

Safety data sheet
according to 1907/2006/EC, Article 31 Commission
regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

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

1.1 Product identifier

• **Trade name:** Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmapur®, Ph Eur, BP, USP

• **Article number:** AC0963

• **CAS Number:**
6381-92-6

• **EC number:**
205-358-3

• **Registration number** 01-2119486775-20-XXXX

• **1.2 Relevant identified uses of the substance or mixture and uses advised against**
No further relevant information available.

• **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**



health hazard

STOT RE 2 H373 May cause damage to organs through prolonged or repeated exposure.



Acute Tox. 4 H332 Harmful if inhaled.

2.2 Label elements

• **Labelling according to Regulation (EC) No 1272/2008**

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

(Contd. on page 2)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission
regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 1)

· Hazard pictograms

GHS07 GHS08

- **Signal word** Warning
- **Hazard statements**
H332 Harmful if inhaled.
H373 May cause damage to organs through prolonged or repeated exposure.
- **Precautionary statements**
P260 Do not breathe dust/fume/gas/mist/vapours/spray.
P271 Use only outdoors or in a well-ventilated area.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P312 Call a POISON CENTER/doctor if you feel unwell.
P314 Get medical advice/attention if you feel unwell.
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 Substances**
- **CAS No. Description**
6381-92-6 Ácido etilendiaminotetraacético, EDTA, sal disódica dihidrato
- **Identification number(s)**
- **EC number:** 205-358-3

SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:**
Take affected persons out of danger area and lay down.
Seek medical treatment.
- **After inhalation:** Take affected persons into fresh air and keep quiet.
- **After skin contact:**
Generally the product does not irritate the skin.
Immediately remove contaminated clothing.
- **After eye contact:**
Rinse opened eye for several minutes under running water.
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.
Prevent the affected person from rubbing or closing their eyes.
Protect unharmed eye.
Seek medical treatment.
- **After swallowing:**
Clean mouth with water and drink afterwards plenty of water.
Never give anything by mouth to an unconscious person.
If symptoms persist consult doctor.

(Contd. on page 3)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission
regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 2)

- **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**
Treat symptomatically.

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.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- **5.2 Special hazards arising from the substance or mixture**
Fire may cause evolution of:
Nitrogen oxides (NO_x)
- **5.3 Advice for firefighters**
- **Protective equipment:**
Wear fully protective suit.
Wear self-contained respiratory protective device.
- **Additional information**
Collect contaminated fire fighting water separately. It must not enter the sewage system.
Dispose of fire debris and contaminated fire fighting water in accordance with official regulations.

SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures**
Ensure adequate ventilation
Wear protective clothing.
Avoid formation of dust.
Evacuate and restrict access.
Keep away from ignition sources.
Eliminate all sources of ignition.
- **6.2 Environmental precautions:**
Do not allow to penetrate the ground/soil.
Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**
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**
Avoid breathing mist/vapours/spray.
Do not eat, drink or smoke during use.
Wash hands after any manipulation.
- **Information about fire - and explosion protection:**
Use explosion-proof apparatus / fittings and spark-proof tools.

(Contd. on page 4)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission
regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 3)

- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**
Store in a cool, dry, well-ventilated place.
Store only in unopened original receptacles.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**
See product's label for recommended storage temperature.
- **7.3 Specific end use(s)** No further relevant information available.

SECTION 8: Exposure controls/personal protection

- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:** Not required.
- **DNELs** DNEL worker, cronic. Systematic effects: Inhalative - 1.5 mg/m³
- **PNECs**
PNEC (Fresh water): 2.5 mg/L
PNEC (Sea water): 0.25 mg/L
PNEC (Soil): 0.84 mg/kg
PNEC (Residual water depuration system): 50 mg/kg
- **Additional information:** The lists valid during the making were used as basis.
- **8.2 Exposure controls**
- **Appropriate engineering controls** No further data; see item 7.
- **Individual protection measures, such as personal protective equipment**
- **General protective and hygienic measures:**
Keep away from foodstuffs, beverages and feed.
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **Hand protection**
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.
- **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/face protection** Not required.

SECTION 9: Physical and chemical properties

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Physical state** Solid
- **Colour:** White
- **Odour:** Odourless
- **Odour threshold:** Not determined.

(Contd. on page 5)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 4)

• Melting point/freezing point:	Undetermined.
• Boiling point or initial boiling point and boiling range	Undetermined.
• Flammability	Product is not flammable.
• Lower and upper explosion limit	
• Lower:	Not determined.
• Upper:	Not determined.
• Flash point:	Not applicable.
• Ignition temperature:	>200 °C
• Decomposition temperature:	Not determined.
• pH	4-5
• Viscosity:	
• Kinematic viscosity	Not applicable.
• Dynamic:	Not applicable.
• Solubility	
• water at 20 °C:	100 g/l
• Partition coefficient n-octanol/water (log value)	
• Vapour pressure:	Not determined.
• Density and/or relative density	Not applicable.
• Density:	
• Relative density	Not determined.
• Vapour density	Not applicable.
• 9.2 Other information	
• Appearance:	
• Form:	Dust
• Important information on protection of health and environment, and on safety.	
• Auto-ignition temperature:	Not determined.
• Explosive properties:	Product does not present an explosion hazard.
• Change in condition	
• Evaporation rate	Not applicable.
• Information with regard to physical hazard classes	
• Explosives	Void
• Flammable gases	Void
• Aerosols	Void
• Oxidising gases	Void
• Gases under pressure	Void
• Flammable liquids	Void
• Flammable solids	Void
• Self-reactive substances and mixtures	Void
• Pyrophoric liquids	Void
• Pyrophoric solids	Void
• Self-heating substances and mixtures	Void
• Substances and mixtures, which emit flammable gases in contact with water	Void
• Oxidising liquids	Void
• Oxidising solids	Void
• Organic peroxides	Void
• Corrosive to metals	Void

(Contd. on page 6)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission
regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

• **Desensitised explosives**

Void

(Contd. of page 5)

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

Forms explosive gas mixture with air.

• 10.4 Conditions to avoid

No further relevant information available.

• 10.5 Incompatible materials:

No further relevant information available.

• 10.6 Hazardous decomposition products:

Carbon oxides

Nitrogen oxides (NOx)

SECTION 11: Toxicological information

• 11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

• **Acute toxicity**

Harmful if inhaled.

• **LD/LC50 values relevant for classification:**

Oral LD50 >2,000 mg/kg (rat)

Inhalative LC50/4 h 1-5 mg/l (rat)

• **Skin corrosion/irritation**

Skin - Rabbit

Result: No irritation.

• **Serious eye damage/irritation**

Eyes - Rabbit

Result: No eye irritation

• **Respiratory or skin sensitisation**

Maximisation test - Guinea pig

Result: negative

• **STOT-repeated exposure**

May cause damage to organs through prolonged or repeated exposure.

• 11.2 Information on other hazards

• **Endocrine disrupting properties**

Substance is not listed.

SECTION 12: Ecological information

• 12.1 Toxicity

• **Aquatic toxicity:**

Toxicity to fish

CL50 - Danio rerio (pez zebra) - >>100 mg/l (96h)

NOEC - Danio rerio (zebra fish) - >>25.7 mg/l (35d)

Toxicity to daphnia and other aquatic invertebrates

EC50 - Daphnia magna (large sea flea) - 140 mg/L - 48 h

NOEC - Daphnia magna (large sea flea) - >25 mg/L - 21h

Toxicity to bacteria

EC50 static test - Activated sludge - >500 mg/L - 0.5 min

• **12.2 Persistence and degradability**

The product is biodegradable after prolonged adaptation.

• **12.3 Bioaccumulative potential**

Due to the distribution coefficient n-octanol/water an accumulation in organisms is not expected.

(Contd. on page 7)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 6)

- **12.4 Mobility in soil** No absorption in soils or sediments.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **12.6 Endocrine disrupting properties**
The product does not contain substances with endocrine disrupting properties.
- **12.7 Other adverse effects**
- **Additional ecological information:**
- **General notes:**
Water hazard class 2 (German Regulation) (Assessment by list): hazardous for water
Do not allow product to reach ground water, water course or sewage system.
Danger to drinking water if even small quantities leak into the ground.

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.

SECTION 14: Transport information

- | | |
|---|-----------------|
| • 14.1 UN number or ID 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 Maritime transport in bulk according to IMO instruments | Not applicable. |
| • UN "Model Regulation": | Void |

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 -**

(Contd. on page 8)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission
regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 7)

- **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.

- **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)

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 (UK REACH)

PNEC: Predicted No-Effect Concentration (UK 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

STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2

(Contd. on page 9)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission
regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, 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
- **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
- **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**
- **Other operational conditions affecting environmental exposure** No special measures required.
- **Other operational conditions affecting consumer exposure** No special measures required.
- **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.
For special applications, it is recommended to verify the chemical resistance of the above stated protective gloves with the manufacturer.
The appropriate type of chemical protective glove has to be selected specifically, depending on the concentration and quantity of hazardous substances in the workplace.
- **Technical protective measures**
Ensure that suitable extractors are available on processing machines
- **Personal protective measures**
Protective work clothing
Wear suitable protective gloves and protective goggles /face protection during work.
Check protective gloves prior to each use for their proper condition.
Avoid contact with the skin.
Do not inhale dust / smoke / mist.
- **Measures for consumer protection** Ensure adequate labelling.
- **Environmental protection measures**
- **Air** No special measures required.
- **Water** No special measures required.
- **Soil** No special measures required.

(Contd. on page 10)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission
regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 9)

- **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: 0.33 (mg/m³)

PROC 3: 0.67 (mg/m³)

PROC 4: 0.33 (mg/m³)

PROC 5: 0.33 (mg/m³)

PROC 15: 0.33 (mg/m³)

- **Environment**

Water: No exposure

Soil: No exposure

Purification plant: No exposure

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**

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.

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

(Contd. on page 11)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 10)

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**
PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions.
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
PROC5 Mixing or blending in batch processes
PROC6 Calendering operations
PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
PROC10 Roller application or brushing
PROC13 Treatment of articles by dipping and pouring
PROC14 Tableting, compression, extrusion, pelletisation, granulation
PROC15 Use as laboratory reagent
PROC17 Lubrication at high energy conditions in metal working operations
PROC18 General greasing /lubrication at high kinetic energy conditions
PROC19 Manual activities involving hand contact
PROC21 Low energy manipulation and handling of substances bound in/on materials or articles
- **Environmental release category**
ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
ERC8b Widespread use of reactive processing aid (no inclusion into or onto article, indoor)
ERC8c Widespread use leading to inclusion into/onto article (indoor)
ERC8d Widespread use of non-reactive processing aid (no inclusion into or onto article, outdoor)
ERC8e Widespread use of reactive processing aid (no inclusion into or onto article, outdoor)
ERC8f Widespread use leading to inclusion into/onto article (outdoor)
ERC9a Widespread use of functional fluid (indoor)
ERC9b Widespread use of functional fluid (outdoor)
- **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**
Regional use tonnage (tons/year): 12
Maximum daily tonnage of the place (kg / day): 39
Emission days (days/year): 300
- **Worker**
Regular use with exposure up to 8 hrs. per workday.
Emission days (days/year): ≤ 365
- **Environment**
Flow rate: 18000 m3/d
Local dissolution factor in fresh water: 10
Local dissolution factor in seawater: 100
Wastewater is to be treated by a municipal STP. Municipal STP discharge rate <2E3 m3/d.
Assumed domestic sewage treatment plant flow ≥ 2000 m3/day.
Estimated substance removal from wastewater via domestic sewage treatment (%): 0

(Contd. on page 12)

Safety data sheet

according to 1907/2006/EC, Article 31 Commission regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 11)

- **Physical parameters** Vapor pressure: < 0.001 Pa
- **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**
- **Other operational conditions affecting environmental exposure** No special measures required.
- **Other operational conditions affecting consumer exposure** No special measures required.
- **Other operational conditions affecting consumer exposure during the use of the product**
Not applicable.
- **Risk management measures**
- **Worker protection**
- **Organisational protective measures**
Handle the substance within a closed system.
Drain transfer lines before decoupling.
Do not exceed normal working hours per worker.
Ensure that the working area is organised, well lit and ventilated, with enough space to handle spilled product.
Clean equipment and the work area every day.
Clear spills immediately.
Keep good industrial hygiene.
Drain and flush the system before opening or servicing the equipment.
- **Technical protective measures**
Ensure that suitable extractors are available on processing machines
Carry out filling operations only at sites with extractors available.
Drain the system before performing running operations or maintenance of equipment.
Ensure good ventilation/exhaustion at the workplace.
When the concentration is > 25%, provide and guarantee exhaust ventilation at the emission and transfer points of the material. Measurement efficiency: 80 %
- **Personal protective measures**
Protective work clothing
Wear suitable protective gloves and protective goggles /face protection during work.
Check protective gloves prior to each use for their proper condition.
Avoid contact with the skin.
Do not inhale dust / smoke / mist.
When the concentration is > 5%, use a disposable mask FFP1 (APF = 4) or better. Efficiency: 75%
- **Measures for consumer protection** Ensure adequate labelling.
- **Environmental protection measures**
- **Air** Emission or discharge factor: 100 %
- **Water** Emission or discharge factor: 100 %
- **Soil** Emission or discharge factor: 20 %
- **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 1: 0.01 mg/m³, RCR 0.01
PROC 2: 0.01 mg/m³, RCR 0.01
PROC 3: 0.1 mg/m³, RCR 0.07
PROC 4: 0.2 mg/m³, RCR 0.13
PROC 5: 0.2 mg/m³, RCR 0.13

(Contd. on page 13)

Safety data sheet
according to 1907/2006/EC, Article 31 Commission
regulation (EU) 2020/878

Printing date 08.03.2023

Version number 7.0 (replaces version 6.0)

Revision: 08.03.2023

Trade name: Ethylenediaminetetraacetic acid, EDTA, disodium salt, dihydrate, Pharmpur®, Ph Eur, BP, USP

(Contd. of page 12)

PROC 6: 0.2 mg/m³, RCR 0.13PROC 8a: 0.5 mg/m³, RCR 0.33PROC 8b: 0.5 mg/m³, RCR 0.33PROC 9: 0.5 mg/m³, RCR 0.33PROC 10: 0.5 mg/m³, RCR 0.33PROC 13: 0.5 mg/m³, RCR 0.33PROC 14: 0.2 mg/m³, RCR 0.13PROC 15: 0.1 mg/m³, RCR 0.07PROC 17: 0.5 mg/m³, RCR 0.33PROC 18: 0.25 mg/m³, RCR 0.17PROC 19: 0.5 mg/m³, RCR 0.33PROC 21: 0.6 mg/m³, RCR 0.4**Environment**

ERC8d: Fresh water 2 mg/L, RCR 0.8

ERC8d: Sea water 0.2 mg/L, RCR 0.8

ERC8d: Soil 19.6 mg/kg, RCR 0.084

The maximum exposure to expect on sewage treatment plants 19.6 mg/L mg/L. RCR: 0.39

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

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.

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