

KIT

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Insulin ELISA

Catalog #: KAP1251

Kit Components: Microtiter plate
 Conjugate
 Calibrators (0 to 5)
 Controls (1 and 2)
 Washing Solution
 Chromogenic TMB
 Stop Solution

1.2 Intended Use

For In Vitro Diagnostic Use. See product literature for details.

1.3 Company

DIAsource ImmunoAssays S.A.
 Rue du Bosquet, 2
 B-1348 Louvain-la-Neuve
 Belgium
 Tel. Nr. +32 (0)10/84.99.11
 E-mail: products.support@diasource.be

1.4 Emergency telephone

DIAsource (only office hours): +32 (0)10/84.99.11
 Centre Anti-Poisons (BE) 070 245 245
 Please refer to your local Anti-Poison Center!

2 OTHER INFORMATION

	ADR	ADN/ADNR	IMDG	IATA
UN number	Not applicable			
UN proper shipping name	Not applicable			
Transport hazard class(es)	Not applicable		Not applicable	Not applicable
Packing group	Not applicable		Not applicable	Not applicable
Environmental hazards	Not available	Not available	Not available	Not available
Hazard label	Not applicable			
Classification code	Not applicable			
Special precautions for user	Not available			
Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not available			
Other information	Not available	Not available	Not available	Not available

3 OTHER INFORMATION

3.1 Single components with dangerous ingredients:

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.

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 $\geq 1\%$ 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 $\geq 1\%$ posing human health or environmental hazards; nor a substance in a concentration $\geq 0.1\%$ 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 products.

3.2 General Precautions:

- The products are for professional laboratory use only.
- Users should have a thorough understanding of the Instructions for Use prior to their use of this kit.
- Good Laboratory Practices (GLP) should be followed to ensure the safe use and disposal of the reagents.
- Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.
- Do not smoke, eat, drink or apply cosmetics in areas where specimens or kit reagents are handled.
- Wear disposable latex gloves when handling reagents

3.3 Other hazard

Conjugate Contains material from bovine origin

This kit contains material of human origin. Although these materials have been tested for HBsAg, anti-HCV and anti-HIV-1/2 and have been found not reactive, they should be considered as potentially infectious.

Calibrators Contains material from human origin

Controls Contains material from human origin

3.4 Other information

Microtiter plate : Each well can only be used once



STOP SOLUTION

1 INFORMATION OF THE SUBSTANCE/PREPARATION AND COMPANY

1.1 Product identifier

Product Name: Stop Solution

Catalog #: Component the kits mentioned on the first page

1.2 Intended Use

For In Vitro Diagnostic Use. See product literature for details.

1.3 Company

DIAsource ImmunoAssays S.A.

Rue du Bosquet, 2

B-1348 Louvain-la-Neuve

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2 HAZARDS IDENTIFICATION

2.1 Classification according to the regulation (EC) n°1272/2008 (CLP) and its amendments

Skin Corr. 1B

H314 Causes severe skin burns and eye damage.

2.2 Label elements according to the regulation (EC) n°1272/2008 (CLP) and its amendments

Danger symbol



Signal word

Warning

Product Identifier

Hydrochloric Acid, 3.08% v/v

Danger

H314 Causes severe skin burns and eye damage.

Supplemental Hazard Information

-

Prevention statements

P280 Wear protective gloves, protective clothing, eye protection, face protection.

Response statements

P301+330+331 If swallowed: rinse mouth. Do NOT induce vomiting.
 P305+P351+P338 If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
 P309+310 IF exposed or if you feel unwell: Call a POISON CENTER or doctor/physician.

Storage statements

-

Disposal statements -

2.3 Other hazards

PBT & vPvB: PBT: Not applicable
vPvB: Not applicable

3 COMPOSITION/INFORMATION ON INGREDIENTS

Name	(% w/w)	Classification	Specific concentration limits
Hydrochloric acid...%* CAS: 7647-01-0 EC: 231-595-7 Index number: 017-002-01-X	< 5%	Skin Corr. 1B, H314	Skin Corr. 1B; H314: 10 - < 25% Eye Irrit. 2; H319: >= 10%

***Note B:** Some substances (acids, bases, etc.) are placed on the market in aqueous solutions at various concentrations and, therefore, these solutions require different classification and labelling since the hazards vary at different concentrations. In Part 3 entries with Note B have a general designation of the following type: 'nitric acid ...%'. In this case the supplier must state the percentage concentration of the solution on the label. Unless otherwise stated, it is assumed that the percentage concentration is calculated on a weight/weight basis.

4 FIRST AID MEASURES

4.1 Description of first aid measures

General information In general, in case of doubt or if symptoms persist, always call a doctor. Never give anything by mouth to an unconscious person.

Following inhalation If person experiences nausea, headache or dizziness, person should stop work immediately and move to fresh air until these symptoms disappear. If breathing is difficult, administer oxygen by a qualified person, keep the person warm and at rest. Call a physician. In the event that an individual inhales enough vapour to lose consciousness, person should be moved to fresh air at once and a physician should be called immediately. If breathing has stopped, artificial respiration should be given immediately. In all case, ensure adequate ventilation and provide respiratory protection before the person returns to work.

Following skin contact IF ON SKIN (or hair): Remove contaminated clothing. Rinse skin with water / with vegetable oil. Take a shower.
If irritation or rash occurs: Get medical advice.

Following eye contact IF IN EYES: Rinse cautiously with plenty water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If eye irritation persists: Get medical advice/attention.

Following ingestion IF SWALLOWED: Rinse thoroughly mouth with water. Immediately call a POISON CENTER/doctor.
Do NOT induce vomiting.

For emergency responders No data available.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms No data available.

Effects No data available.

4.3 Indication of any immediate medical attention and special treatment needed

No data available.

5 FIRE FIGHTING MEASURES**5.1 Extinguishing media**

Appropriated: Use water spray or other suitable agent on fires adjacent to non-leaking tanks or intact containers of acid. If only a small amount of combustibles is present, smother fire with dry chemical.

Small fire: Dry powder or CO₂. Move containers from fire area, if it can be done without risk.

Large fire: Flood fire area with large quantities of water, while knocking down vapours with water fog. Cool containers with flooding quantities of water until well after fire is out. Do not get water inside containers. Withdraw immediately in case of rising sound from venting safety devices or discoloration of tank.

Non-appropriated: For this substance/mixture no limitations of extinguishing agents are given.

5.2 Special hazards arising from the substance or mixture

Hydrogen chloride gas

Not combustible.

Ambient fire may liberate hazardous vapours.

5.3 Advice for fire fighters

In the event of fire, wear self-contained breathing apparatus.

5.4 Further information

Suppress (knock down) gases/vapors/mists with a water spray jet. Prevent fire extinguishing water from contaminating surface water or the ground water system

6 ACCIDENTAL RELEASE MEASURES**6.1 Personal precaution, protective equipment and emergency procedures**

Advice for non-emergency personnel: Do not breathe vapors, aerosols. Avoid substance contact. Ensure adequate ventilation. Evacuate the danger area, observe emergency procedures, consult an expert.

For personal protection see section 8.

6.2 Environmental Precautions

Do not let product enter drains.

6.3 Methods and material for containment and cleaning-up

Cover drains. Collect, bind, and pump off spills. Observe possible material restrictions (see sections 7 and 10). Take up with liquid-absorbent material (e.g. Chemizorb®).

Dispose of properly. Clean up affected area.

6.4 Reference to other sections

For disposal see section 13.

7 HANDLING AND STORAGE**7.1 Precautions for safe handling**

For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities**Storage conditions**

No metal containers.

Tightly closed.

Corrodes metal Metal containers must be lined.

Storage class

Storage class (TRGS 510): 8B: Non-combustible, corrosive hazardous materials.

7.3 Specific Use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated.

8 EXPOSURE CONTROLS/PERSONAL PROTECTION**8.1 Control parameters**

Ingredients with workplace control parameters

8.2 Exposure controls**Appropriate engineering controls**

Good general ventilation should be provided to keep vapour and mist concentrations below the exposure limits.

Eye/face protection: Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses.

Skin protection: Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.

The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

Full contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

Splash contact

Material: Nitrile rubber

Minimum layer thickness: 0,11 mm

Break through time: 480 min

Material tested: Dermatril® (KCL 740 / Aldrich Z677272, Size M)

data source: KCL GmbH, D-36124 Eichenzell, phone +49 (0)6659 87300, e-mail sales@kcl.de, test method: EN374

If used in solution, or mixed with other substances, and under conditions which differ from EN 374, contact the supplier of the EC approved gloves. This recommendation is advisory only and must be evaluated by an industrial hygienist and safety officer familiar with the specific situation of anticipated use by our customers. It should not be construed as offering an approval for any specific use scenario

Body Protection: protective clothing.

Respiratory protection: required when vapours/aerosols are generated.

Recommended Filter type: Filter type ABEK.

Environmental exposure controls Do not let product enter drains.

9 PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Physical state	Liquid
Color	Colorless
Odour	Not available
Odor threshold	Not available
pH	<1
Melting / Freezing point	Not available
Boiling point	Not available
Flash point	Not applicable
Evaporation rate	Not available
Flammability	Not available
Lower limit of flammability or explosive	Not applicable
Upper limit of flammability or explosive	Not applicable
Vapour pressure	23hPa @ 20°C
Vapour density	Not available
Relative density	Not available
Water solubility	Completely miscible @ 20°C soluble
Solubility in other Solvents	Not available
Log Kow	Not available
Auto-inflammability temperature	Not applicable
Decomposition temperature	Not available
Viscosity	Kinematic: Not available Dynamic: Not available
Explosive properties	Not explosive
Oxidizing properties	None
Refractive index	Not available

9.2 Other information

No data available.

10 STABILITY AND REACTIVITY

10.1 Reactivity

No data available.

10.2 Chemical Stability

Stable.

10.3 Possibility of hazardous reactions

Violent reactions possible with:
The generally known reaction partners of water.

10.4 Conditions to Avoid

No information available.

10.5 Incompatible materials

Reactions with: metals.

10.6 Hazardous Decomposition Products

In the event of fire: see section 5.

11 TOXICOLOGICAL INFORMATION

Acute toxicity	Oral: No data available. Inhalation: No data available. Dermal: No data available.
Skin irritation	Slight irritation.
Skin corrosion	Slight irritation.
Eye damage	Slight irritation.
Respiratory sensibilisation	Not available.
Germ cell mutagenicity	No data available.
Carcinogenicity	No data available.
Toxic for reproduction	No data available.
Unique specific toxicity	The substance or mixture is not classified as specific target organ toxicant, single exposure.
Repeated specific toxicity	The substance or mixture is not classified as specific target organ toxicant, repeated exposure.
Aspiration hazard	No data available.
Other information	Ingestion of large amounts may cause: Local irritation Hazardous properties cannot be excluded but are unlikely when the product is handled appropriately. Components hydrochloric acid <u>Acute toxicity</u> Oral: No data available Inhalation: Cough Difficulty in breathing Inhalation: Absorption Symptoms: Mucosal irritations, Cough, Shortness of breath, Inhalation may lead to the formation of oedemas in the respiratory tract., Possible damages:., damage of respiratory tract, tissue damage Dermal: No data available <u>Skin corrosion/irritation</u> Skin - reconstructed human epidermis (RhE) Result: Corrosive (OECD Test Guideline 431) <u>Serious eye damage/eye irritation</u> Eyes - Bovine cornea Result: Corrosive (OECD Test Guideline 437) <u>Respiratory or skin sensitization</u> Maximization Test - Guinea pig Result: negative (OECD Test Guideline 406)

Germ cell mutagenicity

Test Type: Chromosome aberration test in vitro

Test system: Chinese hamster ovary cells

Result: Conflicting results have been seen in different studies.

Carcinogenicity

Carcinogenicity - Did not show carcinogenic effects in animal experiments. (IUCLID)

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

May cause respiratory irritation.

The substance or mixture is classified as specific target organ toxicant, single exposure, category 3 with respiratory tract irritation.

Acute inhalation toxicity - mucosal irritations, Cough, Shortness of breath, Inhalation may lead to the formation of oedemas in the respiratory tract., Possibledamages:, damage of respiratory tract, tissue damage

Specific target organ toxicity - repeated exposure

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

Aspiration hazard

No aspiration toxicity classification

12 ECOLOGICAL INFORMATION**12.1 Ecotoxicity**Mixture: No data available.**12.2 Persistence and degradability**

No data available.

12.3 Bioaccumulation

No data available.

12.4 Mobility in soil

No data available.

12.5 Results of PBT and vPvB assessment

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Other adverse effects

May be harmful to aquatic organisms due to the shift of the pH.

Components: hydrochloric acid

No data available

Toxicity to fish LC50 - *Gambusia affinis* (Mosquito fish) - 282 mg/l - 96 h

Remarks: (IUCLID).

13 DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods

Do not use the empty containers.

Waste disposal according to the Directives EC 75/442/EEC and 91/689/EEC in their latest versions by incineration or dispose of waste material.

13.2 Waste code numbers/Waste identification

No data available.

14 TRANSPORT INFORMATION

	ADR	ADN/ADNR	IMDG	IATA
14.1. UN number	Not applicable			
14.2. UN proper shipping name	Not applicable			
14.3. Transport hazard class(es)	Not applicable		Not applicable	Not applicable
14.4. Packing group	Not applicable		Not applicable	Not applicable
14.5. Environmental hazards	Not available	Not available	Not available	Not available
Hazard label	Not applicable			
Classification code	Not applicable			
14.6. Special precautions for user	Not available			
14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not available			
Other information	Not available	Not available	Not available	Not available

15 REGULATORY INFORMATION
15.1 Safety, health and environmental regulation/legislation specific for the substance or mixture

This material safety data sheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out.

16 OTHER INFORMATION
Key or legend to abbreviations and acronyms

°C – Degrees Celsius

°F – Degrees Fahrenheit

ADR – European Agreement concerning the International Carriage of Dangerous Goods by Road.
ACGIH – American Conference of Governmental Industrial Hygienists
ATE – Acute Toxicity Estimate
BCF – Bioconcentration Factor
BEI – Biological Exposure Index
CAS – Chemical Abstracts Service
CLP – Regulation (EC) No 1272/2008 on the Classification, Labeling and Packaging of substances and mixtures.
cP – centipoise (unit of dynamic viscosity)
cSt – centistokes (unit of kinematic viscosity)
DNEL – Derived No-effect Level
EC50 – Half maximal effective concentration
ECHA – European Chemicals Agency
EC-No. – European Community number
EU – European Union
GHS – Globally Harmonized System of Classification and Labelling of Chemicals
h – Hours
IATA – International Air Transport Association
IDLH – Immediately Dangerous to Life or Health
IMDG – International Maritime Dangerous Goods
IOELV – Indicative Occupational Exposure Limit Value
kPa – kilopascal
Kow – Octanol-Water Partition Coefficient
LC50 – Median Lethal Concentration
LD50 – Median Lethal Dose
mg/l – Milligram per liter
mg/kg – Milligram per kilogram
mg/m³ – Milligram per cubic meter
Min – Minutes
NIOSH – National Institute for Occupational Safety and Health
NOEC – No Observed Effect Concentration
N.O.S. – Not Otherwise Specified
OEL – Occupational Exposure Limit
PBT - Persistent, Bioaccumulative and Toxic
ppm – Parts per million
PVC – Polyvinyl chloride
REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID – European Agreement concerning the International Carriage of Dangerous Goods by Rail
SDS – Safety Data Sheet
STEL – Short Term Exposure Limit
TLV – Threshold Limit Value
TWA – Time Weighted Average
UN – United Nations
vPvB - Very Persistent and Very Bioaccumulative

Key literature references and sources for data

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.

Procedure used to derive the classification according to regulation (EC) n°1272/2008 (CLP)

Classification of the mixture is consistent with the method of valuation of regulation (EC) n°1272/2008.

List of relevant hazard statements and/or precautionary statements. (Full text of any statements which are not written out in full under section 3)Hazard statements (H):

H314 Causes severe skin burns and eye damage.

Advice on any training appropriate for workers to ensure protection of human health and the environment

No data available

Disclaimer: We believe the statements, technical information and recommendations contained herein are reliable, but they are given without warranty or guarantee of any kind. The information contained in this document applies to this specific material as supplied. It may not be valid for this material if it is used in combination with any other materials. It is the user's responsibility to satisfy oneself as to the suitability and completeness of this information for the user's own particular use.

The information given in this Safety Data Sheet is based on our present knowledge on European and regulations. This Safety Data Sheet describes safety requirements relative to identified uses, it does not guarantee all the product properties particularly in the case of non-identified uses. The product must not be used for any uses other than those identified under heading 1. Since the user's working conditions are not known by us, it is the responsibility of the user to take all necessary measures to comply with legal requirements for specific uses and avoid negative health effects.

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Notification:

English is acceptable for our MSDS as the following conditions are met:

- Medical specialists (users) are well educated in the English language

MSDS established : 2023-03-29

Revision number : 5