



Copan Italia SPA

UTM 3 ml TUBE IN BULK

Revision nr.5
Dated 04/08/2016
Printed on 04/08/2016
Page n. 1 / 8

EN

Safety data sheet

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

1.1. Product identifier.

Code: **330C** **Cepheid Product Code: NASL-100N-100**
Product name: **UTM 3 ml TUBE IN BULK**
Cepheid Product Name: Nasal Collection Kit (100)

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

Intended use: **Collection and transport media of clinical specimens**

Identified Uses	Industrial.	Professional.	Consumer.
Transport and conservation of clinical specimens for diagnostic analysis	-	✓	-

1.3. Details of the supplier of the safety data sheet.

Name: **Copan Italia SPA**
Full address: **Via Perotti 10**
District and Country: **25125 Brescia (BS)**
Italy
Tel. **0302687200**
Fax. **0302687250**

e-mail address of the competent person responsible for the Safety Data Sheet: **msds@copangroup.com**

Legal Manufacturer: Copan Italia SpA - Italy

1.4. Emergency telephone number.

For urgent inquiries refer to: **+39 0302687200**

SECTION 2. Hazards identification.

2.1. Classification of the substance or mixture.

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to EC Regulation 1907/2006 and subsequent amendments.

Hazard classification and indication: --

2.2. Label elements.

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements:
EUH210 Safety data sheet available on request.

Precautionary statements: --

2.3. Other hazards.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.



Copan Italia SPA

UTM 3 ml TUBE IN BULK

Revision nr.5
Dated 04/08/2016
Printed on 04/08/2016
Page n. 2 / 8

EN

SECTION 3. Composition/information on ingredients.

3.1. Substances.

Information not relevant.

3.2. Mixtures.

Contains:

Identification. x = Conc. %. Classification 1272/2008 (CLP).

WATER

CAS. 7732-18-5 90 ≤ x < 94

EC. 231-791-2

INDEX.

Sucrose

CAS. 57-50-1 6 ≤ x < 7

EC. 200-334-9

INDEX.

POLYETHYLENGLYCOL

CAS. 25322-68-3 0,1 ≤ x < 0,15

EC. 500-038-2

INDEX.

The full wording of hazard (H) phrases is given in section 16 of the sheet.

SECTION 4. First aid measures.

4.1. Description of first aid measures.

Not specifically necessary. Observance of good industrial hygiene is recommended.

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

No episodes of damage to health ascribable to the product have been reported.

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

Information not available.

SECTION 5. Firefighting measures.

5.1. Extinguishing media.

SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

5.2. Special hazards arising from the substance or mixture.

HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

5.3. Advice for firefighters.

GENERAL INFORMATION

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

SECTION 6. Accidental release measures.

6.1. Personal precautions, protective equipment and emergency procedures.

Block the leakage if there is no hazard.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in



Copan Italia SPA

UTM 3 ml TUBE IN BULK

Revision nr.5
Dated 04/08/2016
Printed on 04/08/2016
Page n. 3 / 8

EN

SECTION 6. Accidental release measures. ... / >>

emergency procedures.

6.2. Environmental precautions.

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

6.3. Methods and material for containment and cleaning up.

Collect the leaked product into a suitable container. If the product is flammable, use explosion-proof equipment. Evaluate the compatibility of the container to be used, by checking section 10. Absorb the remainder with inert absorbent material.

Make sure the leakage site is well aired. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

6.4. Reference to other sections.

Any information on personal protection and disposal is given in sections 8 and 13.

SECTION 7. Handling and storage.

7.1. Precautions for safe handling.

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use.

7.2. Conditions for safe storage, including any incompatibilities.

Keep the product in clearly labelled containers. Keep containers away from any incompatible materials, see section 10 for details.

7.3. Specific end use(s).

Product Pack Insert may be available, ask to legal manufacture.

SECTION 8. Exposure controls/personal protection.

8.1. Control parameters.

Information not available.

8.2. Exposure controls.

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration. Personal protective equipment must be CE marked, showing that it complies with applicable standards.

HAND PROTECTION

Protect hands with category III work gloves (see standard EN 374).

The following should be considered when choosing work glove material: compatibility, degradation, failure time and permeability.

The work gloves' resistance to chemical agents should be checked before use, as it can be unpredictable. The gloves' wear time depends on the duration and type of use.

SKIN PROTECTION

Wear category I professional long-sleeved overalls and safety footwear (see Directive 89/686/EEC and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

EYE PROTECTION

Wear airtight protective goggles (see standard EN 166).

RESPIRATORY PROTECTION

If the threshold value (e.g. TLV-TWA) is exceeded for the substance or one of the substances present in the product, use a mask with a type B filter whose class (1, 2 or 3) must be chosen according to the limit of use concentration. (see standard EN 14387). In the presence of gases or vapours of various kinds and/or gases or vapours containing particulate (aerosol sprays, fumes, mists, etc.) combined filters are required.

Respiratory protection devices must be used if the technical measures adopted are not suitable for restricting the worker's exposure to the threshold values considered. The protection provided by masks is in any case limited.

If the substance considered is odourless or its olfactory threshold is higher than the corresponding TLV-TWA and in the case of an emergency, wear open-circuit compressed air breathing apparatus (in compliance with standard EN 137) or external air-intake breathing apparatus (in compliance with standard EN 138). For a correct choice of respiratory protection device, see standard EN 529.

ENVIRONMENTAL EXPOSURE CONTROLS.

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.



SECTION 9. Physical and chemical properties.

9.1. Information on basic physical and chemical properties.

Appearance	liquid
Colour	orange
Odour	Not available.
Odour threshold.	Not available.
pH.	7,25 - 7,35 a 20°C-25°C
Melting point / freezing point.	Not available.
Initial boiling point.	Not available.
Boiling range.	Not available.
Flash point.	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Lower inflammability limit.	Not available.
Upper inflammability limit.	Not available.
Lower explosive limit.	Not available.
Upper explosive limit.	Not available.
Vapour pressure.	Not available.
Vapour density	Not available.
Relative density.	Not available.
Solubility	Not available.
Partition coefficient: n-octanol/water	Not available.
Auto-ignition temperature.	Not available.
Decomposition temperature.	Not available.
Viscosity	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

9.2. Other information.

Total solids (250°C / 482°F)	9,19 %
VOC (Directive 2010/75/EC) :	0
VOC (volatile carbon) :	0

SECTION 10. Stability and reactivity.

10.1. Reactivity.

There are no particular risks of reaction with other substances in normal conditions of use.

POLYETHYLENGLYCOL

POLYETHYLENGLYCOL: decomposes slowly at high temperatures in the presence of air.

10.2. Chemical stability.

The product is stable in normal conditions of use and storage.

10.3. Possibility of hazardous reactions.

No hazardous reactions are foreseeable in normal conditions of use and storage.

10.4. Conditions to avoid.

None in particular. However the usual precautions used for chemical products should be respected.

10.5. Incompatible materials.

Sucrose

Incompatible with: strong oxidising agents.

POLYETHYLENGLYCOL

POLYETHYLENGLYCOL: avoid contact with oxidising agents and concentrated inorganic acids.

10.6. Hazardous decomposition products.

Information not available.



SECTION 11. Toxicological information.

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

11.1. Information on toxicological effects.

ACUTE TOXICITY.

LC50 (Inhalation - vapours) of the mixture:	Not classified (no significant component).
LC50 (Inhalation - mists / powders) of the mixture:	Not classified (no significant component).
LD50 (Oral) of the mixture:	Not classified (no significant component).
LD50 (Dermal) of the mixture:	Not classified (no significant component).

Sucrose LD50 (Oral).	29700 mg/kg
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POLYETHYLENGLYCOL LD50 (Oral).	> 50000 mg/kg ratto
LD50 (Dermal).	> 20000 mg/kg coniglio

SKIN CORROSION / IRRITATION.

Does not meet the classification criteria for this hazard class.

SERIOUS EYE DAMAGE / IRRITATION.

Does not meet the classification criteria for this hazard class.

RESPIRATORY OR SKIN SENSITISATION.

Does not meet the classification criteria for this hazard class.

GERM CELL MUTAGENICITY.

Does not meet the classification criteria for this hazard class.

CARCINOGENICITY.

Does not meet the classification criteria for this hazard class.

REPRODUCTIVE TOXICITY.

Does not meet the classification criteria for this hazard class.

STOT - SINGLE EXPOSURE.

Does not meet the classification criteria for this hazard class.

STOT - REPEATED EXPOSURE.

Does not meet the classification criteria for this hazard class.

ASPIRATION HAZARD.

Does not meet the classification criteria for this hazard class.

SECTION 12. Ecological information.

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

12.1. Toxicity.

Information not available.

12.2. Persistence and degradability.

POLYETHYLENGLYCOL Solubility in water.	> 10000 mg/l
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12.3. Bioaccumulative potential.



Copan Italia SPA

UTM 3 ml TUBE IN BULK

Revision nr.5
Dated 04/08/2016
Printed on 04/08/2016
Page n. 6 / 8

EN

SECTION 12. Ecological information. ... / >>

POLYETHYLENGLYCOL
Partition coefficient: n-octanol/water. -2,2972
BCF. 3,2

12.4. Mobility in soil.

POLYETHYLENGLYCOL
Partition coefficient: soil/water. 1

12.5. Results of PBT and vPvB assessment.

On the basis of available data, the product does not contain any PBT or vPvB in percentage greater than 0,1%.

12.6. Other adverse effects.

Information not available.

SECTION 13. Disposal considerations.

13.1. Waste treatment methods.

Neat product residues should be considered special non-hazardous waste.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information.

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

14.1. UN number.

Not applicable.

14.2. UN proper shipping name.

Not applicable.

14.3. Transport hazard class(es).

Not applicable.

14.4. Packing group.

Not applicable.

14.5. Environmental hazards.

Not applicable.

14.6. Special precautions for user.

Not applicable.

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

Information not relevant.

SECTION 15. Regulatory information.

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

Seveso Category - Directive 2012/18/EC: None.



Copan Italia SPA

UTM 3 ml TUBE IN BULK

Revision nr.5
Dated 04/08/2016
Printed on 04/08/2016
Page n. 7 / 8

EN

SECTION 15. Regulatory information. ... / >>

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006.
None.

Substances in Candidate List (Art. 59 REACH).

On the basis of available data, the product does not contain any SVHC in percentage greater than 0,1%.

Substances subject to authorisation (Annex XIV REACH).

None.

Substances subject to exportation reporting pursuant to (EC) Reg. 649/2012:

None.

Substances subject to the Rotterdam Convention:

None.

Substances subject to the Stockholm Convention:

None.

Healthcare controls.

Information not available.

15.2. Chemical safety assessment.

No chemical safety assessment has been processed for the mixture and the substances it contains.

SECTION 16. Other information.

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

EUH210 Safety data sheet available on request.

LEGEND:

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- CAS NUMBER: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE NUMBER: Identifier in ESIS (European archive of existing substances)
- CLP: EC Regulation 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX NUMBER: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent bioaccumulative and toxic as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PNEC: Predicted no effect concentration
- REACH: EC Regulation 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA STEL: Short-term exposure limit
- TWA: Time-weighted average exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very Persistent and very Bioaccumulative as for REACH Regulation



Copan Italia SPA

UTM 3 ml TUBE IN BULK

Revision nr.5
Dated 04/08/2016
Printed on 04/08/2016
Page n. 8 / 8

EN

SECTION 16. Other information. ... / >>

- WGK: Water hazard classes (German).

GENERAL BIBLIOGRAPHY

1. Regulation (EU) 1907/2006 (REACH) of the European Parliament
2. Regulation (EU) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 790/2009 (I Atp. CLP) of the European Parliament
4. Regulation (EU) 2015/830 of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- ECHA website

Note for users:

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

Changes to previous review:

The following sections were modified:

01 / 02 / 03 / 06 / 08 / 09 / 10 / 11 / 12 / 14 / 15 / 16.