

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Reference number: SDS281

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

1.1. Product identifier

Product form : Mixture
Trade name : Alpha
Product code : Alpha
Type of product : Enzyme
Product group : End product

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

1.2.1. Relevant identified uses

No additional information available

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

1.4. Emergency telephone number

Emergency number : +115 978 5494

Office Hours Only

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Not classified

Adverse physicochemical, human health and environmental effects

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

2.2. Label elements

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

EUH-statements : EUH208 - Contains AMYLASE, ALPHA-(9000-90-2). May produce an allergic reaction.

2.3. Other hazards

Contains no PBT and/or vPvB substances ≥ 0.1% assessed in accordance with REACH Annex XIII

The mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or substance(s) are not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

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3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
GLYCEROL	CAS-No.: 56-81-5 EC-No.: 200-289-5	50 – 75	Not classified
AMYLASE, ALPHA-	CAS-No.: 9000-90-2 EC-No.: 232-565-6 EC Index-No.: 647-015-00-4	< 1	Resp. Sens. 1, H334

Full text of H- and EUH-statements: see section 16

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Call a poison center or a doctor if you feel unwell.

First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. If experiencing respiratory

symptoms: Call a poison center or a doctor.

First-aid measures after skin contact : Wash skin with plenty of water. If irritation persists, consult a doctor.

First-aid measures after eye contact : Rinse eyes with water as a precaution. If irritation persists, consult an eye specialist.

First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell. Do NOT induce vomiting unless directed

to do so by medical personnel. Get medical attention if symptoms occur.

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

Symptoms/effects after inhalation : May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Symptoms/effects after skin contact : None under normal conditions. Symptoms/effects after eye contact : None under normal conditions. Symptoms/effects after ingestion : None under normal conditions.

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 : Water spray. Dry powder. Foam. Carbon dioxide.

Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No fire hazard.

Explosion hazard : No direct explosion hazard. Hazardous decomposition products in case of fire : Toxic fumes may be released.

5.3. Advice for firefighters

Firefighting instructions : Fight fire from safe distance and protected location. Do not enter fire area without proper

protective equipment, including respiratory protection.

Protection during firefighting : Do not attempt to take action without suitable protective equipment. Self-contained

breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures : Stop leak if safe to do so. Notify authorities if product enters sewers or public waters.

Absorb spillage to prevent material damage.

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6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.

Emergency procedures : Ventilate spillage area. Avoid breathing dust/fume/gas/mist/vapours/spray.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. For further information

refer to section 8: "Exposure controls/personal protection".

Emergency procedures : Evacuate unnecessary personnel. Stop leak if safe to do so.

6.2. Environmental precautions

Avoid release to the environment.

6.3. Methods and material for containment and cleaning up

For containment : Absorb spilled material with sand or earth. Contain any spills with dikes or absorbents to

prevent migration and entry into sewers or streams. Stop leak without risks if possible.

Methods for cleaning up : Take up liquid spill into absorbent material.

Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.

: Ensure good ventilation of the work station. Wear personal protective equipment. Avoid

breathing dust/fume/gas/mist/vapours/spray.

Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the

product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Keep in a cool, well-ventilated place away from heat.

Storage conditions : Keep cool. Protect from sunlight.

Packaging materials : Store always product in container of same material as original container.

7.3. Specific end use(s)

Precautions for safe handling

No additional information available

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

GLYCEROL (56-81-5)		
United Kingdom - Occupational Exposure Limits		
Local name	Glycerol	
WEL TWA (OEL TWA)	10 mg/m³ mist	
Regulatory reference	EH40/2005 (Fourth edition, 2020). HSE	

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

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8.1.4. DNEL and PNEC

Alpha		
DNEL/DMEL (Workers)		
Long-term - local effects, inhalation	60 ng/m³	
DNEL/DMEL (General population)		
Long-term - local effects, inhalation	15 ng/m³	
PNEC (Water)		
PNEC aqua (freshwater)	103.7 μg/l	
PNEC aqua (marine water)	10.37 μg/l	
PNEC aqua (intermittent, freshwater)	1037 μg/l	
PNEC (Soil)		
PNEC soil	12.4 µg/kg dw	
PNEC (STP)		
PNEC sewage treatment plant	65000 μg/l	

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment.

Personal protective equipment symbol(s):







8.2.2.1. Eye and face protection

Eye protection:

Safety glasses

Eye protection			
Туре	Field of application	Characteristics	Standard
Safety glasses, Safety goggles	Droplet	Plastic	EN 166

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

Hand protection:

Protective gloves

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Hand protection					
Туре	Material	Permeation	Thickness (mm)	Penetration	Standard
Protective gloves	Nitrile rubber (NBR), Butyl rubber, Natural rubber, Neoprene rubber (HNBR), Polyvinylchloride (PVC), Vinyl				EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection:

[In case of inadequate ventilation] wear respiratory protection.

Respiratory protection				
Device Filter type Condition Standard				
			EN 136, EN 140, EN 143, EN 149, EN 1827	

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Liquid
Colour : light brown.

Odour : Slight fermentation odour.

Odour threshold : Not available Melting point : Not applicable : Not available Freezing point Boiling point : Not available Flammability Not applicable Lower explosion limit Not available Upper explosion limit Not available Flash point Not available Auto-ignition temperature Not available Decomposition temperature : Not available рΗ : Not available Viscosity, kinematic Not available Not available Solubility Partition coefficient n-octanol/water (Log Kow) Not available Vapour pressure : Not available Vapour pressure at 50°C Not available Density : Not available Relative density : Not available : Not available Relative vapour density at 20°C : ≈ 1.17 Relative density of saturated gas/air mixture Particle characteristics : Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

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9.2.2. Other safety characteristics

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

None under recommended storage and handling conditions (see section 7).

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

AMYLASE,	ALPHA-	(9000-90-2)

LC50 Inhalation - Rat	> 4.96 mg/l air Animal: rat, Guideline: OECD Guideline 403 (Acute Inhalation Toxicity)
LOGO IIII alation - Ital	7 4.30 mg/r air Ariinai. rat, Odideiine. OEGD Guideiine 403 (Acute iinaiation roxicity)

> 2000 mg/kg

: Not classified

LC50 Inhalation - Rat > 4.96 mg/l air

Skin corrosion/irritation : Not classified

Serious eye damage/irritation : Not classified

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : Not classified

Alpha

STOT-repeated exposure

Alpha

LD50 oral rat

NOAEL (oral, rat, 90 days)	≥ 1519.2 mg/kg bodyweight Animal: rat, Guideline: OECD Guideline 408 (Repeated Dose
	90-Day Oral Toxicity Study in Rodents)

Aspiration hazard : Not classified

11.2. Information on other hazards

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SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse

effects in the environment.

Hazardous to the aquatic environment, short-term

(acute)

: Not classified

Hazardous to the aquatic environment, long-term

: Not classified

(chronic)

Alpha	
LC50 - Fish [1]	> 227.9 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
EC50 - Crustacea [1]	> 227.9 mg/l Test organisms (species): Daphnia magna
EC50 72h - Algae [1]	> 227.9 mg/l Test organisms (species): Pseudokirchneriella subcapitata (previous names: Raphidocelis subcapitata, Selenastrum capricornutum)
GLYCEROL (56-81-5)	
LC50 - Fish [1]	54000 mg/l Test organisms (species): Oncorhynchus mykiss (previous name: Salmo gairdneri)
AMYLASE, ALPHA- (9000-90-2)	
EC50 - Crustacea [1]	2000 mg/l Test organisms (species): Daphnia magna
EC50 - Crustacea [2]	212 mg/l Test organisms (species): Daphnia magna

12.2. Persistence and degradability

Alpha		
Persistence and degradability	Not rapidly degradable	
GLYCEROL (56-81-5)		
Persistence and degradability	Not rapidly degradable	
AMYLASE, ALPHA- (9000-90-2)		
Persistence and degradability	Not rapidly degradable	

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Endocrine disrupting properties

No additional information available

12.7. Other adverse effects

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SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional waste regulation : Disposal must be done according to official regulations.

Waste treatment methods : Dispose of contents/container in accordance with licensed collector's sorting instructions.

Sewage disposal recommendations : Disposal must be done according to official regulations. Product/Packaging disposal recommendations : Disposal must be done according to official regulations.

Additional information : Do not re-use empty containers.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA / ADN / RID

ADR	IMDG	IATA	ADN	RID
14.1. UN number or ID n	umber			
Not regulated for transport				
14.2. UN proper shippin	g name			
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard o	class(es)			
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
No supplementary information available				

14.6. Special precautions for user

Overland transport

Not regulated

Transport by sea

Not regulated

Air transport

Not regulated

Inland waterway transport

Not regulated

Rail transport

Not regulated

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-Regulations

REACH Annex XVII (Restriction List)

Contains no substance(s) listed on REACH Annex XVII (Restriction Conditions)

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REACH Annex XIV (Authorisation List)

Contains no substance(s) listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Contains no substance(s) listed on the PIC list (Regulation EU 649/2012 concerning the export and import of hazardous chemicals)

POP Regulation (Persistent Organic Pollutants)

Contains no substance(s) listed on the POP list (Regulation EU 2019/1021 on persistent organic pollutants)

Ozone Regulation (1005/2009)

Contains no substance(s) listed on the Ozone Depletion list (Regulation EU 1005/2009 on substances that deplete the ozone layer)

Dual-Use Regulation (428/2009)

Contains no substance subject to the COUNCIL REGULATION (EC) No 428/2009 of 5 May 2009 setting up a Community regime for the control of exports, transfer, brokering and transit of dual-use items.

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Abbreviations and acronyms:		
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways	
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road	
ATE	Acute Toxicity Estimate	
BCF	Bioconcentration factor	
BLV	Biological limit value	
BOD	Biochemical oxygen demand (BOD)	
COD	Chemical oxygen demand (COD)	
DMEL	Derived Minimal Effect level	
DNEL	Derived-No Effect Level	
EC-No.	European Community number	
EC50	Median effective concentration	
EN	European Standard	
IARC	International Agency for Research on Cancer	
IATA	International Air Transport Association	
IMDG	International Maritime Dangerous Goods	
LC50	Median lethal concentration	
LD50	Median lethal dose	

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Abbreviations and acronyms:		
LOAEL	Lowest Observed Adverse Effect Level	
NOAEC	No-Observed Adverse Effect Concentration	
NOAEL	No-Observed Adverse Effect Level	
NOEC	No-Observed Effect Concentration	
OECD	Organisation for Economic Co-operation and Development	
OEL	Occupational Exposure Limit	
PBT	Persistent Bioaccumulative Toxic	
PNEC	Predicted No-Effect Concentration	
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail	
SDS	Safety Data Sheet	
STP	Sewage treatment plant	
ThOD	Theoretical oxygen demand (ThOD)	
TLM	Median Tolerance Limit	
VOC	Volatile Organic Compounds	
CAS-No.	Chemical Abstract Service number	
N.O.S.	Not Otherwise Specified	
vPvB	Very Persistent and Very Bioaccumulative	
ED	Endocrine disrupting properties	

Full text of H- and EUH-statements:	
EUH208	Contains AMYLASE, ALPHA-(9000-90-2). May produce an allergic reaction.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Resp. Sens. 1	Respiratory sensitisation, Category 1

Safety Data Sheet (SDS), EU

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.