

SAFETY DATA SHEET

Revision date: 2025/05/05

Compliant with 29 CFR §1910.1200 HCS 2012

Compliant with HPR WHMIS 2015

Fungamyl® 4000 SG

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name	Fungamyl® 4000 SG
Chemical Name	Enzyme preparation
Declared activity	Alpha-amylase

Use of the substance/preparation	Novozymes' enzyme preparations are biocatalysts used in a variety of industrial processes within food manufacturing
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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 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-%
Alpha-amylase (aep.)	9000-90-2	3.2.1.1	30 - 50

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

4. FIRST AID MEASURES

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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. The product can be transported at ambient temperature.
Following delivery, the product should be stored as recommended. Temperature 0-25 °C (32-77 °F)

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

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

Derived No Effect Level (DNEL)

Derived Minimal Effect Level (DMEL)

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

No special technical protective measures are necessary

General Hygiene Considerations

Environmental exposure controls

Handle in accordance with good industrial hygiene and safety practice
Local authorities should be advised if significant spillages cannot be contained

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical State	granulate
Color	Yellow to light brown
Odor	Slight fermentation odor
pH	No data available
Melting point / freezing point	No data available
Boiling Point/Range	No data available

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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)	0.6
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 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

Information on toxicological effects (product level)

Product Information

Inhalation	Specific test data for the substance or mixture is not available.
Eye contact	Specific test data for the substance or mixture is not available.
Skin contact	Specific test data for the substance or mixture is not available.
Ingestion	Specific test data for the substance or mixture is not available.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms	No information available.
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Numerical measures of toxicity

No information available

Acute toxicity

LD50 Oral:	No information available
LD50 Dermal:	No information available
LC50 Inhalation:	No information available
LC50 Inhalation	No information available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Skin corrosion/irritation	No information available.
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Serious eye damage/eye irritation No information available.

Respiratory or skin sensitization No information available.

Germ cell mutagenicity No information available.

Carcinogenicity No information available
Reproductive toxicity No information available

Developmental Effects No information available
Teratogenic Effects No information available

STOT - single exposure No information available

STOT - repeated exposure No information available

Aspiration hazard No information available.

Information on toxicological effects (component level)

Chemical name	Alpha-amylase (aep.)
Acute oral toxicity	Data conclusive but not sufficient for classification. No signs of toxicity were observed at the highest possible dose among the rats treated with a single oral dose of 2562 mg enzyme concentrate dry matter/kg body weight (equivalent to 858.9 mg active enzyme protein/ kg body weight).
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 sensitization	Sensitizer (Human experience)
Skin sensitization	Data conclusive but not sufficient for classification
Genetic toxicity	No indication of mutagenic effects (OECD TG 471, 476)
Carcinogenicity	Data conclusive but not sufficient for classification
Reproductive toxicity	No data available
Specific target organ toxicity (single exposure)	Data conclusive but not sufficient for classification
Specific target organ systemic toxicity (repeated exposure)	Data conclusive but not sufficient for classification
Aspiration hazard	Not applicable
Other information	No information available

12. ECOLOGICAL INFORMATION

Toxicity

Chemical name	Daphnia, acute	Algae, acute	Fish, acute
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)
Alpha-amylase (aep.)	Readily biodegradable (OECD 301F)	LogPow: <0

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

Mobility in soil Not relevant

Other adverse effects No information available

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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

Transport Regulations

No dangerous goods according to transport regulations
No special precautions required

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

International Regulations

IATA	Not regulated
IMDG	Not regulated

15. REGULATORY INFORMATION

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).

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 intentionally added Proposition 65 chemicals.

Canada

Canada - CEPA 1999

Compliant with the Canadian Environmental Protection Act 1999 (CEPA) and the New Substance Notification Regulations in Canada

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.

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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

GHS-Classification

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

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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