

Isagel

25. February 2015
Version 2.0

Safety Data Sheet

Based on template version 1.0

Section 1

Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Product name: Isagel
Product code: 61644, 61645, 61647 and 67041

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

Product information: Skin care product, OTC
No-rinse, antiseptic hand cleansing gel with added moisturizers.

1.3 Details of the supplier of the safety data sheet:

Manufacturer: Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Denmark
Telephone +45 49111111
msds@coloplast.com

1.4 Emergency telephone number:

(DK) +45 82 12 12 12
(US) 1-800-222-1222
(CA) 1-877-820-7008

USA

Coloplast Corp.
1601 West River Road N
Minneapolis, MN 55411
Telephone: +1-800-533-0464
www.us.coloplast.com

Canada

Coloplast Canada Corporation
3300 Ridgeway Drive, Unit 12
Mississauga, Ont. L5L 5Z9
Telephone: +1-877-820-7008
www.coloplast.ca

Europe

Coloplast A/S
Holtedam 1
DK-3050 Humlebaek
Telephone: +45 49 11 11 11
www.coloplast.com

Section 2

Hazards identification

The product is a cosmetic product and therefore not covered by the classification and labelling rules that apply to chemical products. The product is assessed and supplied with a safety data sheet in accordance with Regulation (EC) no 1272/2008.

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2.1 Classification of the substance or mixture

Classification according to Regulation (EC)

No 1272/2008:

Flam. Liq. 2;H225

Wording of H-statements – see section 16.

Most serious harmful effects:

Highly flammable liquid vapour.

May cause slight irritation to the skin and eyes.

The product is a cosmetic product and therefore not covered by the classification and labelling rules that apply to chemical products.

2.2. Label elements

The product is a cosmetic product and therefore the labelling elements from the CLP regulations do not apply, according to Regulation (EC) No 1272/2008, Title I, Article 1, Section 5.

Contains:

Reg. (EC) No 1223/2009:

INCI: ALCOHOL DENAT., AQUA, TRIETHANOLAMINE, CARBOMER, GLYCERETH-26, PEG-12, PARFUM, LIMONENE, CITRAL.

According to Regulation (EC) No 1272/2008:

Pictogram(s):

Signal word:



Warning

Hazard statement(s):

Highly flammable liquid and vapour. (H225)

Precautionary statement(s):

-

2.3 Other hazards

Assessment to determine PBT and vPvP has not been made.

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Section 3

Composition/information on ingredients

3.1 Substances

N/A

3.2 Mixtures

The following substances have to be declared according to legislation:

| w/w % | CAS No | EC No | Index No | REACH reg. No | Chemical Name | Classification (EC 1272/2008) |
|-------|---------|-----------|----------|---------------|---------------|-------------------------------|
| 60-70 | 64-17-5 | 200-578-6 | - | - | Ethanol | Flam. Liq. 2;H225 |

Wording of H-statements - see section 16.

Contains:

Reg. (EC) No 1223/2009:

INCI: ALCOHOL DENAT., AQUA, TRIETHANOLAMINE, CARBOMER, GLYCERETH-26, PEG-12, PARFUM, LIMONENE, CITRAL.

Section 4

First-AID measures

4.1 Description of first aid measures

Inhalation: Move the affected person to fresh air. Keep at rest. If needed: Get medical attention.

Skin Contact: In case of skin problems: Seek medical advice.

Eye Contact: Immediately flush with water or physiological salt water for at least 15 minutes, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.

Ingestion: Rinse mouth and drink plenty of water. Do not induce vomiting. If vomiting occurs keep head down to avoid vomit in the lungs. In case of discomfort: Seek medical advice.

Burns: Flush with water until pain ceases. Remove clothes that are not burnt to the skin. If needed seek medical attention, continue to flush on the way.

Other information: When obtaining medical advice, show the safety data sheet or label

4.2 Most important symptoms and effects, both acute and delayed

May cause slight irritation to the skin and eyes

4.3 Indication of any immediate medical attention and special treatment needed

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Treat symptoms. No special immediate treatment required.

Section 5 Fire fighting measures

5.1 Suitable extinguishing media

Extinguish with powder, foam, carbon dioxide or water mist.

Use water or water mist to cool non-ignited stock.

Unsuitable extinguishing media:

Do not use water stream, as it may spread the fire.

5.2 Special hazards arising from the substance or mixture

Can generate harmful flue gases containing carbon monoxide in the event of fire.

5.3 Advice for firefighters

Move containers from danger area if it can be done without risk.

Avoid inhalation of vapour and flue gases – seek fresh air.

Wear Self-Contained Breathing Apparatus (SCBA) With chemical resistant gloves.

Section 6 Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel: Stay upwind/keep distance from source. Stop leak if this can be done without risk. Smoking and naked flames prohibited.

Wear gloves.

For emergency responders: In addition to the above: Normal protective clothing equivalent to EN 469 is recommended.

6.2 Environmental precautions

Prevent spillage from entering drains and/or surface water.

6.3 Methods and materials for containment and cleaning up:

Contain and absorb spill with sand or other absorbent, non-combustible material and transfer to suitable waste containers. Wipe up minor spills with a cloth.

6.4 Reference to other sections

See section 8 for type of protective equipment.

See section 13 for instructions on disposal.

Section 7 Handling and storage

7.1 Precautions for safe handling

Running water and eye wash equipment must be available. Wash hands before breaks, before using restroom facilities, and at the end of work. Smoking and naked flames prohibited.

7.2 Conditions for safe storage, including any incompatibilities

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Store safely and keep out of reach of children.

7.3 Specific end use(s)

None.

Section 8

Exposure controls/personal protection

8.1 Control parameters

Commission Directive 2000/39/EC (Occupational Exposure Limits). Last amended by Commission Directive 2009/161/EU.

Contains no substances subject to reporting requirements.

8.2 Exposure controls

Appropriate engineering controls: Wear the personal protective equipment specified below.

Personal protective equipment, eye/face protection: Not required.

Personal protective equipment, skin protection: Not relevant, as the product is a cosmetic product.

Personal protective equipment, respiratory protection: Not required.

Environmental exposure controls: Ensure compliance with local regulations for emissions.

Section 9

Physical and chemical properties

9.1 Information on basic physical and chemical properties

| | |
|---|---------------------|
| Appearance: | Viscous liquid. |
| Odour: | Alcohol |
| pH: | 6-8 |
| Melting point / freezing point (°C): | - |
| Initial boiling point and boiling range (°C): | 84 °C |
| Decomposition temperature (°C): | - |
| Flash point (°C): | 18 °C |
| Evaporation rate: | - |
| Flammability (solid, gas): | - |
| Upper/lower flammability or explosive limits (vol-%): | 3,3 – 19% (Ethanol) |
| Vapour pressure (hPa, 20°C): | - |
| Vapour density (air=1): | Approx. 0,9 |
| Relative density (g/ml, 25°C): | - |
| Solubility: | Dispersible |
| Partition coefficient: n-octanol/water, Log K _{ow} : | - |
| Autoignition temperature (°C): | - |
| Viscosity (mPa*s, 25°C): | - |
| Explosive properties: | - |
| Oxidising properties: | - |

9.2 Other information:

None

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Section 10 Stability and reactivity

10.1 Reactivity

Reacts with the following: Strong oxidisers/ Strong acids.

10.2 Chemical stability

The product is stable when used in accordance with the supplier's directions.

10.3 Possibility of hazardous reactions

None known.

10.4 Conditions to avoid

Avoid heating and contact with ignition sources.

10.5 Incompatible materials

Strong oxidisers/ Strong acids.

10.6 Hazardous decomposition products

Carbonmonoxide and carbon dioxide.

Section 11 Toxicological information

This product is a cosmetic product and has been assessed in accordance with Directive 1223/2009 on cosmetic products

11.1 Information on toxicological effects

Toxicological data:

The product has passed dermatological testing.

Information on likely routes of exposure: Inhalation, skin and ingestion:

Symptoms:

| | |
|------------------------------------|---|
| Acute toxicity – oral: | Ingestion may cause discomfort. The product does not have to be classified. Test data are not available. |
| Acute toxicity - dermal: | The product does not have to be classified. Test data are not available. |
| Acute toxicity - inhalation: | The product does not have to be classified. Test data are not available. |
| Skin corrosion/irritation: | May cause slight irritation. The product does not have to be classified. The product has passed a 21-day cumulative irritation study in humans. |
| Serious eye damage/eye irritation: | Temporary irritation. The product does not have to be classified. Test data are not available. |
| Sensitisation: | The product does not have to be classified. Test data are not available. |
| Mutagenicity: | The product does not have to be classified. Test data are not available. |
| Carcinogenic properties: | The product does not have to be classified. Test data are not available. |
| Reproductive toxicity: | The product does not have to be classified. Test data are not available. |

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| | |
|------------------------------|--|
| Single STOT exposure: | The product does not have to be classified. Test data are not available. |
| Repeated STOT exposure: | The product does not have to be classified. Test data are not available. |
| Aspiration hazard: | The product does not have to be classified. Test data are not available. |
| Other toxicological effects: | None known. |

Section 12 Ecological information

12.1 Toxicity

The product does not have to be classified. Test data are not available.

12.2 Persistence and degradability

Test data are not available.

12.3 Bioaccumulative potential

Test data are not available.

12.4 Mobility in soil

Test data are not available.

12.5 Results of PBT and vPvB assessment

No assessment has been made.

12.6 Other adverse effects

None known.

Section 13 Disposal considerations

13.1 Waste treatment methods

The recommended disposal technology at any approved facility. The disposal should always be in compliance with national, federal, state and local regulations. The product should not be discharged to the environment.

European Union

Avoid discharge to drain or surface water.

Collect spills and waste in closed, leak-proof containers for disposal at the local hazardous waste site.

EWC code: Depends on line of business and use, for instance 16 05 08* discarded organic chemicals consisting of or containing dangerous substances.

Absorbent/cloth contaminated with the product: EWC code: 15 02 02 absorbents, filter materials (including oil filters not otherwise specified), wiping cloths, protective clothing contaminated by dangerous substances.

Uncleansed packaging is to be disposed of via the local waste-removal scheme. Empty, cleansed packaging should be disposed of for recycling.

Section 14

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Transport information

| | |
|---|--|
| 14.1 UN-no.: | 1170 |
| 14.2 UN proper shipping name: | ETHYL ALCOHOL SOLUTION |
| 14.3 Transport hazard class(es): | 3 |
| 14.4 Packing group: | II |
| 14.5 Environmental hazards: | The product should not be labelled as an environmental hazard (symbol: fish and tree). |
| 14.6 Special precautions for user: | None |
| 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: | Not applicable |

| | |
|---------------------------|-----|
| ADR - Classification: | |
| - Classification code: | F1 |
| - ADR limited Quantities: | 1 I |
| - Hazard label: | 3 |

Special provisions applicable to certain articles or substance: Not relevant

| | |
|----------------------------|----------|
| IMDG - Classification: | |
| - IMDG limited Quantities: | 1 I |
| - Hazard label: | 3 |
| - EMS: | F-E, S-D |

Special provisions applicable to certain articles or substance: Not relevant

| | |
|------------------------|---|
| IATA - Classification: | |
| - Hazard label: | 3 |

Transportation on road in other countries than ADR-countries:

US: UN1170 ETHYL ALCOHOL SOLUTION
Canada: UN1170 ETHYL ALCOHOL SOLUTION
Brazil: UN1170 ÁLCOOL ETÍLICO EM SOLUÇÃO
Australia: UN1170 ETHYL ALCOHOL SOLUTION
New Zealand: UN1170 ETHYL ALCOHOL SOLUTION
Hongkong / China: UN1170 ETHYL ALCOHOL SOLUTION

Section 15

Regulatory information

Covered by: Regulation (EC) No 1223/2009 of the European Parliament and of the Council of 30 November 2009 on cosmetic products.

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

Special provisions: None

15.2 Chemical Safety Assessment:

Chemical safety assessment has not been performed.

Section 16

Other information

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H-statements mentioned in section 2 and 3:
H225 Highly flammable liquid and vapour.

Abbreviations:

PBT = Persistent, Bioaccumulative and Toxic
vPvB = Very Persistent and Very Bioaccumulative
STOT = Specific Target Organ Toxicity

Classification method:

Calculation based on the hazards of the known components.

Changes since the previous edition:

Not relevant.

Training:

No special training is required, but a thorough knowledge of this safety data sheet should be a prerequisite condition.

Other information:

This safety data sheet has been prepared for and applies to this product only. It is based on our current knowledge and the information that the supplier was able to provide about the product at the time of preparation. The safety data sheet complies with applicable law on preparation of safety data sheets in accordance with 1907/2006/EC (REACH) as subsequently changed.

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