acc. to Safe Work Australia - Code of Practice

#### **ß-Amylase 16-24 U/mg, lyophilised**

article number: 8717 date of compilation: 2016-06-09 Version: GHS 4.0 en

Replaces version of: 2023-07-20

Version: (GHS 3)

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

#### **Product identifier** 1.1

Identification of the substance **ß-Amylase** 16-24 U/mg, lyophilised

Article number 8717

CAS number 9000-91-3

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

Relevant identified uses: Laboratory chemical

Laboratory and analytical use

Uses advised against: Do not use for products which come into contact

with foodstuffs. Do not use for private purposes (household). Food, drink and animal feeding-

stuffs.

#### 1.3 Details of the supplier of the safety data sheet

Carl Roth GmbH + Co. KG Schoemperlenstr. 3-5 D-76185 Karlsruhe Germany

Telephone:+49 (0) 721 - 56 06 0 Telefax: +49 (0) 721 - 56 06 149 e-mail: sicherheit@carlroth.de Website: www.carlroth.de

Competent person responsible for the safety data Department Health, Safety and Environment

sheet:

sicherheit@carlroth.de e-mail (competent person):

#### 1.4 **Emergency telephone number**

Name	Street	Postal code/city	Telephone	Website
NSW Poisons Information Centre Childrens Hospital	Hawkesbury Road	2145 West- mead, NSW	131126	

# **SECTION 2: Hazards identification**

#### 2.1 Classification of the substance or mixture

### Classification acc. to GHS

Section	Hazard class	Cat- egory	Hazard class and category	Hazard statement
3.4R	Respiratory sensitisation	1	Resp. Sens. 1	H334

For full text of abbreviations: see SECTION 16

#### 2.2 **Label elements**

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Signal word Danger

**Pictograms** 

GHS08



#### **Hazard statements**

H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled

#### **Precautionary statements**

#### **Precautionary statements - prevention**

P261 Avoid breathing dust/fume/gas/mist/vapours/spray

P284 In case of inadequate ventilation wear respiratory protection

## **Precautionary statements - response**

P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfort-

able for breathing

P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician

# **Precautionary statements - disposal**

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.

#### **Endocrine disrupting properties**

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq$  0,1%.

# **SECTION 3: Composition/information on ingredients**

#### 3.1 Substances

Name of substance ß-Amylase CAS No 9000-91-3

#### Impurities/additives/constituents:

Name of substance	Identifier	Wt%
Albumin	CAS No 9048-46-8	< 90
Ammonium sulphate	CAS No 7783-20-2	< 90

#### Remarks

For full text of abbreviations: see SECTION 16

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# **SECTION 4: First aid measures**

#### 4.1 Description of first aid measures



#### **General notes**

Take off contaminated clothing.

#### Following inhalation

Provide fresh air. In all cases of doubt, or when symptoms persist, seek medical advice.

# **Following skin contact**

Rinse skin with water/shower.

#### Following eye contact

Rinse cautiously with water for several minutes.

# **Following ingestion**

Rinse mouth. Call a doctor if you feel unwell.

#### 4.2 Most important symptoms and effects, both acute and delayed

Allergic reactions, Cough, Dyspnoea

#### 4.3 Indication of any immediate medical attention and special treatment needed

none

# **SECTION 5: Firefighting measures**

#### 5.1 Extinguishing media



# Suitable extinguishing media

co-ordinate firefighting measures to the fire surroundings! water, foam, dry extinguishing powder, ABC-powder

# Unsuitable extinguishing media

water jet

# 5.2 Special hazards arising from the substance or mixture

Combustible.

# **Hazardous combustion products**

Carbon monoxide (CO), Carbon dioxide (CO<sub>2</sub>), May produce toxic fumes of carbon monoxide if burning.

# 5.3 Advice for firefighters

In case of fire and/or explosion do not breathe fumes. Fight fire with normal precautions from a reasonable distance. Wear self-contained breathing apparatus.

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# **SECTION 6: Accidental release measures**

# 6.1 Personal precautions, protective equipment and emergency procedures



# For non-emergency personnel

Avoid contact with skin, eyes and clothes. Do not breathe dust.

### 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. Control of dust.

#### Other information relating to spills and releases

Place in appropriate containers for disposal.

#### 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.

# **SECTION 7: Handling and storage**

### 7.1 Precautions for safe handling

Provision of sufficient ventilation. Avoid dust formation.

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

Removal of dust deposits.

#### Advice on general occupational hygiene

Wash hands before breaks and after work. Keep away from food, drink and animal feedingstuffs.

#### 7.2 Conditions for safe storage, including any incompatibilities

Store in a dry place. Keep in a cool place.

# **Incompatible substances or mixtures**

Observe hints for combined storage.

# Consideration of other advice:

# **Ventilation requirements**

Use local and general ventilation.

#### Specific designs for storage rooms or vessels

Recommended storage temperature: -20 °C

#### 7.3 Specific end use(s)

No information available.

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# **SECTION 8: Exposure controls/personal protection**

#### **Control parameters**

### **National limit values**

### Occupational exposure limit values (Workplace Exposure Limits)

Coun try	Name of agent	CAS No	Identifi- er	TWA [mg/ m³]	STEL [mg/ m³]	Ceil- ing-C [mg/ m³]	Nota- tion	Source
AU	nuisance dusts		WES	10			i	WES

Notation

Ceiling value is a limit value above which exposure should not occur Inhalable fraction Ceiling-C

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) STEL

**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)

#### **Relevant DNELs of components** Name of sub-**CAS No** End-**Threshol Protection Used** in **Exposure time** goal, route of stance point d level exposure 11.17 mg/ 7783-20-2 DNEL human, inhalat-Ammonium sulphchronic - systemic worker (industry) ${\rm m}^{\rm 3}$ ate ory effects Ammonium sulph-7783-20-2 **DNEL** 42.67 mg/ human, dermal chronic - systemic worker (industry) ate kg bw/day effects

#### **Environmental values**

Relevant	Relevant PNECs and other threshold levels							
End- point	Threshold level	Organism	Environmental com- partment	Exposure time				
PNEC	5.2 <sup>µg</sup> / <sub>l</sub>	aquatic organisms	freshwater	short-term (single instance)				
PNEC	0.52 <sup>µg</sup> / <sub>I</sub>	aquatic organisms	marine water	short-term (single instance)				
PNEC	65,000 <sup>µg</sup> / <sub>l</sub>	aquatic organisms	sewage treatment plant (STP)	short-term (single instance)				
PNEC	0.062 <sup>µg</sup> / <sub>kg</sub>	terrestrial organisms	soil	short-term (single instance)				

Relevant PNECs	Relevant PNECs of components								
Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time			
Ammonium sulph- ate	7783-20-2	PNEC	0.53 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	water	intermittent re- lease			
Ammonium sulph- ate	7783-20-2	PNEC	0.312 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	freshwater	short-term (single instance)			
Ammonium sulph- ate	7783-20-2	PNEC	0.031 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	marine water	short-term (single instance)			
Ammonium sulph- ate	7783-20-2	PNEC	16.18 <sup>mg</sup> / <sub>l</sub>	aquatic organ- isms	sewage treatment plant (STP)	short-term (single instance)			

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Relevant PNECs of components							
Name of sub- stance	CAS No	End- point	Threshol d level	Organism	Environmental compartment	Exposure time	
Ammonium sulph- ate	7783-20-2	PNEC	0.063 <sup>mg</sup> / kg	aquatic organ- isms	freshwater sedi- ment	short-term (single instance)	
Ammonium sulph- ate	7783-20-2	PNEC	62.6 <sup>mg</sup> / <sub>kg</sub>	terrestrial organ- isms	soil	short-term (single instance)	

#### 8.2 Exposure controls

### Individual protection measures (personal protective equipment)

#### **Eye/face protection**





Use safety goggle with side protection.

#### Skin protection





#### hand protection

Wear suitable gloves. Chemical protection gloves are suitable, which are tested according to EN 374. For special purposes, it is recommended to check the resistance to chemicals of the protective gloves mentioned above together with the supplier of these gloves. The times are approximate values from measurements at 22 °C and permanent contact. Increased temperatures due to heated substances, body heat etc. and a reduction of the effective layer thickness by stretching can lead to a considerable reduction of the breakthrough time. If in doubt, contact manufacturer. At an approx. 1.5 times larger / smaller layer thickness, the respective breakthrough time is doubled / halved. The data apply only to the pure substance. When transferred to substance mixtures, they may only be considered as a guide.

# type of material

NBR (Nitrile rubber)

### material thickness

>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.

#### **Respiratory protection**





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

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Keep away from drains, surface and ground water.

# **SECTION 9: Physical and chemical properties**

### 9.1 Information on basic physical and chemical properties

Physical state solid
Form powder
Colour whitish
Odour odourless

Melting point/freezing point not determined

Boiling point or initial boiling point and boiling not determined

range

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) not applicable

Kinematic viscosity not relevant

Solubility(ies)

Water solubility (soluble)

Partition coefficient

Partition coefficient n-octanol/water (log value): -1.3 (20 °C) (ECHA)

Vapour pressure not determined

Density and/or relative density

Density not determined

Relative vapour density Information on this property is not available.

Particle characteristics No data available.

Other safety parameters

Oxidising properties none

9.2 Other information

Information with regard to physical hazard classes acc. to GHS (physical hazards): not relevant

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Other safety characteristics:



There is no additional information.

# **SECTION 10: Stability and reactivity**

### 10.1 Reactivity

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

# 10.2 Chemical stability

The material is stable under normal ambient and anticipated storage and handling conditions of temperature and pressure.

# 10.3 Possibility of hazardous reactions

Violent reaction with: strong oxidiser

#### 10.4 Conditions to avoid

There are no specific conditions known which have to be avoided.

# 10.5 Incompatible materials

There is no additional information.

#### 10.6 Hazardous decomposition products

Hazardous combustion products: see section 5.

# **SECTION 11: Toxicological information**

#### 11.1 Information on toxicological effects

Classification acc. to GHS

# **Acute toxicity**

Shall not be classified as acutely toxic.

#### Acute toxicity of components

Name of substance	CAS No	Exposure route	Endpoint	Value	Species
Ammonium sulphate	7783-20-2	oral	LD50	4,250 <sup>mg</sup> / <sub>kg</sub>	rat
Ammonium sulphate	7783-20-2	dermal	LD50	>2,000 <sup>mg</sup> / <sub>kg</sub>	rat

#### 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

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

# **Germ cell mutagenicity**

Shall not be classified as germ cell mutagenic.

#### Carcinogenicity

Shall not be classified as carcinogenic.

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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

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

#### **Aspiration hazard**

Shall not be classified as presenting an aspiration hazard.

# Symptoms related to the physical, chemical and toxicological characteristics

#### If swallowed

Data are not available.

#### • If in eyes

Data are not available.

#### If inhaled

May produce an allergic reaction, cough, Dyspnoea

#### • If on skin

Data are not available.

#### Other information

none

# 11.2 Endocrine disrupting properties

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq 0.1\%$ .

# **SECTION 12: Ecological information**

# 12.1 Toxicity

Harmful to aquatic life.

#### Aquatic toxicity (acute) Exposure time **Endpoint Value Species Source** EC50 1,758 mg/<sub>I</sub> aquatic invertebrates **ECHA** 48 h 43.1 <sup>mg</sup>/<sub>I</sub> ErC50 algae **ECHA** 72 h

Aquatic toxicity (acute) of components							
Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time		
Ammonium sulphate	7783-20-2	LC50	53 <sup>mg</sup> / <sub>l</sub>	fish	96 h		
Ammonium sulphate	7783-20-2	EC50	121.7 <sup>mg</sup> / <sub>l</sub>	aquatic invertebrates	48 h		

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Aquatic toxicity (chronic) of components							
Name of sub- stance	CAS No	Endpoint	Value	Species	Exposure time		
Ammonium sulphate	7783-20-2	EC50	2,700 <sup>mg</sup> / <sub>l</sub>	algae	18 d		
Ammonium sulphate	7783-20-2	ErC50	1,605 <sup>mg</sup> / <sub>l</sub>	algae	5 d		

### 12.2 Persistence and degradability

#### **Biodegradation**

The substance is readily biodegradable.

Process	Degradation rate	Time
DOC removal	99 %	28 d

# 12.3 Bioaccumulative potential

Does not significantly accumulate in organisms.

n a standal (water (la n KOM)	1.2 (20.95) (55114)
n-octanol/water (log KOW)	-1.3 (20 °C) (ECHA)

#### 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

Does not contain an endocrine disruptor (ED) at a concentration of  $\geq$  0,1%.

#### 12.7 Other adverse effects

Data are not available.

# **SECTION 13: Disposal considerations**

#### 13.1 Waste treatment methods



This material and its container must be disposed of as hazardous waste. Dispose of contents/container in accordance with local/regional/national/international regulations.

#### Sewage disposal-relevant information

Do not empty into drains.

#### Waste treatment of containers/packagings

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

#### 13.3 Remarks

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

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# **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) not assigned
 14.4 Packing group not assigned

**14.5 Environmental hazards** non-environmentally hazardous acc. to the dan-

gerous goods regulations

14.6 Special precautions for user

There is no additional information.

14.7 Transport in bulk according to IMO instruments

The cargo is not intended to be carried in bulk.

14.8 Information for each of the UN Model Regulations

Transport informationNational regulationsAdditional information(UN RTDG)

Not subject to transport regulations. UN RTDG

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 There is no additional information.

National regulations(Australia)

**Australian Inventory of Chemical Substances(AICS)** 

Substance is listed.

#### Other information

Directive 94/33/EC on the protection of young people at work. Observe employment restrictions under the Maternity Protection Directive (92/85/EEC) for expectant or nursing mothers.

# **National inventories**

Country	Inventory	Status
AU	AIIC	substance is listed
CN	IECSC	substance is listed
EU	ECSI	substance is listed
EU	REACH Reg.	substance is listed
JP	ISHA-ENCS	substance is listed
KR	KECI	substance is listed
NZ	NZIoC	substance is listed

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Country	Inventory	Status
TW	TCSI	substance is listed
US	TSCA	substance is listed (ACTIVE)
VN	NCI	substance is listed

Legend

AIIC ECSI

Australian Inventory of Industrial Chemicals EC Substance Inventory (EINECS, ELINCS, NLP) Inventory of Existing Chemical Substances Produced or Imported in China

IECSC Inventory (EINECS, ELINCS, NLP)
IECSC Inventory of Existing Chemical Substances Produced or Imported Inventory of Existing and New Chemical Substances (ISHA-ENCS)
KECI Korea Existing Chemicals Inventory
NCI National Chemical Inventory
NZIOC New Zealand Inventory of Chemicals
REACH Reg. REACH registered substances
TCSI Taiwan Chemical Substance Inventory Toxic Substance Control Act

# 15.2 Chemical Safety Assessment

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

# **SECTION 16: Other information**

# Indication of changes (revised safety data sheet)

Section	Former entry (text/value)	Actual entry (text/value)	Safety- relev- ant
2.3	Endocrine disrupting properties: Does not contain an endocrine disruptor (EDC) in a concentration of ≥ 0,1%.	Endocrine disrupting properties: Does not contain an endocrine disruptor (ED) at a concentration of ≥ 0,1%.	yes

### **Abbreviations and acronyms**

Abbr.	Descriptions of used abbreviations
CAS	Chemical Abstracts Service (service that maintains the most comprehensive list of chemical substances)
Ceiling-C	Ceiling value
DGR	Dangerous Goods Regulations (see IATA/DGR)
DNEL	Derived No-Effect Level
EC50	Effective Concentration 50 %. The EC50 corresponds to the concentration of a tested substance causing 50 % changes in response (e.g. on growth) during a specified time interval
ED	Endocrine disruptor
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
ErC50	≡ EC50: in this method, that concentration of test substance which results in a 50 % reduction in either growth (EbC50) or growth rate (ErC50) relative to the control
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

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Abbr.	Descriptions of used abbreviations
LC50	Lethal Concentration 50%: the LC50 corresponds to the concentration of a tested substance causing 50 % lethality during a specified time interval
LD50	Lethal Dose 50 %: the LD50 corresponds to the dose of a tested substance causing 50 % lethality during a specified time interval
NLP	No-Longer Polymer
PBT	Persistent, Bioaccumulative and Toxic
PNEC	Predicted No-Effect Concentration
STEL	Short-term exposure limit
TWA	Time-weighted average
UN RTDG	UN Recommendations on the Transport of Dangerous Good
vPvB	Very Persistent and very Bioaccumulative
WES	Safe Work Australia: Workplace exposure standards for airborne contaminants

### Key literature references and sources for data

Safe Work Australia's Code of Practice for Labelling of Workplace Hazardous Chemicals (under WHS Regulations).

UN Recommendations on the Transport of Dangerous Good. 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 section 2 and 3)

Code	Text
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.

## Disclaimer

This information is based upon the present state of our knowledge. This SDS has been compiled and is solely intended for this product.

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