

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

Product name **SANITER 454 P**
UFI : **CE32-00N0-8001-4UAJ**

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

Intended use **Biocide for industrial water**

Identified Uses	Industrial	Professional	Consumer
Additive for biocidal effect	✓	✓	-
Uses Advised Against			
Any use non-professional			
Any use not included among those recommended			

1.3. Details of the supplier of the safety data sheet

Name **N.C.R. BIOCHEMICAL S.P.A.**
Full address **Via dei Carpentieri, 8-Zona Industriale il Prato**
District and Country **40050 Castello d'Argile (BO) Italia**
Tel. **+39 051 6869611 Lun-Ven 8.30-13.00/14.00-16.30**
Fax **+39 051 6869617**
e-mail address of the competent person responsible for the Safety Data Sheet **regulatory@ncr-biochemical.com**

1.4. Emergency telephone number

For urgent inquiries refer to **Italy:**
CAV Ospedale Niguarda Ca' Granda - Milano 02 66101029
CAV Azienda Ospedaliera Papa Giovanni XXII - Bergamo 800 883300
CAV Centro Nazionale di Informazione Tossicologica - Pavia 0382 24444
CAV Az. Osp. Careggi - Firenze 055 7947819
CAV Policlinico Gemelli - Roma 06 3054343
CAV Policlinico Umberto I - Roma 06 49978000
CAV Osp. Pediatrico Bambino Gesù - Roma 06 68593726
CAV Az. Osp. Cardarelli - Napoli 081 7472870
CAV Az. Osp. Univ. Foggia - 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:

Acute toxicity, category 4	H302	Harmful if swallowed.
Skin corrosion, category 1C	H314	Causes severe skin burns and eye damage.
Serious eye damage, category 1	H318	Causes serious eye damage.
Skin sensitization, category 1A	H317	May cause an allergic skin reaction.
Hazardous to the aquatic environment, acute toxicity, category 1	H400	Very toxic to aquatic life.
Hazardous to the aquatic environment, chronic toxicity, category 1	H410	Very toxic to aquatic life with long lasting effects.

SECTION 2. Hazards identification ... / >>

2.2. Label elements

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

Hazard pictograms:



Signal words:

Danger

Hazard statements:

H302	Harmful if swallowed.
H314	Causes severe skin burns and eye damage.
H317	May cause an allergic skin reaction.
H410	Very toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

Precautionary statements:

P261	Avoid breathing dust, fume, gas, mist, vapours, spray.
P273	Avoid release to the environment.
P280	Wear protective gloves/ protective clothing / eye protection / face protection.
P303+P361+P353	IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P310	Immediately call a POISON CENTER/doctor.

Contains:

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)
Bronopol (INN)

2.3. Other hazards

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

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

SECTION 3. Composition/information on ingredients

3.1. Substances

Information not relevant

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
Sodium nitrate		
INDEX	5 \leq x < 10	Ox. Sol. 3 H272, Eye Irrit. 2 H319
EC	231-554-3	
CAS	7631-99-4	
REACH Reg.	01-2119488221-41-XXXX	
Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)		
INDEX	613-167-00-5	3 \leq x < 3,3
EC		Acute Tox. 2 H310, Acute Tox. 2 H330, Acute Tox. 3 H301, Skin Corr. 1C H314, Eye Dam. 1 H318, Skin Sens. 1A H317, Aquatic Acute 1 H400 M=100, Aquatic Chronic 1 H410 M=100, EUH071
		Skin Corr. 1C H314: \geq 0,6%, Skin Irrit. 2 H315: \geq 0,06%, Skin Sens. 1A H317: \geq 0,0015%, Eye Dam. 1 H318: \geq 0,6%, Eye Irrit. 2 H319: \geq 0,06%

SECTION 3. Composition/information on ingredients ... / >>

CAS 55965-84-9

LD50 Oral: 66 mg/kg, LD50 Dermal: >141 mg/kg, LC50 Inhalation mists/powders: 0,17 mg/l/4h

REACH Reg. EXEMPTED – Art. 15 (2) of REACH regulation

Bronopol (INN)

INDEX 603-085-00-8 $1 \leq x < 2,5$

Acute Tox. 4 H302, Acute Tox. 4 H312, Eye Dam. 1 H318, Skin Irrit. 2 H315, STOT SE 3 H335, Aquatic Acute 1 H400 M=10, Aquatic Chronic 1 H410 M=1

EC 200-143-0

CAS 52-51-7

REACH Reg. 01-2119980938-15-XXXX

LD50 Oral: 324 mg/kg, LD50 Dermal: 1600 mg/kg

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 any contact lenses. Wash immediately and abundantly with water for at least 30/60 minutes, opening your eyelids well. Consult a physician immediately.

Skin: Remove contaminated clothing. Immediately take the shower. Consult a physician immediately.

Ingestion: Consult a physician immediately. Do not induce vomiting unless specifically authorized by your doctor.

Inhalation: Call a physician immediately. Bring the subject outdoors, away from the scene. If breathing ceases, practice artificial respiration. Take appropriate precautions for the rescuer.

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

Other relevant symptoms / effects are described in Section 11: Toxicological Information and refer to the finished product or its components.

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

The product is corrosive. It is not advisable to cause vomiting. Possible mucosal damage makes the use of gastric lavage contraindicated. Always refer to the instructions of a competent physician. Measures can be taken against circulatory shocks and convulsions.

SECTION 5. Firefighting measures

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

Wear suitable respirator, approved CEN or equivalent (fitted with a cartridge for organic vapor / acid gases and dust / aerosol filter) during cleaning and disinfection of this material. The material is CORROSIVE. During decontamination and cleaning procedures of this product, wear protective clothing including spray goggles, full length nitrile and butyl rubber gloves, rubber apron or butyl or nitrile rubber clothing and rubber overcapacity. If the material comes into contact with the skin during cleaning, immediately remove contaminated clothing and wash contaminated areas with soap and water. See section 4 - First-aid interventions for more information.

SECTION 6. Accidental release measures ... / >>

6.2. Environmental precautions

Do not contaminate the water supply with the material. Do not discharge the product into sewers.

6.3. Methods and material for containment and cleaning up

Keep leakages and residues of cleaning products away from public watercourses and sewers. Absorb leak with absorbent pads or inert solid material such as clay or vermiculite and transfer contaminated materials into a suitable container for disposal. Decontaminate the area of the leak with a solution prepared at the moment to 5% sodium bicarbonate and 5% sodium hypochlorite in water. Apply the solution to the leak area to a ratio of 10 volumes of decompression solution for the estimated residual volume volume to disable any remaining residual amount of active principle. Leave to work for 30 minutes. Rinse the area of the leak with abundant amounts of water and convey it to a water treatment plant, observing the current legislation. DO NOT add the decontaminant solution to the waste container to disable the absorbed material. See Section 13 - Disposal considerations, for information regarding the disposal of materials used to contain leaks.

6.4. Reference to other sections

References to other sections, if applicable, have been provided in the preceding subsections.

SECTION 7. Handling and storage

7.1. Precautions for safe handling

This material is corrosive. See Section 8 for Personal Protective Equipment. Do not handle the material near food, feed or drinking water.

7.2. Conditions for safe storage, including any incompatibilities

Storage temperature: 1 - 55 ° C.

Keep in a well-ventilated place. The product, as supplied, may slowly develop gases (predominantly carbon dioxide). To prevent pressure buildup, the product is packaged in specially designed breather containers, where necessary. When not in use, the product must be kept in the original container. The container must be stored and transported vertically to prevent the contents coming out of the vent where it is placed. Do not store this product in containers of the following material: steel. Do not store the material near food, feed or drinking water. Empty containers may be hazardous. Since product residues remain in empty containers, carefully follow the safety data sheet and label warnings even after emptying.

Storage class TRGS 510 (Germany): 8B

7.3. Specific end use(s)

Refer to the product data sheet and the instructions of the technicians who propose it for treatment.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

Exposure limits are listed below when they exist.

Regulatory References:

DEU Deutschland Technischen Regeln für Gefahrstoffe (TRGS 900) - Liste der Arbeitsplatzgrenzwerte und Kurzzeitwerte. MAK- und BAT-Werte-Liste 2020, Ständige Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe, Mitteilung 56

Sodium nitrate

Predicted no-effect concentration - PNEC

Normal value of STP microorganisms	18	mg/l
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Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Threshold Limit Value

Type	Country	TWA/8h mg/m3	ppm	STEL/15min mg/m3	ppm	Remarks / Observations
AGW	DEU	0,2		0,4		INHAL

SECTION 8. Exposure controls/personal protection ... / >>

Bronopol (INN)

Predicted no-effect concentration - PNEC

Normal value in fresh water	0,00125	mg/l
Normal value in marine water	0,00052	mg/l
Normal value for fresh water sediment	0,0215	mg/kg
Normal value for marine water sediment	0,00894	mg/kg
	4	
Normal value for water, intermittent release	0,00026	mg/l
	5	
Normal value of STP microorganisms	0,43	mg/l
Normal value for the terrestrial compartment	0,21	mg/kg

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	0,5 mg/kg bw/d	VND	0,18 mg/kg bw/d				
Inhalation	0,6 mg/m3	1,8 mg/m3	0,6 mg/m3	0,6 mg/m3	2,5 mg/m3	10,5 mg/m3	2,5 mg/m3	3,5 mg/m3
Skin	0,004 mg/cm2	0,7 mg/kg bw/d	0,004 mg/cm2	2,1 mg/kg bw/d	0,008 mg/cm2	6 mg/kg bw/d	0,008 mg/cm2	2 mg/kg bw/d

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.

8.2. Exposure controls

Control Systems Engineering: Use only in areas provided with appropriate ventilation systems.

Protective equipment: The premises for storage or use of this material must be equipped with lavaoffs and emergency shower.

Individual protection measures

Eye / face protection: Eye protection: Use anti-splash goggles and facial mask (EN166). Eye protection must be compatible with the system used for the protection of the respiratory tract.

Skin and Hand Protection: When handling this material, wear chemical resistant gloves. The gloves listed below protect against permeability (gloves of other chemical-resistant materials may not provide adequate protection): butyl rubber Nitrile rubber PVC gloves with thickness <1 mm Remove and replace gloves immediately as signs of wear or tear of the substance chemistry. Wash and remove gloves immediately after use. Wash hands with soap and water. NOTE: Material is a possible skin sensitizer.

Other Protective Equipment: Properly Wear: Chemical resistant apron complete with chemical resistant protection.

Respiratory protection: Typical use of this material does not produce workplace exposures that exceed the exposure limits listed in the Exposure Control section. In case of special conditions in which the exposure limits are exceeded, follow a respiratory protection program compliant with the requirements of Directive 89/686 / EEC and EN133 and 134. For concentrations up to 10 times the exposure limits, Wear a CEN or equivalent respirator, complete with a full face cover (EN136) or half mask (EN140), fitted with CEN or equivalent approvals for the protection of organs vapor (EN 14387) and dust / aerosol filters (EN143). In the presence of oily aerosols, combine with the use of dust / aerosol filters FFP3 (EN143). In case of unlikely situations where the exposure exceeds the listed exposure limits (ie greater than 10 times), or in any emergency situations, wear appropriate self-contained breathing apparatus, approved CEN or equivalent, at pressure or a respirator with mask Full face with positive pressure air demand and with emergency device. See Section 6, Accidental Release Measures, Respiratory Requirements and Protective Clothing to be used for cleaning and decontamination of spills in this material.

Environmental exposure controls

See Section 7: Handling and Storage and Section 13: Disposal Considerations for Preventive Environmental Exposure Measures During Use and Waste Disposal.

ENVIRONMENTAL EXPOSURE CONTROLS

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

Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	from colourless to light yellow	
Odour	pungent	
Melting point / freezing point	not determined	
Initial boiling point	100 °C	

SECTION 9. Physical and chemical properties ... / >>

Flammability	not flammable	
Lower explosive limit	not applicable	
Upper explosive limit	not applicable	
Flash point	> 60 °C	Method:ASTM D93
Auto-ignition temperature	not determined	
Decomposition temperature	not determined	
pH	2,5 ÷ 4,5	Method:ITL 70 Temperature: 25 °C
Kinematic viscosity	not determined	
Solubility	soluble in water	Method:ITL 73
Partition coefficient: n-octanol/water	not determined	
Vapour pressure	not determined	
Density and/or relative density	1,05 ± 0,02 g/ml	Method:ITL 15 B Temperature: 20 °C
Relative vapour density	not determined	
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

Evaporation rate	< 1
Explosive properties	not applicable because it does not contain any explosives functional groups
Oxidising properties	the product is not oxidizing

SECTION 10. Stability and reactivity

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.

Bronopol (INN)

In order to avoid adverse effects on the active substance, the product must not be diluted or mixed with other chemicals before use.

10.3. Possibility of hazardous reactions

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

Bronopol (INN)

No dangerous reactions are known.

10.4. Conditions to avoid

Avoid storing the product or reaching temperatures above 55 ° C. These temperatures can cause product degradation.

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

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Avoid exposure to: high temperatures,heat,light,UV rays.

Bronopol (INN)

Keep away from direct sunlight and moisture. Protect from temperatures above 60 °C.

10.5. Incompatible materials

Avoid contact with the following substances: strong bases, reducing agents, strong oxidants, nucleophiles.

Bronopol (INN)

SECTION 10. Stability and reactivity ... / >>

Strong alkalis.

10.6. Hazardous decomposition products

Oxides of nitrogen (NOx), Sulfur oxides, hydrochloric acid.

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

In decomposition develops: sulphur oxides, nitric oxide, carbon dioxide, carbon monoxide, metal oxides.

Bronopol (INN)

Nitric oxides, carbon oxides, hydrobromic acid.

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.

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

Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

The most likely routes of exposure are the skin route and the respiratory tract.

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

Excessive exposure may cause irritation to the upper respiratory tract (nose and throat).

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation - mists / powders) of the mixture:	> 5 mg/l
ATE (Oral) of the mixture:	1732,62 mg/kg
ATE (Dermal) of the mixture:	>2000 mg/kg

Corrosive to the respiratory tract.

Sodium nitrate	
LD50 (Dermal):	> 5000 mg/kg Rat, according to OECD Guideline 402, reliability 2
	3430 mg/kg Rat, equivalent or similar to guideline OECD Guideline 401, reliability 2
LD50 (Oral):	

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

LD50 (Dermal):	> 141 mg/kg
LD50 (Oral):	66 mg/kg
LC50 (Inhalation mists/powders):	0,17 mg/l/4h

Bronopol (INN)	
LD50 (Dermal):	1600 mg/kg Rat, according to CLH report, reliability 2
LD50 (Oral):	324 mg/kg Rat, according to OECD Guideline 425, reliability 1
LC50 (Inhalation mists/powders):	> 0,588 mg/l/4h Rat (aerosol tested), according to CLH report, reliability 2

Sodium nitrate
The LC50 value by inhalation has not been determined.

Bronopol (INN)
Harmful if swallowed or in contact with skin.

SKIN CORROSION / IRRITATION

Corrosive for the skin

SECTION 11. Toxicological information ... / >>

Bronopol (INN)

The substance has caused skin irritation in tested rabbits (OECD 404 or equivalent, reliability 2).

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye damage

Bronopol (INN)

It causes serious eye damage.

RESPIRATORY OR SKIN SENSITISATION

Sensitising for the skin

Bronopol (INN)

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

Respiratory sensitization

No significant data were detected.

Skin sensitization

The product causes sensitization.

GERM CELL MUTAGENICITY

The active ingredient is non-mutagenic.

Does not meet the classification criteria for this hazard class

Sodium nitrate

In vitro genetic toxicity studies have yielded negative results in some cases and positive in others. The results of animal genetic toxicity tests failed.

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

In vitro assays did not show mutagenic effects. In vivo assays did not show mutagenic effects.

Bronopol (INN)

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

CARCINOGENICITY

The active ingredient is not carcinogenic in either a mammalian or mouse cancer-carcinogenic study in rats.

Does not meet the classification criteria for this hazard class

Sodium nitrate

It contains materials that may react and form a nitrosamine. Some nitrosamines have been shown to be carcinogenic in laboratory animals.

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

It did not cause tumors in tested animals.

Bronopol (INN)

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

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

Bronopol (INN)

Based on available data, the classification criteria are not met. The results of studies on animals show no effects of fertility damage.

Adverse effects on sexual function and fertility

This product is not hazardous for reproduction.

SECTION 11. Toxicological information ... / >>

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

In studies on animals it does not interfere with reproduction.

Adverse effects on development of the offspring

The active substance did not show any teratogenic effects in animal experiments.

Sodium nitrate

It did not cause birth defects or any other effect on the fetus in laboratory animals.

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

It has not caused birth defects or other effects in the fetus even at doses that have caused toxic effects on the mother.

STOT - SINGLE EXPOSURE

Product test data not available. Refer to component data.

Does not meet the classification criteria for this hazard class

Sodium nitrate

The evaluation of available data suggests that this material is not a toxic substance STOT-SE.

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

The evaluation of available data suggests that this material is not a toxic substance STOT-SE.

Bronopol (INN)

It may irritate the respiratory tract.

STOT - REPEATED EXPOSURE

Product test data not available. Refer to component data.

Does not meet the classification criteria for this hazard class

Sodium nitrate

Symptoms for humans may include: May cause central nervous system depression, resulting in drowsiness and dizziness, headache, incoordination, low blood pressure. It can cause methoglobinemia, thus reducing the blood's ability to carry oxygen.

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Excessive exposure may cause irritation of the upper respiratory tract (nose and throat).

Bronopol (INN)

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

Target organs

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Nose and throat.

ASPIRATION HAZARD

Product test data not available. Refer to component data.

Does not meet the classification criteria for this hazard class

Sodium nitrate

On the basis of physical properties, it is unlikely that it represents an aspiration hazard.

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Aspiration into the lungs can occur during ingestion or vomiting, causing damage to the tissues or lungs themselves.

Bronopol (INN)

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

SECTION 11. Toxicological information ... / >>

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

This product is dangerous for the environment and highly toxic for aquatic organisms. In the long term, it have negative effects on aquatic environment.

12.1. Toxicity

Sodium nitrate

Toxicity to bacteria:

EC50 (3 h) > 1000 mg/l, OECD TG 209.

Bronopol (INN)

Toxicity on activated sludge organisms:

EC50/3h = 11 mg/l (OECD 209)

EC20/3h = 2 mg/l (literature).

Bronopol (INN)

LC50 - for Fish

11 mg/l *Lepomis macrochirus*, flow-through, according to OECD Guideline 203, reliability 1

EC50 - for Crustacea

1,04 mg/l *Daphnia magna*, OECD 202

EC50 - for Algae / Aquatic Plants

0,068 mg/l *Anabaena flos aqua*, OECD 201

Chronic NOEC for Fish

2,61 mg/l/28d *Oncorhynchus mykiss*, flow-through, according to OECD Guideline 215, reliability 1

Chronic NOEC for Crustacea

0,06 mg/l/21d *Daphnia magna*, OECD 211

Chronic NOEC for Algae / Aquatic Plants

0,0025 mg/l/72h *Anabaena flos aqua*, OECD 201

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

LC50 - for Fish

0,22 mg/l/96h *Oncorhynchus mykiss*, flow-through, according to OECD Guideline 203 or equivalent

EC50 - for Crustacea

0,16 mg/l/48h *Daphnia magna*, flow-through, according to OECD Guideline 202 or equivalent

EC50 - for Algae / Aquatic Plants

0,048 mg/l/72h *Pseudokirchneriella subcapitata*, according to OECD Guideline 201 or equivalent

Chronic NOEC for Fish

0,098 mg/l/28d *Oncorhynchus mykiss*, OECD 215

Chronic NOEC for Crustacea

0,004 mg/l/21d *Daphnia magna*, OECD 211

Chronic NOEC for Algae / Aquatic Plants

0,0012 mg/l/72h *Pseudokirchneriella subcapitata*, OECD 201

Sodium nitrate

LC50 - for Fish

> 100 mg/l/96h *Oncorhynchus mykiss*, according to guideline OECD Guideline 203, reliability 2

EC50 - for Crustacea

8609 mg/l/24h *Daphnia magna*, equivalent or similar to guideline OECD TG 202, reliability 2

EC50 - for Algae / Aquatic Plants

> 1700 mg/l/10d Benthic diatoms, no guideline followed, publication on Marine Biology 43:307-315, reliability 2

Chronic NOEC for Fish

157 mg/l *Pimephales promelas*, according to Annual Book of ASTM Standards, Vol 11.05, reliability 2

12.2. Persistence and degradability

Bronopol (INN)

NOT rapidly degradable

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Entirely degradable

<50%, 10d OECD Test, but considered rapidly degradable. photodegradation 0,38-1,3d

Sodium nitrate

Degradability: information not available

12.3. Bioaccumulative potential

SECTION 12. Ecological information ... / >>

Bronopol (INN)

Based on the log Kow, accumulation in organisms is not to be expected.

Bronopol (INN)

Partition coefficient: n-octanol/water

0,38 Log Kow OECD 107

BCF

3,16 - Calculated

Reaction mass of: 5-chloro-2-methyl-4-isothiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (3:1)

Partition coefficient: n-octanol/water

< 0,71 OECD 117

BCF

3,16 (calculated)

12.4. Mobility in soil

Bronopol (INN)

Partition coefficient: soil/water

5

12.5. Results of PBT and vPvB assessment

On the basis of available data, the product does not contain any PBT or vPvB in percentage \geq than 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

Dispose of as special waste according to local and national regulations.

The correct attribution of both the CER group and the CER code to this product depends on the use made of it. Contact your authorized waste disposal service.

SECTION 14. Transport information

14.1. UN number or ID number

ADR / RID, IMDG, IATA: 3265

14.2. UN proper shipping name

ADR / RID: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (mixture containing 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1))

IMDG: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (mixture containing 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1))

IATA: CORROSIVE LIQUID, ACIDIC, ORGANIC, N.O.S. (mixture containing 5-Chloro-2-methyl-2H-isothiazol-3-one and 2-Methyl-2H-isothiazol-3-one (3:1))

SECTION 14. Transport information ... / >>

14.3. Transport hazard class(es)

ADR / RID: Class: 8 Label: 8

IMDG: Class: 8 Label: 8

IATA: Class: 8 Label: 8



14.4. Packing group

ADR / RID, IMDG, IATA: III

14.5. Environmental hazards

ADR / RID: Environmentally Hazardous

IMDG: Marine Pollutant

IATA: NO



For Air transport, environmentally hazardous mark is only mandatory for UN 3077 and UN 3082.

14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 80 Special provision: 274	Limited Quantities: 5 L	Tunnel restriction code: (E)
IMDG:	EMS: F-A, S-B	Limited Quantities: 5 L	
IATA:	Cargo: Passengers: Special provision:	Maximum quantity: 60 L Maximum quantity: 5 L A3, A803	Packaging instructions: 856 Packaging instructions: 852

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

Other legislation:
REGULATION (EU) No 528/2012 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 May 2012 concerning the making available on the market and use of biocidal products

Regulation (EU) 2019/1148 on the marketing and use of explosives precursors - This product is regulated by Regulation (EU) 2019/1148: all suspicious transactions, and significant disappearances and thefts should be reported to the relevant national contact point.

Seveso Category - Directive 2012/18/EU: E1

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

Product	
Point	3
Contained substance	
Point	75

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

Regulated explosives precursor

The acquisition, introduction, possession or use of that regulated explosives precursor by members of the general public is subject to reporting obligations as set out in Article 9.

SECTION 15. Regulatory information ... / >>

All suspicious transactions and significant disappearances and thefts must be reported to the relevant national contact point.

Substances in Candidate List (Art. 59 REACH)

On the basis of available data, the product does not contain any SVHC in percentage \geq than 0,1%.

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

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.

German regulation on the classification of substances hazardous to water (AwSV, vom 18. April 2017)

WGK 2: Hazard to waters

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:

Ox. Sol. 3	Oxidising solid, category 3
Acute Tox. 2	Acute toxicity, category 2
Acute Tox. 3	Acute toxicity, category 3
Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1C	Skin corrosion, category 1C
Eye Dam. 1	Serious eye damage, category 1
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Skin Sens. 1A	Skin sensitization, category 1A
Aquatic Acute 1	Hazardous to the aquatic environment, acute toxicity, category 1
Aquatic Chronic 1	Hazardous to the aquatic environment, chronic toxicity, category 1
H272	May intensify fire; oxidiser.
H310	Fatal in contact with skin.
H330	Fatal if inhaled.
H301	Toxic if swallowed.
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H314	Causes severe skin burns and eye damage.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.
H317	May cause an allergic skin reaction.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
EUH071	Corrosive to the respiratory tract.

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

SECTION 16. Other information ... / >>

- 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
- 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
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)

- 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.