

PULMOZYME Ampoules 2,5 mg/2,5mlVersion
1.0Revision Date:
06/13/2025Date of last issue: -
Date of first issue: 06/13/2025**SECTION 1. IDENTIFICATION**

Product name : PULMOZYME Ampoules 2,5 mg/2,5ml

Product code : RO045-2087/V01-00

Manufacturer or supplier's details

Company name of supplier : Genentech, Inc.

Address : 1 DNA Way
South San Francisco, CA 94080
USA

Telephone : 001-(650) 225-1000

E-mail address : info.sds@roche.com

Emergency telephone

In case of emergencies: : US CHEMTREC PHONE (800)-424-9300

Recommended use of the chemical and restrictions on use

Recommended use : Formulated pharmaceutical active substance

SECTION 2. HAZARDS IDENTIFICATION**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Dornase alfa	143831-71-4	0.1
Sodium chloride (NaCl)	7647-14-5	0.88
Calcium chloride dihydrate	10035-04-8	0.02
Water	7732-18-5	99

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

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If inhaled	:	If unconscious, place in recovery position and seek medical advice. If symptoms persist, call a physician.
In case of skin contact	:	Wash off with soap and water.
In case of eye contact	:	Remove contact lenses. Protect unharmed eye. If eye irritation persists, consult a specialist.
If swallowed	:	Keep respiratory tract clear. Do not give milk or alcoholic beverages. Never give anything by mouth to an unconscious person. If symptoms persist, call a physician.
Most important symptoms and effects, both acute and delayed	:	None known.
Protection of first-aiders	:	First Aid responders should pay attention to self-protection and use the recommended protective clothing
Notes to physician	:	Treat symptomatically.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during fire fighting	:	No information available.
Hazardous combustion products	:	No hazardous combustion products are known
Further information	:	Standard procedure for chemical fires. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Special protective equipment for fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions,	:	Refer to protective measures listed in sections 7 and 8.
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emergency procedures

Environmental precautions : No special environmental precautions required.

Methods and materials for : Wipe up with absorbent material (e.g. cloth, fleece).
containment and cleaning up : Keep in suitable, closed containers for disposal.**SECTION 7. HANDLING AND STORAGE**Advice on protection against : Normal measures for preventive fire protection.
fire and explosionAdvice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the
application area.Conditions for safe storage : Electrical installations / working materials must comply with
the technological safety standards.

Materials to avoid : No materials to be especially mentioned.

Storage temperature : Protect from heat and light

Further information on : No decomposition if stored and applied as directed.
storage stabilityPackaging material : Suitable material: Plastic container of HDPE, Keep it in the
outer carton in order to protect from light, Stainless steel,
glass**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION****Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Dornase alfa	143831-71-4	IOEL	0.0025 mg/m ³	Roche Industrial Hygiene Committee (RIHC)

Personal protective equipmentRespiratory protection : No personal respiratory protective equipment normally
required.

Hand protection

In case of contact through splashing:

Material : Nitrile rubber

Break through time : > 30 min

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Glove thickness : > 0.11 mm

In case of full contact:

Material : butyl-rubber
Break through time : > 480 min
Glove thickness : > 0.4 mm

Remarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

Eye protection : Safety glasses

Skin and body protection : Protective suit

Hygiene measures : General industrial hygiene practice.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : Aqueous solution, Clear liquid, sterile

Color : colorless

Odor : No data available

Odor Threshold : No data available

pH : 6.3

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

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Density	:	No data available
Solubility(ies)		
Water solubility	:	No data available
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Autoignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	No data available
Oxidizing properties	:	No data available
Particle characteristics		
Particle Size Distribution	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	No data available
Incompatible materials	:	No data available Not applicable
Hazardous decomposition products	:	No data available No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Components:**Dornase alfa:**

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Acute oral toxicity : Remarks: Not bioavailable by oral administration

Sodium chloride (NaCl):

Acute oral toxicity : LD50 Oral (Rat): 3,000 mg/kg

Acute inhalation toxicity : LC50 (Rat): > 42 mg/l
Test atmosphere: dust/mist

Acute dermal toxicity : LD50 Dermal (Rabbit): > 10,000 mg/kg

Calcium chloride dihydrate:Acute oral toxicity : LD50 Oral (Rat, male): 2,120 mg/kg
Test substance: anhydrous substance
Remarks: anhydrous substanceAcute dermal toxicity : LD50 Dermal (Rabbit, male and female): > 5,000 mg/kg
Test substance: anhydrous substance
Remarks: anhydrous substance**Skin corrosion/irritation**

Not classified due to lack of data.

Components:**Sodium chloride (NaCl):**Species : Rabbit
Result : No skin irritation**Calcium chloride dihydrate:**Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Test substance : anhydrous substance**Serious eye damage/eye irritation**

Not classified due to lack of data.

Components:**Sodium chloride (NaCl):**Species : Rabbit
Result : No eye irritation

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Species : Rabbit
Result : Irritating to eyes.
Method : OECD Test Guideline 405
Test substance : anhydrous substance

Respiratory or skin sensitization**Skin sensitization**

Not classified due to lack of data.

Respiratory sensitization

Not classified due to lack of data.

Germ cell mutagenicity

Not classified due to lack of data.

Components:**Dornase alfa:**

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Test Type: Micronucleus test
Result: negative

Sodium chloride (NaCl):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Metabolic activation: with and without metabolic activation
Method: Mutagenicity (micronucleus test)
Result: negative

Genotoxicity in vivo : Test Type: Chromosome aberration test in vitro
Species: Rat (female)
Cell type: Bone marrow
Application Route: Intraperitoneal injection
Method: OECD Test Guideline 475
Result: positive

Calcium chloride dihydrate:

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium
Metabolic activation: Metabolic activation
Method: Mutagenicity (Salmonella typhimurium - reverse mutation assay)

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Result: negative

Test substance: anhydrous substance

Test Type: Microbial mutagenesis assay (Ames test)

Result: negative

Test substance: anhydrous substance

Remarks: Information taken from reference works and the literature.

Test Type: In vitro mammalian cell gene mutation test

Test system: Chinese hamster fibroblasts

Method: OECD Test Guideline 473

Result: negative

Test substance: anhydrous substance

Carcinogenicity

Not classified due to lack of data.

Components:**Dornase alfa:**Species : Rat
Result : negative**IARC** No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.**NTP** No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.**Reproductive toxicity**

Not classified due to lack of data.

Components:**Dornase alfa:**Effects on fetal development : Species: laboratory animal
Result: No teratogenic effects., No embryotoxic effects.**STOT-single exposure**

Not classified due to lack of data.

STOT-repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

Further information**Product:**

Remarks : No data available

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Remarks : anaphylactic reactions may occur following the intravenous application of proteins; rare cases of hypersensitivity have been described with other monoclonal antibodies

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****Sodium chloride (NaCl):**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 7,650 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): 5,840 mg/l
Exposure time: 96 h

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 874 mg/l
aquatic invertebrates Exposure time: 48 h
Test Type: static test

LC50 (Daphnia magna (Water flea)): 4,136 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50: 2,430 mg/l
plants Exposure time: 120 h
Test Type: static test
Method: OECD Test Guideline 201

Toxicity to fish (Chronic : NOEC (Pimephales promelas (fathead minnow)): 252 mg/l
toxicity) Exposure time: 33 d
Test Type: flow-through test
Method: OECD Test Guideline 210
GLP: no

Toxicity to daphnia and other : NOEC (Daphnia): 314 mg/l
aquatic invertebrates Exposure time: 21 d
(Chronic toxicity) Test Type: semi-static test
Method: OECD Test Guideline 211

Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available

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the environment

Calcium chloride dihydrate:

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 4,630 mg/l
Exposure time: 96 h
Test substance: anhydrous substance
Remarks: anhydrous substance

Toxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 2,400 mg/l
aquatic invertebrates : Exposure time: 48 h
Test substance: anhydrous substance
Method: OECD Test Guideline 202
Remarks: anhydrous substance

Toxicity to algae/aquatic : ErC50 (Pseudokirchneriella subcapitata (green algae)): >
plants : 4,000 mg/l
Exposure time: 72 h
Test substance: anhydrous substance
Method: OECD Test Guideline 201

Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to : No data available
the environment

Persistence and degradability**Components:****Dornase alfa:**

Biodegradability : Result: Globular proteins are generally well biodegradable

Sodium chloride (NaCl):

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Calcium chloride dihydrate:

Biodegradability : Remarks: The methods for determining the biological degradability are not applicable to inorganic substances.

Bioaccumulative potential**Components:****Dornase alfa:**

Partition coefficient: n- : Remarks: No data available
octanol/water

Sodium chloride (NaCl):

Partition coefficient: n- : Remarks: Not applicable
octanol/water

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Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : Remarks: Not applicable

Water:

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects**Product:**

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

Additional ecological information : No data available

Components:**Dornase alfa:**

Additional ecological information : Protein with highly specific affinity to a certain antigen; therefore, no appreciable ecotoxic potential is to be expected

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

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Not regulated as a dangerous good

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable

Domestic regulation**49 CFR**

Not regulated as a dangerous good

Special precautions for userRemarks : Not dangerous goods in the meaning of ADR/RID, ADN,
IMDG-Code, ICAO/IATA-DGR

SECTION 15. REGULATORY INFORMATION**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

Components	CAS-No.	Component TPQ (lbs)
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SARA 311/312 Hazards : No SARA Hazards**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM I Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

This product does not contain any priority pollutants related to the U.S. Clean Water Act

US State Regulations**Massachusetts Right To Know****Pennsylvania Right To Know**

Water

7732-18-5

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AIIC	: Not in compliance with the inventory
DSL	: This product contains the following components that are not on the Canadian DSL nor NDSL. Dornase alfa
NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: Not in compliance with the inventory
ISHL	: Not in compliance with the inventory
KECI	: Not in compliance with the inventory
PICCS	: Not in compliance with the inventory
IECSC	: Not in compliance with the inventory
TCSI	: Not in compliance with the inventory
TSCA	: Product contains substance(s) not listed on TSCA inventory.
TECI	: Not in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

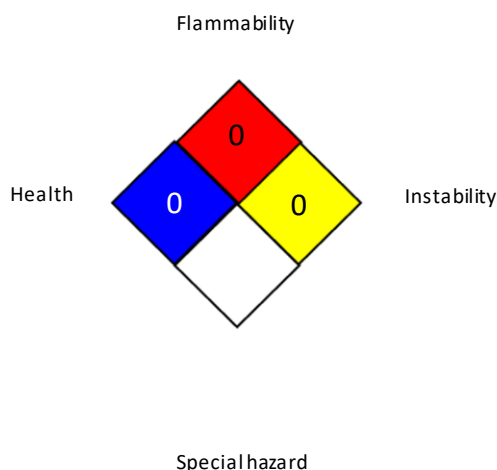
SECTION 16. OTHER INFORMATION**Further information**

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NFPA 704:

HMIS® IV:

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Full text of other abbreviations

AIIIC - Australian Inventory of Industrial Chemicals; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TECL - Thailand Existing Chemicals Inventory; TSCA - Toxic Substances Control Act (United States); UN - United

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Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods;
vPvB - Very Persistent and Very Bioaccumulative

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The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

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