

according to Regulation (EC) No 1907/2006

1. Identification of the substance/preparation and of the company/undertaking

Product name	Dornase alfa	
Product code	CSE-1040	
Use	<ul style="list-style-type: none">- pharmaceutical active substance- hydrolyzes the DNA present in sputum/mucus of cystic fibrosis patients and reduces viscosity in the lungs, promoting improved clearance of secretions	
Company information	Enquiries: F. Hoffmann-La Roche AG Postfach CH-4070 Basel Switzerland	Local representation:
	Phone +41-61/688 54 80	
	Fax +41-61/681 72 76	
	E-Mail info.sds@roche.com	

2. Hazards identification

Most important hazards - No particular hazards known.

3. Composition/Information on ingredients

Characterization	recombinant human glycoprotein	
Synonyms	<ul style="list-style-type: none">- Deoxyribonuclease- DNase- EC 3.1.21.1- Pulmozyme	*1
CAS number	143831-71-4	
Molecular mass	~ 37000 g/mol	
*1 referring to:	Pulmozyme solution for inhalation	

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4. 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 and keep him/her calm - in the event of symptoms get medical treatment
Note to physician	- treat symptomatically

5. Fire-fighting measures

Suitable extinguishing media	- adapt extinguishing media to surrounding fire conditions
Protection of fire-fighters	- precipitate gases/vapours/mists with water spray

6. Accidental release measures

Methods for cleaning up	- collect solids (avoid dust formation) and hand over to waste removal
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7. Handling and storage

Handling

Suitable materials	- aluminium, glass, enamel, stainless steel, food-approved plastics
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Storage

Storage conditions	- 2 - 8 °C *1
	- protected from light *1
Validity	- see expiry date on the label *1

*1 referring to: Pulmozyme solution for inhalation

8. Exposure controls/Personal protection

Engineering Measures	- see 7.
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Personal protective equipment

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

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9. Physical and chemical properties

Form	freeze-dried powder aqueous solution	*1
Melting temperature	67 °C	
*1 referring to:	Pulmozyme solution for inhalation	

10. Stability and reactivity

Stability	- stable under the conditions mentioned in chapter 7	
Conditions to avoid	- temperatures above 30 °C	
Note	- the solution must be clear and colourless, otherwise it must be disposed of	*1
*1 referring to:	Pulmozyme solution for inhalation	

11. Toxicological information

Acute toxicity	- not bioavailable by oral administration	
Sensitization	- asymptomatic sensitization via inhalation has been reported	
Mutagenicity	- not mutagenic (various in vivo and in vitro test systems)	
Carcinogenicity	- no indication for carcinogenicity	
Reproduction toxicity	- not teratogenic, not embryotoxic (several species)	
Note	- dosage (inhalation): 2.5 mg/d	

12. Ecological information

Ready biodegradability	- globular proteins are generally well biodegradable	
Air pollution	- observe local/national regulations	

13. Disposal considerations

Waste from residues	- observe local/national regulations regarding waste disposal	
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14. Transport information

Note	- not classified by transport regulations	
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15. Regulatory information

Note	- no classification and labelling according to EU directives
Water hazard class (Germany)	1: weakly hazardous for water (own classification according to directive VwVwS of 17.05.1999)

16. Other information

NFPA Rating	- Health: 0 Fire: 1 Reactivity: 0
Edition documentation	- changes from previous version in sections 1, 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.