SAFETY DATA SHEET
Revision date: 2023/02/22
Version No: 3
REACH Regulation (EC) no. 1907/2006

Medley® Glow 200 L

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

1.1. Product identifier

Product Name	Medley® Glow 200 L
Chemical Name	Enzyme preparation
Declared activity	Cellulase
Unique Formula Identifier (UFI)	N972-V08E-V005-NGJA

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 and in certain consumer products
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

Respiratory sensitisation	Category 1

2.2 Label elements

Contains Cellulase (aep.)

Signal word
Danger

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

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

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
Mild 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 (EU Index No)	CLP Classification (No 1272/2008)	Specific concentration limit (SCL)	M-Factor
Cellulase (aep.)	1 – <2.5	9012-54-8	232-734-4	Resp. Sens. 1;H334	-	1

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
Cellulase	5 - <10	3.2.1.4	01-2119949289-21

*: 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

Acute Toxicity Estimate
No information available

Chemical name	mg/kg oral LD50 (rat)	Dermal LD50	Inhalation LC50 - 4 hour - dust/mist - mg/L	Inhalation LC50 - 4 hour - vapour - mg/L	Inhalation LC50 - 4 hour - gas - ppm
Cellulase (aep.)	2880	-	-	-	-

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	May cause slight irritation
Symptoms	Slight irritation
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 0-25 °C (32-77 °F)
In unbroken packaging - dry and protect from the sun. The product has been formulated for optimal stability. Extended storage or adverse conditions such as higher temperatures or higher humidity may lead to a higher dosage requirement.
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
When enzymes are used for spray products or hard surface cleaning, exposure of enzymes may exceed the safety level (15 ng/m³ DMEL). If you intend to develop such products, please contact Novozymes for further safety evaluation.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Chemical name	Belgium	Denmark	Finland	Germany MAK	Ireland	Norway
Cellulase (aep.)				respiratory sensitizer		

DNEL/DMEL/PNEC

Chemical name	DNEL Dermal Acute Local (Workers)	DMEL Inhalation Long term Local (Workers)
Cellulase (aep.)	-	DMEL = 60 ng/m³

Derived No Effect Level (DNEL)
Derived Minimal Effect Level (DMEL)

When enzymes are used for spray products or hard surface cleaning, exposure of enzymes may exceed the safety level (15 ng/m³ DMEL). If you intend to develop such products, please contact Novozymes for further safety evaluation.

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	Skin should be washed after contact.
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	Amber
Odour	Slight fermentation odor
Melting point / freezing point	No information available
Boiling point or initial boiling point and boiling range	No information available
Flammability	No information available
Lower and upper explosion limit	No information available
Flash Point	> 100 °C
Autoignition temperature	No information available
Decomposition temperature	No information available
pH	Adjusted to the range where active enzyme is stable – typically pH 4 – 9
Kinematic viscosity	No information available
Solubility	Readily soluble in application-relevant solutions at all levels of concentration, temperature and pH which may occur in normal usage.
Partition Coefficient (n-octanol/water)	No information available
Vapour Pressure	No information available
Density (g/ml)	1.14
Relative vapour density	No information available
Particle characteristics	Not applicable

9.2. Other information

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 hazard classes as defined in Regulation (EC) No 1272/2008
Information on toxicological effects (component level)

Chemical name	Cellulase (aep.)
Acute oral toxicity	LD50: > 2000 mg/kg bw (OECD TG 401, 420)
Acute inhalation toxicity	No data available
Skin corrosion/irritation	Not irritating (OECD TG 404)
Serious eye damage/eye irritation	Not irritating (OECD TG 405)
Respiratory sensitisation	Sensitizer (Human experience)
Skin sensitisation	No data available
Genetic toxicity	No indication of mutagenic effects (OECD TG 471, 476)
Carcinogenicity	No data available
Reproductive toxicity	No data available
Specific target organ toxicity — single exposure	No data available
Specific target organ toxicity - repeated exposure	No data available
Aspiration hazard	No data available

Information on toxicological effects (product level)

Actual Product Data No information available

11.2. Information on other hazards
Endocrine disrupting properties
No information available
Other information
No information available

SECTION 12: Ecological information

12.1. Toxicity

Chemical name	Daphnia, acute	Acute fish toxicity =	Algae, Acute
Cellulase (aep.)	EC50 (48 hours): >39.5 mg aep/l (OECD TG 202)	LC50 (96 hours): >39.5 mg aep/l (OECD TG 203)	-

12.2. Persistence and degradability

Chemical name	Persistence and degradability	Partition coefficient (n-octanol/water)
Cellulase (aep.)	Readily biodegradable (OECD 301E/F)	LogPow: <0

12.3. Bioaccumulative potential

Chemical name	Bioaccumulative potential
Cellulase (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 Endocrine disrupting properties
No information available

12.7. Other adverse effects
No information available

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

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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	
Maritime transport in bulk according to IMO instruments	Not applicable

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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)

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

CLP Classification
According to Commission Delegated Regulation (EU) 2021/849 of 11 March 2021, 18 ATP, amendment of regulation (EC) No. 1272/2008 CLP
Safety data sheet according to REACH Regulation (EC) no. 1907/2006 amended by Regulation (EU) no. 2020/878.

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.

End of Safety Data Sheet

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Annex to SDS

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Exposure Scenarios for identified uses of the product:

Medley® Glow 200 L

Formulation
4. Non-protease - Formulation of enzyme containing products at downstream users

Consumer use
36. Non-protease - Consumer use of laundry products
46. Non-protease - Consumer use of fabric softeners

(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)

4. Exposure Scenario - Non-proteolytic enzyme: 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):
Alpha-amylase
Arabinofuranosidase, alpha-L
Catalase
Cellulase
Deoxyribonuclease
Gluco-amylase
Lipase
Mannanase
Pectate Lyase
Pullulanase
Xylanase (endo-1,4-)

4.1: 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	PROC 8a, PROC 8b
CS 4	Transfer of the substance/mixtures into small containers	PROC 9
CS 5	Tabletting, compression, extrusion or pelletisation	PROC 14
CS 6	Use of the substance within laboratory settings, including material transfers and equipment cleaning	PROC 15

4.2 Conditions of use affecting exposure

4.2.1. 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: <= 1.0 tonnes/day
Annual use at a site: <= 10.0 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

4.2.2. 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
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 and Safety Data Sheets are available for Novozymes customer. Safety material can be requested by the customer by contacting Novozymes. Additionally, safety e-learning modules can be found at: http://www.novozymes.tv/safety-material.
Supervision: Management/supervision in place to check that the risk management measures (RMMs) are being used correctly and operational conditions (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: No (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.

4.2.3. 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 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 and Safety Data Sheets are available for Novozymes customer. Safety material can be requested by the customer by contacting Novozymes. Additionally, safety e-learning modules can be found at: http://www.novozymes.tv/safety-material.
Supervision: Management/supervision in place to check that the risk management measures (RMMs) are being used correctly and operational conditions (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: No (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.

4.2.4. 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 and Safety Data Sheets are available for Novozymes customer. Safety material can be requested by the customer by contacting Novozymes. Additionally, safety e-learning modules can be found at: http://www.novozymes.tv/safety-material.
Supervision: Management/supervision in place to check that the risk management measures (RMMs) are being used correctly and operational conditions (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: No (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.

4.2.5. 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 and Safety Data Sheets are available for Novozymes customer. Safety material can be requested by the customer by contacting Novozymes. Additionally, safety e-learning modules can be found at: http://www.novozymes.tv/safety-material.
Supervision: Management/supervision in place to check that the risk management measures (RMMs) are being used correctly and operational conditions (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: No (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.

4.2.6. 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 and Safety Data Sheets are available for Novozymes customer. Safety material can be requested by the customer by contacting Novozymes. Additionally, safety e-learning modules can be found at: http://www.novozymes.tv/safety-material.
Supervision: Management/supervision in place to check that the risk management measures (RMMs) are being used correctly and operational conditions (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: No (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.

4.3. Exposure estimation and reference to its source

4.3.1. 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: <= 20 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: <0.00026 mg/l	RCR < 0.05
Marine water	Local PEC: <0.000026 mg/l	RCR < 0.05
Sewage treatment plant	Local PEC: ~0.001 mg/l	RCR < 0.01
Agricultural soil	Local PEC: <1.0E-11 mg/kg dw	RCR < 0.01

4.3.2. 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	<20 ng/m³ (Measured data)	<0.33

4.3.3. 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	<10 ng/m³ (Measured data)	<0,17

4.3.4. 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	<6 ng/m³ (Measured data)	<0.1

4.3.5. 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	<30 ng/m³ (Measured data)	<0.5

4.3.6. 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	<6 ng/m³ (Measured data)	<0.1

4.4. 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.

36. Exposure Scenario - Non-proteolytic enzyme: 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):
Alpha-amylase
Cellulase
Deoxyribonuclease
Lipase
Mannanase
Pectate Lyase
Catalase

36.1: 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

36.2 Conditions of use affecting exposure

36.2.1. Environmental contributing scenario 1: Consumer use of laundry products

Amount used, frequency and duration of use (or from service life)
Daily use at site: Daily local widespread use amount: <= 0.0000055 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)

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

Product (article) characteristics
Concentration of substance in mixture: <= 0.5 % based on active enzyme protein (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)

36.3. Exposure estimation and reference to its source

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

Release factor estimation method	Explanation / Justification
Water Release factor	Local release rate: <= 0.00275 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: <0.00026 mg/l	RCR < 0.05
Marine water	Local PEC: <0.000026 mg/l	RCR < 0.05
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

36.3.2. 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	<3 ng/m³ (Measured data)	<0.2

36.4. 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.

46. Exposure Scenario - Non-proteolytic enzyme: Consumer use of fabric softeners

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

46.1: Title: Consumer use of fabric softeners

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

46.2 Conditions of use affecting exposure

46.2.1. Environmental contributing scenario 1: Consumer use of fabric softeners (ERC 8a)

Amount used, frequency and duration of use (or from service life)
Daily use at site: Daily local widespread use amount: <= 0.0000055 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)

46.2.2. Consumer contributing scenario 2: Consumer use of fabric softeners (PC 35)

Product (article) characteristics
Concentration of substance in mixture: Regular softeners: <= 0.002 % based on active enzyme protein (AEP) Compact softener: <= 0.004 % based on active enzyme protein (AEP)
Physical property - Liquid: Products are in liquid form
Amount used (or contained in articles), frequency and duration of use/exposure
Duration of activity: Exposure time per event: = 0.1 hour
Amount of product used: Regular softeners: <= 140.0 g fabric softener per dosing to laundry machine Compact softener: <= 40.0 g fabric softener per dosing to laundry machine 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)

46.3. Exposure estimation and reference to its source

46.3.1. Environmental release and exposure: Consumer use of fabric softeners (ERC 8a)

Release factor estimation method	Explanation / Justification
Water Release factor	Local release rate: <= 0.00275 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: <0.00026 mg/l	RCR < 0.05
Marine water	Local PEC: <0.000026 mg/l	RCR < 0.05
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

46.3.2. Consumer contributing scenario 2: Consumer use of fabric softeners (PC 35)

Route of exposure and type of effects	Exposure concentration	Risk characterisation ratio
Inhalation, local, long term	<4 ng/m³ (Measured data)	<0.27

46.4. 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.