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

## 9307-Boric acid PH.EUR

GUINAMA ABSOLUTA CALIDAD

Version 1Date of compilation: 10/11/2015Version 6 (replaces version 5)Revision date: 05/09/2023

Page 1 of 12 Print date: 05/09/2023

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

### 1.1 Product identifier.

Product Name:	Boric acid PH.EUR
Product Code:	9307
Chemical Name:	boric acid
Index No:	005-007-00-2
CAS No:	10043-35-3
EC No:	233-139-2
Registration No:	01-2119486683-25-0026

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

Excipient pharmaceutical use

### Uses advised against:

Consumer uses are included with a concentration limit of less or equal to 0.29 %. Consumer uses with higher concentrations are advised against.

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

GUINAMA
C/ Oslo Nº3
46185 La Pobla de Vallbona
Valencia
+34961869090 / 902119816
+34961850352
ventas@guinama.com
www.guinama.com

**1.4 Emergency telephone number:** +34961869090 / 902119816 (Only available during office hours; Monday-Friday; 08:00-18:00)

### SECTION 2: HAZARDS IDENTIFICATION.

### 2.1 Classification of the substance or mixture.

In accordance with Regulation (EC) No 1272/2008: Repr. 1B : May damage fertility or the unborn child.

### 2.2 Label elements.

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



Signal Word: **Danger** Hazard statements: H360FD May damage fertility. May damage the unborn child.

Precautionary statements:

,	
P201	Obtain special instructions before use.
P280	Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/
P308+P313	IF exposed or concerned: Get medical advice/attention.

P 281- Use personal protective equipment required

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

## 9307-Boric acid PH.EUR

Version 1Date of compilation: 10/11/2015Version 6 (replaces version 5)Revision date: 05/09/2023



Page 2 of 12 Print date: 05/09/2023

### 2.3 Other hazards.

The substance is not PBT The substance is not vPvB Substance does not have endocrine disrupting properties.

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.

			(*)Classification - Regulation (EC) No 1272/2008	
Identifiers	Name Concentra		Classification	Specifics concentration limits and Acute toxicity estimate
Index No: 005-007- 00-2 CAS No: 10043-35-3 EC No: 233-139-2	boric acid	0 - 0.3 %	-	-

### 3.2 Mixtures.

Not applicable.

### **SECTION 4: FIRST AID MEASURES.**

### 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.

### Eve contact.

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. Dont 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.

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 CO2. In case of more serious fires, also alcohol-resistant foam and water spray.

### Unsuitable extinguishing media:

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

## 9307-Boric acid PH.EUR

Version 1 Date of compilation: 10/11/2015

Version 6 (replaces version 5) Revision date: 05/09/2023



Page 3 of 12 Print date: 05/09/2023

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).

### 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 the indications of the tag. Store the containers preferably between 20 and 35  $^{\circ}$ C, avoid temperatures between -5 $^{\circ}$ C and > 40 $^{\circ}$ C, in a dry and well-ventilated place, away from sources of heat and direct sunlight. Keep away from ignition points. Keep away from oxidizing agents and strongly acid or alkaline materials. No Smoking. Send the invite to unauthorized people. Once the containers have been opened, they must be carefully closed again and placed vertically to avoid spillage.

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

### 7.3 Specific end use(s).

Not available.

### SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION.

8.1 Control parameters.

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

## 9307-Boric acid PH.EUR



Version 1 Date of compilation: 10/11/2015

Version 6 (replaces version 5)

Revision date: 05/09/2023

Page 4 of 12 Print date: 05/09/2023

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	Туре	Value
	DNEL	Inhalation, Chronic, Systemic effects	8,3
	(Workers)		(mg/m <sup>3</sup> )
	DNEL	Dermal, Chronic, Systemic effects	392
	(Workers)		(mg/Kg
1			bw/day)
	DNEL	Inhalation, Short term, Systemic effects	0,98
boric acid	(Consumers)		(mg/kg
CAS No: 10043-35-3			bw/day)
FC No: 233-139-2	DNEL	Dermal, Chronic, Systemic effects	196
	(Consumers)		(mg/kg
			bw/dayd)
	DNEL	Inhalation, Chronic, Systemic effects	4,15
	(Consumers)		(mg/m3)
	DNEL (Caracina and)	Innalation, Chronic, Systemic effects	0,98
	(Consumers)		(mg/kg
		Inhalation Chronic Systemic offects	Dw/udy)
	(Workers)	Initialation, Chronic, Systemic effects	(mg/m <sup>3</sup> )
	DNFI	Dermal Chronic Systemic effects	392
	(Workers)	Dermal, emonie, systemic circets	(ma/Ka
	(Wonters)		bw/dav)
	DNFI	Inhalation, Short term, Systemic effects	0.98
	(Consumers)		(ma/ka
boric acid	(,		bw/day)
CAS NO: 10043-35-3	DNEL	Dermal, Chronic, Systemic effects	196
EC NO: 255-159-2	(Consumers)		(mg/kg
	-		bw/dayd)
	DNEL	Inhalation, Chronic, Systemic effects	4,15
	(Consumers)		(mg/m3)
	DNEL	Inhalation, Chronic, Systemic effects	0,98
	(Consumers)		(mg/kg
			bw/day)

DNEL: Derived No Effect Level, level of exposure to the substance below which adverse effects are not anticipated. DMEL: Derived Minimal Effect Level, exposure level corresponding to a low risk, that risk should be considered a tolerable minimum.

Concentration levels PNEC:

Name	Details	Value
	Fresh water	2,9 (mg B/l)
	Marine water	2,9 (mg B/l)
	Intermittent releases	13,7 (mg/l)
boric acid	Air- No expusre of expected	- (.)
CAS No: 10043-35-3	Soil	5,7 (mg B/kg
EC No: 233-139-2		soil dw)
	Sediment (fresh water)- Dispensed because of non-	- (-)
	separation of sediment	
	STP	10 (mg B/l)
	Fresh water	2,9 (mg B/I)
	Marine water	2,9 (mg B/I)
	Intermittent releases	13,7 (mg/l)
boric acid	Air- No expusre of expected	- (.)
CAS No: 10043-35-3	Soil	5,7 (mg B/kg
EC No: 233-139-2		soil dw)
	Sediment (fresh water)- Dispensed because of non-	- (-)
	separation of sediment	
	STP	10 (mg B/l)

PNEC: Predicted No Effect Concentration, concentration of the substance below which adverse effects are not expected in the environmental compartment.

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

## 9307-Boric acid PH.EUR

 Version 1
 Date of compilation: 10/11/2015

 Version 6 (replaces version 5)
 Revision date: 05/09/2023



Page 5 of 12 Print date: 05/09/2023

### 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.

The use of adequate technical measures should always have priority over personal protective equipment, ensure good ventilation in the workplace through effective local aspiration. For the choice of personal protective equipment, if necessary, ask your chemical suppliers for advice.

Personal protective equipment must bear the CE marking which certifies their compliance with current regulations.

Provide an emergency shower with face and eye basin.

Hand protection: Hand protection: protect hands with category III work gloves (ref. Standard EN 374). For the final choice of the material of the work gloves it is necessary to consider compatibility, degradation, breakage time and permeability. In the case of preparations, the resistance of work gloves must be checked before use as it is not foreseeable. The gloves have a wear that depends on the duration and method of use. Skin protection: wear category I work clothes with long sleeves and safety footwear for professional use (ref. Regulation 2016/425 and standard EN ISO 20344). Wash with soap and water after removing protective clothing.

Eye protection: it is recommended to wear airtight safety goggles (ref. Standard EN 166). Respiratory protection: in case of exceeding the threshold value (e.g., TLV-TWA) of the substance or of one or more of a substance presents in the product, it is recommended to wear a mask with type A filter whose class (1, 2 or 3), must be chosen in relation to the utilization limit agreement (ref. Standard EN 14387). If there are gases or vapours of a different nature and / or gases or vapours with particles (aerosols, fumes, mists, etc.), combined filters must be provided.

The use of means of protection of the streets is necessary in case of technical measures adopted are not sufficient to limit the exposure of the worker to the threshold values taken into consideration. However, the protection offered by mosquitoes is limited.

If the substance is odourless or its olfactory threshold is higher than the relative TLV-TWA and in the event of an emergency, wear an open-circuit compressed air breathing apparatus (ref. EN 137 standard) or an air supplied respirator. external (ref. EN 138 standard). For the correct choice of the respiratory protection device, refer to the EN 529 standard.

Environmental Exposure Controls: Emissions from production processes, including from production equipment, should be controlled for compliance with environmental protection legislation. Product residues must not be discharged without control into wastewater or water courses.

Concentration:	100 %			
Uses:	Excipient pharmaceutical use			
Breathing protect	ion:			
PPE:	Filter mask for protection against gases and particles.			
Characteristics:	«CE» marking, category III. The mask must have a wide field of vision and an anatomically designed form in order to be sealed and watertight.			
CEN standards:	EN 136, EN 140, EN 405			
Maintenance:	Should not be stored in places exposed to high temperatures and damp environments before use. Special attention should be paid to the state of the inhalation and exhalation valves in the face adaptor.			
Observations:	Read carefully the manufacturer's instructions regarding the equipment's use and maintenance. Attach the necessary filters to the equipment according to the specific nature of the risk (Particles and aerosols: P1-P2-P3, Gases and vapours: A-B-E-K-AX), changing them as advised by the manufacturer.			
Filter Type needed:	A2			
Hand protection:				
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 > 480 Material thickness 0,35 (mm):			
Eye protection:				
PPE:	Protective goggles against particle impacts.			
Characteristics:	«CE» marking, category II. Eye protector against dust and smoke.			

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

## 9307-Boric acid PH.EUR



Page 6 of 12

Print date: 05/09/2023

Version 1Date of compilation: 10/11/2015Version 6 (replaces version 5)Revision date: 05/09/2023

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.
Skin protection:	
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.

Physical state: Solid - Dust

Colour: White

Odour: Odorless

Odour threshold: Not applicable/Not available due to the nature/properties of the product Melting point: Not applicable/Not available due to the nature/properties of the product Freezing point: Not applicable/Not available due to the nature/properties of the product Boiling point or initial boiling point and boiling range: >300 °C

Flammability: Not flammable

Lower explosion limit: Not applicable/Not available due to the nature/properties of the product Upper explosion limit: Not applicable/Not available due to the nature/properties of the product Flash point: Not applicable/Not available due to the nature/properties of the product Auto-ignition temperature: Not applicable/Not available due to the nature/properties of the product Decomposition temperature: >100 °C

pH: 6.1 (1%)

Kinematic viscosity: Not applicable/Not available due to the nature/properties of the product Solubility: Not applicable/Not available due to the nature/properties of the product Hydrosolubility: 49 kg/m3

Liposolubility: Not applicable/Not available due to the nature/properties of the product Partition coefficient n-octanol/water (log value): -1.09

Vapour pressure: 0.000099 Pa

Absolute density: Not applicable/Not available due to the nature/properties of the product Relative density: 1.49

Relative vapour density: Not applicable/Not available due to the nature/properties of the product Particle characteristics: Not applicable/Not available due to the nature/properties of the product

### 9.2 Other information

Not applicable/Not available due to the nature/properties of the product

### SECTION 10: STABILITY AND REACTIVITY.

### 10.1 Reactivity.

There are no particular dangers of reaction with other substances in normal conditions of use. Boric acid: decomposes at temperatures above 100°C/212°F.

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

## 9307-Boric acid PH.EUR

 Version 1
 Date of compilation: 10/11/2015

 Version 6 (replaces version 5)
 Revision date: 05/09/2023

Page 7 of 12 Print date: 05/09/2023

### 10.2 Chemical stability.

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

### 10.3 Possibility of hazardous reactions.

Boric Acid: risk of explosion on contact with acetic anhydride.

### 10.4 Conditions to avoid.

Avoid any improper handling.

#### 10.5 Incompatible materials.

Keep away from oxidising agents and from highly alkaline or acidic materials in order to prevent exothermic reactions.

### 10.6 Hazardous decomposition products.

When heated the product losses water forming Metaboric Acid (HBO2) first and becoming Boric Oxide (B2O3) warming later.

### SECTION 11: TOXICOLOGICAL INFORMATION.

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

### Toxicological information.

Name		Acute toxicity				
Na	me	Туре	Test	Kind	Value	
		Oral	LD50	Rat	2000 - 5000 mg/kg bw (-)	
boric acid		Dermal	LD50	Rabbit	2000 mg/kg bw (-)	
CAS No: 10043-35-3	EC No: 233-139-2	Inhalation	LC50	Rat	>2 mg/l (4h)	
		Oral	LD50	Rat	2000 - 5000 mg/kg bw (-)	
boric acid		Dermal	LD50	Rabbit	2000 mg/kg bw (-)	
CAS No: 10043-35-3	EC No: 233-139-2	Inhalation	LC50	Rat	>2 mg/l (4h)	

Acute toxicity;

Inconclusive data for classification.

Skin corrosion/irritation Test substance: Boric acid Species\_Outcome\_Exposure\_Score New Zealand White Rabbit Skin: Primary Dermal Irritation Index (PDII) 0.1 -New Zealand white rabbit eyes: corneal opacity <1 -Resume Skin: non-irritating to the skin. Mean Primary Irritation Score: 0.1. Based on the available data, the classification criteria are not met.

Eyes: non-irritating to the eyes. Based on mean scores less than 1, the effects were fully reversible within 7 days. Based on available data, the classification criteria are not met. many years of work

exposure do not indicate adverse effects on human eyes.

Sensitization - Test substance: Boric acid

Species\_Outcome\_Route of exposure Guinea pig Not sensitizing Respiratory

Guinea pig Not sensitizing Kespira

Resume

Skin: not sensitizing to the skin. Based on available data, the classification criteria are not met. Respiratory: Respiratory sensitization studies have not been performed. There is no data to suggest that Boric acid is a respiratory sensitizer. Based on available data, the classification criteria are not met.

Mutagenicity - Test substance: Boric acid Test experiment result

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

## 9307-Boric acid PH.EUR

Version 1Date of compilation: 10/11/2015Version 6 (replaces version 5)Revision date: 05/09/2023



Page 8 of 12 Print date: 05/09/2023

Based on boric acid Experiment: in vitro Subject: Mammalian Animal Negative Cell: Germ Negative result Resume. Not mutagenic. Based on available data, the classification criteria are not met.

Carcinogenicity - Test substance: Boric acid Species\_Dose\_Exposure\_Outcome Mouse\_446 to 1150 mg/kg bw/day\_Oral Feeding Study\_Negative - Oral - CT Resume.

There is no evidence of carcinogenicity in mice. Based on available data, the classification criteria are not met.

Reproductive toxicity - Test substance: Boric acid Species\_Exposure\_Maternal Toxicity\_Fertility effects\_Developmental effects\_Effects Rat\_Oral feeding study\_Positive\_NOAEL in rats for effects on male fertility is 17.5 mg B/kg bw.

Human\_Oral pool, ingestion and inhalation\_Negative\_Negative\_Negative\_No adverse effects on fertility in male workers. Epidemiological studies of human development have shown a lack of effects in borate-exposed workers and populations living in areas with high ambient boron levels.

Epidemiological studies of the effects of human development have shown no effects in workers exposed to borate and populations living in areas with high environmental impact boron levels.

Rat\_Oral feeding study\_Positive\_-----\_ Positive\_NOAEL in rats for effects on fetal development

including fetal weight loss and minor skeletal problems the variations are 9.6 mg B/kg bw. NOAEL in rats for maternal toxicity is 13.3 mg B/kg bw.

Resume.

Reprotoxicity studies have been performed with boric acid and disodium tetraborate. A multigenerational study in the rat gave a NOAEL for male fertility of 17.5 mg B/kg/day. Effects have been observed on the development of laboratory animals, the most sensitive species being the rat with a NOAEL of 9.6 mg B/kg bw/day. Boric acid is classified under the 1st ATP to CLP as Repr. 1B; H360FD. Although boron has been shown to negatively affect male reproduction in laboratory animals, there was no clear evidence of male reproductive effects attributable to boron in studies of highly exposed workers.

teratogenicity See reproductive toxicity.

STOT-single exposure

Based on available data, the classification criteria are not met.

STOT repeated exposure

Based on available data, the classification criteria are not met.

aspiration hazard

The physical form of solid dust indicates that there is no potential aspiration hazard.

toxicokinetics

In the blood, boric acid is the main species present and is not further metabolized. Boric acid is distributed rapidly and evenly throughout the body, with concentrations in bone 2 - 3 times higher than in other tissues. Boric acid is rapidly excreted, with elimination half-lives of 1 hour in the mouse, 3 hours in the rat, and <27.8 hours in humans, and has low potential for accumulation. Boric acid is mainly excreted in the urine. Oral absorption of borates is

almost 100%. For the inhalation route, 100% absorption is also assumed as the worst case. Dermal

absorption through intact skin is very low with a percentage absorbed dose < 0.5%.

Information on likely routes of exposure

Inhalation is the most important route of exposure in work and other settings. Dermal exposure is not

generally a concern because the product is poorly absorbed 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. Small amounts (eg, a teaspoon) are not likely to be ingested accidentally to cause effects. Symptoms of accidental overexposure to high doses of inorganic borate salts have been associated with ingestion or absorption through large areas of severely damaged skin. These may include nausea, vomiting and diarrhoea, with delayed effects of reddening and peeling of the skin.

Delayed and immediate effects as well as chronic effects from short and long-term exposure Human epidemiological studies do not show an increase in lung disease in chronically ill occupational populations. exposure to boric acid dust and sodium borate. Human epidemiological studies do not indicate any effect on fertility in occupational populations with chronic exposures.

Potential chronic health effects -Test substance: Boric acid

Resume.

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

## 9307-Boric acid PH.EUR

GUINAMA ABSOLUTA CALIDAD

Version 1 Date of compilation: 10/11/2015

Version 6 (replaces version 5) Revision date: 05/09/2023

Page 9 of 12 Print date: 05/09/2023

A NOAEL of 17.5 mg B/kg bw/day equivalent to 100 mg boric acid/kg bw/day was determined in a feeding study (2 years) in rats and is based on effects on the testes. Human epidemiological studies do not show an increase in lung diseases in occupational populations with chronic exposures to boric acid dust and sodium borate. Human epidemiological studies do not indicate any effect on fertility in occupational populations with chronic exposures. to borate dust and do not indicate any effect for a general population with high exposure to borates in the environment.

### 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.

Name	Ecotoxicity				
Name	Туре	Test	Kind	Value	
	Fish	LC50 NOEC	Primephales promelas Brachydanio rerio	79.7 mg/l (as Boron) (Fresh water-acute) 6.4 mg/l (as Boron) (Fresh water-chronic)	
boric acid	Aquatic	LC50 NOEW	Crustacean Daphnia magna	91 mg/l (48 h) [1] 14.2 mg/l (as Boron) (Fresh water-chronic)	
	invertebrates	[1] Marcussen, C.E., and J.J. Yurk 1990. Boron: Acute Toxicity to Mysids (Mysidopsis bahia) Under Flow-Through Conditions. Lab.Proj.ID No.3903004000-0215-3140, ESE, Gainesville, FL :44 p.			
CAS No: 10043-35-3 EC No: 233-139-2	Aquatic plants	EC50 NOEC	Pseudokirchneriell a subcapitata Pseudokirchneriell a subcapitata	52.4 mg/l (as Boron) (Fresh water-acute) 17.5 mg/l (as Boron) (Fresh water-chronic)	
	Fish	LC50 NOEC	Primephales promelas Brachydanio rerio	79.7 mg/l (as Boron) (Fresh water-acute) 6.4 mg/l (as Boron) (Fresh water-chronic)	
boric acid	Aquatic	LC50 NOEW	Crustacean Daphnia magna	91 mg/l (48 h) [1] 14.2 mg/l (as Boron) (Fresh water-chronic)	
	invertebrates	[1] Marcus Toxicity to Conditions. Gainesville	sen, C.E., and J.J. Yu Mysids (Mysidopsis b Lab.Proj.ID No.390 , FL :44 p.	urk 1990. Boron: Acute pahia) Under Flow-Through 13004000-0215-3140, ESE,	
CAS No: 10043-35-3 EC No: 233-139-2	Aquatic plants	EC50 NOEC	Pseudokirchneriell a subcapitata Pseudokirchneriell a subcapitata	52.4 mg/l (as Boron) (Fresh water-acute) 17.5 mg/l (as Boron) (Fresh water-chronic)	

Boron occurs naturally in sea water at an average concentration of 5mg B/l and fresh water at 1mg B/l or less. In dilute aqueous solutions the predominant boron species present is undissociated boric acid. To convert boric acid into equivalent boron (B) content, multiply by 0,1748. Boron is an essential micronutrient for healthy growth of plants; however, it can be harmful to boron sensitive plants in higher quantities. Care should be taken to minimize the amount of borate product released to the environment.

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

## 9307-Boric acid PH.EUR

GUINAM ABSOLUTA CALIDA

Version 1 Date of compilation: 10/11/2015

Version 6 (replaces version 5) Revision date: 05/09/2023

Page 10 of 12 Print date: 05/09/2023

### 12.2 Persistence and degradability.

No information is available regarding the biodegradability

No information is available on the degradability

No information is available about persistence and degradability of the product.

### 12.3 Bioaccumulative potential.

### Information about the bioaccumulation.

Name		Bioaccumulation			
		Log Pow	BCF	NOECs	Level
boric acid		1.00			Vonclow
CAS No: 10043-35-3	EC No: 233-139-2	-1.09	-	-	very low
boric acid		1.00			Maria
CAS No: 10043-35-3	EC No: 233-139-2	-1.09	-	-	very low

### 12.4 Mobility in soil.

Nutriment for species vegetables. The product is soluble in water and is leachable through normal soil

### 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.

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.

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.

### 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.

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

## 9307-Boric acid PH.EUR

 Version 1
 Date of compilation: 10/11/2015

 Version 6 (replaces version 5)
 Revision date: 05/09/2023



Page 11 of 12 Print date: 05/09/2023

### 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.

Not classified as hazardous for transport.

### **SECTION 15: REGULATORY INFORMATION.**

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

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.**

Classification codes:

Repr. 1B : Reproductive toxicant, Category 1B

Changes regarding to the previous version:

- Changes in the information of the supplier (SECTION 1.3).
- Changes in the composition of the product (SECTION 3.2).
- Modification of the information of the stability and reactivity conditions (SECTION 10.4).
- Modification of the information of the stability and reactivity conditions (SECTION 10.5).

Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:Physical hazardsOn basis of test dataHealth hazardsCalculation methodEnvironmental hazardsCalculation method

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

### Information on the TSCA Inventory (Toxic Substances Control Act) USA:

CAS No	Name	State
10043-35-3	boric acid	Registered

Risk classification system NFPA 704:

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

## 9307-Boric acid PH.EUR

GUINAMA ABSOLUTA CALIDAD

 Version 1
 Date of compilation: 10/11/2015

 Version 6 (replaces version 5)
 Revision date: 05/09/2023

Page 12 of 12 Print date: 05/09/2023



Health hazard: 3 (Extreme Danger)

Flammability: 0 (Will not burn)

Reactivity: 0 (Stable)

Abbreviations and acronyms used:

- BCF: Bioconcentration factor.
- 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.
- EC50: Half maximal effective concentration.
- PPE: Personal protection equipment.
- LC50: Lethal concentration, 50%.
- LD50: Lethal dose, 50%.
- NOEC: No observed effect concentration.
- PNEC: Predicted No Effect Concentration, concentration of the substance below which adverse effects are not expected in the environmental compartment.

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.

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.