



PURITAN MEDICAL PRODUCTS COMPANY

Safety Data Sheet EU

10 Jan 2024

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

- 1.1 Product Identifier
Product Name: **Puritan® Opti-Swab® Liquid Amies Collection and Transport System**
Product Number(s): **LA-106, LA-106 US, LA-116, LA-117**
- 1.2 Relevant identified uses of the substance or the mixture and uses advised against
Recommended use:
Puritan® Opti-Swab® Liquid Amies Collection and Transport System is intended for use in the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the patient to the laboratory for bacteriological examination and culture.
- 1.3 Details of the supplier of the safety data sheet
- | | |
|-----------------------------------|--|
| Company Identification: | Contact information: |
| Puritan Medical Products Company | Tel: +1 207-876-3311 |
| P.O. Box 149, 31 School Street | Fax: +1 207-876-3130 |
| Guilford, Maine 04443-0149 U.S.A. | Emergency Contact: National Poison Center 1-800-222-1222 |

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:
None
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

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:
None

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.



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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

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

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

7. Handling and storage

7.1 Precautions for safe handling
Avoid contact with skin and eyes, inhalation of vapors 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 Package Insert may be available; ask the legal manufacturer

8. Exposure controls/personal protection

8.1 Control parameters



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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 to 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

9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

Properties	Value	Method	Notes
Color	N/A	--	--
Appearance	N/A	--	--
Odor	N/A	--	--
Odor threshold	N/A	--	--
pH	7.0-7.6	--	--
Melting point/freezing point	N/A	--	--
Flash point	N/A	--	--
Evaporation rate	N/A	--	--
Solid/gas flammability	N/A	--	--
Upper/lower flammability or explosive limits	N/A	--	--
Vapor pressure	N/A	--	--
Vapor 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	--	--



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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.

11. Toxicology information

- 11.1 Information on toxicological effects
Toxicological information of the product:
Puritan® Opti-Swab® Liquid Amies Collection and Transport System
 - 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 sensitization
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:
N.A.

12. Ecological Information



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- 12.1 Toxicity
Adopt good working practices, so that the product is not released into the environment.
Puritan® Opti-Swab® Liquid Amies Collection and Transport System
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
N.A.
- 12.7 Other adverse effects
None

13. Disposal considerations

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

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.

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)



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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

No Chemical Safety Assessment has been carried out for the mixture.

Substances for which a Chemical Safety Assessment has been carried out:

None

16. Other information

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 responsibility of the user to research and understand safe methods of handling, storing, and disposal of this product. Puritan Medical makes no warranty with respect to such information and assume no liability for any loss or injury, which may result from the use of this information. It is the buyer's responsibility to comply with local, state, and federal regulations concerning use and disposal of this product.

Acronyms:

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.

CLP: Classification, Labeling, Packaging.

DNEL: Derived No Effect Level.

IMDG: International Maritime Code for Dangerous Goods.

PNEC: Predicted No Effect Concentration.

STOT: Specific Target Organ Toxicity.