Chorus Gliadin-A (REF: 86054 and REF: 86054/12) is an immunoenzymatic method for the semi-quantitative determination of anti-Alpha Gliadin IgA antibodies in human serum. REF 86054: each package contains 6 bags with 6 devices each (sufficient for 36 determinations of total). REF 86054/12: each package contains 2 bags with 6 devices each (sufficient for 12 determinations of total).

Each kit consists of:

- **Device:**

  **Position 8:** Space for application of bar code label
  
  **Position 7:** Empty
  
  **Position 6:** MICROPLATE WELL
  Coated with alpha-gliadin
  
  **Position 5:** MICROPLATE WELL
  Uncoated.
  
  **Position 4:** TMB SUBSTRATE 0.400 ml.
  The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.
  For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.
  Contents: Tetramethylbenzidine 0.26 mg/mL and H₂O₂ 0.01% stabilized in 0.05 mol/L citrate buffer (pH 3.8)
  
  **Position 3:** SAMPLE DILUENT 0.400 ml
  The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.
  For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.
  Contents: Saline proteic solution containing Proclin
  
  **Position 2:** CONJUGATE 0.300 ml
  The substance is not classified as dangerous according to Regulation 1272/2008 and does not contain hazardous substances and/or with limit values for exposure in concentrations above the established limits.
  For this mixture, according to EC Regulations 1907/2006 and 453/2010, is not necessary to develop a material safety data sheet.
  Contents: anti-human IgA monoclonal antibodies labeled with horse radish peroxidase, in phosphate buffer containing phenol 0.05% and Bronidox 0.02%.
  
  **Position 1:** EMPTY WELL
  In which the operator must place the undiluted serum
  
  - **CALIBRATOR** 0.175 ml
    Diluted human serum containing anti-Gliadin IgA antibodies and Proclin.
  
  - **POSITIVE CONTROL** 0.425 ml
    Diluted human serum containing anti-Gliadin IgA antibodies and Proclin.

Both the mixtures are classified as **dangerous** according to Regulation 1272/2008/EC. For these mixtures, the material safety data sheet, prepared in accordance with EC regulations 1907/2006 and 453/2010, is available below.
1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 PRODUCT IDENTIFIERS

Product name: CALIBRATOR/POSITIVE CONTROL
Product number: 86840-C1 (CAL) 86840-C2 (POSITIVE CONTROL)
Brand: DIESSE

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCES OR MIXTURE AND USES ADVISED AGAINST

Identified use: Professional use as laboratory reagents.
Calibrator: diluted human serum, necessary for the calibration of the instrument.
Positive Control: diluted human serum, used to verify the correctness of the obtained results and for the subsequent validation of the test.

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Company: DIESSE Diagnostica Senese SpA
Registered office: Via A. Solari 19
Production plant: Via delle Rose, 10 – Loc. Tognazza
Tel: +39 02 4859121
Fax: +39 02 48008530
Tel: +39 0577 319560/61
Fax: +39 0577 318763

1.4 EMERGENCY TELEPHONE NUMBER

Emergency number: Centro Antiveleini, Ospedale Niguarda Ca’ Granda - Milano
Tel: +39 02 66101029

Centro Antiveleini, Azienda Ospedaliera “S.G.Battista” – Molinette di Torino - Torino
Tel: +39 011 6637637

Centro Antiveleini – U.O. Tossicologia Medica, Azienda Ospedaliera Careggi – Firenze
Tel: +39 055 4277238

Centro Antiveleini, Policlinico A. Gemelli – Università Cattolica del Sacro Cuore - Roma
Tel: +39 06 3054343

Centro Antiveleini, Azienda Ospedaliera A. Cardarelli – Napoli
Tel: +39 81 7472870


2. HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCES OR MIXTURE

Classification according to Regulation (EC) No. 1272/2008:
Skin Sensitizer– Category 1

Hazard statement:
H317 – May cause an allergic skin reaction.

2.2 LABEL ELEMENTS

Pictograms: GHS07

Signal word: Warning

Hazard statement(s):
H317 – May cause an allergic skin reaction.

Precautionary statement(s):
Prevention:
P261 – Avoid breathing dust/fume/gas/mist/vapors/spray.
P272 – Contaminated work clothing should not be allowed out of the workplace.
P280 – Wear protective gloves/protective clothing/eye protection/face protection.

Response:
P302+P352 – IF ON SKIN: Wash with plenty of soap and water.
P333+P313 – If skin irritation or rash occurs: Get medical advice/attention.
P363 – Wash contaminated clothing before reuse.
Disposal:
P501- Dispose of contents/container in accordance with local regulation

Contains:
Reaction mass of: 5-chloro-2-methyl-4-iso-thiazolin-3-one [EC no. 247-500-7] and 2-methyl-2H -isothiazol-3-one [EC no. 220-239-6] (2:1);
Index No: 613-167-00-5

2.3 OTHER HAZARDS
None

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 SUBSTANCES
Not applicable

3.2 MIXTURES

<table>
<thead>
<tr>
<th>International Chemical Identification</th>
<th>Concentration</th>
<th>Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reaction mass of: 5-chloro-2-methyl-</td>
<td>0.0015-0.06%</td>
<td>Acute Tox. 3</td>
</tr>
<tr>
<td>4-iso-thiazolin-3-one [EC no. 247-</td>
<td></td>
<td>H331</td>
</tr>
<tr>
<td>500-7] and 2-methyl-2H -isothiazol-</td>
<td></td>
<td>Acute Tox. 3</td>
</tr>
<tr>
<td>3-one [EC no. 220-239-6] (3:1);</td>
<td></td>
<td>H301</td>
</tr>
<tr>
<td>Cas No 55965-84-9</td>
<td></td>
<td>Skin Corr. 1B</td>
</tr>
<tr>
<td>Index No 613-167-00-5</td>
<td></td>
<td>Skin Sens. 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Acute 1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Aquatic Chronic 1</td>
</tr>
</tbody>
</table>

The entire text of Hazard Statements is reported at Section 16 of the sheet.

4. FIRST AID MEASURES

4.1 DESCRIPTION OF FIRST AID MEASURES

General advice:
Move the person from the exposure to open air. Consult a physician immediately and show this Material Safety Datasheet.

Skin contact:
Wear off the contaminated clothes and wash with copious amounts of water.

Eye contact:
If present, remove immediately contact lenses. Wash with plenty of water at least 15 minutes, keeping eyelids opened. Consult an oculist if the irritation persists.

Inhalation:
Consult a physician

Ingestion:
Rinse mouth immediately and drink a copious amounts of water. Call a physician immediately. Do not cause vomiting.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS
No data available

4.3 INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED
No data available

5. FIREFIGHTING MEASURES

5.1 EXTINGUISH MEDIA

Suitable extinguishing media:
Use extinguishing measures (water, CO₂, foam, powder) that are appropriate to local circumstances and the surrounding environment

Not Suitable extinguishing media:
None

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE
The mixture is not flammable, however in case of fire may release irritating and/or toxic gases (CO₂, CO, NOₓ, SOₓ, HCl).

5.3 ADVICE FOR FIREFIGHTERS
In case of fire wear self-contained breathing apparatus. Avoid that fire extinguishing water contaminates surface water and/or groundwater.
6. ACCIDENTAL RELEASE MEASURES

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES
Keep people not involved in the intervention operations away. Avoid inhalation contact with vapors/aerosols. Ensure an adequate ventilation of the affected area. Do not handle damaged containers or the leaked product before wearing appropriate protective outfit.

6.2 ENVIRONMENTAL PRECAUTIONS
Avoid the contamination of surface water, soil and the dispersion in the air. Do not let product enter into drains. Discharge into the environment must be avoided.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP
Contain the leakages with earth and sand. Collect the spilled material with mechanical means avoiding raising of dust and store it in suitable containers for disposal. Use water only to remove residuals, to avoid the danger of spill of product into the sewers.

6.4 REFERENCE TO OTHER SECTIONS
For further information see section 8 and 13.

7. HANDLING AND STORAGE

7.1 PRECAUTION FOR SAFE HANDLING
Work in well ventilated areas and in the presence of ventilation systems or personal protective equipment. Do not inhale vapors or mists. Avoid contact with eyes and skin.

7.2 CONDITION FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES
Keep the containers at 2-8°C in a cool, well-ventilated area, away from heat sources and from humidity.

7.3 SPECIFIC END USE
None

8. EXPOSURE CONTROL/PERSONAL PROTECTION

8.1 CONTROL PARAMETERS
Applicable exposure limits: The product contains no substances with occupational exposure limit value.

Other information:

8.2 EXPOSURE CONTROLS
Work and handle according to the usual precautionary measures for handling chemicals. Do not eat, drink or smoke while handling the product; wash hands thoroughly with soap and water before meals and after the work shift. Immediately remove all contaminated clothing.

Appropriate engineering controls: Ensure an adequate ventilation of the working area.

Personal Protective Equipment: The suggestions on the use of specific PPE are indicative. Their choice should be made according to the use of the product and the instructions given by the supplier of the device.

Hand protections:
Chemical-resistant gloves, compliant with EN 374.
Suitable material: nitrile rubber (thickness: 0.11 mm).
Gloves have to be checked by the user, before using.

Eye protections:
Side Shields Safety Goggles compliant with EN 166

Body protections:
Work outfits.

Respiratory protections:
Based on the results of the risk assessment the use a full face mask with combined filter type AP (EN 14387) may be need.
**MATERIAL SAFETY DATA SHEET**

**CALIBRATOR/POSITIVE CONTROL**

**CHORUS GLIADIN-A**


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### 8.3 Environmental Exposure Controls:

Do not discard residuals in the environment.

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### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### 9.1 Information on Basic Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance</td>
<td>Liquid</td>
</tr>
<tr>
<td>Odor</td>
<td>Odorless</td>
</tr>
<tr>
<td>Odor threshold</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>pH</td>
<td>No data available</td>
</tr>
<tr>
<td>Melting point/freezing point</td>
<td>No data available</td>
</tr>
<tr>
<td>Initial boiling point and boiling range</td>
<td>No data available</td>
</tr>
<tr>
<td>Flash point</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Evaporation rate</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Flammability</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Upper/lower flammability or explosive limit</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Vapor pressure</td>
<td>No data available</td>
</tr>
<tr>
<td>Vapor density</td>
<td>No data available</td>
</tr>
<tr>
<td>Relative density</td>
<td>No data available</td>
</tr>
<tr>
<td>Water solubility</td>
<td>Soluble in water</td>
</tr>
<tr>
<td>Partition coefficient: n-octano/water</td>
<td>No data available</td>
</tr>
<tr>
<td>Autoignition temperature</td>
<td>Not pertinent</td>
</tr>
<tr>
<td>Decomposition temperature</td>
<td>No data available</td>
</tr>
<tr>
<td>Viscosity</td>
<td>No data available</td>
</tr>
<tr>
<td>Explosive properties</td>
<td>Not explosive</td>
</tr>
<tr>
<td>Oxidizing properties</td>
<td>No data available</td>
</tr>
</tbody>
</table>

#### 9.2 Other Safety Information

None

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### 10. STABILITY AND REACTIVITY

#### 10.1 Reactivity

No data available

#### 10.2 Chemical Stability

Stable under the recommended transport, handling and storage conditions

#### 10.3 Possibility of Hazardous Reactions

No data available

#### 10.4 Conditions to Avoid

Avoid the formation and dispersion of vapors.

#### 10.5 Incompatible Materials

Strong oxidizing and reducing agents.

#### 10.6 Hazardous Decomposition Products

When heated or in case of fire, vapors potentially dangerous to health may be produced.

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### 11. TOXICOLOGICAL INFORMATION

#### 11.1 Information on Toxicological Effects

The product in case of skin contact may cause an allergic reaction.

<table>
<thead>
<tr>
<th>Effect</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Skin irritation/corrosion</td>
<td>No data available</td>
</tr>
<tr>
<td>Eye lesions/severe eye irritation</td>
<td>No data available</td>
</tr>
<tr>
<td>Respiratory/skin sensitization</td>
<td>No data available</td>
</tr>
<tr>
<td>Mutagenicity for germ cells</td>
<td>No data available</td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>No data available</td>
</tr>
<tr>
<td>Toxicity for target organs (single and repeated exposures)</td>
<td>No data available</td>
</tr>
<tr>
<td>Hazards in case of inhalation</td>
<td>No data available</td>
</tr>
</tbody>
</table>
12. ECOCLOGICAL INFORMATION

12.1 TOXICITY

Use according to the good working practices, avoiding the disposal in the environment. In case the product reach waterways or sewers or contaminate soil or vegetation, inform the competent authorities.

12.2 PERSISTENCE AND DEGRADABILITY

No data available

12.3 BIOACCUMULATIVE POTENTIAL

No data available

12.4 MOBILITY IN SOIL

No data available

12.5 RESULTS OF PBT AND vPvB ASSESSMENT

No data available

12.6 OTHER ADVERSE EFFECTS

No data available

13. DISPOSAL CONSIDERATIONS

13.1 WASTE TREATMENT METHODS

The product and its containers should be considered special waste. Their transport and disposal should be performed by authorized specialized companies according to the law.

14. TRANSPORT INFORMATION

Not hazardous good according to the transport regulations.

15. REGULATORY INFORMATION

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

Hazard classification and labeling under directives 1272/2008 (EC) and its subsequent amendments.

Legislative Decree 81/2008:
The use of this chemical entails the obligation of "Risk Assessment" by the employer in accordance with the provisions of the Decree April 9, 2008 n. 81 and subsequent amendments. Workers exposed to this chemical agent must not undergo health checks whether the results of the risk assessment show that, depending on the type and quantity of chemical agent and the method and frequency of exposure to this agent, there is only one "Low risk to the safety and irrelevant to the health" of the workers and the measures provided for in the same Decree are sufficient to reduce the risk.

European Standard 1907/2006/EC:
Not applicable

Directive 96/82/EC (Seveso Directive):
Not applicable

15.2 CHEMICAL SAFETY ASSESSMENT

Not performed for the product

16. OTHER INFORMATION

This product has to be used for diagnostic use only by personnel who is qualified and trained on the hazards shown in this safety sheet.

Text of the hazard statements present at point 3
H301 Toxic if swallowed
H311 Toxic in contact with skin
H314 Causes severe skin burns and eye damage
H317 May cause an allergic skin reaction
H331 Toxic if inhaled.
H400 Very toxic to aquatic life.
H410 Very toxic to aquatic life with long lasting effects.
REFERENCES:
1. Directive 1999/45/EC and following amendments
2. Regulation (EC) 1907/2006 of the European Parliament (REACH) as amended
5. ECHA European Chemicals Agency www.echa.europa.eu
6. The Merck Index.
7. Handling Chemical Safety
8. NIOSH - Registry of Toxic Effects of Chemical Substances
9. INRS - Fiche Toxicologique

DIESSE Diagnostica Senese SpA declares that the information contained in this data sheet is based on the knowledge available to us on the date of the last version. Users must verify the suitability and accuracy of the provided information according to the specific use of the product. The document has not be accepted as a guarantee of any specific product property. Because of the use of this product is not subject to our direct control, the users, under their own responsibility, must observe the laws and regulations relating to health and safety. We accept no responsibility for improper use.

This data sheet supersedes each previous edition.