

**TC86800 - BUFFER solution pH 9.18 ± 0.02
at 25°C standard**

Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878 and to Annex II to UK REACH

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

1.1. Product identifier

Code: TC86800
Product name: BUFFER solution pH 9.18 ± 0.02 at 25°C standard

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

Identified Uses: Reagent for laboratory and process control, industrial use

1.3. Details of the supplier of the safety data sheet

Name: TITOLCHIMICA SPA
Full address: VIA S.PIETRO MARTIRE 1054
District and Country: 45030 PONTECCHIO POLESINE (RO)
ITALIA
Tel. +39425492644

e-mail address of the competent person

responsible for the Safety Data Sheet: utecnico@titolchimica.it
Supplier: TITOLCHIMICA SPA

1.4. Emergency telephone number

For urgent inquiries refer to:
Poison Centers (24 / 24h):
Pavia - 038224444;
Milan - 0266101029;
Bergamo - 80083300;
Verona - 800011858;
Florence - 0557947819;
Rome - Gemini 063054343;
Rome - Umberto I 0649978000;
Rome - Baby Jesus 0668593726;
Naples - 0815453333;
Foggia - 800183459.

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

The product is classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878. Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

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

2.2. Label elements

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

Hazard pictograms:



Signal words: Danger

**TC86800 - BUFFER solution pH 9.18 ± 0.02
at 25°C standard**
Hazard statements:

H360FD May damage fertility. May damage the unborn child.
Restricted to professional users.

Precautionary statements:

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

Contains: Sodium tetraborate decahydrate

2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage ≥ than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration ≥ 0.1%.

SECTION 3. Composition/information on ingredients
3.2. Mixtures
Contains:

Identification	Conc. %	Classification (EC) 1272/2008 (CLP)
Sodium tetraborate decahydrate		
INDEX 005-011-01-1	0,3 – 0,4	Repr. 1B H360FD, Eye Irrit. 2 H319
EC 215-540-4		
CAS 1303-96-4		
REACH Reg. 01-2119490790-32-xxxx		
Mercury Iodide		
(44% - metallic element)		
INDEX 080-002-00-6	<0,01	Acute Tox. 1 H310, Acute Tox. 2 H300, Acute Tox. 2 H330, STOT RE 2 H373, Aquatic Acute 1 H400 M=1, Aquatic Chronic 1 H410 M=1, Classification note according to Annex VI to the CLP Regulation: 1, A STOT RE 2 H373: ≥ 1%
EC 231-873-8		
CAS 7774-29-0		STA Oral: 5,001 mg/kg, STA Dermal: 5 mg/kg, STA Inhalation mists/powders: 0,051 mg/l

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

SECTION 4. First aid measures
4.1. Description of first aid measures

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.

SKIN: Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless authorised by a doctor.

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

No specific information is known on the immediate symptoms and effects caused by the product.

**TC86800 - BUFFER solution pH 9.18 ± 0.02
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Information not available

SECTION 5. Firefighting measures

The product is not flammable and does not feed the flames.

5.1. Extinguishing media**SUITABLE EXTINGUISHING EQUIPMENT**

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

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.

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

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures**6.1. Personal precautions, protective equipment and emergency procedures**

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

6.2. Environmental precautions

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up

Collect the leaked product into a suitable container. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

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.

SECTION 7. Handling and storage**7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

7.2. Conditions for safe storage, including any incompatibilities

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Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s)

Information not available

SECTION 8. Exposure controls/personal protection
8.1. Control parameters
Regulatory References:

ESP	España	Límites de exposición profesional para agentes químicos en España 2021
FRA	France	Valeurs limites d'exposition professionnelle aux agents chimiques en France. ED 984 - INRS
ITA	Italia	Decreto Legislativo 9 Aprile 2008, n.81
GBR	United Kingdom	EH40/2005 Workplace exposure limits (Fourth Edition 2020)
EU	OEL EU	Directive (EU) 2022/431; Directive (EU) 2019/1831; Directive (EU) 2019/130; Directive (EU) 2019/983; Directive (EU) 2017/2398; Directive (EU) 2017/164; Directive 2009/161/EU; Directive 2006/15/EC; Directive 2004/37/EC; Directive 2000/39/EC; Directive 98/24/EC; Directive 91/322/EEC.
	TLV-ACGIH	ACGIH 2022

Sodium tetraborate decahydrate
Threshold Limit Value

Type	Country	TWA/8h	STEL/15min	Remarks / Observations
		mg/m3	ppm	
VLA	ESP	2	6	
VLEP	FRA	5		
WEL	GBR	5		
TLV-ACGIH		2	6	INHAL

Predicted no-effect concentration - PNEC

Normal value in fresh water	2,02	mg/l
Normal value in marine water	2,02	mg/l
Normal value for fresh water sediment	NEA	
Normal value for marine water sediment	NEA	
Normal value for water, intermittent release	13,7	mg/l
Normal value of STP microorganisms	10	mg/l
Normal value for the terrestrial compartment	5,4	mg/kg
Normal value for the atmosphere	NEA	

Health - Derived no-effect level - DNEL / DMEL

Route of exposure	Effects on consumers				Effects on workers			
	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral	VND	1,15 mg/kg bw/d	VND	1,15 mg/kg bw/d	VND	VND	VND	VND
Inhalation	17,04 mg/m3	VND	17,04 mg/m3	4,9 mg/m3	VND	VND	14,04 mg/m3	9,8 mg/m3
Skin	VND	VND	VND	231,8 mg/kg bw/d	VND	VND	VND	458,2 mg/kg bw/d

Potassium iodide
Threshold Limit Value

Type	Country	TWA/8h	STEL/15min	Remarks / Observations
		mg/m3	ppm	
TLV-ACGIH			0,01	A4; Hypothyroidism; URT irr

**TC86800 - BUFFER solution pH 9.18 ± 0.02
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Predicted no-effect concentration - PNEC

Normal value in fresh water	0,007	mg/l
Normal value for fresh water sediment	0,007	mg/kg/d
Normal value for the food chain (secondary poisoning)	0,3	mg/kg
Normal value for the terrestrial compartment	0,0397	mg/kg

Health - Derived no-effect level - DNEL / DMEL

Effects on consumers				Effects on workers				
Route of exposure	Acute local	Acute systemic	Chronic local	Chronic systemic	Acute local	Acute systemic	Chronic local	Chronic systemic
Oral		0,01 mg/kg bw/d		0,01 mg/kg bw/d				
Inhalation				0,035 mg/m3				0,07 mg/m3
Skin				1 ma/ka bw/d				1 ma/ka bw/d

Mercury Iodide
Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		Remarks / Observations
		mg/m3	ppm	mg/m3	ppm	
VLEP	ITA	0,02				SKIN (come Hg)
OEL	EU	0,02				(come Hg)
TLV-ACGIH		0,025				SKIN A4, IBE

Legend:

(C) = CEILING ; INHAL = Inhalable Fraction ; RESP = Respirable Fraction ; THORA = Thoracic Fraction.

VND = hazard identified but no DNEL/PNEC available ; NEA = no exposure expected ; NPI = no hazard identified ; LOW = low hazard ; MED = medium hazard ; HIGH = high hazard.

Sodium tetraborate decahydrate

It is recommended to consider in the risk assessment process the occupational exposure limit values established by the ACGIH for inert dusts not otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). If these limits are exceeded, the use of a type P filter is recommended, the class of which (1, 2 or 3) must be chosen based on the outcome of the risk assessment.

Mercury Iodide

sampling method: <http://amcaw.ifa.dguv.de/substance/methoden/075-L-Mercury.pdf>;

IBE elemental mercury: 20ug / g creatine

Mercury, inorganic and elemental forms:

Notations: Leather, A4, BEI

Critical effects: damage to the central nervous system, damage to the kidneys.

8.2. Exposure controls

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

When choosing personal protective equipment, ask your chemical substance supplier for advice.

Personal protective equipment must be CE marked, showing that it complies with applicable standards.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

Protect hands with category III work gloves.

The following should be considered when choosing work glove material (see standard EN 374): compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

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EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

SECTION 9. Physical and chemical properties
9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	colourless	
Odour	odourless	
Melting point / freezing point	not available	
Initial boiling point	0 °C	
Flammability	not applicable	
Lower explosive limit	not applicable	
Upper explosive limit	not applicable	
Flash point	not applicable	
Auto-ignition temperature	not applicable	
Decomposition temperature	not available	
pH	9,16 - 9,20	
Kinematic viscosity	not available	
Solubility	in water	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	not available	
Relative vapour density	not available	
Particle characteristics	not applicable	

9.2. Other information
9.2.1. Information with regard to physical hazard classes

Information not available

9.2.2. Other safety characteristics

Explosive properties	Not applicable
Risk of explosion	no

**TC86800 - BUFFER solution pH 9.18 ± 0.02
at 25°C standard****SECTION 10. Stability and reactivity**

In the absence of information on the mixture, the literature information on the components is reported. This information is not characteristic of the solution but of the dangerous components.

10.1. Reactivity

There are no particular risks of reaction with other substances in normal conditions of use.

10.2. Chemical stability

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

Sodium tetraborate decahydrate

The product is stable at normal room temperatures. When heated, the product loses water first forming metaboric acid (HBO₂) and transforming into boric anhydride on subsequent heating (B₂O₃).

10.3. Possibility of hazardous reactions

No hazardous reactions are foreseeable in normal conditions of use and storage.

Sodium tetraborate decahydrate

Risk of explosion on contact with: strong oxidizing agents, acids, humidity, water, metal salts.

Boric acid is a weak acid capable of corroding common metals. Reaction with strong reducing agents, such as metal hydrides or alkali metals, generates hydrogen gas which may cause an explosion hazard.

Mercury Iodide

Reacts with: alkaline metals, halogenated compounds.

10.4. Conditions to avoid

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

Sodium tetraborate decahydrate

Keep away from strong reducing agents. Possibility of explosion.

Mercury Iodide

Decomposes if exposed to: high temperatures, direct light.

10.5. Incompatible materials

Mercury Iodide

Incompatible with: alkaline metals.

10.6. Hazardous decomposition products

Sodium tetraborate decahydrate

May develop boron oxides, sodium oxides.

Mercury Iodide

Iododric acid, iodine, mercury oxides.

SECTION 11. Toxicological information

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

**TC86800 - BUFFER solution pH 9.18 ± 0.02
at 25°C standard**
11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008
Metabolism, toxicokinetics, mechanism of action and other information
Sodium tetraborate decahydrate

In the blood, boric acid is the major species present and is not further metabolised. Boric acid spreads rapidly and evenly throughout the body, with concentrations in bone 2 to 3 times higher than in other tissues. Boric acid is rapidly excreted, with elimination half-lives of 1 hour in mice, 3 hours in rats, and < 27.8 hours in humans, and has a low potential for accumulation. Boric acid is mainly excreted in the urine. Oral absorption of borates is approximately 100%. For the inhaled route, 100% absorption is also assumed in the worst case scenario. Dermal absorption through intact skin is very low, with a percent absorbed dose of < 0.5%.

Information on likely routes of exposure
Sodium tetraborate decahydrate

Inhalation is the most important route of exposure in occupational and non-occupational environments.

Dermal exposure is not always a problem as the product is poorly absorbed through intact skin. The product must not be ingested.

Delayed and immediate effects as well as chronic effects from short and long-term exposure
Sodium tetraborate decahydrate

Symptoms related to the physical, chemical and toxicological characteristics:

At high concentrations, irritation of the nose, throat and eyes may be observed. The products must not be ingested. Small doses (e.g. one teaspoon) accidentally ingested are unlikely to cause any effects. Symptoms caused by accidental overexposure to high doses of inorganic borate salts have been associated with ingestion or absorption through large areas of severely damaged skin. Among these it is possible to mention nausea, vomiting and diarrhea, with delayed effects of redness and skin exfoliation.

Human epidemiological studies do not show an increase in pulmonary disease in occupational populations with chronic exposures to boric acid and sodium borate dusts. These studies indicate that there is no effect on fertility in occupational populations with chronic exposures to borate dusts and in the general population with high exposures to borates in the environment.

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	Not classified (no significant component)
ATE (Dermal) of the mixture:	Not classified (no significant component)

Sodium tetraborate decahydrate

LD50 (Dermal):	10000 mg/kg coniglio
LD50 (Oral):	2660 mg/kg ratto

Method: Acute Oral Toxicity Assay - US EPA-FIFRA Guidelines Species: Rat.

Dose: 3,200 to 3,400 mg/kg of body weight Routes of Exposure: Oral

Results: Low acute oral toxicity. LD50 in rats is 3,305 mg/kg of body weight. Based on available data, the classification criteria are not met.

Method: Acute Dermal Toxicity Assay - US EPA-FIFRA Guidelines Species: Rabbit

Dose: 2,000 mg/kg of body weight. Routes of Exposure: Dermal

Results: Low acute dermal toxicity; LD50 in rabbits is > 2,000 mg/kg body weight. Poorly absorbed in case of intact skin.

Based on available data, the classification criteria are not met. Method: Acute Inhalation Toxicity Test – OECD Guideline 403 Species: Rat

Dose: 2.12 mg/L

Routes of exposure: inhalation

Results: Low acute inhalation toxicity; LC50 in rats is > 2.0 mg/l (or g/m3). Based on available data, the classification criteria are not met.

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

Sodium tetraborate decahydrate

Method: Primary Dermal Irritation Study - US EPA-FIFRA Guidelines Species: New Zealand White Rabbit

Dose: 0.5 g moistened with saline. Routes of exposure: dermal

Results: No skin irritation. Mean primary irritation score: 0. Based on available data, the classification criteria are not met.

**TC86800 - BUFFER solution pH 9.18 ± 0.02
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Does not meet the classification criteria for this hazard class

Sodium tetraborate decahydrate

Method: Eye irritation assay - similar to OECD Guideline 405 Species: New Zealand white rabbit

Dose: 0.08 ml equivalent Routes of exposure: ocular

Results: irritating, completely reversible in 14 days.

Classification: eye irritation category 2 (hazard statement: H319:

Causes serious eye irritation). Many years of occupational exposure indicate no adverse effects to the human eye.

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

Sodium tetraborate decahydrate

There is no data to suggest that disodium tetraborates are skin or respiratory sensitisers. Based on available data, the classification criteria are not met.

Respiratory sensitization

Sodium tetraborate decahydrate

Respiratory sensitization studies have not been conducted.

Skin sensitization

Sodium tetraborate decahydrate

Method: Buehler Test - OECD Guideline 406 Species: guinea pig

Dose: 0.4g

Routes of exposure: dermal

Results: Not a skin sensitizer.

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

Sodium tetraborate decahydrate

Method: Numerous in vitro mutagenicity studies of boric acid have been conducted, including mammalian cell gene mutation, unscheduled DNA synthesis, chromosomal aberration, and sister chromatid exchange in mammalian cells.

Species: L5178Y mouse lymphoma, V79 Chinese hamster cells, C3H/10T1/2 cells, hepatocytes, Chinese hamster ovary (CHO cells). Dose: 1.0 to 10.0 mg/mL (1,000 to 10,000 ppm) boric acid

Routes of exposure: in vitro

Results: Non-mutagenic (based on boric acid). Based on available data, the classification criteria are not met.

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

Sodium tetraborate decahydrate

Method: OECD 451 equivalent. Species: B6C3F1 mice

Dose: 446; 1,150 mg boric acid/kg bw/day Routes of exposure: Oral feeding study

Results: No evidence of carcinogenicity (based on boric acid). Based on available data, the classification criteria are not met.

REPRODUCTIVE TOXICITY

May damage fertility - May damage the unborn child

Sodium tetraborate decahydrate

Method: Three-generation feeding study, similar to the OECD's Two-Generation Study 416

Species: rat. Dose: 0; 34 (5.9); 100 (17.5); and 336 (58.5) mg boric acid (mg B)/kg body weight/day; and 0; 50 (5.9); 155 (17.5); and 518 (58.5) mg borax (mg B)/kg body weight/day

Routes of Exposure: Oral feeding study

Results: The No Observed Adverse Effect Level (NOAEL) in rats for effects on fertility in males is 100 mg boric acid/kg body weight and 155 mg sodium tetraborate decahydrate/kg body weight; equivalent to 17.5 mg B/kg of body weight. Method: Prenatal Developmental Toxicity Assay - OECD Guideline 414

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

Routes of Exposure: Oral feeding study Results: The No Observed Adverse Effect Level (NOAEL) in rats for effects on fetal development, including fetal weight loss and minimal skeletal changes, is 55 mg boric acid /kg of body weight or 9.6 mg B/kg; equivalent to 64.7 mg disodium tetraborate pentahydrate/kg body weight.

Classification: Reproductive toxicity, category 1B (Hazard statement: H360FD: May damage fertility. May damage the unborn child.)

Method: Occupational studies for the evaluation of sperm-sensitive parameters in workers heavily exposed to borates. Epidemiological studies have been conducted that evaluated environmental exposures to boron and the effects on the development of individuals. Species: Human Dose: A subset of workers were exposed to 125 mg B/day. Routes of Exposure: Oral ingestion and inhalation combined Results: No adverse effects on male worker fertility. Epidemiological studies of the effects on human development have demonstrated an absence of effects in workers exposed to borates and in populations living in areas characterized by high environmental levels of boron. Summary of the assessment of CMR properties:

Boric acid is not mutagenic and biological tests lasting 2 years have shown its negativity in terms of carcinogenicity.

It follows that a classification of these endpoints for disodium tetraborates is not required according to EC Directive 67/548/EEC or CLP Regulation (EC) No. 1272/2008. A multigeneration study in rats yielded a NOAEL dose for male fertility of 17.5 mg B/kg/day. Effects on development were observed in laboratory animals and the most sensitive species was the rat, with a NOAEL dose of 9.6 mg B/kg bw/day. Disodium tetraborate is classified under the 1st ATP of the CLP Regulations as Repr. 1B; H360FD.

Although boron has been shown to have an adverse effect on male reproduction in laboratory animals, there has not been full evidence of boron-attributable effects on male reproduction in studies of highly exposed workers.

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Sodium tetraborate decahydrate

Method: Standard Test Method for Estimating Sensory Irritation of Airborne Chemicals - ASTM E981-04 (2004)

Species: mouse. Dose: 186 to 1704 mg/m³ Routes of Exposure: Inhalation Results: Maximum exposure of 1704 mg/m³ resulted in a 33% decreased respiratory rate, assessed as moderate irritation.

The lowest tested exposure of 186 mg/m³ sodium tetraborate pentahydrate resulted in a decreased respiratory rate of 11%, rated as non-irritating. Based on available data, the classification criteria are not met. Method: sensory irritation in volunteers Species: human Dose: 5 to 40 mg/m³ Routes of exposure: inhalation. Results: A NOAEL dose for irritation caused by sodium tetraborate pentahydrate of 10 mg/m³ between male and female volunteers under controlled laboratory conditions. At the value of 10 mg/m³ an increase in nasal secretion was observed, which occurred in the absence of other irritant effects at a concentration lower than that considered irritating by the volunteers, then no longer found in a subsequent study.

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Sodium tetraborate decahydrate

Method: Chronic toxicity test of boric acid and disodium tetraborate decahydrate, similar to OECD Guideline 452. Species: Rat Dose: 0; 33 (5.9); 100 (17.5); 334 (58.5) mg boric acid (B)/kg body weight per day (nominal in diet); and 0; 52 (5.9); 155 (17.5); 516 (58.5) mg borax (B)/kg/day (nominal in diet).

Routes of Exposure: Oral feeding study. Results: A NOAEL dose of 17.5 mg B/kg bw/day equivalent to 118 mg sodium tetraborate pentahydrate/kg bw/day was established in a chronic feeding assay (2 years) in rats and is based on the tested effects. Other effects (kidneys, hematopoietic system) are only considered at even higher dosage levels. Based on available data, the classification criteria are not met.

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

Sodium tetraborate decahydrate

The physical form of the solid powder indicates the absence of a potential aspiration hazard. Toxicokinetics: In the blood, boric acid is the major species present and is not further metabolised. Boric acid spreads rapidly and evenly throughout the body, with concentrations in bone 2 to 3 times higher than in other tissues.

Boric acid is rapidly excreted, with elimination half-lives of 1 hour in mice, 3 hours in rats, and < 27.8 hours in humans, and has a low potential for accumulation.

Boric acid is mainly excreted in the urine. Oral absorption of borates is approximately 100%. For the inhaled route, 100% absorption is also assumed in the worst case scenario. Dermal absorption through intact skin is very low, with a percent absorbed dose of < 0.5%.

11.2. Information on other hazards

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

SECTION 12. Ecological information

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

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12.1. Toxicity

Sodium tetraborate decahydrate

LC50 - for Fish	79,7 mg/l/96h Fathead minnow
EC50 - for Crustacea	133 mg/l/48h Daphnia magna
EC50 - for Algae / Aquatic Plants	40 mg/l/72h Pseudokirchneriella subcapitata

Boron occurs naturally in seawater at an average concentration of 5 mg b/l and fresh water at 1 mg b/l or less. To convert acid boric acid to boron (B) equivalent, multiply by 0.1134.

Fresh water

Chronic Studies

Taxonomic group / No. of taxa tested / Range of endpoint values (NOEC/CE10 geometric).

Algae / 4 / From 10mgB/L (Chlorella pyrenoidosa) to 50mg B/L (Anacystis nidulans).

Higher plants / 3 / From 4.0mgB/L (Phragmites australis) to 60mg B/L (Lemna minor)

Invertebrates and protozoa / 7 / From 5.7mgB/L (Daphnia magna) to 32mg B/L (Chironomus riparius)

Fish / 6 / From 2.9mgB/L (Micropterus salmoides) to 17mg B/L (Carassius auratus)

Amphibians / 2 / From 86 mg B/L (Rana pipiens) to 104 mg B/L (Bufo fowleri)

Results: Based on a comprehensive dataset of 22 species, the HC5 value of the species sensitivity distribution is 4.05 mg B/L.

Acute Studies

Taxonomic group / No. of taxa tested / Range of endpoint values (EC/LC50 geometric)

Algae / 2 / From 10 mg B/L (Chlorella pyrenoidosa) to 28 mg B/L (Selenastrum capricornutum)

Invertebrates and protozoa / 9 / From 113 mg B/L (Ceriodaphnia dubia) to 1376 mg B/L (Chironomus decorus)

Fish / 7 / From 80 mg B/L (Pimephales promelas) to 627 mg B/L (Onchorhynchus tshawytscha)

Amphibians / 2 / From 29 mg B/L (Rana pipiens) to 41 mg B/L (Bufo fowleri)

Results: Based on a comprehensive data set from 46 studies with 20 species, the species sensitivity distribution HC5 value is 27.3 mg B/L.

Classification: Based on acute data for freshwater species, this substance is not classified as environmentally hazardous.

Data relating to the sea and estuaries

Chronic Studies

Taxonomic group / No. of taxa tested / Range of endpoint values (NOEC/CE10 geometric)

Algae / 19 / 5 mg B/L (Emiliana huxleyi) to >100 mg B/L (Agmenellum quadruplicatum, Anacystis marina, Thallassiosira pseudonana)

Results: No data available for vertebrate or invertebrate species. The results from the freshwater dataset are recommended as applicable to marine and estuarine species.

Acute Studies

Taxonomic group / No. of taxa tested / Range of endpoint values (EC/LC50 geometric)

Invertebrates / 3 / 45 mg B/L (Litopenaeus vannamei) to 83 mg B/L (Americamysis bahia)

Fish / 2 / 74 mg B/L (Limanda limanda) to 600 mg B/L (Oncorhynchus tshawytscha)

No data available for algal species.

Sediments

Taxonomic group / No. of taxa tested / Range of endpoint values (EC/LC50 geometric)

Invertebrates / 1 / 82.4 mg B/kg sediment dw (Chironomus riparius)

Results: Although limited, the data suggest that the sediment-dwelling organisms are in the toxic range for aquatic organisms. Furthermore, the substance will not partition in sediment, therefore a sediment/water partitioning approach is warranted.

Sewage Treatment Plants : STP

Taxonomic group / No. of taxa tested / Range of endpoint values (NOEC/CE10 geometric)

Activated sludge / n.a. / >17.5 mg B/L to 100 mg B/L

Microbes / 3 / 10 mg B/L (Opercularia bimarginata) to 20 mg B/L (Paramecium caudatum)

Terrestrial data

Chronic Studies

Taxonomic group / No. of taxa tested / Range of endpoint values (NOEC/CE10 geometric)

Plants / 2 / 7.2 mg B/kg dw (Zea mays) to 56 mg B/kg dw (Allium cepa)

Invertebrates / 9 / 15.4 mg B/kg dw (Folsomia candida) to 87 mg B/kg dw (Caenorhabditis elegans)

Soil microorganisms / 7 / 12 mg B/kg dw (nitrogen mineralization and nitrification test) to 420 mg B/kg dw (soil nitrogen transformation test)

Results: Based on a comprehensive dataset, the HC5 value of the species sensitivity distribution is 10.8 mg B/kg dry weight.

Phytotoxicity: boron is an essential micronutrient for the healthy development of plants. May be harmful to plants sensitive to boron in large quantities.

Use caution to minimize the amount of borates released into the environment.

12.2. Persistence and degradability

Sodium tetraborate decahydrate

Biodegradation is not an applicable endpoint as the product is an inorganic substance.

Solubility in water: 47000 mg/l.

**TC86800 - BUFFER solution pH 9.18 ± 0.02
at 25°C standard**

Mercury Iodide

NOT rapidly degradable

12.3. Bioaccumulative potential

Sodium tetraborate decahydrate

The product undergoes hydrolysis in water with the formation of undissociated boric acid. Boric acid does not undergo biomagnification through the food chain. Coeff. Octanol/Water Partition Rate: Log Pow = - 1.53

12.4. Mobility in soil

Sodium tetraborate decahydrate

The product is soluble in water and is releasable in normal soils. Adsorption to soils or sediments is irrelevant.

12.5. Results of PBT and vPvB assessment

Sodium tetraborate decahydrate

In accordance with Annex XIII of the REACH regulation, the criteria for the assessment of PBT and vPvB properties do not apply to inorganic substances. Based on available data, the product does not contain PBT or vPvB substances in a percentage ≥ 0.1%.

12.6. Endocrine disrupting properties

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

12.7. Other adverse effects

Information not available

SECTION 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.

SECTION 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.

14.1. UN number or ID number

not applicable

14.2. UN proper shipping name

not applicable

14.3. Transport hazard class(es)

not applicable

14.4. Packing group

**TC86800 - BUFFER solution pH 9.18 ± 0.02
at 25°C standard**

not applicable

14.5. Environmental hazards

not applicable

14.6. Special precautions for user

not applicable

14.7. Maritime transport in bulk according to IMO instruments

Information not relevant

SECTION 15. Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

Seveso Category - Directive 2012/18/EU: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006Product

Point 3

Contained substance

Point 30-75 Sodium tetraborate decahydrate REACH Reg.: 01-2119490790-32-xxxx

Point 18 Mercury iodide

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors

not applicable

Substances in Candidate List (Art. 59 REACH)

Sodium tetraborate decahydrate

REACH Reg.: 01-2119490790-32-xxxx

Substances subject to authorisation (Annex XIV REACH)

None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:

None

Substances subject to the Rotterdam Convention:

None

Substances subject to the Stockholm Convention:

None

**TC86800 - BUFFER solution pH 9.18 ± 0.02
at 25°C standard**
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

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

SECTION 16. Other information

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

Repr. 1B	Reproductive toxicity, category 1B
Acute Tox. 1	Acute toxicity, category 1
Acute Tox. 2	Acute toxicity, category 2
STOT RE 2	Specific target organ toxicity - repeated exposure, category 2
Eye Irrit. 2	Eye irritation, category 2
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
H360FD	May damage fertility. May damage the unborn child.
H310	Fatal in contact with skin.
H300	Fatal if swallowed.
H330	Fatal if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.
H319	Causes serious eye irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation

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at 25°C standard**

- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
 2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
 3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
 4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
 5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
 6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
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 8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
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- The Merck Index. - 10th Edition
 - Handling Chemical Safety
 - INRS - Fiche Toxicologique (toxicological sheet)
 - Patty - Industrial Hygiene and Toxicology
 - N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
 - IFA GESTIS website
 - ECHA website
 - Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

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.

Provide appointed staff with adequate training on how to use chemical products.

CALCULATION METHODS FOR CLASSIFICATION

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

Changes to previous review n.6 – 15/03/18:

The following sections were modified:

01 / 02 / 03 / 04 / 06 / 07 / 08 / 09 / 10 / 11 / 12 / 13 / 15 / 16.