

# Material Safety Data Sheet

According to Regulation (EC) No.1907/2006 (REACH) and No.453/2010

Version: 02, Revision Date: 31.08.2015

For Product:



**recoveryELISA IgE/Omalizumab Kit (RIO)**

**Product Code: R111**

MSDS comprises of the following individual components:

Name of Components	Marking	Volume
Sample dilution buffer	RIO-SAMPLE-BUF	1 x 6 mL
IgE calibrators 0-4	IgE-CAL 0-4	5 x 1 mL = 5mL
Therapy antibody calibrators 0-3	RIO-TAK 0-3	4 x 0.8 mL = 3.2 mL
Control	RIO-CONTROL	1 x 0.8 mL
Conjugate dilution buffer	RIO-CONJ-BUF	1 x 6mL
TMB reagent	RIO-TMB	1 x 10.5 mL
Stopping solution (1M H <sub>2</sub> SO <sub>4</sub> )	RIO-STOP-H2SO4	1 x 3 mL
Washing buffer concentrate	RIO-WASHBUF 10x	1 x 30 mL

Non-listed components do not contain any concentration of hazardous substances that require declaration. Labeling of components in these cases is not necessary.



## 1. Product and Company Identification

### **Product Information:**

- **Product Name:** *recovery*ELISA IgE/Omalizumab Kit (RIO)
- **Product Code:** R111
- **Use of the material / preparation:**  
Laboratory reagent / Immunoassay  
The product is intended for the professional user.

### **Manufacturer / Supplier:**

BioTeZ Berlin-Buch GmbH  
Robert Rösslestr. 10  
D-13125 Berlin  
Tel.: +49-30-9489 2130  
Fax.: +49-30-9494 509  
E-Mail: [info@biotez.de](mailto:info@biotez.de)  
<http://www.biotez.de>

**Further Information provider:** Safety Personnel

**Emergency contact:** +49-30-9489 2130

## 2. Potential Hazards

- **Hazard description:** Not applicable.
- **Information pertaining to particular dangers for man and environment:**  
The product is not subject to classification according to the calculation methods of the "General Classification Guideline for Preparations of the EU" as issued in the latest valid version. This product has no special effects on hazards. Please observe the information on the safety data sheet for special materials at all times.
- **Classification system according Regulation (EC) No.1272/2008 (CLP):**  
Only for Single-component Stopping solution with GHS05 Corrosivity  
Corrosive to metals 1 H290: May be corrosive to metals.  
Irritation of skin 2 H315: Causes skin irritation.  
Irritation of eyes 2 H319: Causes serious eye irritation.
- **Labelling according to Regulation (EC) No.1272/2008:**  
Only for Single-component Stopping solution with hazard pictogram:



GHS05 Signal word: Warning

### **Hazard Statement(s):**

H290: May be corrosive to metals.  
H315: Causes skin irritation.  
H319: Causes serious eye irritation.

**Precautionary statement(s):**

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

P305+P351+P338: IF IN EYES: Rinse continuously with water for several minutes.

Remove contact lenses if present and easy to do – continue rinsing.

P337+P313: Get medical advice/attention.

P302+P352: IF ON SKIN: Wash with soap and water.

• **Classification system according European Directive No 67/548 or 1999/45:**

Only for Single-component Stopping solution with Xi Irritant



**Xi Irritant**

R35/36: Irritating to eyes and skin.

• **Labelling according to European Directive No 67/548 or 1999/45:**

Only for Single-component Stopping solution with hazard pictogram:



**Xi Irritant**

R35/36: Irritating to eyes and skin.

S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

S37: Wear suitable gloves.

S45: In case of accident or if you feel unwell, seek medical advice immediately (show label where possible).


**3. Composition / Information on ingredients**



**Chemical characterization (Preparation)**

• **Description:**

Sample dilution buffer\*, IgE calibrators 0-4\*, Therapy antibody calibrators 0-3\*, Control\*, Conjugate dilution buffer\* and Washing buffer concentrate\* containing ProClin 300. TMB Reagent contains Tetramethylbenzidine. Stopping solution contains sulphuric acid.

• **Hazardous Substances:**

Registry Number CAS and EINECS	Chemical name ( pure ingredients)	Hazard symbol/ R-phrases (1)	Hazard symbol/ Hazard statements (2)	Quantity in components
CAS: 7664-93-9 EINECS: 231-639-5	<b>Sulphuric acid</b>	Xi, R 35	 Danger, Corrosive to metals 1; H290;Irritation of skin 1A ; H314	< 10% in Stopping solution

CAS: 54827-17-7 EINECS: 259-364-6	<b>3,3',5,5'- Tetramethyl- benzidine</b>	Xn R 20/21/22- 36/37/38-40	 Warning H315-319-335	<0,05% in TMB substrate
CAS-Nr.: 55965-84-9	2.3% 5-Chlor-2- methyl-2H- isothiazoline-3-on  0.70 % 2-Methyl-4- isothiazoline-3-on	T,N, R 23/24/25- R34-R43- R51/53	 Danger H302-314-317- 332-400-411	<0,06% in components: (*)

(1): according EC directive No 67/548 or 1999/45

(2): according to EC regulation No 1272/2008

• **Additional Information:**

The reagents contain material of animal origin. Despite testing, the presence of infectious agents can not be excluded with absolute certainty. The reagents should be treated as potentially infectious material. For the wording of the listed risk phrases, refer to section 16.

**4. First-aid measures**

- **General information:** No special measures required.
- **After inhalation:** Supply fresh air, consult a doctor.
- **After skin contact:** Rinse with water. The product generally does not irritate the skin. Caution with Stopping Solution (classified as skin irritant).
- **After eye contact:** Rinse the eyes with open eye lids for several minutes under running water.
- **After ingestion:** Seek immediate medical attention.

**5. Fire fighting measures**

- **Suitable extinguishing agents:**  
CO<sub>2</sub>, extinguishing powder or water spray. Major fires should be fought with water spray or alcohol resistant foam.
- **Protective equipment:** No special measures required.

**6. Accidental release measures**

- **Personal safety precautions:** Not required.
- **environmental protection:** Dilute with lot of water.
- **Measures for cleaning / collecting:** Absorb with absorbent material.
- **Additional information:** No dangerous substances are released.

## 7. Handling and Storage

### Handling:

- **Information on safe handling:** No special measures required.
- **Precautions against fire and explosion:** No special measures required.

### Storage:

- **Requirements for storage rooms and containers:** No special requirements.
- **Common Storage:** Keep away from food.
- **Further information on storage conditions:**  
The kit is shipped at ambient temperature and should be stored at 2-8 ° C.  
Protect from heat and direct sunlight. Information on storage and stability of prepared reagents is stated in the relevant chapters of the manual.
- **Storage class:** 8B for Stopping Solution
- **General Classification Guideline for Preparations of the EC :** no special requirements

## 8. Exposure controls and personal protective equipment

- **Components with critical values that require monitoring at the workplace:**  
The product contains no relevant quantities of materials with critical values that require monitoring at the workplace.

### Personal protective equipment:

- **General protective and hygiene measures:**  
The usual precautions for handling chemicals are observed.
- **Respiratory protection:** not required.
- **Protection of hands:** Protective gloves.
- **Glove material:** Chemical protective gloves should be selected according to the requirements of workplaces involved. The glove material has to be impermeable and resistant. Note the details about the product/ substance / preparation.
- **Eye protection:** Safety glasses are recommended.
- **Body protection:** Lab coat

## 9. Physical and chemical properties:

### General information:

- **Form:** Liquid
- **Colour:** Varied
- **Odor:** Odorless

### Change in condition:

- **Melting point / Melting range:** Not determined.
- **Boiling point / Boiling range:** Not determined.
- **Flash Point:** Not applicable.
- **Self-igniting:** Product is not explosive.
- **Danger of explosion:** Product is not explosive.
- **Density:** Not determined.
- **Solubility in / Miscibility with water:** Miscible.

## 10. Stability and reactivity:

- **Stability and Reactivity:** The products are stable under normal handling and storage conditions
- **Dangerous reactions:** Not known.
- **Conditions to Avoid / Stability:** Excess heat, flame or pressure.
- **Incompatibility with Substances:** Not applicable.
- **Dangerous products of decomposition:** Not known.

## 11. Information on Toxicology:

- **Acute toxicity:** Not available.

### **Primary irritant effect**

- **On the skin:** No irritation effect known.  
Single-component Stopping solution: GHS05 corrosivity
- **Inhalation:** No irritation effect known.  
Single-component Stopping solution: Mucous membrane irritation, coughing and breathlessness.
- **On the eye:** No irritant effect known. Single-component Stopping Solution: GHS05
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**  
The product is not labeled (calculation method of the General Classification guideline for preparations of the EU, in the latest edition).  
To our knowledge, the product has no harmful effects when handled properly for its intended purpose with it.

## 12. Information on Ecology

Data on the ecological effect of the product are not known.

- **Aquatic toxicity:** Single-component Stopping Solution is slightly hazardous to water (Class 1).
- **Persistence and degradability:** No information.
- **Mobility in soil:** No information.
- **Results of PBT and vPvB assessment:** Not applicable.
- **Other adverse effects:** No.

## 13. Information on Disposal

- **Product:** Disposal in accordance with applicable regulations.
- **Contaminated packaging:** Disposal in accordance with applicable regulations.
- **Recommended cleaning agent:** Lots of Water.

#### **14. Transport information**

- **Land transport RID/ADR**

UN#: 3316

Class: 9

PG: II

Proper Shipping Name: Chemical kit

- **Inland waterways ADN / ADR:**

UN#: 3316

Class: 9

PG: II

Proper Shipping Name: Chemical kit

- **Maritime transport IMDG**

UN#: 3316

Class: 9

PG: II

Proper Shipping Name: Chemical kit

Marine Pollutant: No

Severe Marine Pollutant: No

- **Air transport IATA**

UN#: 3316

Class: 9

PG: II

Proper Shipping Name: Chemical kit

Inhalation Packing Group I: No

- **Environmental hazards:** Slightly hazardous to water.

Do not allow product to reach ground water, water bodies or sewage system.

- **Special precautions for user:** Observe the general safety regulations when handling chemicals and carefully read the instruction manual of the product.

- **Transportation in bulk according to Annex II of MARPOL73/78 and IBC:** Not applicable.

- **Additional information:** Information in this section relate to the kit as a whole.

#### **15. Regulatory Information**

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

**Labelling according to EC regulation:**

Regulation (EC) No. 1272/2008 (CLP)

(CLP: Regulation on Classification, Labelling and Packaging of Substances and Mixtures)

The following regulations apply only for the Stopping Solution:



GHS05 with signal word: Warning

**Hazard Statement(s):**

H290: May be corrosive to metals.

H315: Causes skin irritation.

H319: Causes serious eye irritation.

**Precautionary statement(s):**

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

P305+P351+P338: IF IN EYES: Rinse continuously with water for several minutes.

Remove contact lenses if present and easy to do – continue rinsing.

P337+P313: Get medical advice/attention.

P302+P352: IF ON SKIN: Wash with soap and water.

• **Special designation of certain preparations:**

Safety data sheet available for professional users.

**National regulations:**

• **Classification according to regulation of industrial safety:** -

• **Water hazard class:** Generally not hazardous to water.

Single-component Stopping Solution is less hazardous to water (Class 1).

## **16. Other Information**

The contained information is based on the present state of our knowledge. It characterizes the product with regard to the appropriate safety precautions. However the above named supplier assumes any liability whatever for the accuracy or completeness of the information contained herein. It does not represent a guarantee of the properties of the product.

Final determination of suitability of any material is the sole responsibility of the user. All materials may contain unknown hazards and should be used with caution. Although certain hazards are mentioned above, we cannot guarantee that these are the only hazards that exist.

**Relevant Risk phrases:**

R19: May form explosive peroxides.

R20/21/22: Harmful by inhalation, in contact with skin, if swallowed.

R23/24/25: Toxic by inhalation, in contact with skin, if swallowed.

R34: Causes burns.

R35: Causes severe burns.

R36/37/38: Irritating to eyes, respiratory system and skin.

R40: Limited evidence of a carcinogenic effect.

R43: May cause sensitization by skin contact.

R51/53: Toxic to aquatic organisms, May cause long-term adverse effects in the aquatic environment.



**Relevant Hazard Statement(s):**

H302: Harmful if swallowed.  
H314: Causes severe skin burns and eye damage.  
H315: Causes skin irritation.  
H317: May cause an allergic skin reaction.  
H319: Causes serious eye irritation.  
H332: Harmful if inhaled.  
H335: May cause respiratory irritation.  
H400: Very toxic to aquatic life.  
H411: Toxic to aquatic life with long lasting effects.

**Department issuing MSDS:** Safety Personnel

**Contact:** BioTeZ Berlin-Buch GmbH

**Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route  
(European Agreement concerning the International Carriage of Dangerous Goods by Road)  
RID: Règlement international concernant le transport des marchandises dangereuses par chemin de fer (Regulations Concerning the International Transport of Dangerous Goods by Rail)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonized System of Classification and Labelling of Chemicals  
CLP: Regulation on Classification, Labelling and Packaging of Substances and Mixtures