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In conformity to Regulation (EU) 2015/830

SECTION 1. Identification of the substance/mixture and of the company/enterprise

1.1. Product identifier

Product name : ENDOZYM ALPHAMYL FJ

Product code: refer to sales department

1.2. Relevant identified uses of the substance or mixture and uses advised against

Enzyme preparations

Sectors of use:

Industrial Manufacturing[SU3], Manufacture of food products[SU4], Public domain (administration, education, entertainment, services, craftsmen)[SU22]

Product category:

Process aid for food-limited use

Not recommended uses

Do not use for purposes other than those listed

1.3. Details of the supplier of the safety data sheet

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1.4. Emergency telephone number

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SECTION 2. Hazards identification

2.1. Classification of the substance or mixture

2.1.1 Classification according to Regulation (EC) No 1272/2008:

Pictograms:

GHS08

Hazard Class and Category Code(s):

Resp. Sens. 1

Hazard statement Code(s):

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

The product, if inhaled, can cause sensitization.

2.2. Label elements

Labelling according to Regulation (EC) No 1272/2008:

Pictogram, Signal Word Code(s):

GHS08 - Danger

Hazard statement Code(s):





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

Supplemental Hazard statement Code(s):

not applicable

Precautionary statements:

Prevention

P261 - Avoid breathing vapours/spray.

P284 - In case of inadequate ventilation wear respiratory protection.

Response

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.

Contains:

AMYLASE, GLUCOAMYLASE

Only for professional use

For limited use in foodstuffs

2.3. Other hazards

The substance / mixture does NOT contain substances PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII

The use of this chemical agent involves the obligation of "risk assessment" by the employer in accordance with the provisions of Dlgs n. 81. April 9, 2008. Workers exposed to this chemical agent should not be subject to health surveillance if the results of the risk assessment show that, depending on the type and quantity of dangerous chemical agent and method and frequency of exposure to the agent, there is only a "moderate Risk" for the health and safety of workers and that the measures laid down in the Decree are sufficient to reduce the risk.

SECTION 3. Composition/information on ingredients

3.1 Substances

Irrilevant

3.2 Mixtures

Refer to paragraph 16 for full text of hazard statements

Substance	Concentration	Classification	Index	CAS	EINECS	REACH
GLUCOAMYLASE	> 1 <= 40%	Resp. Sens. 1, H334	647-016-00-X	9032-08-0	237-877-2	01-2119480 439-28-XXX X
AMYLASE	> 1 <= 40%	Resp. Sens. 1, H334		9000-90-2	232-565-6	01-2119938 627-26-XXX X

SECTION 4. First aid measures

4.1. Description of first aid measures

Inhalation:

Ventilate the area. Move immediately the contaminated patient from the area and keep him at rest in a well ventilated area. If you feel unwell seek medical advice.

Direct contact with skin (of the pure product):

Wash thoroughly with soap and running water.

Direct contact with eyes (of the pure product):

Wash immediately and thoroughly with running water for at least 10 minutes.



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Ingestion:

Not hazardous. It's possible to give activated charcoal in water or medicinal mineral vaseline oil.

4.2. Most important symptoms and effects, both acute and delayed

No data available.

4.3. Indication of any immediate medical attention and special treatment needed

If experiencing respiratory symptoms: Call a POISON CENTER or doctor.

SECTION 5. Firefighting measures

5.1. Extinguishing media

Suggested extinguishing media:

Water spray, CO₂, foam, dry chemical, depending on the materials involved in the fire.

Extinguishing media to avoid:

Water jets. Use water jets only to cool the surfaces of the containers exposed to fire.

5.2. Special hazards arising from the substance or mixture

No data available.

5.3. Advice for firefighters

Use protection for the breathing apparatus

Safety helmet and full protective clothing.

The water spray can be used to protect the people involved in the extinction.

You may also use self-contained breathing apparatus, especially when working in confined and poorly ventilated areas and if you use halogenated extinguishers (Halon 1211 fluobrene, Solkan 123, NAF, etc...)

Keep containers cool with water spray

SECTION 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1 For non-emergency personnel:

Leave the area surrounding the spill or release. Do not smoke

Wear gloves and protective clothing

6.1.2 For emergency responders:

Eliminate all unguarded flames and possible sources of ignition. No smoking.

Provide a sufficient ventilation.

Evacuate the danger area and, in case, consult an expert.

6.2. Environmental precautions

Contain spills with earth or sand.

If the product has entered a watercourse, sewers or has contaminated soil or vegetation, notify the authorities.

Dispose of the waste material in compliance with the regulations



6.3. Methods and material for containment and cleaning up

6.3.1 Containment:

Rapidly recover the product, wear a mask and protective clothing
Recover the product for reuse, if possible, or for removal. Possibly absorb it with inert material.
Prevent it from entering the sewer system.

6.3.2 Cleaning up:

After wiping up, wash with water the area and materials involved

6.3.3 Other information:

None in particular.

6.4. Reference to other sections

Refer to paragraphs 8 and 13 for more information

SECTION 7. Handling and storage

7.1. Precautions for safe handling

Avoid contact and inhalation of vapors
In residential areas do not use on large surfaces.
At work do not eat or drink.
See also paragraph 8 below.

7.2. Conditions for safe storage, including any incompatibilities

Keep in original container closed tightly. Do not store in open or unlabelled containers.
Keep containers upright and safe by avoiding the possibility of falls or collisions.
Store in a cool and dry place at $T < 20^{\circ}\text{C}$, away from heat sources and direct exposure to sunlight.

7.3. Specific end use(s)

Industrial Manufacturing:

Handle with extreme caution.

Store in a well ventilated place away from heat sources.

Manufacture of food products:

Handle with care.

Store in a clean, dry, ventilated area away from heat and direct sunlight.

Keep container tightly closed.

Public domain (administration, education, entertainment, services, craftsmen):

Handle with care. Store in a ventilated area and away from heat, keep the container tightly closed.

SECTION 8. Exposure controls/personal protection

8.1. Control parameters

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Related to contained substances:

AMYLASE:

Occupational exposure limits

Project data: use only in a well ventilated area.

Hygiene measures: do not eat, do not drink and not smoke during use. Wash hands after handling compounds and before eating, smoking, the bathroom, as well as the end of the day.



8.2. Exposure controls



Appropriate engineering controls:

Industrial Manufacturing:

No specific monitoring foreseen (act according to good practice and specific rules for the type of risk associated)

Manufacture of food products:

No specific monitoring foreseen (act according to good practice and specific rules for the type of risk associated)

Public domain (administration, education, entertainment, services, craftsmen):

No specific monitoring foreseen (act according to good practice and specific rules for the type of risk associated)

Individual protection measures:

(a) Eye / face protection

When handling the pure product use safety glasses (spectacles cage) (EN 166).

(b) Skin protection

(i) Hand protection

When handling the pure product use chemical resistant protective gloves (EN 374-1/EN374-2/EN374-3)

(ii) Other

When handling the pure product wear full protective skin clothing.

(c) Respiratory protection

Use adequate protective respiratory equipment (EN 141)

(d) Thermal hazards

No hazard to report

Environmental exposure controls:

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Related to contained substances:

AMYLASE:

Personal protective measures, such as personal protective equipment:

Eye protection: safety glasses

Skin protection: protective clothing suitable

Hand protection: protective gloves

Respiratory protection: use a dust mask type P3.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical and chemical properties	Value	Determination method
Appearance	Brown liquid	
Odour	slight smell of fermentation	
Odour threshold	not determined	
pH	4,5 ± 0,5 (20°C)	
Melting point/freezing point	not determined	
Initial boiling point and boiling range	not determined	
Flash point	irrelevant	ASTM D92
Evaporation rate	irrelevant	
Flammability (solid, gas)	irrelevant	
Upper/lower flammability or explosive limits	irrelevant	
Vapour pressure	irrelevant	
Vapour density	irrelevant	
Relative density	not determined	
Solubility	not determined	



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Physical and chemical properties	Value	Determination method
Water solubility	not determined	
Partition coefficient: n-octanol/water	not determined	
Auto-ignition temperature	irrelevant	
Decomposition temperature	irrelevant	
Viscosity	irrelevant	
Explosive properties	irrelevant	
Oxidising properties	irrelevant	

9.2. Other information

No data available.

SECTION 10. Stability and reactivity

10.1. Reactivity

No reactivity hazards

10.2. Chemical stability

No hazardous reaction when handled and stored according to provisions.

10.3. Possibility of hazardous reactions

There are no hazardous reactions

10.4. Conditions to avoid

Exposure to heat

10.5. Incompatible materials

None in particular.

10.6. Hazardous decomposition products

Does not decompose when used for intended uses.

SECTION 11. Toxicological information



11.1. Information on toxicological effects

ATE(mix) oral = ∞

ATE(mix) dermal = ∞

ATE(mix) inhal = ∞

(a) acute toxicity: based on available data, the classification criteria are not met.

(b) skin corrosion/irritation based on available data, the classification criteria are not met.

(c) serious eye damage/irritation: based on available data, the classification criteria are not met.

(d) respiratory or skin sensitization: The product, if inhaled, can cause sensitization.

(e) germ cell mutagenicity: based on available data, the classification criteria are not met.

(f) carcinogenicity: based on available data, the classification criteria are not met.

(g) reproductive toxicity: based on available data, the classification criteria are not met.

(h) specific target organ toxicity (STOT) single exposure: based on available data, the classification criteria are not met.

(i) specific target organ toxicity (STOT) repeated exposure based on available data, the classification criteria are not met.

(j) aspiration hazard: based on available data, the classification criteria are not met.

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Related to contained substances:

AMYLASE:

Potential acute health effects inhalation: May cause sensitization by inhalation.

Ingestion: no information available.

Skin contact: no information available.

Eye contact: no information available.

Acute toxic: no information available.

Irritation/corrosion

awareness

Potential chronic health effects

Chronic effects: once sensitized, a severe allergic reaction can be enabled further exposure at very low levels.

Cancerogenicit: no information available.

Mutagenicit: no information available.

Teratogenicit: no information available.

Developmental effects: no information available.

Effects on fertility: no information available.

Chronic toxic: no information available.

Cancerogenicit: no information available.

Mutagenicit: no information available.

Teratogenicit: no information available.

Reproductive toxic: no information is available

SECTION 12. Ecological information

12.1. Toxicity

Use according to good working practices and avoid to disperse the product into the environment.

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Related to contained substances:

AMYLASE:

The preparation is not considered dangerous for the environment

12.2. Persistence and degradability

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Related to contained substances:

AMYLASE:

No information available



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12.3. Bioaccumulative potential

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Related to contained substances:
AMYLASE:
No information available

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB assessment

The substance / mixture does NOT contain substances PBT/vPvB according to Regulation (EC) No 1907/2006, Annex XIII

12.6. Other adverse effects

No adverse effects

SECTION 13. Disposal considerations

13.1. Waste treatment methods

Do not reuse empty containers. Dispose of them in accordance with the regulations in force. Any remaining product should be disposed of according to applicable regulations by addressing to authorized companies.
Recover if possible. Operate according to local or national regulations

SECTION 14. Transport information

14.1. UN number

Not included in the field of application of regulations concerning the transport of dangerous goods: by road (ADR); by rail (RID); by air (ICAO / IATA); by sea (IMDG).

14.2. UN proper shipping name

None

14.3. Transport hazard class(es)

None

14.4. Packing group

None



14.5. Environmental hazards

None

14.6. Special precautions for user

No data available.

14.7. Transport in bulk according to Annex II of MARPOL73/78 and IBC Code

Transport in bulk is not foreseen

SECTION 15. Regulatory information

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

Leg. 3/2/1997 n. 52 (Classification, packaging and labeling of dangerous substances). Decree No. 14/3/2003. 65 (Classification, packaging and labeling of dangerous substances). Leg. 2/2/2002 n. 25 (risks related to chemical agents at work). Ministerial Decree Jobs 26/02/2004 (occupational exposure limits); DM 04/03/2007 (Implementation of Directive no. 2006/8/EC). Regulation (EC) n. 1907/2006 (REACH) Regulation (EC) n. 1272/2008 (CLP), Regulation (EC) n.790/2009.D.Lgs. September 21, 2005 n. 238 (Seveso Directive Ter).

15.2. Chemical safety assessment

No chemical safety assessment was carried out by the supplier

SECTION 16. Other information

16.1. Other information

Description of hazard statements set out in paragraph 3

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

Classification based on data of all mixture components

Main normative references:

Directive 1999/45/EC.

Directive 2001/60/EC.

Regulation 1272/2008/EC.

Regulation 2010/453/EC.

This msds was made in good faith by AEB technical Office on the basis of the information available at the date of the last revision. The person in charge must regularly inform the employees about the specific risks they encounter when using this substance/product. The information contained here relate only to the substance/the preparation indicated and may not apply if the product is used improperly or in combination with others. Nothing contained herein shall be construed as a guarantee, either express or implied. It is the responsibility of the user to ensure the opportunities and completeness of the information contained herein for their own particular use.

*** this tab annuls and replaces any previous edition. (IIXX1241-CLP-REG.830)

Changes to the previous edition: conformity Reg. 830