

SENSIS*Strip* Allergen tests

(Cat. nr. HU00301xx)

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

1.1. Product identifier

Trade name:

SENSIS*Strip* Allergen tests

Article Number:

HU0030110, HU0030111 HU0030112, HU0030113, HU0030114, HU0030115, HU0030116, HU0030117, HU0030118, HU0030119, HU0030120, HU0030121, HU0030122, HU0030123, HU0030124, HU0030125, HU0030126, HU0030127, HU0030128, HU0030129, HU0030130, HU0030131, HU0030132, HU0030133, HU0030134, HU0030136, HU0030137, HU0030138 HU0030139, HU0030147, HU0030148, HU0030149, HU0030150, HU0030151, HU0030152, HU0030153, HU0030154, HU0030155, HU0030156, HU0030157, HU0030158, HU0030159, HU0030160, HU0030161, HU0030162, HU0030163, HU0030164, HU0030165, HU0030166, HU0030167, HU0030168, HU0030169, HU0030170, HU0030171, HU0030172, HU0030173, HU0030242, HU0030243, HU0030202, HU0030209, HU0030271, HU0030210, HU0030207, HU0030214

Components:

- 0) Test Strips
- 1) Reaction vials
- 2) Extraction tubes
- 3) Disposable Pipettes, 0.3 mL
- 4) Disposable Pipettes, 3 mL
- 5) Disposable Spatula
- 6) Swab Sticks
- 7) Evaluation card
- 8) Tubes and vials racks
- 9) Instruction Manual
- 10) *Extraction/Dilution buffer*

CONCERNING SAFETY: THE COMPONENTS 0-9 ARE INOFFENSIVE AND FOR THIS REASON NOT PART OF THIS DOCUMENT. THE MIXTURE 10 IS TREATED AND DEALT WITH BELOW.

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

Lateral flow immunoassays for the qualitative and semi-quantitative determination of allergens in food, on surfaces and in rinse water.

1.3. Details of the supplier of the safety data sheet

Supplier: Gold Standard Diagnostics Budapest Kft.

Fóti út 56/A.

1047 BUDAPEST

HUNGARY

Contact information: www.goldstandarddiagnostics.com/contacts

Phone: + 36 20 457 1204

Responsible person email: CustomerService.Bud@eu.goldstandarddiagnostics.com

1.4. Emergency telephone

Hungary: Egészségügyi Toxikológiai Tájékoztató Szolgálat (ETTSZ)
The National Public Health and Medical Officer Service
1097 Budapest, Nagyvárad tér 2.
Tel.: +36 1 476 6464, +36 80 201 199
e-mail: ettsz@nngyk.gov.hu.

For national poison centres in EU see: <https://poisoncentres.echa.europa.eu/hu/appointed-bodies>

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP]:

The mixture is classified as non-hazardous according to the criteria of Directive 67/548/EEC and Directive 1999/45/EC or Regulation (EC) No 1272/2008.

For the full text of H-statements mentioned in this Section: see Section 16.

Information concerning particular hazards for human and environment:

The mixture does not have to be labelled due to the calculation procedure of the *“General Classification guideline for preparations of the EU”* in the latest version.

2.2. Label elements

Hazard Pictograms:

-

Signal word:

-

Hazard statements:

-

Precautionary statements:

-

Supplemental hazard information:

-

Substances contributing of hazard identification:

-

2.3. Other hazards

All chemicals are potentially dangerous. They should only be handled by specially trained personnel.

See PBT and vPvB assessment results in section 12.5.

Endocrine disrupting properties: see sections 11.2. and 12.6.

SECTION 3: Composition/information on ingredients

3.1. Substances

Not applicable

3.2. Mixtures

Chemical characterization: Mixture

Description: Mixtures of substances with nonhazardous additions.
Dangerous components: Void.
Additional information:
For the wording of the listed risk phrases refer to section 16.
The product does not contain Substances of Very High Concern (SVHC).

SECTION 4: First aid measures

4.1. Description of first aid measures

GENERAL INFORMATION:

First aider: Pay attention for self-protection!!
Remove any clothing soiled by the product.
In case of accident or feeling sick immediately consult a physician. Show this safety data sheet or the product label to the doctor in attendance!

FOLLOWING INGESTION:

Rinse out mouth and drink a glass of water. Do not induce vomiting. If there is any trouble seek medical help.

FOLLOWING INHALATION:

Remove to fresh air. Consult a doctor in case of complaints.

AFTER SKIN CONTACT:

Immediately rinse with water. If skin irritation continues, consult a doctor.

FOLLOWING EYE CONTACT:

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

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

No further relevant information available.

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

No further relevant information available.

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions. CO₂, powder, or water spray.
Fight larger fires with water spray or alcohol resistant foam.
For safety reasons unsuitable extinguishing agents:
For this mixture no limitations of extinguishing agents are given.

5.2. Special hazards arising from the substance or mixture

Ambient fire may liberate hazardous vapours.
In the event of fire development of hazardous combustion gases or vapours possible.
In case of fire, the following gases can be released: Dioxide, carbon monoxide and carbon dioxide.

5.3. Advice for firefighters

Protective equipment:

Wear self-contained respiratory protective device. Wear fully protective suit.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- 6.1.1. For non-emergency personnel
Wear appropriate personal protective equipment.
- 6.1.2. For emergency personnel
Wear appropriate personal protective equipment.

6.2. Environmental precautions

Do not allow to enter sewers/ground water or penetrate the soil.

6.3. Methods and material for containment and cleaning up

Absorb with liquid binding material (sand diatomite, acid binders, universal binders, sawdust).
Dispose of the material according to regulations.

6.4. Reference to other sections

See section 7, 8 and 13.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

No special precautions are necessary if used correctly.
Information about fire – and explosion protection:
No special measures required.

7.2. Conditions for safe storage, including any incompatibilities

Requirements to be met by storerooms and receptacles: Store at a cool place.
Information about storage in one common storage facility: Store away from foodstuffs.
Further information about storage conditions: None.
Recommended storage temperature: 2-8°C

7.3. Specific end use(s)

No further relevant information available.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

Exposure limit values

Ingredients with limit values that require monitoring at workplace:
The mixture does not contain any relevant quantities of materials with critical values that have to be monitored at the working place.
Additional information:
The lists valid during the making were used as basis.

8.2. Exposure controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.
Caution is necessary to prevent skin contact, eye contact, cloth contact and spilling into the floor.

Personal protective equipment:

General protective and hygienic measures

Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages, and feed.

Avoid contact with the eyes and skin.

Immediately remove all soiled and contaminated clothing.

Appropriate engineering controls

No further data; see item 7.

Individual protection measures, such as personal protective equipment

Protective clothing needs to be selected specifically for the workplace, depending on concentrations and quantities of hazardous substances handled. The chemical resistance of the protective equipment should be enquired at the respective supplier.



a) eye/face protection

Safety eyewear and/or face protection complying with an approved standard (European Standard EN 166) should be used if the product is sprayed or when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. Tightly sealed goggles.

b) skin protection

- i. hand protection: Chemical-resistant, impervious gloves complying with an approved standard (European Standard EN374) should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Protective gloves – The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation.

Nitrile, thickness: ≥ 0.11 mm

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material cannot be calculated in advance and has therefore to be checked prior to the application.

Penetration time of glove material:

Value of the permeation: Level ≥ 6

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

- ii. other: body protection: Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product. Protective work clothing

c) respiratory protection

Not required.

d) thermal hazards

None.

Environmental exposure controls

No information available.

Personal protective equipment selections vary based on potential exposure conditions such as applications, handling practices, concentration, and ventilation. Information on the selection of protective equipment for use with this material, as provided above, is based upon intended, normal usage. If there is different than normal usage of the material, it is advised to consult a safety specialist about the type of personal protective equipment and other actions that should be taken.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Property	Extraction Buffer
General information	
Appearance:	
Form	fluid
Colour	colourless
Odour	odourless
Odour threshold	No information available
pH value at 25°C:	8.0 – 8.4
Change in condition:	
Melting point/melting point range	No information available
Boiling point and boiling range	100 °C
Flash point	No information available
Flammability	not flammable
Auto-ignition temperature	The mixture is not self-igniting
Decomposition temperature	No information available
Self-igniting	No information available
Danger of explosion	No information available
Explosion limits:	
Lower	No information available
Upper	No information available
Oxidizing properties	No information available
Vapour pressure at 20°C	No information available
Density:	
Density at 20 °C	No information available
Relative Vapour density	No information available
Evaporation rate	No information available
Solubility in / Miscibility with water	Fully miscible
Partition coefficient: n-octanol/water	No information available
Viscosity:	
Dynamic	No information available
Kinematic	No information available
Particle characteristics	Not applicable

9.2. Other information

9.2.1. Information with regard to physical hazard classes

Not classified based on available information.

The mixture does not present an explosion hazard.

9.2.2. Other safety characteristics

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No information available.

10.2. Chemical stability

Thermal decomposition / conditions to be avoided

No decomposition if used and stored according to specifications.

10.3. Possibility of hazardous reactions

No hazardous reactions known.

10.4. Conditions to avoid

No information available.

10.5. Incompatible materials

No information available.

10.6. Hazardous decomposition products

No dangerous decomposition products known.

In case of fire see section 5.

SECTION 11: Toxicological information

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

Acute Toxicity:

LD/LC50 values relevant for classification:

Quantitative data on the toxicity of the mixtures are not available.

Skin corrosion / irritation:

No irritating effect known.

Serious eye damage/irritation:

No irritating effect known.

Respiratory or skin sensitization:

No sensitizing effects known.

Germ cell mutagenicity:

No information available.

Carcinogenicity:

No information available.

Reproductive toxicity:

No information available.

STOT-single exposure:

After inhalation:

No irritating effect known.

The mixture is not classified as specific target organ toxicant, single exposure.

STOT-repeated exposure:

The mixture is not classified as specific target organ toxicant, repeated exposure.

Aspiration hazard:

Not classified as aspiration hazard.

Relevant toxicological data:

We have no description of any toxicological symptoms.

Information on likely routes of exposure:

No information available.

Symptoms related to the physical, chemical and toxicological characteristics:

- Skin contact: No specific information available.
- Eye contact: No specific information available.
- Inhalation: No specific information available.
- Ingestion: No specific information available.
- Other: No information available.

Delayed and immediate effects as well as chronic effects from short and long term exposure:

No information available.

Interactive effects:

No information available.

Absence of specific data:

No information available.

Mixtures:

No information available.

Mixture versus substance information:

No information available.

11.2 Information on other hazards

Endocrine disrupting properties

No information available.

Other information

The product should be handled with the care usual when dealing with chemicals.

When used and handled according to specifications, the mixtures do not have any harmful effects to our experience and the information provided to.

SECTION 12: Ecological information

Do not allow product to reach surface water, waterways or soil.

12.1. Toxicity

Aquatic toxicity: Quantitative data on the ecological effect of the mixtures are not available.

12.2. Persistence and degradability

No further relevant information available.

12.3. Bioaccumulative potential

No further relevant information available.

12.4. Mobility in soil

No further relevant information available.

12.5. Results of PBT and vPvB assessment

PBT: Not applicable.

vPvB: Not applicable.

12.6. Endocrine disruptive properties

No information available.

12.7 Other adverse effects:

Ecotoxicological effects:

Remark: Water hazard class 1 (German Regulation) (Self-assessment) – Do not allow to enter waters, sewers or soil.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Product disposal

Recommendation:

This material and its container must be disposed of as hazardous waste.

The disposal is regionally differently regulated; therefore, the kind of disposal is to be inquired at the responsible authorities.

Dispose of contents in accordance with local/regional/national/international regulations.

According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user based on the application for which the product was used.

Packaging disposal

Uncleaned packaging: Recommendation: Disposal according to official regulations.

Recommended Cleansing agents: Water, if necessary, together with cleansing agents.

Physical, chemical properties, which could influence waste management:

No information available.

Sewage disposal-relevant information:

No information available.

SECTION 14: Transport information

Product is not classified as a dangerous good for transport.

ADR/RID

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

ADN

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

IMDG

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

ICAO-TI/IATA-DGR

14.1 UN number or ID number: -

14.2 UN proper shipping name: -

14.3 Transport Hazard Class(es): -

14.4 Packing group: -

14.5 Environmental hazards: -

14.6 Special precautions for user: -

14.7 Maritime transport in bulk according to IMO instruments

Not applicable.

SECTION 15: Regulatory information

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

EU Regulations:

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.

COMMISSION REGULATION (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2015/830 of 28 May 2015 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

COMMISSION REGULATION (EU) 2020/878 of 18 June 2020 amending Annex II to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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 (Text with EEA relevance)

15.2. Chemical safety assessment

A chemical safety assessment has not been carried out.

SECTION 16: Other information

Identification of changes

Rev 8.0 Revision and harmonization of the data sheet in accordance with applicable international legislation.

Rev 8.1 New catalogue numbers for SENSIS*Strip* Peanut PowerLine

Rev 8.2 New catalogue numbers for SENSIS*Strip* Milk PowerLine

Abbreviations and acronyms:

ATE: Acute Toxicity Estimate. PBT: persistent, bioaccumulative and toxic. vPvB: very persistent, very bioaccumulative. LD50 lethal dose, LC50 Lethal concentration. EC50 Effective concentration. EWC: European Waste Catalog. IARC: International Agency for Research on Cancer. RTECS: Registry of Toxic Effects of Chemical Substances. VOC: Volatile Organic Carbon. PNEC: Predicted no

effect concentration. LFL: Lower Inflammatory Limit. UFL: Upper Flammability Limit. LEL lower explosion limit. UEL: Upper explosion limit. STOT: Specific Target Organ Toxicity. LDLo Lethal dose, low. IC50: Inhibitory concentration. SVHC: Substances of very high concern. NOAEL: No-observed-adverse-effect level. LOAEL: Lowest-observed-adverse-effect level

RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)

IATA-DGR: Dangerous Goods Regulations by the "International Air Transport Association" (IATA)

ICAO: International Civil Aviation Organization

ICAO-TI: Technical Instructions by the "International Civil Aviation Organization" (ICAO)

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

GefStoffV: Gefahrstoffverordnung (Ordinance on Hazardous Substances, Germany)

LD50: Letale Dose, 50 percent (Not relevant for classification)

LC50: Letale concentration, 50 percent (Not relevant for classification)

Full text of H-statements from section 2 and 3: -

Precautionary statements: -

Further training advice:

No information available.

Recommended restrictions on use:

No information available.

This Safety Data Sheet was prepared on the basis of documentation provided by the manufacturer and complies with the requirements of Regulation (EC) No. 878/2020