

SENSISpec Total Soy Protein (Cat. nr. HU0030075, HU0030076)

SECTION 1: Identification of the substance/preparation and of the Company/Undertaking

1.1. Product identifiers

Product names:

SENSISpec ELISA Total Soy Protein

Cat. Nr.

HU0030075, HU0030076

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

In vitro diagnostic kit.

The kit contains the following non-hazardous components:

- 0) Microtiter Plate
- 1) Substrate Solution
- 2) Conjugate
- 3) Washing Solution (10x Concentrate)
- 4) Extraction Buffer (10x Concentrate)
- 5) Dilution Buffer A
- 6) Dilution Buffer B
- 7) Standards

6) Hazardous component: Stop Solution

1.3. Details of the supplier of the safety data sheet

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's E-mail address: CustomerService.Bud@eu.goldstandarddiagnostics.com

1.4. Emergency telephone number

Hungary: Egészségügyi Toxikológiai Tájékoztató Szolgálat (ETTSZ)
1097 Budapest, Nagyvárad tér 2.
Tel.: +36 1 476 6464, +36 80 201 199
e-mail: ettsz@nnk.gov.hu

For national Poison Centres in EU see: <https://poisoncentres.echa.europa.eu/appointed-bodies>.

SECTION 2: Hazards Identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

The kit contains the following non-hazardous components:

Microtiter Plate, Substrate Solution, Conjugate, Washing Solution (10x Concentrate), Extraction and Sample Dilution Buffer (10x Concentrate), Standards

Hazardous component: Stop Solution

Corrosive to metals, Category 1, H290 (Corr. Met. 1)

Skin irritation, Category 2, H315 (Skin Irrit. 2)

Eye irritation, Category 2, H319 (Eye Irrit. 2)

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

2.2. Label elements

Hazard Pictograms:



Signal word:

Warning

Hazard statements:

H290 – May be corrosive to metals.

H315 – Causes skin irritation.

H319 – Causes serious eye irritation.

Precautionary statements:

P234 – Keep only in original packaging.

P264 – Wash skin thoroughly after handling.

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.

Reduced Labelling (<= 125 ml)

Hazard Pictograms: -

Signal word: Warning

Hazard statements: -

Precautionary statements: -

Supplemental hazard information: -

Substances contributing of hazard identification: Sulphuric acid

2.3. Other hazards

None.

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

Stop Solution:

Component	CAS No.	EC-No.	Index-No.	REACH-No.	Concentration	Classification according to Regulation (EC) No. 1272/2008 [CLP]	H-statements	Special concentration limits/M-factor/ATE
Sulphuric acid*	7664-93-9	231-639-5	016-020-00-8	-	1<x<10%	Skin Corr. 1A Met. Corr. 1	H290 H314	Skin Corr. 1A; H314: C ≥ 15 % Skin Irrit. 2; H315: 5 % ≤ C < 15 % Eye Irrit. 2; H319: 5 % ≤ C < 15 %

*: Manufacturer's classification which differs from harmonised classification.

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

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!

First aider: Pay attention for self-protection!

Remove contaminated clothing immediately.

Eye –washing and skin-washing facilities should be available at the workplace for specific and immediate treatment.

FOLLOWING INGESTION:

If chemical has been swallowed, wash out mouth with water. Do not swallow mouthwash. DO NOT induce vomiting. Do not administer anything if victim is unconscious. Get medical aid.

FOLLOWING INHALATION:

There is a minimal risk of inhalation. In case there appear to be symptoms of exposure, supply fresh air. Monitor respiration. If breathing becomes difficult, consult a doctor and give oxygen. Get medical aid.

FOLLOWING SKIN CONTACT

Immediately flush with large amounts of water and soap. Remove all contaminated clothing and wash them before reusing. In case of irritation consult a physician.

FOLLOWING EYE CONTACT:

Rinse thoroughly with plenty of water for at least 15 minutes. Insure adequate washing by keeping eyelids open with fingers. Consult a physician.

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

Stop Solution: Causes skin irritation. Causes serious eye irritation.

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

Treat symptoms.

SECTION 5: Firefighting Measures

Kit components are not flammable.

5.1. Extinguishing media

Suitable extinguishing media: use agent most appropriate to extinguish surrounding fire. Use water spray, alcohol-resistant foam, dry chemical, or carbon dioxide. Keep surrounding materials cool with water spray.

5.2. Special hazards arising from the mixture.

Hazardous combustion products of Stop Solution: sulphur oxides

5.3. Advice for firefighters

In case of fire, if necessary, wear approved self-contained breathing apparatus and appropriate protective clothing. Keep surrounding materials cool with water spray.

SECTION 6: Accidental Release Measures

6.1. Personal precautions, protective equipment, and emergency procedures

6.1.1. For non-emergency personnel

The small, supplied volumes and packaging insure minimal risk of accidental release. In case of spill, wear protective clothing as indicated in section 8. Ensure adequate ventilation.

6.1.2 For emergency personnel

In case of spill, wear protective clothing as indicated in section 8. Ensure adequate ventilation. See sections 7 and 8.

6.2. Environmental precautions

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

6.3. Methods and materials for containment and cleaning up.

Absorb with liquid binding material (sand diatomite, acid binders, universal binders, sawdust).

Dispose of the material according to regulations.

Ensure adequate ventilation.

6.4. Reference to other sections

See sections 7, 8 and 13.

SECTION 7: Handling and Storage

7.1. Precautions for safe handling

Avoid skin and eyes contact. Avoid inhalation of vapour or mist. Wear appropriate personal protective equipment as specified in section 8.

Remove contaminated clothing immediately. Wash hands and face after working with substance.

Advice on protection against fire and explosion: Normal measures for preventive fire protection

7.2. Conditions for safe storage, including any incompatibilities.

Keep products tightly sealed in their original containers. Store bottles between +2°C and +8°C. Avoid physical damage to containers. Do not expose to heat or direct light. Store away from foodstuffs
The packaging guarantees the component isolation from incompatible material.
Unsuitable packaging material: Metal or light metal containers cannot be used.

7.3. Specific end use(s)

In vitro diagnostic reagents, as described in section 1.2.

SECTION 8: Exposure Controls/Personal Protection

8.1. Control parameters

Exposure limit values

Components with workplace control parameters.

Substance Sulphuric acid

CAS No. 7664-93-9

Remarks: mist

	Limit value - Eight hours		Limit value - Short term	
	ppm	mg/m ³	ppm	mg/m ³
Austria		0,1 inhalable aerosol		0,2 inhalable aerosol
Belgium		0,2 (1)		
Denmark		0,05		0,1 (1)
European Union		0,05 (1)(2)		
Finland		0,05 (1)		0,1 (1)(2)
France		0,05 thoracic fraction		3
Germany (AGS)		0,1 inhalable aerosol		0,1 inhalable aerosol (1)
Germany (DFG)		0,1 (1)		0,1 (1)(2)
				0,2 (1)(3)
Hungary		0,05		
Ireland		0,05		
Italy		0,05 (1)(2)		
Latvia		0,05		
New Zealand		0,1		
Norway		0,1 (1)		
Poland		0,05 (1)		
Romania		0,05		
Sweden		0,1 (1)		0,2 (1)(2)
The Netherlands		0,05 (1)		

Remarks

Belgium (1) Additional indication "C" means that the agent falls within the scope of Title 2 concerning carcinogenic, mutagenic and reprotoxic agents of Book VI of the Codex on well-being at work.

Denmark (1) 15 minutes average value

European Union (1) Thoracic fraction (2) When selecting an appropriate exposure monitoring method, account should be taken of potential limitations and interferences that may arise in the presence of other sulphur compounds. Bold-type: Indicative Occupational Exposure Limit Value (IOELV) ~ (for references see bibliography)

Finland (1) thoracic fraction (2) 15 minutes average value

France Italics type: Indicative statutory limit values

Germany (AGS) (1) 15 minutes average value

Germany (DFG) (1) Inhalable fraction (2) 15 minutes average value (3) Ceiling limit value

Italy (1) thoracic fraction (2) When selecting an appropriate method of exposure monitoring, the limitations and potential interference that may result from the presence of other phosphorus compounds should be taken into account

Norway (1) Thoracic fraction

Poland (1) Thoracic fraction
 Sweden (1) Inhalable fraction (2) 15 minutes average value
 The Netherlands (1) Thoracic fraction

DNEL values (Sulphuric acid):

Workers

long-term exposition – local effects:

Inhalativ: DNEL 0.05 mg/m³ (worker)

short-term exposition – local effects:

Inhalativ: DNEL 0.1mg/m³ (worker)

PNEC values (Sulphuric acid):

PNEC

8.8 mg/L (sewage treatment plant)

0.002 mg/kg (sea water sediment)

0.25 mg/L (seawater)

0.002 mg/kg (freshwater sediment)

0.0025 mg/L (fresh water)

8.2. Exposure controls

5/2020. (II. 6.) ITM decree on the protection of the health and safety of workers exposed to chemical pathogenic factors, pursuant to Section 11(2) in the case of hazardous substances not regulated by limit values, the employer is obliged to reduce the level of exposure to the lowest level expected according to scientific and technical standards, at which level, according to the current state of science, the dangerous substance has no health-damaging effect. When using in an open system, use local exhaust where possible. If local extraction is not possible or is insufficient, adequate ventilation of the work area must be ensured.

General protective and hygienic measures

Adhere to instructions and good laboratory practice.. Always avoid direct contact of the solution with eyes, skin and clothing. Avoid inhalation. Avoid prolonged or repeated exposure. Wash hands before breaks and at the end of work.

Keep away from foodstuffs, beverages and feed. Immediately remove all soiled and contaminated clothing.

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.

Appropriate engineering controls

Handle in a fume cupboard or under local exhaust ventilation. Have emergency shower and eye wash stations available

Individual protection measures, such as personal protective equipment:



a) eye/face protection

Safety eyewear or face protection complying with an approved standard (European Standard EN 166) should be used. Safety glasses with shields.

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. 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. Material of gloves: 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: Protective work clothing.

c) respiratory protection

Respiratory protection is not required under normal and intended conditions of use.

d) thermal hazards

None.

Environmental exposure controls

Do not let product enter drains.

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	Standards	Substrate Solution	Conjugate	Washing Solution (10x Conc.)	Extraction and Sample Dilution Buffer	Dilution Buffer A	Dilution Buffer B	Stop Solution
General information								
Appearance:								
Form:	fluid	fluid	fluid	fluid	fluid	fluid	fluid	fluid
Colour:	red	colourless	red	colourless	red	red	red	colourless
Odour:	odourless	odourless	odourless	odourless	odourless	odourless	odourless	odourless
Odour threshold:	No information available	No information available	No information available	No information available	No information available	No information available	No information available	No information available
pH-value at 25°C:	8.0 - 8.4	3.3 - 3.8	6.2 - 7.2	6.2 - 7.2	8.8 - 9.2	8.0 - 8.4	8.0 - 8.4	~ 0,6
Change in condition:								
Melting point/Melting range:	No information available	No information available	No information available	No information available	No information available	No information available	No information available	No information available
Boiling point/Boiling range	100 °C	No information available	100 °C	100 °C	100 °C	100 °C	100 °C	100 °C
Flash point:	No information available	No information available	No information available	No information available	No information available	No information available	No information available	No information available

Flammability(solid, gaseous)	Not flammable							
Auto Ignition temperature:	No information available							
Decomposition temperature:	No information available							
Self-igniting:	The mixture is not self-igniting							
Danger of explosion:	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard	The mixture does not present an explosion hazard
Explosion limits:								
Lower:	No information available							
Upper:	No information available							
Oxidizing properties	No information available							
Vapour pressure at 20 °C:	No information available	23 hPa						
Density:								
Density at 20 °C:	No information available	1,03 g/cm3						
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

Stop Solution: May be corrosive to metals

9.2.2. Other safety characteristics

No information available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under the conditions for storage and handling described in the instructions. Keep in their original containers.

10.3. Possibility of hazardous reactions:

Stop Solution: Reacts with alkali (lyes).

10.4. Conditions to avoid

Avoid heat, flame, sparks, direct light, incompatible materials.

10.5. Incompatible materials

Stop Solution: bases, halides, organic materials, carbides, nitrates, picrates, cyanides, chlorates, alkali halides, zinc salts, permanganates, hydrogen peroxide, azides, perchlorates, nitromethane, phosphorous, cyclopentadiene, cyclopentanone oxime, nitroaryl amines, hexalithium disilicide, phosphorous(iii) oxide, powdered metals.

10.6. Hazardous decomposition products

No data available. 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:

No information available.

Skin corrosion / irritation:

Causes skin irritation.

Serious eye damage/irritation:

Causes serious eye irritation.

Respiratory or skin sensitization:

No sensitizing effects known.

Germ cell mutagenicity:

No information available.

Carcinogenicity:

No information available.

Reproductive toxicity:

No information available.

Aspiration hazard:

Not classified as aspiration hazard.

Relevant toxicological data:

No information available.

STOT-single exposure:

Not classified as specific target organ toxicant.

STOT-repeated exposure:

Not classified as specific target organ toxicant.

Aspiration hazard:

Not classified as aspiration hazard.

Relevant toxicological data:

No information available.

Information on likely routes of exposure:

No information available.

Symptoms related to the physical, chemical and toxicological characteristics:

- Skin contact: Stop Solution: Causes skin irritation.
- Eye contact: Stop Solution: Causes serious eye irritation.
- Inhalation: Stop Solution: It may irritate mucous and upper respiratory tract.
- Ingestion: No specific information available.
- Other: No information available.

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

See section 4.2.

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

Sulphuric acid is not listed.

Other information

Toxicological properties have not been further investigated.

Further information: RTECS: WS5600000 (sulphuric acid).

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

SECTION 12: Ecological Information

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

12.1 Toxicity

No information available.

12.2. Persistence and degradability

No information available.

12.3 Bioaccumulative potential

No information available.

12.4 Mobility in soil

No information available.

12.5. Results of PBT and vPvB assessment

This product contains no components considered to be either persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB).

12.6. Endocrine disrupting properties

Sulphuric acid is not listed.

12.7. Other adverse effects

The components are furnished in volumes that do not represent hazard for the environment if used and disposed of correctly. 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:

Avoid release to the environment.

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

According to the European Waste Catalogue, Waste Codes are not product specific, but ap Send surplus and non-recyclable solutions to a licensed disposal company application specific. Waste codes should be assigned by the user based on the application for which the product was used.

Packaging disposal:

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

Physical, chemical properties, which could influence waste management:

No information available.

Sewage disposal-relevant information:

Do not allow product to reach sewage system.

SECTION 14: Transport Information

STOP SOLUTION

ADR/RID

14.1 UN number or ID number: UN 2796

14.2 UN proper shipping name: UN 2796 SULPHURIC ACID

14.3 Transport Hazard Class(es): 8

14.4 Packing group: II

14.5 Environmental hazards: -

14.6 Special precautions for user: LQ:1 I; Tunnel restriction code: (E)

ADN:

14.1 UN number or ID number: UN 2796

14.2 UN proper shipping name: UN 2796 SULPHURIC ACID

14.3 Transport Hazard Class(es): 8

14.4 Packing group: II

14.5 Environmental hazards: -

14.6 Special precautions for user: -

IMDG

- 14.1 UN number or ID number:** UN 2796
14.2 UN proper shipping name: UN 2796 SULPHURIC ACID
14.3 Transport Hazard Class(es): 8
14.4 Packing group: II
14.5 Environmental hazards: Marine pollutant: no
14.6 Special precautions for user: -

ICAO-TI/IATA-DGR

- 14.1 UN number or ID number:** UN 2796
14.2 UN proper shipping name: UN 2796 Sulphuric acid
14.3 Transport Hazard Class(es): 8
14.4 Packing group: II
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 substance 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)

REGULATION (EU) 2019/1148 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 20 June 2019 on the marketing and use of explosives precursors, amending Regulation (EC) No 1907/2006 and repealing Regulation (EU) No 98/2013

ANNEX I: Sulphuric acid 15 % (m/m) -40 % (m/m)

All suspicious transactions, and significant disappearances and thefts should be reported to the relevant national contact point within 24 hours of detection to the national contact point of the Member State where the disappearance or theft took place.

15.2. Chemical safety assessment:

Chemical safety assessment has not been carried out for this product.

SECTION 16: Other information

Identification of changes

Rev: 4.0 Creation and harmonization of the data sheet in accordance with applicable international legislation.

Rev: 4.1 Section 11 extension

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.

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

H290 – May be corrosive to metals.

H314 – Causes severe skin burns and eye damage.

H315 – Causes skin irritation.

H319 – Causes serious eye irritation.

Precautionary statements:

P234 – Keep only in original packaging.

P264 – Wash skin thoroughly after handling.

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.

Further training advice:

No information available.

Recommended restrictions on use:

This product is intended to be used for laboratory use only by technical staff trained in microbiological techniques. Classification and labelling have been performed according to CLP Regulations.

Read the Instructions for Use for further information on limitations of use.