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Safety Data Sheet dated 16/1/2020, version 7

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

1.1. Product identifier

Mixture identification:

Trade name: 1ml Preservation Medium For Nucleic Acids Pernasal Flocc.

Applic.

Trade code: 608CS01P

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

Recommended use:

eNAT PRESERVATION MEDIUM FOR NUCLEIC ACIDS

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

Centro Antiveleno di Milano 02 66101029 (CAV Ospedale Niguarda Ca' Grande - Milano)

Centro Antiveleno di Pavia 0382 24444 (CAV IRCCS Fondazione Maugeri - Pavia)

Centro Antiveleno di Bergamo 800883300 (CAV Ospedali Riuniti - Bergamo)

Centro Antiveleno di Firenze 0557947819 (CAV Ospedale Careggi - Firenze)

Centro Antiveleno di Roma 06 3054343 (CAV Policlinico Gemelli - Roma)

Centro Antiveleno di Roma 06 49978000 (CAV Policlinico Umberto I - Roma)

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, Acute Tox. 4, Harmful if swallowed.
- Warning, Skin Irrit. 2, Causes skin irritation.
- Danger, Eye Dam. 1, Causes serious eye damage. Aquatic Chronic 3, Harmful to aquatic life with long lasting effects.

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

Hazard pictograms:



Danger

Hazard statements:

H302 Harmful if swallowed.

H315 Causes skin irritation.

H318 Causes serious eye damage.

H412 Harmful to aquatic life with long lasting effects.

Precautionary statements:

P264 Wash ... Thoroughly after handling.



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P273 Avoid release to the environment.

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

P302+P352 IF ON SKIN: Wash with plenty of water/...

P305+P351+P338+P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor/...

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

Special Provisions:

None

Contains

Guanidine Thiocyanate

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

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. Numb	er	Classification
>= 40% - < 50%	Guanidine Thiocyanate	CAS: EC:	593-84-0 209-812-1	
>= 0.1% - < 0.25%	N-Lauroylsarcosine	CAS: EC:	97-78-9 202-608-3	♦ 3.1/2/Inhal Acute Tox. 2 H330 ♦ 3.2/2 Skin Irrit. 2 H315 ♦ 3.3/2 Eye Irrit. 2 H319 ♦ 3.8/3 STOT SE 3 H335

SECTION 4: First aid measures

4.1. Description of first aid measures

In case of skin contact:

Immediately take off all contaminated clothing.

OBTAIN IMMEDIATE MEDICAL ATTENTION.

Remove contaminated clothing immediatley and dispose off safely.

After contact with skin, wash immediately with soap and plenty of water.

In case of eyes contact:

After contact with the eyes, rinse with water with the eyelids open for a sufficient length of time, then consult an opthalmologist immediately.

Protect uninjured eye.

In case of Ingestion:

Give nothing to eat or drink.

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



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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, inhaltion 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:

Contamined 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



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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.Ä.

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
Color:	white		
Appearance:	liquid		
Odour:	N.A.		
Odour threshold:	N.A.		
pH:	7.20 +/- 0.60		
Melting point / freezing point:	N.A.		
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.		



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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

None in particular.

10.6. Hazardous decomposition products None.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological information of the product:

1ml Preservation Medium For Nucleic Acids Pernasal Flocc. Applic.

a) acute toxicity

The product is classified: Acute Tox. 4 H302

ATEmix - Oral 1367,2 mg/kg

b) skin corrosion/irritation

The product is classified: Skin Irrit. 2 H315

c) serious eye damage/irritation



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The product is classified: Eye Dam. 1 H318

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:

Guanidine Thiocyanate - CAS: 593-84-0

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat = 593 mg/kg Test: LD50 - Route: 1 - Species: Mouse = 300 mg/kg

SECTION 12: Ecological information

12.1. Toxicity

Adopt good working practices, so that the product is not released into the environment.

1ml Preservation Medium For Nucleic Acids Pernasal Flocc. Applic.

The product is classified: Aquatic Chronic 3 - H412

Guanidine Thiocyanate - CAS: 593-84-0

a) Aquatic acute toxicity:

Endpoint: EC50 - Species: Daphnia = 42.4 mg/l - Duration h: 48

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

None

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions. In so doing, comply with the local and national regulations currently in force.

SECTION 14: Transport information

14.1. UN number



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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-Enviromental 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)

Regulation (EU) n. 2017/776 (ATP 10 CLP)

Regulation (EU) n. 2018/699 (ATP 11 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:

H312 Harmful in contact with skin.

H302 Harmful if swallowed.

H332 Harmful if inhaled.

H318 Causes serious eye damage.



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H315 Causes skin irritation.

H412 Harmful to aquatic life with long lasting effects.

EUH032 Contact with acids liberates very toxic gas.

H330 Fatal if inhaled.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

Hazard class and hazard category	Code	Description
Acute Tox. 2	3.1/2/Inhal	Acute toxicity (inhalation), Category 2
Acute Tox. 4	3.1/4/Dermal	Acute toxicity (dermal), Category 4
Acute Tox. 4	3.1/4/Inhal	Acute toxicity (inhalation), Category 4
Acute Tox. 4	3.1/4/Oral	Acute toxicity (oral), Category 4
Skin Irrit. 2	3.2/2	Skin irritation, Category 2
Eye Dam. 1	3.3/1	Serious eye damage, Category 1
Eye Irrit. 2	3.3/2	Eye irritation, Category 2
STOT SE 3	3.8/3	Specific target organ toxicity - single exposure, Category 3
Aquatic Chronic 3	4.1/C3	Chronic (long term) aquatic hazard, category 3

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
Acute Tox. 4, H302	Calculation method
Skin Irrit. 2, H315	Calculation method
Eye Dam. 1, H318	Calculation method
Aquatic Chronic 3, H412	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



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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.