boric / m3 acid.

Routes of exposure: inhalation.

Results: The highest concentration of boric acid obtained with an acceptable control of the aerosol concentration was 1096 mg / m3 with 19% DR%. The minimum specified in the test exposure of 221 mg / m3 of boric acid, resulted in a reduction in respiratory rate of 9%, classified as no irritation. According to available data, the classification criteria are not met.

Method: sensory irritation in human volunteers.

Species: Human.

Doses: 2.5, 5, 10 mg of boric / m3 acid.

Routes of exposure: inhalation.

Results: no irritation was observed caused by boric acid exposure levels up to 10 mg / m3 between men and women volunteers under controlled laboratory conditions.

#### - STOT- repeated exposure:

Method: chronic toxicity study boric acid, similar to OECD Guideline 452.

Species: rat.

Dose: 0; 33 (5.9); 100 (17.5); 334 (58.5) mg of boric acid (B) / kg body weight per day (nominal in diet).

Routes of exposure oral feeding.

Results: As a result of a chronic feeding study (2 years) in rats and its effects based on a NOAEL of 17.5 mg B / kg bw / day, equivalent to 100 mg of boron / kg bw / day was established acid . Other effects (kidney, hematopoietic system) only contemplate even higher doses. According to available data, the classification criteria are not met.

- **Risk of aspiration:** to be a solid in powder form no risk of aspiration.

### Toxicokinetics

The main species present in the bloodstream is boric acid, which is not metabolized. Boric acid is spread quickly and uniformly throughout the body, with concentrations in bone 2 or 3 times higher than in other tissues. Boric acid is rapidly excreted, with elimination half-lives in mice 1 h, 3 h in rats and <27.8 h in humans. Also, the potential for accumulation is low. Boric acid is mainly excreted in the urine. Borates absorption by the oral route is almost 100%. The worst case scenario has a 100% absorption through inhalation. Skin absorption levels through intact skin are very low, with the absorbed dose of <0.5%.

### Information on likely routes of exposure:

The most significant route of exposure in workplaces and other is inhalation. Dermal exposure is not usually present problems due to the low level of absorption of the product through intact skin. The product is not intended for ingestion.

### Symptoms related to the physical, chemical and toxicological characteristics:

The products are not intended for ingestion. No effects resulting from accidental ingestion of small amounts, equivalent to a teaspoon anticipated. Symptoms of accidental exposure to high doses of inorganic borate salts have been associated with ingestion or absorption through large areas of very damaged skin. Such symptoms can include nausea, vomiting and diarrhea, as well as delayed effects consistent redness and peeling of the skin.

### Delayed and immediate effects as well as chronic effects from exposure to short and long term:

Epidemiological studies in humans show that an increase in pulmonary disease in workers exposed chronically to boric acid and sodium borate dust occurs. Epidemiological studies in humans indicate that fertility of workers chronically exposed to dust borate is not affected, nor that of the general population exposed to high concentrations of borates in the environment.

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### 11.2 Information on other hazards.

#### Endocrine disrupting properties

This product does not contain components with endocrine-disrupting properties with effects on human health.

#### Other information

There is no information available on other adverse health effects.

## SECTION 12: ECOLOGICAL INFORMATION.

### 12.1 Toxicity.

Ecotoxicological information about the substances present in the composition.

#### POTASSIUM CARBONATE (CAS N° 584-08-7)

Type	Assay	Specie	Result
Fishes	CL50	Oncorhynchus mykiss	68 mg/L (96h)
Aquatic invertebrates	CE50	Daphnia pulex	200 mg/l (48h)

#### **Chronic toxicity to fish**

NOEC (no observed effect concentration) is not considered necessary to conduct the study, the substance dissociates in water to give potassium and carbonate ions, essential for almost all living organisms.

#### **Chronic toxicity to crustaceans**

NOEC (no observed effect concentration) is not considered necessary to conduct the study, the substance dissociates in water to give potassium and carbonate ions, essential for almost all living organisms.

#### **Acute toxicity to algae and other aquatic plants**

CE50 (no observed effect concentration) is not considered necessary to conduct the study, the substance dissociates in water to give potassium and carbonate ions, essential for almost all living organisms.

#### **Toxicity data and macro-micro soil organisms and other environmentally relevant organisms, such as bees, birds, plants**

Species: Eisenia sp. (annelid)

(Test conducted with Potassium Bicarbonate. Study of 18 months).

NOEC: 4238 mg/kg dry weight soil.

LC50 (14 d): 5595 mg / kg soil dry weight

It is not considered necessary, further studies because potassium carbonate are present ubiquitously in the environment, minerals, soils and sediments, natural waters (oceans, lakes, rivers), biomass and humans and also in wastewater .

#### **BORIC ACID (CAS No 10043-35-3)**

Note that the values are expressed in equivalent boron. To convert the amounts of this product is to be split between the equivalent of boron 0.175. They have rejected those studies considered unreliable or offer little information for evaluation.

#### Fresh water

*Chronic toxicity studies.*

Taxonomic group	Number of taxa studied	Interval parameters (geometric mean NOEC/EC10)	Reference
Algae	4	Between 10 mg B/L (Chlorella pyrenoidosa) and 50 mg B/L (Anacystis nidulans)	3, 4
Higher plants	3	Between 4 mg B/L (Phragmites australis) and 60 mg B/L (Lemna minor)	5, 6
Invertebrates and protozoa	7	Between 5.7 mg B/L (Daphnia magna) and 32 mg B/L (Chironomus riparius)	7, 8
Fish	6	Between 2.9 mg B/L (Micropterus salmoides) and 17 mg B/L	9

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		(Carassius auratus)	
Amphibians	2	Between 29 mg B/L (Rana pipiens) and 41 mg B/L (Bufo fowleri)	9

Results<sup>2</sup>: according to the set corresponding to 22 species complete data, the HC5 value of the distribution of species sensitivity is 4.05 mg B / L.

*Acute toxicity studies.*

Taxonomic group	Number of taxa studied	Interval parameters (geometric mean NOEC/EC10)	Reference
Algae	2	Between 10 mg B/L (Chlorella pyrenoidosa) and 28 mg B/L (Selenastrum capricornutum)	3, 10
Invertebrates and protozoa	9	Between 113 mg B/L (Ceriodaphnia dubia) and 1376 mg B/L (Chironomus decorus)	11, 12
Fish	7	Between 80 mg B/L (Pimephales promelas) and 627 mg B/L (Onchorhynchus tshawytscha)	11, 13
Amphibians	2	Between 86 mg B/L (Rana pipiens) and 104 mg B/L (Bufo fowleri)	9

Results<sup>2</sup>: according to the corresponding set of 46 studies with 20 species comprehensive data, the HC5 value of the distribution of species sensitivity is 27.3 mg B / L.

Classification: based on acute toxicity data on freshwater species, this substance is not classified as dangerous for the environment.

### Data for marine environments and estuaries

*Chronic toxicity studies*

Taxonomic group	Number of taxa studied	Interval parameters (geometric mean NOEC/EC10)	Reference
Algae	19	Between 5 mg B/L (Emiliana huxleyi) and >100 mg B/L (Agmenellum quadruplicatum, Anacystis marina, Thallassiosira pseudonana).	4

Results: there are no data on invertebrate and vertebrate species. We recommend applying the results for the dataset fresh to saltwater species and study water.

*Acute toxicity studies*

Taxonomic group	Number of taxa studied	Interval parameters (geometric mean NOEC/EC10)	Reference
Invertebrates	3	Between 45 mg B/L (Lipopenaeus vannamei) and 83 mg B/L (Americamysis bahía)	14, 15
Fish	2	Between 74 mg B/L (Limanda limanda) and 600 mg B/L (Onchorhynchus tshawytscha)	13, 16

There are no data on species of algae.

### Sediment

Taxonomic group	Number of taxa studied	Interval parameters (geometric mean NOEC/EC10)	Reference
Invertebrates	1	82.4 mg B/kg sediment dw (Chironomus riparius)	17, 18

Results: although limited, data suggest that the organisms present in sediments are within the range of toxicity to aquatic organisms. It also does a deal of substance in the sediment, so the sediment distribution strategy / water occurs justified.

### Plant wastewater treatment (STP)

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Taxonomic group	Number of taxa studied	Interval parameters (geometric mean NOEC/EC10)	Reference
Activated sludge	NA	Between >17.5 mg B/L and 100 mg B/L	19
Microbes	3	Between 10 mg B/L ( <i>Opercularia bimarginata</i> ) and 20 mg B/L ( <i>Paramecium caudatum</i> )	20

## Data for the terrestrial environment

### Chronic toxicity studies

Taxonomic group	Number of taxa studied	Interval parameters (geometric mean NOEC/EC10)	Reference
Plant	28	Between 7.2 mg B/kg dw ( <i>Zea mays</i> ) and 56 mg B/kg dw ( <i>Allium cepa</i> )	21, 22
Invertebrates	9	Between 15.4 mg B/kg dw ( <i>Folsomia candida</i> ) and 87 mg B/kg dw ( <i>Caenorhabditis elegans</i> )	23, 24
Soil microorganisms	3	Between 12 mg B/kg dw (assay nitrogen mineralization and nitrification) and 420 mg B/kg dw (assay nitrogen mineralization and nitrification)	25, 26

Results<sup>2</sup>: according to the complete data set, the HC5 value of the distribution of species sensitivity is 10.8 mg B / kg dw.

### Phytotoxicity:

Boron is an essential to ensure a healthy plant growth micronutrient. In larger quantities can be harmful to boron sensitive plants. It should minimize the amount of borate product released into the environment.

### 12.2 Persistence and degradability.

No information is available regarding the biodegradability of the substances present.  
No information is available on the degradability of the substances present.  
No information is available about persistence and degradability of the product.

### 12.3 Bioaccumulative potential.

No information is available regarding the bioaccumulation of the substances present.

### 12.4 Mobility in soil.

No information is available about the mobility in soil.  
The product must not be allowed to go into sewers or waterways.  
Prevent penetration into the ground.

### 12.5 Results of PBT and vPvB assessment.

No information is available about the results of PBT and vPvB assessment of the product.

### 12.6 Endocrine disrupting properties.

This product doesn't contain components with environmental endocrine disrupting properties.

### 12.7 Other adverse effects.

No information is available about other adverse effects for the environment.

## SECTION 13: DISPOSAL CONSIDERATIONS.

### 13.1 Waste treatment methods.

Do not dump into sewers or waterways. Waste and empty containers must be handled and eliminated according to current, local/national legislation.  
Follow the provisions of Directive 2008/98/EC regarding waste management.

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### SECTION 14: TRANSPORT INFORMATION.

Transportation is not dangerous. In case of road accident causing the product's spillage, proceed in accordance with point 6.

#### 14.1 UN number or ID number.

Transportation is not dangerous.

#### 14.2 UN proper shipping name.

Description:

ADR/RID: Not classified as hazardous for transport.  
IMDG: Not classified as hazardous for transport.  
ICAO/IATA: Not classified as hazardous for transport.

#### 14.3 Transport hazard class(es).

Transportation is not dangerous.

#### 14.4 Packing group.

Transportation is not dangerous.

#### 14.5 Environmental hazards.

Transportation is not dangerous.

Transport by ship, FEM – Emergency sheets (F – Fire, S - Spills): Not applicable.

#### 14.6 Special precautions for user.

Transportation is not dangerous.

#### 14.7 Maritime transport in bulk according to IMO instruments.

Transportation is not dangerous.

### SECTION 15: REGULATORY INFORMATION.

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

The product is not affected by the Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009 on substances that deplete the ozone layer.

Product classification according to Annex I of Directive 2012/18/EU (SEVESO III): N/A

The product is not affected by Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products.

The product is not affected by the procedure established Regulation (EU) No 649/2012, concerning the export and import of dangerous chemicals.

#### 15.2 Chemical safety assessment.

No Chemical Safety Assessment has been carried out for this substance/mixture by the supplier.

### SECTION 16: OTHER INFORMATION.

Complete text of the H phrases that appear in section 3:

H315 Causes skin irritation.  
H319 Causes serious eye irritation.  
H335 May cause respiratory irritation.  
H360FD May damage fertility. May damage the unborn child.

Classification codes:

Eye Irrit. 2 : Eye irritation, Category 2

Repr. 1B : Reproductive toxicant, Category 1B

STOT SE 3 : Specific target organ toxicity following a single exposure, Category 3

Skin Irrit. 2 : Skin irritant, Category 2

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### **Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:**

Physical hazards	On basis of test data
Health hazards	Calculation method
Environmental hazards	Calculation method

It is advisable to carry out basic training with regard to health and safety at work in order to handle this product correctly.

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#### **Modifications compared to the previous version:**

- Emergency telephone number update (SECTION 1.4)
- Change of "H and P statements" for "Hazard statement" and "Precautionary statement" (SECTION 2.2)
- Modification of 2.3 section (SECTION 2)
- Modification of substances (SECTION 3.2)
- Modification of SECTION 8.1.
- Properties addition (SECTION 9.1)
- Addition of 11.2 section (SECTION 11)
- Modification of 12.6 and 12.7 sections (SECTION 12)
- Change of title in 14.1 and 14.7 sections (SECTION 14)
- Modification SECTION 16

#### Abbreviations and acronyms used:

CEN:	European Committee for Standardization.
DMEL:	Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.
DNEL:	Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated.
PPE:	Personal protection equipment.

#### Key literature references and sources for data:

<http://eur-lex.europa.eu/homepage.html>  
<http://echa.europa.eu/>  
Regulation (EU) 2020/878.  
Regulation (EC) No 1907/2006.  
Regulation (EC) No 1272/2008.

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The information given in this Safety Data Sheet has been drafted in accordance with COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemical substances and mixtures (REACH).

The information in this Safety Data Sheet on the Preparation is based on current knowledge and on current EC and national laws, as far as the working conditions of the users is beyond our knowledge and control. The product must not be used for purposes other than those that are specified without first having written instructions on how to handle. It is always the responsibility of the user to take the appropriate measures in order to comply with the requirements established by current legislation. The information contained in this Safety Sheet only states a description of the safety requirements for the preparation, and it must not be considered as a guarantee of its properties.