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

## 1.1. Product identifier

Product name: PULMOZYME® Ampoules 1 mg/ml

Product code: SAP-10054034

## 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: Roche Products Pty Limited
P.O. Box 255
Dee Why, N.S.W. 2099
AUS-Australia
Australia

Phone: 0061-2-9454-9624
Fax: 0061-2-9971-7401
E-Mail: info.sds@roche.com

## 1.4. Emergency telephone number

Emergency telephone number: Phone 0061-2-9454-9624

# SECTION 2: Hazards identification

## 2.1. / 2.2. Classification of the substance or mixture / Label elements

- **GHS Classification**: no classification and labelling according to GHS

- **Australian Remark**:
  - Poisons Schedule - Schedule 4 *1
  - Not listed on the Australian Inventory of Chemical Substances (AICS) *1
  - Listed on the Australian Inventory of Chemical Substances (AICS) *2
  - Listed on the Australian Inventory of Chemical Substances (AICS) *3
2.3. Other hazards

Note - no information available

*1 referring to: Dornase alfa
*2 referring to: Sodium chloride
*3 referring to: Calcium chloride dihydrate

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

Synonyms - PULMOZYME Ampoules 2.5 mg/2.5 ml

<table>
<thead>
<tr>
<th>Ingredient</th>
<th>Concentration</th>
<th>GHS-Classification (pure ingredient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dornase alfa</td>
<td>1 mg/ml</td>
<td></td>
</tr>
<tr>
<td>Sodium chloride</td>
<td>8.77 mg/ml</td>
<td></td>
</tr>
<tr>
<td>Calcium chloride dihydrate</td>
<td>0.15 mg/ml</td>
<td>- Acute toxicity (Category 4), H302</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Serious eye damage/eye irritation (Category 2A), H319</td>
</tr>
</tbody>
</table>

water solution suitable for injection

For the full text of the 'Hazard statements’ mentioned in this Section, see Section 16.

*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 at least 20 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

5.2. Special hazards arising from the substance or mixture

Specific hazards - no particular hazards known
- Does not present a fire hazard

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
PULMOZYME® Ampoules 1 mg/ml

- 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
- breathing apparatus in case of aerosol mist formation
Hand protection
- protective gloves (eg made of neoprene, nitrile or butyl rubber)
Eye protection
- safety glasses

*1 referring to: Dornase alfa

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties
Colour
- colourless, 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

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - not bioavailable by oral administration *1
Local effects - no information available
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
STOT-single exposure - no information available
STOT-repeated exposure - no information available
Aspiration hazard - no information available
Note - dosage (inhalation): 2.5 mg/d *1

*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
12.2. Persistence and degradability

Ready biodegradability - globular proteins are generally well biodegradable *1

12.3. Bioaccumulative potential

Note - no information available

12.4. Mobility in soil

Note - no information available

12.5. Results of PBT and vPvB assessment

Note - no information available

12.6. Other adverse effects

Note - no information available

*1 referring to: Dornase alfa

SECTION 13: Disposal considerations

13.1. Waste treatment methods

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

SECTION 14: Transport information

Australian Remark - ADG Code: This product is not classified as a dangerous good. No special transport conditions are necessary unless required by other regulations.

SECTION 15: Regulatory information

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

Water hazard class (Germany) 1: weakly hazardous for water (according to annex 4 of directive VwVwS of 17.05.1999)

SECTION 16: Other information

Full text of H-Statements referred to under section 3

H302 Harmful if swallowed.
H319 Causes serious eye irritation.
PULMOZYME® Ampoules 1 mg/ml

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 1, 3

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.