

**Elecsys Syphilis**

Version  
3.1

Revision Date:  
10-08-2024

Date of last issue: 10-08-2024  
Date of first issue: 07-22-2020

**Cover letter for product:**


Trade name : Elecsys Syphilis  
Product code : 09015051190

The product is sold as a kit, and contains the following components:

- R1
- R2
- SA Coat-Beads
- Syphilis Elecsys Cal 1
- Syphilis Elecsys Cal 2

**The following is an overview of the labeling elements of the kit:**

**GHS label elements**

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**  
P261 Avoid breathing mist or vapors.  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves.  
**Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.  
P363 Wash contaminated clothing before reuse.  
**Disposal:**  
P501 Dispose of contents/ container to an approved waste disposal plant.

**Other hazards**

None known.

**The product was evaluated per International Air Transport Association (IATA) specifications with the following outcome:**

Not assigned by regulation



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### SECTION 1. IDENTIFICATION

Product name : R1

#### Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics  
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Address : 9115 Hague Road  
Indianapolis, IN 46250  
USA

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

Recommended use : Laboratory chemicals  
Refer to product literature for further details.


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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin sensitization : Category 1

#### GHS label elements

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**  
P261 Avoid breathing mist or vapors.  
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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

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1)	26172-54-3	>= 0.0015 - < 0.1

Actual concentration is withheld as a trade secret

**SECTION 4. FIRST AID MEASURES**

- General advice : Move out of dangerous area.  
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 on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
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 give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.  
May cause an allergic skin reaction.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.



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**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 : No information available.
- Hazardous combustion products : No hazardous combustion products are known
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for fire-fighters : Wear self-contained breathing apparatus for firefighting if necessary.

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**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.  
Local authorities should be advised if significant spillages cannot be contained.
- 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 exposure - obtain special instructions before use.  
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.  
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being



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- used.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

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**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Contains no substances with occupational exposure limit values.

**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

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

Hygiene measures : Wash hands before breaks and at the end of workday.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

Color : light yellow

Odor : odorless

Odor Threshold : No data available

pH : 5.5 - 7.5



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Melting point/ range	:	30 °F / -1 °C
Boiling point/boiling range	:	203 - 221 °F / 95 - 105 °C
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.007 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	completely miscible
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
Explosive properties	:	Not explosive
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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### SECTION 10. STABILITY AND REACTIVITY

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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	:	Exposure to light.
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified due to lack of data.  
Not classified due to lack of data.

#### Components:

##### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Acute oral toxicity	:	LD50 Oral (Rat, female): 175 mg/kg Method: OECD Test Guideline 425
Acute inhalation toxicity	:	LC50 (Rat, male and female): 0.11 mg/l Exposure time: 4 h Test atmosphere: dust/mist Method: OECD Test Guideline 403 Assessment: Corrosive to the respiratory tract. Remarks: Based on data from similar materials The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one
Acute dermal toxicity	:	LD50 Dermal (Rat, male): 246 mg/kg Method: OECD Test Guideline 402 Remarks: Based on data from similar materials The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

#### Skin corrosion/irritation

Not classified due to lack of data.  
Not classified due to lack of data.

#### Product:

Remarks : May cause skin irritation and/or dermatitis.

#### Components:

##### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Species	:	reconstructed human epidermis (RhE)
Method	:	OECD Test Guideline 431

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Result : Causes severe burns.

### Serious eye damage/eye irritation

Not classified due to lack of data.

Not classified due to lack of data.

### Product:

Remarks : Vapors may cause irritation to the eyes, respiratory system and the skin.

### Components:

#### 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Result : Risk of serious damage to eyes.

### Respiratory or skin sensitization

#### Skin sensitization

May cause an allergic skin reaction.

#### Skin sensitization

May cause an allergic skin reaction.

#### Respiratory sensitization

Not classified due to lack of data.

#### Respiratory sensitization

Not classified due to lack of data.

### Product:

Remarks : Causes sensitization.

### Components:

#### 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Test Type : Local lymph node assay (LLNA)

Method : OECD Test Guideline 429

Result : The product is a skin sensitizer, sub-category 1A.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test

Species : Guinea pig

Method : OECD Test Guideline 406

Result : positive

Remarks : Based on data from similar materials

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### Germ cell mutagenicity

Not classified due to lack of data.

Not classified due to lack of data.

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### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Method: OECD Test Guideline 476  
Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 474  
Result: negative  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay  
Species: Rat (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 486  
Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### **Carcinogenicity**

Not classified due to lack of data.

Not classified due to lack of data.

**IARC** 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.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**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 due to lack of data.

Not classified due to lack of data.

### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Effects on fetal development : Species: Rat  
Application Route: Oral

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Dose: 40 mg/kg bw/day  
Result: No effects on fetal development.  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### STOT-single exposure

Not classified due to lack of data.  
Not classified due to lack of data.

### STOT-repeated exposure

Not classified due to lack of data.  
Not classified due to lack of data.

### Repeated dose toxicity

#### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog  
NOAEL : 40.9 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### Aspiration toxicity

Not classified due to lack of data.  
Not classified due to lack of data.

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## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
Exposure time: 48 h

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Test Type: static test  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

M-Factor (Chronic aquatic toxicity) : 1

1

### Persistence and degradability

#### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### Bioaccumulative potential

#### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

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

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)  
Method: OECD Test Guideline 107

### Mobility in soil

No data available

### Other adverse effects

#### Product:

Ozone-Depletion Potential : Regulation: 40 CFR Protection of Environment; Part 82



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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).

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**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

- Waste from residues : 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.

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**SECTION 14. TRANSPORT INFORMATION**

**International Regulations**

**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

**Domestic regulation**

**49 CFR**

Not regulated as a dangerous good

**Special precautions for user**

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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**SECTION 15. REGULATORY INFORMATION**

**CERCLA Reportable Quantity**

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



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**SARA 304 Extremely Hazardous Substances Reportable Quantity**

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

**SARA 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Respiratory or skin sensitization

**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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

**US State Regulations**

**Massachusetts Right To Know**

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

**Pennsylvania Right To Know**

Water 7732-18-5

**Maine Chemicals of High Concern**

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

**Washington Chemicals of High Concern**

Product does not contain any listed chemicals

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

AIIC : Not in compliance with the inventory

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.



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Bovine Serum Albumin  
hydroxyl-2-pyridone  
Antigen / Protein, recombinant  
Antigen rec.-Biotin-conjugate

- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not 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**

**Further information**

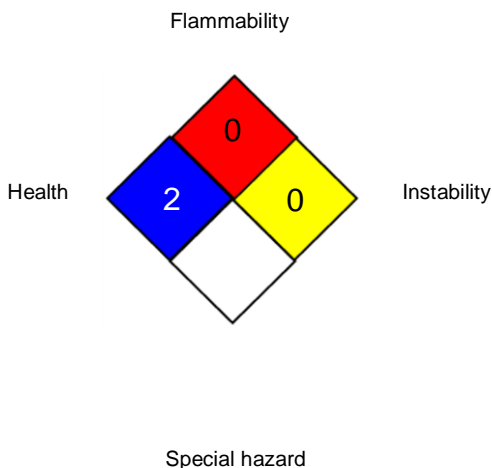
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**NFPA 704:**



**HMIS® IV:**

<b>HEALTH</b>	/	2
<b>FLAMMABILITY</b>	0	
<b>PHYSICAL HAZARD</b>	0	

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; 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); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - 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; IC50 - 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - 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 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; TECl - Thailand



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Existing Chemicals 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

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The information provided in this 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 / 2304



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**SECTION 1. IDENTIFICATION**

Product name : R2

**Manufacturer or supplier's details**

Company name of supplier : Roche Diagnostics

Address : 9115 Hague Road  
Indianapolis, IN 46250  
USA

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**

Recommended use : Laboratory chemicals  
Refer to product literature for further details.


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**SECTION 2. HAZARDS IDENTIFICATION**

**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Skin sensitization : Category 1

**GHS label elements**

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**  
P261 Avoid breathing mist or vapors.  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves.  
**Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.



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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

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1)	26172-54-3	>= 0.0015 - < 0.1

Actual concentration is withheld as a trade secret

**SECTION 4. FIRST AID MEASURES**

- General advice : Move out of dangerous area.  
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 on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
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 give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.  
May cause an allergic skin reaction.
- Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.



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### 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 : No information available.
- Hazardous combustion products : Carbon oxides
- Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- 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.  
Local authorities should be advised if significant spillages cannot be contained.
- 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.

---

### 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 exposure - obtain special instructions before use.  
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.  
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being



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- used.
- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

**Personal protective equipment**

Hand protection

In case of contact through splashing:

- Material : Nitrile rubber
- Break through time : > 30 min
- Glove thickness : > 0.11 mm

In case of full contact:

- Material : butyl-rubber
- Break through time : > 480 min
- Glove thickness : > 0.4 mm

- 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
- Skin and body protection : Impervious clothing  
Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Wash hands before breaks and at the end of workday.

**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance : liquid
- Color : light yellow

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Odor	:	odorless
Odor Threshold	:	No data available
pH	:	5.5 - 7.5
Melting point/ range	:	30 °F / -1 °C
Boiling point/boiling range	:	203 - 221 °F / 95 - 105 °C
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (liquids)	:	Does not sustain combustion.
Self-ignition	:	Not applicable
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	No data available
Relative density	:	No data available
Density	:	1.007 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	completely miscible
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
Explosive properties	:	Not explosive



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

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### SECTION 10. STABILITY AND REACTIVITY

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 : Exposure to light.

Incompatible materials : Strong oxidizing agents

Hazardous decomposition products : No decomposition if stored and applied as directed.

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified due to lack of data.  
Not classified due to lack of data.

#### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg  
Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

#### Skin corrosion/irritation

Not classified due to lack of data.  
Not classified due to lack of data.

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**Product:**

Remarks : May cause skin irritation and/or dermatitis.

**Components:**

**3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Causes severe burns.

**Serious eye damage/eye irritation**

Not classified due to lack of data.  
Not classified due to lack of data.

**Product:**

Remarks : Vapors may cause irritation to the eyes, respiratory system and the skin.

**Components:**

**3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Result : Risk of serious damage to eyes.

**Respiratory or skin sensitization**

**Skin sensitization**

May cause an allergic skin reaction.

**Skin sensitization**

May cause an allergic skin reaction.

**Respiratory sensitization**

Not classified due to lack of data.

**Respiratory sensitization**

Not classified due to lack of data.

**Product:**

Remarks : Causes sensitization.

**Components:**

**3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Test Type : Local lymph node assay (LLNA)  
Method : OECD Test Guideline 429  
Result : The product is a skin sensitizer, sub-category 1A.  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : positive

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Remarks : Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### Germ cell mutagenicity

Not classified due to lack of data.  
Not classified due to lack of data.

### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Method: OECD Test Guideline 476  
Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 474  
Result: negative  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay  
Species: Rat (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 486  
Result: negative

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### Carcinogenicity

Not classified due to lack of data.  
Not classified due to lack of data.

**IARC** 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.

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**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.

**Elecsys Syphilis**Version  
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Not classified due to lack of data.**Components:****3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**Effects on fetal development : Species: Rat  
Application Route: Oral  
Dose: 40 mg/kg bw/day  
Result: No effects on fetal development.  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one**STOT-single exposure**Not classified due to lack of data.  
Not classified due to lack of data.**STOT-repeated exposure**Not classified due to lack of data.  
Not classified due to lack of data.**Repeated dose toxicity****Components:****3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog  
NOAEL : 40.9 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

**Aspiration toxicity**Not classified due to lack of data.  
Not classified due to lack of data.

---

**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l

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Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1  
  
1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

M-Factor (Chronic aquatic toxicity) : 1  
  
1

### Persistence and degradability

#### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### Bioaccumulative potential

#### Components:

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

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

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)  
Method: OECD Test Guideline 107



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### Mobility in soil

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).

---

## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : 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 Regulations

#### **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

### Domestic regulation

#### **49 CFR**

Not regulated as a dangerous good

### Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN,  
IMDG-Code, ICAO/IATA-DGR



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**SECTION 15. REGULATORY INFORMATION**

**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 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Respiratory or skin sensitization

**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 I 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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

**US State Regulations**

**Massachusetts Right To Know**

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

**Pennsylvania Right To Know**

Water 7732-18-5

**Maine Chemicals of High Concern**

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

**Washington Chemicals of High Concern**

Product does not contain any listed chemicals

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



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- AIIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
  
Bovine Serum Albumin  
  
hydroxyl-2-pyridone  
  
MAB / PAB  
  
Streptavidin  
  
rec. Antigen-Conjugat
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not 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**

**Further information**

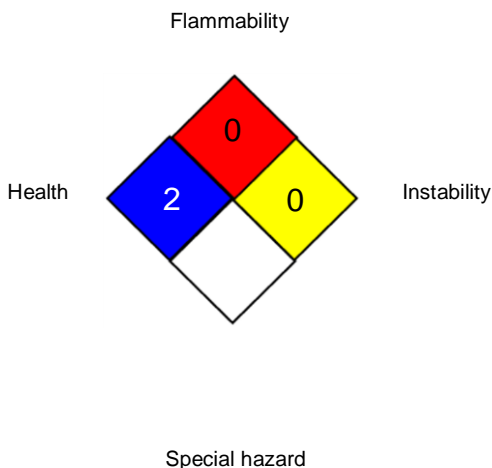
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**NFPA 704:**



**HMIS® IV:**

<b>HEALTH</b>	/	2
<b>FLAMMABILITY</b>	0	
<b>PHYSICAL HAZARD</b>	0	

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; 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); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - 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; IC50 - 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - 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 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; TECl - Thailand



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Existing Chemicals 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

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The information provided in this 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 / 2304



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**SECTION 1. IDENTIFICATION**

Product name : SA Coat-Beads

**Manufacturer or supplier's details**

Company name of supplier : Roche Diagnostics  
-

Address : 9115 Hague Road  
Indianapolis, IN 46250  
USA

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**

Recommended use : Laboratory chemicals  
Refer to product literature for further details.


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**SECTION 2. HAZARDS IDENTIFICATION**

**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Skin sensitization : Category 1

**GHS label elements**

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**  
P261 Avoid breathing mist or vapors.  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves.  
**Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

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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

### Components

Chemical name	CAS-No.	Concentration (% w/w)
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	>= 1 - < 5
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9	>= 1 - < 5
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1)	26172-54-3	>= 0.0015 - < 0.1

Actual concentration is withheld as a trade secret

## SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.  
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 on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
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 give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and : May cause an allergic skin reaction.  
May cause an allergic skin reaction.



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delayed

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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### 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 : No information available.

Hazardous combustion products : Carbon oxides  
Nitrogen oxides (NO<sub>x</sub>)  
Sulfur oxides

Further information : The product itself does not burn.  
  
Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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.  
Local authorities should be advised if significant spillages cannot be contained.

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.

---

### 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 exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.



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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.  
Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated place.  
Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl	57-50-1	TWA	10 mg/m3	ACGIH
		TWA (Respirable)	5 mg/m3	NIOSH REL
		TWA (total)	10 mg/m3	NIOSH REL
		TWA (total dust)	15 mg/m3	OSHA Z-1
		TWA (respirable fraction)	5 mg/m3	OSHA Z-1
		TWA (Total dust)	15 mg/m3	OSHA P0
		TWA (respirable dust fraction)	5 mg/m3	OSHA P0

**Engineering measures** : No data available

**Personal protective equipment**

Respiratory protection : In the case of vapor formation use a respirator with an approved filter.

Hand protection

In case of contact through splashing:





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Nitrogen oxides (NOx)  
Sulfur oxides

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified due to lack of data.  
Not classified due to lack of data.

#### Product:

Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

#### Components:

##### **.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Acute oral toxicity : LD50 Oral (Rat): 29,700 mg/kg

##### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
GLP: yes  
Assessment: The substance or mixture has no acute oral toxicity  
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
GLP: yes  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: No mortality observed at this dose.

##### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg  
Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg  
Method: OECD Test Guideline 402

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Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

**Skin corrosion/irritation**

Not classified due to lack of data.  
Not classified due to lack of data.

**Product:**

Remarks : May cause skin irritation and/or dermatitis.

**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rabbit  
Exposure time : 4 h  
Method : OECD Test Guideline 404  
Result : No skin irritation  
GLP : yes

**3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Causes severe burns.

**Serious eye damage/eye irritation**

Not classified due to lack of data.  
Not classified due to lack of data.

**Product:**

Remarks : Vapors may cause irritation to the eyes, respiratory system and the skin.

**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rabbit  
Result : No eye irritation  
Exposure time : 30 s  
Method : OECD Test Guideline 405  
GLP : yes

**3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Result : Risk of serious damage to eyes.

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

May cause an allergic skin reaction.

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### Skin sensitization

May cause an allergic skin reaction.

### Respiratory sensitization

Not classified due to lack of data.

### Respiratory sensitization

Not classified due to lack of data.

### Product:

Remarks : Causes sensitization.

### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Test Type : Maximization Test  
Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Method : OECD Test Guideline 406  
Result : Does not cause skin sensitization.  
GLP : yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Test Type : Local lymph node assay (LLNA)  
Method : OECD Test Guideline 429  
Result : The product is a skin sensitizer, sub-category 1A.  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : positive  
Remarks : Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### Germ cell mutagenicity

Not classified due to lack of data.

Not classified due to lack of data.

### Components:

#### **.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test  
Result: negative

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

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Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Escherichia coli  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Test Type: Chromosome aberration test in vitro  
Test system: Human lymphocytes  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 473  
Result: negative  
GLP: yes

### 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative

Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Method: OECD Test Guideline 476  
Result: negative  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 474  
Result: negative  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay  
Species: Rat (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 486  
Result: negative  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### Carcinogenicity

Not classified due to lack of data.  
Not classified due to lack of data.

### Components:

#### .alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:

Remarks : 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.

### 1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

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

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**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 due to lack of data.

Not classified due to lack of data.

### Components:

#### 1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:

Effects on fetal development : Species: Rat, female  
Application Route: Oral  
Dose: 100, 300, 1000 mg/kg bw/day  
Duration of Single Treatment: 14 d  
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight  
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight  
Method: OECD Test Guideline 414  
GLP: yes

#### 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Effects on fetal development : Species: Rat  
Application Route: Oral  
Dose: 40 mg/kg bw/day  
Result: No effects on fetal development.  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### STOT-single exposure

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

### Product:

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

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### Components:

#### **.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, single exposure.

### **STOT-repeated exposure**

Based on available data, the classification criteria are not met.

Based on available data, the classification criteria are not met.

### Product:

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

### Components:

#### **.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Assessment : The substance or mixture is not classified as specific target organ toxicant, repeated exposure.

### **Repeated dose toxicity**

#### Components:

##### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rat, male and female  
NOEL : 1000 mg/kg  
Application Route : Oral  
Exposure time : 28 d  
Dose : 100, 300, 1000 mg/kg bw/day  
Method : OECD Test Guideline 407  
GLP : yes

##### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog  
NOAEL : 40.9 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

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### Aspiration toxicity

Not classified due to lack of data.  
Not classified due to lack of data.

### Components:

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

No data available

### Further information

### Components:

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Remarks : Health injuries are not known or expected under normal use.

---

## SECTION 12. ECOLOGICAL INFORMATION

### Ecotoxicity

#### Product:

#### Ecotoxicology Assessment

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

#### Components:

**.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

#### 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-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l  
End point: mortality  
Exposure time: 96 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 203  
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
End point: Immobilization  
Exposure time: 48 h  
Test Type: static test  
Analytical monitoring: yes

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Method: OECD Test Guideline 202  
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 201  
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 201  
GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l  
End point: Respiration inhibition  
Exposure time: 3 h  
Test Type: static test  
Analytical monitoring: no  
Method: OECD Test Guideline 209  
GLP: yes

### Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

### 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
Exposure time: 72 h  
Test Type: static test

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Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

M-Factor (Chronic aquatic toxicity) : 1

1

### Persistence and degradability

#### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Biodegradability : aerobic  
Inoculum: activated sludge, non-adapted  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D  
GLP: yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### Bioaccumulative potential

#### Components:

#### **.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl:**

Partition coefficient: n-octanol/water : log Pow: -3.7 (68 °F / 20 °C)

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Partition coefficient: n-octanol/water : log Pow: < -3.85 (68 °F / 20 °C)  
Method: OECD Test Guideline 107  
GLP: yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**



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

Partition coefficient: n-octanol/water : log Pow: ca. -0.44 (68 °F / 20 °C)  
Method: OECD Test Guideline 107

### Mobility in soil

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).

#### Components:

##### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Additional ecological information : No data available

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## SECTION 13. DISPOSAL CONSIDERATIONS

### Disposal methods

Waste from residues : 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 Regulations

#### **UNRTDG**

Not regulated as a dangerous good

#### **IATA-DGR**

Not regulated as a dangerous good

#### **IMDG-Code**



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Not regulated as a dangerous good

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

Not applicable

**Domestic regulation**

**49 CFR**

Not regulated as a dangerous good

**Special precautions for user**

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR

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**SECTION 15. REGULATORY INFORMATION**

**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 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Respiratory or skin sensitization

**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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

**US State Regulations**

**Massachusetts Right To Know**

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl

57-50-1



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**Pennsylvania Right To Know**

Water 7732-18-5  
.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

**Maine Chemicals of High Concern**

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

**Washington Chemicals of High Concern**

Product does not contain any listed chemicals

**California Permissible Exposure Limits for Chemical Contaminants**

.alpha.-D-Glucopyranoside, .beta.-D-fructofuranosyl 57-50-1

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

- AIIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
  
hydroxyl-2-pyridone  
  
Beads
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not 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.

---

**SECTION 16. OTHER INFORMATION**

**Further information**

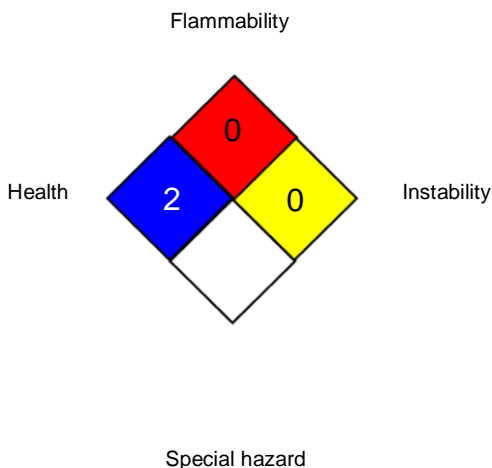
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**NFPA 704:**



**HMIS® IV:**

<b>HEALTH</b>	/	2
<b>FLAMMABILITY</b>		0
<b>PHYSICAL HAZARD</b>		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

- ACGIH : USA. ACGIH Threshold Limit Values (TLV)
- NIOSH REL : USA. NIOSH Recommended Exposure Limits
- OSHA P0 : USA. Table Z-1-A Limits for Air Contaminants (1989 vacated values)
- OSHA Z-1 : USA. Occupational Exposure Limits (OSHA) - Table Z-1 Limits for Air Contaminants
- ACGIH / TWA : 8-hour, time-weighted average
- NIOSH REL / TWA : Time-weighted average concentration for up to a 10-hour workday during a 40-hour workweek
- OSHA P0 / TWA : 8-hour time weighted average
- OSHA Z-1 / TWA : 8-hour time weighted average

AIIIC - Australian Inventory of Industrial Chemicals; 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); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - 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; IC50 - 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - 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



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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 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; TECl - Thailand Existing Chemicals 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

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The information provided in this 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 / 2304



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### SECTION 1. IDENTIFICATION

Product name : Syphilis Elecsys Cal 1

#### Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

Address : 9115 Hague Road  
Indianapolis, IN 46250  
USA

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

Recommended use : Laboratory chemicals  
Refer to product literature for further details.

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### SECTION 2. HAZARDS IDENTIFICATION

#### GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)

Skin sensitization : Category 1

#### GHS label elements

Hazard pictograms :



Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements :

#### Prevention:

P261 Avoid breathing dust.

P272 Contaminated work clothing must not be allowed out of the workplace.

P280 Wear protective gloves.

#### Response:

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

P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.

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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

Chemical nature : Handle as potentially infectious.

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9	$\geq 5 - < 10$
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1)	26172-54-3	$\geq 0.1 - < 1$

Actual concentration is withheld as a trade secret

### SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.  
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 on skin, rinse well with water.
- In case of eye contact : Immediately flush eye(s) with plenty of water.  
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 give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.
- Most important symptoms and effects, both acute and : May cause an allergic skin reaction.  
May cause an allergic skin reaction.



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delayed

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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**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 : Carbon oxides  
Nitrogen oxides (NOx)  
Sulfur oxides
- 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.  
Avoid dust formation.  
Avoid breathing dust.
- 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 : Keep in suitable, closed containers for disposal.

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**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the



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application area.  
 Dispose of rinse water in accordance with local and national regulations.  
 Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- 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.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

**Personal protective equipment**

Hand protection

In case of contact through splashing:  
 Material : Nitrile rubber  
 Break through time : > 30 min  
 Glove thickness : > 0.11 mm

In case of full contact:  
 Material : butyl-rubber  
 Break through time : > 480 min  
 Glove thickness : > 0.4 mm

- 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
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Wash hands before breaks and at the end of workday.



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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

- Appearance : solid, (lyophilized)
  
- Color : light yellow
  
- Odor : characteristic
  
- Odor Threshold : Not applicable
  
- pH : Not applicable
  
- Melting point/ range : No data available
  
- Boiling point/boiling range : No data available
  
- Flash point : does not flash
  
- Evaporation rate : No data available
  
- Flammability (solid, gas) : Sustains combustion
  
- Flammability (liquids) : Sustains combustion
  
- Self-ignition : No data available
  
- Upper explosion limit / Upper flammability limit : No data available
  
- Lower explosion limit / Lower flammability limit : No data available
  
- Vapor pressure : No data available
  
- Relative vapor density : Not applicable
  
- Relative density : No data available
  
- Bulk density : 1,000 - 2,000 g/cm<sup>3</sup>
  
- Solubility(ies)
  - Water solubility : soluble
  
  - Solubility in other solvents : No data available
  
- Partition coefficient: n-octanol/water : No data available



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Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
GLP: yes  
Assessment: The substance or mixture has no acute oral toxicity  
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
GLP: yes  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: No mortality observed at this dose.

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg  
Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### **Skin corrosion/irritation**

Not classified due to lack of data.  
Not classified due to lack of data.

### Product:

Remarks : May cause skin irritation and/or dermatitis.

**Elecsys Syphilis**Version  
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Species : Rabbit  
Exposure time : 4 h  
Method : OECD Test Guideline 404  
Result : No skin irritation  
GLP : yes

**3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Causes severe burns.

**Serious eye damage/eye irritation**

Not classified due to lack of data.  
Not classified due to lack of data.

**Product:**

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

**Components:****1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rabbit  
Result : No eye irritation  
Exposure time : 30 s  
Method : OECD Test Guideline 405  
GLP : yes

**3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Result : Risk of serious damage to eyes.

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

May cause an allergic skin reaction.

**Skin sensitization**

May cause an allergic skin reaction.

**Respiratory sensitization**

Not classified due to lack of data.

**Respiratory sensitization**

Not classified due to lack of data.

**Product:**

Remarks : Causes sensitization.

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### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Test Type : Maximization Test  
Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Method : OECD Test Guideline 406  
Result : Does not cause skin sensitization.  
GLP : yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Test Type : Local lymph node assay (LLNA)  
Method : OECD Test Guideline 429  
Result : The product is a skin sensitizer, sub-category 1A.  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : positive  
Remarks : Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### **Germ cell mutagenicity**

Not classified due to lack of data.  
Not classified due to lack of data.

### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Escherichia coli  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Test Type: Chromosome aberration test in vitro  
Test system: Human lymphocytes  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 473  
Result: negative  
GLP: yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**



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- Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative
- Test Type: In vitro mammalian cell gene mutation test  
Test system: Chinese hamster ovary cells  
Method: OECD Test Guideline 476  
Result: negative  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one
- Genotoxicity in vivo : Test Type: Micronucleus test  
Species: Mouse (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 474  
Result: negative  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one
- Test Type: unscheduled DNA synthesis assay  
Species: Rat (male and female)  
Application Route: Oral  
Method: OECD Test Guideline 486  
Result: negative  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

**Carcinogenicity**

Not classified due to lack of data.  
Not classified due to lack of data.

**Components:**

**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

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

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**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 due to lack of data.  
Not classified due to lack of data.

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### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Effects on fetal development : Species: Rat, female  
Application Route: Oral  
Dose: 100, 300, 1000 mg/kg bw/day  
Duration of Single Treatment: 14 d  
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight  
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight  
Method: OECD Test Guideline 414  
GLP: yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Effects on fetal development : Species: Rat  
Application Route: Oral  
Dose: 40 mg/kg bw/day  
Result: No effects on fetal development.  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### **STOT-single exposure**

Not classified due to lack of data.  
Not classified due to lack of data.

### **STOT-repeated exposure**

Not classified due to lack of data.  
Not classified due to lack of data.

### **Repeated dose toxicity**

### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rat, male and female  
NOEL : 1000 mg/kg  
Application Route : Oral  
Exposure time : 28 d  
Dose : 100, 300, 1000 mg/kg bw/day  
Method : OECD Test Guideline 407  
GLP : yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog  
NOAEL : 40.9 mg/kg bw/day

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Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### Aspiration toxicity

Not classified due to lack of data.  
Not classified due to lack of data.

---

## 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

#### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l  
End point: mortality  
Exposure time: 96 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 203  
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
End point: Immobilization  
Exposure time: 48 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 202  
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 201  
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
End point: Growth rate  
Exposure time: 72 h



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Test Type: static test  
 Analytical monitoring: yes  
 Method: OECD Test Guideline 201  
 GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l  
 End point: Respiration inhibition  
 Exposure time: 3 h  
 Test Type: static test  
 Analytical monitoring: no  
 Method: OECD Test Guideline 209  
 GLP: yes

**Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

**3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l  
 Exposure time: 96 h  
 Test Type: flow-through test  
 Method: OECD Test Guideline 203  
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
 Exposure time: 48 h  
 Test Type: static test  
 Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
 Exposure time: 72 h  
 Test Type: static test  
 Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1  
 1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
 Exposure time: 21 d  
 Method: OECD Test Guideline 211  
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

M-Factor (Chronic aquatic toxicity) : 1

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### Persistence and degradability

#### Components:

##### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Biodegradability : aerobic  
Inoculum: activated sludge, non-adapted  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D  
GLP: yes

##### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### Bioaccumulative potential

#### Components:

##### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Partition coefficient: n- : log Pow: < -3.85 (68 °F / 20 °C)  
octanol/water Method: OECD Test Guideline 107  
GLP: yes

##### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).  
  
Partition coefficient: n- : log Pow: ca. -0.44 (68 °F / 20 °C)  
octanol/water Method: OECD Test Guideline 107

### Mobility in soil

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).



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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.

**Components:**

**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Additional ecological information : No data available

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).  
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 Regulations**

**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

**Domestic regulation**

**49 CFR**

Not regulated as a dangerous good

**Special precautions for user**

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR



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**SECTION 15. REGULATORY INFORMATION**

**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 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Respiratory or skin sensitization

**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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

**US State Regulations**

**Massachusetts Right To Know**

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

**Pennsylvania Right To Know**

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9

**Maine Chemicals of High Concern**

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

**Washington Chemicals of High Concern**

Product does not contain any listed chemicals



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

- AIIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
  
Human serum /-plasma / -hemolysate, lyophilized  
  
hydroxyl-2-pyridone
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not 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**

**Further information**

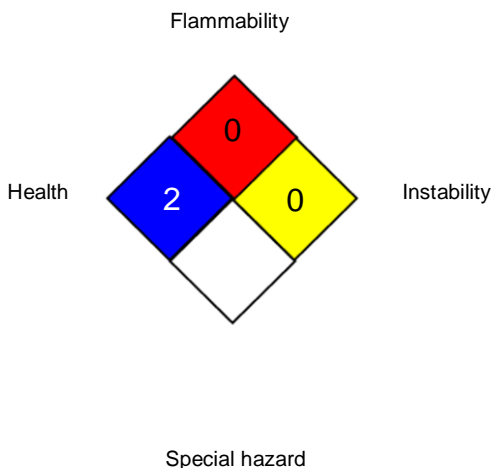
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**NFPA 704:**



**HMIS® IV:**

<b>HEALTH</b>	/	<b>2</b>
<b>FLAMMABILITY</b>	<b>0</b>	
<b>PHYSICAL HAZARD</b>	<b>0</b>	

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; 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); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - 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; IC50 - 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - 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 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; TECl - Thailand



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Existing Chemicals 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

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The information provided in this 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 / 2304



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**SECTION 1. IDENTIFICATION**

Product name : Syphilis Elecsys Cal 2

**Manufacturer or supplier's details**

Company name of supplier : Roche Diagnostics

Address : 9115 Hague Road  
Indianapolis, IN 46250  
USA

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**

Recommended use : Laboratory chemicals  
Refer to product literature for further details.


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**SECTION 2. HAZARDS IDENTIFICATION**

**GHS classification in accordance with the OSHA Hazard Communication Standard (29 CFR 1910.1200)**

Skin sensitization : Category 1

**GHS label elements**

Hazard pictograms : 

Signal Word : Warning

Hazard Statements : H317 May cause an allergic skin reaction.

Precautionary Statements : **Prevention:**  
P261 Avoid breathing dust.  
P272 Contaminated work clothing must not be allowed out of the workplace.  
P280 Wear protective gloves.  
**Response:**  
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.  
P333 + P313 If skin irritation or rash occurs: Get medical advice/attention.



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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

Chemical nature : Handle as potentially infectious.

**Components**

Chemical name	CAS-No.	Concentration (% w/w)
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9	$\geq 5 - < 10$
3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1)	26172-54-3	$\geq 0.1 - < 1$

Actual concentration is withheld as a trade secret

**SECTION 4. FIRST AID MEASURES**

General advice : Move out of dangerous area.  
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 on skin, rinse well with water.

In case of eye contact : Immediately flush eye(s) with plenty of water.  
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 give milk or alcoholic beverages.  
Never give anything by mouth to an unconscious person.  
If symptoms persist, call a physician.  
Rinse mouth with water.

Most important symptoms and effects, both acute and : May cause an allergic skin reaction.  
May cause an allergic skin reaction.



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delayed

Notes to physician : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

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**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 : Carbon oxides  
Nitrogen oxides (NOx)  
Sulfur oxides
- 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.  
Avoid dust formation.  
Avoid breathing dust.
- 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 : Keep in suitable, closed containers for disposal.

---

**SECTION 7. HANDLING AND STORAGE**

- Advice on protection against fire and explosion : Avoid dust formation.  
Provide appropriate exhaust ventilation at places where dust is formed.
- Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapors/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the



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application area.  
 Dispose of rinse water in accordance with local and national regulations.  
 Persons susceptible to skin sensitization problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

- 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.
- Further information on storage conditions : See label, package insert or internal guidelines
- Further information on storage stability : No decomposition if stored and applied as directed.

**SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**

**Ingredients with workplace control parameters**

Contains no substances with occupational exposure limit values.

**Engineering measures** : No data available

**Personal protective equipment**

Hand protection

In case of contact through splashing:  
 Material : Nitrile rubber  
 Break through time : > 30 min  
 Glove thickness : > 0.11 mm

In case of full contact:  
 Material : butyl-rubber  
 Break through time : > 480 min  
 Glove thickness : > 0.4 mm

- 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
- Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.
- Hygiene measures : Wash hands before breaks and at the end of workday.



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### SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	:	solid, (lyophilized)
Color	:	light yellow
Odor	:	characteristic
Odor Threshold	:	Not applicable
pH	:	Not applicable
Melting point/ range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Sustains combustion
Flammability (liquids)	:	Sustains combustion
Self-ignition	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapor pressure	:	No data available
Relative vapor density	:	Not applicable
Relative density	:	No data available
Bulk density	:	1,000 - 2,000 g/cm <sup>3</sup>
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available



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- Autoignition temperature : No data available
- Decomposition temperature : No data available
- Viscosity
- Viscosity, dynamic : Not applicable
- Viscosity, kinematic : Not applicable
- Explosive properties : Not explosive
- Oxidizing properties : The substance or mixture is not classified as oxidizing.

---

### SECTION 10. STABILITY AND REACTIVITY

- 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 : Direct sources of heat.
- Incompatible materials : Strong oxidizing agents
- Hazardous decomposition products : No decomposition if stored and applied as directed.

---

### SECTION 11. TOXICOLOGICAL INFORMATION

#### Acute toxicity

Not classified due to lack of data.  
Not classified due to lack of data.

#### **Product:**

- Acute oral toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method
- Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method
- Acute inhalation toxicity : Acute toxicity estimate: > 10 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method
- Acute toxicity estimate: 15.49 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: Calculation method

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Acute dermal toxicity : Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

Acute toxicity estimate: > 5,000 mg/kg  
Method: Calculation method

### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Acute oral toxicity : LD50 Oral (Rat, male and female): > 2,000 mg/kg  
Method: OECD Test Guideline 423  
GLP: yes  
Assessment: The substance or mixture has no acute oral toxicity  
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rat, male and female): > 2,000 mg/kg  
Method: OECD Test Guideline 402  
GLP: yes  
Assessment: The substance or mixture has no acute dermal toxicity  
Remarks: No mortality observed at this dose.

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg  
Method: OECD Test Guideline 425

Acute inhalation toxicity : LC50 (Rat, male and female): 0.11 mg/l  
Exposure time: 4 h  
Test atmosphere: dust/mist  
Method: OECD Test Guideline 403  
Assessment: Corrosive to the respiratory tract.  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Acute dermal toxicity : LD50 Dermal (Rat, male): 246 mg/kg  
Method: OECD Test Guideline 402  
Remarks: Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### **Skin corrosion/irritation**

Not classified due to lack of data.  
Not classified due to lack of data.

### Product:

Remarks : May cause skin irritation and/or dermatitis.

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### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rabbit  
Exposure time : 4 h  
Method : OECD Test Guideline 404  
Result : No skin irritation  
GLP : yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Species : reconstructed human epidermis (RhE)  
Method : OECD Test Guideline 431  
Result : Causes severe burns.

### **Serious eye damage/eye irritation**

Not classified due to lack of data.  
Not classified due to lack of data.

### Product:

Remarks : Product dust may be irritating to eyes, skin and respiratory system.

### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rabbit  
Result : No eye irritation  
Exposure time : 30 s  
Method : OECD Test Guideline 405  
GLP : yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Result : Risk of serious damage to eyes.

### **Respiratory or skin sensitization**

#### **Skin sensitization**

May cause an allergic skin reaction.

#### **Skin sensitization**

May cause an allergic skin reaction.

#### **Respiratory sensitization**

Not classified due to lack of data.

#### **Respiratory sensitization**

Not classified due to lack of data.

### Product:

Remarks : Causes sensitization.

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### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Test Type : Maximization Test  
Species : Guinea pig  
Assessment : Does not cause skin sensitization.  
Method : OECD Test Guideline 406  
Result : Does not cause skin sensitization.  
GLP : yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Test Type : Local lymph node assay (LLNA)  
Method : OECD Test Guideline 429  
Result : The product is a skin sensitizer, sub-category 1A.  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type : Maximization Test  
Species : Guinea pig  
Method : OECD Test Guideline 406  
Result : positive  
Remarks : Based on data from similar materials  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### **Germ cell mutagenicity**

Not classified due to lack of data.  
Not classified due to lack of data.

### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Salmonella typhimurium  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Test Type: Microbial mutagenesis assay (Ames test)  
Test system: Escherichia coli  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 471  
Result: negative  
GLP: yes

Test Type: Chromosome aberration test in vitro  
Test system: Human lymphocytes  
Metabolic activation: with and without metabolic activation  
Method: OECD Test Guideline 473  
Result: negative  
GLP: yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**



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Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)  
 Test system: Salmonella typhimurium  
 Metabolic activation: with and without metabolic activation  
 Method: OECD Test Guideline 471  
 Result: negative

Test Type: In vitro mammalian cell gene mutation test  
 Test system: Chinese hamster ovary cells  
 Method: OECD Test Guideline 476  
 Result: negative  
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Genotoxicity in vivo : Test Type: Micronucleus test  
 Species: Mouse (male and female)  
 Application Route: Oral  
 Method: OECD Test Guideline 474  
 Result: negative  
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Test Type: unscheduled DNA synthesis assay  
 Species: Rat (male and female)  
 Application Route: Oral  
 Method: OECD Test Guideline 486  
 Result: negative  
 The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

**Carcinogenicity**

Not classified due to lack of data.  
 Not classified due to lack of data.

**Components:**

**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

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

**OSHA** No component of this product present at levels greater than or equal to 0.1% is on OSHA's list of regulated carcinogens.

**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 due to lack of data.  
 Not classified due to lack of data.

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### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Effects on fetal development : Species: Rat, female  
Application Route: Oral  
Dose: 100, 300, 1000 mg/kg bw/day  
Duration of Single Treatment: 14 d  
General Toxicity Maternal: NOEL: 1,000 mg/kg body weight  
Embryo-fetal toxicity.: NOEL: 1,000 mg/kg body weight  
Method: OECD Test Guideline 414  
GLP: yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Effects on fetal development : Species: Rat  
Application Route: Oral  
Dose: 40 mg/kg bw/day  
Result: No effects on fetal development.  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### **STOT-single exposure**

Not classified due to lack of data.  
Not classified due to lack of data.

### **STOT-repeated exposure**

Not classified due to lack of data.  
Not classified due to lack of data.

### **Repeated dose toxicity**

### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Species : Rat, male and female  
NOEL : 1000 mg/kg  
Application Route : Oral  
Exposure time : 28 d  
Dose : 100, 300, 1000 mg/kg bw/day  
Method : OECD Test Guideline 407  
GLP : yes

#### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Species : Rat  
NOEL : 94 mg/kg bw/day  
Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 408  
Remarks : No significant adverse effects were reported  
No human information is available.

The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Species : Dog  
NOAEL : 40.9 mg/kg bw/day

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Application Route : Oral  
Exposure time : 90 d  
Method : OECD Test Guideline 409  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

### Aspiration toxicity

Not classified due to lack of data.  
Not classified due to lack of data.

---

## 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

#### Components:

#### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Toxicity to fish : LC50 (Brachydanio rerio (zebrafish)): > 100 mg/l  
End point: mortality  
Exposure time: 96 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 203  
GLP: yes

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): > 100 mg/l  
End point: Immobilization  
Exposure time: 48 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 202  
GLP: yes

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
End point: Growth rate  
Exposure time: 72 h  
Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 201  
GLP: yes

NOEC (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l  
End point: Growth rate  
Exposure time: 72 h

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Test Type: static test  
Analytical monitoring: yes  
Method: OECD Test Guideline 201  
GLP: yes

Toxicity to microorganisms : EC50 (activated sludge): > 1,000 mg/l  
End point: Respiration inhibition  
Exposure time: 3 h  
Test Type: static test  
Analytical monitoring: no  
Method: OECD Test Guideline 209  
GLP: yes

### Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

### 3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 4.77 mg/l  
Exposure time: 96 h  
Test Type: flow-through test  
Method: OECD Test Guideline 203  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 2.33 mg/l  
Exposure time: 48 h  
Test Type: static test  
Method: OECD Test Guideline 202

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289 mg/l  
Exposure time: 72 h  
Test Type: static test  
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

1

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC (Daphnia magna (Water flea)): 0.0442 mg/l  
Exposure time: 21 d  
Method: OECD Test Guideline 211  
The value is given in analogy to the following substances: 2-methyl-2H-isothiazol-3-one

M-Factor (Chronic aquatic toxicity) : 1

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### Persistence and degradability

#### Components:

##### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Biodegradability : aerobic  
Inoculum: activated sludge, non-adapted  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301D  
GLP: yes

##### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Biodegradability : aerobic  
Result: Not readily biodegradable.  
Biodegradation: 0 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301B

### Bioaccumulative potential

#### Components:

##### **1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Partition coefficient: n- : log Pow: < -3.85 (68 °F / 20 °C)  
octanol/water Method: OECD Test Guideline 107  
GLP: yes

##### **3(2H)-Isothiazolone, 2-methyl-, hydrochloride (1:1):**

Bioaccumulation : Remarks: No bioaccumulation is to be expected (log Pow <= 4).  
  
Partition coefficient: n- : log Pow: ca. -0.44 (68 °F / 20 °C)  
octanol/water Method: OECD Test Guideline 107

### Mobility in soil

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).



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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.

**Components:**

**1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-:**

Additional ecological information : No data available

**SECTION 13. DISPOSAL CONSIDERATIONS**

**Disposal methods**

Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).  
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 Regulations**

**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

**Domestic regulation**

**49 CFR**

Not regulated as a dangerous good

**Special precautions for user**

Remarks : Not dangerous goods in the meaning of ADR/RID, ADN, IMDG-Code, ICAO/IATA-DGR



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**SECTION 15. REGULATORY INFORMATION**

**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 302 Extremely Hazardous Substances Threshold Planning Quantity**

This material does not contain any components with a section 302 EHS TPQ.

**SARA 311/312 Hazards** : Respiratory or skin sensitization

**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 I 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

This product does not contain any priority pollutants related to the U.S. Clean Water Act

**US State Regulations**

**Massachusetts Right To Know**

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

**Pennsylvania Right To Know**

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9

**Maine Chemicals of High Concern**

Product does not contain any listed chemicals

**Vermont Chemicals of High Concern**

Product does not contain any listed chemicals

**Washington Chemicals of High Concern**

Product does not contain any listed chemicals



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

- AIIC : Not in compliance with the inventory
- DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.  
  
Human serum /-plasma / -hemolysate, lyophilized  
  
hydroxyl-2-pyridone
- NZIoC : Not in compliance with the inventory
- ENCS : Not in compliance with the inventory
- ISHL : Not in compliance with the inventory
- KECI : Not in compliance with the inventory
- PICCS : Not in compliance with the inventory
- IECSC : Not in compliance with the inventory
- TCSI : Not in compliance with the inventory
- TSCA : Product contains substance(s) not listed on TSCA inventory.
- TECI : Not 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**

**Further information**

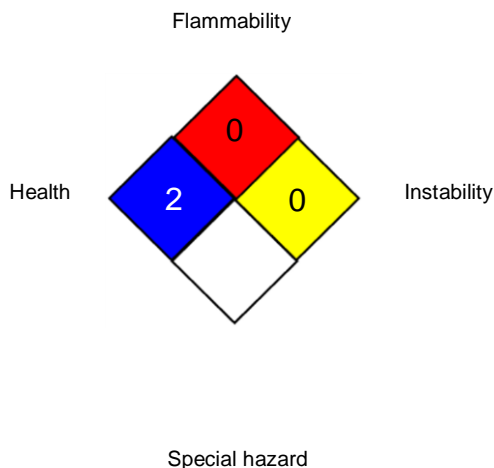
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**NFPA 704:**



**HMIS® IV:**

<b>HEALTH</b>	/	2
<b>FLAMMABILITY</b>	0	
<b>PHYSICAL HAZARD</b>	0	

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "\*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

**Full text of other abbreviations**

AIIC - Australian Inventory of Industrial Chemicals; 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); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - 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; IC50 - 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; LC50 - Lethal Concentration to 50 % of a test population; LD50 - 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 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; TECl - Thailand



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Existing Chemicals 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

Revision Date : 10-08-2024

The information provided in this 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.

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