

Trade name: Anti-R-TSH Ab RIA
Product number: DETCT100

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name: Anti-R-TSH Ab RIA
Catalogue no: DETCT100 (100 tube)

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

Detection of autoantibodies to the TSH receptor (TSHR) in human serum

1.3 Details of the supplier of the safety data sheet:

Demeditec Diagnostics GmbH
Lise-Meitner-Str. 2
24145 Kiel
Germany
Phone: +49-(0)431 / 71922 0
Fax: +49-(0)431 / 71922 55
E-Mail: info@demeditec.de
www.demeditec.de

1.4 Emergency telephone number:

+49-(0)431 / 71922-0 (during opening time: 8:00 h – 16:30 h)

2. HAZARDS IDENTIFICATION

2. Classification of the substance or mixture

The Anti-R-TSH Ab RIA Kit is not considered hazardous in accordance with Regulation (EC) No. 1272/2008.

2.2 Label elements

This product does not require a hazard warning label according to EC directives.

2.3 Other Hazards

No single component of the kit contains a hazardous ingredient in a concentration which qualifies the product as hazardous according to Regulation (EC) No. 1272/2008. However, ingestion or exposure to large amounts from improper handling can be potentially hazardous.

This kit contains both animal and human proteins and should be treated as a potential biohazard. All animal and human sera have been tested to ensure the absence of infectious agents but all materials should be handled as though capable of transmitting infectious disease and disposed of accordingly.

This kit contains ¹²⁵Iodine, a radioisotope with a half-life of approximately 60 days which emits gamma radiation with a maximum energy of 35 keV. Evidence exists of mutagenic, teratogenic and carcinogenic effects by ionising radiation.

The following precautionary statements should be taken into consideration:

P233, P270, P281, P301 + P330 + P331, P302 + P352, P304 + P340, P305 + P351 + P338 (see section 16 for full text).

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

¹²⁵I-labelled TSH, start buffer, calibrators and positive and negative controls contain animal proteins and/or human proteins and should be treated as potential biohazards.

¹²⁵I-labelled TSH is radioactive, ~100 kBq/~2.703 µCi per vial (~180 kBq/~4.865 µCi per vial for 100 tube kits)

The ingredients listed for the kit components below are considered hazardous but are not present in high enough concentrations to be classified under Regulation (EC) No 1272/2008.

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Kit Component	Ingredient(s)	Concentration
¹²⁵ I-labelled TSH	Tergitol™ Sodium azide	<0.1% v/v <0.04% w/v
Start Buffer	Tergitol™ Sodium azide	0.5% v/v 0.04% w/v
Concentrated Wash Solution	Tergitol™ 2-Chloroacetamide N-Methylisothiazolone (MIT) Antifoam A	0.5% v/v 0.05% w/v 0.01% w/v 0.01% v/v
Calibrators, Positive and Negative Controls	Sodium azide	0.05% w/v

Ingredient	CAS No.	EC No.	Classification GHS/CLP
Antifoam A	N/A	N/A	Eye Irrit. 2, STOT SE3; <i>H319, H335</i>
2-Chloroacetamide	79-07-02	201-174-2	Acute Tox. 3 (Oral), Skin Sens. 1, Repr. 2; <i>H301, H317, H361f</i>
MIT	26172-54-3	247-499-3	Acute Tox. 3 (Oral & Dermal), Acute Tox. 2 (inhalation), Skin Corr. 1A, Skin Sens. 1A, Aquatic Chronic 1;
Sodium Azide	26628-22-8	247-852-1	Acute Tox. 2 (Oral & Inhalation), Acute Tox. 1(Dermal), STOT RE 2, Aquatic Acute 1, Aquatic Chronic 1; <i>H300, H310, H330, H373, H400, H410, EUH302</i>
Tergitol™	84133-50-6	617-534-0	Acute Tox. 4 (Oral & Inhalation), Skin Irrit. 2, Eye Dam. 1; <i>H302, H315, H318, H332</i>

The full text for the hazard statements can be found in section 16.

4. FIRST AID MEASURES

4.1 Description of first aid measures

After skin contact: Wash off skin thoroughly with water for at least 15 minutes. Remove contaminated clothing. In severe cases or if skin is broken, OBTAIN MEDICAL ATTENTION.

After eye contact: Separate eyelids with fingers and flush eye with copious amounts of water for at least 15 minutes. OBTAIN MEDICAL ATTENTION.

After Inhalation: Remove from exposure, rest and keep warm. If breathing becomes difficult, OBTAIN MEDICAL ATTENTION.

After Ingestion: If patient is conscious, wash out mouth with water and give plenty of water to drink. OBTAIN MEDICAL ATTENTION.

4.2 Most important symptoms and effects, both acute and delayed

Not available.

4.3 Indication of any immediate medical attention and special treatment needed

Not available.

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5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Use water, dry powder or foam as appropriate to supporting fire.

5.2 Special hazards arising from the substance or mixture

May evolve toxic fumes in fire. Hazardous combustion products are not known for kit components but combustion products for the ingredients listed in subsection 3.2 can be found in the following table:

Ingredient	Hazardous combustion product(s)
Antifoam A	Nature of decomposition products not known
2-Chloroacetamide	Carbon oxides, nitrogen oxides (NOx) and hydrogen chloride gas
MIT	Carbon oxides, nitrogen oxides (NOx), sulphur oxides and hydrogen
Sodium Azide	Nitrogen oxides (NOx)
Tergitol™	Nature of decomposition products not known

5.3 Advice for fire-fighters

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Wear appropriate protective clothing as described in subsection 8.2. Ventilate area and avoid breathing vapours, mist or gas.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Prevent any reagents from entering drains.

6.3 Methods and material for containment and cleaning up

Radioactive spills should be dealt with immediately in accordance with the current local and national regulations and guidelines.

Wipe up liquid spills with absorbent paper. For solid spills, sweep up without raising dust. Once pick up is complete, wash site with detergent and water and decontaminate with a suitable disinfectant solution. Any surfaces contaminated with 125Iodine should be washed with a suitable detergent to remove all traces of radioactivity. Dispose of radioactive waste via an authorised route

6.4 Reference to other sections

See sections 8 and 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Users should make themselves aware of, and observe any national and local legislation and codes of practice governing the use, storage, transportation and disposal of radioactive materials.

Radioactive materials should only be used by authorised personnel and in designated areas. Wash hands thoroughly after handling. Monitor hands and clothing before leaving the designated area. Report contamination to the responsible person and take remedial action.

Material of human origin has been tested and found non-reactive for HIV 1 and 2 and HCV antibodies and HBsAg. All animal sourced material has been obtained from animals certified as healthy and free from disease. However all potentially biohazardous components should be considered as potentially infectious. Level II containment should be applied.

Do not eat, drink or smoke in the laboratory. Do not pipette by mouth. Avoid skin and eye contact. Wear appropriate protective clothing as described in subsection 8.2. Avoid the use of needles or other sharp implements. Avoid prolonged or repeated exposure.

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7.2 Conditions for safe storage, including any incompatibilities

Keep containers tightly closed. Store in a dry place in the box supplied at a temperature between +2 and +8°C.

7.3 Specific end use(s)

The Anti-R-TSH Ab RIA is intended for professional use only and to be used solely for the purpose as specified in subsection 1.2. Refer to kit instructions for details.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

No occupational exposure limits exist for any kit components. However, the following limits apply to component ingredients: sodium azide (see subsection 3.2 for components containing these substances):

Value	Control Parameters	Basis
Sodium Azide		
STEL	0.3 mg/m ³	UK: EH40 Workplace Exposure Limits (WEL)
TWA	0.1 mg/ m ³	Europe: Commission Directive 2000/39/EC

8.2 Exposure controls

Appropriate engineering controls

Good laboratory practice should be followed (see Section 7). Avoid contact with skin or eyes. Wash hands after use.

Individual protection measures (personal protective equipment)

Eye/face protection

Chemical safety glasses or goggles conforming to appropriate government standards such as EN166 (EU) or NIOSH (US).

Skin and body protection

Chemical resistant gloves to be used in accordance with standard EN374 derived from EU Directive 89/686/EEC. Latex or vinyl gloves will provide sufficient protection. Inspect gloves for damage prior to use and change if any sign of degradation. Proper glove removal technique must be used. Wash hands after use.

Respiratory protection

Local exhaust.

Environmental exposure controls

Prevent further leakage or spillage if safe to do so. Prevent any reagents from entering drains

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on the basic physical and chemical properties

Kit component	Appearance	Odour	pH	Solubility
Anti-R-TSH Ab Coated Tubes	Colourless polystyrene tubes	N/A	N/A	N/A
¹²⁵ I-labelled TSH	Red liquid	None	N/A	N/A
Start Buffer	Yellow liquid	None	~7.6	N/A
Concentrated Wash Solution	Colourless liquid	None	~7.8	N/A
Calibrators, Positive and Negative Controls	Pale yellow liquid	None	N/A	N/A

There is no information available for the following categories: odour threshold, melting/freezing point, initial boiling point/boiling range, flash point, evaporation rate, flammability (solid, gas), upper/lower flammability or explosive limits, vapour pressure, vapour density, relative density, partition coefficient, autoignition temperature, decomposition temperature, viscosity, explosive properties or oxidising properties.

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9.2 Other information

All liquid components are miscible with water in all proportions.

10. STABILITY AND REACTIVITY

10.1 Reactivity

Data is not available.

10.2 Chemical stability

All components of the Anti-R-TSH Ab RIA have been found stable for stated shelf life when stored under the recommended conditions.

10.3 Possibility of hazardous reactions

No hazardous reactions known for kit components although, hazardous reactions occur for the following substances listed in subsection 3.2:

Ingredient	Hazardous Reaction
Sodium Azide	Risk of explosion and/or toxic gas formation exists with heavy metals, bromine, lead, chromyl chloride, dichloromethane, dimethylsulfate, halogenated hydrocarbon, acid, carbon disulphide, sulphuric acid, copper and nitric acid. Generates dangerous gases or fumes with acids and water, leading to the release of hydrazoic acid. Violent reactions possible with nitrates, benzoyl chloride and potassium nitrate.

10.4 Conditions to avoid

Proteins, sodium azide and Tergitol™ are heat sensitive and storage or use at the improper temperature may compromise the integrity of the kit.

10.5 Incompatible materials

No data is known for kit components but the following data is known for components listed in subsection 3.2:

Ingredient	Incompatible materials
2-Chloroacetamide	Strong oxidising agents, strong acids, strong bases and strong reducing agents
MIT	Strong oxidising agents
Antifoam A	Strong oxidising agents and strong acids
Sodium Azide	Aluminium and heavy metals
Tergitol™	Strong acids, strong bases and strong oxidising agents

10.6 Hazardous decomposition products

No decomposition products are formed if kit is stored and used under the specified storage and handling conditions.

May evolve toxic fumes in fire. Thermal decomposition products are not known for the kit components but hazardous combustion products of the ingredients listed in subsection 3.2 can be found in subsection 5.2.

11. TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

The kit components have not been directly tested for their toxicological effects, therefore no information is known for these mixtures. The following toxicological data is known for ingredients listed in subsection 3.2:

Trade name: Anti-R-TSH Ab RIA
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(a) Acute toxicity
**Definitions can be found in section 16*

Ingredient	Measurement*	Value	Species
2-Chloroaceamide	LD ₅₀ (Oral)	138 mg/kg	Rat
MIT	LD ₅₀ (Oral)	175 mg/kg	Rat
	LC ₅₀ (Inhalation)	0.11 mg/L /4h)	Rat
	LD ₅₀ (Dermal)	246 mg/kg	Rat
Sodium Azide	LD ₅₀ (Oral)	27 mg/kg	Rat
	LC ₅₀ (Inhalation)	0.054 – 0.52 mg/L (4h)	Rat
	LD ₅₀ (Dermal)	20 mg/kg	Rabbit

No data available for other ingredients listed in subsection 3.2.

(b) Skin corrosion/irritation

Ingredient	Test/Result
MIT	Skin (reconstructed human epidermis (RhE) – Corrosive
Sodium Azide	In vitro study, human skin model test – No skin irritation
Tergitol™	Irritating to skin

No data available for other ingredients listed in subsection 3.2.

(c) Serious eye damage/irritation

Ingredient	Test/Result
Sodium Azide	In vitro study, exposure time 4 hours – No eye irritation
MIT	Causes serious eye damage
Tergitol™	Causes severe eye irritation

No data available for other ingredients listed in subsection 3.2.

(d) Respiratory or skin sensitisation

Ingredient	Test/Result
2-Chloroaceamide	Maximisation test, Guinea pig – May cause sensitisation by skin contact
Sodium Azide	Sensitisation test, Mouse – Negative
MIT	Maximisation test, Guinea pig – Result: Positive
Tergitol™	Patch test on human volunteers did not demonstrate sensitisation properties.

No data available for other ingredients listed in subsection 3.2.

(e) Germ cell mutagenicity

Ingredient	Test/Result
2-Chloroaceamide	Hamster, lungs – Negative Mouse, male and female – Negative
MIT	Ames test, Salmonella typhimurium – Negative , Mouse – Negative, Rat - Negative

No data available for other ingredients listed in subsection 3.2.

(f) Carcinogenicity

Ingredient	Test/Result
Antifoam A	IARC: No component of this product present at levels ≥0.1% is identified as probable, possible or confirmed human carcinogen by IARC
2-Chloroaceamide	
MIT	
Tergitol™	

No data available for other ingredients listed in subsection 3.2.

(g) Reproductive toxicity

Ingredient	Test/Result
2-Chloroaceamide	Suspected human reproductive toxicant

No data available for other ingredients listed in subsection 3.2.

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(h) STOT-single exposure

No data available.

(i) STOT-repeated exposure

No data available.

(j) Aspiration hazard

No data available.

12. ECOLOGICAL INFORMATION

The kit components have not been tested for their ecological effects, therefore no information is known for these mixtures. The following ecological data is known for ingredients listed in subsection 3.2:

12.1 Toxicity

Ingredient	Toxicity to	Measurement*	Value
2-Chloroaceamide	Fish (<i>Carassius auratus (goldfish)</i>)	LC ₅₀	19.8 mg/L (96h)
	Daphnia (<i>Daphnia magna (water flea)</i>)	EC ₅₀	14 mg/L (48h)
MIT	Fish (<i>Oncorhynchus mykiss (rainbow trout)</i>)	LC ₅₀	4.77 mg/L (96h)
	Daphnia (<i>Daphnia magna (water flea)</i>)	EC ₅₀	2.33 mg/L (48h)
	Algae (<i>Pseudokirchneriella subcapitata (green algae)</i>)	ErC ₅₀	0.289 mg/L (72h)
Sodium Azide	Fish (<i>Lepomis macrochirus (bluegill sunfish)</i>)	LC ₅₀	0.70 mg/L (96h)
	Daphnia (<i>Daphnia pulex (water flea)</i>)	EC ₅₀	4.2 mg/L (48h)
	Algae (<i>mixed culture of green algae</i>)	IC ₅₀	272 mg/L
	Microorganisms (<i>Photobacterium phosphoreum</i>)	EC ₅₀	38.5 mg/L

No data available for other ingredients listed in subsection 3.2.

12.2 Persistence and degradability

Ingredient	Test/Result
2-Chloroaceamide	Biodegradability: aerobic, exposure time 28 days Results: 94% - Readily degradable
MIT	Biodegradability: aerobic, exposure time 28 days Results: 0% - Not readily degradable
Tergitol™	Result: >60% - Readily biodegradable

No data available for other ingredients listed in subsection 3.2.

12.3 Bioaccumulative potential

Ingredient	Test/Result
Sodium Azide	Partition coefficient: n-octanol/water - log Pow: 0.3 (Bioaccumulation is not expected)

No data available for other ingredients listed in subsection 3.2.

12.4 Mobility in soil

No data available.

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12.5 Results of PBT and vPvB assessment

Ingredient	Test/Result
Antifoam A	This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of $\geq 0.1\%$
MIT	
2-Chloroacetamide	
Sodium Azide	
Tergitol™	

No data available for MIT.

12.6 Other adverse effects

The concentrations of ingredients listed in subsection 3.2 are below the acceptable limit for hazardous substances; the ecological risk is minimal. However, it is recommended that reagents do not enter drains in large quantities.

13. DISPOSAL CONSIDERATIONS
13.1 Waste treatment methods

Chemical and biological residues are classified as special waste and as such, are covered by regulations which may vary according to location. Contact your local waste disposal authority for advice or pass to a licensed disposal company. Observe all national and local environmental regulations. Contaminated packaging should be disposed of using the same routes.

14. TRANSPORT INFORMATION

This product is not covered by international regulation on the transport of dangerous goods (IMDG, IATA, ADR/RID). Transport of this product can be carried out at ambient temperature but in the event of delays store at 2 – 8°C with all reagents contained within the packaging provided.

14.1 UN number

UN2910 for excepted quantity of radioactive materials.

14.2 UN proper shipping name

Not applicable.

14.3 Transport hazard class(es)

Not applicable.

14.4 Packing group

Not applicable.

14.5 Environmental hazards

Not applicable.

14.6 Special precautions for user

See sections 6 to 8.

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC code

Not applicable.

15. REGULATORY INFORMATION
15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture.

None known

15.2 Chemical safety assessment

Not applicable.

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16. OTHER INFORMATION

This SDS has been compiled in accordance with Commission Regulation (EC) No.1907/2006 as amended by Commission Regulation (EU) 2015/830.

All information provided on ingredients listed in subsection 3.2 has been obtained from the appropriate chemical safety data sheets.

Full text of precautionary statements (listed in subsection 2.3) and hazard statements (listed in subsection 3.2) according to Regulation (EC) No. 1272/2008:

P233: Keep container tightly closed.

P270: Do not eat, drink or smoke when using this product.

P281: Use personal protective equipment as required.

P301 + P330: IF SWALLOWED rinse mouth. Do NOT induce vomiting.

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

P304 + P340: IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

P305 + P351 + P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do so. Continue rinsing.

H300: Fatal if swallowed.

H301: Toxic if swallowed.

H302: Harmful if swallowed.

H310: Fatal in contact with skin.

H311: Toxic in contact with skin.

H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H318: Causes serious eye damage.

H319: Causes serious eye irritation.

H330: Fatal if inhaled.

H332: Harmful if inhaled.

H335: May cause respiratory irritation.

H361f: Suspected of damaging fertility.

H373: May cause damage to organs through prolonged or repeated exposure.

H400: Very toxic to aquatic life.

H410: Very toxic to aquatic life with long lasting effects.

EUH032: Contact with acids liberates toxic gas.

Definitions:

LC50: The lethal concentration of a substance that kills 50% of the test population within a designated period.

LD50: Lethal dose for 50% of the test population.

EC50: The effective concentration of a substance that causes adverse effects in 50% of the test population within a designated period.

ErC50: The concentration of a substance which results in 50% reduction in growth rate of the test population relative to the control within 72 hours exposure.

IC50: The inhibition concentration of a substance that causes a 50% inhibition of growth of the test population relative to the control within a designated period.

STEL: Short term exposure limit (15 minute reference period).

TWA: Time weighted average, long term exposure limit (8 hour reference period).

The above information is believed to be correct but does not purport to be all-inclusive and is provided for guidance only. Demeditec shall not be held liable for any damage or injury resulting from handling or from contact with the above product and assumes no responsibility to the accuracy or completeness of the data contained herein. It is the responsibility of the purchaser to ensure that laboratory workers who use this product are aware of its hazards and take all necessary precautions to prevent contact, ingestion, inhalation or any other mode of exposure.