

Safety Data Sheet

PULMOZYME(R) Inhalation Solution (2.5 mg)

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

1.1. Product identifier

Product name PULMOZYME(R) Inhalation Solution (2.5 mg)
Product code SAP-10054623
Synonyms - PULMOZYME Ampules 2.5 mg/2.5 ml

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

Use - hydrolyzes the DNA present in sputum/mucus of cystic fibrosis patients and reduces viscosity in the lungs, promoting improved clearance of secretions

1.3. Details of the supplier of the safety data sheet

Company information Enquiries: Local representation:
Genentech, Inc.
1 DNA Way
South San Francisco
USA-CA 94080
United States of America

Phone 001-(650) 225-1000
E-Mail info.sds@roche.com
US Chemtrec phone:
(800)-424-9300

1.4. Emergency telephone number

Emergency telephone number US Chemtrec phone: (800)-424-9300

SECTION 2: Hazards identification

Classification of the substance or mixture / Label elements

GHS Classification no classification and labelling according to GHS

Other hazards

Note - no information available

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SECTION 3: Composition/information on ingredients

Characterization 2500 U Dornase alfa, a recombinant human glycoprotein, with other inactive ingredients in 2.5 ml inhalation solution active substance in the class of enzyme *1

Ingredients	Concentration	GHS-Classification (pure ingredient)
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Dornase alfa 143831-71-4	0.1 %	
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*1 referring to: Dornase alfa

SECTION 4: First aid measures

4.1. Description of first aid measures

Eye contact	- rinse immediately with tap water for 10 minutes - open eyelids forcibly
Skin contact	- remove immediately contaminated clothes, wash affected skin with water and soap - do not use any solvents
Inhalation	- remove the casualty to fresh air - in the event of symptoms get medical treatment

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

Note - no information available

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

Note to physician - treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions
Flash point (liquid)	not applicable

5.2. Special hazards arising from the substance or mixture

Specific hazards	- no particular hazards known - Does not present a fire hazard
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SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions - no special precautions required

6.2. Environmental precautions

Environmental protection - no special environmental precautions required

6.3. Methods and material for containment and cleaning up

Methods for cleaning up - collect spilled solutions with inert adsorbent and hand over to waste removal
- flush afterwards with plenty of water

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Technical measures - protected from light

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions - 2 - 8 °C
- protected from light

Validity - after opening the content should be used within a short period
- 24 months, 2 to 8 °C, see "best use before" date stated on the label

Packaging materials - low density polyethylene (LDPE) ampoules
- keep it in the outer carton in order to protect from light
- store only in the original container

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Threshold value (Roche) air - IOEL (Internal Occupational Exposure Limit): 0.0025 mg/m³ *1

8.2. Exposure controls

Respiratory protection - Respiratory protection is recommended as a precaution to minimize exposure. Effective engineering controls are considered to be the primary means to control worker exposure. Respiratory protection should not substitute for feasible engineering controls.
- breathing apparatus in case of aerosol mist formation

Hand protection - protective gloves (eg made of neoprene, nitrile or butyl rubber)

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Eye protection - safety glasses

*1 referring to: Dornase alfa

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Color colorless, clear
Form sterile liquid
aqueous solution
pH value 6.3

9.2. Other information

Note - no information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Note - no information available

10.2. Chemical stability

Stability - does not contain any antimicrobial preservative; the complete contents of the ampoule must be used after opening

10.3. Possibility of hazardous reactions

Note - no information available

10.4. Conditions to avoid

Conditions to avoid - temperatures above 30 °C
- keep refrigerated during transport and do not expose to room temperatures for a total time of 24 hours

10.5. Incompatible materials

Note - no information available

10.6. Hazardous decomposition products

Note - the solution should be discarded if it is cloudy or discolored

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity	- not bioavailable by oral administration	*1
Sensitization	- asymptomatic sensitization via inhalation has been reported	*1
Mutagenicity	- not mutagenic (various in vivo and in vitro test systems)	*1
Carcinogenicity	- no indication for carcinogenicity	*1
Reproductive toxicity	- not teratogenic, not embryotoxic (several species)	*1
Note	- dosage (inhalation): 2.5 mg/d	*1
Potential Health Effects	- Exposure: Inhalation, Ingestion, Skin contact, Eye contact - Acute Effects: May cause conjunctivitis., May cause mucous membrane irritation (inflammation)., May cause respiratory effects., Signs and symptoms may include difficulty in breathing, coughing, wheezing, irritation (inflammation) and respiratory arrest. - Chronic Effects: May cause allergic reactions. - Carcinogenicity: not listed by NTP, IARC or OSHA	

*1 referring to: Dornase alfa

SECTION 12: Ecological information

12.1. Toxicity

Ecotoxicity	- based on the ingredients, no adverse effects on the environment are to be expected	
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12.2. Persistence and degradability

Ready biodegradability	- globular proteins are generally well biodegradable	*1
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12.3. Bioaccumulative potential

Note	- no information available	
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12.4. Mobility in soil

Note	- no information available	
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12.5. Results of PBT and vPvB assessment

Note	- no information available	
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12.6. Other adverse effects

Note - no information available

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste from residues - observe local/national regulations regarding waste disposal

SECTION 14: Transport information

Note - not classified by transport regulations, proper shipping name non-regulated

SECTION 15: Regulatory information

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

TSCA Status - FDA Exemption - not on inventory

Reporting Requirements - The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material.
- In New Jersey, report all releases which are likely to endanger the public health, harm the environment or cause a complaint to the NJDEPE Hotline (1-609-292-5560) and to local officials.
- State and local regulations vary and may impose additional reporting requirements.

SECTION 16: Other information

Note - the recommended dose for use in most cystic fibrosis patients is the contents of one 2.5 mg single-use ampoule inhaled once daily using a recommended nebulizer

Edition documentation - changes from previous version in sections 2, 3, 16

The information in this safety data sheet is based on current scientific knowledge. It should not be taken as expressing or implying any warranty concerning product characteristics.