

Information Sheet

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

1.1. Product identifier

Code: A160
Product name: ORALSAN COLLUTORIO

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

Intended use: Mouthwash

1.3. Details of the supplier of the safety data sheet

Name: GERMO S.P.A.
Full address: Via Giotto, 19/21
District and Country: 20032 Cormano (MI)
Italia
Tel. +39 02 66.30.19.38
Fax +39 02 66.30.19.39

e-mail address of the competent person
responsible for the Safety Data Sheet

direzionetecnica@germodis.com

1.4. Emergency telephone number

For urgent inquiries refer to

Numeri telefonici dei principali Centri Antiveleni italiani (attivi 24/24 ore):
Centro Antiveleni Osp. Di Niguarda Ca Granda Milano Tel 02/66101029
Centro Antiveleni Osp Pediatrico Bambin Gesù Roma Tel 06/68593726
Centro Antiveleni Policlinico Umberto I Roma Tel 06/49978000
Centro Antiveleni Policlinico A. Gemelli Roma Tel 06/3054343
Centro Antiveleni Centro Naz. Info Tossicolog Pavia Tel 0382/24444
Centro Antiveleni Azienda Universitaria Integrata Verona Tel 800 011 858
Ospedale Careggi U.O. Tossicologia Medica Firenze - Tel 055/7947819
Azienda Ospedaliera Papa Giovanni XXII Bergamo Tel 800/8833
Azienda Universitaria Foggia Tel 0881/732326
Ospedale A. Cardarelli Napoli Tel 081/7472870

SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

Cosmetic product compliant with Regulation (EC) No. 1223/2009, not subject to the provisions of Regulation (EC) 1272/2008 (CLP) (and subsequent modifications and adjustments).

2.2. 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

3.2. Mixtures

INGREDIENTS: Aqua (Water), Glycerin, Sorbitol, Chlorhexidine Digluconate, Polysorbate 20, Xylitol, Aroma, Aloe barbadensis leaf extract, Sodium saccharin, CI 19140, CI 42051.

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 30-60 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention.

INGESTION: Have the subject drink as much water as possible. Get medical advice/attention. Do not induce vomiting unless explicitly authorised by a doctor.

INHALATION: Get medical advice/attention immediately. Remove victim to fresh air, away from the accident scene. If the subject stops breathing, administer artificial respiration. Take suitable precautions for rescue workers.

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

Specific information on symptoms and effects caused by the product are unknown.

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 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.

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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)

Information not available

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

Information not available

8.2. Exposure controls

Comply with the safety measures usually applied when handling chemical substances.
Comply with the safety measures usually applied when handling chemical substances.

HAND PROTECTION

None required.

SKIN PROTECTION

None required.

EYE PROTECTION

None required.

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 A 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	Green	
Odour	Mint	
Melting point / freezing point	Not applicable	
Initial boiling point	Not applicable	

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Flammability	Not applicable
Lower explosive limit	Not applicable
Upper explosive limit	Not applicable
Flash point	> 60 °C
Auto-ignition temperature	Not applicable
pH	Not applicable
Kinematic viscosity	Not applicable
Solubility	Not applicable
Partition coefficient: n-octanol/water	Not applicable
Vapour pressure	Not applicable
Density and/or relative density	1,02 - 1,05 g/ml
Relative vapour density	Not applicable
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
Information not available

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.

10.3. Possibility of hazardous reactions

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

10.4. Conditions to avoid

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

10.5. Incompatible materials

Information not available

10.6. Hazardous decomposition products

Information not available

SECTION 11. Toxicological information

According to currently available data, this product has not yet produced health damages. Anyway, it must be handled according to good industrial practices.

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

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Information not available

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)

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

Respiratory sensitization

Information not available

Skin sensitization

Information not available

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

Does not meet the classification criteria for this hazard class

Adverse effects on sexual function and fertility

Information not available

Adverse effects on development of the offspring

Information not available

Effects on or via lactation

Information not available

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Target organs

Information not available

Route of exposure

Information not available

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

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Target organs

Information not available

Route of exposure

Information not available

ASPIRATION HAZARD

Does not meet the classification criteria for this hazard class

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.

12.1. Toxicity

Information not available

12.2. Persistence and degradability

Information not available

12.3. Bioaccumulative potential

Information not available

12.4. Mobility in soil

Information not available

12.5. Results of PBT and vPvB assessment

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**

Reuse, when possible. Neat product residues should be considered special non-hazardous waste.

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

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14.3. Transport hazard class(es)

Not applicable

14.4. Packing group

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 40

Contained substance

Point 75

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

Not applicable

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

Information not available

15.2. Chemical safety assessment

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

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SECTION 16. Other information

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
- 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)
- 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

ORALSAN COLLUTORIO**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.