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Version number 2.0

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

- 1.1 Product identifier
- · Trade name: Sodium carbonate anhydrous, Pharmpur®, Ph Eur, BP, NF
- · Article number: SO0115
- · CAS Number:
- 497-19-8
- · EC number: 207-838-8
- Index number: 011-005-00-2
- Registration number 01-2119485498-19-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

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.

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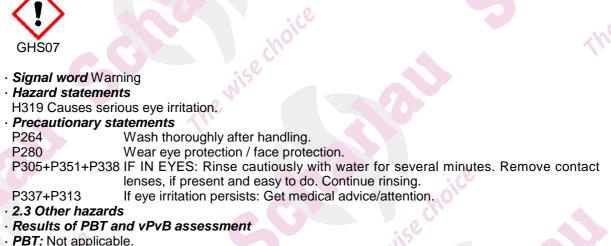
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Hazard pictograms



· vPvB: Not applicable.

SECTION 3: Composition/information on ingredients

- 3.1 Chemical characterisation: Substances CAS No. Description
- 497-19-8 sodium carbonate
- · Identification number(s)
- · EC number: 207-838-8
- · Index number: 011-005-00-2

SECTION 4: First aid measures

- · 4.1 Description of first aid measures
- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- · After eye contact:
- Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- · After swallowing: If symptoms persist consult doctor.
- **4.2** Most important symptoms and effects, both acute and delayed No further relevant information available.
- **4.3** Indication of any immediate medical attention and special treatment needed No further relevant information available.

SECTION 5: Firefighting measures

- · 5.1 Extinguishing media
- Suitable extinguishing agents: CO2, powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
- 5.2 Special hazards arising from the substance or mixture No further relevant information available.

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- · 5.3 Advice for firefighters
- · Protective equipment: No special measures required.

SECTION 6: Accidental release measures

- · 6.1 Personal precautions, protective equipment and emergency procedures Not required.
- · 6.2 Environmental precautions: Do not allow to enter sewers/ surface or ground water.
- · 6.3 Methods and material for containment and cleaning up: Pick up mechanically.
- 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 Prevent formation of dust.
- · Information about fire and explosion protection: No special measures required.
- · 7.2 Conditions for safe storage, including any incompatibilities
- · Storage:
- Requirements to be met by storerooms and receptacles: No special requirements.
 Information about storage in one common storage facility: Not required.
- · Further information about storage conditions: Keep container tightly sealed.
- 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: Not required.
- · 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

· 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.

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- 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:
 - Colour:
- · Odour:
- · Odour threshold:
- · pH-value:
- Change in condition
 Melting point/freezing point: 854 °C
 Initial boiling point and boiling range: Undetermined.
- · Flash point:
- · Flammability (solid, gas):
- Decomposition temperature:
- · Auto-ignition temperature:
- Explosive properties:
- Explosion limits: Lower: Upper:
- · Vapour pressure:
- Density at 20 °C:
- · Bulk density:
- Relative density
- Vapour density
 Evaporation rate
- Solubility in / Missibili
- · Solubility in / Miscibility with water at 20 °C:
- · Partition coefficient: n-octanol/water:

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- Viscosity: Dynamic: Kinematic:
- · 9.2 Other information

Crystalline powder White Odourless Not determined.

11.5

Not applicable.

Product is not flammable.

Not determined.

Not determined.

Product does not present an explosion hazard.

Not determined. Not determined.

Not applicable.

2.533 g/cm³

500-600 kg/m³ Not determined. Not applicable. Not applicable.

212 g/l Not determined.

Not applicable. Not applicable.

No further relevant information available.

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SECTION 10: Stability and reactivity

- · 10.1 Reactivity No further relevant information available.
- · 10.2 Chemical stability
- Thermal decomposition / conditions to be avoided:
- No decomposition if used according to specifications.
- 10.3 Possibility of hazardous reactions No dangerous reactions known.
- 10.4 Conditions to avoid No further relevant information available.
- 10.5 Incompatible materials: No further relevant information available.
- · 10.6 Hazardous decomposition products: No dangerous decomposition products known.

SECTION 11: Toxicological information

- 11.1 Information on toxicological effects
- · Acute toxicity Based on available data, the classification criteria are not met.
- · LD/LC50 values relevant for classification:
- Oral LD50 4090 mg/kg (rat)
- · Primary irritant effect:
- · Skin corrosion/irritation Based on available data, the classification criteria are not met.
- Serious eye damage/irritation
- Causes serious eye irritation.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- Additional toxicological information:
- · CMR effects (carcinogenity, 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: No further relevant information available.
- 12.2 Persistence and degradability No further relevant information available.
- · 12.3 Bioaccumulative potential No further relevant information available.
- · 12.4 Mobility in soil No further relevant information available.
- · 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.

Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

- 12.5 Results of PBT and vPvB assessment
- · PBT: Not applicable.
- · vPvB: Not applicable.
- · 12.6 Other adverse effects No further relevant information available.

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SECTION 13: Disposal considerations

· 13.1 Waste treatment methods

· Recommendation

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

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

SECTION 14: Transport information	
 14.1 UN-Number ADR, ADN, IMDG, IATA 14.2 UN proper shipping name ADR, ADN, IMDG, IATA 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. · UN "Model Regulation": Void 	22

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 -
- 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)
- ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International Carriage of Dangerous Goods by Road)

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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) LC50: Lethal concentration, 50 percent LD50: Lethal dose, 50 percent PBT: Persistent, Bioaccumulative and Toxic vPvB: very Persistent and very Bioaccumulative Eye Irrit. 2: Serious eye damage/eye irritation – Category 2

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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
- Product category PC21 Laboratory chemicals

· Process category

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition

- PROC4 Chemical production where opportunity for exposure arises
- PROC5 Mixing or blending in batch processes

PROC15 Use as laboratory reagent

- Environmental release category
- ERC2 Formulation into mixture
- ERC6a Use of intermediate
- ERC7 Use of functional fluid at industrial site
- **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

5 workdays/week.

8hrs (full working shift).

Physical parameters

- · Physical state Solid
- Concentration of the substance in the mixture Raw material.

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 eyes.

Avoid contact with the skin and mucous membranes.

- Keep locked up.
- Other operational conditions affecting consumer exposure during the use of the product Not applicable.
- · Risk management measures
- Worker protection
- · Organisational protective measures Keep good industrial hygiene.
- · Technical protective measures
- Ensure that suitable extractors are available on processing machines **Personal protective measures**
- Do not inhale dust / smoke / mist.
- Avoid contact with the eyes. Tightly sealed goggles Wear suitable gloves (tested to EN374)
- Use protective suit.
- Measures for consumer protection
 Ensure adequate labelling.
 Keep locked up and out of the reach of children.
- · Environmental protection measures
- Air The exhaust air is lead to a scrubber
- · Water
- Generally, prior to the introduction of wastewater into wastewater treatment plants a neutralisation is required.

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- Soil Prevent contamination of soil.
 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 (inhalation) PROC 2: <1 (mg/m3) PROC 3: <1 (mg/m3) PROC 4: <1 (mg/m3)
- PROC 5: <1 (mg/m3)
- PROC 5. <1 (mg/m3) PROC 15: <1 (mg/m3)

The exposure estimation was carried out in accordance with ECETOC TRA.

Detailed information on the exposure estimation can be found at http://www.ecetoc.org/tra.

Environment

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ERC 2: RCR <1 ERC 6a: RCR <1 ERC 7: RCR <1

Detailed information on the estimation of the environmental exposure can be found at http:// ecb.jrc.ec.europa.eu/euses/.

Consumer Not relevant for this Exposure Scenario.

4 - Guidance for downstream users

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No further relevant information available.

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

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.

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For the risk assessment, the tools recommended by ECHA can be used.

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Annex: Exposure scenario 2

- · 1 Short title of the exposure scenario Laboratory use
- · Sector of Use
- SU22 Professional uses: Public domain (administration, education, entertainment, services, craftsmen)
- Product category PC21 Laboratory chemicals
- Process category PROC15 Use as laboratory reagent
- Environmental release category ERC2 Formulation into mixture 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 5 workdays/week.
- 8hrs (full working shift).
- Physical parameters
- · Physical state Solid
- Concentration of the substance in the mixture Raw material.
- 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 eyes.

Avoid contact with the skin and mucous membranes. Keep locked up.

- Other operational conditions affecting consumer exposure during the use of the product Not applicable.
- · Risk management measures
- · Worker protection
- · Organisational protective measures Keep good industrial hygiene.
- Technical protective measures
- Ensure that suitable extractors are available on processing machines
- Personal protective measures
- Do not inhale dust / smoke / mist.
- Avoid contact with the eyes.
- Tightly sealed goggles
- Wear suitable gloves (tested to EN374) Use protective suit.
- Measures for consumer protection
 Ensure adequate labelling.
- Keep locked up and out of the reach of children.
- Environmental protection measures
- · Air The exhaust air is lead to a scrubber
- · Water

Generally, prior to the introduction of wastewater into wastewater treatment plants a neutralisation is required.

- · Soil Prevent contamination of soil.
- · 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.

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· Waste type Partially emptied and uncleaned packaging

- · 3 Exposure estimation
- · Worker (inhalation)
- PROC 15: <1 (mg/m3)

The exposure estimation was carried out in accordance with ECETOC TRA.

Detailed information on the exposure estimation can be found at http://www.ecetoc.org/tra.

- Environment ERC 2: RCR <1
- ERC 6a: RCR <1 ERC 6b: RCR <1

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Detailed information on the estimation of the environmental exposure can be found at http:// ecb.jrc.ec.europa.eu/euses/.

· Consumer Not relevant for this Exposure Scenario.

- 4 Guidance for downstream users
- No further relevant information available.

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

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.

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For the risk assessment, the tools recommended by ECHA can be used.

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