

SAFETY DATA SHEET

Version 6.3 Revision Date 06/16/2022 Print Date 10/01/2022

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

1.1 Product identifiers

Product name : Lactase, United States Pharmacopeia (USP) Reference Standard

Product Number	:	1356698
Brand	:	US Pharmacopeia
CAS-No.	:	9031-11-2

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

Identified uses	:	Laboratory	chemicals,	Synthesis	of substances
-----------------	---	------------	------------	-----------	---------------

1.3 Details of the supplier of the safety data sheet

Company	:	Sigma-Aldrich Inc. 3050 SPRUCE ST ST. LOUIS MO 63103 UNITED STATES
Telephone Fax	-	+1 314 771-5765 +1 800 325-5052
Emergency telephone		

Emergency Phone # : 800-424-9300 CHEMTREC (USA) +1-703-527-3887 CHEMTREC (International) 24 Hours/day; 7 Days/week

SECTION 2: Hazards identification

1.4

2.1 Classification of the substance or mixture

Not a hazardous substance or mixture.

2.2 GHS Label elements, including precautionary statements

Not a hazardous substance or mixture.

2.3 Hazards not otherwise classified (HNOC) or not covered by GHS - none

SECTION 3: Composition/information on ingredients

3.1 Substances CAS-No. : 9031-11-2

US Pharmacopeia - 1356698

Page 1 of 8



No components need to be disclosed according to the applicable regulations.

SECTION 4: First aid measures

4.1 Description of first-aid measures

If inhaled

If breathed in, move person into fresh air. If not breathing, give artificial respiration.

In case of skin contact

Wash off with soap and plenty of water.

In case of eye contact

Flush eyes with water as a precaution.

If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water.

- **4.2 Most important symptoms and effects, both acute and delayed** The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11
- **4.3 Indication of any immediate medical attention and special treatment needed** No data available

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture Nature of decomposition products not known.

5.3 Advice for firefighters Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information No data available

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures Avoid dust formation. Avoid breathing vapors, mist or gas. For personal protection see section 8.

6.2 Environmental precautions No special environmental precautions required.

- **6.3 Methods and materials for containment and cleaning up** Sweep up and shovel. Keep in suitable, closed containers for disposal.
- **6.4 Reference to other sections** For disposal see section 13.

US Pharmacopeia - 1356698

Page 2 of 8



SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling

Further processing of solid materials may result in the formation of combustible dusts. The potential for combustible dust formation should be taken into consideration before additional processing occurs.

Advice on protection against fire and explosion

Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures

General industrial hygiene practice. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Storage conditions

Keep container tightly closed in a dry and well-ventilated place.

Storage stability

Recommended storage temperature -20 °C

Storage class

Storage class (TRGS 510): 11: Combustible Solids

7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Ingredients with workplace control parameters Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

General industrial hygiene practice.

Personal protective equipment

Eye/face protection

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

Body Protection

Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective

US Pharmacopeia - 1356698

Page 3 of 8



equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Control of environmental exposure

No special environmental precautions required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

	•	<i>, , , , , , , , , ,</i>
a)	Appearance	Form: solid
b)	Odor	No data available
c)	Odor Threshold	No data available
d)	рН	No data available
e)	Melting point/freezing point	No data available
f)	Initial boiling point and boiling range	No data available
g)	Flash point	()No data available
h)	Evaporation rate	No data available
i)	Flammability (solid, gas)	No data available
j)	Upper/lower flammability or explosive limits	No data available
k)	Vapor pressure	No data available
I)	Vapor density	No data available
m)	Density	No data available
	Relative density	No data available
n)	Water solubility	No data available
o)	Partition coefficient: n-octanol/water	No data available
p)	Autoignition temperature	No data available
q)	Decomposition temperature	No data available
r)	Viscosity	No data available
s)	Explosive properties	Not classified as explosive.
t)	Oxidizing properties	none
arma	anaia 1256609	

US Pharmacopeia - 1356698

Page 4 of 8



SECTION 10: Stability and reactivity

10.1 Reactivity

No data available

- **10.2 Chemical stability** Stable under recommended storage conditions.
- **10.3 Possibility of hazardous reactions** No data available
- **10.4 Conditions to avoid** No data available
- **10.5 Incompatible materials** Strong oxidizing agents
- **10.6 Hazardous decomposition products** In the event of fire: see section 5

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Acute toxicity

Oral: No data available Inhalation: No data available Dermal: No data available LD50 Intraperitoneal - Rat - 660 mg/kg Remarks: Behavioral:Somnolence (general depressed activity). Behavioral:Muscle weakness.

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation No data available

Respiratory or skin sensitization

Prolonged or repeated exposure may cause allergic reactions in certain sensitive individuals.

Germ cell mutagenicity

No data available

Carcinogenicity

- IARC: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.
- NTP: No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

OSHA: No component of this product present at levels greater than or equal to 0.1% is US Pharmacopeia - 1356698

Page 5 of 8



on OSHA's list of regulated carcinogens.

Reproductive toxicity

No data available No data available

Specific target organ toxicity - single exposure No data available

Specific target organ toxicity - repeated exposure No data available

Aspiration hazard

No data available

11.2 Additional Information

To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

SECTION 12: Ecological information

12.1 Toxicity

No data available

- 12.2 Persistence and degradability No data available
- **12.3 Bioaccumulative potential** No data available
- **12.4 Mobility in soil** No data available

12.5 Results of PBT and vPvB assessment PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

- **12.6 Endocrine disrupting properties** No data available
- **12.7 Other adverse effects** No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product

Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging

Dispose of as unused product.

US Pharmacopeia - 1356698

Page 6 of 8



SECTION 14: Transport information

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

ΙΑΤΑ

Not dangerous goods

Further information

Not classified as dangerous in the meaning of transport regulations.

SECTION 15: Regulatory information

SARA 302 Components

No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Hazards

No SARA Hazards

Massachusetts Right To Know Components

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know Components B-Galactosidase	CAS-No. 9031-11-2	Revision Date
ß-Galactosidase	CAS-No. 9031-11-2	Revision Date
New Jersey Right To Know Components B-Galactosidase	CAS-No. 9031-11-2	Revision Date

California Prop. 65 Components

This product does not contain any chemicals known to the State of California to cause cancer, birth, or any other reproductive defects.

US Pharmacopeia - 1356698

Page 7 of 8

SECTION 16: Other information

Further information

Copyright 2020 Sigma-Aldrich Co. LLC. License granted to make unlimited paper copies for internal use only.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. Sigma-Aldrich Corporation and its Affiliates shall not be held liable for any damage resulting from handling or from contact with the above product. See www.sigma-aldrich.com and/or the reverse side of invoice or packing slip for additional terms and conditions of sale.

The branding on the header and/or footer of this document may temporarily not visually match the product purchased as we transition our branding. However, all of the information in the document regarding the product remains unchanged and matches the product ordered. For further information please contact mlsbranding@sial.com.

Version: 6.3

Revision Date: 06/16/2022

Print Date: 10/01/2022

US Pharmacopeia - 1356698

Page 8 of 8

