

SAFETY DATA SHEET

Revision date: 2024/07/18

REACH Regulation (EC) no. 1907/2006

Vinozym® Ultra FCE

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

1.1. Product identifier

Product Name	Vinozym® Ultra FCE
Chemical Name	Enzyme preparation
Declared activity	Polygalacturonase
Unique Formula Identifier (UFI)	S8R4-E0YV-Y00H-9FNW

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

1.3. Details of the supplier of the safety data sheet

Novozymes A/S
Krogshøjvej 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
IR: + 353 1 809 2166
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 Polygalacturonase (aep)

Signal word

Danger

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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

Endocrine disrupting properties

This product does not contain any substance with endocrine disrupting properties with respect to non-target organisms and humans in accordance with Article 59(1).

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

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
Polygalacturonase (aep)	2.5 - <5	9032-75-1	232-885-6	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
Polygalacturonase	5 - <10	3.2.1.15	-

*: 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
Polygalacturonase (aep)	-	-	-	-	-

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SECTION 4: First aid measures

4.1. Description of first aid measures

Inhalation

Effects

Symptoms

May cause allergic respiratory reaction

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

Symptoms

First Aid

May cause slight irritation

Slight irritation

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

Symptoms

First Aid

May cause slight irritation

Slight irritation

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

Symptoms

First Aid

Ingestion may cause gastrointestinal irritation.

Irritation

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

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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

See section 16 for Training advice.

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

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

DNEL/DMEL/PNEC

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

Derived No Effect Level (DNEL)

Derived Minimal Effect Level (DMEL)

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

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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	Light brown
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/flammability 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)	1.17
Relative vapour density	No information available
Particle characteristics	Not applicable

9.2. Other information

Other information	No information available
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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

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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	Polygalacturonase (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, 487)
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

This product does not contain any substance with endocrine disrupting properties with respect to non-target organisms and humans in accordance with Article 59(1).

Other information

No information available

SECTION 12: Ecological information

12.1. Toxicity

Chemical name	Daphnia, acute	Acute fish toxicity =	Algae, Acute
Polygalacturonase (aep)	EC50 (48 hours): 31.7 - 457 mg aep/l (OECD TG 202)	LC50 (96 hours): 58.3 - 326.7 mg aep/l (OECD TG 203)	ErC50 (72 hours): >= 5.2 mg aep/l (OECD TG 201)

12.2. Persistence and degradability

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

12.3. Bioaccumulative potential

Chemical name	Bioaccumulative potential
Polygalacturonase (aep)	Does not bioaccumulate

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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

This product does not contain any substance with endocrine disrupting properties with respect to non-target organisms and humans in accordance with Article 59(1).

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

SECTION 14: Transport information

Transport Regulations

No dangerous goods according to transport regulations

No special precautions required

IATA	Not regulated
IMDG	Not regulated

14.1

UN number or ID number	Not relevant
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14.2

UN proper shipping name	Not applicable
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14.3

Transport hazard class(es)	Not applicable
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14.4

Packing group	Not applicable
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14.5

Environmental hazards	Not applicable
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14.6

Special precautions for user	Not applicable
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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)

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

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No chemical safety assessment has been carried out

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

Safety data sheet according to REACH Regulation (EC) no. 1907/2006 amended by Regulation (EU) no. 2020/878.

According to Commission Delegated Regulation (EU) 2021/849 of 11 March 2021, 18 ATP, amendment of 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.

End of Safety Data Sheet

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