

SAFETY DATA SHEET

Release Date: 09-08-2016, revision 1.0

REF Number

B83544

Name

Lipase NG Cal

COMPOSITION:

1) Lipase NG Cal Lyo x 3 mL

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1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

1.1. Product identifier

Mixture identification:

Trade name: Lipase NG Cal Lyo x 3 mL

Trade code: 2640101

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

Recommended use:

For In Vitro Diagnostic use only.

For professional users only.

1.3. Details of the supplier of the safety data sheet

Company:

SENTINEL CH. SpA - Via Robert Koch 2 - 20152 Milan - Italy

SENTINEL CH. SpA - Phone n. [(+39) 02 3455 141 working time.

Competent person responsible for the safety data sheet:

customerservice@sentinel.it

1.4. Emergency telephone number

SENTINEL CH. SpA - Phone n. [(+39) 02 3455 1495 working time: Mon-Fri 9.00 am - 1.00 pm, 2.00 pm - 6.00 pm

2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

EC regulation criteria 1272/2008 (CLP)

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Adverse physicochemical, human health and environmental effects:

No other hazards

2.2. Label elements

The product is not classified as dangerous according to Regulation EC 1272/2008 (CLP).

Symbols:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

2.3. Other hazards

vPvB Substances: None - PBT Substances: None

Other Hazards:

No other hazards

CAUTION : For the production of the preparation has been used material of human origin . The material of each

donor was tested using approved reagents and found negative to HBsAg, HCV and anti - HIV1 antibodies

and anti- HIV2 . Nevertheless , since no test is able to ensure that the products derived from human blood

not pose a risk of transmission of infectious agents , it is recommended to treat this product with the same

caution used for the above material .

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

N.A.

vPvB Substances: None - PBT Substances: None

Hazardous components within the meaning of the CLP regulation and related classification:

None.

4. FIRST AID MEASURES

4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

Rinse continuously with water for several minutes. Remove contact lenses if present and easy to do.

Continue rinsing. If eye irritation persists: Get medical advice/attention.

In case of Ingestion:

Get Medical advice/attention if you feel unwell.

In case of Inhalation:

Remove victim to fresh air and keep at rest in a position comfortable for breathing.

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

None

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

Treatment:

None

5. FIRE-FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media:

Water.

Carbon dioxide (CO₂).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment.

Remove all sources of ignition.

Remove persons to safety.

See protective measures under point 7 and 8.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

Do not eat or drink while working.

See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

2 - 8°C

Keep away from food, drink and feed.

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.
7.3. Specific end use(s)
None in particular

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters
No occupational exposure limit available
DNEL Exposure Limit Values
N.A.
PNEC Exposure Limit Values
N.A.
8.2. Exposure controls
Eye protection:
Eye glasses.
Protection for skin:
Lab coat.
Protection for hands:
One-time gloves.
Respiratory protection:
Not needed for normal use.
Thermal Hazards:
None
Environmental exposure controls:
None
Appropriate engineering controls:
None

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

Properties	Value	Method:	Notes:
Appearance and colour:	Lyophilisate slight yellow	--	--
Odour:	Odorless	--	--
Odour threshold:	N.A.	--	--
pH:	6.95	--	--
Melting point / freezing point:	N.A.	--	--
Initial boiling point and boiling range:	N.A.	--	--
Flash point:	N.A.	--	--
Evaporation rate:	N.A.	--	--
Solid/gas flammability:	N.A.	--	--
Upper/lower flammability or explosive limits:	N.A.	--	--
Vapour pressure:	N.A.	--	--
Vapour density:	N.A.	--	--
Relative density:	N.A.	--	--
Solubility in water:	Soluble	--	--
Solubility in oil:	N.A.	--	--
Partition coefficient (n-octanol/water):	N.A.	--	--
Auto-ignition temperature:	N.A.	--	--
Decomposition temperature:	N.A.	--	--
Viscosity:	N.A.	--	--
Explosive properties:	N.A.	--	--
Oxidizing properties:	N.A.	--	--

9.2. Other information

Properties	Value	Method:	Notes:
Miscibility:	N.A.	--	--
Fat Solubility:	N.A.	--	--
Conductivity:	N.A.	--	--
Substance Groups relevant properties	N.A.	--	--

10. STABILITY AND REACTIVITY

- 10.1. Reactivity
No hazardous reactions known.
- 10.2. Chemical stability
Stable when properly stored.
- 10.3. Possibility of hazardous reactions
None
- 10.4. Conditions to avoid
Heat sources
- 10.5. Incompatible materials
None in particular.
- 10.6. Hazardous decomposition products
None.

11. TOXICOLOGICAL INFORMATION

- 11.1. Information on toxicological effects
Toxicological information of the mixture:
N.A.
- Toxicological information of the main substances found in the mixture:

N.A.

If not differently specified, the information required in Regulation 453/2010/EC listed below must be considered as N.A.:

- a) acute toxicity;
- b) skin corrosion/irritation;
- c) serious eye damage/irritation;
- d) respiratory or skin sensitisation;
- e) germ cell mutagenicity;
- f) carcinogenicity;
- g) reproductive toxicity;
- h) STOT-single exposure;
- i) STOT-repeated exposure;
- j) aspiration hazard.

12. ECOLOGICAL INFORMATION

- 12.1. Toxicity
Adopt good working practices, so that the product is not released into the environment.
Do not use when plants are in flower: the product is toxic for bees.
N.A.
- 12.2. Persistence and degradability
None
N.A.
- 12.3. Bioaccumulative potential
N.A.
- 12.4. Mobility in soil
N.A.
- 12.5. Results of PBT and vPvB assessment
vPvB Substances: None - PBT Substances: None
- 12.6. Other adverse effects
None

13. DISPOSAL CONSIDERATIONS**13.1. Waste treatment methods**

Recover, if possible. Send to authorised disposal plants or for incineration under controlled conditions.
In so doing, comply with the local and national regulations currently in force.

14. TRANSPORT INFORMATION**14.1. UN number**

Not classified as dangerous in the meaning of transport regulations.

14.2. UN proper shipping name

N.A.

14.3. Transport hazard class(es)

N.A.

14.4. Packing group

N.A.

14.5. Environmental hazards

N.A.

14.6. Special precautions for user

N.A.

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

N.A.

15. REGULATORY INFORMATION

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture
Dir. 67/548/EEC (Classification, packaging and labelling of dangerous substances). Dir. 99/45/EEC (Classification, packaging and labelling of dangerous preparations). Dir. 98/24/EC (Risks related to chemical agents at work). Dir. 2000/39/EC (Occupational exposure limit values); Dir. 2006/8/CE. Regulation (CE) n. 1907/2006 (REACH), Regulation (CE) n.1272/2008 (CLP), Regulation (CE) n.790/2009.

Where applicable, refer to the following regulatory provisions :

Directive 2003/105/CE ('Activities linked to risks of serious accidents') and subsequent amendments.

Regulation (EC) nr 648/2004 (detergents).

1999/13/EC (VOC directive)

Provisions related to directives 82/501/EC(Seveso), 96/82/EC(Seveso II):

N.A.

15.2. Chemical safety assessment

No

16. OTHER INFORMATION

Paragraphs modified from the previous revision:

9. PHYSICAL AND CHEMICAL PROPERTIES

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre,
Commission of the European Communities

SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van Nostrand
Reinold

CCNL - Appendix 1

Insert further consulted bibliography

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.