SAFETY DATA SHEET
Revision date: 2022/06/02
Version No: 3
Regulation (EC) No 1272/2008

Alcalase® 2.4 L FG

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

1.1. Product identifier

Product Name	Alcalase® 2.4 L FG
Chemical Name	Enzyme preparation
Declared activity	Protease (Subtilisin)
Unique Formula Identifier (UFI)	N520-20H0-C005-DHUV

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

Novozymes' enzyme preparations are biocatalysts used in a variety of industrial processes within food manufacturing
Identified uses are described in the annex to the safety data sheet

1.3. Details of the supplier of the safety data sheet

Novozymes A/S
Krogshoejvej 36
2880 Bagsvaerd
Denmark
Tel.: +45 44460000
Fax.: +45 44469999
E-mail: SafetyDataSheet@novozymes.com
www.novozymes.com

1.4. Emergency telephone number

+45 44462223 (24/7)

National helpdesk
CY: +35722405611
IS: +354 543 22 22
MT: +356 2395 2000

SECTION 2: Hazard identification

2.1. Classification of the substance or mixture

Regulation (EC) No 1272/2008

Serious eye damage/eye irritation	Category 2
Respiratory sensitisation	Category 1
Chronic aquatic toxicity	Category 3

The classification of eye effects is based on testing of a similar mixture.

2.2 Label elements

Contains Protease (Subtilisin) (aep.)

Signal word
Danger

Hazard statements
H319 - Causes serious eye irritation
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H412 - Harmful to aquatic life with long lasting effects

Precautionary Statements - EU (§28, 1272/2008)
P261 - Avoid breathing dust/fume/gas/mist/vapours/spray
P280 - Wear protective gloves/protective clothing and eye/face protection
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 or doctor/physician
P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing

2.3. Other hazards
Human health effects
Repeated inhalation of enzyme dust or aerosols resulting from improper handling may induce sensitization and may cause allergic type 1 reactions in sensitized individuals
Mild skin irritation
May cause eye irritation

Effects of overexposure
See Section 4

The mixture does not meet the criteria for PBT or vPvB.
See Section 11 and 12 for additional Toxicological information

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SECTION 3: Composition/information on ingredients

3.2. Mixtures

Chemical name	Weight-%	CAS No	EC No	CLP Classification (No 1272/2008)
Protease (Subtilisin) (aep.)	2.5 - <5	9014-01-1	232-752-2	Acute Tox. 4;H302 STOT SE 3;H335 Skin Irrit. 2;H315 Eye Dam. 1;H318 Resp. Sens. 1;H334 Aquatic Acute 1;H400 Aquatic Chronic 2; H411

Active enzyme protein (aep) is the part of the enzyme concentrate contributing to the classification of the mixture.

Regulatory information *

Chemical name	Weight-%	IUB No.	REACH Registration No
Protease (Subtilisin)	5 - <10	3.4.21.62	01-2119480434-38

*: In the scope of REACH registration enzymes are defined as enzyme concentrate (dry matter basis)

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

SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Effects	May cause allergic respiratory reaction
Symptoms	Shortness of breath, wheezing and coughing The effect of inhalation may be delayed
First Aid	Remove person to fresh air. If signs/symptoms continue, get medical attention Show this safety data sheet to the doctor in attendance

Skin Contact

Effects	May cause slight irritation
Symptoms	Slight irritation
First Aid	Remove and wash contaminated clothing before re-use. Wash off immediately with plenty of water. If symptoms persist, call a doctor. Show this safety data sheet to the doctor in attendance.

Eye Contact

Effects	Irritating to eyes
Symptoms	Irritation. Redness
First Aid	Hold eye open and rinse slowly and gently with water for 15-20 min. Remove contact lenses, if present, after the first five minutes, then continue rinsing eye. If symptoms persist, call a doctor. Show this safety data sheet to the doctor in attendance

Ingestion

Effects	Ingestion may cause gastrointestinal irritation.
Symptoms	Irritation
First Aid	Rinse mouth with water and drink plenty of water. If symptoms persist, call a doctor. Show this safety data sheet to the doctor in attendance.

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

See section 4.1

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

Notes to Physician Treat symptomatically

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable Extinguishing Media	Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide
Unsuitable Extinguishing Media	None
Hazardous Combustion Products	None

5.2. Special hazards arising from the substance or mixture

May cause allergic respiratory reaction

5.3. Advice for firefighters

Self-contained breathing apparatus

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

For personal protection see section 8

6.2. Environmental precautions

Collect spillage

6.3. Methods and material for containment and cleaning up

Avoid formation of dust and aerosols
Spilled preparation should be removed immediately to avoid formation of dust from dried preparation. Take up by mechanical means preferably by a vacuum cleaner equipped with a high efficiency filter. Flush remainder carefully with plenty of water. Avoid splashing and high pressure washing (avoid formation of aerosols). Ensure sufficient ventilation. Wash contaminated clothing.

6.4. Reference to other sections
For personal protection see section 8

SECTION 7: Handling and storage

7.1. Precautions for safe handling
Avoid formation of dust and aerosols.
Ensure adequate ventilation
Liquid enzyme preparations are dustfree preparations
However, inappropriate handling may cause formation of dust or aerosols

7.2. Conditions for safe storage, including any incompatibilities
Keep tightly closed in a dry and cool place
The product can be transported at ambient temperature. Following delivery, the product should be stored as recommended. 0-10 °C (32-50 °F)

Storage Class (TRGS 510) LGK10 - Combustible liquids unless storage class 3

7.3. Specific end use(s)
Handle in accordance with good industrial hygiene and safety practice
See Exposure Scenario(s) in the annex

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Chemical name	ACGIH TLV
Protease (Subtilisin) (aep.)	Ceiling: 0.00006 mg/m³ Ceiling (as crystalline active enzyme, listed under Subtilisins)

Chemical name	Belgium	Denmark	Finland	Germany MAK	Ireland	Norway
Protease (Subtilisin) (aep.)	0.00006 mg/m³ Maximum Limit Value (8 hours)	Ceiling: 0.00006 mg/m³		respiratory sensitizer	TWA: 0.00006 mg/m³ STEL: 0.00006 mg/m³	0.00006 mg/m³ Ceiling

Chemical name	Netherlands	Portugal	Sweden	Spain	Switzerland	The United Kingdom
Protease (Subtilisin) (aep.)		Ceiling: 0.00006 mg/m³	1 glycineunit/m³ LLV 3 glycineunit/m³ LLV	STEL: 0.00006 mg/m³	STEL: 0.00006 mg/m³	0.00004 mg/m³ TWA

DNEL/DMEL/PNEC

Chemical name	DNEL Dermal Acute Local (Workers)	DMEL Inhalation Long term Local (Workers)
Protease (Subtilisin) (aep.)	DNEL = 0,2% in mixture (W/W)	DMEL = 60 ng/m³

Derived No Effect Level (DNEL)
Derived Minimal Effect Level (DMEL)
Predicted No Effect Concentration (PNEC)

8.2. Exposure controls
Ensure adequate ventilation, especially in confined areas

Personal Protective Equipment

Respiratory protection	In case of insufficient ventilation wear an approved mask with a particle filter type P3 used according to the manufactures instruction
Eye Protection	Wear safety glasses with side shields (or goggles)
Skin Protection	Long sleeved clothing
Hand Protection	Protective gloves of e.g. nitrile rubber or neoprene (thickness > 0.3 mm) according to EN 374-3. Expected breakthrough time: > 4 hours. The recommendation is a qualified estimate based on the knowledge of the components in the mixture.
General Hygiene Considerations	Handle in accordance with good industrial hygiene and safety practice
Environmental exposure controls	Local authorities should be advised if significant spillages cannot be contained

Waste water should be discharged to sewage treatment plant

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical State	Liquid
Colour	Brown
Odour	Slight fermentation odor
Density (g/ml)	1.17
pH	Adjusted to the range where active enzyme is stable – typically pH 4 – 9
Solubility	Active component is readily soluble in application-relevant solutions at all levels of concentration, temperature and pH which may occur in normal usage
Vapour Pressure	Not available

9.2. Other information
No information available

SECTION 10: Stability and reactivity

10.1. Reactivity
Not relevant

10.2. Chemical stability
Stable under recommended storage conditions

10.3. Possibility of hazardous reactions
None under normal processing

10.4. Conditions to avoid
None

10.5. Incompatible materials

None

10.6. Hazardous decomposition products
None

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Actual Product Data — An eye irritation study, Isolated Chicken Eye (ICE) on similar mixture concluded the classification as Eye Cat. 2

Chemical name	Acute oral toxicity	Respiratory sensitisation	Genetic toxicity	Skin corrosion/irritation	Serious eye damage/eye irritation
Protease (Subtilisin) (aep.)	LD50: 1800 mg/kg bw (OECD TG 401)	Sensitizer (Human experience)	No indication of mutagenic effects (OECD TG 471, 473, 476)	Slightly irritating (OECD TG 404)	Slightly irritating (OECD TG 405)

Chemical name	Acute inhalation toxicity	Specific target organ toxicity — single exposure	Specific target organ toxicity — repeated exposure
Protease (Subtilisin) (aep.)	Exposure based waiving	Irritating, respiratory tract (ACGIH 2001)	

SECTION 12: Ecological information

12.1. Toxicity

Chemical name	Daphnia, acute	Acute fish toxicity =	Algae, Acute
Protease (Subtilisin) (aep.)	EC50 (48 hours):586 µg aep/l (OECD TG 202)	LC50 (96 hours): 8.2 mg aep/l (OECD TG 203)	ErC50 (72 hours): 830 µg aep/l (OECD TG 201)

12.2. Persistence and degradability

Chemical name	Persistence and degradability	Partition coefficient (n-octanol/water)
Protease (Subtilisin) (aep.)	Readily biodegradable (OECD TG 301B)	LogPow: <0

12.3. Bioaccumulative potential

Chemical name	Bioaccumulative potential
Protease (Subtilisin) (aep.)	Does not bioaccumulate

12.4. Mobility in soil
Not relevant

12.5. Results of PBT and vPvB assessment
The components in this formulation do not meet the criteria for classification as PBT or vPvB

12.6 Other adverse effects

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Dispose of in accordance with local regulations
Waste water should be discharged to sewage treatment plant
Waste codes should be assigned by the user based on the application for which the product was used

SECTION 14: Transport information

Transport Regulations
No dangerous goods according to transport regulations
No special precautions required

Not regulated

14.1	
UN number	not applicable
14.2	
UN proper shipping name	Not applicable
14.3	
Transport hazard class(es)	Not applicable
14.4	
Packing group	Not applicable
14.5	
Environmental hazards	Not applicable
14.6	
Special precautions for user	Not applicable
14.7	
Transport in bulk according to Annex II of MARPOL and the IBC Code	Not applicable

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
WGK Classification slightly hazardous to water (WGK 1)

The product complies with the recommended purity specifications for food-grade enzymes given by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the Food Chemical Codex (FCC).

15.2. Chemical safety assessment
Chemical safety assessment has been carried out for the registered component(s)

SECTION 16: Other information

Full text of H-Statements referred to under section 3
H315 - Causes skin irritation
H318 - Causes serious eye damage
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H335 - May cause respiratory irritation
H302 - Harmful if swallowed
H400 - Very toxic to aquatic life
H411 - Toxic to aquatic life with long lasting effects

CLP Classification
The classification of eye effects is based on testing of a similar mixture.
Classification according to Regulation (EC) No. 1272/2008 [CLP]

Further information

For further information please consult available product documentation including 'Product Application Guidelines' and/or 'Application Sheets', which are available on market.novozymes.com or from Novozymes sales representatives.

Training advice
Details on the safe handling of this product can be found in the "Handling enzymes" on market.novozymes.com

Disclaimer
The information provided on this SDS is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guide for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered as a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other material or in any process, unless specified in the text. Furthermore, as the conditions of use are beyond the control of Novozymes, it is the responsibility of the customer to determine the conditions of safe use of these products.

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Annex to SDS

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Exposure Scenarios for identified uses of the product:

Alcalase® 2.4 L FG

Formulation
3. Subtilisin - Formulation of enzyme containing products at downstream users

Use at industrial site
5. Subtilisin - Enzymes used as processing aids at industrial sites - including Cleaning in Place (CIP)

Use by professional worker
23. Subtilisin - Professional septic tank maintenance, drain cleaning and grease trap maintenance

Consumer use
35. Subtilisin - Consumer use of laundry products

(Please note that exposure scenario numbers are internal Novozymes ID numbers. A missing number does not mean exposure scenarios are missing in this extended safety data sheet)

3. Exposure scenario - Subtilisin: Formulation or re-packing

This exposure scenario covers the substance(s) below (please see section 3 of the Safety Data Sheet for content in this specific product):
Protease (Subtilisin)
Glutamyl endopeptidase
Protease aspartic

3.1: Title: Formulation of enzyme containing products at downstream users

Product categories [PC]
PC0 - Other Products
PC21 - Laboratory chemicals
PC35 - Washing and cleaning products (including solvent based products)
PC37 - Water treatment chemicals
PC39 - Cosmetics, personal care products

Environment contributing scenario(s):		
CS 1	Formulation of enzyme products at downstream users' sites	ERC 2
Worker contributing scenario(s):		
CS 2	Mixing operations	PROC 1, PROC 2, PROC 3, PROC 4, PROC 5
CS 3	Transfer substance/mixtures from/to containers	
CS 4	Transfer of the substance/mixtures into small containers	PROC 8a, PROC 8b
CS 5	Tabletting, compression, extrusion or pelletisation	PROC 9
CS 6	Use of the substance within laboratory settings, including material transfers and equipment cleaning	PROC 14 PROC 15

3.2 Conditions of use affecting exposure

3.2.1. Environmental contributing scenario 1: Formulation of enzyme products at downstream users' sites

Amount used, frequency and duration of use (or from service life)
Daily use at site: Daily use at site: <= 10.0 tonnes/year
Annual use at a site: <= 2500 tonnes/year
Conditions and measures related to sewage treatment plant
Conditions and measures related to sewage treatment plant: 99.99% degradation
Biological STP: Standard
Discharge rate of effluent: >= 2.000 m3/d
Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to external treatment of waste (including article waste)
Particular considerations on the waste treatment operations: No (Waste disposal according to national/local legislation)
Other conditions affecting environmental exposure
Receiving surface water flow rate: >= 18.000 m3/d

3.2.2. Worker contributing scenario 2: Mixing operations (PROC 5, PROC 1; PROC 2; PROC 3; PROC 4)

Product (article) characteristics
Concentration of substance in mixture: <15% active enzyme protein before formulation processes (Finished products after entire formulation processes contain < 0.5 % active enzyme protein.)
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: Yes (Unless measurement of exposure by air sampling demonstrates airborne enzyme concentrations are below the DMEL, or if the mixing process is closed with no risk of exposure)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)
Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: No (Respiratory protection, with P3 filter, is only used as secondary protection if LEV is insufficient to control peak exposures above the DMEL.

Task-specific assessment should dictate the level of personal respiratory protection required to ensure that exposures remain below the DMEL. At closed mixing process there is very limited risk of exposure)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)
Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

3.2.3. Worker contributing scenario 3: Transfer substance/mixtures from/to containers (PROC 8a, PROC 8b)

Product (article) characteristics
Concentration of substance in mixture: <15% active enzyme protein before formulation processes (Finished products after entire formulation processes contain < 0.5 % active enzyme protein.) The concentration can be up to 30% aep if the transfer process is conduced at dedicated facilities (PROC 8b), where the process is closed, e.g. use of automatic pumping system.
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: Yes (Unless measurement of exposure by air sampling demonstrates airborne enzyme concentrations are below the DMEL.)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)
Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: No (Respiratory protection, with P3 filter, is only used as secondary protection if LEV is insufficient to control peak exposures above the DMEL. Task-specific assessment should dictate the level of personal respiratory protection required to ensure that exposures remain below the DMEL)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)
Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

3.2.4. Worker contributing scenario 4: Transfer of substance or mixture into small containers (dedicated filling line, including weighing) (PROC 9)

Product (article) characteristics
Concentration of substance in mixture: <= 0.5 % based on active enzyme protein (AEP)
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: Yes (Unless measurement of exposure by air sampling demonstrates airborne enzyme concentrations are below the DMEL.)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)
Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: No (Respiratory protection, with P3 filter, is only used as secondary protection if LEV is insufficient to control peak exposures above the DMEL. Task-specific assessment should dictate the level of personal respiratory protection required to ensure that exposures remain below the DMEL)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)
Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

3.2.5. Worker contributing scenario 5: Tabletting, compression, extrusion or pelletisation (PROC 14)

Product (article) characteristics

Concentration of substance in mixture: <= 0.5 % based on active enzyme protein (AEP)
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: Yes (Unless measurement of exposure by air sampling demonstrates airborne enzyme concentrations are below the DMEL.)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)
Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: No (Respiratory protection, with P3 filter, is only used as secondary protection if LEV is insufficient to control peak exposures above the DMEL. Task-specific assessment should dictate the level of personal respiratory protection required to ensure that exposures remain below the DMEL)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)
Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

3.2.6. Worker contributing scenario 6: Use of the substance within laboratory settings, including material transfers and equipment cleaning (PROC 15)

Product (article) characteristics
Concentration of substance in mixture: <= 15.0 % based on active enzyme protein (AEP). (Finished products after entire formulation processes contain <= 0.5 % active enzyme protein)
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: Yes (For laboratory use. LEV or fume cupboard is used for the processes where high exposures are expected e.g. handling solid enzyme substance/mixtures.)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)
Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: No (Respiratory protection, with P3 filter, is only used as secondary protection if LEV is insufficient to control peak exposures above the DMEL. Task-specific assessment should dictate the level of personal respiratory protection required to ensure that exposures remain below the DMEL)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)
Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

3.3. Exposure estimation and reference to its source

3.3.1. Environmental release and exposure: Formulation of enzyme products at downstream users' sites (ERC 2)

Release factor estimation method	Explanation / Justification
Water Release factor	Local release rate: <= 100 kg/day
Air Release factor	Local release rate: 0 kg/day
Soil Release factor	Final release factor: 0%

Protection target	Exposure concentration	Risk characterisation
Freshwater	Local PEC: <0.0009 mg/l	RCR < 0.53
Marine water	Local PEC: <0.00009 mg/l	RCR < 0.53
Sewage treatment plant	Local PEC: ~0.005 mg/l	RCR < 0.01
Agricultural soil	Local PEC: <1.0E-11 mg/kg dw	RCR < 0.01

3.3.2. Worker contributing scenario 2: Mixing operations (PROC 5, PROC 1; PROC 2; PROC 3; PROC 4)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<20 ng/m³ (Measured data)	<0.33

3.3.3. Worker contributing scenario 3: Transfer substance/mixtures from/to containers (PROC 8a, PROC 8b)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<10 ng/m³ (Measured data)	<0,17

3.3.4. Worker contributing scenario 4: Transfer of the substance/mixtures into small containers (PROC 9)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<6 ng/m³ (Measured data)	<0.1

3.3.5. Worker contributing scenario 5: Production of products by tabletting (PROC 14)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<30 ng/m³ (Measured data)	<0.5

3.3.6. Worker contributing scenario 6: Use as laboratory reagent (PROC 15)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<6 ng/m³ (Measured data)	<0.1

3.3.7. Worker exposure: Skin and eye exposure (qualitative)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Dermal, local Eye, local	≤0.2% active subtilisin in aqueous solution (short time (<10 min) exposure, hands only) >0.2% active subtilisin in aqueous solution Accidental exposure to Subtilisin has the potential to cause eye irritation	Qualitative: Regarded as non-irritant to skin Qualitative: Impermeable glove must be used Qualitative: Effects are highly reversible. Rinse eyes with plenty of water

3.4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Downstream User (DU) must check that his uses are covered in Section 2. If tasks or activities not in compliance with this exposure scenario have been assessed by competent authority or by actual measurements they may still be in compliance. To be in compliance the generated data and/or information must support a risk characterization ratio (RCR)<1. This assessment should be performed in collaboration with Novozymes A/S to ensure REACH compliance.

The inhalation exposure of enzyme(s) needs to be assessed using high tier methods, i.e. actual measurements. It is thus not possible to adjust the use conditions in this exposure scenario using Tier 1 or Tier 2 tools such as ECETOC TRA. Please contact Novozymes A/S, if you need to modify the exposure scenario.

If enzyme products with higher concentration of active enzyme protein (aep) than stated under 'Product (article) characteristics' are used please contact Novozymes A/S to modify the exposure scenario.

5. Exposure Scenario - Subtilisin: Industrial processing aid (incl. CIP)

This exposure scenario covers the substance(s) below (please see section 3 of the Safety Data Sheet for content in this specific product):
Protease (Subtilisin)
Glutamyl endopeptidase
Protease aspartic

5.1: Title: Industrial use as processing aid - including Cleaning in Place (CIP)

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
SU 23 - Electricity, steam, gas water supply and sewage treatment
SU 24 - Scientific research and development

Environment contributing scenario(s):		
CS 1	Processing aid	ERC 4
Worker contributing scenario(s):		
CS 2	Mixing operations	PROC 1, PROC 2, PROC 3, PROC 4, PROC 5
CS 3	Transfer substance/mixtures from/to containers	
CS 4	Industrial spraying	PROC 8a, PROC 8b
CS 5	(Drum filter spraying - starch industry only)	PROC 7
CS 6	Treatment of articles by dipping and pouring (Textile industry only)	PROC 13 PROC 15
	Use of the substance within laboratory settings, including material transfers and equipment cleaning	

5.2 Conditions of use affecting exposure

5.2.1. Environmental contributing scenario 1: Processing aid (ERC 4)

Amount used, frequency and duration of use (or from service life)
Daily use at site: Daily use at site: <=0.8 tonnes/day
Annual use at a site: <= 200 tonnes/year
Conditions and measures related to sewage treatment plant
Conditions and measures related to sewage treatment plant: 99.99% degradation
Biological STP: Standard
Discharge rate of effluent: >= 2.000 m3/d
Application of the STP sludge on agricultural soil: Yes
Conditions and measures related to external treatment of waste (including article waste)
Particular considerations on the waste treatment operations: No (Waste disposal according to national/local legislation)
Other conditions affecting environmental exposure
Receiving surface water flow rate: >= 18.000 m3/d

5.2.2. Worker contributing scenario 2: Mixing operations (PROC 5, PROC 1; PROC 2; PROC 3; PROC 4)

Product (article) characteristics
Concentration of substance in mixture: <15% active enzyme protein (After the mixing processes <= 0.5 % active enzyme protein.)
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: Yes (Unless measurement of exposure by air sampling demonstrates airborne enzyme concentrations are below the DMEL, or if the mixing process is closed with no risk of exposure)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)

Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: No (Respiratory protection, with P3 filter, is only used as secondary protection if LEV is insufficient to control peak exposures above the DMEL. Task-specific assessment should dictate the level of personal respiratory protection required to ensure that exposures remain below the DMEL. At closed mixing process there is very limited risk of exposure)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)
Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

5.2.3. Worker contributing scenario 3: Transfer substance/mixtures from/to containers (PROC 8a, PROC 8b)

Product (article) characteristics
Concentration of substance in mixture: <= 15.0 % based on active enzyme protein (AEP). The concentration can be up to 30% aep if the transfer process is conduced at dedicated facilities (PROC 8b), where the process is closed, e.g. use of automatic pumping system.
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: Yes (Unless measurement of exposure by air sampling demonstrates airborne enzyme concentrations are below the DMEL.)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)
Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: No (Respiratory protection, with P3 filter, is only used as secondary protection if LEV is insufficient to control peak exposures above the DMEL. Task-specific assessment should dictate the level of personal respiratory protection required to ensure that exposures remain below the DMEL)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)
Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

5.2.4. Worker contributing scenario 4: Industrial spraying (PROC 7)
The assessment of PROC 7 is only valid for drum filter spraying in the starch industry

Product (article) characteristics
Concentration of substance in mixture: <= 0.0065 % based on active enzyme protein (AEP) in the process water that is used to spray onto a drum filter
Physical property - Liquid: Products are in liquid form
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: Yes (Unless measurement of exposure by air sampling demonstrates airborne enzyme concentrations are below the DMEL.)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)
Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: No (Respiratory protection, with P3 filter, is not necessary if the drum filter is enclosed, or fresh water is used in the spray process instead of process water (containing enzymes). Respiratory protection, with P3 filter, is only used as secondary protection if the drum filter cannot be enclosed, or if LEV is insufficient to control peak exposures above the DMEL.)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)

Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

5.2.5. Worker contributing scenario 5: Treatment of articles by dipping and pouring (PROC 13)
The assessment of PROC 13 is only valid for the textile industry

Product (article) characteristics
Concentration of substance in mixture: <= 0.1 % based on active enzyme protein (AEP)
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: No (Unless measurement of exposure by air sampling demonstrates airborne enzyme concentrations are above the DMEL.)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)
Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: Yes (Unless enzyme concentration is less than 0.005% or measurement of exposure by air sampling demonstrates airborne enzyme concentrations are below the DMEL)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)
Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

5.2.6. Worker contributing scenario 6: Use of the substance within laboratory settings, including material transfers and equipment cleaning (PROC 15)

Product (article) characteristics
Concentration of substance in mixture: <= 30.0 % based on active enzyme protein (AEP).
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Covers daily exposures up to 12 hours
Technical and organisational conditions and measures
HEPA air filtrations: Yes (HEPA air filtrations should be used if air is recirculated into the work environment provided that air monitoring confirms airborne enzyme concentrations remain below the DMEL.)
Local Exhaust Ventilation: Yes (For laboratory use. LEV or fume cupboard is used for the processes where high exposures are expected e.g. handling solid enzyme substance/mixtures.)
Worker training: Train workers in safe enzyme handling. (Safety materials like posters, booklets, e-learning and Safety Data Sheets are available for customers)
Supervision: Management/supervision in place to check that the RMMs are being used correctly and OCs followed.
Conditions and measures related to personal protection, hygiene and health evaluation
Respiratory protection: No (Respiratory protection, with P3 filter, is only used as secondary protection if LEV is insufficient to control peak exposures above the DMEL. Task-specific assessment should dictate the level of personal respiratory protection required to ensure that exposures remain below the DMEL)
Dermal protection: Yes (When handling concentrated enzyme formulation corresponding to more than 0.2% aep. impermeable glove must be used. In case of skin contact, rinse skin thoroughly.)
Good housekeeping: Regular cleaning. (Spilled preparation should be removed immediately either by a vacuum cleaner equipped with HEPA filter and/or by flushing carefully with plenty of water and avoid splashing. Ensure sufficient ventilation. Wash contaminated clothing.)
Medical surveillance: Conduct appropriate health surveillance.

5.3. Exposure estimation and reference to its source

5.3.1. Environmental release and exposure: Processing aid (ERC 4)

Release factor estimation method	Explanation / Justification
Water Release factor	Local release rate: <= 80 kg/day
Air Release factor	Local release rate: 0 kg/day
Soil Release factor	Final release factor: 0%

Protection target	Exposure concentration	Risk characterisation
Freshwater	Local PEC: <0.0009 mg/l	RCR < 0.5
Marine water	Local PEC: <0.00009 mg/l	RCR < 0.5
Sewage treatment plant	Local PEC: ~0.005 mg/l	RCR < 0.01
Agricultural soil	Local PEC: <1.0E-11 mg/kg dw	RCR < 0.01

5.3.2. Worker contributing scenario 2: Mixing operations (PROC 5, PROC 1; PROC 2; PROC 3; PROC 4)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<20 ng/m³ (Measured data)	<0.33

5.3.3. Worker contributing scenario 3: Transfer substance/mixtures from/to containers (PROC 8a, PROC 8b)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<10 ng/m³ (Measured data)	<0,17

5.3.4. Worker contributing scenario 4: Industrial spraying (PROC 7)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<40 ng/m³ (Measured data)	<0.67

5.3.5. Worker contributing scenario 5: Treatment of articles by dipping and pouring (PROC 13)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<20 ng/m³ (Measured data)	<0.33

5.3.6. Worker contributing scenario 6: Use as laboratory reagent (PROC 15)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<6 ng/m³ (Measured data)	<0.1

5.3.7. Worker exposure: Skin and eye exposure (qualitative)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Dermal, local Eye, local	≤0.2% active subtilisin in aqueous solution (short time (<10 min) exposure, hands only) >0.2% active subtilisin in aqueous solution Accidental exposure to Subtilisin has the potential to cause eye irritation	Qualitative: Regarded as non-irritant to skin Qualitative: Impermeable glove must be used Qualitative: Effects are highly reversible. Rinse eyes with plenty of water

5.4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Downstream User (DU) must check that his uses are covered in Section 2. If tasks or activities not in compliance with this exposure scenario have been assessed by competent authority or by actual measurements they may still be in compliance. To be in compliance the generated data and/or information must support a risk characterization ratio (RCR)<1. This assessment should be performed in collaboration with Novozymes A/S to ensure REACH compliance.

The inhalation exposure of enzyme(s) needs to be assessed using high tier methods, i.e. actual measurements. It is thus not possible to adjust the use conditions in this exposure scenario using Tier 1 or Tier 2 tools such as ECETOC TRA. Please contact Novozymes A/S, if you need to modify the exposure scenario.

If enzyme products with higher concentration of active enzyme protein (aep) than stated under 'Product (article) characteristics' are used please contact Novozymes A/S to modify the exposure scenario.

23. Exposure Scenario - Subtilisin: Professional septic tank maintenance, drain cleaning and grease trap maintenance

This exposure scenario covers the substance(s) below (please see section 3 of the Safety Data Sheet for content in this specific product):
Protease (Subtilisin)

23.1: Title: Professional septic tank maintenance, drain cleaning and grease trap maintenance

Product categories [PC]
PC37 - Water treatment chemicals

Environment contributing scenario(s):		
CS 1	Septic tank maintenance, drain cleaning and grease trap maintenance	ERC 8a
Worker contributing scenario(s):		
CS 2	Septic tank maintenance, drain cleaning and grease trap maintenance	PROC 2
CS 3	Transfer of substance or mixture (charging/discharging) at non dedicated-facilities	PROC 8a

23.2 Conditions of use affecting exposure

23.2.1. Environmental contributing scenario 1: Professional septic tank maintenance, drain cleaning and grease trap maintenance (ERC 8a)

Amount used, frequency and duration of use (or from service life)
Daily use at site: Daily local widespread use amount: <= 0.0000017 tonnes/day
Conditions and measures related to sewage treatment plant
Conditions and measures related to sewage treatment plant: 99.99% degradation
Biological STP: Standard
Conditions and measures related to external treatment of waste (including article waste)
Particular considerations on the waste treatment operations: No (Waste disposal according to national/local legislation)

23.2.2. Worker contributing scenario 2: Septic tank maintenance, drain cleaning and grease trap maintenance (PROC 2)

Product (article) characteristics
Concentration of substance in mixture: <= 0.2 % based on active enzyme protein (AEP) Enzyme products are further diluted in septic tanks or drains.
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: <= 1.0 hours/day
Technical and organisational conditions and measures
Containment: Closed continuous process with occasional controlled exposure
Conditions and measures related to personal protection, hygiene and health evaluation
Dermal protection: No (In case of skin contact, rinse skin thoroughly.)

23.2.3. Worker contributing scenario 3: Transfer of substance or mixture (charging/discharging) at non dedicated-facilities (PROC 8a)

Product (article) characteristics
Concentration of substance in mixture: <= 0.2 % based on active enzyme protein (AEP) Enzyme products are further diluted in septic tanks or drains.
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: <= 0.1 hours/day (Several dosings can take place during a working day.)
Conditions and measures related to personal protection, hygiene and health evaluation
Dermal protection: No (In case of skin contact, rinse skin thoroughly.)

23.3. Exposure estimation and reference to its source

23.3.1. Environmental release and exposure: Septic tank maintenance, drain cleaning and grease trap maintenance (ERC

8a)

Release factor estimation method	Explanation / Justification
Water Release factor	Local release rate: <= 0.000165 kg/day
Air Release factor	Local release rate: 0 kg/day
Soil Release factor	Final release factor: 0%

Protection target	Exposure concentration	Risk characterisation
Freshwater	Local PEC: <0.0005 mg/l	RCR < 0.3
Marine water	Local PEC: <0.00005 mg/l	RCR < 0.3
Sewage treatment plant	Local PEC: <0.000001 mg/l	RCR < 0.01
Agricultural soil	Local PEC: <1.0E-11 mg/kg dw	RCR < 0.01

23.3.2. Worker contributing scenario 2: Septic tank maintenance, drain cleaning and grease trap maintenance (PROC 2)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<2 ng/m³ (Measured data)	<0.14

23.3.3. Worker contributing scenario 3: Transfer of substance or mixture (charging/discharging) at non dedicated-facilities (PROC 8a)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term (For skin and eyes - see below)	<2 ng/m³ (Measured data)	<0.14

23.3.4. Worker exposure: Skin and eye exposure (qualitative)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Dermal, local	≤0.2% active subtilisin in aqueous solution (short time (<10 min) exposure, hands only)	Qualitative: Regarded as non-irritant to skin
Eye, local	Accidental exposure to Subtilisin has the potential to cause eye irritation	Qualitative: Effects are highly reversible. Rinse eyes with plenty of water

23.4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Downstream User (DU) must check that his uses are covered in Section 2. If tasks or activities not in compliance with this exposure scenario have been assessed by competent authority or by actual measurements they may still be in compliance. To be in compliance the generated data and/or information must support a risk characterization ratio (RCR)<1. This assessment should be performed in collaboration with Novozymes A/S to ensure REACH compliance.

The inhalation exposure of enzyme(s) needs to be assessed using high tier methods, i.e. actual measurements. It is thus not possible to adjust the use conditions in this exposure scenario using Tier 1 or Tier 2 tools such as ECETOC TRA. Please contact Novozymes A/S, if you need to modify the exposure scenario.

35. Exposure Scenario - Subtilisin: Consumer use of laundry products

This exposure scenario covers the substance(s) below (please see section 3 of the Safety Data Sheet for content in this specific product):
Protease (Subtilisin)

35.1: Title: Consumer use of laundry products

Environment contributing scenario(s):		
CS 1	Consumer use of laundry products	ERC 8a
Consumer contributing scenario(s):		
CS 2	Consumer use of laundry products	PC 35

35.2 Conditions of use affecting exposure

35.2.1. Environmental contributing scenario 1: Consumer use of laundry products (ERC 8a)

Amount used, frequency and duration of use (or from service life)
Daily use at site: Daily local widespread use amount: <= 0.0011 tonnes/day
Conditions and measures related to sewage treatment plant
Conditions and measures related to sewage treatment plant: 99.99% degradation
Biological STP: Standard
Conditions and measures related to external treatment of waste (including article waste)
Particular considerations on the waste treatment operations: No (Waste disposal according to national/local legislation)

35.2.2. Consumer contributing scenario 2: Consumer use of laundry products (PC 35)

Product (article) characteristics
Concentration of substance in mixture: <= 0.2 % based on active enzyme protein (AEP) For laundry detergent packed in pouches, where there is no skin contact, the detergent concentration is <0.5% aep. Enzymes are diluted in the washing liquids according to dosing instruction of the products.
Physical property - Liquid: Products are in liquid form
Physical property - Granulate: Products are in the form of encapsulated low dust granulates
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Exposure time per event: = 0.1 hour (Dosing detergent to the laundry machine. Several dosings can take place during a day.)
Amount of product used: LAUNDRY REGULAR/Powder: Grams/Task Max: 290 LAUNDRY COMPACT/Powder Grams/Task Max: 200 LAUNDRY COMPACT/Tablet Grams/Task Max 135 LAUNDRY REGULAR/Liquid: Grams/Task Max: 230 LAUNDRY COMPACT/Liquid: Grams/Task Max: 140 Laundry pre-treatment: 10 min. / task, 50-60% paste (powder) or neat liquid. Ref.: TABLE OF HABITS AND PRACTICES FOR CONSUMER PRODUCTS IN WESTERN EUROPE /AISE, 2009 (https://www.aise.eu/documents/document/20150602150650-aise_sceds_supportingexplanation_document_may2015_v1.pdf)

35.3. Exposure estimation and reference to its source

35.3.1. Environmental release and exposure: Consumer use of laundry products (ERC 8a)

Release factor estimation method	Explanation / Justification
Water Release factor	Local release rate: <= 0.11 kg/day
Air Release factor	Local release rate: 0 kg/day
Soil Release factor	Final release factor: 0%

Protection target	Exposure concentration	Risk characterisation
Freshwater	Local PEC: <0.0004 mg/l	RCR < 0.25
Marine water	Local PEC: <0.00004 mg/l	RCR < 0.25
Sewage treatment plant	Local PEC: <0.00001 mg/l	RCR < 0.01
Agricultural soil	Local PEC: <1.0E-11 mg/kg dw	RCR < 0.01

35.3.2. Consumer contributing scenario 2: Consumer use of laundry products (PC 35)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio

Inhalation, local, long term All routes, systemic, long term	<3 ng/m³ (Measured data) 0 mg/kg bw/day (TRA Consumers)	<0.2 <0.01

35.4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

Downstream User (DU) must check that his uses are covered in Section 2. If tasks or activities not in compliance with this exposure scenario have been assessed by competent authority or by actual measurements they may still be in compliance. To be in compliance the generated data and/or information must support a risk characterization ratio (RCR)<1. This assessment should be performed in collaboration with Novozymes A/S to ensure REACH compliance.

The inhalation exposure of enzyme(s) needs to be assessed using high tier methods, i.e. actual measurements. It is thus not possible to adjust the use conditions in this exposure scenario using Tier 1 or Tier 2 tools such as ECETOC TRA. Please contact Novozymes A/S, if you need to modify the exposure scenario.