

PRODUCT: INGEZIM GLUTEN HIDROLIZADO	REF: 30.GLH.K.2
LAST REVISION: 06/23	Page 1 of 34

1 IDENTIFICATION OF THE PRODUCT AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

INgezim® GLUTEN HIDROLIZADO
Ref. 30.GLH.K2

REAGENTS INCLUDED

Washing Solution
Diluent
Substrate
Stop Solution
Conjugate
Gliadin European Standard
Coated Plates
Extraction Buffer

1.2 Relevant identifier use

For in vitro diagnostic use

1.3 Details of the supplier of the safety data sheet

MANUFACTURER:	GOLD STANDARD DIAGNOSTICS MADRID, S.A.
ADDRESS:	C. de los Hermanos García Noblejas 39, 8ª planta, 28037 MADRID (SPAIN)
TELEPHONE NUMBER:	+34 91 3680501
FAX:	+34 91 4087598
e-mail:	info.spain@eu.goldstandarddiagnostics.com

1.4 Emergency telephone number

Tel: +34 915 620 420
Chemtrec US: (800) 424-9300
Chemtrec EU: 001 (202) 483-761

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 2 of 34

REAGENT: **Washing Solution**

1. IDENTIFICATION:

- 1.1 **Product Identifier:** Washing Solution 25x concentrated
 1.2 **Product use:** Laboratory reagent for diagnostic or research use
 Chemical reagents are purchased from SIGMA, MERCK and PANREAC, and finally handled in GOLD STANDARD DIAGNOSTICS MADRID.

2. HAZARDS IDENTIFICATION:

Statement of hazardous nature: Kathon CG, is used in this composition as preservative (CAS: 55965-84-9)

Hazardous Ingredients	CAS NUMBER	REACH REGISTRATION NUMBER	Approximate concentration	Classification according to regulation (EC) No 1272/2008
Kathon CG	55965-84-9	NA	<=0,28 % vol/vol	Acute Tox. 3, Skin Corr. 1B, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1 ;H311 H314 H317 H400 H410

2.1 Classification of the substance or mixture (CLP classification)

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008 and its amendments

2.2 Label elements

None: the product does not need to be labelled in accordance with EC directives or respective national law

2.3 Other hazards

Due to the composition and the concentration of the reagents used for the formulation of this solution, it can be considered as non-hazardous.

3. COMPOSITION/INFORMATION ON INGREDIENTS:

Mixture of salts and detergent, in distilled water and Kathon 0.1% as preservative.

4. FIRST AID MEASURES:

4.1 Description of first aid measures

Although the reagent can be considered non-hazardous, in case of:

- Skin contact: Flush with water. Obtain medical attention if irritation occurs.
 Eyes contact: Flush with copious amount of water. Obtain medical attention if irritation occurs.
 Inhalation: Remove to fresh air and keep at rest in a comfortable position for breathing.
 Ingestion: Drink as much water as possible. Obtain medical attention if any gastric disorders appear.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.
 Symptoms/injuries after inhalation: May cause respiratory irritation.
 Symptoms/injuries after skin contact: May cause skin irritation.
 Symptoms/injuries after eye contact: May cause slight temporary irritation.
 Symptoms/injuries after ingestion: May cause gastrointestinal irritation.

4.3 Indication of any immediate medical attention and special treatment needed

No additional information available

5. FIRE AND EXPLOSION HAZARD DATA:

- Flammability: No
 Means of extinction: Not applicable
 Hazardous combustion products: Not known

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 3 of 34

6 ACCIDENTAL RELEASE MEASURES:

6.1 Personal precautions, protective equipment and emergency procedures

We recommend wearing adequate laboratory clothes.

6.2 Environmental precautions

No special environmental precautions

6.3 Methods and material for containment and cleaning up

Clean up the area with paper towel with water and disinfect.

6.4 Reference to other sections

See Section 8 and 13

7 HANDLING AND STORAGE:

7.1 Precautions for safe handling

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes.

7.2 Conditions for safe storage, including any incompatibilities

The reagent must be stored between 2° and 8°C

7.3 Specific end use(s)

Laboratory use.

8 EXPOSURE AND CONTROL:

8.1 Control parameters

Contains no substances with occupational exposure limit values

8.2 Exposure controls

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes

Engineering controls: Ensure adequate ventilation.

Respiratory protection: None required.

Hand protection: Wear disposable gloves while handling the reagent. Wash hands after use.

Eye protection: Wear safety glasses with side-shields.

Skin and body protection: Wear suitable protective clothing.

8.3 Environmental exposure controls

Non special controls are required

9 PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid

Boiling point: 100°C

Odour and appearance: Clear solution with no odour

Freezing point: 0°C

pH: 7,0 - 7,4

Water solubility: Reagent soluble

10 STABILITY AND REACTIVITY

10.1 Reactivity: -

10.2 Chemical stability: Stable at +4°C

10.3 Possibility of hazardous reactions: Not known

10.4 Conditions to avoid: -

10.5 Incompatible materials: Not known

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 4 of 34

11 TOXICOLOGICAL INFORMATION

Toxicological properties:	Not known
Acute toxicity:	Not classified. No known significant effects or critical hazards.
Skin corrosion/irritation:	Not classified. No known significant effects or critical hazards.
Serious eye damage/eye irritation:	Not classified. No known significant effects or critical hazards. Splash may cause mild irritation.
Respiratory or skin sensitization:	Not classified. Mild irritation may occur. Some allergic reaction cannot be ruled out.
Germ cell mutagenicity:	Not classified. No known significant effects or critical hazards.
Carcinogenicity:	Not classified. No data available.
Reproductive toxicity:	Not classified. No data available.
Aspiration hazard:	Not classified. No data available.

12 ECOLOGICAL INFORMATION

Toxicity:	No known significant effects or critical hazards.
Persistence and degradability:	No data available.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Results of PBT and vPvB:	No data available.
Other adverse effects:	No data available.

13 DISPOSAL CONSIDERATIONS

Observe local, state and federal rules for proper disposal

14 TRANSPORT INFORMATION

The transport of this product is not regulated by IMO/IMDG, ADR/RID or IATA/ICAO as a hazardous material or dangerous goods.

15 REGULATORY INFORMATION

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

This safety data sheet complies with the amendment Regulation (EU) No. 2020/878 of the Regulation (EC) No. 1907/2006 REACH.

15.2 Chemical safety assessment

No data available

16 OTHER INFORMATION

Update in line with REACH/CLP/GHS regulations

This MSDS contains only safety-related information. For other data, contact with GOLD STANDARD DIAGNOSTICS MADRID.

NOTE

Although the information and recommendations contained in this GOLD STANDARD DIAGNOSTICS MADRID Material Health and Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility its accuracy, sufficiency or reliability or for any loss or injury resulting from use of this information.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 5 of 34

REAGENT: Diluent

1 IDENTIFICATION:

- 1.1 **Product Identifier:** Diluent DE12-05
 1.2 **Product use:** Laboratory reagent for diagnostic or research use
 Chemical reagents are purchased from SIGMA, MERCK and PANREAC, and finally handled in GOLD STANDARD DIAGNOSTICS MADRID.

2 HAZARDS IDENTIFICATION:

Statement of hazardous nature: Kathon CG is used in this composition.

Hazardous Ingredients	CAS NUMBER	REACH REGISTRATION NUMBER	Approximate concentration	Classification according to regulation (EC) No 1272/2008
Kathon CG	55965-84-9	NA	<=0,28 % vol/vol	Acute Tox. 3, Skin Corr. 1B, Skin Sens. 1, Aquatic Acute 1, Aquatic Chronic 1 ;H331 H314 H317 H400 H410

2.1 Classification of the substance or mixture (CLP classification)

Not a hazardous substance or mixture according to Regulation (EC) No 1272/2008 and its amendments

2.2 Label elements

None: the product does not need to be labelled in accordance with EC directives or respective national law

2.3 Other hazards

Due to the composition and the concentration of the reagents used for the formulation of this solution, it can be considered as non-hazardous.

3 COMPOSITION/INFORMATION ON INGREDIENTS:

Mixture of salts, detergent and preservative, in distilled water and Kathon 0.1% as preservative

4 FIRST AID MEASURES:

4.1 Description of first aid measures

Although the reagent can be considered non-hazardous, in case of:

- Skin contact: Flush with water. Obtain medical attention if irritation occurs.
 Eyes contact: Flush with copious amount of water. Obtain medical attention if irritation occurs.
 Inhalation: Remove to fresh air and keep at rest in a comfortable position for breathing.
 Ingestion: Drink as much water as possible. Obtain medical attention if any gastric disorders appear.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.
 Symptoms/injuries after inhalation: May cause respiratory irritation.
 Symptoms/injuries after skin contact: May cause skin irritation.
 Symptoms/injuries after eye contact: May cause slight temporary irritation.
 Symptoms/injuries after ingestion: May cause gastrointestinal irritation.

4.3 Indication of any immediate medical attention and special treatment needed

No additional information available

5 FIRE AND EXPLOSION HAZARD DATA:

- Flammability: No
 Means of extinction: Not applicable
 Hazardous combustion products: Not known

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 6 of 34

6 ACCIDENTAL RELEASE MEASURES:

6.1 Personal precautions, protective equipment and emergency procedures

We recommend wearing adequate laboratory clothes.

6.2 Environmental precautions

No special environmental precautions

6.3 Methods and material for containment and cleaning up

Clean up the area with paper towel with water and disinfect.

6.4 Reference to other sections

See Section 8 and 13

7 HANDLING AND STORAGE:

7.1 Precautions for safe handling

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes.

7.2 Conditions for safe storage, including any incompatibilities

The reagent must be stored between 2° and 8°C

7.3 Specific end use(s)

Laboratory use.

8 EXPOSURE AND CONTROL:

8.1 Control parameters

Contains no substances with occupational exposure limit values

8.2 Exposure controls

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes

Engineering controls:

Ensure adequate ventilation.

Respiratory protection:

None required.

Hand protection:

Wear disposable gloves while handling the reagent. Wash hands after use.

Eye protection:

Wear safety glasses with side-shields.

Skin and body protection:

Wear suitable protective clothing.

8.3 Environmental exposure controls

Non special controls are required

9 PHYSICAL AND CHEMICAL PROPERTIES:

Physical state:

Liquid

Boiling point:

100°C

Odour an appearance:

Clear solution with no odour

Freezing point:

0°C

pH:

7,0 - 7,4

Water solubility:

Reagent soluble

10 STABILITY AND REACTIVITY:

10.1 Reactivity:

-

10.2 Chemical stability

Stable at +4°C

10.3 Possibility of hazardous reactions:

Not known

10.4 Conditions to avoid

-

10.5 Incompatible materials

Not known

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 7 of 34

11 TOXICOLOGICAL INFORMATION

Toxicological properties:	Not known
Acute toxicity: Not classified:	No known significant effects or critical hazards.
Skin corrosion/irritation:	Not classified. No known significant effects or critical hazards.
Serious eye damage/eye irritation:	Not classified. No known significant effects or critical hazards. Splash may cause mild irritation.
Respiratory or skin sensitisation:	Not classified. Mild irritation may occur. Some allergic reaction cannot be ruled out.
Germ cell mutagenicity:	Not classified. No known significant effects or critical hazards.
Carcinogenicity:	Not classified. No data available.
Reproductive toxicity:	Not classified. No data available.
Aspiration hazard:	Not classified. No data available.

12 ECOLOGICAL INFORMATION

Toxicity:	No known significant effects or critical hazards.
Persistence and degradability:	No data available.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Results of PBT and vPvB:	No data available.
Other adverse effects:	No data available.
WGK:	Substance slightly dangerous for water.

13 DISPOSAL CONSIDERATIONS

Observe local, state and federal rules for proper disposal

14 TRANSPORT INFORMATION

The transport of this product is not regulated by IMO/IMDG, ADR/RID or IATA/ICAO as a hazardous material or dangerous goods.

15 REGULATORY INFORMATION

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

This safety data sheet complies with the amendment Regulation (EU) No. 2020/878 of the Regulation (EC) No. 1907/2006 REACH.

15.2 Chemical safety assessment

No data available

16 OTHER INFORMATION

Update in line with REACH/CLP/GHS regulations

This MSDS contains only safety-related information. For other data, contact with GOLD STANDARD DIAGNOSTICS MADRID.

NOTE

Although the information and recommendations contained in this GOLD STANDARD DIAGNOSTICS MADRID Material Health and Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility its accuracy, sufficiency or reliability or for any loss or injury resulting from use of this information.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 8 of 34

REAGENT SUBSTRATE

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

1.1 Product identifier:

Enhanced K-Blue Substrate

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

TMB-Substrate for diagnostic test kit.

1.3 Details of the supplier of the safety data sheet (Ed. No 7):

Neogen Europe, Ltd.

Cunningham Building International Phone: + 44 1292 525 275

Auchincruive, Ayr, KA6 5HW International Fax: + 44 1292 525 477

Scotland, UK

Responsible person for the safety data sheet (e-mail): info_uk@neogeneurope.com

1.4 Emergency telephone

(UK) E-mail: UKREACHCA@hse.gsi.gov.uk

NHS (England or Wales): 0845 46 47

NHS 24 (Scotland): 08454 24 24 24

2 Hazards identification

2.1 Classification of the substance or mixture:

Health hazard.

CLP (1272/2008): Repr. 1B;H360D

2.2 Label elements:



DANGER

Contents: N-Methyl-2- pyrrolidone

H360: May damage the unborn child.

P201: Obtain special instructions before use.

P280: Wear protective gloves/protective clothing/eye protection/face protection.

P308+P313: IF exposed or concerned: Get medical advice/attention.

P405: Store locked up.

P501: Dispose of contents/container in accordance with applicable regulations.

Restricted to professional users

2.3 Other hazards: **None known.**

PBT/vPvB: The ingredients are not considered PBT/vPvB according to criteria in Annex XIII.

3 Composition/information on ingredients

3.1 Mixtures:

% w/w	Name	CAS-no.	EC-no.	Index-no.	REACH-reg.no.	Classification	Note
1-<5	N-Methyl-2-Pyrrolidone (NMP)	872-50-4	212-828-1	606-021-00-7	-	Repr. 1B;H360D Skin Irrit. 2;H315 1 Eye Irrit. 2;H319 STOT SE 3;H335	1

1)The substance is included on the candidate list (EC, REACH, SVHC)

Wording of hazard statements - see section 16.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 9 of 34

4 First-aid measures

4.1 Description of first aid measures:

- Inhalation: Move the affected person to fresh air. Keep at rest. If needed: Get medical attention.
- Skin contact: Remove contaminated clothing and wash skin with water and mild soap. If irritation persists: Seek medical advice.
- Eye contact: Flush thoroughly with water or physiological salt water, holding eye lids open, remember to remove contact lenses, if any. If irritation persists: Seek medical advice.
- Ingestion: Rinse mouth and drink plenty of water. Keep at rest. In case of discomfort: Seek medical advice.

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

Larger amounts of vapours may cause fatigue, dizziness, headache, nausea and vomiting. May cause irritation of eyes and skin. Prolonged exposure to vapours may result in damage on liver, kidneys, blood or central nervous system (including brain damage).

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

Show this Safety Data Sheet to a physician or emergency ward.

5 SECTION 5: Fire-fighting measures

5.1 Extinguishing media:

Not relevant.

5.2 Special hazards arising from the substance or mixture:

Not flammable. Do not breathe smoke fumes. In case of strong heat or fire, the product may form hazardous decomposition product such as oxides of carbon and nitrogen.

5.3 Advice for fire-fighters:

When entering burning area: Wear self-contained breathing apparatus.

6 SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures:

Use personal protective equipment - see section 8. Avoid further spreading. Ventilate area of leak or spill.

6.2 Environmental precautions:

Do not empty into drains - see section 12. Inform appropriate authorities in accordance with local regulations.

6.3 Methods and material for containment and cleaning up:

Sweep up with paper towels or absorb with inert material and place in a suitable container for disposal. Flush area of spill with plenty of water. Further handling of spillage - see section 13.

6.4 Reference to other sections:

See above.

7 SECTION 7: Handling and storage

7.1 Precautions for safe handling:

AVOID ALL CONTACT! Careful personal hygiene is a necessity. After use wash contaminated skin with soap and plenty of water. Avoid breathing vapours. Provide adequate ventilation e.g. by working in a fume cupboard. Change contaminated clothes immediately. Do not carry or consume food, gum, tobacco products, or drinks in the work area. Close container after use to avoid spillage. After work wash hands with water and mild soap.

7.2 Conditions for safe storage, including any incompatibilities:

In tightly closed container locked up, at temperatures from 4 to 8°C.

7.3 Specific end use(s):

See section 1.

8 SECTION 8: Exposure controls/Personal protection

8.1 Control parameters:

Occupational exposure limits(EH40):	8-hour TWA	15-min STEL	Comments
N-methyl-2-pyrrolidone:	10 ppm /40 mg.m-3	20 ppm / 80 mg.m-3	Sk = Absorbed through skin
DNEL/PNEC:	No		

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 10 of 34

8.2 Exposure controls:

Appropriate engineering controls:

Work in fume cupboard or use process ventilation.

Personal protective equipment:

Respiratory protection: Not required when sufficient ventilation is provided. In case of inadequate ventilation: Use an approved mask (EN 140) with gas filter type A (Brown - for organic vapours). The filter has a limited lifetime and must be changed. Read the Instruction.

Skin protection:

Wear protective gloves (EN 374) of e.g. nitrile. Data on Breakthrough times is not available for all ingredients and therefore it is recommended to change the glove when spilled on.

Eye protection:

Use safety goggles (EN 166) when there is a risk of splashes.

Environmental exposure controls:

None particular.

9 Physical and chemical properties

9.1 Information on basic physical and chemical properties:

Appearance:	Clear to faint blue solution
Odour:	Characteristic
Odour threshold:	Not determined
pH:	Not determined
Melting point/freezing point (oC):	Not determined
Initial boiling point and boiling range (oC):	Not determined
Decomposition temperature (oC):	Not determined
Flash point (oC):	Not determined
Evaporation rate (water = 1):	Not determined
Flammability (solid, gas):	Not relevant
Upper/lower flammability or explosive limits (vol-%):	Not determined
Vapour pressure (mmHg, 20oC):	Not determined
Vapour density (Water = 1):	Not determined
Relative density (Water = 1):	Not determined
Solubility (water):	Complete
Partition coefficient: n-octanol/water:	Not determined
Auto-ignition temperature (°C):	Not determined
Viscosity:	Not determined
Explosive properties:	Not relevant
Oxidising properties:	Not relevant

9.2 Other information:

None relevant.

10 Stability and reactivity

10.1 Reactivity:

No available information.

10.2 Chemical stability:

Stable under normal conditions.

10.3 Possibility of hazardous reactions:

None known.

10.4 Conditions to avoid:

None known.

10.5 Incompatible materials:

Strong oxidizing agents.

10.6 Hazardous decomposition products:

Thermal decomposition may produce oxides of carbon and nitrogen.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 11 of 34

11 Toxicological information

11.1 Information on toxicological effects:

Hazard class	Data (NMP)	Test	Reference
Acute toxicity:			
Inhalation	LC50 (rat) > 5,1 mg/l/4h	OECD 403	IUCLID
Dermal	LD50 (rabbit) = 2000-4000 mg/kg	No info	IUCLID
Oral	LD50 (rat) = 3600 mg/kg	No info	IUCLID
Corrosion/irritation:	Moderate skin irritation, human and eye irritation, rabbit	Observations / Draize	IUCLID
Sensitization:	No skin sensitization, human	Patch	IUCLID
CMR:	No mutagenicity, in vivo, mouse, oral No carcinogenicity, rat, inhalation TDLo (Inhalation., rat) = 116 ppm/6H: "Effects on embryo or fetus"	Micronucleus 2 year study Multigeneration	IUCLID IUCLID RTECS

Information on likely routes of exposure: Lungs, skin and gastrointestinal tract.

Symptoms:

Inhalation:	May cause irritation of the mucous membranes. Larger amounts may cause dizziness, headache and nausea.
Skin:	May cause irritation. N-methyl-2-pyrrolidone may be absorbed through the skin.
Eyes:	May cause irritation with redness.
Ingestion:	May cause irritation to mucous membranes in mouth, throat and stomach and symptoms as for "Inhalation" .
Chronic effects:	Prolonged or frequent exposure to vapours of volatile organic compounds may result in damage on liver, kidneys, blood or central nervous system (including brain damage). According to animal tests, N-methyl-2-pyrrolidone may cause harm to the unborn child.

12 Ecological information

12.1 Toxicity:

Aquatic	Data (NMP)	Test (Media)	Reference
Fish	LC50 (Lepomis macrochirus, 96h) = 832 mg/ l	Static (FW)	IUCLID
Crustacean	EC50 (Daphnia magna, 48h) = 4897 mg/l	No info (FW)	IUCLID
Algae	EC50 (Scenedesmus subspicatus, 72h) > 500 mg/l	DIN 38412 (FW)	IUCLID

12.2 Persistence and degradability:

N-Methyl-2-pyrrolidone is readily biodegradable.

12.3 Bioaccumulative potential:

N-Methyl-2-pyrrolidone: Log Kow < 1. No significant bioaccumulation.

12.4 Mobility in soil:

N-Methyl-2-pyrrolidone: Koc (estimated) < 10. Very large mobility is expected in soil.

12.5 Results of PBT and vPvB assessment:

Ingredients are not considered PBT/vPvB according to criteria in Annex XIII.

12.6 Other adverse effects:

None known.

13 Disposal considerations

13.1 Waste treatment methods:

Disposal should be according to local, state or national legislation. Dispose of through authority facilities or pass to chemical disposal company.

EWC-Code: 16 05 06

14 Transport information

Not dangerous goods (ADR/RID/IMDG/IATA).

14.1 UN number: -

14.2 UN proper shipping name: -

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 12 of 34

- 14.3 Transport hazard class(es): -
- 14.4 Packing group: -
- 14.5 Environmental hazards: **None.**
- 14.6 Special precautions for user: **None.**
- 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: **Not relevant.**

15 Regulatory information

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

Restricted use by REACH (1907/2006), Annex XVII, 30. Restricted to professional users.

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions (Directive 92/85/EEC). Must not be used by persons under 18 years of age.

15.2 Chemical Safety Assessment:

No CSR.

16 Other information

R-phrases and hazard statements mentioned in section 2 and 3:

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H335: May cause respiratory irritation.

H360D: May damage the unborn child.

Abbreviations:

CMR = Carcinogenicity, mutagenicity and reproductive toxicity

CSR = Chemical Safety Report

DNEL = Derived No-Effect Level

EC50 / LC50 / LD50 = Effect/Lethal Concentration/Dose 50%

PBT = Persistent, Bioaccumulative, Toxic

PNEC = Predicted No-Effect Concentration

TDLo = Toxic Dose Low

vPvB = very Persistent, very Bioaccumulative

Literature:

IUCLID: International Uniform Chemical Database Information.

RTECS: Register of Toxic Effects of Chemicals Substances.

Training advice:

No special training is required. However, the user should be well instructed in the execution of the task, be familiar with this Safety Data Sheet and have normal training in the use of personal protective equipment.

Other information:

Contains < 0,1% of a substance listed in the PIC Regulation. CAS no. 54827-17-7 – Benzidine, its salts and benzidine.

NOTE

Although the information and recommendations contained in this GOLD STANDARD DIAGNOSTICS MADRID Material Health and Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility its accuracy, sufficiency or reliability or for any loss or injury resulting from use of this information.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 13 of 34

REAGENT STOP SOLUTION

1 IDENTIFICATION:

- 1.1 **Product Identifier:** Sulphuric acid in water solution 0.5M (1N)
 1.2 **Product use:** Laboratory reagent for diagnostic or research use
 Chemical reagent is purchased from PANREAC, and finally diluted at GOLD STANDARD DIAGNOSTICS MADRID.

2 HAZARDS IDENTIFICATION:

- 2.1 **Classification of the substance or mixture:**
 CLP Regulation (EC) No 1272/2008:
 The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.
 2.2 **Label elements:**
 CLP Regulation (EC) No 1272/2008:
 Hazard statements:
 Non-applicable
 Precautionary statements:
 Non-applicable
 Supplementary information:
 EUH210: Safety data sheet available on request
 2.2 **Other hazards:**
 Product fails to meet PBT/vPvB criteria

3 COMPOSITION/INFORMATION ON INGREDIENTS:

- 3.1 **Substance:**
 Non-applicable
 3.2 **Mixture:**
Chemical description: Aqueous solution of inorganic acids
Components:
 In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/Classification	Concentration
CAS: 7664-93-9 EC: 231-639-5 Index:016-020-00-8 REACH01-2119458838-20-XXXX	Sulphuric acid ¹ Regulation 1272/2008 ATP CLP00 Skin Corr. 1A: H314 - Danger	1 - <5 %



⁽¹⁾ Substances presenting a health or environmental hazard which meet criteria laid down in Regulation (EU) No. 2020/878
 To obtain more information on the hazards of the substances consult sections 8, 11, 12, 15 and 16.

Other information:

Identification	Specific concentration limit
Sulphuric acid CAS: 7664-93-9 EC: 231-639-5	% (w/w) >=15: Skin Corr. 1A - H314 5 <= % (w/w) <15: Skin Irrit. 2 - H315 % (w/w) >=15: Eye Dam. 1 - H318 5 <= % (w/w) <15: Eye Irrit. 2 - H319

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 14 of 34

4 FIRST AID MEASURES:

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

Inhalation: This product does not contain substances classified as hazardous for inhalation, however, in case of symptoms of intoxication remove the person affected from the exposure area and provide with fresh air. Seek medical attention if the symptoms get worse or persist.

Skin contact: This product is not classified as hazardous when in contact with the skin. However, in case of skin contact it is recommended to remove contaminated clothes and shoes, rinse the skin or if necessary shower the affected person thoroughly with cold water and neutral soap. In case of serious reaction consult a doctor.

Eye contact: Rinse eyes thoroughly with water for at least 15 minutes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case removal could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS for the product.

Ingestion/aspiration: Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

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

Non-applicable

5 FIRE AND EXPLOSION HAZARD DATA:

5.1 Extinguishing media:

Product is non-flammable under normal conditions of storage, handling and use. In the case of combustion as a result of improper handling, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

5.2 Special hazards arising from the substance or mixture:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit,...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

6 ACCIDENTAL RELEASE MEASURES:

6.1 Personal precautions, protective equipment and emergency procedures:

Isolate leaks provided that there is no additional risk for the people performing this task. Personal protection equipment must be used against potential contact with the spilt product (See section 8). Evacuate the area and keep out those who do not have protection.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 15 of 34

7 HANDLING AND STORAGE:

7.1 Precautions for safe handling:

A.- Precautions for safe manipulation

Comply with the current legislation concerning the prevention of industrial risks. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

B.- Technical recommendations for the prevention of fires and explosions

Product is non-flammable under normal conditions of storage, handling and use. It is recommended to transfer at slow speeds to avoid the generation of electrostatic charges that can affect flammable products. Consult section 10 for information on conditions and materials that should be avoided.

C.- Technical recommendations to prevent ergonomic and toxicological risks

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

8 EXPOSURE AND CONTROL:

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (EH40/2005 Workplace exposure limits):

Identification	Environmental limits		
Sulphuric acid CAS: 7664-93-9 EC: 231-639-5	WEL (8h)		0.05 mg/m ³
	WEL (15 min)		

DNEL (Workers):

Identification		Short exposure		Long exposure	
		Systemic	Local	Systemic	Local
Sulphuric acid CAS: 7664-93-9 EC: 231-639-5	Oral	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Dermal	Non-applicable	Non-applicable	Non-applicable	Non-applicable
	Inhalation	Non-applicable	0.1 mg/m ³	Non-applicable	0.05 mg/m ³

DNEL (General population):

Non-applicable

PNEC:

Identification				
Sulphuric acid CAS: 7664-93-9 EC: 231-639-5	STP	8.8 mg/L	Fresh water	0.0025 mg/L
	Soil	Non-applicable	Marine water	0.00025 mg/L
	Intermittent	Non-applicable	Sediment(Fresh water)	0.002 mg/kg
	Oral	Non-applicable	Sediment (Marine water)	0.002 mg/kg

8.2 Exposure controls:

A.- General security and hygiene measures in the work place

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection,...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1.

All information contained herein is a recommendation which needs some specification from the labour risk prevention services as it is not known whether the company has additional measures at its disposal.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 16 of 34

B.- Respiratory protection


The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	NON-disposable chemical protective gloves (NBR), Breakthrough Time 48min, thickness 0.4 mm		EN 374-1:2003 EN374-3:2003/AC:2006 EN 420:2003+A1:2009	The Breakthrough Time indicated by the manufacturer must exceed the period during which the product is being used. Do not use protective creams after the product has come into contact with skin.

"As the product is a mixture of several substances, the resistance of the glove material can not be predicted in advance with total reliability and has therefore to be checked prior to the application"



D.- Ocular and facial protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections.		EN 166:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2001, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
	Anti-slip work shoes		EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345 y EN 13832-1

F.- Additional emergency measures

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2002	 Eyewash stations	DIN 12 899 ISO 3864-1:2002

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m ³ (0 g/L)
Average carbon number:	Non-applicable
Average molecular weight:	Non-applicable

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 17 of 34

9 PHYSICAL AND CHEMICAL PROPERTIES:

9.1 Information on basic physical and chemical properties:

*Not relevant due to the nature of the product, not providing information property of its hazards
For complete information see the product datasheet.

Appearance:

Physical state at 20 °C:	Liquid
Appearance:	Not available
Colour:	Not available
Odour:	Not available
Odour threshold:	Non-applicable *

Volatility:

Boiling point at atmospheric pressure:	102 °C
Vapour pressure at 20 °C:	2338 Pa
Vapour pressure at 50 °C:	92.38 (12.32 kPa)
Evaporation rate at 20 °C:	Non-applicable *

Product description:

Density at 20 °C:	1045 kg/m ³
Relative density at 20 °C:	1.045
Dynamic viscosity at 20 °C:	1.04 cP
Kinematic viscosity at 20 °C:	1 cSt
Kinematic viscosity at 40 °C:	Non-applicable *
Concentration:	Non-applicable *
pH:	Non-applicable *
Vapour density at 20 °C:	Non-applicable *
Partition coefficient n-octanol/water 20 °C:	Non-applicable *
Solubility in water at 20 °C:	Non-applicable *
Solubility properties:	Non-applicable *
Decomposition temperature:	Non-applicable *
Melting point/freezing point:	Non-applicable *
Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *

Flammability:

Flash Point:	Non Flammable (>60 °C)
Flammability (solid, gas):	Non-applicable *
Autoignition temperature:	Non-applicable *
Lower flammability limit:	Non-applicable *
Upper flammability limit:	Non-applicable *

Explosive:

Lower explosive limit:	Non-applicable *
Upper explosive limit:	Non-applicable *

9.2 Other information:

Surface tension at 20 °C:	Non-applicable *
Refraction index:	Non-applicable *

*Not relevant due to the nature of the product, not providing information property of its hazards

10 STABILITY AND REACTIVITY:

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7

10.2 Chemical stability:

Chemically stable under the conditions of storage, handling and use.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 18 of 34

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidising materials	Combustible materials	Others
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products.

11 TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects:

The experimental information related to the toxicological properties of the product itself is not available

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A- Ingestion (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for consumption. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

B- Inhalation (acute effect):

- Acute toxicity : Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

C- Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous for skin contact. For more information see section 3.
- Contact with the eyes: Based on available data, the classification criteria are not met. However, it does contain substances classified as dangerous for this effect. For more information see section 3.

D- CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for the effects mentioned. For more information see section 3.
IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.
- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

E- Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous with sensitising effects. For more information see section 3.
- Cutaneous: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

F- Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3

G- Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 19 of 34

- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

H- Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as dangerous for this effect. For more information see section 3.

Other information:

Non-applicable

Specific toxicology information on the substances:

Identification	Acute toxicity		Genus
Sulphuric acid	LD50 oral	2140 mg/kg	Rat
CAS: 7664-93-9	LD50 dermal	Non-applicable	
EC: 231-639-5	LC50 inhalation	Non-applicable	

11.2 Information on other hazards

Endocrine disrupting properties:

To assess endocrine disrupting properties in human health. This product does not contain any known or suspected endocrine disruptors.

12 ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

12.1 Toxicity:

Not available

12.2 Persistence and degradability:

Not available

12.3 Bioaccumulative potential:

Not available

12.4 Mobility in soil:

Not available

12.5 Results of PBT and vPvB assessment:

Product fails to meet PBT/vPvB criteria

12.6 Endocrine disrupting properties:

This product does not contain any known or suspected endocrine disruptors.

12.7 Other adverse effects:

Persistent Organic Pollutants: This product does not contain any known or suspected substances.

Ozone Depleting Potential: This product does not contain any known or suspected substances.

13 DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste class (Regulation (EU) No 1357/2014)
16 03 03*	inorganic wastes containing hazardous substances	Dangerous

Type of waste (Regulation (EU) No 1357/2014):

HP4 Irritant — skin irritation and eye damage

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC, The Waste Regulations 2011, 2011 No. 988). As under 15 01 (2014/955/EU) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. We do not recommend disposal down the drain. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated
Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 20 of 34

14 TRANSPORT INFORMATION

Transport of dangerous goods by land:

With regard to ADR 2017 and RID 2017:

14.1 UN number: UN3264



14.2 UN proper shipping name: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Sulphuric acid)

14.3 Transport hazard class(es): 8

Labels: 8

14.4 Packing group: III

14.5 Environmental hazards: No

14.6 Special precautions for user

Special regulations: 274

Tunnel restriction code: E

Physico-Chemical properties: see section 9

Limited quantities: 5 L

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Non-applicable

Transport of dangerous goods by sea:

With regard to IMDG 38-16:



14.1 UN number N3264

14.2 UN proper shipping name: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Sulphuric acid)

14.3 Transport hazard class(es): 8

Label 8

14.4 Packing group: III

14.5 Environmental hazards: No

14.6 Special precautions for user

Special regulations: 223, 274

EmS Codes: F-A, S-B

Physico-Chemical properties: see section 9

Limited quantities: 5 L

Segregation group: 1

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Non-applicable

Transport of dangerous goods by air:

With regard to IATA/ICAO 2018:



14.1 UN number: UN3264

14.2 UN proper shipping name: CORROSIVE LIQUID, ACIDIC, INORGANIC, N.O.S. (Sulphuric acid)

14.3 Transport hazard class(es): 8

Labels: 8

14.4 Packing group: III

14.5 Environmental hazards: No

14.6 Special precautions for user

Physico-Chemical properties: see section 9

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code: Non-applicable

15 REGULATORY INFORMATION

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

Candidate substances for authorisation under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: Non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 21 of 34

Seveso III:

Non-applicable

Limitations to commercialisation and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc...):

Regulation (EU) No 98/2013 of the European Parliament and of the Council of 15 January 2013 on the marketing and use of explosives precursors:

Contains Sulphuric acid. Product under the provisions of Article 9

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2009 (CDG 2009), SI 2009 No 1348

The Carriage of Dangerous Goods and Use of Transportable Pressure Equipment (Amendment) Regulations 2011, 2011 No. 1885

Control of Substances Hazardous to Health Regulations 2002 (as amended)

EH40/2005 Workplace exposure limits

The Waste Regulations 2011, 2011 No. 988

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

16 OTHER INFORMATION

Legislation related to safety data sheets:

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (Regulation (EC) No 2020/878)

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008:

Skin Corr. 1A: H314 - Causes severe skin burns and eye damage

Classification procedure:

Non-applicable

Advice related to training:

Minimal training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

This MSDS contains only safety-related information. For other data, contact with GOLD STANDARD DIAGNOSTICS MADRID.

NOTE

Although the information and recommendations contained in this GOLD STANDARD DIAGNOSTICS MADRID Material Health and Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility its accuracy, sufficiency or reliability or for any loss or injury resulting from use of this information.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 22 of 34

REAGENT	CONJUGATE
---------	-----------

1 IDENTIFICATION:

- 1.1 Product Identifier: Conjugate
- 1.2 Product use: Laboratory reagent for diagnostic or research use

2 HAZARDS IDENTIFICATION:

This reagent contains StabilZyme® stabilizer from SurModics.

- 2.1 Classification of the substance or mixture
 - Classification according to Regulation (EC) No1272/2008 (CLP)
 - Not classified
 - Adverse physicochemical, human health and environmental effects
 - No additional information available
- 2.2 Label elements
 - No labelling applicable
- 2.3 Other hazards
 - Other hazards not contributing to the classification: None under normal conditions

3 COMPOSITION/INFORMATION ON INGREDIENTS:

Dilution of purified monoclonal antibodies specific of secalin in stabilising solution (StabilZyme® SELECT from SurModics), peroxidase conjugated. The mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

4 FIRST AID MEASURES:

- 4.1 Description of first aid measures
 - Although the reagent can be considered non-hazardous, in case of:
 - Skin contact: Flush with water. Obtain medical attention if irritation occurs.
 - Eyes contact: Flush with copious amount of water. Obtain medical attention if irritation occurs.
- 4.2 Inhalation: **Remove to fresh air and keep at rest in a comfortable position for breathing.**
 - Ingestion: Drink as much water as possible. Obtain medical attention if any gastric disorders appear.
- 4.3 Most important symptoms and effects, both acute and delayed
 - Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.
 - Symptoms/injuries after inhalation: May cause respiratory irritation.
 - Symptoms/injuries after skin contact: May cause skin irritation.
 - Symptoms/injuries after eye contact: May cause slight temporary irritation.
 - Symptoms/injuries after ingestion: May cause gastrointestinal irritation.
- 4.4 Indication of any immediate medical attention and special treatment needed
 - No additional information available

5 FIRE AND EXPLOSION HAZARD DATA:

- Flammability: No
- Means of extinction: Not applicable
- Hazardous combustion products: Not known

6 ACCIDENTAL RELEASE MEASURES:

- 6.1 Personal precautions, protective equipment and emergency procedures
 - We recommend wearing adequate laboratory clothes.
- 6.2 Environmental precautions
 - No special environmental precautions
- 6.3 Methods and material for containment and cleaning up
 - Clean up the area with paper towel with water and disinfect.
- 6.4 Reference to other sections
 - See Section 8 and 13

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 23 of 34

7 HANDLING AND STORAGE:

7.1 Precautions for safe handling

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes.

7.2 Conditions for safe storage, including any incompatibilities

The reagent must be stored between 2° and 8°C

7.3 Specific end use(s)

Laboratory use.

8 EXPOSURE AND CONTROL:

8.1 Control parameters

Contains no substances with occupational exposure limit values

8.2 Exposure controls

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes

Engineering controls: Ensure adequate ventilation.

Respiratory protection: None required.

Hand protection: Wear disposable gloves while handling the reagent. Wash hands after use.

Eye protection: Wear safety glasses with side-shields.

Skin and body protection: Wear suitable protective clothing.

8.3 Environmental exposure controls

Non special controls are required

9 PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid

Boiling point: 100°C

Odour and appearance: Clear solution with no odour

Freezing point: 0°C

pH: 7,0 - 7,4

Water solubility: Reagent soluble

10 STABILITY AND REACTIVITY

10.1 Reactivity: Non dangerous reactions known under normal conditions of use

10.2 Chemical stability: Stable at +4°C

10.3 Possibility of hazardous reactions: Not known

10.4 Conditions to avoid: Not known

10.5 Incompatible materials: Not known

11 TOXICOLOGICAL INFORMATION

Toxicological properties: Not known

Acute toxicity: Not classified. No known significant effects or critical hazards.

Skin corrosion/irritation: Not classified. No known significant effects or critical hazards.

Serious eye damage/eye irritation: Not classified. No known significant effects or critical hazards. Splash may cause mild irritation.

Respiratory or skin sensitisation: Not classified. Mild irritation may occur. Some allergic reaction cannot be ruled out.

Germ cell mutagenicity: Not classified. No known significant effects or critical hazards.

Carcinogenicity: Not classified. No data available.

Reproductive toxicity: Not classified. No data available.

Aspiration hazard: Not classified. No data available.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 24 of 34

12 ECOLOGICAL INFORMATION

Toxicity:	No known significant effects or critical hazards.
Persistence and degradability:	No data available.
Bioaccumulative potential:	N data available.
Mobility in soil:	No data available.
Results of PBT and vPvB:	No data available.
Other adverse effects	No data available.

13 DISPOSAL CONSIDERATIONS

Observe local, state and federal rules for proper disposal

14 TRANSPORT INFORMATION

The transport of this product is not regulated by IMO/IMDG, ADR/RID or IATA/ICAO as a hazardous material or dangerous goods.

15 REGULATORY INFORMATION

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

This safety data sheet complies with the amendment Regulation (EU) No. 2020/878 of the Regulation (EC) No. 1907/2006 REACH.

15.2 Chemical safety assessment

No data available

16 OTHER INFORMATION

Update in line with REACH/CLP/GHS regulations

This MSDS contains only safety-related information. For other data, contact with GOLD STANDARD DIAGNOSTICS MADRID.

NOTE

Although the information and recommendations contained in this GOLD STANDARD DIAGNOSTICS MADRID Material Health and Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility its accuracy, sufficiency or reliability or for any loss or injury resulting from use of this information.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 25 of 34

REAGENT Gliadin Standard

1 IDENTIFICATION:

- 1.1 **Product Identifier:** Gliadin Standard
- 1.2 **Product use:** Laboratory reagent for diagnostic or research use

2 HAZARDS IDENTIFICATION:

This reagent contains StabilZyme® stabilizer from SurModics.

- 2.1 **Classification of the substance or mixture**
Classification according to Regulation (EC) No1272/2008 (CLP)
Not classified
Adverse physicochemical, human health and environmental effects
No additional information available

- 2.2 **Label elements**
No labelling applicable

- 2.3 **Other hazards**
Other hazards not contributing to the classification: None under normal conditions

3 COMPOSITION/INFORMATION ON INGREDIENTS:

Gliadin from wheat diluted in stabilizing solution. (StabilZyme® SELECT from SurModics), peroxidase conjugated. The mixture does not contain any substances to be mentioned according to the criteria of section 3.2 of REACH Annex II

4 FIRST AID MEASURES:

- 4.1 **Description of first aid measures**
Although the reagent can be considered non-hazardous, in case of:
Skin contact: Flush with water. Obtain medical attention if irritation occurs.
Eyes contact: Flush with copious amount of water. Obtain medical attention if irritation occurs.
- 4.2 **Inhalation: Remove to fresh air and keep at rest in a comfortable position for breathing.**
Ingestion: Drink as much water as possible. Obtain medical attention if any gastric disorders appear.
- 4.3 **Most important symptoms and effects, both acute and delayed**
Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.
Symptoms/injuries after inhalation: May cause respiratory irritation.
Symptoms/injuries after skin contact: May cause skin irritation.
Symptoms/injuries after eye contact: May cause slight temporary irritation.
Symptoms/injuries after ingestion: May cause gastrointestinal irritation.
- 4.4 **Indication of any immediate medical attention and special treatment needed**
No additional information available

5 FIRE AND EXPLOSION HAZARD DATA:

- Flammability: No
- Means of extinction: Not applicable
- Hazardous combustion products: Not known

6 ACCIDENTAL RELEASE MEASURES:

- 6.1 **Personal precautions, protective equipment and emergency procedures**
We recommend wearing adequate laboratory clothes.
- 6.2 **Environmental precautions**
No special environmental precautions

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 26 of 34

6.3 Methods and material for containment and cleaning up

Clean up the area with paper towel with water and disinfect.

6.4 Reference to other sections

See Section 8 and 13

7 HANDLING AND STORAGE:

7.1 Precautions for safe handling

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes.

7.2 Conditions for safe storage, including any incompatibilities

The reagent must be stored between 2° and 8°C

7.3 Specific end use(s)

Laboratory use.

8 EXPOSURE AND CONTROL:

8.1 Control parameters

Contains no substances with occupational exposure limit values

8.2 Exposure controls

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes

Engineering controls: Ensure adequate ventilation.

Respiratory protection: None required.

Hand protection: Wear disposable gloves while handling the reagent. Wash hands after use.

Eye protection: Wear safety glasses with side-shields.

Skin and body protection: Wear suitable protective clothing.

8.3 Environmental exposure controls

Non special controls are required

9 PHYSICAL AND CHEMICAL PROPERTIES

Physical state: Liquid

Boiling point: 100°C

Odour and appearance: Clear solution with no odour

Freezing point: 0°C

pH: 7,0 - 7,4

Water solubility: Reagent soluble

10 STABILITY AND REACTIVITY

10.1 Reactivity: Non dangerous reactions known under normal conditions of use

10.2 Chemical stability: Stable at +4°C

10.3 Possibility of hazardous reactions: Not known

10.4 Conditions to avoid: Not known

10.5 Incompatible materials: Not known

11 TOXICOLOGICAL INFORMATION

Toxicological properties: Not known

Acute toxicity: Not classified. No known significant effects or critical hazards.

Skin corrosion/irritation: Not classified. No known significant effects or critical hazards.

Serious eye damage/eye irritation: Not classified. No known significant effects or critical hazards. Splash may cause mild irritation.

Respiratory or skin sensitisation: Not classified. Mild irritation may occur. Some allergic reaction cannot be ruled out.

Germ cell mutagenicity: Not classified. No known significant effects or critical hazards.

Carcinogenicity: Not classified. No data available.

Reproductive toxicity: Not classified. No data available.

Aspiration hazard: Not classified. No data available.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 27 of 34

12 ECOLOGICAL INFORMATION

Toxicity:	No known significant effects or critical hazards.
Persistence and degradability:	No data available.
Bioaccumulative potential:	No data available.
Mobility in soil:	No data available.
Results of PBT and vPvB:	No data available.
Other adverse effects	No data available.

13 DISPOSAL CONSIDERATIONS

Observe local, state and federal rules for proper disposal

14 TRANSPORT INFORMATION

The transport of this product is not regulated by IMO/IMDG, ADR/RID or IATA/ICAO as a hazardous material or dangerous goods.

15 REGULATORY INFORMATION

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

This safety data sheet complies with the amendment Regulation (EU) No. 2020/878 of the Regulation (EC) No. 1907/2006 REACH.

15.2 Chemical safety assessment

No data available

16 OTHER INFORMATION

Update in line with REACH/CLP/GHS regulations

This MSDS contains only safety-related information. For other data, contact with GOLD STANDARD DIAGNOSTICS MADRID.

NOTE

Although the information and recommendations contained in this GOLD STANDARD DIAGNOSTICS MADRID Material Health and Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility its accuracy, sufficiency or reliability or for any loss or injury resulting from use of this information.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 28 of 34

REAGENT Microtitre plates

1 IDENTIFICATION:

- 1.1 **Product Name:** Coated plates
 1.2 **Product use:** Laboratory reagent for diagnostic or research use

2 HAZARDS IDENTIFICATION:

Statement of hazardous nature: Non hazardous reagents are used in its composition.

Classification of the substance or mixture (CLP classification): It is not a substance neither a mix

2.1 Label elements

None: the product does not need to be labelled in accordance with EC directives or respective national law

2.2 Other hazards

Due to the composition and the concentration of the reagents fixed to this plate, it can be considered as non hazardous.

3 COMPOSITION/INFORMATION ON INGREDIENTS:

Polystyrene plates coated with MAb specific of gliadin, secalin and hordein.

4 FIRST AID MEASURES:

- Skin contact: Not applicable
 Eyes contact: Not applicable
 Inhalation: Not applicable
 Ingestion: Not applicable

5 FIRE AND EXPLOSION HAZARD DATA:

5.1 Extinguishing media

Choose suitable extinguishing media according to the environment.

5.2 Special hazards arising from the substance or mixture

The plastic components of the Microtitre Plates will melt and/or decompose under fire conditions. Once ignited, the plastic materials will add to the intensity of the fire and can be expected to emit hazardous gases, vapours, fumes and smoke particles.

5.3 Advice for fire-fighters

Wear self-contained breathing apparatus and protective suit for firefighting if necessary.

6 ACCIDENTAL RELEASE MEASURES:

Not applicable

7 HANDLING AND STORAGE:

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes.
 The reagent must be stored between 2° and 8°C.

8 EXPOSURE AND CONTROL:

Non special equipment is required.

9 PHYSICAL AND CHEMICAL PROPERTIES

- Physical state: Solid
 Boiling point: Not applicable
 Odour and appearance: Not applicable
 Solubility in water at 20°C: Not applicable
 Freezing point: Not applicable
 pH: Not applicable

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 29 of 34

10 STABILITY AND REACTIVITY

Stability: Not applicable
Incompatible materials: Not known

11 TOXICOLOGICAL INFORMATION

Toxicological properties: Not known

12 ECOLOGICAL INFORMATION

Toxicity: No known significant effects or critical hazards.
Persistence and degradability: No data available.
Bioaccumulative potential: No data available.
Mobility in soil: No data available.
Results of PBT and vPvB: No data available.
Other adverse effects: No data available.

13 DISPOSAL CONSIDERATIONS

Observe local, state and federal rules for proper disposal

14 TRANSPORT INFORMATION

The transport of this product is not regulated by IMO/IMDG, ADR/RID or IATA/ICAO as a hazardous material or dangerous goods.

15 REGULATORY INFORMATION

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

This safety data sheet complies with the amendment Regulation (EU) No. 2020/878 of the Regulation (EC) No. 1907/2006 REACH.

15.2 Chemical safety assessment

No data available

16 OTHER INFORMATION

Update in line with REACH/CLP/GHS regulations

This MSDS contains only safety-related information. For other data, contact with GOLD STANDARD DIAGNOSTICS MADRID.

NOTE

Although the information and recommendations contained in this GOLD STANDARD DIAGNOSTICS MADRID Material Health and Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility its accuracy, sufficiency or reliability or for any loss or injury resulting from use of this information.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 30 of 34

REAGENT: Extraction Buffer

1 IDENTIFICATION:

- 1.1 **Product Identifier:** Extraction Buffer
 1.2 **Product use:** Laboratory reagent for diagnostic or research use
 Chemical reagents are purchased from SIGMA, MERCK and PANREAC, and finally handled in GOLD STANDARD DIAGNOSTICS MADRID

2 HAZARDS IDENTIFICATION:


Statement of hazardous nature: Guanidium chloride is used in this composition.

Hazardous Ingredients	CAS NUMBER	REACH REGISTRATION NUMBER	Approximate concentration	Classification according to regulation (EC) No 1272/2008
Guanidinium chloride	50-01-1	-	19% p/v	Acute Tox. 4: H302 Eye irrit. 2:H319 Skin Irrit.2 :H315

2.1 **Classification of the substance or mixture (CLP classification)**

Acute Tox. 4: H302; Skin Irrit. 2: H315; Eye Irrit. 2: H319;

2.2 **Label elements**

Hazard pictograms	
Signal Word	Warning
Hazard Statement	Acute Tox. 4: H302 - Harmful if swallowed. Skin Irrit. 2: H315 - Causes skin irritation. Eye Irrit. 2: H319 - Causes serious eye irritation.
Precautionary Statement: Prevention	P264 - Wash thoroughly after handling. P270 - Do not eat, drink or smoke when using this product. P280 - Wear protective gloves/protective clothing/eye protection/face protection.
Precautionary Statement: Response	P301+P312 - IF SWALLOWED: Call a POISON CENTER/doctor/ /if you feel unwell. 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. P330 - Rinse mouth. P332+P313 - If skin irritation occurs: Get medical advice/attention. P337+P313 - If eye irritation persists: Get medical advice/attention.
Precautionary Statement: Disposal	P501 - Dispose of contents/container to an approved waste disposal facility in accordance with local and national regulations.

2.3 **Other hazards**

Not known.

3 COMPOSITION/INFORMATION ON INGREDIENTS:

3.1 **EC 1272/2008**

Chemical Name	Index No.	CAS No.	EC No.	REACH Registration Number	Conc.	Classification (%w/w)
Guanidinium chloride	607-148-00-0	50-01-1	200-002-3		10 - 20%	Acute Tox. 4: H302; Eye Irrit. 2: H319; Skin Irrit. 2: H315;

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 31 of 34

Description

Concentrations listed are not product specifications

Further information

Full text of Hazard Statements listed in this Section is provided in Section 16.

4 FIRST AID MEASURES:

4.1 Description of first aid measures

- Skin contact: Remove contaminated clothing. Wash with soap and water. Seek medical attention if irritation or symptoms persist
- Eyes contact: Rinse immediately with plenty of water. Contact lenses should be removed. Seek medical attention if irritation or symptoms persist.
- Inhalation: Move the exposed person to fresh air. If breathing is difficult give oxygen. If breathing stops, provide artificial respiration. Seek medical attention if irritation or symptoms persist.
- Ingestion: Do not induce vomiting unless told to do so by the poison control center or doctor. Rinse mouth thoroughly. Never give anything by mouth to an unconscious person. Get medical advice/attention if you feel unwell.

4.2 Most important symptoms and effects, both acute and delayed

- Symptoms/injuries: Not expected to present a significant hazard under anticipated conditions of normal use.
- Symptoms/injuries after inhalation: May cause dizziness and headache. May cause respiratory irritation.
- Symptoms/injuries after skin contact: May cause skin irritation.
- Symptoms/injuries after eye contact: May cause slight temporary irritation.
- Symptoms/injuries after ingestion: Harmful if swallowed. Ingestion may cause nausea and vomiting. May cause oral mucosal irritation.

4.3 Indication of any immediate medical attention and special treatment needed

Remove the affected person from the source of contamination immediately. Transfer to hospital if there are burns or symptoms of poisoning. Seek medical attention if irritation or symptoms persist. **If medical advice is needed, have product container or label at hand.**

5 FIRE AND EXPLOSION HAZARD DATA:

- 5.1 Extinguishing media: Use extinguishing media appropriate to the surrounding fire conditions.
- 5.2 Special hazards arising from the substance of mixture: Irritant. Do not breathe vapor or spray mist
- 5.3 Advice for firefighters: Do not breathe vapor or spray mist. Wear suitable respiratory equipment when necessary

6 ACCIDENTAL RELEASE MEASURES:

6.1 Personal precautions, protective equipment and emergency procedures

Use as appropriate: Protective equipment, Protective clothing. Ensure adequate ventilation of the working area. Avoid prolonged or repeated exposure.

6.2 Environmental precautions

Prevent further spillage if safe. Clean spillage area thoroughly with plenty of water. Do not flush into surface water. Do not let product contaminate subsoil.

6.3 Methods and material for containment and cleaning up

Prevent further spillage if safe. Absorb spillage to prevent material damage. Clean spillage area thoroughly with plenty of water. Do not contaminate water by cleaning of equipment or disposal of wastes.

6.4 Reference to other sections

See Section 2, 8 and 13 for further information

7 HANDLING AND STORAGE:

7.1 Precautions for safe handling

Adopt best Manual Handling considerations when handling, carrying and dispensing. Avoid contact with eyes. Do not eat, drink or smoke in areas where this product is used or stored. Ensure adequate ventilation of the working area. Do not contaminate water by cleaning of equipment or disposal of wastes. Read the entire label and follow all use directions, restrictions, and precautions. Use as appropriate: Protective clothing.

7.2 Conditions for safe storage, including any incompatibilities

The reagent must be stored between 2° and 8°C

7.3 Specific end use(s)

Laboratory use.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 32 of 34

8 EXPOSURE AND CONTROL:

8.1 Control parameters

Contains no substances with occupational exposure limit values

8.2 Exposure controls

Personal protective equipment is not required. Any case, we recommend wearing adequate laboratory clothes

- Engineering controls: Ensure adequate ventilation.
- Respiratory protection: None required.
- Hand protection: Wear disposable gloves while handling the reagent. Wash hands after use.
- Eye protection: Wear safety glasses with side-shields.
- Skin and body protection: Wear suitable protective clothing.

8.3 Environmental exposure controls

Non special controls are required

9 PHYSICAL AND CHEMICAL PROPERTIES:

- State: Liquid
- Color: Clear
- Odor : Odorless/Slight
- Odor threshold: No data available
- pH: No data available
- Melting point: No data available
- Freezing Point: No data available
- Boiling point: No data available
- Flash point: No data available
- Evaporation rate: No data available
- Flammability limits: Not applicable.
- Vapor pressure: No data available
- Vapor density: No data available
- Relative density: No data available
- Partition coefficient: No data available
- Autoignition temperature: No data available
- Viscosity: No data available
- Explosive properties: Not applicable.
- Oxidizing properties: No data available
- Solubility: Soluble in water

10 STABILITY AND REACTIVITY:

- 10.1 Reactivity:** Stable under normal conditions
- 10.2 Chemical stability** Stable under normal conditions
- 10.3 Possibility of hazardous reactions:** **Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.**
- 10.4 Conditions to avoid** **Keep away from extreme temperatures**
- 10.5 Incompatible materials** Not known

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 33 of 34

11 TOXICOLOGICAL INFORMATION

Information on toxicological effects

Acute toxicity

Harmful if swallowed. Ingestion may cause nausea and vomiting.

Skin corrosion/irritation

Causes skin irritation.

Serious eye damage/irritation

Causes serious eye irritation.

Respiratory or skin sensitization

May cause allergic reactions in susceptible people.

Germ cell mutagenicity

No mutagenic effects reported.

Carcinogenicity Not found to be a potential carcinogen in the International Agency for Research on Cancer (IARC)

Monographs, Volumes 1-123. Not listed in the National Toxicology Program (NTP) 14th Report on Carcinogens. Not listed in the American Conference of Governmental Industrial Hygienists (ACGIH) Guide to Occupational Exposure Values. Not listed in the OSHA standard 1910.1003 Carcinogens.

Reproductive toxicity. No teratogenic effects reported. STOT-single exposure May cause allergy or asthma symptoms or breathing difficulties if inhaled.

STOT-repeated exposure

Components(s) may cause damage to human organs based on animal data.

Aspiration hazard

No Significant Hazard.

Repeated or prolonged exposure

Avoid prolonged or repeated exposure.

Mixtures

See Section(s) 3 for further information.

Hazard Information

See Section(s) 2 and 3 for further information.

Toxicological information

Gliadin Renaturing Cocktail Solution

Oral Rat LD50: 2439 Dermal Rabbit LD50: 10204

Hazard Class

See Section(s) 2 and 14 for further information.

Classification Criteria

Based on the Globally Harmonized System (GHS) considerations for the classification of mixtures. See Section 15 for regulatory citations.

Information on likely routes of exposure

Eye contact. Ingestion. Skin contact.

Symptoms related to the physical, chemical and toxicological characteristics

See Section(s) 4.2 for further information.

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

See Section(s) 4.2 for further information.

Interactive effects

No data available.

Absence of specific data

<1% of this mixture consists of ingredients of unknown acute toxicity.

Mixture versus substance information

See Section(s) 3 for further information.

Other information

Caution - substance not yet fully tested.

12 ECOLOGICAL INFORMATION

Toxicity:

No known significant effects or critical hazards.

Persistence and degradability:

No data available.

Bioaccumulative potential:

No data available.

Mobility in soil:

No data available.

Results of PBT and vPvB:

No data available.

Other adverse effects:

No data available.

WGK:

Substance slightly dangerous for water.

PRODUCT: INGEZIM GLUTEN HIDROLIZADO

REF: 30.GLH.K.2

LAST REVISION: 06/23

Page 34 of 34

13 DISPOSAL CONSIDERATIONS

Observe local, state and federal rules for proper disposal.

14 TRANSPORT INFORMATION

The transport of this product is not regulated by IMO/IMDG, ADR/RID or IATA/ICAO as a hazardous material or dangerous goods.

15 REGULATORY INFORMATION

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

This safety data sheet complies with the amendment Regulation (EU) No. 2020/878 of the Regulation (EC) No. 1907/2006 REACH.

15.2 Chemical safety assessment

No data available

16 OTHER INFORMATION

Update in line with REACH/CLP/GHS regulations

This MSDS contains only safety-related information. For other data, contact with GOLD STANDARD DIAGNOSTICS MADRID.

NOTE

Although the information and recommendations contained in this GOLD STANDARD DIAGNOSTICS MADRID Material Health and Safety Data Sheet are compiled from sources believed to be reliable, we accept no responsibility its accuracy, sufficiency or reliability or for any loss or injury resulting from use of this information.