

SAFETY DATA SHEET

Revision date: 2020/09/03

Version No: 3

Code of Practice - Preparation of Safety Data Sheets for Hazardous Chemicals

Ondea® Pro A

1. PRODUCT IDENTIFIER & IDENTITY FOR THE CHEMICAL

Product Name Ondea® Pro A
Chemical Name Enzyme preparation
Declared activity Pullulanase

Use of the substance/preparation

Novozymes' enzyme preparations are biocatalysts used in a variety of industrial processes within food manufacturing

Company/Undertaking Identification

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2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Respiratory sensitisation Category 1

2.2 Label elements



Signal word

Danger

Hazard statements

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

Precautionary Statements

P261 - Avoid breathing dust/fume/gas/mist/vapours/spray

P284 - In case of inadequate ventilation wear respiratory protection

Rethink Tomorrow

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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
 P402 + P404 - Store in a dry place. Store in a closed container
 P501 - Dispose of contents/containers in accordance with local regulations

2.3 Other Information

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

Physical and Chemical Hazards None known

Specific hazards None known

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS No	IUB No.	Weight-%
Cellulase (aep.)	9012-54-8	3.2.1.4	<5
Alpha-amylase (aep.)	9000-90-2	3.2.1.1	<5
Protease (neutral) (aep.)	9080-56-2	3.4.24.28	<5
Pullulanase (aep.)	9075-68-7	3.2.1.41	<5
Lipase (aep.)	9001-62-1	3.1.1.3	<5
Xylanase (endo-1,4-) (aep.)	9025-57-4	3.2.1.8	<5

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

4. FIRST AID MEASURES

In case of unintended overexposure, the following measures apply

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, nausea, vomiting and diarrhoea
 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.

5. FIRE-FIGHTING MEASURES

Suitable Extinguishing Media Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

Unsuitable Extinguishing Media None.

Hazardous Combustion Products None.

Specific hazards arising from the chemical May cause allergic respiratory reaction.

Protective equipment and precautions for firefighters Self-contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions For personal protection see section 8.

Environmental Precautions Collect spillage.

Methods for 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.

Other information For personal protection see section 8.

7. HANDLING AND STORAGE

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.

Storage 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. Temperature 0-10 °C (32-50 °F).

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Occupational exposure controls

Derived No Effect Level (DNEL)

Derived Minimal Effect Level (DMEL)

Chemical name	DNEL Dermal Acute Local (Workers)	DMEL Inhalation Long term Local (Workers)
Cellulase (aep.)		DMEL = 60 ng/m ³
Alpha-amylase (aep.)	-	DMEL = 60 ng/m ³

Protease (neutral) (aep.)	-	DMEL = 60 ng/m ³
Pullulanase (aep)	-	DMEL = 60 ng/m ³
Lipase (aep.)		DMEL = 60 ng/m ³
Xylanase (endo-1,4-) (aep)		DMEL = 60 ng/m ³

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.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	Liquid
Colour	Brown
Odour	Slight fermentation odor
Density (g/ml)	1.21
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
Other information	No information available

10. STABILITY AND REACTIVITY

Chemical stability	Stable under recommended storage conditions
Conditions to Avoid	None
Materials to avoid	None
Hazardous Decomposition Products	None
Possibility of hazardous reactions	None

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Skin contact Mild skin irritation
 Eye contact Mild eye irritation
 Ingestion

Chemical name	Acute oral toxicity	Acute inhalation toxicity	Skin corrosion/irritation	Serious eye damage/eye irritation
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Cellulase (aep.)	LD50: > 2000 mg/kg bw (OECD TG 401, 420)		Not irritating (OECD TG 404)	Not irritating (OECD TG 405)
Alpha-amylase (aep.)	LD50: > 2000 mg/kg bw (OECD TG 401, 420)		Not irritating (OECD TG 404)	Not irritating (OECD TG 405)
Protease (neutral) (aep.)	LD50: > 2000 mg/kg bw (OECD TG 401)		irritating	Slightly irritating (OECD TG 405)
Pullulanase (aep)	LD50: > 2000 mg/kg bw (OECD TG 401, 420)		Not irritating (OECD TG 404)	Not irritating (OECD TG 405)
Lipase (aep.)	LD50: > 2000 mg/kg bw (OECD TG 401, 420)		Not irritating (OECD TG 404)	Not irritating (OECD TG 405)
Xylanase (endo-1,4-) (aep)	LD50: > 2000 mg/kg bw (OECD TG 401, 420)		Not irritating (OECD TG 404)	Not irritating (OECD TG 405)

Chemical name	Specific target organ toxicity (single exposure)	Genetic toxicity	Skin sensitisation	Respiratory sensitisation
Cellulase (aep.)		No indication of mutagenic effects (OECD TG 471, 476)		Sensitizer (Human experience)
Alpha-amylase (aep.)		No indication of mutagenic effects (OECD TG 471, 476)		Sensitizer (Human experience)
Protease (neutral) (aep.)		No indication of mutagenic effects (OECD TG 471, 473)		Sensitizer (Human experience)
Pullulanase (aep)		No indication of mutagenic effects (OECD TG 471, 476, 487)		Sensitizer (Human experience)
Lipase (aep.)	No data available	No indication of mutagenic effects (OECD TG 471, 476)		Sensitizer (Human experience)
Xylanase (endo-1,4-) (aep)		No indication of mutagenic effects (OECD TG 471, 476, 487)		Sensitizer (Human experience)

12. ECOLOGICAL INFORMATION

Toxicity

Chemical name	Daphnia, acute	Algae, Acute	Acute fish toxicity =
Cellulase (aep.)	EC50 (48 hours): >39.5 mg aep/l (OECD TG 202)	-	LC50 (96 hours): >39.5 mg aep/l (OECD TG 203)
Alpha-amylase (aep.)	EC50 (48 hours): 31.7 - 457 mg aep/l (OECD TG 202)	ErC50 (72 hours): >= 5.2 mg aep/l (OECD TG 201)	LC50 (96 hours): 58.3 - 326.7 mg aep/l (OECD TG 203)
Protease (neutral) (aep.)	EC50 (48 hours): 3.24 mg aep/l (OECD TG 202)	ErC50 (72 hours): 0.518 mg aep/l (OECD TG 201)	LC50 (96 hours): >18.4 mg aep/l (OECD TG 203)
Pullulanase (aep)	EC50 (48 hours): 31.7 - 457 mg aep/l (OECD TG 202)	ErC50 (72 hours): >= 5.2 mg aep/l (OECD TG 201)	LC50 (96 hours): 58.3 - 326.7 mg aep/l (OECD TG 203)
Lipase (aep.)	EC50 (48 hours): >37.4 mg aep/l (OECD TG 202)	ErC50 (72 hours): > 18 mg aep/l (OECD TG 201)	LC50 (96 hours): >68.3 mg aep/l (OECD TG 203)
Xylanase (endo-1,4-) (aep)	EC50 (48 hours): >42 mg test substance/l (OECD TG 202)	ErC50 (72 hours): > 1000 mg test substance/l (OECD TG 201)	LC50 (96 hours): > 1000mg test substance/l (OECD TG 203)

Persistence/Degradability

Chemical name	Persistence and degradability	Partition coefficient (n-octanol/water)	Bioaccumulative potential
Cellulase (aep.)	Readily biodegradable (OECD 301E/F)	LogPow: <0	Does not bioaccumulate
Alpha-amylase (aep.)	Readily biodegradable (OECD 301F)	LogPow: <0	Does not bioaccumulate
Protease (neutral) (aep.)	Readily biodegradable (OECD 301)	LogPow: <0	Does not bioaccumulate
Pullulanase (aep)	Readily biodegradable (OECD 301)	LogPow: <0	Does not bioaccumulate
Lipase (aep.)	Readily biodegradable (OECD 301)	LogPow: <0	Does not bioaccumulate
Xylanase (endo-1,4-) (aep)	Readily biodegradable (OECD 301)	LogPow: <0	Does not bioaccumulate

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Mobility in soil	Not relevant
Other adverse effects	No information available

13. DISPOSAL CONSIDERATIONS

Disposal of wastes	Dispose of in accordance with local regulations
Contaminated Packaging	Dispose of wastes in an approved waste disposal facility
Other information	Waste codes should be assigned by the user based on the application for which the product was used

14. TRANSPORT INFORMATION

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

UN number	Not applicable
Transport hazard class(es)	not applicable
Packing group	not applicable
Environmental hazards	Not applicable
Special precautions for user	not applicable
Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code	not applicable

15. REGULATORY INFORMATION

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

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).

Please check the consequences of national regulations on this product yourself.

16. OTHER INFORMATION

GHS-Classification
The GHS calculation method has been used for classification of this mixture.

Further information
This SDS is compiled according to the UN GHS rev. 5 Guideline.

Training advice

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Details on the safe handling of this product are located in the Novozymes Customer Center Document Library on www.mynovozymes.com. 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.

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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