



Safety Data Sheet

according to Regulation (EC) No. 1907/2006 (REACH)

EDTA disodium salt dihydrate pure EP, USP (pharma grade)

Version number: GHS 1.0

Date of compilation: 2021-01-04

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

1.1 Product identifier

Identification of the substance	EDTA disodium salt dihydrate pure EP, USP (pharma grade)
Registration number (REACH)	01-2119486775-20-XXXX
CAS number	6381-92-6
Article number	LC-5658

1.2 Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses	General use
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1.3 Details of the supplier of the safety data sheet

NeoFroxx GmbH
Marie-Curie-Str. 3
D-64683 Einhausen
Germany

Telephone: +49 (6251) 989 24 - 0
e-mail: info@neofroxx.com
Website: neofroxx.com

e-mail (competent person) info@neofroxx.com (neoFroxx GmbH)

1.4 Emergency telephone number

Poison centre			
Country	Name	Postal code/city	Telephone
United Kingdom	National Poisons Information Service		111

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 (CLP)

Section	Hazard class	Category	Hazard class and category	Hazard statement
3.1I	acute toxicity (inhal.)	4	Acute Tox. 4	H332
3.9	specific target organ toxicity - repeated exposure	2	STOT RE 2	H373

For full text of abbreviations: see SECTION 16.

The most important adverse physicochemical, human health and environmental effects

Delayed or immediate effects can be expected after short or long-term exposure.

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 (CLP)

- Signal word warning



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- Pictograms

GHS07, GHS08



- 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 CENTRE/doctor if you feel unwell.

P501

Dispose of contents/container to industrial combustion plant.

2.3 Other hazards

Results of PBT and vPvB assessment

According to the results of its assessment, this substance is not a PBT or a vPvB.

SECTION 3: Composition/information on ingredients

3.1 Substances

Name of substance

EDTA disodium salt dihydrate pure EP, USP
(pharma grade)

Identifiers

REACH Reg. No

01-2119486775-20-XXXX

CAS No

6381-92-6

EC No

205-358-3

Molecular formula

$C_{10}H_{14}N_2Na_2O_8 \cdot 2H_2O$

Molar mass

372.2 g/mol

SECTION 4: First aid measures

4.1 Description of first aid measures

General notes

Do not leave affected person unattended. Remove victim out of the danger area. Keep affected person warm, still and covered. Take off immediately all contaminated clothing. In all cases of doubt, or when symptoms persist, seek medical advice. In case of unconsciousness place person in the recovery position. Never give anything by mouth.

Following inhalation

If breathing is irregular or stopped, immediately seek medical assistance and start first aid actions. Provide fresh air.

Following skin contact

Brush off loose particles from skin. Rinse skin with water/shower.

Following eye contact

Remove contact lenses, if present and easy to do. Continue rinsing. Irrigate copiously with clean, fresh water for at least 10 minutes, holding the eyelids apart.



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Following ingestion

Rinse mouth with water (only if the person is conscious). Do NOT induce vomiting.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and effects are not known to date.

4.3 Indication of any immediate medical attention and special treatment needed

none

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media

Water, Foam, Alcohol resistant foam, ABC-powder

Unsuitable extinguishing media

Water jet

5.2 Special hazards arising from the substance or mixture

Deposited combustible dust has considerable explosion potential.

Hazardous combustion products

Nitrogen oxides (NO_x), Carbon monoxide (CO), Carbon dioxide (CO₂)

5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Co-ordinate firefighting measures to the fire surroundings. Do not allow firefighting water to enter drains or water courses. Collect contaminated firefighting water separately. Fight fire with normal precautions from a reasonable distance.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Remove persons to safety.

For emergency responders

Wear breathing apparatus if exposed to vapours/dust/spray/gases.

6.2 Environmental precautions

Keep away from drains, surface and ground water. Retain contaminated washing water and dispose of it.

6.3 Methods and material for containment and cleaning up

Advice on how to contain a spill

Covering of drains, Take up mechanically

Advice on how to clean up a spill

Take up mechanically.

Other information relating to spills and releases

Place in appropriate containers for disposal. Ventilate affected area.

6.4 Reference to other sections

Hazardous combustion products: see section 5. Personal protective equipment: see section 8. Incompatible materials: see section 10. Disposal considerations: see section 13.



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SECTION 7: Handling and storage

7.1 Precautions for safe handling

Recommendations

- Measures to prevent fire as well as aerosol and dust generation

Use local and general ventilation. Take precautionary measures against static discharge. Use only in well-ventilated areas. Ground/bond container and receiving equipment.

- Specific notes/details

Dust deposits may accumulate on all deposition surfaces in a technical room. The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

Advice on general occupational hygiene

Wash hands after use. Do not eat, drink and smoke in work areas. Remove contaminated clothing and protective equipment before entering eating areas. Never keep food or drink in the vicinity of chemicals. Never place chemicals in containers that are normally used for food or drink. Keep away from food, drink and animal feedingstuffs.

7.2 Conditions for safe storage, including any incompatibilities

Managing of associated risks

- Explosive atmospheres

Removal of dust deposits.

- Ventilation requirements

Keep any substance that emits harmful vapours or gases in a place that allows these to be permanently extracted. Use local and general ventilation.

7.3 Specific end use(s)

See section 16 for a general overview.

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Occupational exposure limit values (Workplace Exposure Limits)											
Country	Name of agent	CAS No	Identifier	TWA [ppm]	TWA [mg/m ³]	STEL [ppm]	STEL [mg/m ³]	Ceiling-C [ppm]	Ceiling-C [mg/m ³]	Notation	Source
GB	dust		WEL		10					i	EH40/2005
GB	dust		WEL		4					r	EH40/2005

Notation

Ceiling-C

ceiling value is a limit value above which exposure should not occur

i

inhalable fraction

r

respirable fraction

STEL

short-term exposure limit: a limit value above which exposure should not occur and which is related to a 15-minute period (unless otherwise specified)

TWA

time-weighted average (long-term exposure limit): measured or calculated in relation to a reference period of 8 hours
time-weighted average (unless otherwise specified)



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Human health values

Relevant DNELs and other threshold levels				
Endpoint	Threshold level	Protection goal, route of exposure	Used in	Exposure time
DNEL	1.5 mg/m ³	human, inhalatory	worker (industry)	chronic - local effects
DNEL	3 mg/m ³	human, inhalatory	worker (industry)	acute - local effects

Environmental values

Relevant PNECs and other threshold levels				
Endpoint	Threshold level	Organism	Environmental compartment	Exposure time
PNEC	2.2 mg/l	aquatic organisms	freshwater	short-term (single instance)
PNEC	0.22 mg/l	aquatic organisms	marine water	short-term (single instance)
PNEC	43 mg/l	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)

8.2 Exposure controls

Appropriate engineering controls

General ventilation.

Individual protection measures (personal protective equipment)

Eye/face protection

Wear eye/face protection.

Skin protection

- Hand protection

Wear protective gloves.

- Type of material

NBR: acrylonitrile-butadiene rubber

- Material thickness

min. 0,11 mm

- Breakthrough times of the glove material

>480 minutes (permeation: level 6)

- Other protection measures

Take recovery periods for skin regeneration. Preventive skin protection (barrier creams/ointments) is recommended. Wash hands thoroughly after handling.

Respiratory protection

Particulate filter device (EN 143). P2 (filters at least 94 % of airborne particles, colour code: White).

Environmental exposure controls

Use appropriate container to avoid environmental contamination. Keep away from drains, surface and ground water.



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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	solid
Colour	white
Odour	characteristic
Melting point/freezing point	110 °C
Boiling point or initial boiling point and boiling range	not determined
Flammability	this material is combustible, but will not ignite readily
Lower and upper explosion limit	not determined
Flash point	not applicable
Auto-ignition temperature	not determined
Decomposition temperature	not relevant
pH (value)	4 – 5 (in aqueous solution: 50 g/l, 20 °C)
Kinematic viscosity	not relevant

Solubility(ies)

Water solubility	100 g/l at 20 °C
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Partition coefficient

Partition coefficient n-octanol/water (log value)	this information is not available
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Vapour pressure	not determined
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Density and/or relative density

Density	not determined
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Particle characteristics	no data available
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9.2 Other information

Information with regard to physical hazard classes	hazard classes acc. to GHS (physical hazards): not relevant
Other safety characteristics	there is no additional information

SECTION 10: Stability and reactivity

10.1 Reactivity

Concerning incompatibility: see below "Conditions to avoid" and "Incompatible materials".

10.2 Chemical stability

Crystal water release on heating.

10.3 Possibility of hazardous reactions

Strong oxidiser.

10.4 Conditions to avoid

Strong heating.

Hints to prevent fire or explosion

The product in the delivered form is not dust explosion capable; the enrichment of fine dust however leads to the danger of dust explosion.

10.5 Incompatible materials

Oxidisers, Aluminium, Copper, Copper alloys, Nickel, Zinc

10.6 Hazardous decomposition products

Reasonably anticipated hazardous decomposition products produced as a result of use, storage, spill and heating are not known. Hazardous combustion products: see section 5.

SECTION 11: Toxicological information

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

Classification according to GHS (1272/2008/EC, CLP)

Acute toxicity

Harmful if inhaled.

GHS of the United Nations, annex 4: May be harmful if swallowed.

- Acute toxicity estimate (ATE)

Inhalation: dust/mist 1.5 mg/l/4h

Skin corrosion/irritation

Shall not be classified as corrosive/irritant to skin.

Serious eye damage/eye irritation

Shall not be classified as seriously damaging to the eye or eye irritant.

Respiratory or skin sensitisation

Shall not be classified as a respiratory or skin sensitiser.

Germ cell mutagenicity

Shall not be classified as germ cell mutagenic.



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Carcinogenicity

Shall not be classified as carcinogenic.

Reproductive toxicity

Shall not be classified as a reproductive toxicant.

Specific target organ toxicity - single exposure

Shall not be classified as a specific target organ toxicant (single exposure).

Specific target organ toxicity - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Aspiration hazard

Shall not be classified as presenting an aspiration hazard.

11.2 Information on other hazards

There is no additional information.

SECTION 12: Ecological information

12.1 Toxicity

Shall not be classified as hazardous to the aquatic environment.

12.2 Persistence and degradability

Data are not available.

12.3 Bioaccumulative potential

Data are not available.

BCF	1.8 (ECHA)
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12.4 Mobility in soil

Data are not available.

12.5 Results of PBT and vPvB assessment

Data are not available.

12.6 Endocrine disrupting properties

Not listed.

12.7 Other adverse effects

Data are not available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Sewage disposal-relevant information

Do not empty into drains. Avoid release to the environment. Refer to special instructions/safety data sheets.

Waste treatment of containers/packagings

Completely emptied packages can be recycled. Handle contaminated packages in the same way as the substance itself.



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Remarks

Please consider the relevant national or regional provisions. Waste shall be separated into the categories that can be handled separately by the local or national waste management facilities.

SECTION 14: Transport information

- 14.1 UN number** not subject to transport regulations
- 14.2 UN proper shipping name** not assigned
- 14.3 Transport hazard class(es)** none
- 14.4 Packing group** not assigned
- 14.5 Environmental hazards** non-environmentally hazardous acc. to the dangerous goods regulations
- 14.6 Special precautions for user**
There is no additional information.
- 14.7 Maritime transport in bulk according to IMO instruments**
The cargo is not intended to be carried in bulk.

Information for each of the UN Model Regulations

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN) - Additional information

not assigned

International Maritime Dangerous Goods Code (IMDG) - Additional information

Not subject to IMDG.

International Civil Aviation Organization (ICAO-IATA/DGR) - Additional information

Not subject to ICAO-IATA.

SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
- Relevant provisions of the European Union (EU)**
- Restrictions according to REACH, Annex XVII**
not listed
- List of substances subject to authorisation (REACH, Annex XIV) / SVHC - candidate list**
not listed
- Deco-Paint Directive (2004/42/EC)**

VOC content	0 %
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Directive on industrial emissions (VOCs, 2010/75/EU)

VOC content	0 %
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Water Framework Directive (WFD)

List of pollutants (WFD)			
Name of substance	CAS No	Listed in	Remarks
EDTA disodium salt dihydrate pure EP, USP (pharma grade)		A)	

Legend

A) Indicative list of the main pollutants

15.2 Chemical Safety Assessment

No Chemical Safety Assessment has been carried out for this substance.

SECTION 16: Other information

Abbreviations and acronyms

Abbr.	Descriptions of used abbreviations
ADN	Accord européen relatif au transport international des marchandises dangereuses par voies de navigation intérieures (European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways)
ADR	Accord européen relatif au transport international des marchandises dangereuses par route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
BCF	Bioconcentration factor
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
CLP	Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC No	The EC Inventory (EINECS, ELINCS and the NLP-list) is the source for the seven-digit EC number, an identifier of substances commercially available within the EU (European Union)
EH40/2005	EH40/2005 Workplace exposure limits (http://www.nationalarchives.gov.uk/doc/open-government-licence/)
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
GHS	"Globally Harmonized System of Classification and Labelling of Chemicals" developed by the United Nations
IATA	International Air Transport Association
IATA/DGR	Dangerous Goods Regulations (DGR) for the air transport (IATA)
ICAO	International Civil Aviation Organization
IMDG	International Maritime Dangerous Goods Code
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic



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Abbr.	Descriptions of used abbreviations
PNEC	Predicted No-Effect Concentration
ppm	Parts per million
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
RID	Règlement concernant le transport International ferroviaire des marchandises Dangereuses (Regulations concerning the International carriage of Dangerous goods by Rail)
STEL	Short-term exposure limit
SVHC	Substance of Very High Concern
TWA	Time-weighted average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and very Bioaccumulative
WEL	Workplace exposure limit

Key literature references and sources for data

Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures. Regulation (EC) No. 1907/2006 (REACH), amended by 2020/878/EU.

Transport of dangerous goods by road, rail and inland waterway (ADR/RID/ADN). International Maritime Dangerous Goods Code (IMDG). Dangerous Goods Regulations (DGR) for the air transport (IATA).

List of relevant phrases (code and full text as stated in chapter 2 and 3)

Code	Text
H332	Harmful if inhaled.
H373	May cause damage to organs through prolonged or repeated exposure.

Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product. The information is intended to give you guidelines for the safe handling of the product mentioned in this safety data sheet during storage, processing, transport and disposal. The information is not transferable to other products. Insofar as the product is mixed, blended or processed with other materials or is subjected to processing, the information in this safety data sheet cannot be transferred to the new material produced in this way, unless expressly stated otherwise.