

SAFETY DATA SHEET

Genentech
A Member of the Roche Group

PULMOZYME Ampoules 2,5 mg/2,5ml

Version
1.0

Revision Date:
06/13/2025

Date 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
containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
Keep in suitable, closed containers for disposal.**SECTION 7. HANDLING AND STORAGE**

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Advice 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 storage stability : No decomposition if stored and applied as directed.

Packaging 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 equipment

Respiratory 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

Material : In case of full contact:
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 substance
Acute 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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 874 mg/l
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 plants : EC50: 2,430 mg/l
Exposure time: 120 h
Test Type: static test
Method: OECD Test Guideline 201

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

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia): 314 mg/l
Exposure time: 21 d
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 aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2,400 mg/l
 Exposure time: 48 h
 Test substance: anhydrous substance
 Method: OECD Test Guideline 202
 Remarks: anhydrous substance

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 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 the environment : No data available

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-octanol/water : Remarks: No data available

Sodium chloride (NaCl):

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

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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 user

Remarks : 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)
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 SOCMI 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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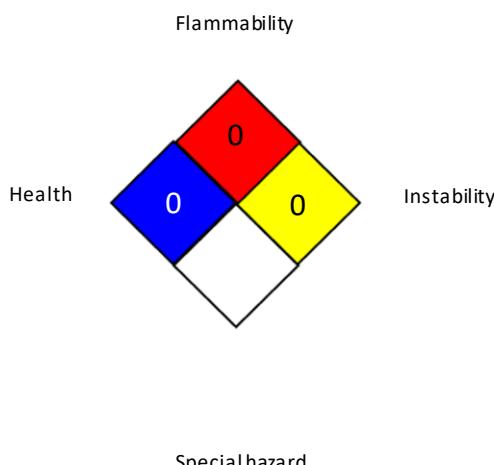
AIIC	:	Not in compliance with the inventory
DSL	:	This product contains the following components that are not on the Canadian DSL nor NDSL. Dornase alfa
NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
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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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

AIIC - 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; TECI - 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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