

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

### 1.1 Product identifier:

**GEDAZYME IBA 12 ZAKJES**

UFI: /

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

/

Concentration in use: /

### 1.3 Details of the supplier of the safety data sheet:

**DS PLASTICS BV**

Mosten 18

9160 Lokeren

Tel: 0032 9 280 78 80

E-mail: sales@dsplastics.be — Website: www.dsplastics.be

### 1.4 Emergency telephone number:

+32 70 245 245

## 2 SECTION 2: Hazards identification:

### 2.1 Classification of the substance or mixture:

Classification of the substance or mixture in accordance with regulation (EU) 1272/2008:

**EUH208**

### 2.2 Label elements:

Pictograms:

Signal word:

None

Hazard statements:

**EUH208:** Contains ( Cellulase; Lipase; subtilisin; Amylase ). May produce an allergic reaction.

Precautionary statements:

None

Contains:

None

### 2.3 Other hazards:

None

## 3 SECTION 3: Composition/information on ingredients:

Lipase	≤ 0.5 %	CAS number: 9001-62-1 EINECS: 232-619-9 REACH Registration number: 01-2119972939-13 CLP Classification: <b>H334 Resp. Sens. 1</b>
subtilisin	≤ 0.5 %	CAS number: 9014-01-1 EINECS: 232-752-2 REACH Registration number: 01-2119480434-38 CLP Classification: <b>H302 Acute tox. 4 H315 Skin Irrit. 2 H318 Eye Dam. 1 H334 Resp. Sens. 1 H335 STOT SE 3 H400 Aquatic Acute 1</b>
Cellulase	≤ 0.3 %	CAS number: 9012-54-8 EINECS: 232-734-4 REACH Registration number: 01-2119949289-21 CLP Classification: <b>H334 Resp. Sens. 1</b>
Amylase	≤ 0.2 %	CAS number: 9000-90-2 EINECS: 232-565-6 REACH Registration number: 01-2119938627-26 CLP Classification: <b>H334 Resp. Sens. 1</b>

For the full text of the H phrases mentioned in this section, see section 16.

## 4 SECTION 4: First aid measures:

### 4.1 Description of first aid measures:

Always ask medical advice as soon as possible should serious or continuous disturbances occur.

<b>Skin contact:</b>	Rinse with water.
<b>Eye contact:</b>	Rinse first with plenty of water, if necessary seek medical attention.
<b>Ingestion:</b>	Rinse first with plenty of water, if necessary seek medical attention.
<b>Inhalation:</b>	In case of serious or continuous discomforts: remove to fresh air and seek medical attention.

### 4.2 Most important symptoms and effects, both acute and delayed:

<b>Skin contact:</b>	None
<b>Eye contact:</b>	Redness
<b>Ingestion:</b>	Diarrhoea, headache, abdominal cramps, sleepiness, vomiting
<b>Inhalation:</b>	None

#### 4.3 Indication of any immediate medical attention and special treatment needed:

None

### 5 SECTION 5: Fire-fighting measures:

#### 5.1 Extinguishing media:

CO<sub>2</sub>, foam, powder, sprayed water

#### 5.2 Special hazards arising from the substance or mixture:

None

#### 5.3 Advice for firefighters:

**Extinguishing agents to be avoided:** None

### 6 SECTION 6: Accidental release measures:

#### 6.1 Personal precautions, protective equipment and emergency procedures:

Do not walk into or touch spilled substances and avoid inhalation of fumes, smoke, dusts and vapours by staying up wind. Remove any contaminated clothing and used contaminated protective equipment and dispose of it safely.

#### 6.2 Environmental precautions:

Do not allow to flow into sewers or open water.

#### 6.3 Methods and material for containment and cleaning up:

Contain released substance, store into suitable containers. If possible, remove by using absorbent material.

#### 6.4 Reference to other sections:

For further information, check sections 8 & 13.

### 7 SECTION 7: Handling and storage:

#### 7.1 Precautions for safe handling:

Handle with care to avoid spillage.

#### 7.2 Conditions for safe storage, including any incompatibilities:

Keep in a sealed container in a closed, frost-free, ventilated room.

#### 7.3 Specific end use(s):

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### 8 SECTION 8: Exposure controls/personal protection:

#### 8.1 Control parameters:

Listing of the hazardous ingredients in section 3, of which the TLV value is known

Cellulase 1 mg/m<sup>3</sup>

## 8.2 Exposure controls:

<b>Inhalation protection:</b>	Respiratory protection is not required. Use ABEK type gas masks in case of irritating exposure. If necessary, use with sufficient exhaust ventilation.	
<b>Skin protection:</b>	Handling with nitril-gloves (EN 374). Breakthrough time: >480' Material thickness: 0,35 mm. Thoroughly check gloves before use. Take of the gloves properly without touching the outside with your bare hands. The manufacturer of the protective gloves has to be consulted about the suitability for a specific work station. Wash and dry your hands.	
<b>Eye protection:</b>	Keep an eye-rinse bottle within reach. Tight-fitting safety goggles. Wear a face shield and protective suit in case of exceptional processing problems.	
<b>Other protection:</b>	Wear impermeable clothing. The type of protective equipment depends on the concentration and amount of hazardous substances at the work station in question.	

## 9 SECTION 9: Physical and chemical properties:

### 9.1 Information on basic physical and chemical properties:

<b>Melting point/melting range:</b>	/
<b>Boiling point/Boiling range:</b>	100 °C — 100 °C
<b>pH:</b>	/
<b>pH 1% diluted in water:</b>	/
<b>Vapour pressure/20°C,:</b>	/
<b>Vapour density:</b>	Not applicable
<b>Relative density, 20°C:</b>	/
<b>Appearance/20°C:</b>	Solid
<b>Flash point:</b>	/
<b>Flammability (solid, gas):</b>	Not applicable
<b>Auto-ignition temperature:</b>	/
<b>Upper flammability or explosive limit, (Vol %):</b>	/
<b>Lower flammability or explosive limit, (Vol %):</b>	/
<b>Explosive properties:</b>	Not applicable
<b>Oxidising properties:</b>	Not applicable
<b>Decomposition temperature:</b>	/
<b>Solubility in water:</b>	Not soluble
<b>Partition coefficient: n-octanol/water:</b>	Not applicable
<b>Odour:</b>	characteristic
<b>Odour threshold:</b>	Not applicable
<b>Dynamic viscosity, 20°C:</b>	/
<b>Kinematic viscosity, 40°C:</b>	/
<b>Evaporation rate (n-BuAc = 1):</b>	0.300

### 9.2 Other information:

<b>Volatile organic component (VOC):</b>	/
<b>Volatile organic component (VOC):</b>	/
<b>Sustained combustion test :</b>	/

## 10 SECTION 10: Stability and reactivity:

### 10.1 Reactivity:

Stable under normal conditions.

### 10.2 Chemical stability:

Extremely high or low temperatures.

### 10.3 Possibility of hazardous reactions:

None

### 10.4 Conditions to avoid:

Protect from sunlight and do not expose to temperatures exceeding + 50°C.

### 10.5 Incompatible materials:

None

### 10.6 Hazardous decomposition products:

Under recommended usage conditions, hazardous decomposition products are not expected.

## 11 SECTION 11: Toxicological information:

### 11.1 Information on toxicological effects:

About the preparation itself: No additional data available

**Calculated acute toxicity, ATE oral:** /

**Calculated acute toxicity, ATE dermal:** /

Lipase	LD50 oral, rat: 2 000 mg/kg LD50 dermal, rabbit: ≥ 5 000 mg/kg LC50, Inhalation, rat, 4h: ≥ 50 mg/l
subtilisin	LD50 oral, rat: 1 800 mg/kg LD50 dermal, rabbit: ≥ 5 000 mg/kg LC50, Inhalation, rat, 4h: ≥ 50 mg/l
Cellulase	LD50 oral, rat: ≥ 5 000 mg/kg LD50 dermal, rabbit: ≥ 5 000 mg/kg LC50, Inhalation, rat, 4h: ≥ 50 mg/l
Amylase	LD50 oral, rat: ≥ 5 000 mg/kg LD50 dermal, rabbit: ≥ 5 000 mg/kg LC50, Inhalation, rat, 4h: ≥ 50 mg/l

## 12 SECTION 12: Ecological information:

### 12.1 Toxicity:

subtilisin	LC50 (Fish): 8,2 mg/l, 96h (Oncorhynchus mykiss) EC50 (Daphnia): EC0 = 0,17 mg/l NOEC (Algae): 0,041 mg (72h) (Pseudokirchneriella subcapitata)
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Amylase	LC50 (Fish):	>100 mg/l (96h)
	EC50 (Daphnia):	>100 mg/l (48h)
	EC50 (Algae):	>100 mg/l (72h)

### 12.2 Persistence and degradability:

The surfactants contained in this preparation comply with the biodegradability criteria as laid down in Regulation (EC) No.648/2004 on detergents.

### 12.3 Bioaccumulative potential:

No additional data available

### 12.4 Mobility in soil:

**Water hazard class, WGK (AwSV):** 1  
**Solubility in water:** Not soluble

### 12.5 Results of PBT and vPvB assessment:

No additional data available

### 12.6 Other adverse effects:

No additional data available

## 13 SECTION 13: Disposal considerations:

### 13.1 Waste treatment methods:

The product may be discharged in the indicated percentages of utilization, provided it is neutralised to pH 7. Possible restrictive regulations by local authority should always be adhered to.

## 14 SECTION 14: Transport information:

### 14.1 UN number:

Not applicable

### 14.2 UN proper shipping name:

ADR, IMDG, ICAO/IATA not applicable

### 14.3 Transport hazard class(es):

**Class(es):** Not applicable  
**Identification number of the hazard:** Not applicable

### 14.4 Packing group:

Not applicable

### 14.5 Environmental hazards:

Not dangerous to the environment

### 14.6 Special precautions for user:

<b>Hazard characteristics:</b>	Not applicable
<b>Additional guidance:</b>	Not applicable

## 15 SECTION 15: Regulatory information:

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

<b>Water hazard class, WGK (AwSV):</b>	1
<b>Volatile organic component (VOC):</b>	/
<b>Volatile organic component (VOC):</b>	/
<b>Composition by regulation (EC 648/2004):</b>	Enzymes < 5%, Nonionic surfactants < 5%

### 15.2 Chemical Safety Assessment:

No data available

## 16 SECTION 16: Other information:

### Legend to abbreviations used in the safety data sheet:

<b>ADR:</b>	The European Agreement concerning the International Carriage of Dangerous Goods by Road
<b>ATE:</b>	Acute Toxicity Estimate
<b>BCF:</b>	Bioconcentration factor
<b>CAS:</b>	Chemical Abstracts Service
<b>CLP:</b>	Classification, Labelling and Packaging of chemicals
<b>EINECS:</b>	European Inventory of Existing commercial Chemical Substances
<b>LC50:</b>	median Lethal Concentration for 50% of subjects
<b>LD50:</b>	median Lethal Dose for 50% of subjects
<b>Nr.:</b>	Number
<b>PTB:</b>	Persistent, Toxic, Bioaccumulative
<b>TLV:</b>	Threshold Limit Value
<b>UFI:</b>	Unique Formula Identifier
<b>vPvB:</b>	very Persistent and very Bioaccumulative substances
<b>WGK:</b>	Water hazard class
<b>WGK 1:</b>	Slightly hazardous for water
<b>WGK 2:</b>	Hazardous for water
<b>WGK 3:</b>	Extremely hazardous for water

### Legend to the H Phrases used in the safety data sheet:

**EUH208:** Contains ( Cellulase; Lipase; subtilisin; Amylase ). May produce an allergic reaction.  
**H302 Acute tox. 4:** Harmful if swallowed. **H315 Skin Irrit. 2:** Causes skin irritation. **H318 Eye Dam. 1:** Causes serious eye damage. **H334 Resp. Sens. 1:** May cause allergy or asthma symptoms or breathing difficulties if inhaled.  
**H335 STOT SE 3:** May cause respiratory irritation. **H400 Aquatic Acute 1:** Very toxic to aquatic life.

### CLP Calculation method:

Calculation method

### Reason of revision, changes of following items:

Not applicable

**SDS reference number:**

ECM-112029,00

*This safety information sheet has been compiled in accordance with annex II/A of the regulation (EU) No 2015/830. Classification has been calculated in accordance with European regulation 1272/2008 with their respective amendments. It has been compiled with the utmost care. We cannot, however, accept responsibility for damage, of any kind, that may be caused by using these data or the product concerned. To use this preparation for an experiment or a new application, the user must carry out a material suitability and safety study himself.*