

Product: ISORAPID[®] OP-Forte AF

SAFETY DATA SHEET

according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

SECTION 1: IDENTIFICATION

Product identifier

Product name: ISORAPID[®] OP-Forte AF
Substance type: Mixture
Use of the substance/mixture: Surface disinfectant

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

Identified uses: ISORAPID[®] OP-Forte AF is a gentle but powerful disinfectant concentrate for the disinfection and cleaning of non-invasive medical devices with sensitive surfaces such as radiology equipment. ISORAPID[®] OP-Forte AF has a fruity scent and is compatible with acrylic glass, polycarbonate (PC), and PVC. It is free of aldehydes, phenols, and caustic potash.

Uses advised against: Do not use for purposes other than those prescribed.

Recommended restrictions on use: For professional use only.

Details of the supplier of the safety data sheet

| | Manufacturer | EU only representative |
|--------------------------------------|---|---|
| Address: | Oro Clean Chemie AG Allmendstrasse 21 8320 Fehraltorf Switzerland | Oro Clean Chemie s.r.o. Vinohradská 2828/151 Žižkov 130 00 Praha 3 Czech Republic |
| Telephone: | +41 (0)44 226 44 44 | |
| Email: | info@oroclean.com | info@oroclean.cz |
| Website: | www.oroclean.com | www.oroclean.cz |
| Downstream user/importer/distributor | | |
| Address: | Oro Clean Chemie s.r.o. Vinohradská 2828/151 Žižkov 130 00 Praha 3 Czech Republic | |
| Telephone: | | |
| Email: | info@oroclean.cz | |
| Website: | www.oroclean.cz | |

Emergency telephone number

Emergency telephone number: 999 / +60 4657 0099 / +60 (0)12 430 9499

* Please check the above numbers regularly as they might be subject to change.

SECTION 2: HAZARDS IDENTIFICATION

Classification of the substance or mixture

Classification according to UN GHS criteria

Product: ISORAPID® OP-Forte AF

| Hazard type | Hazard category | Hazard statement code(s) | Classification procedure |
|----------------------|-------------------|--------------------------|------------------------------------|
| Health hazard | Skin Irrit. 2 | H315 | On basis of test data. |
| Environmental hazard | Aquatic Acute 1 | H400 | Harmonised (legal) classification. |
| Environmental hazard | Aquatic Chronic 2 | H411 | Harmonised (legal) classification. |

The full text for all H-statements is displayed in section 16.

Label elements
Labelling according to UN GHS criteria

Hazard pictograms:



GHS07



GHS09

| | | |
|---------------------------|-----------------|--|
| Signal word: | Warning | |
| Hazard statements: | H315 | Causes skin irritation. |
| | H410 | Very toxic to aquatic life with long lasting effects. |
| Precautionary statements: | P280 | Wear protective gloves/protective clothing/eye protection/face protection. |
| | P302 + P352 | IF ON SKIN: Wash with plenty of soap and water. |
| | P332 + P313 | If skin irritation occurs: Get medical advice/attention. |
| | P362 | Take off contaminated clothing. |
| | P391 | Collect spillage. |
| | P501 | Dispose of contents/container in accordance with local and national regulations. |
| Supplemental information: | Not applicable. | |
| Other hazards: | None known. | |

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
Substances

See below.

Mixtures
Classification according to UN GHS criteria

| Substance name | Identification | Classification | SCL, M-factor, ATE | Concentration |
|---|---|--|-------------------------|---------------|
| Alkyl (C12-16) dimethylbenzyl ammonium chloride | CAS no.: 68424-85-1 EC no.: 939-253-5 Index no.: No data available. REACH no.: 01-2119965180-41-0000 | Acute Tox. 4, H302 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Eye Dam. 1, H318 Skin Corr. 1B, H314 | M = 10, M (chronic) = 1 | 5% - < 15% |
| Didecyldimethylammonium chloride | CAS no.: 7173-51-5 EC no.: 230-525-2 Index no.: 612-131-00-6 REACH no.: 01-2119945987-15-0000 | Acute Tox. 4, H302 Skin Corr. 1B, H314 | No data available. | 2.5% - < 5% |
| (R)-p-Mentha-1,8-diene | CAS no.: 5989-27-5 EC no.: 227-813-5 Index no.: 601-029-00-7 REACH no.: 01-2119529223-47-0000 | Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Flam. Liq. 3, H226 Skin Irrit. 2, H315 Skin Sens. 1B, H317 | No data available. | < 1% |

The full text for all H-statements is displayed in section 16.

SECTION 4: FIRST AID MEASURES
Description of first aid measures

Product: ISORAPID® OP-Forte AF

| | |
|--------------------------|---|
| General notes: | Never give anything by mouth to an unconscious person. Place patient in recovery position and ensure airway patency. When in doubt or if feeling unwell seek medical assistance. Show the safety data sheet and label to the physician. No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. When it is suspected, that there may still be harmful vapours/fumes present in the air, respiratory protection (mask; self contained breathing apparatus) must be used. Wash contaminated clothing with water before removing or use gloves. |
| After inhalation: | Remove patient to fresh air - move out of dangerous area. In case of unconsciousness bring patient into stable side position and seek medical attention. If breathing is irregular or respiratory arrest occurs provide artificial respiration. Keep at rest in a position comfortable for breathing. Seek medical help immediately. |
| After contact with skin: | Take off all contaminated clothing. Areas of the body that have come into contact with the product must be rinsed with water. Immediately obtain professional medical help. |
| After contact with eyes: | Immediately flush eyes with running water, keeping eyelids apart. After 5 minutes of rinsing, remove contact lenses, if present, and continue rinsing. Consult a physician immediately. |
| After ingestion: | Do not induce vomiting. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person. Immediately consult a doctor. Show the physician the safety data sheet or label. |

Most important symptoms and effects, both acute and delayed

See section 11 for more detailed information on health effects and symptoms.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

Extinguishing media

Suitable extinguishing media: Carbon dioxide. Dry chemical powder. Water spray. Alcohol resistant foam.

Unsuitable extinguishing media: Full water jet.

Special hazards arising from the substance or mixture

Specific hazards during firefighting: In case of a fire toxic gases can be generated; do not inhale gases/smoke.

Hazardous combustion products: No data available.

Advice for firefighters

Special protective equipment for firefighters: Firefighters should wear appropriate protective clothing for firefighters (including helmets, protective boots and gloves) (BS EN 469) and self-contained breathing apparatus (SCBA) with a full face-piece (BS EN 137).

Additional information: In case of fire or heating do not breathe fumes/vapours. No action shall be taken involving any personal risk or without suitable training. Prolonged heating can cause an explosion. Vapours can form explosive mixtures with air. Cool containers at risk with water spray. If possible remove containers from endangered area. Contaminated firefighting water and fire residues must be disposed of in accordance with the local regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures

Product: ISORAPID® OP-Forte AF

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|-------------------------------------|--|
| Advice for non-emergency personnel: | Use personal protective equipment (section 8). Ensure adequate ventilation. Keep away from sources of ignition and/or heat; No smoking. No action shall be taken involving any personal risk or without suitable training. Prevent access to unprotected personnel. Evacuate the danger zone. Do not breathe vapour or mist. Avoid contact with skin, eyes and clothing. |
| Advice for emergency responders: | Use personal protective equipment. |

Environmental precautions

Do not allow to enter drains or waterways. Prevent product from getting into subsoil/soil.

Methods and material for containment and cleaning up

Stem the spill if this does not pose risks. Absorb product (with inert material), collect it in special container and dispose it to a licensed hazardous-waste disposal contractor. Use only explosion-proof instruments and equipment. Use spark-proof tools. Prevent release into the sewer, water, basements or confined areas. Ventilate the premises. Clean contaminated area with plenty of water.

Reference to other sections

See also sections 7, 8 and 13.

SECTION 7: HANDLING AND STORAGE

Precautions for safe handling

| | |
|---|--|
| General advice: | Use general or local exhaust ventilation to prevent inhaling vapours and aerosols. Do not discharge into drains, surface water and soil. After use immediately close container tightly. |
| Instructions for protection against fire and explosion: | Ensure adequate ventilation. Keep away from sources of ignition - no smoking. Use spark-proof tools. Take precautionary measures against static discharges. Vapours are heavier than air and spread along the floor. They form explosive mixtures with air. |
| Advice on general occupational hygiene: | Use good personal hygiene practices – wash hands at breaks and when done working with material. Do not eat, drink or smoke while working. Do not breathe vapours/mist. Avoid contact with skin, eyes and clothes. Remove contaminated clothes and wash them before reuse. Wear suitable protective equipment; see section 8. |

Conditions for safe storage, including any incompatibilities

| | |
|---|--|
| Requirements for storage room and containers: | Close opened containers after use. Put the containers upright to prevent from leaking. Do not store in unlabelled containers. |
| Further information about storage conditions: | Keep in a cool, dry and well ventilated place. Protect from open fire, heat and direct sunlight. Keep away from food, drink and animal feeding stuffs. Keep away from oxidising substances. Keep away from sources of ignition - no smoking. Store only in original container. |
| Stocking with different products: | Store separately from beverages, food and feed. Store separately from strong acids, bases and oxidation agents. |

Specific end use(s)

See identified uses in section 1.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters**Occupational exposure limits**

Product: ISORAPID® OP-Forte AF

Please refer to the latest edition of the appropriate source text and consult an industrial hygienist or similar professional, or local agencies, for further information.

Biological limit values

No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls

See section 7. No additional measures necessary.

Individual protection measures

| | |
|-------------------------|--|
| Eye/face protection: | Wear protective glasses during refilling and/or preparation of working solution and during use. |
| Hand protection: | Short-term contact: Gloves with Protection Index of at least Class 2 (Norm EN 374, permeation time > 30 min) for substances of Classes G and K. Long-term contact: Gloves with Protection Index of at least Class 6 (Norm EN 374, permeation time > 480 min) for substances of Classes G and K. (Class G: amines; Class K: inorganic bases). |
| Body protection: | Apron and work shoes or boots. Emergency responders should wear appropriate body protection. |
| Respiratory protection: | Avoid aerosol formation. Use respiratory protection if aerosol is formed. |
| Thermal hazards: | No data available. |
| Hygiene measures: | Use good personal hygiene practices – wash hands at breaks and when done working with material. Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes and clothes. Do not eat, drink or smoke while working. Do not breathe vapours/aerosols. |

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

| | |
|---|---------------------------------|
| Physical state: | Liquid |
| Form: | Clear, slightly viscous liquid |
| Colour: | Green |
| Odour: | Lemon |
| Melting point: | No data available. |
| Freezing point: | No data available. |
| Boiling point or initial boiling point and boiling range: | No data available. |
| Flammability: | The product is not flammable. |
| Lower explosion limit: | Not applicable. |
| Upper explosion limit: | Not applicable. |
| Flash point: | No data available. |
| Auto-ignition temperature: | Not self-igniting. |
| Decomposition temperature: | Not applicable. |
| pH-value (undiluted product): | 6.0 - 8.0 |
| pH-value (diluted product): | 6.0 - 8.0 (1%) |
| Kinematic viscosity: | No data available. |
| Solubility: | Completely miscible with water. |
| Partition coefficient n-octanol/water: | Not applicable. |
| Vapour pressure at 50 °C: | No data available. |
| Density: | 0.99 g/cm ³ |

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Relative density: 0.99
Relative vapour density at 20 °C: No data available.

Other information

Oxidising properties: Not oxidising.
Explosive properties: Product is not explosive.
Evaporation rate: No data available.
Miscibility: Completely miscible with water.

SECTION 10: STABILITY AND REACTIVITY

Reactivity

The mixture is not reactive.

Chemical stability

Stable at normal temperatures and pressure at least up to the expiry date printed on the container.

Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid

Avoid conditions beyond those mentioned in section 7.

Incompatible materials

No specific materials to avoid during intended use.

Hazardous decomposition products

No dangerous decomposition products occur under normal storage and use.

SECTION 11: TOXICOLOGICAL INFORMATION

Information on toxicological effects**Information on likely routes of exposure**

Inhalation: Information on effects are given below.
Skin contact: Information on effects are given below.
Eye contact: Information on effects are given below.
Ingestion: Information on effects are given below.

Acute toxicity

Mixture: ATEmix: LD50 (rat, ingestion) > 2000 mg/kg
Component: No data available.

Skin corrosion/irritation

Mixture: Irritating to skin.
Component: No data available.

Serious eye damage/irritation

Mixture: No irritation is expected.
Component: No data available.

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Respiratory or skin sensitization

Mixture: The product is not classified as sensitising.
Component: No data available.

Germ cell mutagenicity

Mixture: Not a mutagen. Does not contain ingredients with known mutagenic properties.
Component: No data available.

Carcinogenicity

Mixture: Does not contain ingredients with known carcinogenic properties.
Component: No data available.

Reproductive toxicity

Mixture: This product contains no ingredients with known reproductive toxicity effects.
Component: No data available.

STOT-single exposure

Mixture: This product exhibits no known STOT-single exposure.
Component: No data available.

STOT-repeated exposure

Mixture: This product exhibits no known STOT-repeated exposure.
Component: No data available.

Aspiration hazard

Mixture: This product exhibits no known aspiration hazard.
Component: No data available.

Information on other hazards

No data available.

SECTION 12: ECOLOGICAL INFORMATION

Toxicity

The release of the diluted ready-to-use solution of this product is not expected to have any ecotoxic effects. The concentrated solution can have prolonged and widespread toxic effects on aquatic and terrestrial organisms. The release of concentrated solution may negatively affect the function of sewage treatment plants. There is no data available from ecotoxicological tests regarding the entire product. The ecotoxicological risk has been estimated based on available data on product ingredients and concentrations, where available.

Persistence and degradability

The product ingredients possess good biodegradation properties. The surfactants included in the product comply with the requirements for the biological decomposition of Regulation (EC) No. 648/2004 on detergents. Based on available data, the biodegradability in sewage treatment plants can be categorized as high. High product concentrations can affect the biodegradability potential of the activated sludge. Obtain the consent of the local authorities before discharging the concentrated solution to wastewater treatment plants.

| Substance name | Biodegradation | Basis | Remark |
|---|--------------------|--------------------|------------------------|
| Alkyl (C12-16) dimethylbenzyl ammonium chloride | Ca. 60% | OECD 301 D, 28 D | Readily biodegradable. |
| Didecyldimethylammonium chloride | Ca. 60% | OECD 301 D | Readily biodegradable. |
| (R)-p-Mentha-1,8-diene | No data available. | No data available. | No data available. |

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Bioaccumulative potential

| | |
|------------|--|
| Mixture: | Based on available data, no product ingredient is expected to exhibit bioaccumulative potential. |
| Component: | No data available. |

Mobility in soil

| | |
|------------|--|
| Mixture: | The product is not expected to be mobile over long distances because most of the product ingredients possess good biodegradability. The remaining ingredients (e.g. mineral salts) are absorbed into the soil without negative ecological effects. This product reduces the surface tension of water. Because of possible aquatic toxicity, speedy decontamination measures must be taken if there is a danger of large quantities entering the ground water or water systems. |
| Component: | No data available. |

Other adverse effects

The product contains no ingredients with ozone depletion potential or global warming potential. The product contains no heavy metals or their compounds as defined in 2006/11/EG. The product contains no absorbable organic halogens (AOX) or volatile organic compounds (VOC).

SECTION 13: DISPOSAL CONSIDERATIONS

Waste treatment methods

| | |
|-------------------------|---|
| Disposal methods: | Dispose of this product according to national and regional provisions. Waste code EWC Nr: 070699 (Group: waste material of MFSU from fats, lubricants, soaps, detergents, disinfectants and personal protection products). The correctly diluted ready-to-use solution of this product can be disposed of via the sewage system. Small amounts of the product (up to about 100 ml per day) can be disposed of via the sewage system after dilution 1:30 with tap water. |
| Contaminated packaging: | Empty packaging can be treated like household waste or recycled after cleaning with water. Handle the packaging containing the product in the same way as the product itself. Where available, references to local regulations regarding disposal are given in section 15 of the SDS. The user has sole responsibility for acquaintance and compliance with the applicable regulations. |

SECTION 14: TRANSPORT INFORMATION

Land transport (ADR/ADN/RID)

UN number

UN 3082

UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Alkyl (C12-16) dimethylbenzyl ammonium chloride, Didecyldimethylammonium chloride)

Transport hazard class(es)

9

Packing group

III | Danger label: 9 | LQ: 5 L

Product: ISORAPID® OP-Forte AF

Environmental hazards

Environmental hazards: Yes

Special precautions for user

See sections 6 to 8.

Sea transport (IMDG/IMO)

UN number

UN 3082

UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Alkyl (C12-16) dimethylbenzyl ammonium chloride, Didecyldimethylammonium chloride)

Transport hazard class(es)

9

Packing group

III | Danger label: 9 | LQ: 5 L

Environmental hazards

Environmental hazards: Yes

Marine pollutant: Yes

Special precautions for user

See sections 6 to 8.

Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

Air transport (IATA)

UN number

UN 3082

UN proper shipping name

ENVIRONMENTALLY HAZARDOUS SUBSTANCE, LIQUID, N.O.S. (Alkyl (C12-16) dimethylbenzyl ammonium chloride, Didecyldimethylammonium chloride)

Transport hazard class(es)

9

Packing group

III | Danger label: 9 | LQ: 5 L

Environmental hazards

Environmental hazards: Yes

Product: ISORAPID® OP-Forte AF

Special precautions for user

See sections 6 to 8.

SECTION 15: REGULATORY INFORMATION

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

The product has been classified and marked in accordance with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). The product complies with requirements of Regulation (EC) No. 1907/2006 (REACH), Regulation (EC) No. 648/2004 (Detergents Regulation), Regulation (EU) No. 528/2012 (Biocides Regulation), Directive 93/42/EC (Medical Devices Directive), and Regulation (EU) No. 2017/745 on medical devices (MDR), if applicable.

SECTION 16: OTHER INFORMATION

Indication of changes

- 1.1 Product identifier - Updated.
- 1.2 Relevant identified uses of the substance or mixture and uses advised against - Updated.
- 1.3 Details of the supplier of the safety data sheet - Updated.
- 1.4 Emergency telephone number - Updated.
- 4.1 Description of first aid measures - Updated.
- 5.2 Special hazards arising from the substance or mixture - Updated.
- 5.3 Advice for firefighters - Updated.
- 6.1 Personal precautions, protective equipment and emergency procedures - Updated.
- 6.2 Environmental precautions - Updated.
- 7.1 Precautions for safe handling - Updated.
- 7.2 Conditions for safe storage, including any incompatibilities - Updated.
- 8.1 Control parameters - Updated.
- 8.2 Exposure controls - Updated.
- 9.1 Information on basic physical and chemical properties - Updated.
- 9.2 Other information - Updated.
- 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008 / Information on toxicological effects - Updated.
- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture - Updated.

Abbreviations and acronyms

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road
ASTM - American Society for Testing and Materials
AwSV - Ordinance on facilities for handling substances that are hazardous to water
BOD - Biochemical Oxygen Demand
c.c. - Closed cup
CAS - Chemical Abstract Services
CESIO - European Committee of Organic Surfactants and their Intermediates
COD - Chemical Oxygen Demand
DMEL - Derived Minimum Effect Level
DNEL - Derived No Effect Level
EbC50 - Median concentration in terms of reduction of growth
EC - Effective concentration
EINECS - European Inventory of Existing Commercial Chemical Substances
EN - European Norm
ErC50 - Median concentration in terms of reduction of growth rate
GGVSEB - German ordinance for road, rail and inland waterway transportation of dangerous goods
GGVSee - German ordinance for sea transportation of dangerous goods
GLP - Good Laboratory Practice

Product: ISORAPID[®] OP-Forte AF

GMO - Genetic Modified Organism
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
ISO - International Organization For Standardization
LD/LC - Lethal dose/concentration
LOAEL - Lowest Observed Adverse Effect Level
LOEL - Lowest Observed Effect Level
LQ - Limited Quantity
M-Factor - Multiplying factor
NOAEL - No Observed Adverse Effect Level
NOEC - No Observed Effect Concentration
NOEL - No Observed Effect Level
o.c. - Open cup
OECD - Organisation for Economic Cooperation and Development
OEL - Occupational Exposure Limit
PBT - Persistent, bioaccumulative, toxic
PNEC - Predicted No Effect Concentration
REACH - REACH registration
RID - Convention concerning International Carriage by Rail
SVHC - Substances of Very High Concern
TA - Technical Instructions
TRGS - Technical Rules for Hazardous Substances
vPvB - Very persistent, very bioaccumulative
WGK - Water Hazard Class

Key literature references and sources for data

No data available.

List of relevant phrases

H226 Flammable liquid and vapour.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
H411 Toxic to aquatic life with long lasting effects.

Training information

Comply with national laws regulating employee instruction.

The above information describes exclusively the safety requirements of the product and is based on our present-day knowledge. The information is intended to give you advice about the safe handling of the product named in this safety data sheet, for storage, processing, transport and disposal. The information cannot be transferred to other products. In the case of mixing the product with other products or in the case of processing, the information on this safety data sheet is not necessarily valid for the new made-up material.