

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 and uses advised against (if any):

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


2.1 Classification of mixture

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

Kit Component	Hazard Classification	Hazard Statements
Start Buffer	Eye Irritation, Category 2	H319
Concentrated Wash Solution	Eye Irritation, Category 2	H319

2.2 Label elements

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

START BUFFER	
CONCENTRATED WASH SOLUTION	
Hazard pictogram	 Signal word: Warning
Hazard statement(s)	
H319	Causes serious eye irritation
Precautionary statement(s)	
P280	Wear protective gloves/protective clothing/eye protection/face protection
P305 + P351 + P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing
P337 + P313	If eye irritation persists: Get medical advice/attention

2.3 Other Hazards

All other kit components not listed in section 2.1 and 2.2 do not contain hazardous ingredients in concentrations which meet the criteria for classification 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.

The following precautionary statements should be taken into consideration:

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

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3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Not applicable

3.2 Mixtures

Hazardous ingredients according to Regulation (EC) No. 1272/2008:

START BUFFER				
CONCENTRATED WASH SOLUTION				
Ingredient(s)	CAS No.	EC No.	Classification (GHS)	Conc. (v/v)
Triton™ X-100	9002-93-1	N/A	Acute Tox. 4 (Oral), Skin Irrit. 2, Eye Dam.1, Aquatic Acute 1; Aquatic Chronic 1; H302, H315, H318, H400, H410	1.0%
<p><i>Contains p-tertiary-octylphenoxy polyethyl alcohol:</i> Included in Candidate List of Substances of Very High Concern (SVHC) for Authorisation (Article 59). Listed in Annex XVI of REACH Regulation (EC) No. 1907/2006.</p> <p>CAS No. 9002-93-1 EC No. N/A Concentration: ≥90 – 100% Classification: Acute Tox. 4 (Oral), H302; Skin Irrit. 2, H315; Eye Dam. 1, H318; Aquatic Acute 1, H400; Aquatic Chronic 1, H410</p>				

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.

Kit Component	Ingredient(s)	Concentration
¹²⁵ I-labelled TSH	Triton™ X-100	<0.1% v/v
	Sodium azide	<0.04% w/v
Start Buffer	Sodium azide	0.04% w/v
Concentrated Wash Solution	2-Chloroacetamide	0.05% w/v
	N-Methylisothiazolone (MIT)	0.01% w/v
	Antifoam A	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	Asp. Tox. 1, Repr. 2; H304, H361
2-Chloroacetamide	79-07-02	201-174-2	Acute Tox. 3 (Oral), Skin Sens. 1, Repr. 2; H301, H317, H361f
MIT	26172-54-3	247-499-3	Skin Corr. 1B, Resp. Sens.1, Skin Sens. 1; H314, H317, H334
Sodium Azide	26628-22-8	247-852-1	Acute Tox. 2 (Oral), Acute Tox. 1 (Dermal), STOT RE 2, Aquatic Acute 1, Aquatic Chronic 1; H300, H310, H373, H400, H410, EUH302
Triton™ X-100	For chemical information – See “START BUFFER” & “CONCENTRATED WASH SOLUTION”		

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

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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.

5. FIRE-FIGHTING MEASURES

5.1 Suitable 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	Carbon oxides and silicon oxides
2-Chloroacetamide	Carbon oxides, nitrogen oxides (NOx) and hydrogen
MIT	Carbon oxides, nitrogen oxides (NOx) and sulphur oxides
Sodium Azide	Nitrogen oxides (NOx)
Triton™ X-100	Carbon oxides

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

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.

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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. 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.

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.

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

The following controls should be followed as appropriate to the situation and the quantities handled.

General protective measures:

Avoid contact with skin or eyes. Wash hands after use.

Hygiene measures:

General laboratory practice (see section 7).

Respiratory protection:

Local exhaust.

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.

Other equipment:

Eye bath and safety shower

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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.

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 and sodium azide 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
Sodium Azide	Aluminium and heavy metals
Triton™ X-100	Strong acids, strong bases and strong oxidising agents

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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:

(a) Acute toxicity

**Definitions can be found in section 16*

Ingredient	Measurement*	Value	Species
2-Chloroacetamide	LD ₅₀ (Oral)	138 mg/kg	Rat
MIT	LD ₅₀ (Oral)	175 mg/kg	Rat
Sodium Azide	LD ₅₀ (Oral)	27 mg/kg	Rat
	LC ₅₀ (Inhalation)	37 mg/kg	Rat
	LD ₅₀ (Dermal)	20 mg/kg	Rabbit
Triton™ X-100	LD ₅₀ (Dermal)	>3000 mg/kg	Rabbit

No data available for Antifoam A.

(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

No data available for Antifoam A, 2-chloroacetamide or Triton™ X-100.

(c) Serious eye damage/irritation

Ingredient	Test/Result
Sodium Azide	In vitro study, exposure time 4 hours – No eye irritation

No data available for Antifoam A, 2-chloroacetamide, MIT or Triton™ X-100.

(d) Respiratory or skin sensitisation

Ingredient	Test/Result
2-Chloroacetamide	Maximisation test, Guinea pig – May cause sensitisation by skin contact
Sodium Azide	Sensitisation test, Mouse – Negative

No data available for Antifoam A, MIT or Triton™ X-100.

(e) Germ cell mutagenicity

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

No data available for Antifoam A, sodium azide or Triton™ X-100.

(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-Chloroacetamide	
MIT	
Triton™ X-100	

No data available for sodium azide.

(g) Reproductive toxicity

Ingredient	Test/Result
2-Chloroacetamide	Suspected human reproductive toxicant

No data available for Antifoam A, MIT, sodium azide or Triton™ X-100.

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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-Chloroacetamide	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	Daphnia (<i>Daphnia magna (water flea)</i>)	EC ₅₀	2.33 mg/L (48h)
	Algae (<i>Pseudokirchneriella subcapitata (green algae)</i>)	ErC ₅₀ NOEC	0.289 mg/L (72h) 0.047 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
Triton™ X-100	Fish (<i>Pimephales promelas (fathead minnow)</i>)	LC ₅₀	4 – 8.9 mg/L (96h)
	Daphnia (<i>Daphnia magna (water flea)</i>)	LC ₅₀	18 – 26 mg/L (48h)

No data available for Antifoam A.

12.2 Persistence and degradability

Ingredient	Test/Result
2-Chloroacetamide	Biodegradability: aerobic, exposure time 28 days Results: 94% - Readily degradable
MIT	Biodegradability: aerobic, exposure time 28 days Results: 0% - Not readily degradable

No data available for Antifoam A, sodium azide or Triton™ X-100.

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 Antifoam A, 2-chloroacetamide, MIT or Triton™ X-100.

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 $\geq 0.1\%$
2-Chloroacetamide	
Sodium Azide	
Triton™ X-100	

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.

Triton™ X -100 contains p-tertiary-octylphenoxy polyethyl alcohol which is included in Candidate List of Substances of Very High Concern (SVHC) for Authorisation (Article 59). Listed in Annex XVI of REACH Regulation (EC) No.1907/2006.

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.

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.

H304: May be fatal if swallowed and enters airways.

H310: Fatal 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.

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

H361: Suspected of damaging fertility or the unborn child.

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.

NOEC: No-observed-effect-concentration. The highest concentration at which no toxic effects are observed.

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.