



INSTITUTE OF ISOTOPES CO. LTD.
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MATERIAL SAFETY DATA SHEET

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

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

1.1 Product identifier:

Product name: rat TSH Control set
Product code: RK-554Cset
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; Clear, Liquid, 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: 3 vials (0.5 mL), containing freeze-dried rat TSH 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.



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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

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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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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12. Ecological information:

Ecotoxicological 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 an 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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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.



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Abbreviations and Acronyms:

TSH – Thyroid Stimulating 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.