Safety Data Sheet

According to Regulation (EC) No 1907/2006
Version 10
Revision: 2022-09-16

According to Regulation (EC) No 1907/2006 (REACH) in combination with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP) the products *in the following table* **do not** have to be classified as hazardous.

REF	article name
AA E-1200	**SHBG ELISA**
AA E-1200R	**SHBG ELISA**

Single components with dangerous ingredients:

FR E-0080 **Stop Solution** STOP-SOLN

According to Article 31 of Regulation (EC) No 1907/2006 a safety data sheet has to be provided upon request where a mixture **does not** meet the criteria for classification as hazardous but contains a substance in a concentration of ≥ 1 % posing human health hazards.

Therefore the safety data sheet for the single kit component *Stop Solution* is attached.

The other single components in these products neither contain
a substance in a concentration of ≥ 1 % posing human health or environmental hazards; nor
a substance in a concentration ≥ 0.1 % that is carcinogenic category 2 or toxic to reproduction category 1A, 1B and 2, skin sensitizer category 1, respiratory sensitizer category 1, or has effects on or via lactation or is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB)
Therefore a safety data sheet for the other single components in the kit is not required for these product.

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SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Trade name: **Stop Solution**

Product number: Valid for ELISA products listed in the table on the first pages.

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

Identified Use: Reagent for in vitro laboratory use. For professional use only.

1.3 Details of the supplier of the safety data sheet

LDN Labor Diagnostika Nord GmbH & Co.KG
Am Eichenhain 1
D-48531 Nordhorn
Germany

Phone.: +49 5921 8197 200
Fax: +49 5921 8197 201
E-Mail: support@ldn.de

1.4 Emergency telephone number

+49 5921 8197 200

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

This product **does not meet the criteria for classification** in any hazard class according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures.

However a safety data sheet is being supplied for it upon request as some kit components contain a substance which presents a health hazard within the meaning of Regulation (EC) No 1272/2008.

2.2 Label elements

No labelling required.

Hazard pictogram(s): None
Signal word(s): None
Hazard statement(s): None
Precautionary statement(s): None

2.3 Other hazards

Results of PBT and vPvB assessment

- PBT: Not applicable.
- vPvB: Not applicable.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable.

3.2 Mixtures

Description:

Mixture of the substances listed below with non-hazardous additions.

Hazardous ingredients:

Substance name	CAS No. (EC No.) [Index No.]	Concentration in the mixture	Classification according to Regulation (EC) No 1272/2008 [CLP] (related to the concentrated form)	
			Hazard class / Hazard categories	Hazard-statement
Kit component: *Stop Solution*				
sulphuric acid ... %	7664-93-9 (231-639-5) [016-020-00-8]	< 5.0 %	Skin Corr. 1A	H314

Full text of H-phrases: see section 16

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

General information: If symptoms persist or in case of doubt, seek medical advice.

Following inhalation: Supply fresh air; consult doctor in case of complaints.

Following skin contact:
Remove contaminated clothes and shoes.
Clean with water and soap. If possible, also wash with polyethylene glycol 400.
Cover wound with a sterile dressing.
If skin irritation continues, consult a doctor.

Following eye contact:
Protect unharmed eye.
Rinse opened eye for several minutes under running water.
Call a doctor immediately.

Following swallowing:
Rinse mouth with water.
Spit liquid out again.
Drink lots of water and provide fresh air. Call a doctor immediately.
Never give anything by mouth to an unconscious person

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

Symptomatic treatment.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing agents:

The product is not combustible and does not support any combustion.

Use fire fighting measures suiting the environment.

For safety reasons unsuitable extinguishing agents:

No data available

5.2 Special hazards arising from the substance or mixture

In case of fire, the following can be released:

Sulphur oxides (SOx)

Poisonous gases/vapours

5.3 Advice for firefighters

Protective equipment: Wear self-contained respiratory protective device.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear protective clothing.

Avoid any product contact.

6.2 Environmental precautions

Do not allow product to reach sewage system or any water course.

Do not allow to penetrate the ground/soil.

6.3 Methods and material for containment and cleaning up

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

Rinse residues with water.

Make sure to recycle or dispose of in suitable receptacles.

6.4 Reference to other sections

See Section 7 for information on safe handling

See Section 8 for information on personal protection equipment.

See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Ensure good ventilation/exhaustion at the workplace.

Avoid contact with eyes and skin.

Keep the working area dry and clean.

Information about protection against explosions and fires: Observe the general rules of industrial fire protection.

7.2 Conditions for safe storage, including any incompatibilities

Storage:

Requirements to be met by storerooms and receptacles:

Store container tightly sealed at a cool and dry place with sufficient ventilation.

Information about storage in one common storage facility:

Store away from foodstuffs.

Refer to national regulations for storing hazardous chemicals.

Further information about storage conditions:

Store as directed in the relevant instruction for use.

7.3 Specific end use(s)

No further relevant information available.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Following information is available for the *substance* listed in section 3.2

Substance: sulphuric acid **CAS No.:** 7664-93-9					
	Limit value - Eight hours		**Limit value - Short term**		
Country	**ppm**	**mg/m³**	**ppm**	**mg/m³**	**Legal basis**
European Union		**0,05 thoracic fraction**			Directive 2009/161/EU
Germany (AGS)		0,1 inhalable aerosol		0,1 inhalable aerosol *(1)*	TRGS 900
Germany (DFG)		0,1 inhalable aerosol		0,1 inhalable aerosol *(1)(2)*	
Italy		0,05			
Spain		1		3	
USA - NIOSH		1			
USA - OSHA		1			
Remarks					
Germany (AGS)	*(1)* 15 minutes average value				
Germany (DFG)	*(1)* 15 minutes average value *(2)* A momentary value of 0,2 mg/m³ should not be exceeded				

Source: Based on GESTIS International Limit values Database, 2016-12

8.2 Exposure controls

Personal protective equipment:

General protective and hygienic measures:

The usual precautionary measures should be adhered to when handling chemicals.

Provide eye bath and emergency shower.

Respiratory Protection:

Not required under normal use.

Hand Protection:

Protective gloves complying with EN 374 (nitrile rubber, Latex gloves).

The glove material has to be impermeable and resistant to the product/substance/preparation.

The choice of an appropriate glove does not only depend on its material but also on other quality features and is different from one producer to the other.

Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time.

Eye Protection:

Safety glasses

Skin Protection:

Protective work clothing, lab coat

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	form:	liquid
	colour	colourless
Odour:		odourless
Odour threshold:		not determined
pH:		1.0
Melting point/freezing point:		not determined
Initial boiling point and boiling range:		not determined
Flash point:		not determined
Flammability (solid, gaseous):		Not applicable
Ignition temperature:		
Decomposition temperature:		Not determined
Self ingnition temperature:		Product is not self-igniting.
Danger of explosion:		Product does not present an explosion hazard.
Explosion limits:		
Lower:		Not applicable
Upper:		Not applicable
Oxidizing properties:		No data available
Vapour pressure:		Not determined
Density:		Not determined
Relative density:		Not determined
Vapour density:		Not determined
Evaporation rate:		Not determined
Solubility in / Miscibility with		
Water:		Fully miscible
Partition coefficient (n-octanol/water):		Not determined
Viscosity:		Not determined

9.2 Other information

No further relevant information available.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

No further relevant 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

Corrosive effect on metals

10.4 Conditions to avoid

Heat

10.5 Incompatible materials

Metals

10.6 Hazardous decomposition products

No hazardous decomposition products if instructions for storage and handling are followed.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity

Based on available data, the classification criteria are not met.

LD/LC 50 values that are relevant for classification:

7664-93-9 sulphuric acid

Oral	LD50	2140 mg/kg (rat)
Inhalative (aerosol)	LC50/4 h	0.375 mg/L (rat)

Although the LC50 values from the inhalation toxicity study theoretically trigger Classification with 'Toxic by inhalation', classification is not proposed. The effects of sulphuric acid following inhalation are entirely due to local irritation of the respiratory tract: there is no evidence for the systemic toxicity of sulphuric acid in any study as effects are limited to the site of contact. Classification for acute inhalation toxicity is not considered to be appropriate.

Skin corrosion/irritation	May cause irritation to the skin.
Serious eye damage/irritation	May cause irritation to the eyes.
Respiratory or skin sensitisation	Based on available data, the classification criteria are not met.

Additional toxicological information:

After swallowing: irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract

Germ cell mutagenicity	Based on available data, the classification criteria are not met.
Carcinogenicity	Based on available data, the classification criteria are not met.
Reproductive toxicity	Based on available data, the classification criteria are not met.
STOT-single exposure	Based on available data, the classification criteria are not met.
STOT-repeated exposure	Based on available data, the classification criteria are not met.
Aspiration hazard	No data available

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Aquatic toxicity:

7664-93-9 sulphuric acid

EC50/48h (static) > 100 mg/l (Daphnia magna) (OECD Guideline 202)

LC50/72h (static) > 100 mg/l (Desmodesmus subspicatus) (OECD Guideline 201)

LC50/96h (static) > 16 < 28 mg/l (Lepomis macrochirus)

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

Not applicable

12.6 Other adverse effects

No further relevant information available

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Recommendation:

Must be recycled or disposed of according to the regulations. Waste has to be classified according to the European Waste

Catalogue based on the identification of the waste generating source.

Smaller quantities can be disposed of with household waste.

European waste catalogue :

16 00 00	WASTES NOT OTHERWISE SPECIFIED IN THE LIST
16 05 00	gases in pressure containers and discarded chemicals
16 05 06*	laboratory chemicals, consisting of or containing dangerous substances, including mixtures of laboratory chemicals
15 00 00	WASTE PACKAGING; ABSORBENTS, WIPING CLOTHS, FILTER MATERIALS AND PROTECTIVE CLOTHING NOT OTHERWISE SPECIFIED
15 01 00	packaging (including separately collected municipal packaging waste)
15 01 02	plastic packaging

Uncleaned packagings:

Recommendation:

Disposal must be made according to official regulations.

Packagings that cannot be cleaned are to be disposed of in the same manner as the product.

Recommended cleansing agent: Water; if necessary, with cleansing agents

SECTION 14: TRANSPORT INFORMATION

14.1 UN No.	ADR, ADN, IMDG, IATA	Void
14.2 UN Proper shipping name	ADR, ADN, IMDG, IATA	Void
14.3 Transport hazard class(es)	ADR, ADN, IMDG, IATA	Void
14.4 Packing group	ADR, IMDG, IATA	Void
14.5 Environmental hazards	Not applicable	
14.6 Special precautions for user	Not applicable.	
14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.	

SECTION 15: REGULATORY INFORMATION

This Safety Data Sheet is according to Commission Regulation (EU) 2015/830 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

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

Directive 2012/18/EU
Named dangerous substances - ANNEX I Not listed.

National regulations

Water hazard class: Water hazard class 1 (Self-assessment): slightly hazardous for water

Further information: None of the ingredients is listed.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

SECTION 16: OTHER INFORMATION

Complete review for all ELISA products listed in the table.

"H code" used in this safety data sheet
As mentioned in section 3 of the safety data sheet (not relevant for labelling of the product)

H314	Causes severe skin burns and eye damage.

Abbreviations

AGS	Ausschuss für Gefahrstoffe
DFG	Senatskommission zur Prüfung gesundheitsschädlicher Arbeitsstoffe der DFG (MAK-Kommission)
LC50	Lethal concentration, 50 percent
LD50	Lethal dose, 50 percent
NIOSH	National Institute for Occupational Safety and Health of USA
OSHA	Occupational Safety and Health Administration of USA
TRGS	Technische Regeln für Gefahrstoffe
ADR:	Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
RID:	Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)
IMDG:	International Maritime Code for Dangerous Goods
IATA:	International Air Transport Association