



SAFETY DATA SHEET MALTERA STANDARD

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

1.1. Product identifier

Product name MALTERA STANDARD

Product number 63820

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

Identified uses Biocatalyst Food industry
For further information, see attached Exposure Scenario.

1.3. Details of the supplier of the safety data sheet

Supplier Univar Solutions UK Ltd
Aquarius House
6 Mid Point Business Park
Bradford
BD3 7AY
+44 1274 267300
+44 1274 267306
SDS.EMEA@univarsolutions.com

1.4. Emergency telephone number

Emergency telephone SGS - +32 (0)3 575 55 55 (24h)

Sds No. 63820

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification (EC 1272/2008)

Physical hazards Not Classified

Health hazards Resp. Sens. 1 - H334

Environmental hazards Not Classified

2.2. Label elements

Hazard pictograms



Signal word Danger

Hazard statements H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

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Precautionary statements

P261 Avoid breathing vapour/ spray.
P284 [In case of inadequate ventilation] wear respiratory protection.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P342+P311 If experiencing respiratory symptoms: Call a POISON CENTER/ doctor.
P501 Dispose of contents/ container in accordance with national regulations.

Contains AMYLASE, alpha, AMYLASE, B-

2.3. Other hazards

This product does not contain any substances classified as PBT or vPvB.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

AMYLASE, alpha 2.5 < 5%		
CAS number: 9000-90-2	EC number: 232-565-6	REACH registration number: 01-2119938627-26-XXXX
Classification Resp. Sens. 1 - H334		
AMYLASE, B- 1 - < 2.5%		
CAS number: 9000-91-3	EC number: 232-566-1	
Classification Resp. Sens. 1 - H334		

The full text for all hazard statements is displayed in Section 16.

Composition comments The data shown are in accordance with the latest EC Directives.

SECTION 4: First aid measures

4.1. Description of first aid measures

General information Show this Safety Data Sheet to the medical personnel.

Inhalation Remove person to fresh air and keep comfortable for breathing. Get medical attention if any discomfort continues.

Ingestion Immediately rinse mouth and drink plenty of water (200-300 ml). Get medical attention if any discomfort continues.

Skin contact Take off immediately all contaminated clothing and wash it before reuse. Rinse immediately with plenty of water. Get medical attention if any discomfort continues.

Eye contact Rinse immediately with plenty of water. Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes. Get medical attention if symptoms are severe or persist after washing.

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

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Coughing. Shortness of breath. Wheezing/breathing difficulties. Effects may be delayed.

Ingestion May cause irritation. Gastro-intestinal tract

Skin contact May be slightly irritating to skin.

Eye contact May be slightly irritating to eyes.

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

Notes for the doctor Treat symptomatically. Effects may be delayed.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media Extinguish with alcohol-resistant foam, carbon dioxide, dry powder or water fog.

Unsuitable extinguishing media Do not use water jet as an extinguisher, as this will spread the fire.

5.2. Special hazards arising from the substance or mixture

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

Hazardous combustion products Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

5.3. Advice for firefighters

Protective actions during firefighting Contain and collect extinguishing water. Avoid the spillage or runoff entering drains, sewers or watercourses.

Special protective equipment for firefighters Wear positive-pressure self-contained breathing apparatus (SCBA) and appropriate protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Personal precautions Wear protective clothing as described in Section 8 of this safety data sheet. Provide adequate ventilation. Keep unnecessary and unprotected personnel away from the spillage. Avoid handling which leads to dust formation. Avoid the formation of mists.

6.2. Environmental precautions

Environmental precautions Avoid the spillage or runoff entering drains, sewers or watercourses. Spillages or uncontrolled discharges into watercourses must be reported immediately to the Environmental Agency or other appropriate regulatory body.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up Remove spillage with vacuum cleaner or collect with a shovel and broom, or similar. Collect and place in suitable waste disposal containers and seal securely. Do not allow to dry out. Flush contaminated area with plenty of water. Clean contaminated objects and areas thoroughly, observing environmental regulations. Avoid discharge into drains or watercourses or onto the ground.

6.4. Reference to other sections

Reference to other sections For personal protection, see Section 8. For waste disposal, see Section 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Usage precautions Provide adequate ventilation. Wear protective clothing as described in Section 8 of this safety data sheet. Avoid handling which leads to dust formation. Avoid the formation of mists. Avoid breathing vapour/spray. Do not allow to dry out.

Advice on general occupational hygiene When using do not eat, drink or smoke. Take off immediately all contaminated clothing and wash it before reuse. Wash after use and before eating, smoking and using the toilet. Remove contaminated clothing and protective equipment before entering eating areas.

7.2. Conditions for safe storage, including any incompatibilities

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Storage precautions Store in tightly-closed, original container in a dry and cool place.
Store at temperatures between 0°C and 25°C.

7.3. Specific end use(s)

Specific end use(s) The identified uses for this product are detailed in Section 1.2.

SECTION 8: Exposure controls/Personal protection

8.1. Control parameters

AMYLASE, alpha (CAS: 9000-90-2)

DMEL Workers - Inhalation; Long term local effects: 60 ng/m³
Consumer, Professional - Inhalation; Long term local effects: 15 ng/m³

PNEC - Fresh water; 5.2 µg/l
- marine water; 0.52 µg/l
- STP; 65000 µg/l

AMYLASE, B- (CAS: 9000-91-3)

DMEL Workers - Inhalation; Long term local effects: 60 ng/m³

8.2. Exposure controls

Protective equipment



Appropriate engineering controls

Provide adequate ventilation. Observe any occupational exposure limits for the product or ingredients. Provide eyewash station and safety shower.

Eye/face protection

Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. Unless the assessment indicates a higher degree of protection is required, the following protection should be worn: Chemical splash goggles. Personal protective equipment for eye and face protection should comply with European Standard EN166.

Hand protection

Chemical-resistant, impervious gloves complying with an approved standard should be worn if a risk assessment indicates skin contact is possible. The most suitable glove should be chosen in consultation with the glove supplier/manufacturer, who can provide information about the breakthrough time of the glove material. To protect hands from chemicals, gloves should comply with European Standard EN374.

Other skin and body protection

Wear suitable protective clothing as protection against splashing or contamination.

Hygiene measures

Wash after use and before eating, smoking and using the toilet. When using do not eat, drink or smoke. Remove contaminated clothing and protective equipment before entering eating areas. Take off immediately all contaminated clothing and wash it before reuse.

Respiratory protection

If ventilation is inadequate, suitable respiratory protection must be worn. Use respiratory equipment with particle filter, type P3. EN 136/140/141/145/143/149 Ensure all respiratory protective equipment is suitable for its intended use and is 'CE'-marked.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

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Appearance	Liquid.
Colour	Light brown.
Odour	Slight.
Odour threshold	No information available.
pH	No information available.
Melting point	No information available.
Initial boiling point and range	No information available.
Flash point	No information available.
Evaporation rate	No information available.
Evaporation factor	No information available.
Flammability (solid, gas)	No information available.
Upper/lower flammability or explosive limits	No information available.
Other flammability	No information available.
Vapour pressure	No information available.
Vapour density	No information available.
Relative density	1.2
Bulk density	No information available.
Solubility(ies)	Immiscible with water.
Partition coefficient	No information available.
Auto-ignition temperature	No information available.
Decomposition Temperature	No information available.
Viscosity	No information available.
Explosive properties	No information available.
Explosive under the influence of a flame	No information available.
Oxidising properties	No information available.

9.2. Other information

Other information	Not available.
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SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	No information available.
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10.2. Chemical stability

Stability	Stable under the prescribed storage conditions.
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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	Under normal conditions of storage and use, no hazardous reactions will occur.
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10.4. Conditions to avoid

Conditions to avoid Avoid handling which leads to dust formation. Avoid the formation of mists.

10.5. Incompatible materials

Materials to avoid None known.

10.6. Hazardous decomposition products

Hazardous decomposition products Does not decompose when used and stored as recommended. Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Toxicological effects No information available.

Skin corrosion/irritation

Skin corrosion/irritation May be slightly irritating to skin.

Serious eye damage/irritation

Serious eye damage/irritation May be slightly irritating to eyes.

Respiratory sensitisation

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

Skin sensitisation

Skin sensitisation No information available.

Germ cell mutagenicity

Genotoxicity - in vitro No information available.

Carcinogenicity

Carcinogenicity No information available.

Reproductive toxicity

Reproductive toxicity - fertility No information available.

Specific target organ toxicity - single exposure

STOT - single exposure No information available.

Specific target organ toxicity - repeated exposure

STOT - repeated exposure No information available.

Aspiration hazard

Aspiration hazard No information available.

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled. Shortness of breath. Wheezing/breathing difficulties. Coughing. Effects may be delayed.

Ingestion May cause irritation.

Skin contact May be slightly irritating to skin.

Eye contact May be slightly irritating to eyes.

Toxicological information on ingredients.

AMYLASE, alpha

Acute toxicity - oral

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Notes (oral LD₅₀) LD₅₀ >2000 mg/kg, Oral, OECD 401

Skin corrosion/irritation

Skin corrosion/irritation Not irritating. OECD 404

Serious eye damage/irritation

Serious eye damage/irritation Not irritating. OECD 405

Respiratory sensitisation

Respiratory sensitisation Sensitising.

Germ cell mutagenicity

Genotoxicity - in vitro Based on available data the classification criteria are not met. OECD 471 OECD 476

AMYLASE, B-

Acute toxicity - oral

Notes (oral LD₅₀) LD₅₀ >2000 mg/kg, Oral, OECD 401

Skin corrosion/irritation

Skin corrosion/irritation Not irritating. OECD 404

Serious eye damage/irritation

Serious eye damage/irritation Not irritating. OECD 405

Respiratory sensitisation

Respiratory sensitisation Sensitising.

Germ cell mutagenicity

Genotoxicity - in vitro Based on available data the classification criteria are not met. OECD 471 OECD 476

SECTION 12: Ecological information

Ecotoxicity Not regarded as dangerous for the environment. However, large or frequent spills may have hazardous effects on the environment.

12.1. Toxicity

Toxicity No information available.

Ecological information on ingredients.

AMYLASE, alpha

Acute aquatic toxicity

Acute toxicity - fish LC₅₀, 96 hours: 58.3 - 326.7 mg/l, Fish OECD 203

Acute toxicity - aquatic invertebrates EC₅₀, 48 hours: 31.7 - 457 mg/l, Daphnia magna OECD 202

Acute toxicity - aquatic plants EC₅₀, 72 hours: >= 5.2 mg/l, Algae OECD 201

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AMYLASE, B-

Acute aquatic toxicity

Acute toxicity - fish	LC ₅₀ , 96 hours: 58.3 - 326.7 mg/l, Fish OECD 203
Acute toxicity - aquatic invertebrates	EC ₅₀ , 48 hours: 31.7 - 457 mg/l, Daphnia magna OECD 202
Acute toxicity - aquatic plants	EC ₅₀ , 72 hours: >= 5.2 mg/l, Algae OECD 201

12.2. Persistence and degradability

Persistence and degradability No information available.

Ecological information on ingredients.

AMYLASE, alpha

Persistence and degradability	The product is readily biodegradable. OECD 301
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AMYLASE, B-

Persistence and degradability	The product is readily biodegradable. OECD 301
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12.3. Bioaccumulative potential

Bioaccumulative potential	No information available.
Partition coefficient	No information available.

Ecological information on ingredients.

AMYLASE, alpha

Bioaccumulative potential	The product is not bioaccumulating.
Partition coefficient	log Pow: < 0

AMYLASE, B-

Bioaccumulative potential	The product is not bioaccumulating.
Partition coefficient	log Pow: < 0

12.4. Mobility in soil

Mobility	No information available.
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12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment	This product does not contain any substances classified as PBT or vPvB.
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12.6. Other adverse effects

Other adverse effects	No information available.
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SECTION 13: Disposal considerations

13.1. Waste treatment methods

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General information	Waste is classified as hazardous waste. Do not puncture or incinerate, even when empty. May cause allergy or asthma symptoms or breathing difficulties if inhaled. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Disposal methods	Dispose of waste to licensed waste disposal site in accordance with the requirements of the local Waste Disposal Authority.

SECTION 14: Transport information

General	The product is not covered by international regulations on the transport of dangerous goods (IMDG, IATA, ADR/RID).
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14.1. UN number

Not applicable.

14.2. UN proper shipping name

Not applicable.

14.3. Transport hazard class(es)

No transport warning sign required.

14.4. Packing group

Not applicable.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL and the IBC Code

Transport in bulk according to Not applicable.

Annex II of MARPOL 73/78

and the IBC Code

SECTION 15: Regulatory information

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

EU legislation	Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) (as amended). Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures (as amended). Commission Regulation (EU) No 2015/830 of 28 May 2015.
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Restrictions (Annex XVII Regulation 1907/2006)	This product is/contains a substance that is included in REGULATION (EC) No 1907/2006 (REACH) ANNEX XVII - RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, MIXTURES AND ARTICLES. Entry number: 3
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15.2. Chemical safety assessment

A chemical safety assessment has been carried out.

SECTION 16: Other information

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Abbreviations and acronyms used in the safety data sheet

ATE: Acute Toxicity Estimate.
 ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road.
 ADN: European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways.
 CAS: Chemical Abstracts Service.
 DNEL: Derived No Effect Level.
 IATA: International Air Transport Association.
 IMDG: International Maritime Dangerous Goods.
 Kow: Octanol-water partition coefficient.
 LC₅₀: Lethal Concentration to 50 % of a test population.
 LD₅₀: Lethal Dose to 50% of a test population (Median Lethal Dose).
 PBT: Persistent, Bioaccumulative and Toxic substance.
 PNEC: Predicted No Effect Concentration.
 REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006.
 RID: European Agreement concerning the International Carriage of Dangerous Goods by Rail.
 vPvB: Very Persistent and Very Bioaccumulative.
 IARC: International Agency for Research on Cancer.
 MARPOL 73/78: International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978.
 cATpE: Converted Acute Toxicity Point Estimate.
 BCF: Bioconcentration Factor.
 BOD: Biochemical Oxygen Demand.
 EC₅₀: 50% of maximal Effective Concentration.
 LOAEC: Lowest Observed Adverse Effect Concentration.
 LOAEL: Lowest Observed Adverse Effect Level.
 NOAEC: No Observed Adverse Effect Concentration.
 NOAEL: No Observed Adverse Effect Level.
 NOEC: No Observed Effect Concentration.
 LOEC: Lowest Observed Effect Concentration.
 DMEL: Derived Minimal Effect Level.
 EL50: Exposure Limit 50
 hPa: Hectopascal
 LL50: Lethal Loading fifty
 OECD: Organisation for Economic Co-operation and Development
 POW: Octanol-water partition coefficient
 SCBA: self-contained breathing apparatus
 STP: Sewage Treatment Plant
 VOC: Volatile Organic Compounds

Classification abbreviations and acronyms

Acute Tox. = Acute toxicity
 Aquatic Acute = Hazardous to the aquatic environment (acute)
 Aquatic Chronic = Hazardous to the aquatic environment (chronic)

Key literature references and sources for data

Supplier's information.

Classification procedures according to Regulation (EC) 1272/2008

Resp. Sens. 1 - H334: Calculation method.

Revision comments

This is the first issue.

Revision date

03/05/2022

MALTERA STANDARD

Version number	1.000
SDS number	63820
SDS status	Approved.
Hazard statements in full	H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Signature	J Spenceley

This information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process. Such information is, to the best of the company's knowledge and belief, accurate and reliable as of the date indicated. However, no warranty, guarantee or representation is made to its accuracy, reliability or completeness. It is the user's responsibility to satisfy himself as to the suitability of such information for his own particular use.



Exposure scenario
Non-proteolytic enzyme: Formulation or re-packing

Identification

Product name	Alpha-amylase
REACH registration number	01-2119938627-26-XXXX
CAS number	9000-90-2
EC number	232-565-6
EU index number	647-015-00-4
Supplier	Univar Solutions UK Ltd Aquarius House 6 Mid Point Business Park Bradford BD3 7AY +44 1274 267300 +44 1274 267306 SDS.EMEA@univarsolutions.com

1. Title of exposure scenario

Main title	Non-proteolytic enzyme: Formulation or re-packing
Process scope	Formulation of the substance and its mixtures in batch or continuous operations within closed or contained systems, including incidental exposures during storage, materials transfers, mixing, maintenance, sampling and associated laboratory activities.
Product category	PC21 Laboratory chemicals. PC35 Washing and cleaning products PC37 Water treatment chemicals. PC39 Cosmetics, personal care.
Main sector	SU3 Industrial uses
Sector of use	SU10 Formulation [mixing] of preparations and/or re-packaging

Environment

Environmental release category	ERC2 Formulation into mixture
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Worker

Non-proteolytic enzyme: Formulation or re-packing

Process category	PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
	PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
	PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
	PROC4 Chemical production where opportunity for exposure arises
	PROC5 Mixing or blending in batch processes
	PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
	PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
	PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)
	PROC14 Tableting, compression, extrusion, pelletisation, granulation
	PROC15 Use as laboratory reagent.

2. Conditions of use affecting exposure (Industrial - Environment 1)

Control of environmental exposure

Environmental release category	ERC2 Formulation into mixture
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Product characteristics

Physical state	Solid, low dustiness , or: Liquid
Concentration details	Covers concentrations up to 15 %.

Amounts used

Daily amount per site: 1 tonnes
Annual amount per site: 10 tonnes

Frequency and duration of use

Emission days: 365 days/year
Continuous release.

Environmental factors not influenced by risk management measures

Dilution	Receiving surface water flow: 18000 m ³ /day
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Risk management measures

STP type	Municipal STP.
STP details	Assumed domestic sewage treatment plant flow: 2000 m ³ /day Removal efficiency (total): 99.99%

Conditions and measures related to external treatment of waste for disposal

Waste treatment	External treatment and disposal of waste should comply with applicable local and/or national regulations.
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2. Conditions of use affecting exposure (Workers - Health 1)

Product characteristics

Physical state	Solid, low dustiness , or: Liquid
Concentration details	Covers concentrations up to 15 %. Concentration of substance in product: 0.5%

Frequency and duration of use

Covers daily exposure up to 12hours

Non-proteolytic enzyme: Formulation or re-packing

Other given operational conditions affecting workers exposure

Setting	Indoor.
Temperature	Assumes activities are at ambient temperature (unless stated differently).
Ventilation rate	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).

Technical conditions and measures at process level (source) to prevent release

Technical protective measures	High efficiency particulate air filter (HEPA filter) Provide extract ventilation to points where emissions occur. PROC15 Use as laboratory reagent. Handle in a fume cupboard or under extract ventilation.
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Organisational measures to prevent/limit releases, dispersion and exposure

Organisational measures	Assumes a good basic standard of occupational hygiene is implemented. Ensure operatives are trained to minimise exposures. Supervision in place to check that the RMMs in place are being used correctly and OCs followed.
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Risk management measures

Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if hand contact with substance likely. Clean up contamination/spills as soon as they occur. Wash off any skin contamination immediately. Provide basic employee training to prevent/minimise exposures and to report any skin problems that may develop. Wear suitable coveralls to prevent exposure to the skin. Use suitable eye protection. In case of insufficient ventilation, wear suitable respiratory equipment. with filter for particulates: P3.

Additional advice	Avoid splashing.
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2. Conditions of use affecting exposure (Non-industrial - Health 1)

Product characteristics

Physical state	Solid, low dustiness , or: Liquid
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3. Exposure estimation (Environment 1)

Environmental release category	ERC2 Formulation into mixture
Assessment method	Used ECETOC TRA model.
Environmental release	Water: 20 kg/day Air: 0 kg/day Soil: 0 kg/day
Environmental exposure	Fresh water: Exposure 0.00026 mg/l, PNEC 0.0052 mg/l, RCR 0.05 Marine water: Exposure 0.000026 mg/l, PNEC 0.00052 mg/l, RCR 0.05 STP: Exposure 0.001 mg/l, PNEC 65 mg/l, RCR 0.01

3. Exposure estimation (Health 1)

Assessment method	Used ECETOC TRA model.
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Non-proteolytic enzyme: Formulation or re-packing

Exposure

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition

PROC4 Chemical production where opportunity for exposure arises

PROC5 Mixing or blending in batch processes

Worker - inhalation, long-term - local: Exposure 20 ng/m³, DNEL 60 ng/m³, RCR 0.33

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities

Worker - inhalation, long-term - local: Exposure 10 ng/m³, DNEL 60 ng/m³, RCR 0.17

PROC9 Transfer of substance or mixture into small containers (dedicated filling line, including weighing)

PROC15 Use as laboratory reagent.

Worker - inhalation, long-term - local: Exposure 6 ng/m³, DNEL 60 ng/m³, RCR 0.1

PROC14 Tableting, compression, extrusion, pelletisation, granulation

Worker - inhalation, long-term - local: Exposure 30 ng/m³, DNEL 60 ng/m³, RCR 0.5

Worker - dermal Qualitative approach used to conclude safe use.

4. Guidance to check compliance with the exposure scenario (Health 1)

Estimated workplace exposures are not expected to exceed DNELs when the identified risk management measures are adopted.



Exposure scenario

Non-proteolytic enzyme: Industrial processing aid (including Cleaning in Place)

Identification

Product name	Alpha-amylase
REACH registration number	01-2119938627-26-XXXX
CAS number	9000-90-2
EC number	232-565-6
EU index number	647-015-00-4
Supplier	Univar Solutions UK Ltd Aquarius House 6 Mid Point Business Park Bradford BD3 7AY +44 1274 267300 +44 1274 267306 SDS.EMEA@univarsolutions.com

1. Title of exposure scenario

Main title	Non-proteolytic enzyme: Industrial processing aid (including Cleaning in Place)
Main sector	SU3 Industrial uses
Sector of use	SU2b Offshore industries SU5 Manufacture of textiles, leather, fur SU6b Manufacture of pulp, paper and paper products SU8 Manufacture of bulk, large-scale chemicals (including petroleum products) SU9 Manufacture of fine chemicals SU23 Electricity, steam, gas, water supply and sewage treatment SU24 Scientific research and development

Environment

Environmental release category	ERC4 Use of non-reactive processing aid at industrial site (no inclusion into or onto article)
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Worker

Non-proteolytic enzyme: Industrial processing aid (including Cleaning in Place)

Process category	PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions
	PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions
	PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition
	PROC4 Chemical production where opportunity for exposure arises
	PROC5 Mixing or blending in batch processes
	PROC7 Industrial spraying
	PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities
	PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities
	PROC13 Treatment of articles by dipping and pouring.
	PROC15 Use as laboratory reagent.

2. Conditions of use affecting exposure (Industrial - Environment 1)

Product characteristics

Physical state	Solid, low dustiness , or: Liquid
Concentration details	Covers concentrations up to 15 %.

Amounts used

Daily amount per site: 0.5 tonnes
Annual amount per site: 10 tonnes

Frequency and duration of use

Emission days: 365 days/year
Continuous release.

Environmental factors not influenced by risk management measures

Dilution	Receiving surface water flow: 18000 m ³ /day
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Risk management measures

STP type	Municipal STP.
STP details	Assumed domestic sewage treatment plant flow: 2000 m ³ /day Removal efficiency (total): 99.99%

Conditions and measures related to external treatment of waste for disposal

Waste treatment	External treatment and disposal of waste should comply with applicable local and/or national regulations.
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2. Conditions of use affecting exposure (Workers - Health 1)

Product characteristics

Physical state	Solid, low dustiness , or: Liquid
Concentration details	Covers concentrations up to 15 %. Concentration of substance in product: 0.5% PROC7 Industrial spraying Maximum concentration after dilution for use: 0.0065 %

Frequency and duration of use

Covers daily exposure up to 12hours

Other given operational conditions affecting workers exposure

Setting	Indoor.
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Non-proteolytic enzyme: Industrial processing aid (including Cleaning in Place)

Temperature	Assumes activities are at ambient temperature (unless stated differently).
Ventilation rate	Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).
<u>Technical conditions and measures at process level (source) to prevent release</u>	
Technical protective measures	High efficiency particulate air filter (HEPA filter) Provide extract ventilation to points where emissions occur. PROC15 Use as laboratory reagent. Handle in a fume cupboard or under extract ventilation.

Organisational measures to prevent/limit releases, dispersion and exposure

Organisational measures	Assumes a good basic standard of occupational hygiene is implemented. Ensure operatives are trained to minimise exposures. Supervision in place to check that the RMMs in place are being used correctly and OCs followed.
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Risk management measures

Avoid direct skin contact with product. Identify potential areas for indirect skin contact. Wear gloves (tested to EN374) if hand contact with substance likely. Clean up contamination/spills as soon as they occur. Wash off any skin contamination immediately. Provide basic employee training to prevent/minimise exposures and to report any skin problems that may develop. Wear suitable coveralls to prevent exposure to the skin. Use suitable eye protection. In case of insufficient ventilation, wear suitable respiratory equipment. with filter for particulates: P3.

Additional advice	Avoid splashing.
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2. Conditions of use affecting exposure (Non-industrial - Health 1)

Product characteristics

Physical state	Solid, low dustiness , or: Liquid
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3. Exposure estimation (Environment 1)

Assessment method	Used ECETOC TRA model.
Environmental release	Water: 250 kg/day Air: 0 kg/day Soil: 0 kg/day
Environmental exposure	Fresh water: Exposure 0.00026 mg/l, PNEC 0.0052 mg/l, RCR 0.05 Marine water: Exposure 0.000026 mg/l, PNEC 0.00052 mg/l, RCR 0.05 STP: Exposure 0.001 mg/l, PNEC 65 mg/l, RCR 0.01

3. Exposure estimation (Health 1)

Assessment method	Used ECETOC TRA model.
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Non-proteolytic enzyme: Industrial processing aid (including Cleaning in Place)

Exposure

PROC1 Chemical production or refinery in closed process without likelihood of exposure or processes with equivalent containment conditions

PROC2 Chemical production or refinery in closed continuous process with occasional controlled exposure or processes with equivalent containment conditions

PROC3 Manufacture or formulation in the chemical industry in closed batch processes with occasional controlled exposure or processes with equivalent containment condition

PROC4 Chemical production where opportunity for exposure arises

PROC5 Mixing or blending in batch processes

PROC13 Treatment of articles by dipping and pouring.

Worker - inhalation, long-term - local: Exposure 20 ng/m³, DNEL 60 ng/m³, RCR 0.33

PROC8a Transfer of substance or mixture (charging and discharging) at non-dedicated facilities

PROC8b Transfer of substance or mixture (charging and discharging) at dedicated facilities

Worker - inhalation, long-term - local: Exposure 10 ng/m³, DNEL 60 ng/m³, RCR 0.17

PROC15 Use as laboratory reagent.

Worker - inhalation, long-term - local: Exposure 6 ng/m³, DNEL 60 ng/m³, RCR 0.1

PROC7 Industrial spraying

Worker - inhalation, long-term - local: Exposure 40 ng/m³, DNEL 60 ng/m³, RCR 0.5

Worker - dermal Qualitative approach used to conclude safe use.

4. Guidance to check compliance with the exposure scenario (Health 1)

Estimated workplace exposures are not expected to exceed DNELs when the identified risk management measures are adopted.