

# SAFETY DATA SHEET



## ThyroSeq*Preserve*

Version  
1.1

Revision Date:  
04-21-2016

Date of last issue: 11-09-2015  
Date of first issue: 11-09-2015

### SECTION 1. IDENTIFICATION

Product name : ThyroSeq*Preserve*  
Product code : 11934317001

#### Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

Address : 9115 Hague Road  
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone:  
In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or Canada)  
1-703-527-3887 (International)

#### Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

### SECTION 2. HAZARDS IDENTIFICATION

#### GHS Classification

Acute toxicity (Oral) : Category 4

Acute toxicity (Inhalation) : Category 4

Acute toxicity (Dermal) : Category 4

Serious eye damage : Category 1

#### GHS label elements

Hazard pictograms :



Signal Word : Danger

Hazard Statements : H302 + H312 + H332 Harmful if swallowed, in contact with skin or if inhaled.  
H318 Causes serious eye damage.

Precautionary Statements : **Prevention:**  
P261 Avoid breathing dust/ fume/ gas/ mist/ vapors/ spray.  
P264 Wash skin thoroughly after handling.  
P270 Do not eat, drink or smoke when using this product.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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P301 + P312 + P330 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell. Rinse mouth.

P302 + P352 + P312 IF ON SKIN: Wash with plenty of water. Call a POISON CENTER/doctor if you feel unwell.

P304 + P340 + P312 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/doctor if you feel unwell.

P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.

P363 Wash contaminated clothing before reuse.

**Disposal:**

P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Mixture

**Hazardous ingredients**

Chemical name	CAS-No.	Concentration (% w/w)
Guanidinium thiocyanate	593-84-0	>= 50 - < 70
Polyethylenglykol-1,1,3,3,-tetra-methylbutylphenylether	9002-93-1	>= 20 - < 30
1,4-Dithiothreitol (DTT)	3483-12-3	>= 1 - < 5

**SECTION 4. FIRST AID MEASURES**

General advice : Move out of dangerous area.  
Consult a physician.  
Show this material safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.

If inhaled : Move to fresh air.  
If unconscious place in recovery position and seek medical advice.  
If symptoms persist, call a physician.

In case of skin contact : If skin irritation persists, call a physician.  
If on skin, rinse well with water.  
If on clothes, remove clothes.

In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.  
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.  
Continue rinsing eyes during transport to hospital.

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- Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.  
Do NOT induce vomiting.  
Do not give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Take victim immediately to hospital.
- Most important symptoms and effects, both acute and delayed : Harmful if swallowed, in contact with skin or if inhaled.  
Causes serious eye damage.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

### SECTION 5. FIRE-FIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during fire fighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.  
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

### SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.  
Refer to protective measures listed in sections 7 and 8.
- Environmental precautions : Prevent product from entering drains.  
Prevent further leakage or spillage if safe to do so.
- Methods and materials for containment and cleaning up : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).  
Keep in suitable, closed containers for disposal.

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### SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Normal measures for preventive fire protection.
- Advice on safe handling : Do not breathe vapors/dust.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Dispose of rinse water in accordance with local and national regulations.  
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Containers which are opened must be carefully resealed and kept upright to prevent leakage.  
Electrical installations / working materials must comply with the technological safety standards.
- Technical measures/Precautions : See label, package insert or internal guidelines

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### Ingredients with workplace control parameters

Contains no substances with occupational exposure limit values.

#### Hazardous components without workplace control parameters

Ingredients	CAS-No.
Guanidinium thiocyanate	593-84-0
Polyethylenglykol-1,1,3,3,-tetra-methylbutyl-phenylether	9002-93-1
1,4-Dithiothreitol (DTT)	3483-12-3

Engineering measures : No data available

#### Personal protective equipment

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.  
Replace torn or punctured gloves promptly.

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles  
Wear face-shield and protective suit for abnormal processing problems.

Skin and body protection : Impervious clothing  
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

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Hygiene measures : When using do not eat or drink.  
When using do not smoke.  
Wash hands before breaks and at the end of workday.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : light yellow

Odor : characteristic

Odor Threshold : No data available

pH : ca. 6.0

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : No data available

Evaporation rate : No data available

Flammability (solid, gas) : The product is not flammable.

Flammability (liquids) : Does not sustain combustion.

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapor pressure : No data available

Relative vapor density : No data available

Relative density : No data available

Solubility(ies)

    Water solubility : No data available

    Solubility in other solvents : No data available

Partition coefficient: n-octanol/water : No data available

Autoignition temperature : No data available

Decomposition temperature : No data available

Viscosity

    Viscosity, dynamic : No data available

    Viscosity, kinematic : No data available

Oxidizing properties : The substance or mixture is not classified as oxidizing.

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Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No dangerous reaction known under conditions of normal use. No decomposition if stored and applied as directed.
Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

**SECTION 11. TOXICOLOGICAL INFORMATION****Acute toxicity**

Harmful if swallowed, in contact with skin or if inhaled.

**Product:**

Acute oral toxicity	:	Acute toxicity estimate: 703.42 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: 2.54 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: Calculation method
Acute dermal toxicity	:	Acute toxicity estimate: 1,656 mg/kg Method: Calculation method

**Ingredients:****Guanidinium thiocyanate:**

Acute oral toxicity	:	LD50 Oral (Rat): 593 mg/kg
Acute inhalation toxicity	:	Acute toxicity estimate: 1.5 mg/l Test atmosphere: dust/mist Method: Expert judgment
Acute dermal toxicity	:	Acute toxicity estimate: 1,100 mg/kg Method: Expert judgment

**Polyethylenglykol-1,1,3,3,-tetra-methylbutyl-phenylether:**

Acute oral toxicity	:	LD50 Oral (Rat): 1,900 - 5,000 mg/kg  Acute toxicity estimate: 500 mg/kg Method: Expert judgment
Acute dermal toxicity	:	LD50 Dermal (Rabbit): > 3,000 mg/kg

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Acute oral toxicity : LD50 Oral (Rat): 400 mg/kg

Acute toxicity (other routes of administration) : Symptoms: May cause cardiac arrhythmia., Convulsions, Vomiting

**Skin corrosion/irritation**

Not classified based on available information.

**Product:**

Remarks: May cause skin irritation and/or dermatitis.

**Ingredients:****1,4-Dithiothreitol (DTT):**

Result: Irritating to skin.

**Serious eye damage/eye irritation**

Causes serious eye damage.

**Product:**

Remarks: May cause irreversible eye damage.

**Ingredients:****Polyethylenglykol-1,1,3,3,-tetra-methylbutyl-phenylether:**

Result: Risk of serious damage to eyes.

Remarks: May cause irreversible eye damage.

**1,4-Dithiothreitol (DTT):**

Result: Irritating to eyes.

**Respiratory or skin sensitization****Skin sensitization**

Not classified based on available information.

**Respiratory sensitization**

Not classified based on available information.

**Germ cell mutagenicity**

Not classified based on available information.

**Carcinogenicity**

Not classified based on available information.

**Ingredients:****Guanidinium thiocyanate:**

Remarks: No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**IARC**

No ingredient of this product present at levels greater than or

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equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**OSHA**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.

**NTP**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

**Reproductive toxicity**

Not classified based on available information.

**STOT-single exposure**

Not classified based on available information.

**STOT-repeated exposure**

Not classified based on available information.

**Aspiration toxicity**

Not classified based on available information.

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**SECTION 12. ECOLOGICAL INFORMATION**
**Ecotoxicity****Product:****Ecotoxicology Assessment**

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

**Ingredients:****Guanidinium thiocyanate:**

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): 89.1 mg/l  
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia): 42.4 mg/l  
Exposure time: 48 h

**Ecotoxicology Assessment**

Chronic aquatic toxicity : Harmful to aquatic life with long lasting effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

**Polyethylengykol-1,1,3,3,-tetra-methylbutyl-phenylether:**

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 4 - 8.9 mg/l



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Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 18 - 26 mg/l  
Exposure time: 48 h

### Ecotoxicology Assessment

Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

### 1,4-Dithiothreitol (DTT):

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 27 mg/l  
Exposure time: 48 h

### Ecotoxicology Assessment

Toxicity Data on Soil : Not expected to adsorb on soil.

Other organisms relevant to the environment : No data available

### Persistence and degradability

#### Ingredients:

#### **Polyethylenglykol-1,1,3,3,-tetra-methylbutyl-phenylether:**

Biodegradability : Biodegradation: > 60 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### Bioaccumulative potential

#### Ingredients:

#### **Guanidinium thiocyanate:**

Partition coefficient: n-octanol/water : log Pow: -1.38

#### **Polyethylenglykol-1,1,3,3,-tetra-methylbutyl-phenylether:**

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).

Partition coefficient: n-octanol/water : Remarks: No data available

### 1,4-Dithiothreitol (DTT):

Partition coefficient: n-octanol/water : log Pow: ca. -0.48

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No data available

**Other adverse effects****Product:**

- Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances  
Remarks: This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).
- Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.  
Harmful to aquatic life with long lasting effects.

**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

- Waste from residues : The product should not be allowed to enter drains, water courses or the soil.  
Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with local regulations.
- Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

**SECTION 14. TRANSPORT INFORMATION****International Regulation****UNRTDG**

Not regulated as a dangerous good

**IATA-DGR**

Not regulated as a dangerous good

**IMDG-Code**

Not regulated as a dangerous good

**Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable for product as supplied.

**Domestic regulation****49 CFR**

Not regulated as a dangerous good

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**SECTION 15. REGULATORY INFORMATION**
**EPCRA - Emergency Planning and Community Right-to-Know**
**CERCLA Reportable Quantity**

This material does not contain any components with a CERCLA RQ.

**SARA 304 Extremely Hazardous Substances Reportable Quantity**

This material does not contain any components with a section 304 EHS RQ.

**SARA 311/312 Hazards** : Acute Health Hazard

**SARA 302** : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

**SARA 313** : This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

**Clean Air Act**

This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (40 CFR 61).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCM Intermediate or Final VOC's (40 CFR 60.489).

**Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

**US State Regulations**
**Massachusetts Right To Know**

No components are subject to the Massachusetts Right to Know Act.

**Pennsylvania Right To Know**

Guanidinium thiocyanate	593-84-0	50 - 70 %
Polyethylengykol-1,1,3,3,-tetra-methylbutyl-phenylether	9002-93-1	20 - 30 %
Water	7732-18-5	10 - 20 %

**New Jersey Right To Know**

Guanidinium thiocyanate	593-84-0	50 - 70 %
Polyethylengykol-1,1,3,3,-tetra-methylbutyl-phenylether	9002-93-1	20 - 30 %
Water	7732-18-5	10 - 20 %
1,4-Dithiothreitol (DTT)	3483-12-3	1 - 5 %

**The ingredients of this product are reported in the following inventories:**

CH INV Not in compliance with the inventory

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	Polyethylenglykol-1,1,3,3,-tetra-methylbutyl-phenylether
DSL	All components of this product are on the Canadian DSL
AICS	On the inventory, or in compliance with the inventory
NZIoC	On the inventory, or in compliance with the inventory
ENCS	Not in compliance with the inventory Guanidinium thiocyanate Water 1,4-Dithiothreitol (DTT)
ISHL	Not in compliance with the inventory Guanidinium thiocyanate Water 1,4-Dithiothreitol (DTT)
KECI	Not in compliance with the inventory Guanidinium thiocyanate 1,4-Dithiothreitol (DTT)
PICCS	On the inventory, or in compliance with the inventory
IECSC	On the inventory, or in compliance with the inventory

**TSCA list**

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

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**SECTION 16. OTHER INFORMATION**
**Full text of other abbreviations**

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); EC<sub>x</sub> - Concentration associated with x% response; EHS - Extremely Hazardous Substance; EL<sub>x</sub> - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErC<sub>x</sub> - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC<sub>50</sub> - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC<sub>50</sub> - Lethal Concentration to 50 % of a test population; LD<sub>50</sub> - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of

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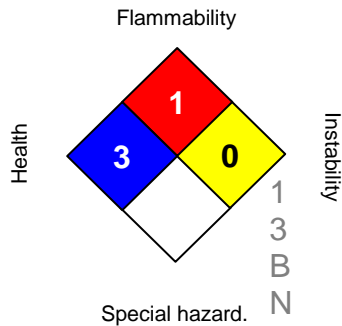
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Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

**Further information**

**NFPA:**



**HMIS III:**

<b>HEALTH</b>	<b>3</b>
<b>FLAMMABILITY</b>	<b>1</b>
<b>PHYSICAL HAZARD</b>	<b>0</b>

0 = not significant, 1 =Slight,  
2 = Moderate, 3 = High  
4 = Extreme, \* = Chronic

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The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

US / Z8 / 1511