

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

SECTION 1: Identification of the substance/mixture and of the company/undertaking**1.1 Product identifier****Trade name:** Ammonium chloride, Pharmpur®, Ph Eur, BP, USP**Article number:** AM0270**CAS Number:**

12125-02-9

EC number:

235-186-4

Index number:

017-014-00-8

Registration number 01-2119487950-27-XXXX**1.2 Relevant identified uses of the substance or mixture and uses advised against****Sector of Use** SU10 Formulation [mixing] of preparations and/or re-packaging (excluding alloys)**Process category**

PROC5 Mixing or blending in batch processes

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

PROC15 Use as laboratory reagent

Application of the substance / the preparation: Laboratory reagent**1.3 Details of the supplier of the safety data sheet****Manufacturer/Supplier:**

Scharlab, S.L.

C/Gato Pérez, 33. Pol.Ind. Mas d'en Cisa

08181 Sentmenat (Barcelona) SPAIN

Tel: (+34) 93 745 64 00 - FAX: (+34) 93 715 27 65

email: scharlab@scharlab.com

Internet Web Site: www.scharlab.com

Regional representation:

Scharlab, S.L.

C/Gato Pérez, 33. Pol.Ind. Mas d'en Cisa

08181 Sentmenat (Barcelona) SPAIN

Tel: (+34) 93 745 64 00 - FAX: (+34) 93 715 27 65

email: scharlab@scharlab.com

Internet Web Site: www.scharlab.com

Further information obtainable from: technical department**1.4 Emergency telephone number:**

Please contact the regional Scharlab distributor/dealer in your country

During normal opening times: Scharlab, S.L. (+34) 93 715 18 11

SECTION 2: Hazards identification**2.1 Classification of the substance or mixture****Classification according to Regulation (EC) No 1272/2008**

GHS07

Acute Tox. 4 H302 Harmful if swallowed.

Eye Irrit. 2 H319 Causes serious eye irritation.

2.2 Label elements**Labelling according to Regulation (EC) No 1272/2008**

The substance is classified and labelled according to the CLP regulation.

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 1)

· Hazard pictograms

GHS07

· Signal word Warning**· Hazard statements**

H302 Harmful if swallowed.

H319 Causes serious eye irritation.

· Precautionary statements

P280 Wear eye protection / face protection.

P264 Wash thoroughly after handling.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P337+P313 If eye irritation persists: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

· 2.3 Other hazards**· Results of PBT and vPvB assessment****· PBT:** Not applicable.**· vPvB:** Not applicable.**SECTION 3: Composition/information on ingredients****· 3.1 Chemical characterisation: Substances****· CAS No. Description**

12125-02-9 ammonium chloride

· Identification number(s)**· EC number:** 235-186-4**· Index number:** 017-014-00-8**SECTION 4: First aid measures****· 4.1 Description of first aid measures****· General information:** Immediately remove any clothing soiled by the product.**· After inhalation:** Supply fresh air; consult doctor in case of complaints.**· After skin contact:**

Generally the product does not irritate the skin.

Immediately wash with water and soap and rinse thoroughly.

· After eye contact:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

In the event that the injured person wears contact lenses, they must be removed as long as they are not stuck to the eyes, otherwise additional damage could occur.

· After swallowing:

Rinse out mouth and then drink plenty of water.

Seek medical treatment.

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

The main symptoms are described for different cases of contact: Skin, eyes, inhalation and ingestion.

Coughing

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 2)

- **4.3 Indication of any immediate medical attention and special treatment needed**
Treat symptomatically.

SECTION 5: Firefighting measures

- **5.1 Extinguishing media**
- **Suitable extinguishing agents:**
The product does not burn by itself.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- **5.2 Special hazards arising from the substance or mixture**
Formation of toxic gases is possible during heating or in case of fire.
Fire may cause evolution of:
Hydrogen chloride (HCl)
Ammonia.
- **5.3 Advice for firefighters**
- **Protective equipment:**
In the work of extinction it is necessary to provide respiratory protection and full chemical protective clothing.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Avoid formation of dust.
Use respiratory protective device against the effects of fumes/dust/aerosol.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
Send for recovery or disposal in suitable receptacles.
Dispose contaminated material as waste according to item 13.
- **6.4 Reference to other sections**
See Section 7 for information on safe handling.
See Section 8 for information on personal protection equipment.
See Section 13 for disposal information.

SECTION 7: Handling and storage

- **7.1 Precautions for safe handling**
Keep receptacles tightly sealed.
Prevent formation of dust.
Ensure good ventilation/exhaustion at the workplace.
Do not eat, drink or smoke during use.
Wash hands after any manipulation.
Wear an individual protective equipment.
Wear chemically sealed goggles and / or face shield.
Avoid contact with eyes and skin.
Have an eye wash bottle or eye shower available at the workplace.
- **Information about fire - and explosion protection:**
No special measures required.
Use only in explosion protected area.
The product is not flammable.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
No special requirements.

(Contd. on page 4)

Safety data sheet according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmapur®, Ph Eur, BP, USP

(Contd. of page 3)

Store in a cool, dry, well-ventilated place.

Store only in unopened original receptacles.

Information about storage in one common storage facility:

Do not store together with strong acids or bases.

Store away from oxidising agents.

Further information about storage conditions:

Keep container tightly sealed.

Avoid sources of heat, radiation, static electricity and contact with food.

7.3 Specific end use(s) No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters**Additional information about design of technical facilities:** No further data; see item 7.**Ingredients with limit values that require monitoring at the workplace:****12125-02-9 ammonium chloride**WEL Short-term value: 20 mg/m³Long-term value: 10 mg/m³**DNELs**

DNEL for workers, cronic. Systematic effects:

- Inhalative: 43.97 mg/m³

- Dermic: 128.9 mg/kg body weight

DNEL consumer, prolonged. Systematic effects:

- Inhalative: 9.4 mg/m³

- Dermic: 55.2 mg/kg body weight

- Oral: 55.2 mg/kg body weight

PNECs

PNEC (Fresh water): 0.25 mg/L

PNEC (Sea water): 0.025 mg/L

PNEC (Freshwater sediments): 0.9 mg/kg

PNEC (Seawater sediments): 0.09 mg/kg

PNEC (Periodic water release): 0.43 mg/L

PNEC (Soil): 50.7 mg/kg

PNEC (Residual water depuration system): 13.1 mg/kg

Additional information: The lists valid during the making were used as basis.**8.2 Exposure controls****Personal protective equipment:****General protective and hygienic measures:**

Keep away from foodstuffs, beverages and feed.

Immediately remove all soiled and contaminated clothing

Wash hands before breaks and at the end of work.

Avoid contact with the eyes.

Avoid contact with the eyes and skin.

Respiratory protection:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation.

Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

(Contd. on page 5)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmapur®, Ph Eur, BP, USP

(Contd. of page 4)

Material of gloves

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye protection:

Tightly sealed goggles

SECTION 9: Physical and chemical properties**9.1 Information on basic physical and chemical properties****General Information****Appearance:****Form:**

Crystalline

Colour:

Colourless

Odour:

Odourless

Odour threshold:

Not determined.

pH-value:(200 g/l H₂O, 25 °C) < 4.7**Change in condition****Melting point/freezing point:**

338 °C

Initial boiling point and boiling range: Undetermined.**Flash point:**

Not applicable.

Flammability (solid, gas):

Product is not flammable.

Decomposition temperature:

Not determined.

Auto-ignition temperature:

Not determined.

Explosive properties:

Product does not present an explosion hazard.

Explosion limits:**Lower:**

Not determined.

Upper:

Not determined.

Vapour pressure at 250 °C:

66 hPa

Density at 20 °C:1.53 g/cm³**Bulk density:**500 kg/m³**Relative density**

Not determined.

Vapour density

Not applicable.

Evaporation rate

Not applicable.

Solubility in / Miscibility with water at 20 °C:

372 g/l

Partition coefficient: n-octanol/water: Not determined.**Viscosity:****Dynamic:**

Not applicable.

Kinematic:

Not applicable.

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmapur®, Ph Eur, BP, USP

(Contd. of page 5)

9.2 Other information

No further relevant information available.

SECTION 10: Stability and reactivity**10.1 Reactivity**

Stable under normal conditions. If used according to the regulation no decomposition occurs.

10.2 Chemical stability**Thermal decomposition / conditions to be avoided:**

No decomposition if used according to specifications.

10.3 Possibility of hazardous reactions

Reacts with alkalis releasing ammonia.

Incompatible with oxidising agents.

10.4 Conditions to avoid

Heat

Exposure to moisture.

10.5 Incompatible materials:

Oxidising agents.

Nitrites and nitrates.

10.6 Hazardous decomposition products:

Hydrogen chloride (HCl)

Ammonia

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Acute toxicity**

Harmful if swallowed.

LD/LC50 values relevant for classification:

Oral LD50 1410 mg/kg (rat)

Dermal LD50 >2000 mg/kg (rat)

Primary irritant effect:**Skin corrosion/irritation** Based on available data, the classification criteria are not met.**Serious eye damage/irritation**

Eyes - Rabbit

Causes serious eye irritation.

Respiratory or skin sensitisation Based on available data, the classification criteria are not met.**Additional toxicological information:****CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)****Germ cell mutagenicity** Based on available data, the classification criteria are not met.**Carcinogenicity** Based on available data, the classification criteria are not met.**Reproductive toxicity** Based on available data, the classification criteria are not met.**STOT-single exposure** Based on available data, the classification criteria are not met.**STOT-repeated exposure** Based on available data, the classification criteria are not met.**Aspiration hazard** Based on available data, the classification criteria are not met.**SECTION 12: Ecological information****12.1 Toxicity****Aquatic toxicity:**

Toxicity to fish

LC50 - Oncorhynchus mykiss (rainbow trout) - 42.91 mg/L - 96 h

Toxicity to daphnia and other aquatic invertebrates

EC50 - Daphnia magna (large sea flea) - 136.6 mg/L - 48 h

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 6)

Toxicity to algae

EC50 - Chlorella vulgaris (fresh water algae) - 2700 mg/l - 18 dias

Bacteria toxicity

CE20 - Activated sludge - 850 mg/L (0.5h)

- **12.2 Persistence and degradability**

Anorganic product, is not eliminable from water by means of biological cleaning processes.

The methods for the determination of biological degradability are not applicable for inorganic substances.

- **12.3 Bioaccumulative potential** Does not accumulate in organisms

- **12.4 Mobility in soil** Absorbed by the soil.

- **Additional ecological information:**

- **General notes:**

Water hazard class 1 (German Regulation) (Assessment by list): slightly hazardous for water

Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

- **12.5 Results of PBT and vPvB assessment**

- **PBT:** Not applicable.

- **vPvB:** Not applicable.

- **12.6 Other adverse effects**

Additional ecological information

Hazard for drinking water supplies.

Discharge into the environment must be avoided.

SECTION 13: Disposal considerations

- **13.1 Waste treatment methods**

- **Recommendation**

Must be specially treated adhering to official regulations.

Must not be disposed together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packaging:**

- **Recommendation:**

Empty contaminated packagings thoroughly. They may be recycled after thorough and proper cleaning.

Packagings that may not be cleansed are to be disposed of in the same manner as the product.

SECTION 14: Transport information

- **14.1 UN-Number**

- **ADR, ADN, IMDG, IATA**

Void

- **14.2 UN proper shipping name**

- **ADR, ADN, IMDG, IATA**

Void

- **14.3 Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class**

Void

- **14.4 Packing group**

- **ADR, IMDG, IATA**

Void

- **14.5 Environmental hazards:**

- **Marine pollutant:**

No

- **14.6 Special precautions for user**

Not applicable.

- **14.7 Transport in bulk according to Annex II of Marpol and the IBC Code**

Not applicable.

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmapur®, Ph Eur, BP, USP• **UN "Model Regulation":**

Void

(Contd. of page 7)

SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I -**
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 65
- **DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment – Annex II**
- Substance is not listed.
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has been carried out.

SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Classification according to Regulation (EC) No 1272/2008**
The classification of the mixture is generally based on the calculation method using substance data according to Regulation (EC) No 1272/2008.
- **Department issuing SDS:** product safety department
- **Contact:** msds@scharlab.com
- **Abbreviations and acronyms:**
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
ICAO: International Civil Aviation Organisation
ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)
IMDG: International Maritime Code for Dangerous Goods
IATA: International Air Transport Association
GHS: Globally Harmonised System of Classification and Labelling of Chemicals
EINECS: European Inventory of Existing Commercial Chemical Substances
CAS: Chemical Abstracts Service (division of the American Chemical Society)
DNEL: Derived No-Effect Level (REACH)
PNEC: Predicted No-Effect Concentration (REACH)
LC50: Lethal concentration, 50 percent
LD50: Lethal dose, 50 percent
PBT: Persistent, Bioaccumulative and Toxic
vPvB: very Persistent and very Bioaccumulative
Acute Tox. 4: Acute toxicity – Category 4
Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

(Contd. on page 9)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 8)

Annex: Exposure scenario 1

- **1 - Short title of the exposure scenario** Industrial use
- **Sector of Use**
SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites
- **Process category**
PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
- **Environmental release category** ERC1 Manufacture of the substance
- **Description of the activities / processes covered in the Exposure Scenario**
See section 1 of the annex to the Safety Data Sheet.
- **2 - Conditions of use**
- **Worker**
8hrs (full working shift).
5 workdays/week.
Supposedly part of the skin exposed : 480 cm² (hands, face)
Long-term.
- **Environment**
No direct exposure.
Indoor use
- **Physical parameters**
- **Physical state** Solid
- **Concentration of the substance in the mixture**
It covers a percentage of substance in the product up to 100 %
- **Other operational conditions** Observe the general safety regulations when handling chemicals.
- **Other operational conditions affecting environmental exposure** No special measures required.
- **Other operational conditions affecting worker exposure**
Avoid contact with the skin, eyes and clothing.
- **Other operational conditions affecting consumer exposure** Keep out of the reach of children.
- **Other operational conditions affecting consumer exposure during the use of the product**
Not applicable.
- **Risk management measures**
- **Worker protection**
- **Organisational protective measures** No special measures required.
- **Technical protective measures**
Ensure that suitable extractors are available on processing machines
- **Personal protective measures** Tightly sealed goggles
- **Measures for consumer protection**
Ensure adequate labelling.
Keep locked up and out of the reach of children.
- **Environmental protection measures**
- **Air** No special measures required.
- **Water** No special measures required.
- **Soil** No special measures required.
- **Disposal measures**
Disposal must be made according to official regulations.
Ensure that waste is collected and contained.
- **Disposal procedures**
Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- **Waste type** Partially emptied and uncleaned packaging
- **3 - Exposure estimation**
- **Worker (dermal)**
PROC2: 1.4 mg/kg/day, RCR 0.01

(Contd. on page 10)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmapur®, Ph Eur, BP, USP

(Contd. of page 9)

PROC9: 6.9 mg/kg/day, RCR 0.05

• **Worker (inhalation)**PROC 2: 0.5 mg/m³, RCR 0.01PROC 9: 5 mg/m³, RCR 0.11• **Environment**

Water: No exposure

Air: No exposure

Soil: No exposure

Purification plant: No exposure

• **Consumer** Not relevant for this Exposure Scenario.• **4 - Guidance for downstream users**

Environment and Health: Used the model ECETOC TRA. If other measures for risk management / operating conditions are adopted, then users should ensure that these risks are at least at equivalent levels.

Whether the downstream user acts within the scope of the Exposure Scenario can be verified based on the information in sections 1 to 8.

(Contd. on page 11)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 10)

Annex: Exposure scenario 2

- **1 - Short title of the exposure scenario** Industrial use. Use as an intermediate.
- **Sector of Use**
 - SU3 Industrial uses: Uses of substances as such or in preparations at industrial sites
 - SU4 Manufacture of food products
 - SU20 Health services
- **Process category**
 - PROC5 Mixing or blending in batch processes
 - PROC14 Tableting, compression, extrusion, pelletisation, granulation
- **Environmental release category** ERC6a Use of intermediate
- **Description of the activities / processes covered in the Exposure Scenario**
See section 1 of the annex to the Safety Data Sheet.
- **2 - Conditions of use**
- **Duration and frequency**
8hrs (full working shift).
5 workdays/week.
- **Environment**
No direct exposure.
Indoor use
- **Physical parameters**
- **Physical state** Solid
- **Concentration of the substance in the mixture**
It covers a percentage of substance in the product up to 100 %
- **Other operational conditions**
- **Other operational conditions affecting environmental exposure** No special measures required.
- **Other operational conditions affecting consumer exposure** Not required.
- **Other operational conditions affecting consumer exposure during the use of the product**
Not applicable.
- **Risk management measures**
- **Worker protection**
- **Organisational protective measures** No special measures required.
- **Personal protective measures**
Avoid contact with the eyes and skin.
Wear suitable protective gloves and protective goggles /face protection during work.
- **Measures for consumer protection** No special measures required.
- **Environmental protection measures**
- **Air** No special measures required.
- **Water** No special measures required.
- **Soil** No special measures required.
- **Disposal measures** Ensure that waste is collected and contained.
- **Disposal procedures** Dispose of product residues with household waste.
- **Waste type** Partially emptied and uncleaned packaging
- **3 - Exposure estimation**
To estimate exposures in the workplace has been used ECETOC TRA tool unless otherwise indicated.
- **Worker (dermal)**
PROC5: 13.7 mg/kg/day, RCR 0.11
PROC14: 3.4 mg/kg/day, RCR 0.03
- **Worker (inhalation)**
PROC 5: 5 mg/m³, RCR 0.11
PROC 14: 1 mg/m³, RCR 0.02
- **Environment**
Water: No exposure
Air: No exposure
Soil: No exposure

(Contd. on page 12)

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 22.06.2022

Version number 12.0

Revision: 22.06.2022

Trade name: Ammonium chloride, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 11)

Purification plant: No exposure

· **Consumer** Not relevant for this Exposure Scenario.· **4 - Guidance for downstream users**

Whether the downstream user uses the substance / the mixture within the scope of the Exposure Scenario can be determined by means of a technical assessment.

Environment and Health: Used the model ECETOC TRA. If other measures for risk management / operating conditions are adopted, then users should ensure that these risks are at least at equivalent levels.

Whether the downstream user acts within the scope of the Exposure Scenario can be verified based on the information in sections 1 to 8.