

SAFETY DATA SHEET

Revision date: 2020/04/16

Version No: 3

Compliant with 29 CFR §1910.1200 HCS 2012

Compliant with HPR WHMIS 2015

Medley® Pure 100 T

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Medley® Pure 100 T
Chemical Name	Enzyme preparation
Declared activity	Protease (Subtilisin), Alpha-amylase, Lipase, Mannanase (Mannan endo-1,4-beta-mannosidase)

Use of the substance/preparation

Novozymes' enzyme preparations are biocatalysts used in a variety of industrial processes and in certain consumer products

Supplier's details

Novozymes North America, Inc.
77 Perry Chapel Church Rd., Box 576
Franklinton, NC 27525
E-mail: SafetyDataSheet@novozymes.com
www.novozymes.com

Information Telephone Number

1-919-494-3000, 8 am - 4:30 pm EST M-F

Emergency Telephone Number

1-800-424-9300 (Chemtrec) 24 hours every day

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2. HAZARD(S) IDENTIFICATION

Classification

Classification of the chemical in accordance with 29CFR §1910.1200
WHMIS Classification

Respiratory sensitization

Category 1

Label elements

Danger

Hazard statements

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

Precautionary Statements - Prevention

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

P284 - In case of inadequate ventilation wear respiratory protection

Precautionary Statements - Response

P304 + P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing

P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTRE or doctor/physician



Hazards not otherwise classified (HNOC)

1	Health
1	Flammability
0	Reactivity
X	Protective Equipment



3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical name	CAS No	IUB No.	Weight-%
Protease (Subtilisin) (aep.)	9014-01-1	3.4.21.62	1 - <2.5
Lipase (aep.)	9001-62-1	3.1.1.3	0.1 - <1
Alpha-amylase (aep.)	9000-90-2	3.2.1.1	0.1 - <1

aep (active enzyme protein) contributes to the GHS classification.

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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 diarrhea.

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

Flammable Properties

Slightly flammable according to HMIS criteria.

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 and standard turn-out apparel

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 HEPA (High Efficiency Particulate Air) filter. Flush remainder carefully with plenty of water. Avoid splashing, high pressure

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washing or compressed air cleaning to 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.
This product is formulated to prevent formation of dust
However, inappropriate handling may release dust

Storage

Keep tightly closed in a dry and cool place. Temperature 0-25 °C (32-77 °F)

Storage Conditions

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.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Chemical name	ACGIH TLV
Protease (Subtilisin) (aep.)	Ceiling: 0.00006 mg/m ³ Ceiling (as crystalline active enzyme, listed under Subtilisins)

Chemical name	DNEL Dermal Acute Local (Workers)	DMEL Inhalation Long term Local (Workers)
Protease (Subtilisin) (aep.)	DNEL = 0,2% in mixutre (W/W)	DMEL = 60 ng/m ³
Lipase (aep.)		DMEL = 60 ng/m ³
Alpha-amylase (aep.)	-	DMEL = 60 ng/m ³

Chemical name	DMEL Inhalation Long term Local (Professionals/Consumers)	DNEL Dermal Acute Local (Professional/Consumers)
Protease (Subtilisin) (aep.)	DMEL = 15 ng/m ³	DNEL = 0,2% in mixutre (W/W)

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.

Occupational exposure controls

Engineering Controls

Ensure adequate ventilation, especially in confined areas.
Maintain good conditions of industrial hygiene. Some processes may require enclosures, local exhaust ventilation, or other engineering controls to control airborne levels. Additional handling and healthy/safety information is available upon request

Personal Protective Equipment

Respiratory protection

In case of insufficient ventilation wear suitable respiratory equipment that meets HEPA/P100 specifications

Eye Protection

Wear safety glasses with side shields (or goggles)

Skin and body protection

Wear protective gloves and protective clothing

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

9. PHYSICAL AND CHEMICAL PROPERTIES

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Information on basic physical and chemical properties

Physical State	granulate
Color	Off-white
Odor	Slight fermentation odor
pH	Not relevant
Melting point / freezing point	No information available
Initial boiling point and boiling range	Not determined
Flash Point	Not determined
Evaporation rate	Not available
Flammability (solid, gas)	Not determined
Upper/lower flammability or explosive limits	Not available
Vapor Pressure	No data available
Vapor density	Not available
Density (g/ml)	1.15
Solubility	Active component is 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 data available
Autoignition temperature	Not available
Decomposition temperature	Not available
Viscosity	Not available
Other information	No information available

10. STABILITY AND REACTIVITY

Reactivity	Not relevant
Chemical stability	Stable under recommended storage conditions
Possibility of hazardous reactions	None under normal processing
Conditions to Avoid	Avoid destruction of granulate
Incompatible materials	None
Hazardous Decomposition Products	None

11. TOXICOLOGICAL INFORMATION

Information on toxicological 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

Ingestion may cause gastrointestinal irritation, nausea, vomiting and diarrhea

Chemical name	Acute oral toxicity	Acute inhalation toxicity	Skin corrosion/irritation	Serious eye damage/eye irritation
Protease (Subtilisin) (aep.)	LD50: 1800 mg/kg bw (OECD TG 401)	Exposure based waiving	Slightly irritating (OECD TG 404)	Slightly 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)
Alpha-amylase (aep.)	LD50: > 2000 mg/kg bw (OECD TG 401, 420)		Not irritating (OECD TG 404)	Not irritating (OECD TG 405)

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Chemical name	Specific target organ toxicity (single exposure)	Genetic toxicity	Skin sensitization	Respiratory sensitization
Protease (Subtilisin) (aep.)	Irritating, respiratory tract (ACGIH 2001)	No indication of mutagenic effects (OECD TG 471, 473, 476)		Sensitizer (Human experience)
Lipase (aep.)	No data available	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)

Carcinogenicity

The product contains calcium carbonate, limestone. The raw material may contain trace amounts of crystalline silica also known as quartz. Quartz is a suspected carcinogen if inhaled. This product has been formulated to prevent dust formulation.
TiO₂ The product contains titanium dioxide. The raw material may contain trace amounts of crystalline silica also known as quartz. Quartz is a suspected carcinogen if inhaled. This product has been formulated to prevent dust formulation.

12. ECOLOGICAL INFORMATION

Toxicity

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

Persistence/Degradability

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

Chemical name	Bioaccumulative Potential
Protease (Subtilisin) (aep.)	Does not bioaccumulate
Lipase (aep.)	Does not bioaccumulate
Alpha-amylase (aep.)	Does not bioaccumulate

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.

14. TRANSPORT INFORMATION

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Transport Regulations

No dangerous goods according to transport regulations
No special precautions required

UN-No	Not applicable
Proper Shipping Name	Not applicable
Hazard Class	Not applicable
Packing Group	Not applicable
Reportable Quantity (RQ)	Not applicable
Marine Pollutant	Not applicable

15. REGULATORY INFORMATION

USA, Federal Regulations

TSCA Inventory

The active ingredient and all components of the enzyme preparation are listed on the TSCA inventory

SARA 313

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and 40 CFR Part 372.

SARA 311/312 Hazardous Categorization

Acute Health Hazard	No
Chronic Health Hazard	No
Fire Hazard	No
Sudden Release of Pressure Hazard	No
Reactive Hazard	No

USA, State Regulations

California Proposition 65

This product does not contain any Proposition 65 chemicals

Canada

DSL/NDSL

All components are listed either on the DSL or NDSL

WHMIS Statement

This product has been classified in accordance with the hazard criteria of the Hazardous Products Regulations (HPR) and the SDS contains all the information required by WHMIS 2015.

16. OTHER INFORMATION

Training advice	Details on the safe handling of this product are located in the Novozymes Customer Center Document Library on www.mynovozymes.com
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GHS-Classification	The classification of eye effects is based on testing of a similar mixture. The GHS calculation method has been used for classification of this mixture.
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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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End of Safety Data Sheet

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