

SAFETY DATA SHEET

Puritan® PurSafe Plus® Collection & Transport System



PurSafe
PLUS®



Puritan®
Quality since 1919



Puritan Medical Products Co.
31 School Street, P.O. Box 149
Guilford, Maine 04443 USA

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IVD

R_x
ONLY



Puritan® PurSafe Plus® Collection & Transport System (Rx only)

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product Identifier

Product Name: Puritan® PurSafe Plus® Collection & Transport System

Product Number(s): PSP-100, PSP-106, PSP-116, PSP-120

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

Recommended use:

Puritan® PurSafe Plus® is intended for the collection, inactivation, and preservation of human upper respiratory specimens suspected of containing SARS-CoV-2.

1.3 Details of the supplier of the safety data sheet

Company Identification:

Puritan Medical Products Company
P.O. Box 149, 31 School Street
Guilford, Maine 04443-0149 U.S.A.

Contact information:

Tel: +1 207-876-3311
Fax: +1 207-876-3130

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:

Hazard statement(s)

H302+H312+H332.....Harmful if swallowed, in contact with skin or if inhaled.

H314.....Causes severe skin burns and eye damage.

H412.....Harmful to aquatic life with long lasting effects.

Precautionary statement(s)

P260.....Do not breathe dust or mist.

P264.....Wash skin thoroughly after handling.

P270.....Do not eat, drink or smoke when using this product.

P273.....Avoid release to the environment.

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

P301+P310.....IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P303+P361+P353.....IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

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.

P330.....Rinse mouth.

P501.....Dispose of contents/container to an approved waste disposal plant.



2.2 Label elements

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

Hazard pictograms:



Health hazards:

Acute oral toxicity	Category 4
Skin corrosion/irritation	Category 1 C
Serious eye damage/eye irritation	Category 1

Physical Hazards: Not Hazardous

Environmental hazards:

Chronic aquatic hazard	Category 3
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2.3 Other hazards

vPvB Substances: None

PBT Substances: None

HMIS:

Health	3
Flammability	0
Reactivity	0

3. COMPOSITION/INFORMATION ON INGREDIENTS

Component	CAS No.	EC-No	Weight-%
Guanidine thiocyanate	593-84-0	209-812-1	5-15%

4 FIRST-AID MEASURES

4.1 Description of first aid measures

In case of skin contact: Rinse with plenty of water. Immediate medical attention is not required.

In case of eyes contact: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

In case of Ingestion: Not expected to present a significant ingestion hazard under anticipated conditions of normal use. If you feel unwell, seek medical advice.

In case of Inhalation: Not expected to be an inhalation hazard under anticipated conditions of normal use of this material. Consult a physician if necessary.

4.2 Most important symptoms and effects, both acute and delayed

H302.....Harmful if swallowed.

H314.....Causes severe skin burns and eye damage.

H412.....Harmful to aquatic life with long last effects.



4.3 Indication of any immediate medical attention and special treatment needed

IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.

IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water spray. Carbon dioxide (CO₂). Foam. Dry chemical.

Extinguishing media which must not be used for safety reasons: None in particular.

5.2 Special hazards arising from the substance or mixture

Not known.

5.3 Advice for firefighters

Standard procedure for chemical fires.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Ensure adequate ventilation.

Wear personal protection equipment.

Use personal protection equipment.

See protective measures under point 7 and 8.

6.2 Environmental precautions

Should not be released into the environment.

6.3 Methods and material for containment and cleaning up

Soak up with inert absorbent material.

6.4 Reference to other sections

See also section 8.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Use personal protective equipment as required.

No special handling advices are necessary.

7.2 Conditions for safe storage, including any incompatibilities

Keep in a dry, cool and well-ventilated place.

Keep in properly labeled containers.

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

No occupational exposure limit available.

DNEL Exposure Limit Values: N.A.

PNEC Exposure Limit Values: N.A.

8.2 Exposure controls

Eye protection: Tight sealing safety goggles.

Protection for skin: Wear suitable protective clothing.

Protection for hands: Wear suitable gloves.

Glove material: Compatible chemical-resistant gloves.

Respiratory protection: In case of insufficient ventilation, wear respirators and components tested and approved under appropriate government standards.

Environmental exposure controls: Should not be released into the environment.

Appropriate engineering controls: Ensure adequate ventilation, especially in confined areas.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Properties	Value
Color	Clear
Appearance	Liquid
Odor	No data
Odor threshold	No data
pH	4.9-5.5
Melting point/freezing point	No data
Flash point	No data
Evaporation rate	No data
Solid/gas flammability	No data
Upper/lower flammability or explosive limits	No data
Vapor pressure	No data
Vapor density	No data
Relative density	No data
Solubility in water	No data
Solubility in oil	No data
Partition coefficient (n-octanol/water)	No data
Auto-ignition temperature	No data
Decomposition temperature	No data



Viscosity	No data
Explosive properties	No data
Oxidizing properties	No data

9.2. Other information

Properties	Value
Properties	Value
Miscibility	No data
Fat solubility	No data
Conductivity	50-100mS/cm
Substance groups relevant properties	No data

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® PurSafe Plus® Collection & Transport System

a) acute toxicity

Harmful if swallowed.

b) skin corrosion/irritation

Causes skin burns Serious Eye Damage/Eye irritation.

c) serious eye damage/irritation

Data are conclusive but insufficient for classification.

d) respiratory or skin sensitization

Data are conclusive but insufficient for classification.

Data are conclusive but insufficient for classification.



- e) **germ cell mutagenicity**
Data are conclusive but insufficient for classification.
- f) **carcinogenicity**
Data are conclusive but insufficient for classification.
- g) **reproductive toxicity**
Data are conclusive but insufficient for classification.
- h) **STOT-single exposure**
Data are conclusive but insufficient for classification.
- i) **STOT-repeated exposure**
Data are conclusive but insufficient for classification.
- j) **aspiration hazard**
Data are conclusive but insufficient for classification.

Toxicological information of the main substances found in the product:

Chemical Name	LD50 (oral, rat/mouse)	LD50 (dermal, rat/rabbit)	LC50(inhalation, rat/mouse)
Guanidine thiocyanate	593mg/kg	No data available	No data available

12. ECOLOGICAL INFORMATION

12.1 Toxicity

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

Not classified for environmental hazards.

Based on available data, the classification criteria are not met.

12.2 Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5 Results of PBT and vPvB assessment

No information available.

12.6 Endocrine disrupting properties

No information available.

12.7 Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

The generation of waste should be avoided or minimized wherever possible. Empty containers or liners may retain some product residues. This material and its container must be disposed of in accordance with approved disposal technique. Disposal of this product, its solutions or of any by-products, shall comply with the requirements of all applicable local, regional or national/federal regulations.

**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

Not Hazardous.

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)

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 .

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.



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