

Safety Data Sheet

According to Annex II to REACH - Regulation 2015/830

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

1.1. Product identifier

Product name **Antibacter**

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

Intended use **Ready to use disinfectant detergent. Medical surgical facility - Ministry of Health
Reg. No. 20051**

Identified Uses	Industrial	Professional	Consumer
Products for washing and cleaning	PROC: 10, 13, 7, 8a, 8b. PC: 35.	PROC: 10, 11, 13, 8a, 8b. PC: 35.	-

Uses Advised Against

None known

1.3. Details of the supplier of the safety data sheet

Name **FIRMA SRL**
 Full address **VIA PER MODENA, 28**
 District and Country **42015 CORREGGIO (RE)**
IT
 Tel. **0522 691880**
 Fax **0522 631277**

e-mail address of the competent person responsible for the Safety Data Sheet **SDS@FIRMACHIMICA.IT**

Product distribution by: **FIRMA SRL**

1.4. Emergency telephone number

For urgent inquiries refer to **Tel. 0039 0522 691880 Office hours: 08.30 - 12.30, 14.00 - 18.00**
Tel. 0039 0522 036527 other times – laboratorio@firmachimica.it

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 2015/830.

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:

Eye irritation, category 2	H319	Causes serious eye irritation.
Skin irritation, category 2	H315	Causes skin irritation.

2.2. Label elements

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

Hazard pictograms:



Signal words: **Warning**

SECTION 2. Hazards identification ... / >>

Hazard statements:

H319 Causes serious eye irritation.
H315 Causes skin irritation.

Precautionary statements:

P280 Wear protective gloves / clothing and face protection.
P302+P352 IF ON SKIN: wash with plenty of water / ...
P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P314 Get medical advice / attention if you feel unwell.

2.3. Other hazards

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

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification 1272/2008 (CLP)
2-BUTOXYETHANOL		
CAS	111-76-2 10 ≤ x < 20	Acute Tox. 4 H302, Acute Tox. 4 H312, Acute Tox. 4 H332, Eye Irrit. 2 H319, Skin Irrit. 2 H315
EC	203-905-0	
INDEX	603-014-00-0	
Reg. no.	01-2119475108-36	
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CAS	7173-51-5 0,25 ≤ x < 1	Acute Tox. 4 H302, Skin Corr. 1B H314, Eye Dam. 1 H318, Aquatic Acute 1 H400 M=10, Aquatic Chronic 1 H410 M=1
EC	230-525-2	
INDEX		

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

SECTION 4. First aid measures

In case of doubt or when symptoms remain, seek medical advice keeping the information sheet of the preparation available. Do not administer unconscious persons by mouth.

4.1. Description of first aid measures

CONTACT WITH SKIN: wash the contaminated part with water and drain. If irritation persists or tissue damage occurs, consult a doctor if necessary.
CONTACT WITH EYES: remove contact lenses if present; wash the eyes with open eyelid with water. Consult a doctor.
INGESTION: Rinse mouth with water. Consult a doctor.
INHALATION: Remove the injured person from the danger area in a well ventilated area; if symptoms of discomfort appear, seek medical assistance.

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

No specific information on the symptoms and effects caused by the product is known.
 For symptoms and effects due to the substances contained, see chap. 11.

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

Information not available.

SECTION 5. Firefighting measures

5.1. Extinguishing media

SUITABLE EXTINGUISHING MEDIA: The extinguishing media are the traditional ones: carbon dioxide, foam and chemical powder. For leaks and spills of the product that have not ignited, the nebulized water can be used to disperse the flammable vapors and to protect the people involved in stopping the loss. **NON-SUITABLE EXTINGUISHING MEDIA:** Do not use water jets. Water is not effective for

SECTION 5. Firefighting measures ... / >>

extinguishing the fire but it can be used to cool closed containers exposed to the flame, preventing bursts and explosions.

5.2. Special hazards arising from the substance or mixture

HAZARDS DUE TO EXPOSURE IN THE EVENT OF FIRE: Avoid breathing combustion products: carbon oxides.

5.3. Advice for firefighters

GENERAL INFORMATION: Cool the containers with water jets to avoid decomposition of the product and the development of substances potentially hazardous for health. Wear, if necessary, complete fire protection equipment. Collect extinguishing water that must not be discharged into drains. Dispose of the contaminated water used for the fire extinguisher and the residue according to the regulations in force. EQUIPMENT: Not necessary for small fires. If necessary, wear fire-fighting clothing such as a fireproof suit (EN469), fireproof gloves (EN659) and boots for firefighters (HO A29 or A30) depending on the amount of product and any other materials involved in the fire.

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

Stop the leak if there is no danger. Wear appropriate protective equipment (including personal protective equipment referred to in section 8 of the safety data sheet) to prevent contamination of the skin, eyes and personal clothing. These indications are valid both for workers involved in the work and for emergency interventions.

6.2. Environmental precautions

Prevent the product from entering sewers, surface waters, water tables.

6.3. Methods and material for containment and cleaning up

Vacuum the leaked product into a suitable container. Evaluate the compatibility of the container to be used with the product, checking section 10. Absorb the remainder with inert absorbent material. Ensure adequate ventilation of the area affected by the loss. Disposal of the contaminated material must be carried out in accordance with the provisions of point 13.

6.4. Reference to other sections

Any information regarding 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

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)

See the exposure scenarios attached to this safety datasheet.
Information not available

SECTION 8. Exposure controls/personal protection**8.1. Control parameters**

Regulatory References:

ITA	Italia	DIRETTIVA (UE) 2017/164 DELLA COMMISSIONE del 31 gennaio 2017
EU	OEL EU	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 91/322/EEC.

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

2-BUTOXYETHANOL

Threshold Limit Value

Type	Country	TWA/8h		STEL/15min		
		mg/m3	ppm	mg/m3	ppm	
VLEP	ITA	98	20	246	50	SKIN
OEL	EU	98	20	246	50	SKIN

Predicted no-effect concentration - PNEC

Normal value in fresh water	8,8	mg/l
Normal value in marine water	0,88	mg/l
Normal value for fresh water sediment	34,6	mg/kg
Normal value for marine water sediment	3,46	mg/kg
Normal value for water, intermittent release	9,1	mg/l
Normal value of STP microorganisms	463	mg/l
Normal value for the food chain (secondary poisoning)	0,02	g/kg
Normal value for the terrestrial compartment	2,33	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		26,7 mg/kg bw/d	VND	6,3 mg/kg bw/d				
Inhalation	147 mg/m3 1h	246 mg/m3		59 mg/m3	246 mg/m3	1091 mg/m3		98 mg/m3
Skin		89 mg/kg bw/d	VND	75 mg/kg bw/d		89 mg/kg bw/d	VND	125 mg/kg bw/d

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Predicted no-effect concentration - PNEC

Normal value in fresh water	2	µg/L
Normal value in marine water	0,2	µg/L
Normal value for fresh water sediment	2,82	mg/kg/d
Normal value for marine water sediment	0,28	mg/kg/d
Normal value for water, intermittent release	0,29	µg/L
Normal value for the terrestrial compartment	1,4	mg/kg/d

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
Inhalation								18,2 mg/m3
Skin								8,6 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.

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.

When choosing risk management measures and operating conditions, consult the exposure scenarios attached.

Provide an emergency shower with face and eye wash station.

HAND PROTECTION

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

SKIN PROTECTION

Wear category III 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.

EYE PROTECTION

None required.

In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.

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

RESPIRATORY PROTECTION None required, unless indicated otherwise in the chemical risk assessment.

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.

For information on controlling environmental exposure, see the exposure scenarios attached to this safety datasheet.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	liquid	
Colour	colourless	
Odour	characteristic	
Odour threshold	Not available	
pH	8,2 ± 0,5	
Melting point / freezing point	Not available	
Initial boiling point	90 °C	
Boiling range	Not available	
Flash point	Not applicable	
Evaporation Rate	Not available	
Flammability of solids and gases	not applicable	
Lower inflammability limit	Not applicable	
Upper inflammability limit	Not applicable	
Lower explosive limit	Not applicable	
Upper explosive limit	Not applicable	
Vapour pressure	Not available	
Vapour density	Not available	
Relative density	0,990-1,000 g/cm ³ /cm ³	
Solubility	miscible	
Partition coefficient: n-octanol/water	Not available	
Auto-ignition temperature	Not available	
Decomposition temperature	Not available	
Viscosity	<200 cps	
Explosive properties	not applicable	
Oxidising properties	not applicable	

9.2. Other information

Information not available

SECTION 10. Stability and reactivity

In the absence of data relating to the preparation, the following information refers to the substances that make up the mixture.

10.1. Reactivity

Avoid mixing with other substances, especially with bleaches and anionic substances.

10.2. Chemical stability

The product is stable in normal conditions of use

10.3. Possibility of hazardous reactions

Under normal conditions of use and storage, no dangerous reaction is expected.

10.4. Conditions to avoid

Avoid direct exposure to light heat sources

SECTION 10. Stability and reactivity ... / >>**10.5. Incompatible materials****2-BUTOXYETHANOL**

Incompatible with: strong oxidants.

Anionic surfatants

10.6. Hazardous decomposition products

In the event of excessive heating the product may decompose.

SECTION 11. Toxicological information**11.1. Information on toxicological effects**Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

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

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

LC50 (Inhalation) of the mixture:	> 20 mg/l
LD50 (Oral) of the mixture:	>2000 mg/kg
LD50 (Dermal) of the mixture:	>2000 mg/kg

2-BUTOXYETHANOL

LD50 (Oral)	1414 mg/kg Ratto
LD50 (Dermal)	> 2000 mg/kg porcellino d'india
LC50 (Inhalation)	450 ppm/4h ratto

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LD50 (Oral)	329 mg/kg Ratto
LD50 (Dermal)	> 1000 mg/kg ratto

SKIN CORROSION / IRRITATION

Causes skin irritation

SERIOUS EYE DAMAGE / IRRITATION

Causes serious eye irritation

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

SECTION 11. Toxicological information ... / >>

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

SECTION 12. Ecological information**12.1. Toxicity****2-BUTOXYETHANOL**

LC50 - for Fish

1474 mg/l/96h Oncorhynchus mykiss

EC50 - for Crustacea

1550 mg/l/48h Daphnia magna

EC50 - for Algae / Aquatic Plants

1840 mg/l/72h Pseudokirchneriella subcapitata

Chronic NOEC for Fish

> 100 mg/l 21 d Brachydanio rerio

Chronic NOEC for Crustacea

100 mg/l 21 d Daphnia magna

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LC50 - for Fish

97 mg/l/96h Danio Rerio

EC50 - for Crustacea

0,057 mg/l/48h Daphnia magna (Pulce d'acqua grande)

EC50 - for Algae / Aquatic Plants

0,026 mg/l/72h Pseudokirchneriella subcapitata (alghe cloroficee)

Chronic NOEC for Fish

0,56 mg/l

Chronic NOEC for Crustacea

0,01 mg/l Daphnia magna (Pulce d'acqua grande)

12.2. Persistence and degradability**2-BUTOXYETHANOL**

Rapidly degradable

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Rapidly degradable

12.3. Bioaccumulative potential**2-BUTOXYETHANOL**

Partition coefficient: n-octanol/water

0,81 Log Kow 25 °C

12.4. Mobility in soil**2-BUTOXYETHANOL**

Partition coefficient: soil/water

0,45

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 greater than 0,1%.

12.6. 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.

SECTION 15. Regulatory information ... / >>**15.2. Chemical safety assessment**

A chemical safety assessment has been performed for the following contained substances
2-BUTOXYETHANOL

SECTION 16. Other information

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

Acute Tox. 4	Acute toxicity, category 4
Skin Corr. 1B	Skin corrosion, category 1B
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin 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
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H332	Harmful if inhaled.
H314	Causes severe skin burns and eye damage.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.

Use descriptor system:

PC 35	Washing and cleaning products
PROC 10	Roller application or brushing
PROC 11	Non industrial spraying
PROC 13	Treatment of articles by dipping and pouring
PROC 7	Industrial spraying
PROC 8a	Transfer of substance or mixture (charging and discharging) at non- dedicated facilities
PROC 8b	Transfer of substance or mixture (charging and discharging) at dedicated facilities

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 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 NUMBER: 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: EC Regulation 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 STEL: Short-term exposure limit
- TWA: Time-weighted average 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) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament

SECTION 16. Other information ... / >>

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. Κανονισμός (ΕΕ) 2018/669 (XI Atp. CLP)
15. Κανονισμός (ΕΕ) 2018/1480 (XIII 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.

Changes to previous review:

The following sections were modified:

10.