

# SAFETY DATA SHEET

In accordance with 1907/2006 annex II and 1272/2008  
(All references to EU regulations and directives are abbreviated into only the numeric term)

Amendment date 2023-03-15

Replaces SDS issued 2022-04-06

Revision date 2022-04-06

Version number 1.1



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

### 1.1. Product identifier

Trade name	Phadebas Detection of Low Amylase Activity
Article number	1331, 1335

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

Identified uses	Use in the food industry
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### 1.3. Details of the supplier of the safety data sheet

Company	Phadebas AB Fjälkestadvägen 334 SE-291 96 Kristianstad Sweden
Telephone	+46 (0)44 751 00
E-mail	info@phadebas.com

### 1.4. Emergency telephone number

Phone number for emergencies: 999 or 112. The numbers are available 24/7.

## SECTION 2: Hazards identification

### 2.1. Classification of the substance or mixture

Skin. Sens. 1, H317  
(See section 16)

### 2.2. Label elements

Hazard pictogram



Signal word	Warning
Hazard statement	
H317	May cause an allergic skin reaction
Precautionary statements	
P280	Wear protective gloves
P302+P352	IF ON SKIN: Wash with plenty of water
P333+P313	If skin irritation or rash occurs: Get medical advice/attention
P501	Dispose of contents and container to authorised waste disposal facility

### Supplemental hazard information

Contains: MALEIC ACID

### 2.3. Other hazards

This product does not contain any substances that are assessed to be a PBT or a vPvB

## SECTION 3: Composition/information on ingredients

### 3.2. Mixtures

Note that the table shows known hazards of the ingredients in pure form. These hazards are reduced or eliminated when mixed or diluted, see Section 16d.

Constituent	Classification	Concentration
<b>TROMETAMOL</b>		
CAS No: 77-86-1 EC No: 201-064-4	Skin Irrit. 2, Eye Irrit. 2, STOT SE 3; H315, H319, H335	<1.5 %
<b>MALEIC ACID</b>		
CAS No: 110-16-7 EC No: 203-742-5 Index No: 607-095-00-3	Acute Tox. 4, Skin Irrit. 2, Eye Irrit. 2, Skin. Sens. 1, STOT SE 3; H302, H315, H319, H317, H335	<1.5 %
<b>SODIUM AZIDE</b>		
CAS No: 26628-22-8 EC No: 247-852-1 Index No: 011-004-00-7	Acute Tox. 2, Aquatic Acute 1, Aquatic Chronic 1; H300, EUH032, H400, H410	<0.05 %

Explanations to the classification and labelling of the ingredients are given in Section 16e. Official abbreviations are printed in normal font. Text in italics are specifications and/or complements used in the calculation of the classification of this mixture, see Section 16b.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

#### Generally

In case of concern, or if symptoms occur, call a doctor/physician.

#### Upon breathing in

Fresh air and rest. If symptoms persist seek medical advice.

#### Upon eye contact

Rinse the eye for several minutes with lukewarm water. If irritation persists call a doctor/ophthalmologist.

#### Upon skin contact

Remove contaminated clothing.  
Wash the skin with soap and water.  
If symptoms occur, contact a physician.  
Wash contaminated clothing before reuse.

#### Upon ingestion

Rinse mouth out thoroughly first with water, then SPIT OUT the rinse water. Drink at least half a litre of water and seek medical advice. DO NOT INDUCE VOMITING.

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

#### Upon skin contact

Rash and itching.  
Allergic reactions.

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

Symptomatic treatment.  
Upon contact with a doctor, make sure to have the label or this safety data sheet with you.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Extinguish with water mist, powder, carbon dioxide or alcoholresistant foam.

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

Gases detrimental to health can be spread in case of fire.

### 5.3. Advice for firefighters

Protective measures should be taken regarding other material at the site of the fire.

In case of fire use proper breathing apparatus.

Wear full protective clothing.

## SECTION 6: Accidental release measures

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

Avoid inhalation and exposure to skin and eyes.

Keep unauthorized and unprotected people at a safe distance.

Use recommended safety equipment, see section 8.

Ensure good ventilation.

### 6.2. Environmental precautions

Avoid release to drains, soil or watercourses.

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

To be collected with caution and transported to a waste disposal facility.

### 6.4. Reference to other sections

See section 8 and 13 for personal protection equipment and disposal considerations.

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Store this product separately from food items and keep it out of the reach of children and pets.

Avoid spillage, inhalation and contact with eyes and skin.

Do not eat, drink or smoke in premises where this product is handled.

Wash your hands after using the product.

Remove contaminated clothing.

Wash contaminated clothing before reuse.

Keep away from incompatible products.

Use recommended safety equipment, see section 8.

Implement appropriate engineering controls if necessary, see Section 8.

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

This product should be stored well out of reach of young children and kept safely apart from products intended for consumption.

The product should be stored in a manner which prevents hazards to health and the environment. Avoid exposure to humans and animals and do not discharge the product in a sensitive environment.

Always use sealed and visibly labeled packages.

Store tightly, in original packaging.

Store in dry and cool area.

### 7.3. Specific end use(s)

See identified uses in Section 1.2.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1. National limit values

##### SODIUM AZIDE

United Kingdom (EH40/2005)

Time-weighted-average exposure limit (TWA) 0.1 mg/m<sup>3</sup>

Short term exposure limit (STEL) 0.3 mg/m<sup>3</sup>

Note Sk

Explanations of abbreviations are given in Section 16b

#### DNEL

##### SODIUM AZIDE

	Type of exposure	Route of exposure	Value
Consumer	Chronic Systemic	Inhalation	0.029 mg/m <sup>3</sup>
Worker	Chronic Systemic	Dermal	0.0467 mg/kg bw
Worker	Chronic Systemic	Inhalation	0.164 mg/m <sup>3</sup>
Consumer	Chronic Systemic	Oral	0.0167 mg/kg bw
Consumer	Chronic Systemic	Dermal	0.0167 mg/kg bw

#### PNEC

##### SODIUM AZIDE

Environmental protection target	PNEC value
Fresh water	0.35 µg/L
Freshwater sediments	0.0167 mg/kg dw
Marine water	3.5 µg/L
Marine sediments	0.00072 mg/kg dw
Microorganisms in sewage treatment	30 µg/L

### 8.2. Exposure controls

The risks posed by the product or its constituents must be considered in the task specific risk assessment, in accordance with current working environment legislation. The risk assessment should be reviewed regularly and updated if necessary.

#### 8.2.1. Appropriate engineering controls

The ventilation in the workplace must ensure an air quality that meets the requirements of the current working environment legislation. Local exhaust ventilation should be used to remove airborne contaminants at the source.

#### Eye/face protection

Use protective glasses with tight seals according to standard EN166.

#### Skin protection

Use suitable protective clothing.

Use protective gloves fulfilling the standard EN374 if there is a risk of direct contact.

During continuous contact use gloves with a minimum breakthrough time of at least 240 minutes, preferably over 480 minutes.

The most suitable protective glove should be chosen in consultation with the glove supplier, taking into account the risk assessment for the specific task and the properties of the chemicals involved. Note that the breakthrough time of the material is affected by the duration of the exposure, temperature conditions, abrasion, etcetera.

Based on the chemical properties of the product, the following glove materials are recommended (EN 374):.

- Neoprene rubber.
- Nitrile rubber.

## Respiratory protection

Use appropriate respiratory protective equipment in case of insufficient ventilation.

The most appropriate respiratory protective equipment should be decided in consultation with the appointed safety representative, taking into account the risk assessment for the specific task.

Based on the physical and chemical properties of the product, the following filter type(s) and/or filter combination(s) are recommended:.

– A/P2.

### 8.2.3. Environmental exposure controls

Work with the product should take place in such a way that the product does not get into drains, waterways, soil and air.

## SECTION 9: Physical and chemical properties

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

(a) Physical state	liquid
	Form: gel
(b) Colour	Not indicated
(c) Odour	Not indicated
(d) Melting point/freezing point	Not indicated
(e) Boiling point or initial boiling point and boiling range	Not indicated
(f) Flammability	Not indicated
(g) Lower and upper explosion limit	Not indicated
(h) Flash point	Not indicated
(i) Auto-ignition temperature	Not indicated
(j) Decomposition temperature	Not indicated
(k) pH	Not indicated
(l) Kinematic viscosity	Not indicated
(m) Solubility	Not indicated
(n) Partition coefficient n-octanol/water (log value)	Not indicated
(o) Vapour pressure	Not indicated
(p) Density and/or relative density	Not indicated
(q) Relative vapour density	Not indicated
(r) Particle characteristics	Not indicated

### 9.2. Other information

#### 9.2.1. Information with regard to physical hazard classes

Not indicated

#### 9.2.2. Other safety characteristics

Not indicated

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

Hazardous reactions not expected to occur under normal conditions.

### 10.2. Chemical stability

The product is stable at normal storage and handling conditions.

### 10.3. Possibility of hazardous reactions

No hazardous reactions known.

### 10.4. Conditions to avoid

No data available.

### 10.5. Incompatible materials

None known.

### 10.6. Hazardous decomposition products

None under normal conditions.

## SECTION 11: Toxicological information

### 11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Information on possible health hazards are based on experience and / or toxicological properties of several components in the product.

#### Acute toxicity

The product is not classified as acutely toxic.

#### MALEIC ACID

LD50 rabbit 24h: 1560 mg/kg Dermal

LD50 rat 24h: 708 mg/kg Orally

#### SODIUM AZIDE

LD50 rabbit 24h: 50 mg/kg Dermal

LC50 rat 4h: 0.037 mg/L Inhalation

LD50 rat 24h: 27 mg/kg Orally

#### Skin corrosion/irritation

The product is not classified for skin corrosion/irritation.

#### Serious eye damage/irritation

The product is not classified for serious eye damage/eye irritation.

#### Respiratory or skin sensitisation

May cause an allergic skin reaction.

#### Germ cell mutagenicity

The product is not classified as mutagen.

#### Carcinogenicity

The product is not classified as carcinogenic.

#### Reproductive toxicity

The product is not classified as a reproductive toxicant.

#### STOT-single exposure

The product is not classified for specific organ toxicity after single exposure.

#### STOT-repeated exposure

The product is not classified for specific organ toxicity after repeated exposure.

#### Aspiration hazard

The product is not classified as being toxic for aspiration.

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

The product does not have any known endocrine-disrupting properties.

#### 11.2.2. Other information

Not indicated.

## SECTION 12: Ecological information

### 12.1. Toxicity

Prevent release on land, in water and drains.

No ecological damage is known or expected in the event of normal use.

#### MALEIC ACID

LC50 Rainbow trout (*Oncorhynchus mykiss*) 96h: 75 mg/l

EC50 Freshwater water flea (*Daphnia magna*) 48 h: 42.81 mg/l

ErC50 Algae 72h: 74.35 mg/l

### 12.2. Persistence and degradability

There is no information regarding persistence or degradability.

### 12.3. Bioaccumulative potential

There is no information regarding bioaccumulation.

### 12.4. Mobility in soil

Information about mobility in nature is not available.

### 12.5. Results of PBT and vPvB assessment

This product does not contain any substances that are assessed to be a PBT or a vPvB.

### 12.6. Endocrine disrupting properties

The product does not have any known endocrine-disrupting properties.

### 12.7. Other adverse effects

No known effects or hazards.

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

#### Waste handling of the product

Avoid discharge into sewers.

The product is not classified as hazardous waste.

Empty, rinsed packaging is sent for recycling where practicable.

See directive 2008/98/EC on waste. Observe national or regional provisions on waste management.

## SECTION 14: Transport information

Where not otherwise stated the information applies to all of the UN Model Regulations, i.e. ADR (road), RID (railway), ADN (inland waterways), IMDG (sea), and ICAO (IATA) (air).

### 14.1. UN number or ID number

Not classified as dangerous goods

### 14.2. UN proper shipping name

Not applicable

### 14.3. Transport hazard class(es)

Not applicable

### 14.4. Packing group

Not applicable

### 14.5. Environmental hazards

Not applicable

### 14.6. Special precautions for user

Not applicable

### 14.7. Maritime transport in bulk according to IMO instruments

Not applicable

### 14.8 Other transport information

Not applicable

## SECTION 15: Regulatory information

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

Not indicated.

### 15.2. Chemical safety assessment

Assessment and chemical safety report in accordance with 1907/2006 Annex I has not yet been performed.

## SECTION 16: Other information

### 16a. Indication of where changes have been made to the previous version of the safety data sheet

#### Revisions of this document

Earlier versions

2022-04-06 Changes in section(s) 1.

### 16b. Legend to abbreviations and acronyms used in the safety data sheet

#### Full texts for Hazard Class and Category Code mentioned in section 3

Skin Irrit. 2      Skin corrosion/irritation, Hazard Category 2 - Skin Irrit. 2, H315 - Causes skin irritation

Eye Irrit. 2      Serious eye damage/eye irritation, Hazard Category 2 - Eye Irrit. 2, H319 - Causes serious eye irritation

STOT SE 3      Specific target organ toxicity — Single exposure, Hazard Category 3, Respiratory tract irritation - STOT SE 3, H335 - May cause respiratory irritation

Acute Tox. 4      Acute toxicity (oral), Hazard Category 4 - Acute Tox. 4, H302 - Harmful if swallowed

Skin. Sens. 1	Respiratory or skin sensitisation, Sensitisation — Skin, hazard category 1 - Skin. Sens. 1, H317 - May cause an allergic skin reaction
Acute Tox. 2	Acute toxicity (oral), Hazard Category 2 - Acute Tox. 2, H300 - Fatal if swallowed
Aquatic Acute 1	Hazardous to the aquatic environment — Acute Hazard, Category 1 - Aquatic Acute 1, H400 - Very toxic to aquatic life
Aquatic Chronic 1	Hazardous to the aquatic environment — Chronic Hazard, Category 1 - Aquatic Chronic 1, H410 - Very toxic to aquatic life with long lasting effects

### **Explanations of the abbreviations in Section 8 United Kingdom**

Sk Can be absorbed through the skin. The assigned substances are those for which there are concerns that dermal absorption will lead to systemic toxicity

### **Explanations of the abbreviations in Section 14**

ADR	European Agreement concerning the International Transport of Dangerous Goods by Road
RID	Regulations concerning the International Transport of Dangerous Goods by Rail
IMDG	International Maritime Dangerous Goods Code
ICAO	International Civil Aviation Organization (ICAO, 999 University Street, Montreal, Quebec H3C 5H7, Canada)
IATA	The International Air Transport Association

## **16c. Key literature references and sources for data**

### **Sources for data**

Primary data for the calculation of the hazards has preferentially been taken from the official European classification list, 1272/2008 Annex I, as updated to 2023-03-15.

Where such data was not available, alternative documentation used to establish the official classification was used, e.g. IUCLID (International Uniform Chemical Information Database). As a second alternative, information was used from reputable international chemical industries, and as a third alternative other available information was used, e.g. material safety data sheets from other suppliers or information from non-profit associations, where reliability of the source was assessed by expert opinion. If, in spite of this, reliable information could not be sourced, the hazards were assessed by expert opinions based on the known hazards of similar substances, and according to the principles in 1907/2006 and 1272/2008.

### **Full texts for Regulations mentioned in this Safety Data Sheet**

1907/2006	REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC
1272/2008	REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006
2008/98/EC	DIRECTIVE 2008/98/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 19 November 2008 on waste and repealing certain Directives

## **16d. Methods of evaluating information referred to in 1272/2008 Article 9 which was used for the purpose of classification**

Hazard calculation for this mixture has been performed as a cumulative assessment with the aid of expert assessments in accordance with 1272/2008 Annex I, where all available information which may be significant to establishing the hazards of the mixture was assessed together, and in accordance with 1907/2006 Annex XI.

## **16e. List of relevant hazard statements and/or precautionary statements**

### **Full texts for hazard statements mentioned in section 3**

H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H302	Harmful if swallowed
H317	May cause an allergic skin reaction
H300	Fatal if swallowed
EUH032	Contact with acids liberates very toxic gas
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life with long lasting effects



**16f. Advice on any training appropriate for workers to ensure protection of human health and the environment**

**Warning for misuse**

Not indicated.

**Other relevant information**

Not indicated

**Editorial information**



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