

Safety Data Sheet dated 4/4/2018, version 1

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

1.1. Product identifier

Mixture identification:

Trade name:

Sputum Liquefying 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 (Sputum Liquefying solution) is a ready-to-use mucolytic agent for liquefying sputum specimens prior to planting and streaking for the isolation of bacteria and fungi that cause respiratory tract infections.

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

Phone : +390266101029 (Centro antiveneni Niguarda ca' Grande - Milano)

Phone : +390881732326 (Az. Osp. Univ. - Foggia)

Phone : +390817472870 (Az. Osp. " A. Caldarelli " Napoli)

Phone : +390649978000 (Policlinico "Umberto I " Roma)

Phone : +39063054343 (Policlinico "A. Gemelli" Roma)

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

EUH210 Safety data sheet available on request.

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

None

2.3. Other hazards

vPvB Substances: None - PBT Substances: None

Other Hazards:

No other hazards

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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
>= 1% - < 3%	TIOGLICOLATO (100%)		⚠ 3.1/4/Oral Acute Tox. 4 H302 ⚠ 3.2/2 Skin Irrit. 2 H315 ⚠ 3.3/2 Eye Irrit. 2 H319

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

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

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

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- 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.
 Do not eat or drink while working.
 See also section 8 for recommended protective equipment.
- 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:
 Not needed for normal use. Anyway, operate according good working practices.
- Protection for skin:
 No special precaution must be adopted for normal use.
- Protection for hands:
 Not needed for normal use.
- 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
Color:	N.A.	--	--
Appearance:	N.A.	--	--
Odour:	N.A.	--	--
Odour threshold:	N.A.	--	--
pH:	7,4	--	--
Melting point / freezing point:	N.A.	--	--

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Initial boiling point and boiling range:	N.A.	--	--
Flash point:	N.A.	--	--
Evaporation rate:	N.A.	--	--
Solid/gas flammability:	N.A.	--	--
Upper/lower flammability or explosive limits:	N.A.	--	--
Vapour pressure:	N.A.	--	--
Vapour density:	N.A.	--	--
Relative density:	N.A.	--	--
Solubility in water:	N.A.	--	--
Solubility in oil:	N.A.	--	--
Partition coefficient (n-octanol/water):	N.A.	--	--
Auto-ignition temperature:	N.A.	--	--
Decomposition temperature:	N.A.	--	--
Viscosity:	N.A.	--	--
Explosive properties:	N.A.	--	--
Oxidizing properties:	N.A.	--	--

9.2. Other information

Properties	Value	Method:	Notes
Miscibility:	N.A.	--	--
Fat Solubility:	N.A.	--	--
Conductivity:	N.A.	--	--
Substance Groups relevant properties	N.A.	--	--

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

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None in particular.

10.6. Hazardous decomposition products

None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological information of the product:

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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

Not classified

Based on available data, the classification criteria are not met

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:

TIOGLICOLATO (100%)

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Mouse = 504 mg/kg

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. Other adverse effects

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None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

14.1. UN 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. Transport in bulk according to Annex II of Marpol and the IBC Code

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) 2015/830

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)

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:

No restriction.

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

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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:
H302 Harmful if swallowed.
H315 Causes skin irritation.
H319 Causes serious eye irritation.

Hazard class and hazard category	Code	Description
Acute Tox. 4	3.1/4/Oral	Acute toxicity (oral), Category 4
Skin Irrit. 2	3.2/2	Skin irritation, Category 2
Eye Irrit. 2	3.3/2	Eye irritation, Category 2

This safety data sheet has been completely updated in compliance to Regulation 2015/830.

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.
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.

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STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.