

SAFETY DATA SHEET

Revision date: 31.10.2022
Revision 3.5
according to 2015/830/EC

Safety data sheet StripAssay®

Section 1. Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Trade name: **StripAssay® (see Section 16)**
Catalogue Number: see Section 16
REACH Reg. number: -----

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses: Laboratory chemicals

1.3. Details of supplier of the safety data sheet

Manufacturer: ViennaLab Diagnostics GmbH
Gaudenzdorfer Guertel 43-45
A-1120 Vienna, Austria
tel: +43-1-8120156 0
fax: +43-1-8120156 19
email: info@viennalab.com

1.4 Emergency telephone number

Call your local emergency center.

Section 2. Hazards identification

2.1 Classification of the substance or mixture

DNAT

Skin Irrit. 2 (H315), Eye Irrit. 2 (H319)

Color Developer

Skin Sens. 1 (H317)

Other components

These mixtures are classified as not hazardous or do not meet the criteria for classification according the 1272/2008/EC.

2.2 Label elements according to Regulation (EC) No 1272/2008

DNAT

Hazard pictograms



Signal word: Warning

Hazard statements:

H315; Causes skin irritation
H319; Causes serious eye irritation

Precautionary statements:

P280; Wear protective gloves/protective clothing/eye protection/face protection
P302+P352; If on skin: Wash with plenty of water
P305+P351+P338; If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P332+P313; If skin irritation occurs: Get medical advice/attention
P337+P313; If eye irritation persists: Get medical advice/attention

SAFETY DATA SHEET

Revision date: 31.10.2022
Revision 3.5
according to 2015/830/EC

Safety data sheet StripAssay®

Color Developer

Hazard pictograms



Signal word: Warning

Hazard statements:

H317; May cause an allergic skin reaction

Precautionary statements:

P261; Avoid breathing dust/fume/gas/mist/vapors/spray

P272; Contaminated work clothing should not be allowed out of workplace

P280; Wear protective gloves/protective clothing/eye protection/face protection

P302+P352; If on skin: Wash with plenty of water

P333+P313; If skin irritation or rash occurs: Get medical advice/attention

Other components

Hazard pictograms and signal word

This mixture is not subject to labeling according to the calculation methods of the regulation 1272/2008/EC.

2.3 Other hazards

Not known.

Section 3. Composition/information on ingredients

3.1 Mixtures

DNAT

Hazardous ingredients

Substance name	CAS No.	EC No.	Index No.	Concentration
Sodium hydroxide	1310-73-2	215-185-5	011-002-00-6	1,6 % w/v

Classification according Regulation (EC) No. 1272/2008: Skin Irrit. 2; H315; Eye Irrit. 2; H319

Color Developer

Hazardous ingredients

Substance name	CAS No.	EC No.	Index No.	Concentration
Maleic acid	110-16-7	03-742-55	607-095-00-3	≤0,4 % w/v

Classification according Regulation (EC) No. 1272/2008: Skin Sens. 1; H317

Other components

The ingredients of the other components of the StripAssay® are not dangerous or their concentrations do not exceed the limits specified in the regulation 1272/2008/EC.

Section 4. First aid measures

4.1 Description of first aid measures

General information: Immediately take off contaminated clothing. If unwell seek medical advice.

Following inhalation: Provide fresh air. In case of irritation of the respiratory tract consult a physician.

Following skin contact: Wash with plenty of water and soap. In case of skin irritation consult a physician.

Following eye contact: Remove contact lenses. Flush immediately with plenty of flowing water for 15 minutes holding eyelids apart, protecting the uninjured eye. If necessary, consult a physician.

Following ingestion: Rinse mouth immediately and drink plenty of water (200-300 mL) in little sips (dilution effect). Avoid vomiting. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

DNAT

Symptoms: Skin irritation. Serious eye irritation. Danger of perforation of esophagus and stomach due to strong caustic effect. Risk of mucosal necrosis.

SAFETY DATA SHEET

Revision date: 31.10.2022
Revision 3.5
according to 2015/830/EC

Safety data sheet StripAssay®

Color Developer

Symptoms: Skin sensitization. Repeated exposure may cause skin irritation. May cause allergic skin reaction. May cause slight irritation to the eyes. Ingestion may cause adverse effects.

Other components

No symptoms known up to now.

4.3 Indication of any immediate medical attention and special treatment needed

First aid, symptomatic treatment.

Section 5. Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media: Adapt extinguishing measures to suit the environment.

5.2. Special hazards arising from the substance or mixture

Not flammable, ambient fire may liberate hazardous vapors.

5.3. Advice for fire-fighters

In case of fire: Use self-contained breathing apparatus.

5.4. Additional information

Prevent fire extinguishing water from contaminating surface water or ground water system.

Section 6. Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Avoid contact with mixture. Use personal protective equipment. Provide fresh air. Leave danger zone. Consult expert.

6.2. Environmental precautions

Do not allow to enter drainage system or water.

6.3. Methods and material for containment and cleaning up

Absorb with liquid binding and neutralizing material and dispose of according to section 13.

6.4. Reference to other sections

Observe protective measures in sections 7, 8 and 13.

Section 7. Handling and storage

7.1. Precautions for safe handling

Advice for safe handling: General occupational hygiene measures. Do not eat, drink or smoke in the work area. Wash hands after use. Change contaminated clothing before entering eating areas. Use personal protective equipment.

Precautions against fire and explosion: General measures of preventive fire protection.

7.2. Conditions for safe storage, including any incompatibilities

Requirements for storage rooms and vessels: No special technical protective measures are necessary. Only store in original containers. Keep container tightly closed.

7.3 Specific end uses

Observe instructions for use.

Section 8. Exposure controls/personal protection

8.1 Control parameters

These mixtures do not contain substances above concentration limits fixing an occupational exposure limit.

SAFETY DATA SHEET

Revision date: 31.10.2022
 Revision 3.5
 according to 2015/830/EC

Safety data sheet StripAssay®

8.2 Exposure controls

Appropriate engineering controls: Technical measures and the design of appropriate work processes go before the use of protective equipment. See section 7.1.

Hygiene measures: Do not eat, drink or smoke at the workplace. Wash hands after working with the mixtures. Preventive skin protection. Immediately change contaminated clothing.

Personal protective equipment: Minimum standards for protective measures during handling of working materials listed in TRGS 500.

Respiratory protection: With proper use, and under normal conditions, breathing protection is not required.

Hand protection: Tested protective gloves are to be worn. Chemical resistance has to be clarified with the supplier.

Eye protection: Tightly sealed goggles.

Other protection measures: Wear protective clothing to prevent contact with skin.

Environmental exposure controls: See section 7. No further action is necessary.

Section 9. Physical and chemical properties

9.1 Information on basic physical and chemical properties

DNAT

Form	liquid
Color	blue
Odor	odorless
Odor threshold	no data available
Melting point	no data available
Boiling point	no data available
Flash point	no data available
Explosion limits lower/upper	not applicable
Density (20°C)	no data available
Water solubility (20°C)	soluble
Corrosion	may be corrosive to metals

Color Developer

Form	liquid
Color	clear, yellow
Odor	minimal odor characteristics
Odor threshold	no data available
Melting point	no data available
Boiling point	no data available
Flash point	no data available
Explosion limits lower/upper	no data available
Density (20°C)	no data available
Water solubility (20°C)	soluble
Corrosion	no data available

Other components

Form	liquid
Color	colorless
Odor	odorless
Odor threshold	no data available
Melting point	no data available
Boiling point	no data available
Flash point	no data available
Explosion limits lower/upper	no data available
Density (20°C)	no data available
Water solubility (20°C)	soluble
Corrosion	no data available

SAFETY DATA SHEET

Revision date: 31.10.2022
Revision 3.5
according to 2015/830/EC

Safety data sheet StripAssay®

9.2. Other information

Not available.

Section 10. Stability and reactivity

10.1 Reactivity

DNAT

Possible formation of hydrogen upon contact with amphoteric metals (such as aluminum, lead, zinc).

Other components

There are expected no hazardous reactions for intended use.

10.2 Chemical stability

Stable under recommended handling and storage conditions.

10.3 Possibility of hazardous reactions

DNAT

Possible formation of hydrogen upon contact with amphoteric metals (such as aluminum, lead, zinc).

Other components

There are expected no hazardous reactions under recommended handling and storage conditions.

10.4 Conditions to avoid

None for the intended use.

10.5 Incompatible materials

DNAT

Strong acids, metals, halogenated hydrocarbons

Color Developer

Strong acids, strong bases, strong oxidizers

Other components

Unknown.

10.6 Hazardous decomposition products

There are expected no hazardous decomposition products under recommended handling and storage conditions.

Section 11. Toxicological information

11.1 Information on toxicological effects

DNAT

Toxicological data for the mixture are not available.

Acute toxicity: No data available.

Skin corrosion/irritation: Irritant

Eye damage/irritation: Strong irritant

Sensitization to respiratory tract/skin: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: No data available on carcinogenicity in humans.

Reproductive toxicity: No data available on reproductive toxicity in humans.

Specific target organ toxicity (repeated exposure): no data available.

Specific target organ toxicity (single exposure): No data available.

Aspiration hazard: No data available.

SAFETY DATA SHEET

Revision date: 31.10.2022
Revision 3.5
according to 2015/830/EC

Safety data sheet StripAssay®

Color Developer

Toxicological data for the mixture are not available.

Acute toxicity: No data available.

Skin corrosion/irritation: No data available.

Eye damage/irritation: No data available.

Sensitization to respiratory tract/skin: May cause allergic skin reaction.

Germ cell mutagenicity: No data available.

Carcinogenicity: No data available on carcinogenicity in humans.

Reproductive toxicity: No data available on reproductive toxicity in humans.

Specific target organ toxicity (repeated exposure): No data available.

Specific target organ toxicity (single exposure): No data available.

Aspiration hazard: No data available.

Other components

Toxicological data for the mixtures are not available.

Acute toxicity: No data available.

Eye damage/irritation: No data available.

Sensitization to respiratory tract/skin: No data available.

Germ cell mutagenicity: No data available.

Carcinogenicity: No data available.

Reproductive toxicity: The mixtures are not classified. The mixtures do not contain any substances that are classified as toxic for reproduction.

Specific target organ toxicity (repeated exposure): No data available.

Specific target organ toxicity (single exposure): No data available.

Aspiration hazard: No data available.

Section 12. Ecological information

12.1 Toxicity

No data available for the mixtures.

12.2 Persistence and degradability

No data available.

12.3 Bioaccumulative potential

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

PBT/vPvB assessment not available.

12.6 Other adverse events

No data available.

Section 13. Disposal considerations

13.1 Waste treatment methods

Disposal according to the Waste Framework Directive 2008/98/EC and in compliance with national and local rules and regulations.

Packaging

Disposal in accordance with applicable national and local statutes and regulations.

SAFETY DATA SHEET

Revision date: 31.10.2022

Revision 3.5

according to 2015/830/EC

Safety data sheet StripAssay®

Section 14. Transport information

14.1 UN-Number

UN No. ---

14.2 UN proper shipping name

ADR/RID: ---

No hazardous material with respect to these transport regulations.

IMDG-Code/ICAO-/IATA-DGR: ---

No hazardous material with respect to these transport regulations.

14.3 Transport hazard class(es)

ADR/RID/IMDG-Code/ICAO-/IATA-DGR: No hazardous material with respect to these transport regulations.

14.4. Packaging group

14.5 Environmental hazards

No hazardous material with respect to these transport regulations.

14.6 Special precautions for user

14.7 Transport in bulk according to Annex II of MARPOL-73/78 and the IBC Code

Not applicable.

Section 15. Regulatory information

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

EU Regulations

REACH regulation (EC) No 1907/2006 in its latest version

CLP regulation (EC) No 1272/2008 in its latest version

National regulations

Refer to the national legal regulations!

15.2 Chemical safety assessment

For these mixtures no chemical safety assessment has been carried out.

Section 16. Other information

Indication of changes compared to revision 3.4:

Update of product list

Catalogue number and Trade name (Section 1.1)

REF 4-125	β -Globin StripAssay® AZE1 a)b)
REF 4-126	β -Globin StripAssay® AZE2 a)b)
REF 4-130	β -Globin StripAssay® MED a)b)
REF 4-140	β -Globin StripAssay® IME a)b)
REF 4-150	β -Globin StripAssay® SEA a)b)
REF 4-160	α -Globin StripAssay® b)c)
REF 4-170	β -Thal Modifier StripAssay® a)b)
REF 4-210	Haemochromatosis StripAssay® B a)b)
REF 4-220	Haemochromatosis StripAssay® A a)b)
REF 4-230	FMF StripAssay® a)b)
REF 4-240	CVD StripAssay® a)b)
REF 4-243	CVD StripAssay® GRC a)b)
REF 4-250	Gaucher Disease StripAssay® a)b)
REF 4-260	FV-PTH-MTHFR StripAssay® a)b)

SAFETY DATA SHEET

Revision date: 31.10.2022
Revision 3.5
according to 2015/830/EC

Safety data sheet StripAssay®

REF 4-280	Apo E StripAssay® a)b)
REF 4-290	FV-PTH StripAssay® a)b)
REF 4-300	Lactose Intolerance StripAssay® a)b)
REF 4-310	Sugar Intolerance StripAssay® a)b)
REF 4-320	HLA-B27 StripAssay® a)b)
REF 4-360	CVD StripAssay® T a)b)
REF 4-370	CVD StripAssay® A a)b)
REF 4-380	CAH StripAssay® a)b)c)
REF 4-390	FMF-SAA1 StripAssay® a)b)
REF 4-410	CF StripAssay® a)b)c)
REF 4-420	CF StripAssay® TUR a)b)c)
REF 4-430	CF StripAssay® GER a)b)c)
REF 4-440	CF StripAssay® EXT a)b)c)
REF 4-710	PGX-HIV StripAssay® a)b)
REF 4-730	PGX-Thrombo StripAssay® a)b)
REF 4-740	PGX-TPMT StripAssay® a)b)
REF 4-750	PGX-CYP2C19 StripAssay® a)b)
REF 4-770	PGX-CYP2D6 XL StripAssay® b)c)
REF 4-780	PGX-5FU XL StripAssay® a)b)c)
REF 5-560	BRAF 600/601 StripAssay® b)c)
REF 5-620	NRAS XL StripAssay® b)c)
REF 5-630	EGFR XL StripAssay® b)c)
REF 5-670	FCGR StripAssay® a)b)
REF 5-680	KRAS XL StripAssay® b)c)
REF CS-012 / CS-017	StripAssay® Detection Reagents d)

Components of the respective StripAssay®:

- a) Lysis Solution, GEN^XTRACT Resin
- b) Taq Dilution Buffer, Amplification Mix(es), DNAT, Hybridization Buffer, Wash Solution A, Conjugate Solution, Wash Solution B, Color Developer
- c) (HS-)Taq DNA Polymerase
- d) Hybridization Buffer, Wash Solution A, Conjugate Solution, Wash Solution B, Color Developer

This information is based on our present knowledge and shall be used only as a guide. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship. ViennaLab Diagnostics GmbH is not held liable for any damage resulting from handling or from contact with the above mentioned products.

The safety data sheet has been prepared in accordance with EC regulation 2015/830/EC.