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

1.1 Product identifier

Product name: Boric acid

Acidum boricum

Boorzuur Borique acide Borsäure

N° CAS: 10043-35-3 N° EC: 233-139-2

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Active Pharmaceutical Ingredient or Excipient.

1.3 Details of the supplier of the safety data sheet

Company: Magis-Pharma NV

Neerlandweg 24 2610 Wilrijk Belgium

Telephone: (+32) (0)3 457 11 76
Email: info@magis-pharma.be
Web page: www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation: Belgisch Antigifcentrum Centre Antipoisons Belge

Telephone: (+32) (0)70 245 245 (Service 24/7)

Web page: www.antigifcentrum.be www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Reproductive toxicity (category 1) H360FD

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Danger

Hazard statements:

H360FD May damage fertility; May damage the unborn child

Precautionary statements:

P201 Obtain special instructions before use.

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

Additional applicable label

elements:

Not applicable.

2.3 Other hazards

Not available.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:

IUPAC name:

Synonyms:

Orthoboric acid

N° CAS:

10043-35-3

N° EC:

233.139-2

Molecular Formula:

H₃BO₃

Content: 99.0 – 100.5 %

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation: Move affected person to fresh air at once. Get medical attention if any discomfort

continues.

After skin contact: Remove contaminated clothing immediately and wash skin with soap and water. Get

medical attention if any discomfort continues.

After eye contact: Rinse immediately with plenty of water. Remove any contact lenses and open eyelids

wide apart. Continue to rinse for at least 15 minutes. Get medical attention if any

discomfort continues.

After ingestion: Move affected person to fresh air and keep warm and at rest in a position comfortable

for breathing. Rinse mouth thoroughly with water. Give plenty of water to drink. Get

medical attention if any discomfort continues.

4.2 Most important symptoms and effects, both acute and delayed

Eye contact: May cause temporary eye irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Notes for the doctor: No specific recommendations. If in doubt, get medical attention promptly.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Use fire-extinguishing media suitable for the surrounding fire.

Unsuitable extinguishing media: Not available.

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5.2 Special hazards arising from the substance/mixture

The product is non-combustible. Irritating gases or vapours.

5.3 Advice for firefighters

Surrounding fires: Not available.

Protection against fire: Wear positive-pressure self-contained breathing apparatus (SCBA)

and appropriate protective clothing.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear protective clothing as described in Section 8 of this safety data sheet. Avoid inhalation of dust. Avoid contact with skin and eyes. Provide adequate ventilation.

For emergency responders

Wear protective clothing as described in Section 8 of this safety data sheet. Avoid inhalation of dust. Avoid contact with skin and eyes. Provide adequate ventilation.

6.2 Environmental precautions

Do not discharge into drains or watercourses or onto the ground. Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.

6.3 Methods and material for containment and cleaning up

Avoid generation and spreading of dust. Collect and place in suitable waste disposal containers and seal securely. Label the containers containing waste and contaminated materials and remove from the area as soon as possible. Flush contaminated area with plenty of water. Collect and place in suitable waste disposal containers and seal securely. For waste disposal, see Section 13.

6.4 Reference to other sections

Wear protective clothing as described in Section 8 of this safety data sheet.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling: Avoid spilling. Avoid contact with skin and eyes. Avoid handling which

leads to dust formation. Provide adequate ventilation.

Personal protection:

Technical protective measures:

Not available.

Not available.

Not available.

7.2 Conditions for safe storage, including any incompatibilities

Storage: Store in tightly closed, original container in a dry, cool and well-

ventilated place. Keep only in the original container.

Conditions for safe storage, including any

incompatibilities:

Not available.

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Storage – away from: Not available.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Workers - Inhalation; Long term systemic effects: 8.28 mg/m³
Workers - Dermal; Long term systemic effects: 392.0 mg/kg/day
Consumer - Oral; Short term systemic effects: 0.98 mg/kg/day
Consumer - Oral; Long term systemic effects: 0.98 mg/kg/day
Consumer - Inhalation; Long term systemic effects: 4.15 mg/m³
Consumer - Dermal; Long term systemic effects: 196.0 mg/kg/day

8.2 Exposure controls

Appropriate engineering control

Not available.

Individual protection measures

Eye/face protection: The following protection should be worn: Chemical splash goggles. EN 166

Skin protection: Wear rubber apron. Wear rubber footwear.

Hand protection: The most suitable glove should be chosen in consultation with the glove supplier/

manufacturer, who can provide information about the breakthrough time of the glove material. The selected gloves should have a breakthrough time of at least 8

hours. Rubber (natural, latex). glove thickness 0.6mm EN 374

Respiratory protection: If ventilation is inadequate, suitable respiratory protection must be worn. EN

136/140/145/143/149

Thermal hazards: Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance: Crystalline solid. Solid, White.

Odour: Not available.
Odour threshold: Not available.

pH: pH (diluted solution): 5.1 (1.0% solution)

Melting/freezing point: > 171°C

Initial boiling point:

Boiling range:

Not available.

Flash point:

Not available.

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Not available. Evaporation rate: Flammability (solid/gas): Not available.

Upper/lower flammability or

explosive limits:

Not available.

Not available. Vapour pressure: Vapour density: Not available. Relative density: 1.49 - 1.51 (23°C) Soluble in water Solubility: 49.2 g/l water (20°C) Solubility in water:

Partition coefficient

-1.09 (22 °C)

(n-octanol/water):

Auto-ignition temperature: Not available. Decomposition temperature: Not available. Not available. Viscosity: Explosive properties: Not available. Oxidising properties: Not available.

9.2 Other information

Not available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

There are no known reactivity hazards associated with this product.

10.2 Chemical stability

Stable at normal ambient temperatures and when used as recommended.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Avoid excessive heat for prolonged periods of time.

10.5 Incompatible materials

Strong reducing agents. Strong acids.

10.6 Hazardous decomposition products

Does not decompose when used and stored as recommended.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Not available.

Skin corrosion/irritation: Animal data: OECD 404 Not irritating. Based on available data the classification

criteria are not met.

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Serious eye damage/irritation: Not irritating. Based on available data the classification criteria are not met.

Respiratory/skin sensitisation: Not available.

Germ cell mutagenicity: Not available.

Carcinogenicity: Not available.

Reproductive toxicity: Fertillity: May impair fertility.

Development: May cause harm to the unborn child

Summary of evaluation of the

CMR properties:

Not available.

STOT-single exposure: Not available.
STOT-repeated exposure: Not available.
Aspiration Hazard: Not available.
Other: Not available.

11.2 Additional information on potential adverse human health effects and symptoms

Eye contact: Irritating to eyes.
Skin contact: Irritating to skin.

Inhalation: May cause respiratory system irritation.

Ingestion: May cause stomach pain or vomiting.

Aspiration: Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

The product components are not classified as environmentally hazardous. However, large or frequent spills may have hazardous effects on the environment.

12.2 Persistence and degradability

There are no data on the degradability of this product.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

The product is soluble in water.

12.5 Results of PBT and vPvB assessment

This substance is not classified as PBT or vPvB according to current EU criteria.

12.6 Other adverse effects

Not available.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

General information: Waste is classified as hazardous waste.

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Disposal methods: Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.2 UN proper shipping name

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.3 Transport hazard class(es)

ADR/RID(Land),IMDG(Sea),

No transport warning sign required.

IATA/ICAO (Air):

14.4 Packing group

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.5 Environmental hazards

ADR/RID(Land),IMDG(Sea),

Not classified.

IATA/ICAO (Air):

14.6 Special precautions for user

Not available.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

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

Hazard symbol: Not available.

Risk phrases: R60 May impair fertility

R61 May cause harm to the unborn child

Safety phrases: Not available.

15.2 Chemical safety assessment

Not available.

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SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR: European Agreement concerning the International Carriage of Dangerous Goods by

Road

CAS: Chemical Abstracts Service (division of the American Chemical Society)

EC (number): European Community (number)

IATA: International Air Transport Association
ICAO: International Civil Aviation Organization

IMDG: International Maritime Code for Dangerous Goods
 IUPAC: International Union of Pure and Applied Chemistry
 PBT: Persistent, Bioaccumulative and Toxic substance

RID: Regulations Concerning the International Transport of Dangerous Goods by Rail

STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)

vPvB: very Persistent and very Bioaccumalative

16.3 Key literature references/sources for data

European Chemicals Agency.

https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

Quality Department FAC SECUNDUM ARTEM NV info@magis-pharma.be