

Date : 15/05/2017

Version: 4

SAFETY DATA SHEET

Mucolyse

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

1.1 Product identifier

Product name : Mucolyse

Trade name : Mucolyse PL.701

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

Identified uses : Mucolyse is a sputum liquefying agent used to digest and thin out the sputum, thus

enhancing the isolation of organisms responsible for chronic lung disease.

1.3 Details of the supplier of the safety data sheet

Supplier's details : Pro-Lab Diagnostics

20 Mural Street, Unit 4 Richmond Hill, ON Canada L4B 1K3 Tel: +1-905-731-0300 Fax: +1-905-731-0206 www.pro-lab.com

e-mail address of person responsible for this SDS

: support@pro-lab.com

1.4 Emergency telephone number

Emergency telephone number (with hours of

: +44 (0)151 353 1613 -Monday to Friday 9:00 am to 5:00 pm. +44 (0)7714 429 646 -Outside the above hours.

operation)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition : Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Skin Irrit. 2, H315 Eye Irrit. 2, H319

The product is classified as hazardous according to Regulation (EC) 1272/2008 as amended.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements





SECTION 2: Hazards identification

Hazard pictograms

Signal word : Warning

Hazard statements : H319 - Causes serious eye irritation.

H315 - Causes skin irritation.

Precautionary statements

Prevention : P280 - Wear protective gloves. Wear eye or face protection.

P264 - Wash hands thoroughly after handling.

: P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Response

Remove contact lenses, if present and easy to do. Continue rinsing.

Storage : Not applicable. **Disposal** : Not applicable. Supplemental label : Not applicable.

elements

articles

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and

: Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant

fastenings

: Not applicable.

Tactile warning of danger : Not applicable.

2.3 Other hazards

Other hazards which do not result in classification : None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures : Mixture

Product/ingredient name	Identifiers	%	Regulation (EC) No. 1272/2008 [CLP]	Туре
(R*,R*)-1,4-Dimercaptobutane-2,3-diol	EC: 222-468-7 CAS: 3483-12-3	≥10 - <20	Acute Tox. 4, H302 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335 See Section 16 for the full text of the H statements declared above.	[1]

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs, vPvBs or Substances of equivalent concern, or have been assigned a workplace exposure limit and hence require reporting in this section.

Type



SECTION 3: Composition/information on ingredients

- [1] Substance classified with a health or environmental hazard
- [2] Substance with a workplace exposure limit
- [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
- [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
- [5] Substance of equivalent concern
- [6] Additional disclosure due to company policy

Occupational exposure limits, if available, are listed in Section 8.

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact

: Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.

Inhalation

Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Skin contact

: Flush contaminated skin with plenty of water. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion

: Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.

Protection of first-aiders

: No special protection is required.

4.2 Most important symptoms and effects, both acute and delayed

Potential acute health effects

Eye contact: Causes serious eye irritation.

Inhalation : No known significant effects or critical hazards.

Skin contact: Causes skin irritation.

Ingestion: No known significant effects or critical hazards.

Over-exposure signs/symptoms

Eye contact

: Adverse symptoms may include the following:

pain or irritation watering

redness

Inhalation : No known significant effects or critical hazards.

Skin contact: Adverse symptoms may include the following:

irritation redness

Ingestion: No known significant effects or critical hazards.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large

quantities have been ingested or inhaled.

Specific treatments: No specific treatment.





SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing

media

: Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing

: None known.

media

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture : No specific fire or explosion hazard.

Hazardous combustion products

: Decomposition products may include the following materials: carbon dioxide carbon monoxide sulfur oxides phosphorus oxides

5.3 Advice for firefighters

Special protective actions for fire-fighters

: Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

metal oxide/oxides

For non-emergency personnel

: Put on appropriate personal protective equipment.

For emergency responders

: If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

: Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Spill

: Move containers from spill area. Approach the release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

: See Section 1 for emergency contact information. See Section 8 for information on appropriate personal protective equipment. See Section 13 for additional waste treatment information.



SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures

: Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene

: Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Keep container tightly closed. Store between 2°C (36°F) to 8°C (46°F).

7.3 Specific end use(s)

Recommendations
Industrial sector specific
solutions

Not available.Not available.

SECTION 8: Exposure controls/personal protection

The information in this section contains generic advice and guidance. Information is provided based on typical anticipated uses of the product. Additional measures might be required for bulk handling or other uses that could significantly increase worker exposure or environmental releases.

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures

: If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment.

DNELs/DMELs

No DNELs/DMELs available.

PNECs

No PNECs available.

8.2 Exposure controls

Appropriate engineering controls

 Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures

: Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Ensure that eyewash stations and safety showers are close to the workstation location.



SECTION 8: Exposure controls/personal protection

Eye/face protection

: Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Hand protection

: Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection

: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection

: Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection

: Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Environmental exposure controls

: Not normally required for the filter itself.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Appearance

Physical state : Solid. [Pellet.]

Colour : White.

Odour : Not available.

Odour threshold : Not available.

pH : Not available.

Melting point/freezing point : Not available.

Initial boiling point and boiling : Not available.

range

Flash point : Not available.

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

Upper/lower flammability or : Not available.

explosive limits

Vapour pressure : Not available.

Vapour density : Not available.

Relative density : Not available.

Solubility(ies) : Not available.

Partition coefficient: n-octanol/ : Not available.

water

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2015/830 - United Kingdom (UK)



Mucolyse

SECTION 9: Physical and chemical properties

Auto-ignition temperature

Decomposition temperature

temperature : Not available.
: Not available.

Explosive properties
Oxidising properties

Viscosity

Not available.Not available.

: Not available.

9.2 Other information

No additional information.

SECTION 10: Stability and reactivity

10.1 Reactivity : No specific test data related to reactivity available for this product or its ingredients.

10.2 Chemical stability : The product is stable.

10.3 Possibility of hazardous reactions

: Under normal conditions of storage and use, hazardous reactions will not occur.

10.4 Conditions to avoid : No specific data.

10.5 Incompatible materials : Not available.

10.6 Hazardous decomposition products

: Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

There is no data available.

Acute toxicity estimates

Route	ATE value
Oral	3972.2 mg/kg

Irritation/Corrosion

There is no data available.

Sensitisation

There is no data available.

Mutagenicity

There is no data available.

Carcinogenicity

There is no data available.

Reproductive toxicity

There is no data available.

Teratogenicity

There is no data available.

Specific target organ toxicity (single exposure)





SECTION 11: Toxicological information

Product/ingredient name	Category	Route of exposure	Target organs
(R*,R*)-1,4-Dimercaptobutane-2,3-diol	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on likely routes

: Dermal contact. Eye contact. Inhalation. Ingestion.

of exposure

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : No known significant effects or critical hazards.

Skin contact : Causes skin irritation.

Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:

pain or irritation

watering redness

Inhalation : No known significant effects or critical hazards.Skin contact : Adverse symptoms may include the following:

irritation redness

Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Short term exposure

Potential immediate

effects

: No known significant effects or critical hazards.

Potential delayed effects

layed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate

: No known significant effects or critical hazards.

effects

Potential delayed effects: No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.
 Carcinogenicity : No known significant effects or critical hazards.
 Mutagenicity : No known significant effects or critical hazards.
 Teratogenicity : No known significant effects or critical hazards.
 Developmental effects : No known significant effects or critical hazards.
 Fertility effects : No known significant effects or critical hazards.

Other information : Not available.





SECTION 12: Ecological information

12.1 Toxicity

There is no data available.

12.2 Persistence and degradability

There is no data available.

12.3 Bioaccumulative potential

There is no data available.

12.4 Mobility in soil

Soil/water partition coefficient (Koc)

: There is no data available.

Mobility : There is no data available.

12.5 Results of PBT and vPvB assessment

PBT : Not applicable.

vPvB : Not applicable.

12.6 Other adverse effects : No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal

: The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste

: The classification of the product may meet the criteria for a hazardous waste.

Packaging

Methods of disposal

: The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions

: This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.



SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not regulated.	Not regulated.	Not regulated.	Not regulated.
14.2 UN proper shipping name	-	-	-	-
14.3 Transport hazard class(es)	-	-	-	-
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

user

14.6 Special precautions for : Transport within user's premises: always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions : Not applicable.

on the manufacture, placing on the market and use of certain dangerous substances, mixtures and

articles

Other EU regulations

Europe inventory : All components are listed or exempted.

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.



Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2015/830 - United Kingdom (UK)



Mucolyse

SECTION 15: Regulatory information

15.2 Chemical safety assessment

: This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

Abbreviations and acronyms : ATE = Acute Toxicity Estimate

CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No.

1272/20081

DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level

EUH statement = CLP-specific Hazard statement
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number

vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Skin Irrit. 2, H315 Eye Irrit. 2, H319	Calculation method Calculation method

Full text of abbreviated H statements

H302	Harmful if swallowed.
H315	Causes skin irritation.
	Causes serious eye irritation.
H335	May cause respiratory irritation.

Full text of classifications [CLP/GHS]

Eye Irrit. 2, H319 Skin Irrit. 2, H315 STOT SE 3, H335	ACUTE TOXICITY (oral) - Category 4 SERIOUS EYE DAMAGE/EYE IRRITATION - Category 2 SKIN CORROSION/IRRITATION - Category 2 SPECIFIC TARGET ORGAN TOXICITY - SINGLE EXPOSURE
· · · · · · · · · · · · · · · · · · ·	(Respiratory tract irritation) - Category 3

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Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.

Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.

