Safety Data Sheet

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

1.1. Product identifier

Code:	**003872**
Product name	**BORIC ACID Ph.Eur.**
Empirical formula	
CAS number	**10043-35-3**
INDEX number	**005-007-00-2**
EC number	**233-139-2**

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

Intended use	**pharmaceutical excipient**

1.3. Details of the supplier of the safety data sheet

Name	**ACEF S.p.A.**
Full address	**Via Umbria, 8/14**
District and Country	**29017 Fiorenzuola d'Arda PC** **Italia** **Tel. 0523/241911** **Fax 0523/241968**
e-mail address of the competent person responsible for the Safety Data Sheet	**sicurezza@acef.it**

1.4. Emergency telephone number

For urgent inquiries refer to

Centro Antiveleni di Milano - Tel. +39 02-66101029 - (Ospedale Niguarda)
Centro Antiveleni di Pavia - Tel. +39 0382-24444 - (IRCCS Fondazione Maugeri)
Centro Antiveleni di Bergamo - Tel. 800-883300 - (Ospedali Riuniti)
Centro Antiveleni di Firenze - Tel. +39 055-7947819 - (Ospedale Careggi)
Centro Antiveleni di Roma - Tel. +39 06-3054343 - (Policlinico Gemelli)
Centro Antiveleni di Roma - Tel. +39 06-49978000 - (Policlinico Umberto I)
Centro Antiveleni di Napoli - Tel. +39 081-7472870 - (Ospedale Cardarelli)

2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in Directives 67/548/EEC and 1999/45/EC and/or EC Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of EC Regulationn 1907/2006 and subsequent amendments.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet

2.1.1. Regulation 1272/2008 (CLP) and following amendments and adjustments

Hazard classification and indication:

Repr. 1B	H360FD

2.1.2. Directive 67/548/EEC and following amendments and adjustments

Danger Symbols:	T
R phrases:	60-61

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet

2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Pictograms:

Warning: Danger

Hazard indication:

H360FD May damage fertility. May damage the unborn child.

Caution recommendations:

P201 Obtain special instructions before use.
P308+P313 IF exposed or concerned: Get medical advice/attention.

Contains: BORIC ACID

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2.3. Other hazards

Information not available

3. Composition/information on ingredients

3.1. Substances

Contains:

Identification	Conc.%	Classification 67/548/EEC	Classification 1272/2008 (CLP)
BORIC ACID *CAS 10043-35-3* *EC 233-139-2* *INDEX 005-007-00-2* *Reg. no. 01-2119486683-25*	100	T R60, T R61, Repr.Cat. 2	Repr. 1B H360FD

T= TOXIC

The full wording of the Risk (R) and hazard (H) phrases is given in section 16 of the sheet

3.2. Mixtures

Information not relevant

4. First aid measures

4.1. Description of first aid measures

No harm to the staff authorised to use has been reported. However, in case of contact, inhalation or ingestion, the following general measures provided for a first aid shall be taken.
INHALATION: remove to open air. If respiration is difficult, administer artificial respiration and seek medical advice.
INGESTION: seek medical attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person.
EYES and SKIN: wash with plenty of water; if the irritation persists, seek medical advice.

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

No episodes of damage to health ascribable to the product have been reported.

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

Follow doctor's orders.

5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING MEDIA

The extinction equipment used should be of the conventional kind: carbon dioxide, foam, powder and nebulised water.

EXTINGUISHING MEDIA WHICH SHALL NOT BE USED FOR SAFETY REASONS

None in particular.

5.2. Special hazards arising from the substance or mixture

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products (carbon oxide, toxic pyrolysis products, etc).

The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

5.3. Advice for firefighters

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Hardhat with visor, fireproof clothing (fireproof jacket and trousers with ties around arms, legs and waist), work gloves (fireproof, cut proof and dielectric), a depressurised mask with facemask covering the whole of the operator's face or a self-respirator (self-protector) in the event of large quantities of fume.

6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear appropriate protective equipment. Send away individuals who are not suitably equipped. Use breathing equipment if fumes or powders are released into the air. Block the leakage if there is no hazard. Do not handle damaged containers or the leaked product before donning appropriate protective gear. For information on risks for the environmental and health, respiratory tract protection, ventilation and personal protection equipment, refer to the other sections of this sheet.

6.2. Environmental precautions

The product must not penetrate the sewers, surface water, ground water and neighbouring areas. Dilute the product well with water after collection.

6.3. Methods and material for containment and cleaning up

For liquid products, suck into a suitable container (made of material not incompatible with the product) and soak up any leaked product with absorbent inert material (sand, vermiculite, diatomeous earth, Kieselguhr, etc). Collect the majority of the remaining material and deposit in containers for disposal. For solid products, use spark proof mechanical tools to collect the leaked product and place in plastic containers. If there are no contraindications, use jets of water to eliminate product residues. Make sure the leakage site is well aired.
Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections

Any information on personal protection and disposal is given in sections 8 and 13.

7. Handling and storage

7.1. Precautions for safe handling

Store in closed, labelled containers

7.2. Conditions for safe storage, including any incompatibilities

Normal storage conditions without particular incompatibilities

7.3. Specific end use(s)

Information not available

8. Exposure controls/personal protection

8.1. Control parameters

Product name	Type	Country	TWA/8h		STEL/15min		
			mg/m3	ppm	mg/m3	ppm	
BORIC ACID	TLV-ACGIH		2		6		

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protection equipment, make sure that the workplace is well aired through effective local aspiration or bad air vent. If such operations do not make it possible to keep the concentration of the product below the permitted workplace exposure thresholds a suitable respiratory tract protection must be used. See product label for hazard details during use. Ask your chemical substance suppliers for advice when choosing personal protection equipment. Personal protection equipment must comply with the rules in force indicated below.

HAND PROTECTION

Protect hands with category III (ref. Directive 89/686/EEC and standard EN 374) work gloves, such as those in PVA, butyl, fluoroelastomer or equivalent. The following should be considered when choosing work glove material: degradation, breakage times and permeation. Work glove resistance to preparations should be checked before use, as it can be unpredictable. Gloves' limit depends on the duration of exposure.

EYE PROTECTION

Wear hood visor or protective visor together with airtight goggles (ref. standard EN 166)

SKIN PROTECTION

Wear category III professional long-sleeved overalls and safety footwear (ref. Directive 89/686/CEE and standard EN 344). Wash body with soap and water after removing overalls.

RESPIRATORY PROTECTION

If the threshold value for one or more of the substances present in the preparation for daily exposure in the workplace or to a fraction established by the company's prevention and protection service is exceeded, wear an FFP3 (ref. standard EN 141) type half mask.

The use of breathing protection equipment, such as masks with organic vapour and dust/mist cartridges, is necessary in the absence of technical measures limiting worker exposure. The protection provided by masks is in any case limited.

If the substance in question is odourless or its olfactory threshold is higher than the relative exposure limit and in the event of an emergency, or when exposure levels are unknown or the concentration of oxygen in the workplace is less than 17% volume, wear self-contained, open-circuit compressed air breathing apparatus (ref. standard EN 137) or fresh air hose breathing apparatus for use with full face mask, half mask or mouthpiece (ref. standard EN 138).

An emergency eye washing and shower system must be provided.

The product must be used in a closed cycle, in well-aired environments fitted with strong localised aspiration systems (capture speed > 1.5 m/s), otherwise it is compulsory to use the personal protection equipment indicated and always in well-aired environments fitted with strong localised aspiration systems (capture speed > 1.5 m/s).

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	powder
Colour	white
Odour	odourless
Odour threshold	Not available
pH	6,1 1 g/l, 20°C.
Melting or freezing point	171 °C
Boiling point	Not available
Distillation range	Not available
Flash point	Not available
Evaporation Rate	Not available
Flammability of solids and gases	Not available
Lower inflammability limit	Not available
Upper inflammability limit	Not available
Lower explosive limit	Not available
Upper explosive limit	Not available
Vapour pressure	Not available
Vapour density	Not available
Specific gravity	1,440 Kg/l
Solubility	in water: 48,8 g/l 20°C, 379.9 g/l a 100°C.
Partition coefficient: n-octanol/water	Not available
Ignition temperature	Not available

Decomposition temperature	Not available
Viscosity	Not available
Reactive Properties	Not available

9.2. Other information

Molecular weight	61,83
VOC (Directive 1999/13/EC) :	0%

10. Stability and reactivity

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.
BORIC ACID: decomposes above 100°C.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage
BORIC ACID: risk of explosion on contact with acetic anhydride.

10.4. Conditions to avoid

None in particular, however the usual precautions used for chemical products should be respected.

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

In the event of thermal decomposition or fire, vapours potentially dangerous to health may be released.
BORIC ACID: boric anhydride, metaboric acid.

11. Toxicological information

11.1. Information on toxicological effects

BORIC ACID
LC50 (Inhalation): 0,160 mg/l/4h Rat
LD50 (Oral): 2660,000 mg/kg Rat
LD50 (Dermal): >2000,000 mg/kg Rabbit

12. Ecological information

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or sewers or contaminate soil or vegetation.

12.1. Toxicity

Information not available

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

Information not available

12.6. Other adverse effects

13. Disposal considerations

13.1. Waste treatment methods

Reuse, when possible. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

14. Transport information

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

15. Regulatory information

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

Seveso category 2

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
None

Substances in Candidate List (Art. 59 REACH)
BORIC ACID

Substances subject to authorisarion (Annex XIV REACH)
None

Healthcare controls
Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

15.2. Chemical safety assessment

No chemical safety assessment has been processed for the mixture and the substances it contains

16. Other information

Key for the CLP classifications mentioned in sections 2 and 3 of the sheet:

Repr. 1B	Reproductive toxicity, category 1B
H360FD	May damage fertility. May damage the unborn child.

Text of risk (R) phrases mentioned in section 2-3 of the sheet:

R60	MAY IMPAIR FERTILITY.
R61	MAY CAUSE HARM TO THE UNBORN CHILD.

GENERAL BIBLIOGRAPHY
1. Directive 1999/45/EC and following amendments
2. Directive 67/548/EEC and following amendments and adjustments
3. Regulation (EC) 1907/2006 (REACH) of the European Parliament
4. Regulation (EC) 1272/2008 (CLP) of the European Parliament
5. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
6. Regulation (EC) 453/2010 of the European Parliament
7. The Merck Index. - 10th Edition
8. Handling Chemical Safety
9. Niosh - Registry of Toxic Effects of Chemical Substances
10. INRS - Fiche Toxicologique (toxicological sheet)
11. Patty - Industrial Hygiene and Toxicology
12. N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition

Note for users:
The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product .
This document must not be regarded as a guarantee on any specific product property.
The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Changes to previous review:
The following sections were modified:
01/02/03/05