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1. Identification of the mixture and the company

1.1. Product identity

Trade name: Anti-MuSK IFA 60 determinations
Article no.: 8049

1.2. Use

Anti-MuSK IFA is a reagent set for the qualitative and semi-quantitative measurement of antibodies against the MuSK antigen in human serum. For this HEp-2 cells, which have been transfected with MuSK antigens.

1.3. Manufacturer

GA Generic Assays GmbH
Ludwig- Erhard- Ring 3
15827 Dahlewitz
Tel: +49-(0)33708-9286-0
Fax: +49-(0)33708-9286-50
Internet: www.genericassays.com
E-mail: info@genericassays.com

1.4. Emergency numbers

GA Generic Assays GmbH Tel.: +49-(0)033708 9286-0

2. Possible hazards

2.1. Classification of the contents

The product / product components are, in accordance to EU regulation 1272/2008/EG, **classified as non-hazardous.**

2.2. Identification elements

According to 1272/2008/EG: none

2.3. Other hazards

The product/product components contain preservatives, which in the present concentrations can cause skin sensitization and weak water pollution. As there are always certain dangers associated with chemicals, the product/product component should only be handled by appropriately trained persons, using proper chemical safety precautions.

Results of the PBT/vPvB evaluation: not applicable

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3. Composition / Information on ingredients

3.1. Description of ingredients

| Component | Ingredients | Preservative |
|--------------------|--|---------------------|
| Slide | coated with HEp-2 MuSK cells and wells coated with HEp-2 cells | |
| PBS Buffer | Na ₂ HPO ₄ , NaH ₂ PO ₄ ; NaCl | |
| Conjugate 1 | anti-human-IgG (heavy- and light-chain specific), labeled to Biotin | 0.09% Sodium azide |
| Conjugate 2 | Streptavidin- labeled to FITC | 0.09% Sodium azide |
| Positive control | diluted human serum | 0.09% Sodium azide |
| Negative control | diluted human serum | 0.09% Sodium azide |
| Mounting medium | Na ₂ HPO ₄ , NaH ₂ PO ₄ , NaCl, Glycerin | 0.09% Sodium azide |
| Blotting templates | | |

3.2. Hazardous components and their concentrations

| CAS No. | EINECS No. | Ingredient | Percent | Classification (in conc. Form) to 1272/2008/EG |
|----------------|-------------------|-------------------|----------------|--|
| 26628-22-8 | 247-852-1 | Sodium azide | < 0.1 | T+ N Acute tox. 2, H300 Aquatic acute 1, H400 Aquat. Chronic 1, H410 |

The full wording of the listed hazard warnings is given in section 16.

4. First aid measures

4.1. Description of first aid measures

Due to the very low concentrations of the hazardous ingredients in the product/components, consultation of a doctor is not necessary.

In cases of contact with skin, wash with copious amounts of water.

In cases of contact with eyes, rinse out for several minutes with water, with eyelids open.

In cases of swallowing, rinse out and drink copious amounts of water.

4.2. Important symptoms and effects

There are no known acute or delayed onset symptoms and effects.

4.3. Indications for immediate medical assistance and special handling

Where necessary consult an ophthalmologist.

Wash contaminated clothing before reuse.

5. Fire-fighting measures

5.1. Extinguishers

Extinguishers indicated: water spray, foam, powder.

5.2. Special hazards arising from the contents

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With fire, sodium azide can release poisonous fumes.

5.3. Notes on firefighting

Surround the fire with appropriate extinguishing material.
If necessary use breathing apparatus and protective clothing for firefighting.

6. Accidental release measures

6.1. Personal precautions

Observe the safety regulations of the laboratory.
To minimize the risk of contact with the skin and eyes, wear appropriate protective clothing. Do not swallow, do not pipette by mouth.

6.2. Environmental precautions

Do not release into drains/surface water/ground water.

6.3. Methods and materials for containment and cleaning

Contain spills with absorbent material, and dispose of appropriately. Following complete removal of the material, clean the affected area thoroughly.

6.4. Reference to other sections

Information on appropriate protective clothing can be found in section 8.2.
For disposal, consult section 13.

7. Handling and Storage

7.1. Protective measures for safe handling

Apart from the usual laboratory safety regulations, no particular protective measures are required.
Information on required protective clothing can be found in section 8.2.

7.2. Conditions for safe storage, including any incompatibilities

When well sealed according to instructions on the product components, storage at 2 - 8°C or -20°C

7.3. Specific end-uses

No further relevant information available.

8. Exposure controls / personal protection

8.1. Parameters/exposure values to be observed

| CAS No. | Ingredient | MAK or AGW (from TRGS 900) |
|------------|--------------|----------------------------|
| 26628-22-8 | Sodium azide | 0.2 mg/m ³ |

With appropriate use of the pack/pack contents, no air pollution is expected.

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8.2. Limitations and monitoring of exposure

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|--------------------------------|--|
| <i>Respiratory protection:</i> | Not required |
| <i>Gloves:</i> | Nitrile or natural latex laboratory gloves |
| <i>Eye protection:</i> | Safety goggles |
| <i>Bodily protection:</i> | Appropriate laboratory wear |

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

| Kit Components | Appearance | odor | pH | solubility |
|-----------------------|-------------------|-------------|-----------|-------------------|
| Slide | na | no | na | na |
| PBS Buffer | colorless | no | 7.4 | na |
| Conjugate 1 | colorless | no | na | na |
| Conjugate 2 | colorless | no | na | na |
| Positive control | colorless | no | na | na |
| Negative control | colorless | no | na | na |

9.2. Other properties

Solubility in / miscibility with water: complete

10. Stability and reactivity

10.1. Reactivity

There are no chemical reactive properties of the product / product components

10.2. Chemical stability

Within the stated storage temperatures and expiry dates, the product / components are chemically stable.

10.3. Possible hazardous reactions

In high concentrations sodium azide and heavy metals, such as copper and lead, can form explosive complexes.

10.4. Conditions to be avoided

Strong light sources can negatively influence the functional ability of the conjugate.

10.5. Incompatible materials

Acids, alkalis and solvents can negatively influence the functional ability of the product / components.

10.6. Hazardous decomposition products

Within the stated storage and handling conditions, the product / components product no known hazardous decomposition products.

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11. Toxicological information

11.1. Information on toxicological effects

Acute Toxicity

| Ingredient | Measurant | Value | Species |
|-------------------|-------------------------|--------------|----------------|
| Sodium azide | LD ₅₀ (oral) | 27 mg/kg | Rat |

Other health effects

| Ingredient | Irritation and corrosion | Sensitization | CMR Effect |
|-------------------|---------------------------------|----------------------|-------------------|
| Sodium azide | No data available | No data available | No data available |

12. Ecological information

12.1. Toxicity

| Ingredient | Measurand | Value | Species |
|-------------------|------------------|--------------|----------------|
| Sodium azide | LC ₅₀ | 0,68 mg/l | Sun perch |
| Sodium azide | EC ₅₀ | 4,2 mg/l | Daphnia pulex |

12.2. Persistence and biodegradability

| Ingredient | Measurand | Value | Remarks |
|-------------------|-------------------|--------------|----------------|
| Sodium azide | No data available | | |

12.3. Bioaccumulation potential

No data available

12.4. Mobility in soil

No data available.

12.5. Results of PBT and vPvB analyses

No data available.

12.6. Other harmful effects

Due to the very low concentration of hazardous ingredients in the product / components, no ecological problems are expected arising from their use.

Disposal considerations

13.1. Disposal methods

Product components

May not be disposed of with household waste.

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Residues of chemical preparations are usually classed as waste which must be disposed of according to the rules issued by the country and government. Information on the disposal of hazardous waste can be given by the local authorities (agency or authorized waste disposal contractor).
Radioactive material is to be disposed of in special waste containers suited to this purpose.

Packaging

Disposal according to official regulations.

Contaminated packaging should be treated as per the product.

Non-contaminated packaging can be handled as household waste and be recycled, when regulations do not state otherwise.

14. Transport information

This product has no transport regulations

14.1. UN number

Not applicable

14.2. Transport hazard class

Not applicable

14.3. Packaging group

Not applicable

14.4. Environmental hazard

Not applicable

14.5. Special precautions for users

Not applicable

14.6. Mass transport in accordance with appendix II MARPOL agreements 73/78 and IBC code

Not applicable.

15. Regulatory information

This safety data sheet fulfils the requirements of regulation 91/155 EG on the registration, evaluation, authorization and restriction of chemicals, (REACH), and the regulation 1999 /45/ EG on the classification, labeling and packaging of chemicals and mixtures, as well as the regulation 453/2010/EG on the production of safety data sheets.

15.1. Safety, health and environmental regulations/ regulations specific to this substance or mixture

When handling the product, the current regulations for handling potentially infectious human sample material should be observed.

Product classification to1272/2008/EG: Skin sensitizing, category 1

Water pollution class: WPC 1 (self-assessment), weakly water polluting

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15.2 Chemical safety assessment

A chemical safety assessment has not been performed.

16. Other information

Full text of risk phrases listed in section 3.2.

| | |
|--------|--|
| R24/25 | Toxic upon contact with the skin or swallowing |
| R28 | Very toxic upon swallowing |
| R32 | Upon contact with acid produces very poisonous gases |
| R34 | Causes burns |
| R43 | Possible sensitization on skin contact |
| R50 | Very poisonous to water organisms |
| R52/53 | Harmful to water organisms, can have long lasting effects in water |
| R53 | Can have long lasting effects in water |
| | |
| H300 | Life-threatening if swallowed |
| H302 | Harmful to health if swallowed |
| H314 | Causes severe skin burns and eye damage |
| H317 | Can cause allergic skin reactions |
| H400 | Very poisonous to water organisms |
| H410 | Very poisonous to water organisms with long-term effects |

Abbreviations and acronyms

| | |
|----------|---|
| AGW | Arbeitsplatzgrenzwert (workplace limit) |
| AP | Alkaline Phosphatase |
| BCIP | Bromo-Chloro-Indolyl-Phosphate |
| BSA | Bovine serum albumin |
| CAS | Chemical Abstract Service (division of the American Chemical Society) |
| CLP | Regulation of Classification, Labelling, and Packaging of Substances and Mixtures |
| CMR | cancerogenic, mutagenic or reprotoxic |
| EC50 | Effective concentration for 50 % of subjects |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| GHS | Globally Harmonized System of Classification and Labeling of Substances |
| IBC-Code | International Code for the Construction and Equipment of Ships carrying dangerous Chemicals in Bulk |
| IARC | International Agency for Research on Cancer |
| LD50 | Lethal dose for 50 % of subjects |
| LC50 | Lethal concentration for 50 % of subjects |
| MAK | Maximale Arbeitsplatzkonzentration (maximum workplace concentration) |
| MARPOL | International Convention for the Prevention of Pollution from Ships |
| MIT | Methyliso Thiazolones |
| NBT | Nitrotetrazolium-Chlorideblue |
| OECD | Organization for Economic Co-operation and Development |
| PBT/vPvB | Persistent, bioaccumulative, and toxic substances / very persistent and very bioaccumulative substances |
| REACH | Registration, Evaluation, and Authorisation of Chemicals |
| TRGS | Technische Regeln für Gefahrstoffe (technical regulations for hazardous chemicals) |
| TBS | Tris buffered saline |
| USDA | US Department of Agriculture |

The information given is based on our most current knowledge. It is intended to describe our products in terms of safety requirements, and should be seen by users as a guide. It does not form a guarantee of

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any specific product features, and does not constitute a legal relationship or state liability for damages which may arise from handling or having contact with this product/product components.