

Reference: Regulation (EC) 1907/2006 878/2020	MATERIAL SAFETY DATA SHEET (MSDS) Product: Bactiseptic Orange	Version 14 Date last revision: 05.12.22 SHEET 1 of 9
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1. SECTION 1. IDENTIFICATION OF SUBSTANCE / MIXTURE AND OF THE COMPANY:

1.1. Product identifier: Bactiseptic Orange

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

Use of the substance: Antiseptic disinfectant for healthy skin.

Spanish Ministry of Health register:

Register num. DGFyPS: 715-DES

1.3. Details of the supplier of the safety data sheet

Manufacturer: Vesimin S.L.U. C/Aribau 230-240, 6th floor, L-O, 08006 Barcelona (Spain) vesimin@vesimin.com

Telephone number: +34 934 095 301

Fax: +34 933 396 628

e-mail: vesimin@vesimin.com

1.4. Emergency number: +34 934 095 301 (working hours)

2. SECTION 2. HAZARD IDENTIFICATION:

2.1. Classification of the substance or mixture

Classification according to EC Regulation num. 1272/2008 [CLP]

LIQUID FLAMMABLE. Category 2 (H225)

EYE IRRITATION. Category 2 (H319)

STOT SE. Category 3 (H336)

AQUATIC CHRONIC. Category 3 (H412)

2.2. Label elements: according to EC Regulation num. 1272/2008 [CLP]

Hazard pictograms:



Signal word: DANGER

Hazard statements:

- Highly flammable liquid and vapour (H225)
- Causes serious eye irritation (H319)
- May cause drowsiness or dizziness (H336)
- Harmful to aquatic life with long lasting effects (H412)
- To avoid risks to human health and the environment, comply with the instructions for use (EUH 401)

Precautionary Statements

- Keep away from heat/sparks/open flames/hot surfaces. — No smoking. (P210)
- Avoid release to the environment (P273)
- IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. (P305 + P351 + P338)
- If eye irritation persists: Get medical advice/attention. (P337+P313)
- Store in a well-ventilated place. Keep container tightly closed. (P403+P233)

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- Dispose of contents and container in accordance with local regulations (P501)

2.3. Other hazards

Flammable (contains isopropyl alcohol). Wait until total evaporation

No significant environmental or health risks if used under standard conditions of commercial and industrial use.

PBT: This product is not identified as PBT/vPvB

This mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal or greater than 0,1%.

3. SECTION 3. COMPONENT COMPOSITION / INFORMATION

3.2. Substance/Mixture: Mixture

Dangerous components:

Ingredient	N° CAS / N° Registro REACH	Classification** 1272/2008	Concentration
Chlorhexidine digluconate D-gluconic acid, compound with N,N"-bis(4-chlorophenyl)-3,12- diimino-2,4,11,13- tetraazatetradecanediamidine (2:1)	18472-51-0 / 01- 211994656 8-22-XXXX	Eye Dam. 1: H318 Acute aquatic 1: 400	2%
Isopropyl alcohol	67-63-0	Flam. liq 2: H225 Eye Irrit. 2: H319 STOT SE 3: H336	70%
Excipients and water	-	-	qsf 100 %

* Complete text of Hazard statements indicated in this Section are explained in Section 16.

4. SECTION 4. FIRST AID MEASURES:

4.1. Description of first aid measures

First aid measures:

Swallowing: (*) Rinse mouth with water and seek immediate medical assistance. If the patient is conscious, supply water.

Inhalation: Transfer the victim to a non contaminated atmosphere. In case of breathing interruption, apply artificial respiration. Maintain the patient in repose and seek medical advice.

Eye contact: Wash with plenty of water for at least 15 minutes. If irritation persists, consult an ophthalmologist.

(*) Medical information: do not induce vomiting. Perform a stomach-pumping previous to adding dimeticone (antifoam).

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

Effects and symptoms: No specific effects and/or symptoms are known. Symptoms derived from isopropyl alcohol: headaches, vertigo, narcosis, drowsiness. The swallowing can cause inebriation, coma. Skin, eye and respiratory tract irritation.

Eye contact: irritating to the eyes

Skin contact: a significant or prolonged irritation by skin contact is not expected. Systemic adverse effects by contact or absorption through the skin are not expected. Avoid contact with eyes, middle ear (risk of perforation of the eardrum if the product reaches in great amounts the external conduit, with possibility of neurosensorial deafness) and meninges.

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

See section 4.1.

5. SECTION 5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing tools: Foam, dry chemical powder, CO₂, sand and water spray fog.

5.2. Special hazards arising from the substance or mixture

Special hazards of fire/explosion: Extremely flammable product with heat, sparks, static electricity or flames. Vapour/air mixtures are explosive. The combustion or thermal decomposition releases toxic fumes. Evacuate the area.

Special measures: Cool the bottles by pulverising water to them if they have been exposed to fire. Do not directly spray with water. Keep away from sources of ignition – Do not smoke. Store used water for its later disposal. The disposal must be done according to local or national regulation. Contain the liquid and avoid the penetration into drains and water course. Contain all the material used in the fire fighting.

5.3. Advice for fire-fighters

Special protective equipment for fire-fighters: Fire-fighters must be provided with adequate protective equipment, and respiratory equipment.

6. SECTION 6. ACCIDENTAL RELEASE MEASURES:

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions: Take common precautions. Extinguish the flames. Eliminate ignition sources. Do not smoke. Avoid sparks. Use suitable respiratory protection equipment. Use adequate protective cloths, gloves and eyes/skin protection. Contaminated clothing must be cleaned thoroughly.

6.2. Environmental precautions

Environmental precautions: Avoid pouring the product into the public drainage. If the product reaches a river course or a sewer, or it has contaminated the soil or vegetation, warn the Authorities. Collect it in plastic containers and eliminate it in appropriate places.

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6.3. Methods and material for containment and cleaning up

Cleaning measures: Do not release product into drainpipes or in the environment. Eliminate the spilled product with materials that act as absorbents (sawdust, peat, or chemical chelating agents). Place the collected product in containers that can be closed. Clean floors and all objects with this material using a damp cloth. Collect the cleaning materials and place them inside containers that can be closed. Ventilate the area and clean the zone once the spillage is collected.

6.4. Reference to other sections

Refer to sections 8, 12 and 13 of SDS.

7. SECTION 7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Handling: Take measures to avoid splashing in the eyes.

7.2. Conditions for safe storage, including any incompatibilities

Storage: Store in high density polyethylene or PET containers. Keep away from direct sunlight and other heat or ignition sources. Do not smoke in storage zones. Keep the container well closed and in a cool and well ventilated place. Store only in the original containers. Do not keep at temperatures higher than 25°C. Avoid freezing.

7.3. Specific end use(s)

Antiseptic for healthy skin. For professional use only.

8. SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Threshold Limit Value (TLV) of Isopropyl alcohol: The ACGIH recommends a TWA of 400 ppm (980 mg/m³) and a STEL of 500 ppm (1225 mg/m³).

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006 (workers):

		Short exposure		Long exposure	
Identification		Sistemic	Local	Sistemic	Local
Chlorhexidine digluconate	Oral	Non relevant	Non relevant	Non relevant	Non relevant
	Cutaneous	Non relevant	Non relevant	5 mg/kg	Non relevant
	Inhalation	Non relevant	Non relevant	0,42 mg/m ³	Non relevant

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006 (population):

		Short exposure		Long exposure	
Identification		Sistémica	Local	Sistemic	Local
Chlorhexidine digluconate	Oral	2 mg/kg	Non relevant	0,03 mg/kg	Non relevant
	Cutaneous	5 mg/kg	Non relevant	3 mg/kg	Non relevant
	Inhalation	Non relevant	Non relevant	0,1 mg/m ³	Non relevant

Predicted No Effect Concentration (PNEC) according to Regulation (EC) No. 1907/2006

Identification				
Chlorhexidine digluconate	STP	0,25 mg/L	Sweet water	0,002 mg/L
	Soil	5,26 mg/kg	Salted water	0,0002 mg/L

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	Intermittent	0,002 mg/L	Sediment (Sweet water)	0,433 mg/kg
	Oral	Non relevant	Sediment (Salted water)	0,0433 mg/kg

8.2. Exposure controls

Hygienic measures: Do not eat, drink or smoke during use.

Exposure control: Avoid spilling, contact with eyes and ingestion.

Equipment to provide adequate personal protection: Non specific protection equipment is required.

9. SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Aspect (physical state, color): Liquid, transparent orange liquid

Odour: Characteristic

Melting point / freezing point: Not available

Boiling point : Not available

Flammability: Flammable

Upper and lower explosive limit: Not available

Auto-ignition temperature: Closed flash point: 21°C

Decomposition temperature: Not available

pH (100% in water): 6 – 8 (20 °C)

Viscosity: Not available

Water solubility: 100% soluble

Partition coefficient n-octanol/water (Log Know): Not available

Vapour pressure: Not available

Density: 0,60 – 1,00 g/cc (20°C)

Relative density: Not available

Relative vapour density at 20°C: Not available

Particle characteristics: Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

Data for Isopropyl Alcohol

Flash Point: 12 °C

Relative density of vapour: > 1.0

10. SECTION 10. STABILITY AND REACTIVITY

10.1. Reactivity: Keep away from heat and direct sunlight. Keep away from direct flames and sources of ignition. Keep away from oxidisers.

10.2. Chemical stability

Product is stable in recommended conditions of handling and storage.

10.3 Possibility of hazardous reactions

It does not present.

10.4. Conditions to avoid

Non applicable

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10.5. Incompatible materials

Materials to avoid: Considering the cationic character of Chlorhexidine salts, these are chemically non-compatible with anionic compounds. Keep away from sulphates, borates, bicarbonates, chlorides...

10.6. Hazardous decomposition products

Combustion or thermal decomposition release toxic fumes.

11. SECTION 11. TOXICOLOGICAL INFORMATION

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

Acute toxicity:

Oral route: Not harmful by oral ingestion. DL₅₀ (oral route) > 2000 mg/kg

Inhalation route:

Isopropyl alcohol: The ACGIH recommends a TLV-TWA of 400 ppm (980 mg/m³) and a STEL of 500 ppm (1225 mg/m³).

These values are not exceeded during the use of the product, according to the indicated use of the product.

Through skin and/or eyes:

*Skin irritation: Non irritating.

*Eye irritation: Irritating to eyes.

*Skin sensitisation: It does not cause hypersensitisation.

Substance data

Chlorhexidine digluconate	
LD50 (rat), oral	2270 mg/kg
LD50 cutaneous	Non relevant
LC50, inhalation	Non relevant

Isopropanol	
LD50 (rat), oral	5000 mg/kg
LD50 (rabbit), dermal	12.800 mg/kg
LC50 (rat), inhalation	500 mg/lg
Eye irritation	Irritating
Dermal irritation	Slightly irritating
Mutagenicity	Mutagenicity in germinal cells Genotoxicity in vitro: Negative
Carcinogenicity	Non carcinogenic
Toxicity for reproduction	Not known

Corrosiveness: Not corrosive.

Carcinogenicity: Not carcinogenic

Mutagenicity: Not mutagenic

Toxicity for reproduction: Not toxic for reproduction

11.2. Information on other hazards

11.2.1. Properties on endocrine alteration

No additional information available.

12. SECTION 12. ECOLOGICAL INFORMATION

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12.1. Toxicity:

In order to avoid human and environmental risks, follow the instructions for use.

Substance data

Digluconato de clorhexidina	
CL50, 96h (Brachydanio rerio)	2,08 mg/L
CE50, 48h (Daphnia magna)	0,087 mg/L
CE50, 72h (Scenedesmus subspicatus)	0,081 mg/L

Isopropanol	
EC50/LC50, 48h (Daphnia magna)	> 100 mg/l
EC50, 72h (Scenedesmus subspicatus)	> 100 mg/l

12.2. Persistence and degradability

The product has powerful microbial action, hence it could affect the EDAR microbial flora.

12.3. Bioaccumulative potential

Not available.

Isopropyl alcohol: Octanol-water partition coefficient (log Kow): ≤ 4

12.4. Movility in soil

Not available

12.5. Results of PBT and vPvB assessment

This product is not identified as a PBT/vPvB substance

12.6. Endocrine disrupting properties

No further information available. This substance does not have endocrine disrupting properties on non-target organisms, as it does not meet the criteria established in section B of Regulation (EU) No. 2017/2100.

12.7. Other adverse effects

Harmful to aquatic organisms

Data for the ingredients

Isopropyl alcohol

- *Mobility:*
 - It is a hydrosoluble substance, which is expected to remain in water.
- *Persistence and degradability:*
 - Easily biodegradable, according to OECD standards.
 - Easily eliminated in a sewage treatment.
- *Bioaccumulation:*
 - A low acute toxicity is predicted for aquatic organisms.
 - No long-term effects are predicted for aquatic organisms.

Chlorhexidine digluconate (active ingredient – concentrated):

Toxic to fish, daphnia and algae. LC50 (fish, 48h) = 13,4 mg/l. EC50 (Dpahnia magna, 48h) = 0.087 mg/l. EC50 (algae, 72h): 0,081 mg/l.

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13. SECTION 13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

It is recommended to package product surplus or waste resulting from normal use. Label it for identification purposes and seal it. Dirty, empty recipients should be handled in the same manner. The product may be taken to a controlled incineration site, always according to local regulations.

14. SECTION 14. TRANSPORT INFORMATION

14.1. UN number or ID number:

1993

14.2. UN proper shipping name

Flammable liquid, n.e.p. (contains isopropyl alcohol)

14.3. Transport hazard class(es)

Class 3

14.4. Packaging group

Group II

14.5. Environmental hazards

Not applicable

14.6. Special precautions for user

Not applicable

14.7. Maritime transport in bulk according to IMO instruments

Not applicable

ADR Classification:

- ONU number: 1993
- Class: 3
- Classification code: F1
- Packaging group: II
- Label: 3 (Flammable)
- Risk:30

MDG Classification:

- Class: 3

Air (IATA/ICAO):

ONU 1993 – Flammable liquid n.e.p.

Label: Flammable liquid

Class 3

Special provisions A3

Packaging group II

Passenger aircraft (PAX): Packing instruction Y341 max quantity package 1 liter. (if it in LQ)

Packing instruction 353 max quantity package 5 litres.

Cargo aircraft (CAO): Packing instruction 364, max quantity of package 60 litres.

15. SECTION 15. REGULATORY INFORMATION

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

The information for safety and health with respect to the label of this product is in accordance with the European Union regulation: n° 1907/2006, 453/2010, 830/2015 and 878/2020.

European legislation: Regulation (EC) n° 1272/2008

15.2. Chemical safety assessment: not required

16. SECTION 16. OTHER INFORMATION

Other information: The text in the SDS which has changed since the last version.

Complete text of hazard statements as referred to in sections 2 and 3:

H225: Highly flammable liquid and vapour.

H318: Causes serious eye damage.

H319: Causes serious eye irritation.

H336: May cause drowsiness or dizziness

H400: Very toxic to aquatic life.

Formation advice:

The product must be handled by specialized personnel, following manufacturer instructions.

Changes from last version refer to format and content of EC Regulation 453/2010.

Calculation method determination according to Regulation (EC) 1272/2008 has been used for the classification of the mixture.

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