INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

KIT

Date of Issue: 28-02-2008 ***Updated: 17-02-2026***

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **rat GH** [I-125] RIA KIT
Product code: RK-551
Kit components: **Tracer**
Calibrator
Antiserum
Separation reagent
Assay buffer

1.2 Relevant identified uses of the substance or mixture and uses advised against
Product use
Application of the substance/preparation: For In-vitro research test KIT

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu
Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number
Information in case of emergency: Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

2. Transport information

According to ADR and IATA (Chapter 10.3.1) regulations, shipment below the exemption quantity (1 MBq for Iodine 125) are considered as not dangerous goods. If the shipment exceed this quantity, please refer to the information given below:

Shipping information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1 UN/ID number	2910	2910	2910	2910	2910
14.2 UN proper shipping name	Radioactive Material, excepted package-limited quantity of material				
14.3 Transport hazardclass(es)	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material
Subsidiary risk	None	None	None	None	None
Classification code	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group					
Special provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional information					
IATA ERG code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG code	Not applicable	Not applicable	161	Not applicable	161
14.5 Environmental hazards					
Marine pollutant	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.6 Special precautions for user	No special precautions for users are required.				

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SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

Tracer

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **tracer**
Product code: Component of RK-551
Product formal name: Research reagent

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product use
Application of the substance/preparation: For In-vitro research test

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu
Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number

Information in case of emergency: Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

2. Hazards identification:

2.1 Classification of the substance or mixture

Product description: For In-vitro research test; White, Solid, Odorless

Classification according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

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izotop@izotop.hu

2.3 Other hazards

Additional information:

Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

Radioactive component - Iodine 125: Iodine-125 is a gamma-rays and X-rays emitter. Radiation can be protected by 1mm of lead. Half-life: 60.2 days.

Biologically derived materials: This component contains animal biologically derived materials and should be considered as potentially capable of transmitting infectious diseases.

3. Composition / Information on ingredients:

3.2 Mixtures

Product description: 1 vial (12.5 mL), freeze-dried
Hazardous ingredient(s): There is no hazardous ingredient in this product.

4. First Aid:

4.1 Description of first aid measures

After inhalation: Remove victim to fresh air. If breath laboured, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

After eye contact: If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. Immediately call in ophthalmologist. Remove contact lenses.

After skin contact: In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

After swallowing: After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

General information: If ingested, or in case of feeling unwell, seek medical advice urgently.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

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izotop@izotop.hu

5. Fire extinguishing measures:

5.1 Extinguishing media: In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards: No special hazards determined.

Hazardous combustion products: No combustion products posing significant hazards are expected from this product.

5.3 Advice for firefighters: Protective equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information: No further relevant information available.

6. Accidental release measures:

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning-up

Spill and Leak Procedures: Absorb liquid and place in container suitable for disposal. Comply with applicable waste disposal regulations. Radioactive material is subject to the regulations of each country. Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

7. Handling and storage:

7.1 Precautions for safe handling: Wear suitable personal protective equipment. Avoid splashing. Use the reagent in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.

7.2 Conditions for safe storage, including any incompatibilities: Store product in accordance with the relevant package insert. Do not store together with ignitable and flammable substances.

7.3 Specific end uses: No further relevant information available.

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izotop@izotop.hu

8. Exposure controls/personal protection:

8.1 Control parameters:

Occupational exposure limits: None established

8.2 Exposure controls

Engineering Controls	Place vial behind a metal shield, away from the user.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

9. Physical and chemical properties:

9.1 Information on basic physical and chemical properties

Physical state	solid	**Transparency**	not applicable
Colour	white	**Decomposition Temperature**	not applicable
Odour	odourless	**pH**	not applicable
Freezing point	not applicable	**Kinematic viscosity**	not determined
Boiling point	not applicable	**Solubility in water**	complete
Flammability	not applicable	**Solubility in organic**	not determined
Lower and upper explosion limit	not applicable	**Partition coefficient n-octanol/water (log value)**	not applicable
Flash Point	not applicable	**Vapour pressure**	not applicable
Autoignition Temp.	not applicable	**Density and/or relative density**	not applicable

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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

9.2 Other information:
No further relevant information available.

10. Stability and reactivity:

10.1 Reactivity: No hazardous reactions when used appropriately.
10.2 Chemical Stability: The product is stable in accordance with recommended storage conditions.
10.3 Possibility of hazardous reactions: None known.
10.4 Conditions to avoid: None known.
10.5 Incompatible materials: None known.
10.6 Hazardous decomposition products: No decomposition products posing significant hazards would be expected from this product.

11. Toxicological information:

11.1 Information on hazard classes

Toxicity data for hazardous ingredients: There are no hazardous ingredients.
Acute toxicity: None known.
Skin corrosion/irritation: None known.
Serious eye damage/eye irritation: None known.
Respiratory or skin sensitization: None known.
Germ cell mutagenicity: None known.
Carcinogenicity: None known.
Reproductive toxicity: None known.
Specific target organ toxicity - single exposure: None known.
Specific target organ toxicity - repeated exposure: None known.
Aspiration hazard: None known.

Primary routes of exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

11.2 Information on other hazards

Endocrine disrupting properties:
The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other information:
This product contains materials of animal origin and should be considered as potentially capable of transmitting infectious diseases.

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izotop@izotop.hu

12. Ecological information:

Ecotoxical effects:

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 determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties:

This product does not contain components considered to have endocrine disrupting properties for environment, according to REACH Article 57(f), Commission Regulation (EU) 2018/605 or Commission Delegated Regulation (EU)

12.7 Other adverse effects: None known.

13.Disposal considerations:

13.1 Waste treatment methods

Product Waste Disposal: Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information
Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

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✉ H-1535 Budapest, P.O.B. 851 Hungary
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14.Transport information:

According to ADR and IATA (Chapter 10.3.1) regulations, shipment below the exemption quantity (1 MBq for Iodine 125) are considered as not dangerous goods. If the shipment exceed this quantity, please refer to the information given below:

Shipping information	IATA	IMDG	US DOT	European ADR	Canadian TDG
14.1 UN/ID number	2910	2910	2910	2910	2910
14.2 UN proper shipping name	Radioactive Material, excepted package-limited quantity of material				
14.3 Transport hazardclass(es)	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material	7 Radioactive Material
Subsidiary risk	None	None	None	None	None
Classification code	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.4 Packing group					
Special provisions	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
Additional information					
IATA ERG code	7L	Not applicable	Not applicable	Not applicable	Not applicable
EmS	Not applicable	F-I, S-S	Not applicable	Not applicable	Not applicable
NAERG code	Not applicable	Not applicable	161	Not applicable	161
14.5 Environmental hazards					
Marine pollutant	Not applicable	Not applicable	Not applicable	Not applicable	Not applicable
14.6 Special precautions for user	No special precautions for users are required.				

15. Regulatory information:

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

EU regulations: This SDS complies with EC Regulations 1907/2006 (REACH and amendments).

Labelling according to EU guidelines: The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials. Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Hazard-determining components of labelling: None.

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✉ H-1535 Budapest, P.O.B. 851 Hungary
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Fax: +36 1 3922575
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Other information: Radioactive material in accordance with "A.R. of 28/02/1963 art. 31" and following, relating to the protection of the population and workers against the danger of ionising radiations.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16. Other information:

Revision changes: Revised to include EC 2020/878 amendment to REACH EC 1907/2006
Document version and issue/revision date: Revision Date (year/month/day) 2024/01/11
Description of hazard class and hazard statements from Section 3: There is no hazardous ingredient in this product.

Abbreviations and Acronyms:
GH – Growth Hormone
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CLP - Classification, Labeling and Packaging
HCS - Hazard Communication Standard
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
TDG - Canadian Transportation Of Dangerous Goods Regulations.
US DOT - United States Department of Transportation
vPvB - Very persistent and very bioaccumulative substances

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✉ H-1535 Budapest, P.O.B. 851 Hungary
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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

Information and recommendations:

- All animal products and derivatives are collected in healthy animals without any disease.
- The BSA (Bovine Serum Albumin) originates from countries where BSE (Bovine Spongiform Encephalopathy) as not been reported.
- The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws and guidelines.
- In no case the product must be administered to humans or animals.
- Do not smoke, drink, eat or apply cosmetics in the working area.
- Do not pipette by mouth.
- This radioactive product can be transferred to and used only by authorised persons; purchase, storage, use and exchange of radioactive products are subject to the legislation of the end-user's country.
- All radioactive handling should be executed in a designated area, away from regular passage.
- A logbook for receipt and storage of radioactive materials must be kept in the lab.
- Laboratory equipment and glassware, which could be contaminated with radioactive substances, should be segregated to prevent cross contamination of different radioisotopes.
- Any radioactive spills must be cleaned immediately in accordance with the radio safety procedures.
- The radioactive waste must be disposed of following the local regulations and guidelines of the notified bodies holding jurisdiction over the laboratory.
- Adherence to the basic rules of the radiation safety provides adequate protection.
- Use protective clothing and disposable gloves.

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H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
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izotop@izotop.hu

SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

Calibrator

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **Calibrator**
Product code: Component of RK-551
Product formal name: Research reagent

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product use
Application of the substance/preparation: For In-vitro research test

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu
Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number

Information in case of emergency: Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

2. Hazards identification:

2.1 Classification of the substance or mixture

Product description: For In-vitro research test; White, Solid, Odorless

Classification according to Regulation (EC) No 1272/2008 [CLP]

Not classified as hazardous per EC 1272/2008 [CLP].

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Not classified as hazardous per EC 1272/2008 [CLP].

2.3 Other hazards

Additional information:

Results of PBT and vPvB assessment:
PBT: Not applicable.

vPvB: Not applicable.

Biologically derived materials: This component contains animal biologically derived materials and should be considered as potentially capable of transmitting infectious diseases.

3. Composition / Information on ingredients:

3.2 Mixtures

Product description: 1 vial (1 mL), containing freeze-dried rat GH in buffer
Hazardous ingredient(s): There is no hazardous ingredient in this product.

4. First Aid:

4.1 Description of first aid measures

After inhalation: Remove victim to fresh air. If breath laboured, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

After eye contact: If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. Immediately call in ophthalmologist. Remove contact lenses.

After skin contact: Wash well with mild soap and copious amount of fresh water.

After swallowing: Flush mouth with copious water (do not swallow rinse water).

General information: If ingested, or in case of feeling unwell, seek medical advice urgently.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. Fire extinguishing measures:

5.1 Extinguishing media: In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards: No special hazards determined.

Hazardous combustion products: No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters: Protective equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information: No further relevant information available.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

6. Accidental release measures:

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning-up

Spill and Leak Procedures: Absorb liquid and place in container suitable for disposal. Comply with applicable waste disposal regulations. Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

7. Handling and storage:

7.1 Precautions for safe handling: Wear suitable personal protective equipment. Avoid splashing. Use the reagent in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.

7.2 Conditions for safe storage, including any incompatibilities: Store product in accordance with the relevant package insert. Do not store together with ignitable and flammable substances.

7.3 Specific end uses: No further relevant information available.

8. Exposure controls/personal protection:

8.1 Control parameters:

Occupational exposure limits: None established

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✉ H-1535 Budapest, P.O.B. 851 Hungary
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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

8.2 Exposure controls

Engineering Controls	None established
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

9. Physical and chemical properties:

9.1 Information on basic physical and chemical properties

Physical state	solid	**Transparency**	not applicable
Colour	white	**Decomposition Temperature**	not applicable
Odour	odourless	**pH**	not applicable
Freezing point	not applicable	**Kinematic viscosity**	not determined
Boiling point	not applicable	**Solubility in water**	complete
Flammability	not applicable	**Solubility in organic**	not determined
Lower and upper explosion limit	not applicable	**Partition coefficient n-octanol/water (log value)**	not applicable
Flash Point	not applicable	**Vapour pressure**	not applicable
Autoignition Temp.	not applicable	**Density and/or relative density**	not applicable

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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

9.2 Other information:
No further relevant information available.

10. Stability and reactivity:

10.1 Reactivity: No hazardous reactions when used appropriately.
10.2 Chemical Stability: The product is stable in accordance with recommended storage conditions.
10.3 Possibility of hazardous reactions: None known.
10.4 Conditions to avoid: None known.
10.5 Incompatible materials: None known.
10.6 Hazardous decomposition products: No decomposition products posing significant hazards would be expected from this product.

11. Toxicological information:

11.1 Information on hazard classes

Toxicity data for hazardous ingredients: There are no hazardous ingredients.
Acute toxicity: None known.
Skin corrosion/irritation: None known.
Serious eye damage/eye irritation: None known.
Respiratory or skin sensitization: None known.
Germ cell mutagenicity: None known.
Carcinogenicity: None known.
Reproductive toxicity: None known.
Specific target organ toxicity - single exposure: None known.
Specific target organ toxicity - repeated exposure: None known.
Aspiration hazard: None known.

Primary routes of exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

11.2 Information on other hazards

Endocrine disrupting properties:
The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other information:
This product contains materials of animal origin and should be considered as potentially capable of transmitting infectious diseases.

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✉ H-1535 Budapest, P.O.B. 851 Hungary
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www.izotop.hu
izotop@izotop.hu

12. Ecological information:

Ecotoxical effects:

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 determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties:

This product does not contain components considered to have endocrine disrupting properties for environment, according to REACH Article 57(f), Commission Regulation (EU) 2018/605 or Commission Delegated Regulation (EU)

12.7 Other adverse effects: None known.

13.Disposal considerations:

13.1 Waste treatment methods

Product Waste Disposal: Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information
Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

14.Transport information:

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID number: Not regulated for transportation
14.2 UN proper shipping name: Not regulated for transportation
14.3 Transport hazard class(es): Not regulated for transportation
14.4 Packing group: Not regulated for transportation
14.5 Environmental hazards: Not regulated for transportation
14.6 Special precautions for user: None
14.7 Maritime transport in bulk according to IMO instruments: Not applicable

15. Regulatory information:

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

EU regulations: This SDS complies with EC Regulations 1907/2006 (REACH and amendments).

Labelling according to EU guidelines: The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials. Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Hazard-determining components of labelling: None.

Other information: None.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16. Other information:

Revision changes: Revised to include EC 2020/878 amendment to REACH EC 1907/2006
Document version and issue/revision date: Revision Date (year/month/day) 2024/01/11
Description of hazard class and hazard statements from Section 3: There is no hazardous ingredient in this product.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

Abbreviations and Acronyms:

GH – Growth Hormone
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CLP - Classification, Labeling and Packaging
HCS - Hazard Communication Standard
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
TDG - Canadian Transportation Of Dangerous Goods Regulations.
US DOT - United States Department of Transportation
vPvB - Very persistent and very bioaccumulative substances

Information and recommendations:

- All animal products and derivatives are collected in healthy animals without any disease.
- The BSA (Bovine Serum Albumin) originates from countries where BSE (Bovine Spongiform Encephalopathy) as not been reported.
- The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws and guidelines.
- In no case the product must be administered to humans or animals.
- Do not smoke, drink, eat or apply cosmetics in the working area.
- Do not pipette by mouth.
- Use protective clothing and disposable gloves.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

Antiserum

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **Antiserum**
Product code: Component of RK-551
Product formal name: Research reagent

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product use
Application of the substance/preparation: For In-vitro research test

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu
Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number

Information in case of emergency:

Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

2. Hazards identification:

2.1 Classification of the substance or mixture

Product description: For In-vitro research test; White, Solid, Odorless

Classification according to Regulation (EC) No 1272/2008 [CLP]

Not classified as hazardous per EC 1272/2008 [CLP].

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]

Not classified as hazardous per EC 1272/2008 [CLP].

2.3 Other hazards

Additional information:

Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

Biologically derived materials: This component contains animal biologically derived materials and should be considered as potentially capable of transmitting infectious diseases.

3. Composition / Information on ingredients:

3.2 Mixtures

Product description: 1 vial, freeze-dried
Hazardous ingredient(s): There is no hazardous ingredient in this product.

4. First Aid:

4.1 Description of first aid measures

After inhalation: Remove victim to fresh air. If breath laboured, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

After eye contact: If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. Immediately call in ophthalmologist. Remove contact lenses.

After skin contact: Wash well with mild soap and copious amount of fresh water.

After swallowing: Flush mouth with copious water (do not swallow rinse water).

General information: If ingested, or in case of feeling unwell, seek medical advice urgently.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. Fire extinguishing measures:

5.1 Extinguishing media: In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards: No special hazards determined.

Hazardous combustion products: No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters: Protective equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information: No further relevant information available.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

6. Accidental release measures:

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

6.3 Methods and material for containment and cleaning-up

Spill and Leak Procedures: Absorb liquid and place in container suitable for disposal. Comply with applicable waste disposal regulations. Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections

Refer sections 8 and 13.

7. Handling and storage:

7.1 Precautions for safe handling: Wear suitable personal protective equipment. Avoid splashing. Use the reagent in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.

7.2 Conditions for safe storage, including any incompatibilities: Store product in accordance with the relevant package insert. Do not store together with ignitable and flammable substances.

7.3 Specific end uses: No further relevant information available.

8. Exposure controls/personal protection:

8.1 Control parameters:

Occupational exposure limits: None established

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

8.2 Exposure controls

Engineering Controls	None established
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

9. Physical and chemical properties:

9.1 Information on basic physical and chemical properties

Physical state	solid	**Transparency**	not applicable
Colour	white	**Decomposition Temperature**	not applicable
Odour	odourless	**pH**	not applicable
Freezing point	not applicable	**Kinematic viscosity**	not determined
Boiling point	not applicable	**Solubility in water**	complete
Flammability	not applicable	**Solubility in organic**	not determined
Lower and upper explosion limit	not applicable	**Partition coefficient n-octanol/water (log value)**	not applicable
Flash Point	not applicable	**Vapour pressure**	not applicable
Autoignition Temp.	not applicable	**Density and/or relative density**	not applicable

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

9.2 Other information:
No further relevant information available.

10. Stability and reactivity:

10.1 Reactivity: No hazardous reactions when used appropriately.
10.2 Chemical Stability: The product is stable in accordance with recommended storage conditions.
10.3 Possibility of hazardous reactions: None known.
10.4 Conditions to avoid: None known.
10.5 Incompatible materials: None known.
10.6 Hazardous decomposition products: No decomposition products posing significant hazards would be expected from this product.

11. Toxicological information:

11.1 Information on hazard classes

Toxicity data for hazardous ingredients: There are no hazardous ingredients.
Acute toxicity: None known.
Skin corrosion/irritation: None known.
Serious eye damage/eye irritation: None known.
Respiratory or skin sensitization: None known.
Germ cell mutagenicity: None known.
Carcinogenicity: None known.
Reproductive toxicity: None known.
Specific target organ toxicity - single exposure: None known.
Specific target organ toxicity - repeated exposure: None known.
Aspiration hazard: None known.

Primary routes of exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

11.2 Information on other hazards

Endocrine disrupting properties:
The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other information:
This product contains materials of animal origin and should be considered as potentially capable of transmitting infectious diseases.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

12. Ecological information:

Ecotoxical effects:

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 determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties:

This product does not contain components considered to have endocrine disrupting properties for environment, according to REACH Article 57(f), Commission Regulation (EU) 2018/605 or Commission Delegated Regulation (EU)

12.7 Other adverse effects: None known.

13.Disposal considerations:

13.1 Waste treatment methods

Product Waste Disposal: Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.

Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information
Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

14.Transport information:

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID number: Not regulated for transportation
14.2 UN proper shipping name: Not regulated for transportation
14.3 Transport hazard class(es): Not regulated for transportation
14.4 Packing group: Not regulated for transportation
14.5 Environmental hazards: Not regulated for transportation
14.6 Special precautions for user: None
14.7 Maritime transport in bulk according to IMO instruments: Not applicable

15. Regulatory information:

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

EU regulations: This SDS complies with EC Regulations 1907/2006 (REACH and amendments).

Labelling according to EU guidelines: The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials. Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Hazard-determining components of labelling: None.

Other information: None.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

16. Other information:

Revision changes: Revised to include EC 2020/878 amendment to REACH EC 1907/2006
Document version and issue/revision date: Revision Date (year/month/day) 2026/02/17
Description of hazard class and hazard statements from Section 3: There is no hazardous ingredient in this product.

Abbreviations and Acronyms:
GH – Growth Hormone
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CLP - Classification, Labeling and Packaging
HCS - Hazard Communication Standard
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
TDG - Canadian Transportation Of Dangerous Goods Regulations.
US DOT - United States Department of Transportation
vPvB - Very persistent and very bioaccumulative substances

Information and recommendations:

- All animal products and derivatives are collected in healthy animals without any disease.
- The BSA (Bovine Serum Albumin) originates from countries where BSE (Bovine Spongiform Encephalopathy) as not been reported.
- The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws and guidelines.
- In no case the product must be administered to humans or animals.
- Do not smoke, drink, eat or apply cosmetics in the working area.
- Do not pipette by mouth.
- Use protective clothing and disposable gloves.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

Separation reagent

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **Separation reagent**
Product code: Component of RK-551
Product formal name: Research reagent

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product use
Application of the substance/preparation: For In-vitro research test

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu
Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number

Information in case of emergency: Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

2. Hazards identification:

2.1 Classification of the substance or mixture

Product description: In vitro research reagent; White, Colloid, Odorless
Classification according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

2.2 Label elements

Labelling according to Regulation (EC) No 1272/2008 [CLP]
Not classified as hazardous per EC 1272/2008 [CLP].

2.3 Other hazards

Additional information:

Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

Sodium azide: This product contains concentrations of sodium azide below the hazardous level, which with repeated contact with lead and copper commonly found in plumbing drains may result in the build-up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Ethylenediaminetetraacetic acid disodium salt dihydrate: It may cause damage to organs (Respiratory Tract).

Biologically derived materials: This component contains animal biologically derived materials and should be considered as potentially capable of transmitting infectious diseases.

See Section 11 Toxicological Information for more detailed health information.

3. Composition / Information on ingredients:

3.2 Mixtures

Hazardous ingredient(s):

International chemical identification	**CAS #**		**EC no**		
Sodium azide	26628-22-8		247-852-1		
(< 0.1 % by wt)	**Classification**		**Labelling**		
	Hazard class and Category Code(s)	*Hazard statement Code(s)*	*Supplementary hazard statement Code(s)*	*Pictogram(s), signal word Code(s)*	
	Acute tox. 2	H300	EUH 032	GHS05	
	Aquatic Acute 1	H400		GHS06	
	Aquatic Chronic 1	H410		GHS09 Dgr	
	Signal words		**Pictogram(s)**		
	Danger		 **Skull and crossbones**	 **Environment**	 **Corrosive to metals**

Hazard statements:

H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life
EUH032	Contact with acids liberates very toxic gas

Precautionary statements:

P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P310 + P330	If swallowed immediately called a POISON CENTER or doctor/physician. Rinse mouth.
P302 + P352 + P310	If on skin gently wash with plenty of soap and water. Immediately called a POISON CENTER or doctor/physician.
P391	Collect spillage.
P501	Dispose of contents/container as waste: in an approved waste.

<table>
<tr><td>International chemical identification</td><td colspan="2">CAS #</td><td colspan="2">EC no</td></tr>
<tr><td>Ethylenediaminetetra-acetic acid disodium salt dihydrate</td><td colspan="2">6381-92-6</td><td colspan="2">205-358-3</td></tr>
<tr><td rowspan="6">(< 0.1 % by wt)</td><td colspan="2">Classification</td><td colspan="2">Labelling</td></tr>
<tr><td>Hazard class and Category Code(s)</td><td>Hazard statement Code(s)</td><td>Supplementary hazard statement Code(s)</td><td>Pictogram(s), signal word Code(s)</td></tr>
<tr><td>Acute tox. 4</td><td>H332</td><td rowspan="2"></td><td>GHS07</td></tr>
<tr><td>STOT SE 2</td><td>H373</td><td>GHS08</td></tr>
<tr><td colspan="2">Signal words</td><td colspan="2">Pictogram(s)</td></tr>
<tr><td colspan="2">Danger</td><td> 
Harmful</td><td> 
Health hazard</td></tr>
</table>

Hazardous statements:

H332	Harmful if inhaled.
H373	May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled.

Precautionary statements:

P260	Do not breathe dust.
P271	Use only outdoors or in a well-ventilated area.
P304 + P340 + P312	IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor if you feel unwell.
P314	Get medical advice/ attention if you feel unwell.
P501	Dispose of contents/ container to an approved waste disposal plant.

Supplemental Hazard Statements: none

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

4. First Aid:

4.1 Description of first aid measures

After inhalation: Remove victim to fresh air. If breath laboured, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

After eye contact: If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. Immediately call in ophthalmologist. Remove contact lenses.

After skin contact: In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

After swallowing: After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

General information: If ingested, or in case of feeling unwell, seek medical advice urgently.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. Fire extinguishing measures:

5.1 Extinguishing media: In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards: No special hazards determined.

Hazardous combustion products: No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters: Protective equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information: No further relevant information available.

6. Accidental release measures:

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

6.3 Methods and material for containment and cleaning-up
Spill and Leak Procedures: Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations. Radioactive material is subject to the regulations of each country.
Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections
Refer sections 8 and 13.

7. Handling and storage:

7.1 Precautions for safe handling: Wear suitable personal protective equipment. Avoid splashing. Use the reagent in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.

7.2 Conditions for safe storage, including any incompatibilities: Store product in accordance with the relevant package insert. Do not store together with ignitable and flammable substances.

7.3 Specific end uses: No further relevant information available.

8. Exposure controls/personal protection:

8.1 Control parameters:
Sodium Azide (CAS # 26628-22-8)
US OSHA: None established
ACGIH: 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)
DFG MAK: 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland: 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption
IOELVs: Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH: None established
Japan: None established

Ethylenediaminetetra-acetic acid disodium salt dihydrate (CAS # 5949-29-1):
Derived No Effect Level (DNEL)

Application Area	Routes of exposure	Health effect	Value
Worker DNEL, acute	inhalation	Local effects	3 mg/m3
Worker DNEL, longterm	inhalation	Local effects	1,5 mg/m3
Consumer DNEL, acute	inhalation	Local effects	1,2 mg/m3
Consumer DNEL, longterm	inhalation	Local effects	0,6 mg/m3
Consumer DNEL, longterm	oral	Systemic effects	-

Fresh water: 2,2 mg/l
Sea water: 0,22 mg/l
Aquatic intermittent release: 1,2 mg/l
Sewage treatment plant: 43 mg/l
Soil: 0,72 mg/kg

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www.izotop.hu
izotop@izotop.hu

8.2 Exposure controls

Engineering Controls	None established.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

9. Physical and chemical properties:

9.1 Information on basic physical and chemical properties

Physical state	liquid	**Transparency**	opaque
Colour	white	**Decomposition Temperature**	not applicable
Odour	odourless	**pH**	6.95 – 7.05
Freezing point	0 °C	**Kinematic viscosity**	not determined
Boiling point	100 °C	**Solubility in water**	complete
Flammability	not applicable	**Solubility in organic**	not determined
Lower and upper explosion limit	not applicable	**Partition coefficient n-octanol/water (log value)**	not applicable
Flash Point	not applicable	**Vapour pressure**	not applicable
Autoignition Temp.	not applicable	**Density and/or relative density**	1.00 @20°C

9.2 Other information:

No further relevant information available.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

10. Stability and reactivity:

10.1 Reactivity: Sodium azide: Contact with acids liberates very toxic gas.

10.2 Chemical Stability: The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions: Sodium azide: forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Do not allow the undiluted product to enter sewers/surface or ground water.

10.4 Conditions to avoid: Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials: Strong oxidizing agents, Strong acids, Aluminum, Heavy metals

10.6 Hazardous decomposition products: No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

11. Toxicological information:

11.1 Information on hazard classes

Toxicity data for hazardous ingredients:
Sodium azide (CAS # 26628-22-8):

Acute toxicity:
LD50 Oral - Rat - 27 mg/kg Remarks: (RTECS)
LC50 Inhalation - Rat - male and female - 4 h - 0,054 - 0,52 mg/l - dust/mist
(US-EPA) LD50 Dermal - Rabbit - 20 mg/kg Remarks: (RTECS)

Skin corrosion/irritation:
Skin - In vitro study Result: No skin irritation (OECD Test Guideline 439)

Serious eye damage/eye irritation:
Eyes - Bovine cornea Result: No eye irritation - 4 h (OECD Test Guideline 437)

Respiratory or skin sensitization:
Local lymph node assay (LLNA) – Mouse Result: negative (OECD Test Guideline 429)

Germ cell mutagenicity
Test Type: Mutagenicity (mammal cell test): chromosome aberration. Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activationMethod: OECD Test Guideline 473 Result: negative
Test Type: unscheduled DNA synthesis assay. Test system: Chinese hamster lung cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 482

Result: negative
Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 479
Result: negative
Carcinogenicity: No data available
Reproductive toxicity: No data available
Specific target organ toxicity - single exposure: No data available
Specific target organ toxicity - repeated exposure:
Oral - May cause damage to organs through prolonged or repeated exposure – Brain
Aspiration hazard: No data available

Ethylenediaminetetra-acetic acid disodium salt dihydrate (CAS # 5949-29-1):
Remarks: (ECHA) The value is given in analogy to the following substances: Ethylenedinitrilotetraacetic acid disodium salt
Acute toxicity:
LD50 Oral - Rat - male and female - 2.800 mg/kg (OECD Test Guideline 401)
Acute toxicity estimate Inhalation - 1,6 mg/l - dust/mist (Expert judgment)
Dermal: No data available
Skin corrosion/irritation: Skin – Rabbit Result: No skin irritation (OECD Test Guidel. 404)
Serious eye damage/eye irritation: Eyes – Rabbit Result: No eye irritation (OECD Test Guideline 405)
Respiratory or skin sensitization: Maximization Test - Guinea pig Result: negative (OECD Test Guideline 406)
Germ cell mutagenicity:
Test Type: Chromosome aberration test in vitro. Test system: Chinese hamster ovary cells. Metabolic activation: with and without metabolic activation. Result: negative
Remarks: (ECHA) The value is given in analogy to the following substances: Ethylenedinitrilotetraacetic acid trisodium salt.
Test Type: In vitro mammalian cell gene mutation test Test system: mouse lymphoma cells
Metabolic activation: with and without metabolic activation Method: OECD Test G. 476
Result: negative
The value is given in analogy to the following substances: Ethylenedinitrilotetraacetic acid trisodium salt
Test Type: Ames test Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471. Result: negative. *Remarks: (ECHA) The value is given in analogy to the following substances: Ethylenedinitrilotetraacetic acid trisodium salt*
Test Type: In vivo micronucleus test. Species: Mouse. Application Route: Oral. Method: OECD Test Guideline 474
Carcinogenicity:
No data available
Reproductive toxicity:
No data available
Specific target organ toxicity - single exposure:
No data available

Specific target organ toxicity - repeated exposure:
Inhalation - May cause damage to organs through prolonged or repeated exposure.
- Respiratory Tract
Aspiration hazard
No data available

Primary routes of exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

11.2 Information on other hazards
Endocrine disrupting properties:
The product does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other information:
This product contains materials of animal origin and should be considered as potentially capable of transmitting infectious diseases.

12. Ecological information:

Ecotoxical effects: Sodium Azide is very toxic for aquatic organisms.

12.1 Toxicity

Sodium azide (CAS # 26628-22-8):
Toxicity to fish: flow-through test LC50 - Oncorhynchus mykiss (rainbow trout) - 2,75 mg/l - 96 h (OECD Test Guideline 203)
Toxicity to algae: static test ErC50 - Pseudokirchneriella subcapitata - 0,35 mg/l - 96 h (OECD Test Guideline 201)

Ethylenediaminetetra-acetic acid disodium salt dihydrate (CAS # 5949-29-1):
Toxicity to fish semi-static test LC50 - Oncorhynchus mykiss (rainbow trout) - > 100 mg/l - 96 h (OECD Test Guideline 203)
Remarks: (ECHA) The value is given in analogy to the following substances: Sodium feredetate.
Toxicity to daphnia and other aquatic invertebrates static test EC50 - Daphnia magna (Water flea) - 140 mg/l - 48 h (DIN 38412)
Remarks: (ECHA) The value is given in analogy to the following substances: Ethylenedinitrilotetraacetic acid disodium salt
NOEC - Daphnia magna (Water flea) - 25 mg/l - 21 d
Remarks: (ECHA) The value is given in analogy to the following substances: Ethylenedinitrilotetraacetic acid disodium salt
Toxicity to algae static test - Pseudokirchneriella subcapitata (green algae) - > 60 mg/l - 72 h (OECD Test Guideline 201)

Remarks: (ECHA) The value is given in analogy to the following substances: Sodium feredetate
Toxicity to bacteria NOEC - activated sludge - > 640 mg/l - 3 h (OECD Test Guideline 209)
Remarks: (ECHA) The value is given in analogy to the following substances: Sodium feredetate

12.2 Persistence and degradability
Sodium azide (CAS # 26628-22-8):
The methods for determining the biological degradability are not applicable to inorganic substances.
Ethylenediaminetetra-acetic acid disodium salt dihydrate (CAS # 5949-29-1):
Biodegradability Result: 2 % - Not readily biodegradable.
(OECD Test Guideline 301D)
Remarks: The value is given in analogy to the following substances: Ethylenedinitrilotetraacetic acid disodium salt

12.3 Bioaccumulative potential
Ethylenediaminetetra-acetic acid disodium salt dihydrate (CAS # 5949-29-1):
Bioaccumulation Lepomis macrochirus (Bluegill sunfish) - 28 d at 21 °C - 0,08 mg/l(Edetate disodium dihydrate) Bioconcentration factor (BCF): 1,8 (OECD Test Guideline 305)
Remarks: The value is given in analogy to the following substances: Ethylenedinitrilotetraacetic acid,Tetrasodiumsalt

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties:
This product does not have substance(s) of endocrine disrupting properties for environment according to REACH Article 57(f).

12.7 Other adverse effects: No data available

13.Disposal considerations:

13.1 Waste treatment methods
Product Waste Disposal: Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Sodium azide preservative may form explosive compounds in metal drain lines.
See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.

Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

14.Transport information:

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID number: Not regulated for transportation
14.2 UN proper shipping name: Not regulated for transportation
14.3 Transport hazard class(es): Not regulated for transportation
14.4 Packing group: Not regulated for transportation
14.5 Environmental hazards: Not regulated for transportation
14.6 Special precautions for user: None
14.7 Maritime transport in bulk according to IMO instruments: Not applicable

15. Regulatory information:

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

EU regulations: This SDS complies with EC Regulations 1907/2006 (REACH and amendments).

Labelling according to EU guidelines: The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials. Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

Hazard-determining components of labelling: *** NaN_3 and EDTA**

** But as mentioned in the REGULATION (EC) No 1272/2008 under point 1.5(a) there is no hazard labelling necessary as the total volume of the components of the KIT is under 125 ml.*

Other information: Take note of Dir 94/33/EC on the protection of young people at work.

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

INSTITUTE OF ISOTOPES CO. LTD.
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✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

16. Other information:

Revision changes: Revised to include EC 2020/878 amendment to REACH EC 1907/2006
Document version and issue/revision date: Revision Date (year/month/day) 2024/01/11
Description of hazard class and hazard statements from Section 3:

H300	Acute tox. 2 - Acute Toxicity, Category 2. Fatal if swallowed.
H400	Aquatic Acute 1 - Aquatic Hazard Acute, Category 1. Very toxic to aquatic life.
H410	Aquatic Chronic 1 - Long-term aquatic hazard, Category 1. Very toxic to aquatic life with long lasting effects.
H332	Acute tox. 4 - Acute Toxicity, Category 4. Harmful if inhaled.
H373	STOT SE 2 May cause damage to organs (Respiratory Tract) through prolonged or repeated exposure if inhaled
EUH032	Contact with acids liberates very toxic gas.

Abbreviations and Acronyms:
ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CLP - Classification, Labeling and Packaging
GHS - Globally Harmonized System
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
TDG - Canadian Transportation Of Dangerous Goods Regulations.
US DOT - United States Department of Transportation
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

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Information and recommendations:

- All animal products and derivatives are collected in healthy animals without any disease.
- The BSA (Bovine Serum Albumin) originates from countries where BSE (Bovine Spongiform Encephalopathy) as not been reported.
- The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws and guidelines.
- For in vitro research only.
- In no case the product must be administered to humans or animals.
- Do not smoke, drink, eat or apply cosmetics in the working area.
- Do not pipette by mouth.
- Use protective clothing and disposable gloves.

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✉ H-1535 Budapest, P.O.B. 851 Hungary
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www.izotop.hu
izotop@izotop.hu

SAFETY DATA SHEET

According to EC Directive 1907/2006/EC **[REACH]** and to Regulation (EC) No 1272/2008 **[CLP]**

Assay Buffer

1. Identification of the substance/preparation and of the company

1.1 Product identifier:

Product name: **Assay buffer**
Product code: Component of RK-551
Product formal name: Research reagent

1.2 Relevant identified uses of the substance or mixture and uses advised against

Product use
Application of the substance/preparation: For In-vitro research test

1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Institute of Isotopes Co., Ltd.
Konkoly-Thege Miklós út 29-33
H-1121 Budapest, Hungary
Phone number: (36-1) 391-0826
Fax number: (36-1) 392-2575, 395-9247

Further information available from: www.izotop.hu
Email address of the competent person: **immuno@izotop.hu**

1.4 Emergency telephone number

Information in case of emergency: Health Toxicological Information Service
+36 80 201 199 (0-24 hours, toll free - only from Hungary)
+36 1 476 6464 (0-24 hours, also from abroad)

2. Hazards identification:

2.1 Classification of the substance or mixture

Product description: In vitro research reagent; Clear, Liquid, Odorless

Classification according to Regulation (EC) No 1272/2008 [CLP]

According to Regulation (EC) No **1272/2008 (CLP)**, the mixture is classified as **hazardous**.

Classification:

- **Acute toxicity (oral), Category 3** – H301
- **Hazardous to the aquatic environment, Acute Category 1** – H400
- **Hazardous to the aquatic environment, Chronic Category 1** – H410

The classification is based on the sodium azide content of the mixture. The mixture is classified as hazardous in its concentrated form. However, when diluted to the working concentration (<0.1%), the mixture no longer meets the criteria for classification according to Regulation (EC) No 1272/2008.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
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izotop@izotop.hu

2.2 Label elements
Labelling according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictograms:
GHS06 – Skull and crossbones
GHS09 – Environment

Signal word:
DANGER

2.3 Other hazards
Additional information:

Results of PBT and vPvB assessment:
PBT: Not applicable.
vPvB: Not applicable.

Sodium azide: This product contains concentrations of sodium azide, which with repeated contact with lead and copper commonly found in plumbing drains may result in the build-up of shock sensitive compounds. Sodium azide forms explosive compounds with heavy metals.

Triton-X 100: Non-ionic surfactant mixtures varying in the number of repeating ethoxy (oxy-1,2-ethanediyl) groups. They are used as detergents in in vitro diagnostic reagents as buffer solutions.

Ecological information: This substance/mixture contains components considered to have endocrine disrupting properties for environment, according to REACH Article 57(f), Commission Regulation (EU) 2018/605 or Commission Delegated Regulation (EU) 2017/2100.

See Section 11 Toxicological Information for more detailed health information.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

3. Composition / Information on ingredients:

3.2 Mixtures

Hazardous ingredient(s):

International chemical identification	**CAS #**		**EC no**		
Sodium azide	26628-22-8		247-852-1		
(< 1 % by wt)	**Classification**		**Labelling**		
	Hazard class and Category Code(s)	*Hazard statement Code(s)*	*Supplementary hazard statement Code(s)*	*Pictogram(s), signal word Code(s)*	
	Acute tox. 2	H300	EUH 032	GHS05 GHS06 GHS09 Dgr	
	Aquatic Acute 1	H400			
	Aquatic Chronic 1	H410			
	Signal words		**Pictogram(s)**		
	Danger		 **Skull and crossbones**	 **Environment**	 **Corrosive to metals**

Hazard statements:

H300	Fatal if swallowed
H400	Very toxic to aquatic life
H410	Very toxic to aquatic life
EUH032	Contact with acids liberates very toxic gas

Precautionary statements:

P273	Avoid release to the environment.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P301 + P310 + P330	If swallowed immediately called a POISON CENTER or doctor/physician. Rinse mouth.
P302 + P352 + P310	If on skin gently wash with plenty of soap and water. Immediately called a POISON CENTER or doctor/physician.
P391	Collect spillage.
P501	Dispose of contents/container as waste: in an approved waste.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

International chemical identification	**CAS #**		**EC no**	
Octylphenyl Polyethylene Glycol (Triton-X100)	9002-93-1		-	
(< 0.1 % by wt)	**Classification**		**Labelling**	
	Hazard class and Category Code(s)	*Hazard statement Code(s)*	*Supplemental hazard statement Code(s)*	*Pictogram(s), signal word Code(s)*
	Acute tox. 4	H302	none	GHS05 GHS07 GHS09
	Aquatic Acute 1	H400		
	Aquatic Chronic 2	H410		
	Skin irritation 2	H315		
	Serious eye damage 1	H318		
	M-Factor - Aquatic Acute: 10 - Aquatic Chronic: 1			
	Signal words		**Pictogram(s)**	
	Danger		 Irritant	 Environment	 Corrosive

Hazard Statements:

H302	Harmful if swallowed
H315	Causes skin irritation
H318	Causes serious eye damage
H410	Very toxic to aquatic life with long lasting effects

Precautionary statements:

P264	Wash skin thoroughly after handling.
P273	Avoid release to the environment.
P280	Wear protective gloves/ eye protection/ face protection.
P301 + P312	Call a POISON CENTER/ doctor if you feel unwell.
P302 + P352	IF ON SKIN: Wash with plenty of water

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www.izotop.hu
izotop@izotop.hu

4. First Aid:

4.1 Description of first aid measures

After inhalation: Remove victim to fresh air. If breath laboured, administer oxygen as needed. If victim is not breathing, administer artificial respiration or CPR.

After eye contact: If product enters eyes, wash eyes gently under running water for 15 minutes or longer, making sure that the eyelids are held open. Immediately call in ophthalmologist. Remove contact lenses.

After skin contact: In case of skin contact, remove any contaminated clothing. Wash affected area with plenty of soap and water for at least 15 minutes. If pain or irritation occur, obtain medical attention.

After swallowing: After swallowing: immediately make victim drink water (two glasses at most). Consult a physician.

General information: If ingested, or in case of feeling unwell, seek medical advice urgently.

4.2 Most important symptoms and effects, both acute and delayed

No adverse symptoms or effects have been identified.

4.3 Indication of any immediate medical attention and special treatment needed

No data available

5. Fire extinguishing measures:

5.1 Extinguishing media: In case of fire use carbon dioxide (CO2), dry chemical, water spray or foam. For large fires use extinguishing media suitable for surrounding fire.

5.2 Special hazards arising from the substance or mixture

Special fire and explosion hazards: No special hazards determined.

Hazardous combustion products: No combustion products posing significant hazards are expected from this product (an aqueous solution).

5.3 Advice for firefighters: Protective equipment Self-contained breathing apparatus is recommended for firefighters in all chemical fire situations.

5.4 Additional information: No further relevant information available.

6. Accidental release measures:

6.1 Personal precaution, protective equipment and emergency procedures

Personal Precautions: This product contains a material of animal origin. Observe general safety guidelines for protection during clean up procedures.
Wear protective gloves, protective clothing and eye/face protection.

6.2 Environmental Precautions

Contain spill to prevent migration. Place absorbed material in container suitable for disposal. Do not allow the undiluted product to enter sewers/surface or ground water. Dispose of all waste material in accordance with local and facility guidelines.

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

6.3 Methods and material for containment and cleaning-up
Spill and Leak Procedures: Absorb liquid and place in container suitable for disposal. Avoid generation of aerosols during clean up. Comply with applicable waste disposal regulations. Dispose of all waste material in accordance with local guidelines.

6.4 Reference to other sections
Refer sections 8 and 13.

7. Handling and storage:

7.1 Precautions for safe handling: Wear suitable personal protective equipment. Avoid splashing. Use the reagent in accordance with relevant package insert. Avoid high temperature and freezing. Do not eat, drink, smoke or apply cosmetics in laboratory areas.

7.2 Conditions for safe storage, including any incompatibilities: Store product in accordance with the relevant package insert. Do not store together with ignitable and flammable substances.

7.3 Specific end uses: Avoid contact with lead and copper plumbing. Dilute the concentrate strictly according to the instructions for use. Upon dilution to <0.1%, the solution is intended for routine laboratory use.

8. Exposure controls/personal protection:

8.1 Control parameters:

Sodium Azide (CAS # 26628-22-8)
US OSHA: None established
ACGIH: 0.29 mg/m3 Ceiling (as Sodium azide); 0.11 ppm Ceiling (as Hydrazoic acid vapor)
DFG MAK: 0.4 mg/m3 Peak (inhalable fraction); 0.2 mg/m3 TWA MAK (inhalable fraction)
Ireland: 0.1 mg/m3 TWA; 0.3 mg/m3 STEL; Potential for cutaneous absorption
IOELVs: Possibility of significant uptake through the skin; 0.1 mg/m3 TWA; 0.3 mg/m3 STEL
NIOSH: None established
Japan: None established

Triton-X 100 (CAS # 9002-93-1):
Occupational exposure limits: None established

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✉ H-1535 Budapest, P.O.B. 851 Hungary
Phone: +36 1 3910826
Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

8.2 Exposure controls

Engineering Controls	No special engineering controls are required. Use with good general ventilation.
Eye Protection	Safety glasses or chemical goggles should be worn to prevent eye contact. Refer U.S. OSHA 29 CFR 1910.133, European Standard EN166 or appropriate government standards.
Skin Protection	Impervious gloves, such as Nitrile or equivalent, should be worn to prevent skin contact. Refer U.S. OSHA 29 CFR 1910.138, European Standard EN374 or appropriate government standards.
Respiratory Protection	Under normal conditions, the use of this product should not require respiratory protection. If overexposure should occur and ventilation is not adequate to maintain airborne concentrations at acceptable levels, the use of respiratory protection should be evaluated by a qualified professional.

For handling the concentrate (<1%), wear nitrile gloves and safety goggles. For the diluted working solution (<0.1%), standard laboratory personal protective equipment is recommended.

9. Physical and chemical properties:

9.1 Information on basic physical and chemical properties

Physical state	solid	**Transparency**	not applicable
Colour	white	**Decomposition Temperature**	not applicable
Odour	odourless	**pH**	not applicable
Freezing point	0 °C	**Kinematic viscosity**	not determined
Boiling point	100 °C	**Solubility in water**	complete
Flammability	not applicable	**Solubility in organic**	not determined
Lower and upper explosion limit	not applicable	**Partition coefficient n-octanol/water (log value)**	not applicable
Flash Point	not applicable	**Vapour pressure**	not applicable
Autoignition Temp.	not applicable	**Density and/or relative density**	1.00 @20°C

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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

9.2 Other information:
No further relevant information available.

10. Stability and reactivity:

10.1 Reactivity: Sodium azide: Contact with acids liberates very toxic gas.

10.2 Chemical Stability: The product is stable in accordance with recommended storage conditions.

10.3 Possibility of hazardous reactions: Sodium azide: forms explosive compounds with heavy metals. Repeated contact of low concentrations of azide with lead and copper commonly found in plumbing drains may result in the build up of shock sensitive compounds. Do not allow the undiluted product to enter sewers/surface or ground water.
Triton X: Violent reactions possible with strong oxidizing agents or strong acids.

10.4 Conditions to avoid: Avoid contact with incompatible materials. Avoid exposure to heat and direct sunlight.

10.5 Incompatible materials: Strong oxidizing agents, Strong acids, Aluminum, Heavy metals

10.6 Hazardous decomposition products: No decomposition products posing significant hazards would be expected from this product (an aqueous solution).

11. Toxicological information:

11.1 Information on hazard classes
Toxicity data for hazardous ingredients:
Acute toxicity:

Sodium azide (CAS # 26628-22-8):
LD50 Oral - Rat - 27 mg/kg Remarks: (RTECS)
LC50 Inhalation - Rat - male and female - 4 h - 0,054 - 0,52 mg/l - dust/mist
(US-EPA) LD50 Dermal - Rabbit - 20 mg/kg Remarks: (RTECS)

Triton-X 100 (CAS # 9002-93-1):

Acute toxicity: LD50 Oral - Rat - 1.900 - 5.000 mg/kg
Symptoms: Vomiting, Irritations of mucous membranes in the mouth, pharynx, oesophagus and gastrointestinal tract. Risk of aspiration upon vomiting. Aspiration may cause pulmonary edema and pneumonitis. Acute toxicity estimate Oral - 1.900 mg/kg (ATE value derived from LD50/LC50 value

INSTITUTE OF ISOTOPES CO. LTD.
H-1121 Budapest, Konkoly-Thege M. út 29-33.
✉ H-1535 Budapest, P.O.B. 851 Hungary
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Fax: +36 1 3922575
www.izotop.hu
izotop@izotop.hu

Skin corrosion/irritation:

Sodium azide (CAS # 26628-22-8):
Skin - In vitro study Result: No skin irritation (OECD Test Guideline 439)

Triton-X 100 (CAS # 9002-93-1):

Skin – Rabbit. Result: irritating - 4 h (OECD Test Guideline 404)

Remarks: The value is given in analogy to the following substances: 4-(1,1,3,3-tetramethylbutyl)phenol

Serious eye damage/eye irritation:

Sodium azide (CAS # 26628-22-8):
Eyes - Bovine cornea Result: No eye irritation - 4 h (OECD Test Guideline 437)

Triton-X 100 (CAS # 9002-93-1):

Eyes – Rabbit. Result: Risk of serious damage to eyes. (Draize Test). Remarks: Risk of corneal clouding.

Respiratory or skin sensitization:

Sodium azide (CAS # 26628-22-8):
Local lymph node assay (LLNA) – Mouse Result: negative (OECD Test Guideline 429)

Triton-X 100 (CAS # 9002-93-1):

Sensitisation test: - Human Result: negative
Patch test on human volunteers did not demonstrate sensitization properties.

Germ cell mutagenicity

Sodium azide (CAS # 26628-22-8):
Test Type: Mutagenicity (mammal cell test): chromosome aberration. Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activationMethod: OECD Test Guideline 473 Result: negative

Test Type: unscheduled DNA synthesis assay. Test system: Chinese hamster lung cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 482
Result: negative
Test Type: sister chromatid exchange assay Test system: Chinese hamster ovary cells
Metabolic activation: without metabolic activation Method: OECD Test Guideline 479
Result: negative

Carcinogenicity: No data available

Reproductive toxicity:

Triton-X 100 (CAS # 9002-93-1):
Ingestion of excessive amounts by pregnant animals resulted in maternal and fetal toxicity. Did not show teratogenic effects in animal experiments.

Specific target organ toxicity - single exposure: No data available

Specific target organ toxicity - repeated exposure:

Sodium azide (CAS # 26628-22-8):
Oral - May cause damage to organs through prolonged or repeated exposure – Brain

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Aspiration hazard: No data available

Primary routes of exposure Common routes of entry include inhalation, ingestion and eye/skin contact. Specific paths of concern for potentially infectious materials are skin puncture, contact with broken skin, contact with mucous membranes and inhalation of aerosolized material.

11.2 Information on other hazards
Endocrine disrupting properties:

Sodium azide (CAS # 26628-22-8):
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Triton-X 100 (CAS # 9002-93-1):
The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Other information:
This product contains materials of animal origin and should be considered as potentially capable of transmitting infectious diseases.

12. Ecological information:

Ecotoxical effects: Sodium Azide and Triton-X 100 are toxic for aquatic organisms.

12.1 Toxicity
Sodium azide (CAS # 26628-22-8):
Toxicity to fish: flow-through test LC50 - Oncorhynchus mykiss (rainbow trout) - 2,75 mg/l - 96 h (OECD Test Guideline 203)
Toxicity to algae: static test ErC50 - Pseudokirchneriella subcapitata - 0,35 mg/l - 96 h (OECD Test Guideline 201)
Triton-X 100 (CAS # 9002-93-1):
Toxicity to fish LC50 - Pimephales promelas (fathead minnow) - 4 - 8,9 mg/l - 96 h
Toxicity to fish semi-static test LC50 - Leuciscus idus (Golden orfe) - 0,26 mg/l – 96 h (OECD Test Guideline 203)
Remarks: The value is given in analogy to the following substances:
4-(1,1,3,3-tetramethylbutyl)phenol
Toxicity to daphnia and other aquatic invertebrates LC50

- Daphnia magna (Water flea) - 18 - 26 mg/l - 48 h
Toxicity to daphnia and other aquatic invertebrates static test EC50
- Daphnia magna (Water flea) - 0,011 mg/l - 48 h
Remarks: (ECOTOX Database) The value is given in analogy to the following substances:
4-(1,1,3,3-tetramethylbutyl)phenol
Toxicity to algae: static test EC50 - Pseudokirchneriella subcapitata (green algae) - 1,9 mg/l - 96 h
Remarks: (ECHA) The value is given in analogy to the following substances:
4-(1,1,3,3-tetramethylbutyl)phenol
Toxicity to fish(Chronic toxicity) flow-through test - Danio rerio (zebra fish) - 0,012 mg/l (OECD Test Guideline 210)
Remarks: The value is given in analogy to the following substances:
4-(1,1,3,3-tetramethylbutyl)phenol
Toxicity to daphnia and other aquatic invertebrates(Chronic toxicity):
semi-static test NOEC - Daphnia magna (Water flea) - 0,03 mg/l - 21 d
(OECD Test Guideline 202)
Remarks: The value is given in analogy to the following substances:
4-(1,1,3,3-tetramethylbutyl)phenol

12.2 Persistence and degradability
Sodium azide (CAS # 26628-22-8):
The methods for determining the biological degradability are not applicable to inorganic substances.
Triton-X 100 (CAS # 9002-93-1):
Biodegradability aerobic - Exposure time 28 d - Result: 22 % - Not readily biodegradable.
(OECD Test Guideline 301C)

12.3 Bioaccumulative potential
No data available
12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not determined for the product. PBT: Not applicable, vPvB: Not applicable.

12.6 Endocrine disrupting properties:

Triton-X 100 (CAS # 9002-93-1): This substance/mixture contains components considered to have endocrine disrupting properties for environment, according to REACH Article 57(f), Commission Regulation (EU) 2018/605 or Commission Delegated Regulation (EU) 2017/2100. The component contains < 0.1 % by wt. Triton-X 100 after diluted to working solution state.

12.7 Other adverse effects: This product contains environmentally hazardous substance below the cutoff level. Refer section 3 for ingredient information. Do not allow undiluted product to enter sewer/surface or ground water.

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13.Disposal considerations:

13.1 Waste treatment methods

Product Waste Disposal: The concentrate must be disposed of as hazardous waste. The diluted solution (<0.1%) should be disposed of in accordance with local and national regulations. Large quantities of diluted solution should not be flushed into drains where lead or copper plumbing is present to prevent the buildup of explosive metal azides. Chemical residues and remains should be routinely handled as special waste. This must be disposed of in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or an approved waste-disposal company for information.
Sodium azide preservative may form explosive compounds in metal drain lines.
See NIOSH Bulletin: Explosive Azide Hazard (8/16/76).
To avoid the possible build-up of azide compounds, flush wastepipes with water after the disposal of undiluted reagent. Sodium azide disposal must be in accordance with appropriate local regulations.
Dispose of as potentially biohazardous waste and in compliance with anti-pollution and other laws of the country concerned. To ensure compliance we recommend that you contact the relevant (local) authorities and/or and approved waste-disposal company for information.
Package disposal: Dispose of waste product, unused product and contaminated packaging in compliance with federal, state and local regulations. If unsure of the applicable requirements, contact the authorities for information.

13.2 Additional Information

Suggested European waste catalogue 18 01 07 - chemicals other than those mentioned in 18 01 06. Dispose in accordance with national, state and local waste regulations.

14.Transport information:

Transportation of this product is not regulated under ICAO, IATA DGR, IMDG, US DOT, European ADR and RID or Canadian TDG.

14.1 UN/ID number: Not regulated for transportation
14.2 UN proper shipping name: Not regulated for transportation
14.3 Transport hazard class(es): Not regulated for transportation
14.4 Packing group: Not regulated for transportation
14.5 Environmental hazards: Not regulated for transportation
14.6 Special precautions for user: None
14.7 Maritime transport in bulk according to IMO instruments: Not applicable

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15. Regulatory information:

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

EU regulations: This SDS complies with EC Regulations 1907/2006 (REACH and amendments).

Labelling according to EU guidelines: The product has been classified and marked in accordance with EU Directives / Ordinance on Hazardous Materials. Harmonised classification - Annex VI of Regulation (EC) No 1272/2008 (CLP Regulation)

The mixture is classified as hazardous under the CLP Regulation and therefore **labelling and a safety data sheet are required**.

Restrictions on use:
For professional laboratory use only.

Other information: None

15.2 Chemical safety assessment

A Chemical Safety Assessment has not been carried out.

16. Other information:

Izotop safety rating:	Flammability: 0	Code
	Health: 1	0=None
	Reactivity with	1=Slight
	water: 0	2=Caution
	Physical contact: 1	3=Severe

Revision changes: Revised to include EC 2020/878 amendment to REACH EC 1907/2006
Document version and issue/revision date: Revision Date (year/month/day) 2026/02/10
Description of hazard class and hazard statements from Section 3:
Aquatic Acute 1 - Aquatic Hazard Acute, Category 1
Acute Tox. Oral 2 - Acute Toxicity Oral, Category 2
Aquatic Longterm 1 - Aquatic Hazard Long term, Category 1
Acute tox. 4 - Acute Toxicity, Category 4
Aquatic Chronic 2 - Long-term aquatic hazard, Category 2
Skin irritation 2 - Skin irritation, Category 2
Serious eye damage 1 - Serious Eye Damage / Eye Irritation, Category 1

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Abbreviations and Acronyms:

ACGIH - American Conference of Governmental Industrial Hygienists
ADR - European Agreement Concerning The International Carriage Of Dangerous Goods By Road
CERCLA - The Comprehensive Environmental Response, Compensation, and Liability Act
CLP - Classification, Labeling and Packaging
DFGMAK - Republic Germany's maximum exposure limit
GHS - Globally Harmonized System
HCS - Hazard Communication Standard
IARC - International Agency for Research on Cancer
IATA - International Air Transport Association
ICAO - International Civil Aviation Organization
IMDG - International Maritime Dangerous Goods
IOELVs - European Unions' Indicative Occupational Exposure Limit Values
NIOSH - National Institute for Occupational Safety and Health
NTP - National Toxicology Program
OSHA - Occupational Safety and Health Administration
PBT - Persistent bioaccumulative and toxic substances
SARA - Superfund Amendments and Reauthorization Act
TDG - Canadian Transportation Of Dangerous Goods Regulations.
UN GHS - United Nations Globally Harmonized System
US DOT - United States Department of Transportation
WHMIS - Workplace Hazardous Material Information System
vPvB - Very persistent and very bioaccumulative substances
LC50 - Lethal Concentration, 50%
LD50 - Lethal Dose, 50%

Information and recommendations:

- All animal products and derivatives are collected in healthy animals without any disease.
- The BSA (Bovine Serum Albumin) originates from countries where BSE (Bovine Spongiform Encephalopathy) as not been reported.
- The information herein is believed to be correct as of the date hereof but is provided without warranty of any kind. The recipient of our products is responsible for observing any laws and guidelines.
- For in vitro research only.
- In no case the product must be administered to humans or animals.
- Do not smoke, drink, eat or apply cosmetics in the working area.
- Do not pipette by mouth.
- Use protective clothing and disposable gloves.