

Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

1.1 Product identifiers

Product Name: **AllerFlow Gluten**
Product Number: ALF-GL
Brand: Hygiena

1.2 Recommended use and restrictions on use

Identified use: Environmental Gluten Surface Residue Test Kit
Restriction on use: These products are not intended for human or animal diagnostics, therapeutic, or other clinical uses. Use per manufacturer's instructions only.

1.3 Details of the supplier of the safety data sheet

Company: Hygiena USA
941 Avenida Acaso
Camarillo, CA 93012
USA
Telephone: 805-388-8007
Fax: 805-388-5531
E-mail: info@hygiena.com

1.4 Emergency telephone number

Emergency Phone: 1-888-494-4362

2. HAZARDS IDENTIFICATION

2.1 Hazard Classification:

Not classified as hazardous according to OSHA Hazard Communication Standard 29 CFR 1910.1200, Regulation EC No. 1272:2008 [CLP/GHS] and WHIMS 2015 (HPR) Hazardous Products Regulation SOR 2015-17.

2.2 Label elements and precautionary statements:

Not a hazardous substance or mixture.

2.3 Hazards not otherwise clarified:

None

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS #	% by Wt
Tris (hydroxymethyl) aminomethane	77-86-1	0.24%
Sodium Chloride	7667-14-5	2.9%
EDTA	6381-92-6	0.74%
Tween 20	9005-64-5	1.0%
Mouse monoclonal Anti-Glia33mer	<i>Confidential trade secret information</i>	< 1%
Immunochromatographic Cassette	<i>Confidential trade secret information</i>	

FORM: The kit consists of: A plastic cassette with a dry strip, a device with 0.65mL of solution in the bulb and wet swabs in the tube. If used according to manufacturer's instructions; the solution in bulb will not come in contact with the operator.

4. FIRST AID MEASURES

4.1 Description of first aid measures

4.2 Inhalation:

If breathed in, move person into fresh air. If not breathing give artificial respiration and seek medical advice.

4.3 Skin contact:

Wash with soap and plenty of water and seek medical advice.

4.4 Eye contact:

Flush eyes with large amounts of water. Remove contact lenses if easy to do. Continue rinsing. If symptoms persist, get medical attention.

4. FIRST AID MEASURES (Continued)

4.5 If swallowed

Never give anything by mouth to an unconscious person. Rinse mouth with water and seek medical advice.

4.6 Most important symptoms and effects, both acute and delayed

None anticipated.

4.7 Indication of any immediate medical attention and special treatment needed

Not anticipated.

5. FIRE-FIGHTING MEASURES

5.1 Extinguishing media

Not readily combustible. Burning plastic will give out fumes.

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

None inherent in the products. Burning plastic will create carbon and nitrogen oxides.

5.3 Advice for firefighters

Wear self-contained breathing apparatus for firefighting if necessary.

5.4 Further information

Use water spray to cool unopened containers.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions protective equipment and emergency procedure

Ensure adequate ventilation. For personal protection see section 8.

6.2 Environmental precautions

Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Contain spill, collect using commercially available inorganic absorbent material and place in container for disposal according to local regulations (see section 13).

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Do not eat, drink or smoke when using this product. Wash hands after handling.

7.2 Conditions for safe storage, including any incompatibilities

Stable under recommended storage conditions.

7.3 Specific end use(s)

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

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice.

Wash hands after use.

Personal protective equipment

Eye/face protection

No eye protection required, safety goggles may be used for added protection.

Skin/hand protection

No protective gloves are required, but may be used for added protection. Wash hands after use.

Respiratory protection

Respiratory protection is not required for intended use.

Control of environmental exposure

Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

- | | | |
|---|--------|--|
| a) Appearance | Form: | The kit consists of: a device with 0.5mL of solution in the bulb and wet swabs in the tube. If used according to manufacturer's instructions; the solution in will not come in contact with the operator. A plastic cassette with a dry strip. |
| b) | Color: | colorless |
| c) Odor | | Odorless |
| d) Odor Threshold | | Not applicable |
| e) pH | | Neutral |
| f) Melting point/
freezing point | | No data available |
| g) Initial boiling point
and boiling range | | No data available |
| h) Flash point | | No data available |
| i) Evaporation rate | | No data available |
| j) Flammability
(solid, gas) | | Not applicable |
| k) Upper/lower
flammability or
explosive limits | | No data available |
| l) Vapour pressure | | No data available |
| m) Vapour density | | No data available |
| n) Specific Gravity | | No data available |
| o) Water solubility | | Readily miscible with water |
| p) Partition coefficient:
n-octanol/water | | No data available |
| q) Auto-ignition
temperature | | Not applicable |
| r) Decomposition
temperature | | No data available |
| s) Viscosity | | No data available |
| t) Explosive properties | | No data available |
| u) Oxidizing properties | | No data available |

10. STABILITY AND REACTIVITY

10.1 Reactivity

Product is considered non reactive under normal intended use.

10.2 Chemical stability

Stable under recommended storage conditions.

10.2 Possibility of hazardous reactions

No data available

10.4 Conditions to avoid

Heat and direct sunlight.

10.5 Incompatible materials

No data available.

10.6 Hazardous decomposition products

Plastic components may emit toxic fumes if combusted

11. TOXICOLOGICAL INFORMATION

Skin corrosion/irritation

No data available

Serious eye damage/eye irritation

No data available

Respiratory or skin sensitisation

No data available

11. TOXICOLOGICAL INFORMATION (Continued)

Germ cell mutagenicity

No data available

Carcinogenicity

IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

Reproductive toxicity

No data available

Specific target organ toxicity - single exposure

No data available

Specific target organ toxicity - repeated exposure

No data available

Aspiration hazard

No data available

Additional Information

RTECS: Not available

12. ECOLOGICAL INFORMATION

12.1 Toxicity

No data available

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

Not applicable

13. DISPOSAL CONSIDERATIONS

Product

Observe local, State and Federal environmental regulations.

Contaminated packaging

Dispose of as unused product.

14. TRANSPORT INFORMATION

DOT (US)

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

No special precautions needed for transport either within or outside premises.

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of OSHA Hazard Communication Standard 29 CFR 1910.1200, Regulation EC No. 1272:2008 [CLP/GHS] and WHIMIS 2015 (HPR) Hazardous Products Regulation SOR 2015-17.

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

No data available

SARA 302 Components

No components are subject to reporting levels established by SARA Title III, Section 302.

SARA 313 Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

SARA 311/312 Components

No SARA Hazards

15. REGULATORY INFORMATION (Continued)

Massachusetts Right To Know Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by Massachusetts Right To Know.

Pennsylvania Right To Know Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by Pennsylvania Right To Know.

New Jersey Right To Know Components

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by New Jersey Right To Know.

California Prop. 65 Components

This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

16. OTHER INFORMATION

The product is non hazardous according to OSHA Hazard Communication Standard 29 CFR 1910.1200, EC No. 1272:2008 [CLP/GSH] and WHIMS 2015 HPR Hazardous Products Regulation SOR 2015-17, and therefore the product is not considered hazardous.

The information on this SDS is based on the SDSs for the ingredients provided by the manufacturers.

The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. Hygiena and its affiliates shall not be held liable for any damage resulting from handling or from contact with the above product.

Preparation Information

Hygiena USA
Product Safety
1-888-494-4362

Issued Date: 12/22/16

Revision: B

End of Safety Data Sheet