



Safety Data Sheet dated 27/3/2023, version 2

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

1.1. Product identifier

Mixture identification:

Trade name:

Sputum Liqueying Solution 1ml Tube in Bulk

Trade code:

0E005N

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

Recommended use:

Copan SLsolution™ is a treatment reagent for fluidification of specimens collected from the respiratory tract prior to subsequent microbiological analyses.

Uses advised against:

Not suitable for any other application other than its intended use

1.3. Details of the supplier of the safety data sheet

Company:

COPAN ITALIA SPA

VIA PEROTTI, 10 – 25125 BRESCIA

Phone : +39 0302687211

Competent person responsible for the safety data sheet:

msds@copangroup.com

Legal Manufacturer:

Copan Italia SpA - Italia

Phone : +39 0302687211

1.4. Emergency telephone number

City Hospital, Birmingham B187QH, United Kingdom Phone: +44 121 507 4123

Phone: +39-055-6120735 (technical Support Hours : 9:00-13:00, 14:00-18:00 GMT+1:00)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

⚠ Warning, Skin Sens. 1, May cause an allergic skin reaction.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Hazard pictograms:



Warning

Hazard statements:

H317 May cause an allergic skin reaction.

Precautionary statements:

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P272 Contaminated work clothing should not be allowed out of the workplace.

P280 Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/...

P333+P313 If skin irritation or rash occurs: Get medical advice/attention.

P362+P364 Take off contaminated clothing and wash it before reuse.

P501 Dispose of contents/container in accordance with applicable regulations.

Special Provisions:

None

Contains

Sodium Thioglycolate

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

No PBT, vPvB or endocrine disruptor substances present in concentration $\geq 0.1\%$

Other Hazards:

No other hazards

SECTION 3: Composition/information on ingredients

3.1. Substances

N.A.

3.2. Mixtures

Hazardous components within the meaning of the CLP regulation and related classification:

| Qty | Name | Ident. Number | Classification |
|-------------------------|----------------------|--|--|
| $\geq 1\%$ - $< 3\%$ | Sodium Thioglycolate | CAS: 367-51-1 EC: 206-696-4 REACH No.: 01-2119968564-24-0010 | <p>⚠ 2.16/1 Met. Corr. 1 H290</p> <p>⚠ 3.1/3/Oral Acute Tox. 3 H301</p> <p>⚠ 3.1/4/Dermal Acute Tox. 4 H312</p> <p>⚠ 3.4.2/1 Skin Sens. 1 H317</p> |

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Immediately take off all contaminated clothing.

Areas of the body that have - or are only even suspected of having - come into contact with the product must be rinsed immediately with plenty of running water and possibly with soap.

Wash thoroughly the body (shower or bath).

Remove contaminated clothing immediately and dispose off safely.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

None

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

In case of accident or unwellness, seek medical advice immediately (show directions for use or

safety data sheet if possible).
Treatment:
None

SECTION 5: Firefighting measures

- 5.1. Extinguishing media
Suitable extinguishing media:
Water.
Carbon dioxide (CO₂).
Extinguishing media which must not be used for safety reasons:
None in particular.
- 5.2. Special hazards arising from the substance or mixture
Do not inhale explosion and combustion gases.
Burning produces heavy smoke.
- 5.3. Advice for firefighters
Use suitable breathing apparatus .
Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Move undamaged containers from immediate hazard area if it can be done safely.

SECTION 6: Accidental release measures

- 6.1. Personal precautions, protective equipment and emergency procedures
Wear personal protection equipment.
Remove persons to safety.
See protective measures under point 7 and 8.
- 6.2. Environmental precautions
Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.
Retain contaminated washing water and dispose it.
In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.
Suitable material for taking up: absorbing material, organic, sand
- 6.3. Methods and material for containment and cleaning up
Wash with plenty of water.
- 6.4. Reference to other sections
See also section 8 and 13

SECTION 7: Handling and storage

- 7.1. Precautions for safe handling
Avoid contact with skin and eyes, inhalation of vapours and mists.
Don't use empty container before they have been cleaned.
Before making transfer operations, assure that there aren't any incompatible material residuals in the containers.
See also section 8 for recommended protective equipment.
Advice on general occupational hygiene:
Contaminated clothing should be changed before entering eating areas.
Do not eat or drink while working.
- 7.2. Conditions for safe storage, including any incompatibilities
Keep away from food, drink and feed.
Incompatible materials:
None in particular.
Instructions as regards storage premises:
Adequately ventilated premises.
- 7.3. Specific end use(s)
Product Pack Insert may be available, ask to legal manufacturer

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No occupational exposure limit available

DNEL Exposure Limit Values

N.A.

PNEC Exposure Limit Values

N.A.

8.2. Exposure controls

Eye protection:

Use close fitting safety goggles, don't use eye lens.

Protection for skin:

Use clothing that provides comprehensive protection to the skin, e.g. cotton, rubber, PVC or viton.

Protection for hands:

Use protective gloves that provides comprehensive protection, e.g. P.V.C., neoprene or rubber.

Respiratory protection:

Not needed for normal use.

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Properties | Value | Method: | Notes |
|---|----------------|---------|-------|
| Physical state: | Liquid | -- | -- |
| Colour: | N.A. | -- | -- |
| Odour: | odorless | -- | -- |
| Odour threshold: | Not applicable | -- | -- |
| Melting point/freezing point: | N.A. | -- | -- |
| Boiling point or initial boiling point and boiling range: | N.A. | -- | -- |
| Flammability: | N.A. | -- | -- |
| Lower and upper explosion limit: | N.A. | -- | -- |
| Flash point: | N.A. | -- | -- |
| Auto-ignition temperature: | N.A. | -- | -- |
| Decomposition temperature: | N.A. | -- | -- |
| pH: | 7,4 | -- | -- |

| | | | |
|--|------|----|----|
| Kinematic viscosity: | N.A. | -- | -- |
| Solubility in water: | N.A. | -- | -- |
| Solubility in oil: | N.A. | -- | -- |
| Partition coefficient n-octanol/water (log value): | N.A. | -- | -- |
| Vapour pressure: | N.A. | -- | -- |
| Density and/or relative density: | N.A. | -- | -- |
| Relative vapour density: | N.A. | -- | -- |
| Particle characteristics: | | | |
| Particle size: | N.A. | -- | -- |

9.2. Other information
 No other relevant information

SECTION 10: Stability and reactivity

- 10.1. Reactivity
 Stable under normal conditions
- 10.2. Chemical stability
 Stable under normal conditions
- 10.3. Possibility of hazardous reactions
 None
- 10.4. Conditions to avoid
 Stable under normal conditions.
- 10.5. Incompatible materials
 None in particular.
- 10.6. Hazardous decomposition products
 None.

SECTION 11: Toxicological information

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

Toxicological information of the product:

Sputum Liquefying Solution 1ml Tube in Bulk

- a) acute toxicity
 Not classified
 Based on available data, the classification criteria are not met
- b) skin corrosion/irritation
 Not classified
 Based on available data, the classification criteria are not met
- c) serious eye damage/irritation
 Not classified
 Based on available data, the classification criteria are not met
- d) respiratory or skin sensitisation
 The product is classified: Skin Sens. 1 H317
- e) germ cell mutagenicity
 Not classified
 Based on available data, the classification criteria are not met

- f) carcinogenicity
Not classified
Based on available data, the classification criteria are not met
 - g) reproductive toxicity
Not classified
Based on available data, the classification criteria are not met
 - h) STOT-single exposure
Not classified
Based on available data, the classification criteria are not met
 - i) STOT-repeated exposure
Not classified
Based on available data, the classification criteria are not met
 - j) aspiration hazard
Not classified
Based on available data, the classification criteria are not met
- Toxicological information of the main substances found in the product:
Sodium Thioglycolate - CAS: 367-51-1
- a) acute toxicity:
Test: LD50 - Route: Oral - Species: Mouse = 504 mg/kg

- 11.2. Information on other hazards
Endocrine disrupting properties:
No endocrine disruptor substances present in concentration $\geq 0.1\%$

SECTION 12: Ecological information

- 12.1. Toxicity
Adopt good working practices, so that the product is not released into the environment.
Sputum Liqueying Solution 1ml Tube in Bulk
Not classified for environmental hazards
Based on available data, the classification criteria are not met
- 12.2. Persistence and degradability
N.A.
- 12.3. Bioaccumulative potential
N.A.
- 12.4. Mobility in soil
N.A.
- 12.5. Results of PBT and vPvB assessment
vPvB Substances: None - PBT Substances: None
- 12.6. Endocrine disrupting properties
No endocrine disruptor substances present in concentration $\geq 0.1\%$
- 12.7. Other adverse effects
None

SECTION 13: Disposal considerations

- 13.1. Waste treatment methods
In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

- 14.1. UN number or ID number
Not classified as dangerous in the meaning of transport regulations.
- 14.2. UN proper shipping name
N.A.
- 14.3. Transport hazard class(es)

- N.A.
- 14.4. Packing group
N.A.
- 14.5. Environmental hazards
ADR-Environmental Pollutant: No
IMDG-Marine pollutant: No
- 14.6. Special precautions for user
N.A.
- 14.7. Maritime transport in bulk according to IMO instruments
N.A.

SECTION 15: Regulatory information

- 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Dir. 98/24/EC (Risks related to chemical agents at work)
Dir. 2000/39/EC (Occupational exposure limit values)
Regulation (EC) n. 1907/2006 (REACH)
Regulation (EC) n. 1272/2008 (CLP)
Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013
Regulation (EU) n. 2020/878
Regulation (EU) n. 286/2011 (ATP 2 CLP)
Regulation (EU) n. 618/2012 (ATP 3 CLP)
Regulation (EU) n. 487/2013 (ATP 4 CLP)
Regulation (EU) n. 944/2013 (ATP 5 CLP)
Regulation (EU) n. 605/2014 (ATP 6 CLP)
Regulation (EU) n. 2015/1221 (ATP 7 CLP)
Regulation (EU) n. 2016/918 (ATP 8 CLP)
Regulation (EU) n. 2016/1179 (ATP 9 CLP)
Regulation (EU) n. 2017/776 (ATP 10 CLP)
Regulation (EU) n. 2018/669 (ATP 11 CLP)
Regulation (EU) n. 2018/1480 (ATP 13 CLP)
Regulation (EU) n. 2019/521 (ATP 12 CLP)
Regulation (EU) n. 2020/217 (ATP 14 CLP)
Regulation (EU) n. 2020/1182 (ATP 15 CLP)
Regulation (EU) n. 2021/643 (ATP 16 CLP)
Regulation (EU) n. 2021/849 (ATP 17 CLP)
Regulation (EU) n. 2022/692 (ATP 18 CLP)
- Restrictions related to the product or the substances contained according to Annex XVII Regulation (EC) 1907/2006 (REACH) and subsequent modifications:
Restrictions related to the product:
Restriction 3
Restrictions related to the substances contained:
No restriction.
- Where applicable, refer to the following regulatory provisions :
Directive 2012/18/EU (Seveso III)
Regulation (EC) nr 648/2004 (detergents).
Dir. 2004/42/EC (VOC directive)
- Provisions related to directive EU 2012/18 (Seveso III):
Seveso III category according to Annex 1, part 1
None
- 15.2. Chemical safety assessment
No Chemical Safety Assessment has been carried out for the mixture.
Substances for which a Chemical Safety Assessment has been carried out:
None

SECTION 16: Other information

Full text of phrases referred to in Section 3:

- H290 May be corrosive to metals.
- H301 Toxic if swallowed.
- H312 Harmful in contact with skin.
- H317 May cause an allergic skin reaction.

| Hazard class and hazard category | Code | Description |
|----------------------------------|--------------|--|
| Met. Corr. 1 | 2.16/1 | Substance or mixture corrosive to metals, Category 1 |
| Acute Tox. 3 | 3.1/3/Oral | Acute toxicity (oral), Category 3 |
| Acute Tox. 4 | 3.1/4/Dermal | Acute toxicity (dermal), Category 4 |
| Skin Sens. 1 | 3.4.2/1 | Skin Sensitisation, Category 1 |

This safety data sheet has been completely updated in compliance to Regulation 2020/878. Classification and procedure used to derive the classification for mixtures according to Regulation (EC) 1272/2008 [CLP]:

| Classification according to Regulation (EC) Nr. 1272/2008 | Classification procedure |
|---|--------------------------|
| Skin Sens. 1, H317 | Calculation method |

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

- ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre, Commission of the European Communities
- SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand Reinold

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality. It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
- ATE: Acute Toxicity Estimate
- ATEmix: Acute toxicity Estimate (Mixtures)
- CAS: Chemical Abstracts Service (division of the American Chemical Society).
- CLP: Classification, Labeling, Packaging.
- DNEL: Derived No Effect Level.
- EINECS: European Inventory of Existing Commercial Chemical Substances.
- GefStoffVO: Ordinance on Hazardous Substances, Germany.
- GHS: Globally Harmonized System of Classification and Labeling of Chemicals.
- IATA: International Air Transport Association.
- IATA-DGR: Dangerous Goods Regulation by the "International Air Transport

| | |
|----------|---|
| | Association" (IATA). |
| ICAO: | International Civil Aviation Organization. |
| ICAO-TI: | Technical Instructions by the "International Civil Aviation Organization" (ICAO). |
| IMDG: | International Maritime Code for Dangerous Goods. |
| INCI: | International Nomenclature of Cosmetic Ingredients. |
| KSt: | Explosion coefficient. |
| LC50: | Lethal concentration, for 50 percent of test population. |
| LD50: | Lethal dose, for 50 percent of test population. |
| PNEC: | Predicted No Effect Concentration. |
| RID: | Regulation Concerning the International Transport of Dangerous Goods by Rail. |
| STEL: | Short Term Exposure limit. |
| STOT: | Specific Target Organ Toxicity. |
| TLV: | Threshold Limiting Value. |
| TWA: | Time-weighted average |
| WGK: | German Water Hazard Class. |