SAFETY DATA SHEET

Release Date: 26-06-2015, Revision 2.0

REF Number	Name
A53704	**Pancreatic Amylase 102 mL (2x40+2x11)**

COMPOSITION:

1)	Pancreatic Amylase REAGENT 1	40 mL	(pag. 2)
2)	Pancreatic Amylase REAGENT 2	11 mL	(pag. 8)

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

1.1. Product identifier

Mixture identification:

Trade name: Pancreatic Amylase REAGENT 1 40 mL

Trade code: 27631E

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

SECTION 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

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:

Qty	Name	Ident. Number	Classification
>= 0.01% - < 0.1%	Sodio Azide	Index number: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	3.1/2/Oral Acute Tox. 2 H300 4.1/A1 Aquatic Acute 1 H400 4.1/C1 Aquatic Chronic 1 H410 EUH032

>= 0.01% - < 0.1%	MIT (Metil-Isotiazolone Cloridrato)	CAS: 26172-54-3 EC: 247-499-3 REACH No.: 247-499-33	3.1/3/Inhal Acute Tox. 3 H331 3.1/4/Oral Acute Tox. 4 H302 3.2/1A Skin Corr. 1A H314 3.8/3 STOT SE 3 H335 4.1/A1 Aquatic Acute 1 H400 3.4.1/1-1A-1B Resp. Sens. 1,1A,1B H334 3.4.2/1-1A-1B Skin Sens. 1,1A,1B H317

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

Sodio Azide - CAS: 26628-22-8

ACGIH - LTE(8h): 0.1 mg/m3 - STE: 0.3 mg/m3 - Behaviour: Indicative
EU - LTE: 0.1 mg/m3 - STE: 0.3 mg/m3 - Notes: Absorption through the skin.

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:	Colourless liquid.	--	--
Odour:	Odorless	--	--
Odour threshold:	N.A.	--	--
pH:	7.15	--	--
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:	1.007	--	--
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

Avoid contact with strong acids.

Sodium azide may react with lead or copper to form explosive metal azide.

10.4. Conditions to avoid

Contact with lead and acide.

10.5. Incompatible materials

Strong acid materials, Oxidizing agents

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:

Sodio Azide - CAS: 26628-22-8

a) acute toxicity:

Test: LD50 - Route: Oral - Species: Rat 27 mg/kg - Source: RTECS

Test: LD50 - Route: Skin - Species: Rabbit 20 mg/kg - Source: RTECS

MIT (Metil-Isotiazolone Cloridrato) - CAS: 26172-54-3

b) skin corrosion/irritation:

Test: Skin Corrosive - Route: Skin Positive

c) serious eye damage/irritation:

Test: Eye Corrosive - Route: Inhalation Dust Positive

d) respiratory or skin sensitisation:

Test: Respiratory Sensitization - Route: Inhalation Positive

Test: Skin Sensitization - Route: Skin Positive

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.
Sodio Azide - CAS: 26628-22-8
Endpoint: LC50 - Species: Fish - Duration h: 96 - mg/l: N.A.
Endpoint: EC50 - Species: Daphnia - Duration h: 48 - mg/l: 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. 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

Full text of phrases referred to in Section 3:

H300 Fatal if swallowed.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
EUH032 Contact with acids liberates very toxic gas.
H331 Toxic if inhaled.
H302 Harmful if swallowed.
H314 Causes severe skin burns and eye damage.
H335 May cause respiratory irritation.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H317 May cause an allergic skin reaction.

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.

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

1.1. Product identifier

Mixture identification:

Trade name: Pancreatic Amylase REAGENT 2 11 mL

Trade code: 27631N

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

SECTION 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

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:

Qty	Name	Ident. Number	Classification
>= 0.01% - < 0.1%	Sodio Azide	Index number: 011-004-00-7 CAS: 26628-22-8 EC: 247-852-1	3.1/2/Oral Acute Tox. 2 H300 4.1/A1 Aquatic Acute 1 H400 4.1/C1 Aquatic Chronic 1 H410 EUH032

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

Sodio Azide - CAS: 26628-22-8

ACGIH - LTE(8h): 0.1 mg/m3 - STE: 0.3 mg/m3 - Behaviour: Indicative

EU - LTE: 0.1 mg/m3 - STE: 0.3 mg/m3 - Notes: Absorption through the skin.

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:	Pale yellow liquid	--	--
Odour:	Odorless	--	--
Odour threshold:	N.A.	--	--
pH:	7.15	--	--
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:	1.000	--	--
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
Avoid contact with strong acids.
Sodium azide may react with lead or copper to form explosive metal azide.
10.4. Conditions to avoid
Contact with lead and acide.
10.5. Incompatible materials
Strong acid materials, Oxidizing agents
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:
Sodio Azide - CAS: 26628-22-8
a) acute toxicity:
Test: LD50 - Route: Oral - Species: Rat 27 mg/kg - Source: RTECS
Test: LD50 - Route: Skin - Species: Rabbit 20 mg/kg - Source: RTECS

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.
Sodio Azide - CAS: 26628-22-8
Endpoint: LC50 - Species: Fish - Duration h: 96 - mg/l: N.A.
Endpoint: EC50 - Species: Daphnia - Duration h: 48 - mg/l: 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. 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

Full text of phrases referred to in Section 3:
H300 Fatal if swallowed.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
EUH032 Contact with acids liberates very toxic gas.
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.