



Safety Data Sheet

According to regulation (EG) 1907/2006

1. Substance/preparation and company identification

Substance/preparation identification:

Article description: Avidity: Anti-Rubella Virus ELISA (IgG)
Order No.: EI 2590-9601-1 G

Usage of the substance/preparation:

This test kit is intended for the avidity determination of IgG class antibodies against Rubella virus in human serum or plasma.

Company identification:

Manufacturer: **EUROIMMUN Medizinische Labordiagnostika AG**
Seekamp 31
23560 Lübeck, Germany
Phone: ++49 (0)451-5855-0; Fax: ++49 (0)451/5855-591 (office hours: 7:00 – 17:00)
E-Mail: euroimmun@euroimmun.de

Emergency information:

Germany: Poisons Information Centre North ++49 (0)551 19240
Austria: Poisons Information Centre Tel. ++43 14064343
Switzerland: Toxicological Information Centre Zürich Tel. ++41 1 2515151
(emergency number: **145**)

2. Potential hazards

Classification of the substance or mixture

In this composition, the product is not hazardous according to the EC directive 1999/45/EC.
The preparation is not subject to specific labelling requirements according to the directive 67/548/EEC.

3. Composition/specifications of components

General description:

The test kit contains microplate strips each with 8 break-off reagent wells coated with Rubella virus antigens. In the first reaction step, diluted patient samples are incubated in the wells. In the case of positive samples, specific IgG antibodies (also IgA and IgM) will bind to the antigens. In the second incubation step, low-avidity antibodies are dissolved from the antigen by means of urea treatment, high-avidity antibodies remain bound. To detect the bound antibodies, a third incubation is carried out using an enzyme-labelled anti-human IgG (enzyme conjugate) catalysing a colour reaction.

Hazardous components:

None

4. First aid procedures:

<i>General information</i>	- Consult a doctor if symptoms persist. Victims at risk of unconsciousness must be placed and transported in recovery position.
<i>In case of eye contact:</i>	- Rinse eye with lid open for several minutes with running water. - After eye contact consult a doctor even if no symptoms occur.
<i>In case of skin contact:</i>	- After contact with skin wash off with plenty of water immediately.
<i>In case of inhalation:</i>	- Ensure supply of fresh air. - Consult a doctor if illness occurs.
<i>In case of ingestion:</i>	- Get medical advice immediately. - Rinse mouth with water (only if victim is conscious). - Never induce vomiting. If vomiting occurs, place person in recovery position.



5. Fire fighting procedures

Suitable extinguishing agents: - Use extinguishing media suitable for the surroundings: foam, extinguishing powder, carbon dioxide, sand, water spray or fog

Particular hazards:

- Hazardous gases may be generated during a fire.
- In a large fire plastic vessels may melt, and the spilled product may release hazardous gases.
- Protect body, face and hands. If necessary, use self-contained breathing equipment.

6. Accidental release procedures

Take up with liquid-absorbent material (e.g. sand, sawdust, Chemizorb®). Dispose of absorbed material according to the regulations. Flush small spilled quantities into an outflow with plenty of water. Ensure adequate air ventilation. Avoid skin and eye contact with released liquids. Use personal protective equipment.

7. Handling and storage

Handling: - Keep container closed tightly.

Storage:

- Keep container closed tightly.
- Store in a dry and preferably dark place at +2°C to +8°C.
- Protect from warming or overheating.

8. Exposure limits, monitoring personal protection equipment

Exposure limits

Does not contain any substances with limits for the workplace.

Limitation and monitoring of exposure:

Technical measures and the use of appropriate work processes take priority over the use of personal protective equipment.

Personal protective equipment:

General protection and hygiene measures:

- Avoid contact with skin and eyes
- Avoid formation of aerosols.
- Clean skin thoroughly after working. Apply skin care products, if necessary.
- Do not eat, drink or smoke at work.

Hand protection: - Gloves made of nitrile rubber.

Penetration properties: nitrile rubber: ≤ 480 min

Eye protection: - Wear protective glasses if necessary.

Inhalation protection: - Not necessary if used as intended.

Instructions for work hygiene:

Remove contaminated clothing. Wash and disinfect hands after working.

Limitation and monitoring of environmental exposure:

Do not allow to enter the drainage system.

9. Physical and chemical characteristics

Aggragate condition:	- not applicable.	Inflammability:	- not available
Colour	- not applicable.	Explosion limits lower:	- not available
Smell:	- not applicable.	upper:	- not available
pH value:	- not applicable.	Oxidising properties:	- not available
Viscosity:	- not available	Relative vapour density:	- not available
Melting point:	- not available	Density:	- not available
Boiling point/range	- not available	Solubility in water:	- not available
Flash point	- does not burn, is not oxidising	Distribution coefficient n-octane/water:	
Vapour density:	- not available	Evaporation rate:	- not available



10. Stability and reactivity

Conditions to be avoided: - According to test instruction
Substances to be avoided: - None
Hazardous decomposition products: - Stable under normal conditions.

11. Toxicological information

Acute toxicity:

Quantitative data on toxicology not available.

12. Environment-specific information

12.1 Ecotoxicity

No information available

12.2 Mobility

No information available

12.3 Persistence and degradability

No information available

12.4 Bioaccumulation potential

No information available

12.5 Results of PBT assessment

No information available

12.6 Other hazardous effects

Do not let reagents enter surface water or groundwater. Adhere to local regulations when discharging into public drainage systems. The function of public waste water treatment plants is not affected.

13. Information for disposal

Product:

There are no standardised regulations for the disposal of chemicals in EU member countries. In Germany the regulations are covered by the Recycling Management and Waste Management Law ((KrW/AbfG). Special cases are regulated by the states. Please contact the appropriate body (authorities or waste disposal companies). Adhere to local regulations when discharging working solutions into public drainage systems.

Packaging:

Packaging must be disposed of in compliance with the respective national regulations. Contaminated packaging must be disposed of in the same way as the substance. If no national regulations apply, dispose of as ordinary domestic waste or pass packaging to a packaging return system.



14. Transport information

Land transport ADR / RID and GGVS7GGVE:

no classification

Ship transport IMDG /GGV See:

no classification

Air transport ICAO; PAX; IATA:

no classification

The transport regulations are cited according to international regulations and in the form applicable in Germany (GGVSE). Possible national deviations in other countries have not been taken into account.

15. Statutory provisions

No chemical safety assessment has been performed for this product.

According to the principles of good laboratory practice, the usual precautions should be taken when handling chemical substances.

16. Other information

Not suitable for use in private households.

Version: 01 from 18/06/2020 Replaces Version: -

The above information is believed to be correct according to our current knowledge and serves as guidelines for the correct use of this product. All chemicals and preparations may have unknown hazardous potentials and should be handled with care.