



SAFETY DATA SHEET GLUCO AMYLASE LIQUID MIXTURE

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

1.1. Product identifier

Product name	GLUCO AMYLASE LIQUID MIXTURE
Product number	12312
Synonyms; trade names	SACZYME, SANFERM YIELD, SPRIZYME PLUS TECH, NOVOZYM 25023, ATTENUZYME CORE, AMG 300 L BREWQ, DEXTROZYME GA, ATTENUZYME PRO, AMYLASE AG XXL, SPIRIZYME EXCEL XHS, SPIRIZYME ULTRA XHS FG, SPIRIZYME FUEL HS, DEXTROZYME GA 1.5X FG

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

Identified uses	Enzyme
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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
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1.4. Emergency telephone number

Emergency telephone	SGS - +32 (0)3 575 55 55 (24h)
Sds No.	12312

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.
P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P501 Dispose of contents/ container in accordance with national regulations.

Contains GLUCO AMYLASE

2.3. Other hazards

This substance is not classified as PBT or vPvB according to current EU criteria.

SECTION 3: Composition/information on ingredients

3.2. Mixtures

GLUCO AMYLASE		20 - 60%
CAS number: 9032-08-0	EC number: 232-877-2	REACH registration number: 01-2119480439-28
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

Inhalation	Move affected person to fresh air at once. Rinse nose and mouth with water. Get medical attention if any discomfort continues.
Ingestion	Never give anything by mouth to an unconscious person. Do not induce vomiting. Rinse mouth thoroughly with water. Get medical attention if any discomfort continues.
Skin contact	Remove affected person from source of contamination. Remove contaminated clothing. Wash skin thoroughly with soap and water. Get medical attention if any discomfort continues.
Eye contact	Remove any contact lenses and open eyelids wide apart. Continue to rinse for at least 15 minutes. Continue to rinse for at least 15 minutes. Get medical attention if any discomfort continues.

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

Inhalation	May cause allergy or asthma symptoms or breathing difficulties if inhaled. Effects may be delayed.
Ingestion	May cause discomfort if swallowed.
Skin contact	May be slightly irritating to skin.
Eye contact	May be slightly irritating to eyes.

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

Notes for the doctor Treat symptomatically.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media	The product is not flammable. Use fire-extinguishing media suitable for the surrounding fire.
Unsuitable extinguishing media	Do not use water jet as an extinguisher, as this will spread the fire.

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5.2. Special hazards arising from the substance or mixture

Specific hazards May cause respiratory allergy.

5.3. Advice for firefighters

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 Avoid inhalation of vapours and contact with skin and eyes. Wear protective clothing as described in Section 8 of this safety data sheet.

6.2. Environmental precautions

Environmental precautions 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 Stop leak if possible without risk. Absorb with inert, damp, non-combustible material, then flush area with water. Provide adequate ventilation.

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 Avoid spilling. Avoid the formation of mists. Provide adequate ventilation. Avoid contact with skin and eyes.

7.2. Conditions for safe storage, including any incompatibilities

Storage precautions Store in tightly-closed, original container in a dry, cool and well-ventilated place. Protect from light. Store at temperatures between 0°C and 10°C. Keep only in the original container.

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

Ingredient comments No exposure limits known for ingredient(s).

GLUCO AMYLASE (CAS: 9032-08-0)

DMEL

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

8.2. Exposure controls

Protective equipment



Appropriate engineering controls

Provide adequate ventilation. Avoid inhalation of vapours. Observe any occupational exposure limits for the product or ingredients.

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Eye/face protection	Eyewear complying with an approved standard should be worn if a risk assessment indicates eye contact is possible. The following protection should be worn: Chemical splash goggles or face shield. 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	Appropriate footwear and additional protective clothing complying with an approved standard should be worn if a risk assessment indicates skin contamination is possible. Wear appropriate clothing to prevent any possibility of skin contact.
Hygiene measures	Wash at the end of each work shift and before eating, smoking and using the toilet. Wash promptly if skin becomes contaminated. Eye wash facilities and emergency shower must be available when handling this product. Good personal hygiene procedures should be implemented.
Respiratory protection	If ventilation is inadequate, suitable respiratory protection must be worn. Particulate filter, type P3. EN 136/140/141/145/143/149

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Appearance	Liquid.
Colour	Light (or pale). to Dark brown.
Odour	Characteristic.
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	1.15 - 1.16
Bulk density	No information available.
Solubility(ies)	Soluble in water.
Partition coefficient	No information available.

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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.
<u>9.2. Other information</u>	
Other information	Not determined.
Refractive index	No information available.
Particle size	No information available.
Molecular weight	No information available.
Volatility	No information available.
Saturation concentration	No information available.
Critical temperature	No information available.
Volatile organic compound	No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity	There are no known reactivity hazards associated with this product.
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10.2. Chemical stability

Stability	Stable at normal ambient temperatures.
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10.3. Possibility of hazardous reactions

Possibility of hazardous reactions	Not determined.
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10.4. Conditions to avoid

Conditions to avoid	Avoid excessive heat for prolonged periods of time.
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10.5. Incompatible materials

Materials to avoid	Not determined.
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10.6. Hazardous decomposition products

Hazardous decomposition products	Thermal decomposition or combustion may liberate carbon oxides and other toxic gases or vapours.
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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity - oral

Notes (oral LD ₅₀)	No information available.
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Skin corrosion/irritation

Skin corrosion/irritation	No information available.
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Animal data No information available.

Serious eye damage/irritation

Serious eye damage/irritation No information available.

Respiratory sensitisation

Respiratory sensitisation Sensitising.

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.

Ingestion May cause discomfort if swallowed.

Skin contact May be slightly irritating to skin.

Eye contact May be slightly irritating to eyes.

Toxicological information on ingredients.

GLUCO AMYLASE

Acute toxicity - oral

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

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

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SECTION 12: Ecological information

Ecotoxicity The product components are not classified as environmentally hazardous. However, large or frequent spills may have hazardous effects on the environment.

12.1. Toxicity

Toxicity Not considered toxic to fish.

Ecological information on ingredients.

GLUCO AMYLASE

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

12.2. Persistence and degradability

Persistence and degradability The product is biodegradable.

Ecological information on ingredients.

GLUCO AMYLASE

Persistence and degradability The product is readily biodegradable. OECD 301

12.3. Bioaccumulative potential

Bioaccumulative potential The product is not bioaccumulating.

Partition coefficient No information available.

Ecological information on ingredients.

GLUCO AMYLASE

Bioaccumulative potential The product is not bioaccumulating.

Partition coefficient log Pow: < 0

12.4. Mobility in soil

Mobility The product is soluble in water.

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment This substance is not classified as PBT or vPvB according to current EU criteria.

Ecological information on ingredients.

GLUCO AMYLASE

Results of PBT and vPvB assessment This substance is not classified as PBT or vPvB according to current EU criteria.

12.6. Other adverse effects

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Other adverse effects Not determined.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

General information Waste to be treated as controlled waste. Disposal to licensed waste disposal site in accordance with local Waste Disposal Authority. Do not puncture or incinerate, even when empty.

SECTION 14: Transport information

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

14.1. UN number

No information required.

14.2. UN proper shipping name

No information required.

14.3. Transport hazard class(es)

No information required.

14.4. Packing group

No information required.

14.5. Environmental hazards

Environmentally hazardous substance/marine pollutant

No.

14.6. Special precautions for user

No information required.

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

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code No information required.

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.

15.2. Chemical safety assessment

No 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.

Revision comments

NOTE: Lines within the margin indicate significant changes from the previous revision.

Revision date

07/10/2019

Version number

2.001

Supersedes date

29/05/2017

SDS number

12312

GLUCO AMYLASE LIQUID MIXTURE

SDS status

Approved.

Hazard statements in full

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

Signature

Jitendra Panchal



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

Identification

Product name	Gluco-amylase
REACH registration number	01-2119480439-28-XXXX
CAS number	9032-08-0
EC number	232-877-2
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
<u>Environment</u>	
Environmental release category	ERC2 Formulation into mixture
<u>Worker</u>	

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.
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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	Gluco-amylase
REACH registration number	01-2119480439-28-XXXX
CAS number	9032-08-0
EC number	232-877-2
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.



Exposure scenario

Non-proteolytic enzyme: Consumer use of toothpaste (environmental only)

Identification

Product name	Gluco-amylase
REACH registration number	01-2119480439-28-XXXX
CAS number	9032-08-0
EC number	232-877-2
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: Consumer use of toothpaste (environmental only)
Product category	PC0 Other products.
Main sector	SU21 Consumer uses

Environment

Environmental release category	ERC8a Widespread use of non-reactive processing aid (no inclusion into or onto article, indoor)
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2. Conditions of use affecting exposure (Workers - Health 1)

Organisational measures to prevent/limit releases, dispersion and exposure

Organisational measures	Assumes a good basic standard of occupational hygiene is implemented.
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2. Conditions of use affecting exposure (Non-industrial - Environment 1)

Amounts used

Daily amount for wide dispersive uses: 0.0000055 tonnes
Amount refers to local.

Risk management measures

STP type	Municipal STP.
STP details	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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Non-proteolytic enzyme: Consumer use of toothpaste (environmental only)

Conditions and measures related to external recovery of waste

Recovery method External recovery and recycling of waste should comply with applicable local and/or national regulations.

2. Conditions of use affecting exposure (Non-industrial - Health 1)

Control of Non-industrial exposure

In accordance to the Article 14 (5b) of the REACH Regulation (EC) No 1907/2006, exposure estimation and risk characterisation for human health does not need to be performed for end uses in cosmetic products within the scope of Directive 76/768/EEC. No exposure assessment presented for human health.

3. Exposure estimation (Environment 1)

Assessment method Used ECETOC TRA model.

Environmental release Water: 0.00275 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 0.00001 mg/l, PNEC 65 mg/l, RCR 0.01

3. Exposure estimation (Health 1)

Assessment method Used ECETOC TRA model.

Exposure Consumer - inhalation, long-term - local and systemic: Exposure 3 ng/m³, DNEL 15 ng/m³, RCR 0.2

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.