

SAFETY DATA SHEET

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

Revision date: 19 Jun 2026

Print date: 19 Jun 2026

Version: 1.1



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CALCINASE EDTA solution

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

1.1 Product identifier

Trade name/designation:

CALCINASE EDTA solution

Other means of identification:

Article No. : 0032301 (50 ml), 0032332 (200 ml), 0032331 (500 ml)

Additional information:

Voluntary safety information following the Safety Data Sheet format according to Regulation (EC) No. 1907/2006 (REACH). As a medical device this product is not subject to Regulation (EC) no. 1272/2008 [CLP] and do not require labeling according this regulation.

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

Use of the substance/mixture:

Medical device for dental application. Observe instructions for use.
for professional use only.

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

lege artis Pharma GmbH + Co. KG

Breitwasenring 1

72135 Dettenhausen

GERMANY

Telephone: +49 (0) 71 57 / 56 45 - 0

Telefax: +49 (0) 71 57 / 56 45 - 50

E-mail: info@legeartis.de

Website: www.legeartis.de

E-mail (competent person): sicherheitsdatenblaetter@legeartis.de

1.4 Emergency phone number

24h: +49 (0) 551 / 192 40, +49 (0) 71 57 / 56 45 - 0 (Only available during office hours.)

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

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

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

2.2 Label elements

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

According to EC directives or the corresponding national regulations the product does not have to be labelled.

Additional information:

As a medical device this product is not subject to Regulation (EC) no. 1272/2008 [CLP] and do not require labeling according this regulation.

2.3 Other hazards

Adverse human health effects and symptoms:

May cause eye irritation. May cause skin irritation.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Description:

EDTA-solution, alkaline

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Ingredients:

Product identifiers	Substance name Classification according to Regulation (EC) No. 1272/2008 [CLP]	Content
CAS No.: 6381-92-6	EDTA disodium salt dihydrate The substance is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].	20 - 40 weight-%
CAS No.: 1310-73-2 EC No.: REACH No.:	sodium hydroxide Eye Dam. 1 (H318), Met. Corr. 1 (H290), Skin Corr. 1A (H314)  Danger Specific concentration limit (SCL) Eye Irrit. 2; H319: $0.5\% \leq C < 2\%$ Skin Irrit. 2; H315: $0.5\% \leq C < 2\%$ Skin Corr. 1A; H314: $C \geq 5\%$ Skin Corr. 1B; H314: $2\% \leq C < 5\%$	< 0.5 weight-%

Full text of H- and EUH-phrases: see section 16.

SECTION 4: First aid measures

4.1 Description of first aid measures

General information:

In case of accident or unwellness, seek medical advice immediately (show directions for use or safety data sheet if possible). Take off contaminated clothing. If unconscious but breathing normally, place in recovery position and seek medical advice. Do not leave affected person unattended.

Following inhalation:

No special measures are necessary.

In case of inhaling spray mist, consult a physician. Provide fresh air.

In case of skin contact:

Gently wash with plenty of soap and water. In case of skin irritation, consult a physician.

After eye contact:

Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.

Following ingestion:

Rinse mouth. Get medical advice/attention if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

May cause eye irritation. May cause skin irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Treat symptomatically.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media:

Co-ordinate fire-fighting measures to the fire surroundings.

5.2 Special hazards arising from the substance or mixture

The product itself does not burn. No special fire protection measures are necessary.

Hazardous combustion products:

In case of fire may be liberated: Gases/vapours, toxic

5.3 Advice for firefighters

Wear a self-contained breathing apparatus and chemical protective clothing. Collect contaminated fire extinguishing water separately. Do not allow entering drains or surface water.

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SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel

Personal precautions:

Avoid breathing dust/fume/gas/mist/vapours/spray. Avoid contact with eyes and skin. Special danger of slipping by leaking/spilling product. Remove persons to safety.

Protective equipment:

Wear protective gloves/protective clothing/eye protection/face protection.

6.1.2 For emergency responders

Personal protection equipment:

Personal protection equipment: see section 8

6.2 Environmental precautions

Do not allow to enter into surface water or drains. Do not allow to enter into soil/subsoil.

6.3 Methods and material for containment and cleaning up

For containment:

Wipe up with absorbent material (eg. cloth, fleece). Handling larger quantities: Absorb with liquid-binding material (sand, diatomaceous earth, acid- or universal binding agents). Collect in closed and suitable containers for disposal.

For cleaning up:

Water (with cleaning agent)

6.4 Reference to other sections

Safe handling: see section 7

Personal protection equipment: see section 8

Disposal: see section 13

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Protective measures

Advices on safe handling:

Avoid contact with eyes and skin. Take off contaminated clothing. Wear personal protection equipment (refer to section 8).

Fire prevent measures:

No special measures are necessary.

Environmental precautions:

Discharge into the environment must be avoided.

Advices on general occupational hygiene

When using do not eat, drink or smoke. Wash hands and face before breaks and after work and take a shower if necessary. Apply skin care products after work.

7.2 Conditions for safe storage, including any incompatibilities

Technical measures and storage conditions:

Keep container tightly closed in a cool, well-ventilated place.

Materials to avoid: metals (including their alloys): Al, Ni, Zn, Sn, Cu.

Recommended storage temperature: 15 - 25 °C

Requirements for storage rooms and vessels:

Floors should be impervious, resistant to liquids and easy to clean. Keep/Store only in original container.

Hints on storage assembly:

Keep away from food, drink and animal feedingstuffs.

7.3 Specific end use(s)

Recommendation:

Medical device for dental application.

Observe instructions for use.

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SECTION 8: Exposure controls / Personal protection

8.1 Control Parameters

8.1.1 Occupational exposure limit values

No data available.

8.1.2 Biological limit values

No data available.

8.1.3 DNEL-/PNEC-values

Substance name	DNEL value	① DNEL type ② Exposure route
sodium hydroxide CAS No.: 1310-73-2 EC No.:	1 mg/m ³	① DNEL worker ② Long-term – inhalation, local effects
sodium hydroxide CAS No.: 1310-73-2 EC No.:	1 mg/m ³	① DNEL consumer ② Long-term – inhalation, local effects

8.2 Exposure controls

8.2.1 Appropriate engineering controls

Technical measures and the application of suitable work processes have priority over personal protection equipment.

8.2.2 Personal protection equipment



Eye/face protection:

Eye glasses with side protection (EN 166).

Skin protection:

Tested protective gloves must be worn (EN ISO 374).

Suitable material: NBR (Nitrile rubber)

Thickness of the glove material: $\geq 0,11$ mm

Breakthrough time: ≥ 480 min

The quality of the protective gloves resistant to chemicals must be chosen as a function of the specific working place concentration and quantity of hazardous substances. The exact breakthrough time must be requested from the protective glove manufacturer and must be observed. Check leak tightness/impermeability prior to use. In the case of wanting to use the gloves again, clean them before taking off and air them well.

Respiratory protection:

Usually no personal respirative protection necessary.

Wear breathing apparatus if exposed to vapours/dusts/aerosols.

Other protection measures:

Wear suitable protective clothing.

8.2.3 Environmental exposure controls

No data available.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state: liquid

Form: liquid

Colour: colourless

Odour: odourless

Flammability: No

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Safety relevant basic data

Parameter	Value	at	① Method ② Remark
pH	7.9 - 8.9	20 °C	
Melting point	< 0 °C		
Freezing point	No data available.		
Initial boiling point and boiling range	> 100 °C		
Flash point	Not applicable.		
Evaporation rate	No data available.		
Auto-ignition temperature	Not applicable.		
Upper/lower Flammability or explosive limits	Not applicable.		
Vapour pressure	No data available.		
Vapour density	No data available.		
Density	1.1 g/mL	20 °C	
Bulk density	Not applicable.		
Water solubility	completely miscible		
Dynamic viscosity	No data available.		
Kinematic viscosity	No data available.		

9.2 Other information

No data available.

SECTION 10: Stability and reactivity

10.1 Reactivity

The product itself does not burn.

10.2 Chemical stability

The product is chemically stable under recommended conditions of storage, use and temperature.

10.3 Possibility of hazardous reactions

No hazardous reaction when handled and stored according to provisions.

10.4 Conditions to avoid

No data available.

10.5 Incompatible materials

Oxidising agent, strong; Acid, concentrated; metals (including their alloys): Al, Ni, Zn, Sn, Cu.

10.6 Hazardous decomposition products

No known hazardous decomposition products. In case of fire may be liberated: Gases/vapours, toxic

SECTION 11: Toxicological information

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

Acute oral toxicity:

Based on available data, the classification criteria are not met.

Acute dermal toxicity:

Based on available data, the classification criteria are not met.

Acute inhalation toxicity:

Based on available data, the classification criteria are not met.

Skin corrosion/irritation:

May cause skin irritation.

Based on available data, the classification criteria are not met.

Serious eye damage/irritation:

May cause eye irritation.

Based on available data, the classification criteria are not met.

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Respiratory or skin sensitisation:

Based on available data, the classification criteria are not met.

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:

aerosol or mist formation: May cause respiratory irritation.

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.

11.2 Information on other hazards

Endocrine disrupting properties:

This product does not contain a substance that has endocrine disrupting properties with respect to humans as no components meets the criteria.

SECTION 12: Ecological information

12.1 Toxicity

Aquatic toxicity:

Based on available data, the classification criteria are not met.

Assessment/classification:

The substance/mixture does not fulfill the criteria of the acute aquatic toxicity according to Regulation (EC) No 1272/2008 [CLP], Annex I. On the basis of existing data about the elimination/degradation and bioaccumulation potential longer term damage to the environment is unlikely.

12.2 Persistence and degradability

Biodegradation:

Some of the components are poorly biodegradable.

12.3 Bioaccumulative potential

Accumulation / Evaluation:

No indication of bioaccumulation potential.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII.

12.6 Endocrine disrupting properties

This product does not contain a substance that has endocrine disrupting properties with respect to non-target organisms as no components meets the criteria.

12.7 Other adverse effects

No data available.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Waste treatment options

Appropriate disposal / Product:

Dispose of waste according to applicable legislation. Consult the appropriate local waste disposal expert about waste disposal.

Appropriate disposal / Package:

Completely emptied packages can be recycled.

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Other disposal recommendations:

The allocation of waste code numbers / waste names must be carried out in accordance with the European Waste Catalogue (EWC). Do not allow to enter into surface water or drains. Collect in closed and suitable containers for disposal. Waste for disposal is to be classified and labelled.

SECTION 14: Transport information

Land transport (ADR/RID)	Inland waterway craft (ADN)	Sea transport (IMDG)	Air transport (ICAO-TI-/IATA-DGR)
14.1 UN number or ID number			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.2 UN proper shipping name			
No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.	No dangerous good in sense of these transport regulations.
14.3 Transport hazard class(es)			
not relevant	not relevant	not relevant	not relevant
14.4 Packing group			
not relevant	not relevant	not relevant	not relevant
14.5 Environmental hazards			
not relevant	not relevant	not relevant	not relevant
14.6 Special precautions for user			
not relevant	not relevant	not relevant	not relevant

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

15.1.1 EU legislation

Authorisations:

Contains no substances listed in REACH Annex XIV.

Restrictions on use:

Contains no substances subject to the restrictions of Annex XVII of the REACH Regulation.

Other regulations (EU):

Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work Observe restrictions to employment for juveniles according to the 'juvenile work protection guideline' (94/33/EC). Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers. Directive 93/42/EEC concerning medical devices.

15.1.2 National regulations

[DE] National regulations

Restrictions of occupation

LGK 12 - Non-combustible liquids that cannot be assigned to any of the above storage classes

Annex Chemikalien-Verbotsverordnung (ChemVerbotsV)

not relevant

Technische Anleitung zur Reinhaltung der Luft (TA-Luft)

Remark:

not relevant

Water hazard class

2 - obviously hazardous to water

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Remark:

Self-classification (mixture; calculation rule).

Technical Rules for Hazardous Substances

TRGS 510 - Storage of hazardous substances in non-stationary containers

Berufsgenossenschaftliche Vorschriften (DGUV-Vorschriften)

DGUV Regel 112-190 (BGR 190): "Benutzung von Atemschutzgeräten"

DGUV Regel 112-192 (BGR 192): "Benutzung von Augen- und Gesichtsschutz"

DGUV Regel 112-195 (BGR 195): "Einsatz von Schutzhandschuhen"

Berufsgenossenschaft Rohstoffe und chemische Industrie (BG RCI), Merkblätter:

A 008 - Persönliche Schutzausrüstungen / A 008-1 - Chemikalienschutzhandschuhe

A 023 - Hand- und Hautschutz

M 050 - Tätigkeiten mit Gefahrstoffen

M 053 - Arbeitsschutzmaßnahmen bei Tätigkeiten mit Gefahrstoffen

M 062 - Lagerung von Gefahrstoffen

15.2 Chemical Safety Assessment

No data available.

SECTION 16: Other information

16.1 Indication of changes

Changes executed in version 1.1:

General revision of all sections

16.2 Abbreviations and acronyms

ADN = Accord européen relatif au transport international des marchandises dangereuses par voie de navigation intérieure

ADR = Accord européen relatif au transport international des marchandises Dangereuses par Route

ATE = acute toxicity estimate

CAS = Chemical Abstracts Service

CLP = Classification, Labelling and Packaging

DMEL = Derived Minimum Effect Level

DNEL = Derived No Effect Level

EC₅₀ = Median effective concentration

ECB = European Chemicals Bureau

EEC = European Economic Community

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

IATA = International Air Transport Association

IBC-Code = International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk

IC₅₀ = Inhibition concentration, 50%

IMDG = International Maritime Code for Dangerous Goods

IUCLID = International Uniform Chemical Information Database

LC₅₀ = Lethal concentration, 50%

LD₅₀ = Median lethal dose

LC0 = lethal concentration, 0%

LOAEL = lowest-observed-adverse-effect level

MARPOL = International Convention for the Prevention of Marine Pollution from Ships

NOAEL = No Observed Adverse Effect Level

NOEC = No Observed Effect Content

PBT = Persistent, Bioaccumulative and Toxic substance

PNEC = Predicted No-Effect Content

RID = Règlement concernant le transport international ferroviaire de marchandises dangereuses

REACH = Registration, Evaluation, Authorisation and Restriction of Chemicals

STP = Sewage Treatment Plant

TLV®/TWA = Threshold limit value - time-weighted average

TLV®STEL = Threshold limit value - short-time exposure limit

VOC = Volatile Organic Compounds

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vPvB = very Persistent and very Bioaccumulative

16.3 Key literature references and sources for data

European Chemicals Agency (ECHA): <https://www.echa.europa.eu>

ECHA, C&L Inventory: <https://echa.europa.eu/information-on-chemicals/cl-inventory-database>

ECHA, Registered substances: <https://echa.europa.eu/information-on-chemicals/registered-substances>

GESTIS, Information system on hazardous substances: <https://www.gestis.dguv.de/search>

GESTIS, International Limit Values: <https://limitvalue.ifa.dguv.de>

Hörath Gefährliche Stoffe und Gemische, 8. Auflage, Dr. Angela Schulz

Safety data sheets of the manufacturers

16.4 Classification for mixtures and used evaluation method according to regulation (EC) No. 1272/2008 [CLP]

The mixture is classified as not hazardous according to regulation (EC) No 1272/2008 [CLP].

16.5 List of relevant hazard statements and/or precautionary statements from sections 2 to 15

Hazard statements	
H290	May be corrosive to metals.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H318	Causes serious eye damage.
H319	Causes serious eye irritation.

16.6 Training advice

No data available.

16.7 Additional information

The information in this safety data sheet has been established to our best knowledge and was up-to-date at time of revision. The information is intended to give you advice about the safe handling of the product for storage, processing, transport and disposal. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.