

SAFETY DATA SHEET

according to Regulation (EC) No 1907/2006 (REACH) Article 31, Annex II as amended

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: actisolve® alcofree
UFI: 050X-3804-N00F-4FFR

Substance type: Mixture

Use of the substance/mixture: Surface disinfectant

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

Identified uses: actisolve® alcofree is a ready-to-use solution for the disinfection and cleaning of

surfaces of non-invasive medical devices such as treatment chairs with high-gloss surfaces that are not compatible with alcohol. The disinfectant is particularly suitable for surfaces of medical devices made of plastic, acrylic glass, artificial

leather and other alcohol-sensitive materials.

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

Recommended restrictions on

use:

For professional use only.

1.3 Details of the supplier of the safety data sheet

| | Manufacturer | EU only representative |
|------------|---|---|
| Address: | United Disinfectant Manufacturers AG Allmendstrasse 21 8320 Fehraltorf Switzerland | United Disinfectant Manufacturers AG Dr. Grass-Strasse 12 9490 Vaduz Liechtenstein |
| Telephone: | +41 (0)55 511 03 33 | |
| Email: | info@udm.swiss | info@udm.li |
| Website: | www.udm.swiss | www.udm.li |
| | Downstream user/importer/distribu | tor |
| Address: | United Disinfectant Manufacturers AG Dr. Grass-Strasse 12 9490 Vaduz Liechtenstein | |
| Telephone: | | |
| Email: | info@udm.li | |
| Website: | www.udm.li | |

Person responsible for preparing the SDS

Lee Moi Wong | Research & Development | Chief Research Officer (CRO)

Telephone: +41 (0)55 511 03 33

Email: ra@udm.swiss

1.4 Emergency telephone number

Emergency telephone number: 94 / 038 200 80 800

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



SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

| Hazard type | Hazard category | Hazard statement code(s) | Classification procedure |
|----------------------|-------------------|--------------------------|------------------------------------|
| Environmental hazard | Aquatic Chronic 3 | H412 | Harmonised (legal) classification. |

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

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008

Hazard pictograms: None.

Signal word: No signal word according to Regulation (EC) 1272/2008.

Hazard statements: H412 Harmful to aquatic life with long lasting effects.

Precautionary statements: P273 Avoid release to the environment.

P305 + P351 + IF IN EYES: Rinse cautiously with water for several minutes. P338 Remove contact lenses, if present and easy to do. Continue

rinsing.

P501 Dispose of contents/container in accordance with local and

national regulations.

Supplemental information: Not applicable.

2.3 Other hazards

PBT or vPvB properties: This substance/mixture contains no components considered to be either

persistent, bioaccumulative and toxic (PBT), or very persistent and very

bioaccumulative (vPvB) at levels of 0.1% or higher.

Endocrine disrupting properties: The substance/mixture does not contain components considered to have

endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

at levels of 0.1% or higher.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

See below.

3.2 Mixtures

Classification according to Regulation (EC) No 1272/2008

| 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 | < 1% |
| Amines, N-C10-16- alkyltrimethylenedi,-reaction products with chloroacetic acid | CAS no.: 139734-65-9 EC no.: 701-317-3 Index no.: Not applicable. REACH no.: 01-2120050368-56-0000 | Acute Tox. 4, H302 Aquatic Acute 1, H400 Aquatic Chronic 1, H410 Eye Dam. 1, H318 Skin Corr. 1C, H314 | No data available. | < 1% |

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

SECTION 4: FIRST AID MEASURES



4.1 Description of first aid measures

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.

After inhalation: Remove patient to fresh air - move out of dangerous area. Obtain professional

medical help.

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. If symptoms develop and persist, seek

medical attention.

After contact with eyes: Immediately flush eyes with running water, keeping eyelids apart. If irritation

persists, seek professional medical attention.

After ingestion: Do not induce vomiting. Rinse mouth thoroughly with water. Never give anything

by mouth to an unconscious person. Consult a physician. Show the physician the

safety data sheet or label.

4.2 Most important symptoms and effects, both acute and delayed

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

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

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

Unsuitable extinguishing media: Full water jet.

5.2 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.

5.3 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. Contaminated firefighting

water and fire residues must be disposed of in accordance with the local

regulations.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Advice for non-emergency

personnel:

Use personal protective equipment (section 8). Ensure adequate ventilation. 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 Use personal protective equipment.



responders:

6.2 Environmental precautions

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

6.3 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. Prevent release into the sewer, water, basements or confined areas. Ventilate the premises. Clean contaminated area with plenty of water.

6.4 Reference to other sections

See also sections 7, 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 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.

Advice on general occupational

hygiene:

7.2

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. Keep away from food, drink and

animal feeding stuffs. 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.

7.3 Specific end use(s)

See identified uses in section 1.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Occupational exposure limits

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).

DNEL values

| Substance name | Pattern of exposure | Route of exposure | Limit value | |
|----------------|---------------------|-------------------|-------------|--|
|----------------|---------------------|-------------------|-------------|--|



| Alkyl (C12-16) dimethylbenzyl ammonium chloride CAS no.:68424-85-1 | No threshold derived. | No threshold derived. | No threshold derived. |
|--|--|-----------------------|-----------------------|
| Amines, N-C10-16-alkyltrimethylened- i,-reaction products with chloroacetic acid CAS no.:139734-65-9 | Worker (long term, systemic effects) | Inhalation | 280 μg/m³ |
| | Consumer (long term, systemic effects) | Inhalation | 50 μg/m³ |
| | Worker (long term, systemic effects) | Dermal | 4 mg/kg bw/day |
| | Consumer (long term, systemic effects) | Dermal | 286 μg/kg bw/day |
| | Consumer (long term, systemic effects) | Oral | 29 μg/kg bw/day |
| PNEC values | | | |
| Substance name | Route of exposure | Limit value | |
| Alkyl (C12-16) dimethylbenzyl ammonium chloride CAS no.:68424-85-1 | Fresh water | 420 ng/L | |
| | Marine water | 96 ng/L | |
| | Intermittent release (fresh water) | 160 ng/L | |
| | Intermittent release (marine water) | 207 ng/L | |
| | Sewage treatment plant | 160 μg/L | |
| | Sediment (fresh water) | 68 mg/kg dw | |
| | Intermittent release (marine water) | 15.75 mg/kg dw | |
| | Soil | 1.66 mg/kg dw | |
| Amines, N-C10-16-alkyltrimethylened- i,-reaction products with chloroacetic acid CAS no.:139734-65-9 | Fresh water | 230 ng/L | |
| | Marine water | 23 ng/L | |
| | Intermittent release (fresh water) | 237 ng/L | |
| | Sewage treatment plant | 220 µg/L | |
| | Sediment (fresh water) | 2.67 mg/kg dw | |
| | Sediment (marine water) | 534 µg/kg dw | |
| | Soil | 6.4 mg/kg dw | |

8.2 Exposure controls

Appropriate engineering controls

See section 7. No additional measures necessary.

Individual protection measures

Eye/face protection: Not required during normal use.

Hand protection: Not required during normal use.

Body protection: Not required during normal use.

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 eyes. Do not eat, drink or smoke while working.

Do not breathe vapours/aerosols.

Environmental exposure controls

Observe the usual precautions for handling chemicals.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state: Liquid

Form: Clear, non-viscous liquid

Colour: Colourless Odour: Apple



Melting point:

Freezing point:

No data available.

No data available.

No data available.

No data available.

and boiling range:

Flammability:

The product is not flammable.

Lower explosion limit:

Upper explosion limit:

Flash point:

Auto-ignition temperature:

Decomposition temperature:

Not applicable.

Not applicable.

Not self-igniting.

Not applicable.

pH-value (diluted product): Not applicable (ready-to-use solution).

8.2 - 8.8

Kinematic viscosity: No data available.

Solubility: Completely miscible with water.

Partition coefficient n-

pH-value (undiluted product):

octanol/water:

Not applicable.

Vapour pressure at 50 °C: No data available.

Density: 1.00 g/cm³

Relative density: 1.00

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

9.2 Other information

Oxidising properties: Not oxidising.

Explosive properties: Product is not explosive.

Evaporation rate: No data available.

Miscibility: Completely miscible with water.

Other information: No data available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

The mixture is not reactive.

10.2 Chemical stability

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

10.3 Possibility of hazardous reactions

No dangerous reaction known under conditions of normal use.

10.4 Conditions to avoid

Avoid conditions beyond those mentioned in section 7.

10.5 Incompatible materials

No specific materials to avoid during intended use.



10.6 Hazardous decomposition products

No dangerous decomposition products occur under normal storage and use.

SECTION 11: TOXICOLOGICAL INFORMATION

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

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) > 5000 mg/kg

Component: No data available.

Skin corrosion/irritation

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

Serious eye damage/irritation

Mixture: Irritating to eyes.

Component: No data available.

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.

11.2 Information on other hazards

Endocrine disrupting properties

Mixture: The substance/mixture does not contain components considered to have

endocrine disrupting properties according to REACH Article 57(f) or Commission



Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605

at levels of 0.1% or higher.

Component: No data available.

Other hazards

Mixture: No data available. Component: No data available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

This product has no known ecotoxic effect. The product is not expected to 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.

12.2 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.

| Substance name | Biodegradation | Basis | Remark |
|--|----------------|------------------|------------------------|
| Alkyl (C12-16) dimethylbenzyl ammonium chloride | Ca. 60% | OECD 301 D, 28 D | Readily biodegradable. |
| Amines, N-C10-16-alkyltrimethylenedi,- reaction products with chloroacetic acid | 94% | OECD 301 A | Readily biodegradable. |

12.3 Bioaccumulative potential

Mixture: Based on available data, no product ingredient is expected to exhibit

bioaccumulative potential.

Component: No data available.

12.4 Mobility in soil

Mixture: The product is not expected to be mobile over long distances because all product

ingredients possess good biodegradability. Surface tension and absorption /

desorption kinetics are not relevant to the product.

Component: No data available.

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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

13.1 Waste treatment methods

Disposal methods: Dispose of 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). Small amounts of the product (up to about 500 ml per day) can be disposed of via the sewage system after dilution

1:5 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)

14.1 UN number

Not regulated as a dangerous good.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not regulated as a dangerous good. | Danger label: Not applicable. | LQ: Not applicable.

14.5 Environmental hazards

Environmental hazards: No

14.6 Special precautions for user

See sections 6 to 8.

Sea transport (IMDG/IMO)

14.1 UN number

Not regulated as a dangerous good.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not regulated as a dangerous good. | Danger label: Not applicable. | LQ: Not applicable.



14.5 Environmental hazards

Environmental hazards: No Marine pollutant: No

14.6 Special precautions for user

See sections 6 to 8.

14.7 Maritime transport in bulk according to IMO instruments

Not applicable for product as supplied.

Air transport (IATA)

14.1 UN number

Not regulated as a dangerous good.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not regulated as a dangerous good. | Danger label: Not applicable. | LQ: Not applicable.

14.5 Environmental hazards

Environmental hazards: No

14.6 Special precautions for user

See sections 6 to 8.

SECTION 15: REGULATORY INFORMATION

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

The product has been classified and marked in accordance with Regulation (EC) No.1272/2008 (CLP). 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.

15.2 Chemical safety assessment

No chemical safety assessment was carried out for this product.

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.
- 2.3 Other hazards 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.
- 11.2 Information on other hazards Updated.
- 12.6 Endocrine disrupting properties 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
- 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.

Classification for mixtures and used evaluation method according to regulation (EC) No 1272/2008 [CLP]

| Hazard category | Hazard statement code(s) | Classification procedure |
|-------------------|--------------------------|------------------------------------|
| Aquatic Chronic 3 | H412 | Harmonised (legal) classification. |

List of relevant phrases

| H302 | Harmful if swallowed | |
|------|------------------------|--|
| | Hallillul II Swallowed | |

H314 Causes severe skin burns and eye damage.

H318 Causes serious eye damage.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

H412 Harmful 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.