


Elecsys Vitamin B12 IIVersion
3.1Revision Date:
22.12.2025Date of last issue: 22.12.2025
Date of first issue: 18.04.2018**Cover letter for product:**Trade name : Elecsys Vitamin B12 II
Product code : 07028121190

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

- PT1
- PT2
- R1 V2
- R2
- SA Coat-Beads

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

Hazard pictograms : 

Signal word : Danger

Hazard statements : H290 May be corrosive to metals.
H301 Toxic if swallowed.
H314 Causes severe skin burns and eye damage.
H317 May cause an allergic skin reaction.

Precautionary statements : **Prevention:**
P234 Keep only in original packaging.
P261 Avoid breathing mist or vapours.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth.
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.
P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.

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

P362 + P364 Take off contaminated clothing and wash it before reuse.

P390 Absorb spillage to prevent material damage.

Storage:

P405 Store locked up.

P406 Store in a corrosion resistant container with a resistant inner liner.

Disposal:

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

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

UN 2922 CORROSIVE LIQUID, TOXIC, N.O.S. (Sodium hydroxide, Sodium Cyanide), 8 (6.1), II

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Product name : PT1

Manufacturer or supplier's detailsCompany : Roche Diagnostics Australia
Pty LimitedAddress : 2 Julius Avenue
North Ryde, NSW 2113, Australia
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

Recommended use of the chemical and restrictions on useRecommended use : Laboratory chemicals
Refer to product literature for further details.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Not a hazardous substance or mixture.

GHS label elements

No hazard pictogram, no signal word, no hazard statement(s), no precautionary statement(s) required.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

No hazardous ingredients

SECTION 4. FIRST AID MEASURES

General advice : Do not leave the victim unattended.

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

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- In case of skin contact : Wash off with soap and water.
- In case of eye contact : Remove contact lenses.
Protect unharmed eye.
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.
- Most important symptoms and effects, both acute and delayed : None known.
- Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING 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 firefighting : No information available.
- Hazardous combustion products : No hazardous combustion products are known
- Specific extinguishing methods : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

- Personal precautions, protective equipment and emergency procedures : Refer to protective measures listed in sections 7 and 8.

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Environmental precautions : If the product contaminates rivers and lakes or drains inform respective authorities.

Methods and materials for containment and cleaning up : Wipe up with absorbent material (e.g. cloth, fleece).
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 : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.

Hygiene measures : General industrial hygiene practice.

Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Materials to avoid : No materials to be especially mentioned.

Further information on storage stability : No decomposition if stored and applied as directed.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Components 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 : Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us.

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Eye protection : Safety glasses

Skin and body protection : Protective suit

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : light yellow

Odour : very faint

Odour Threshold : No data available

pH : 4.5 - 6.5 (25 °C)

Melting point/ range : 3.89 °C

Boiling point/boiling range : 95 - 105 °C

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Does not sustain combustion.

Flammability (liquids) : The product is not flammable., Does not sustain combustion.

Self-ignition : No data available

Upper explosion limit / Upper
flammability limit : No data availableLower explosion limit / Lower
flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.0 g/cm³ (25 °C)

Solubility(ies)

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Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle characteristics		
Particle Size Distribution	:	Not applicable

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	:	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	:	No data available
Incompatible materials	:	No data available
		Not applicable
Hazardous decomposition products	:	No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Skin corrosion/irritation

Not classified due to lack of data.

Serious eye damage/eye irritation

Not classified due to lack of data.

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Not classified due to lack of data.

Respiratory sensitisation

Not classified due to lack of data.

Chronic toxicity**Germ cell mutagenicity**

Not classified due to lack of data.

Carcinogenicity

Not classified due to lack of data.

Reproductive toxicity

Not classified due to lack of data.

STOT - single exposure

Not classified due to lack of data.

STOT - repeated exposure

Not classified due to lack of data.

Aspiration toxicity

Not classified due to lack of data.

Further information**Product:**

Remarks : No data available

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity**

No data available

Persistence and degradability

No data available

Bioaccumulative potential

No data available

Mobility in soil

No data available

Other adverse effects**Product:**

Additional ecological information : No data available

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

- Waste from residues : Can be disposed as waste water, when in compliance with local regulations.
- Contaminated packaging : Empty containers should be taken to an approved waste handling site for recycling or disposal.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

- UN number : Not applicable
- Proper shipping name : Not applicable
- Class : Not applicable
- Subsidiary risk : Not applicable
- Packing group : Not applicable
- Labels : Not applicable
- Environmentally hazardous : no

IATA-DGR

- UN/ID No. : Not applicable
- Proper shipping name : Not applicable
- Class : Not applicable
- Subsidiary risk : Not applicable
- Packing group : Not applicable
- Labels : Not applicable
- Packing instruction (cargo aircraft) : Not applicable
- Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

- UN number : Not applicable
- Proper shipping name : Not applicable
- Class : Not applicable
- Subsidiary risk : Not applicable
- Packing group : Not applicable
- Labels : Not applicable
- EmS Code : Not applicable
- Marine pollutant : Not applicable

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

Not applicable

National Regulations

ADG

- UN number : Not applicable
- Proper shipping name : Not applicable

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Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 Hazchem Code : Not applicable

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : Schedule 5 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

The components of this product are reported in the following inventories:

AICC : On the inventory, or in compliance with the inventory
 DSL : All components of this product are on the Canadian DSL
 NZIoC : On the inventory, or 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 : On the inventory, or in compliance with the inventory
 IECSC : On the inventory, or in compliance with the inventory
 TCSI : On the inventory, or in compliance with the inventory
 TSCA : All substances listed as active on the TSCA inventory
 TECI : Not in compliance with the inventory

SECTION 16: ANY OTHER RELEVANT INFORMATION

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Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - 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; WHMIS - Workplace Hazardous Materials Information System

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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Product name : PT2

Manufacturer or supplier's detailsCompany : Roche Diagnostics Australia
Pty LimitedAddress : 2 Julius Avenue
North Ryde, NSW 2113, Australia
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Corrosive to metals : Category 1

Acute toxicity (Oral) : Category 3

Skin corrosion/irritation : Sub-category 1B

Serious eye damage/eye
irritation : Category 1**GHS label elements**

Hazard pictograms :



Signal word : Danger

Hazard statements : H290 May be corrosive to metals.
H301 Toxic if swallowed.
H314 Causes severe skin burns and eye damage.Precautionary statements : **Prevention:**

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P234 Keep only in original packaging.
P264 Wash skin thoroughly after handling.
P270 Do not eat, drink or smoke when using this product.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection/ hearing protection.

Response:

P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER/ doctor. Rinse mouth.

P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water.

P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER/ doctor.

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

P363 Wash contaminated clothing before reuse.

P390 Absorb spillage to prevent material damage.

Storage:

P405 Store locked up.

P406 Store in a corrosion resistant container with a resistant inner liner.

Disposal:

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sodium hydroxide	1310-73-2	>= 3 -< 5
Sodium cyanide 0.5-2.0% NaOH	143-33-9	< 1

SECTION 4. FIRST AID MEASURES

General advice : Move out of dangerous area.
Consult a physician.
Show this safety data sheet to the doctor in attendance.
Symptoms of poisoning may appear several hours later.
Do not leave the victim unattended.

If inhaled : If unconscious, place in recovery position and seek medical advice.

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- If symptoms persist, call a physician.
- In case of skin contact : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Clean mouth with water and drink afterwards plenty of water.
Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.
- Most important symptoms and effects, both acute and delayed : Toxic if swallowed.
Causes serious eye damage.
Causes severe burns.
- Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING 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 firefighting : Do not allow run-off from fire fighting to enter drains or water courses.
- Hazardous combustion products : Sodium oxides
- Specific extinguishing : Collect contaminated fire extinguishing water separately. This

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methods : 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 firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Hazchem Code : 2X

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.
If the product contaminates rivers and lakes or drains inform respective authorities.

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 vapours/dust.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
To avoid spills during handling keep bottle on a metal tray.
Dispose of rinse water in accordance with local and national regulations.

Hygiene measures : Avoid contact with skin, eyes and clothing.
When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and immediately after handling the product.

Conditions for safe storage : Prevent unauthorized access.
Keep container tightly closed in a dry and well-ventilated

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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

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sodium hydroxide	1310-73-2	Peak limit	2 mg/m ³	AU OEL
		C	2 mg/m ³	ACGIH
Sodium cyanide 0.5-2.0% NaOH	143-33-9	TWA	5 mg/m ³ (Cyanide)	AU OEL
Further information: Skin absorption				
		C	5 mg/m ³ (Cyanide)	ACGIH

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 : Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. The suitability for a specific

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- workplace should be discussed with the producers of the protective gloves.
- Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles
Wear face-shield and protective suit for abnormal processing problems.
- Skin and body protection : Impervious clothing
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid
- Colour : colourless
- Odour : none
- Odour Threshold : No data available
- pH : 9.8 - 11.8
- 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) : Does not sustain combustion.
- Flammability (liquids) : The product is not flammable., 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
- Vapour pressure : No data available

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Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1.041 g/cm ³
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Metal corrosion rate	:	Corrosive to metals
Particle characteristics		
Particle Size Distribution	:	Not applicable

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 decomposition if stored and applied as directed.
Conditions to avoid	:	No data available
Incompatible materials	:	Strong acids Not applicable
Hazardous decomposition products	:	No hazardous decomposition products are known. No hazardous decomposition products are known.

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Toxic if swallowed.

Product:

- Acute oral toxicity : Acute toxicity estimate: 235.85 mg/kg
Method: Calculation method
- Acute inhalation toxicity : Acute toxicity estimate: > 20 mg/l
Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method
- Acute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method

Components**Sodium cyanide 0.5-2.0% NaOH:**

- Acute oral toxicity : LD50 Oral (Rat, female): 5.09 mg/kg
Assessment: The component/mixture is extremely toxic after single ingestion.
- Acute inhalation toxicity : Acute toxicity estimate: > 0.05 mg/l
Test atmosphere: dust/mist
Method: Expert judgement
Assessment: The component/mixture is extremely toxic after short term inhalation.
- Acute dermal toxicity : Acute toxicity estimate (Rat, male): 7.35 mg/kg
Method: Calculation method
Assessment: The component/mixture is extremely toxic after single contact with skin.

Skin corrosion/irritation

Causes severe burns.

Product:

- Remarks : Extremely corrosive and destructive to tissue.

Components**Sodium hydroxide:**

- Species : Rabbit
Result : Causes severe burns.

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Result : Irritating to skin.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks : May cause irreversible eye damage.

Components**Sodium hydroxide:**Species : Rabbit
Result : Risk of serious damage to eyes.
Method : OECD Test Guideline 405**Sodium cyanide 0.5-2.0% NaOH:**

Result : Irritating to eyes.

Respiratory or skin sensitisation**Skin sensitisation**

Not classified due to lack of data.

Respiratory sensitisation

Not classified due to lack of data.

Components**Sodium cyanide 0.5-2.0% NaOH:**

Assessment : Fatal if swallowed, in contact with skin or if inhaled.

Chronic toxicity**Germ cell mutagenicity**

Not classified due to lack of data.

Components**Sodium hydroxide:**Genotoxicity in vitro : Test Type: gene mutation test
Result: negative**Sodium cyanide 0.5-2.0% NaOH:**Genotoxicity in vitro : Test Type: Microbial mutagenesis assay (Ames test)
Test system: Salmonella typhimurium

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Metabolic activation: with and without metabolic activation
Result: negative
GLP: yes

Carcinogenicity

Not classified due to lack of data.

Reproductive toxicity

Not classified due to lack of data.

STOT - single exposure

Not classified due to lack of data.

STOT - repeated exposure

Not classified due to lack of data.

Components**Sodium cyanide 0.5-2.0% NaOH:**

Target Organs : Thyroid
Assessment : Causes damage to organs through prolonged or repeated exposure.

Components**Sodium cyanide 0.5-2.0% NaOH:**

Repeated dose toxicity - : Fatal if swallowed, in contact with skin or if inhaled.
Assessment

Aspiration toxicity

Not classified due to lack of data.

Further information**Product:**

Remarks : No data available

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:**Sodium hydroxide:**

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Toxicity to fish : LC50 (*Gambusia affinis* (Mosquito fish)): 125 mg/l
Test Type: static test

Toxicity to daphnia and other : EC50 (*Ceriodaphnia dubia* (water flea)): 40.40 mg/l
aquatic invertebrates : End point: Immobilization
Exposure time: 48 h
Remarks: nominal concentration

Toxicity to microorganisms : (*Photobacterium phosphoreum*): 22 mg/l
Exposure time: 15 min

Ecotoxicology Assessment

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

Sodium cyanide 0.5-2.0% NaOH:

Toxicity to fish : LC50 (*Gasterosteus aculeatus* (threespine stickleback)): 0.0988 mg/l
Exposure time: 96 h
Test Type: flow-through test

Toxicity to daphnia and other : EC50 (*Chironomus riparius* (harlequin fly)): 0.012 mg/l
aquatic invertebrates : Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202

NOEC (*Chironomus riparius* (harlequin fly)): 0.0069 mg/l
Exposure time: 48 h
Test Type: semi-static test
Method: OECD Test Guideline 202

Toxicity to algae/aquatic : EC50 (Marine Diatom): 0.051 mg/l
plants : Exposure time: 72 h

M-Factor (Acute aquatic : 10
toxicity)

Toxicity to daphnia and other : NOEC (*Chironomus riparius* (harlequin fly)): 0.006 mg/l
aquatic invertebrates : Exposure time: 48 h
(Chronic toxicity) : Test Type: semi-static test

M-Factor (Chronic aquatic : 1
toxicity)

Toxicity to microorganisms : EC50 (Bacteria): 4.9 mg/l
Exposure time: 6 h

Ecotoxicology Assessment

Acute aquatic toxicity : Very toxic to aquatic life.

Chronic aquatic toxicity : Very toxic to aquatic life with long lasting effects.

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

Other organisms relevant to
the environment : No data available**Persistence and degradability****Components:****Sodium hydroxide:**

Biodegradability : Remarks: The methods for determining biodegradability are not applicable to inorganic substances.

Sodium cyanide 0.5-2.0% NaOH:Biodegradability : aerobic
Result: Inherently biodegradable.
Biodegradation: 99 %
Exposure time: 42 d

Chemical Oxygen Demand (COD) : 816 mg/g

Biochemical Oxygen Demand (BOD)/Theoretical oxygen demand (ThOD) : 6 %

Bioaccumulative potential**Components:****Sodium hydroxide:**

Bioaccumulation : Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : Remarks: Not applicable

Sodium cyanide 0.5-2.0% NaOH:Bioaccumulation : Bioconcentration factor (BCF): 3,162
Remarks: Does not bioaccumulate.

Partition coefficient: n-octanol/water : log Pow: ca. -0.25 (20 °C)

Mobility in soil

No data available

Other adverse effects**Product:**

Additional ecological : An environmental hazard cannot be excluded in the event of

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information unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.

Components:

Sodium cyanide 0.5-2.0% NaOH:

Results of PBT and vPvB assessment : Substance is not persistent, bioaccumulative, and toxic (PBT).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : UN 2922
Proper shipping name : CORROSIVE LIQUID, TOXIC, N.O.S.
(Sodium hydroxide, Sodium Cyanide)
Class : 8
Subsidiary risk : 6.1
Packing group : II
Labels : 8 (6.1)
Environmentally hazardous : no

IATA-DGR

UN/ID No. : UN 2922
Proper shipping name : Corrosive liquid, toxic, n.o.s.
(Sodium hydroxide, Sodium Cyanide)
Class : 8
Subsidiary risk : 6.1
Packing group : II
Labels : Corrosive, Toxic
Packing instruction (cargo aircraft) : 855
Packing instruction (passenger aircraft) : 851

IMDG-Code

UN number : UN 2922

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Proper shipping name : CORROSIVE LIQUID, TOXIC, N.O.S.
(Sodium hydroxide, Sodium Cyanide)
Class : 8
Subsidiary risk : 6.1
Packing group : II
Labels : 8 (6.1)
EmS Code : F-A, S-B
Marine pollutant : no

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

Not applicable

National Regulations

ADG

UN number : UN 2922
Proper shipping name : CORROSIVE LIQUID, TOXIC, N.O.S.
(Sodium hydroxide, Sodium Cyanide)
Class : 8
Subsidiary risk : 6.1
Packing group : II
Labels : 8 (6.1)
Hazchem Code : 2X
Environmentally hazardous : no

Special precautions for user

Remarks : No data available

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : Schedule 7 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)
Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

The components of this product are reported in the following inventories:

AIIC : All components are listed on the inventory, regulatory obligations/restrictions apply
DSL : All components of this product are on the Canadian DSL

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NZIoC	:	On the inventory, or in compliance with the inventory
ENCS	:	On the inventory, or in compliance with the inventory
ISHL	:	On the inventory, or in compliance with the inventory
KECI	:	On the inventory, or in compliance with the inventory
PICCS	:	On the inventory, or in compliance with the inventory
IECSC	:	On the inventory, or in compliance with the inventory
TCSI	:	On the inventory, or in compliance with the inventory
TSCA	:	All substances listed as active on the TSCA inventory
TECI	:	On the inventory, or in compliance with the inventory

SECTION 16: ANY OTHER RELEVANT INFORMATION

Revision Date : 22.12.2025

Date format : dd.mm.yyyy

Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
 AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / C : Ceiling limit
 AU OEL / TWA : Exposure standard - time weighted average
 AU OEL / Peak limit : Exposure standard - peak

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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

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- 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - 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; WHMIS - Workplace Hazardous Materials Information System

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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Product name : R1 V2

Manufacturer or supplier's detailsCompany : Roche Diagnostics Australia
Pty LimitedAddress : 2 Julius Avenue
North Ryde, NSW 2113, Australia
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact : National Support Centre: Tel. 1800 645 619
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

Recommended use of the chemical and restrictions on useRecommended use : Laboratory chemicals
Refer to product literature for further details.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Skin sensitisation : 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 vapours.

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

P280 Wear protective gloves.

Response:

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

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P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

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

Other hazards which do not result in classification

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
N-Methylisothiazolone hydrochloride	26172-54-3	>= 0.0015 -< 0.1

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Show this 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.

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

SECTION 5. FIREFIGHTING 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 firefighting : No information available.
- Hazardous combustion products : Oxides of phosphorus
- Specific extinguishing methods : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for firefighters : 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 vapours/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.

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Dispose of rinse water in accordance with local and national regulations.

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

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

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

Components 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 : The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace

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should be discussed with the producers of the protective gloves.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid

Colour : colourless

Odour : none

Odour Threshold : No data available

pH : 5.5 (25 °C)

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) : Does not sustain combustion.

Flammability (liquids) : The product is not flammable., 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

Vapour pressure : No data available

Relative vapour density : No data available

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Relative density	:	No data available
Density	:	1.026 g/cm ³
Solubility(ies)	:	
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition 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.

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 hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Components:**N-Methylisothiazolone hydrochloride:**

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- 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-methylisothiazol-3(2H)-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-methylisothiazol-3(2H)-one

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:**N-Methylisothiazolone hydrochloride:**

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.

Product:

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

Components:**N-Methylisothiazolone hydrochloride:**

Result : Risk of serious damage to eyes.

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified due to lack of data.

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Product:

Remarks : Causes sensitisation.

Components:

N-Methylisothiazolone hydrochloride:

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

Test Type : Maximisation 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-methylisothiazol-3(2H)-one

Chronic toxicity

Germ cell mutagenicity

Not classified due to lack of data.

Components:

N-Methylisothiazolone hydrochloride:

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-methylisothiazol-3(2H)-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-methylisothiazol-3(2H)-one

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

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Result: negative
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one

Carcinogenicity

Not classified due to lack of data.

Reproductive toxicity

Not classified due to lack of data.

Components:**N-Methylisothiazolone hydrochloride:**

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

STOT - single exposure

Not classified due to lack of data.

STOT - repeated exposure

Not classified due to lack of data.

Repeated dose toxicity**Components:****N-Methylisothiazolone hydrochloride:**

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-methylisothiazol-3(2H)-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-methylisothiazol-3(2H)-one

Aspiration toxicity

Not classified due to lack of data.

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Date of first issue: 18.04.2018**SECTION 12. ECOLOGICAL INFORMATION****Ecotoxicity****Components:****N-Methylisothiazolone hydrochloride:**

- 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-methylisothiazol-3(2H)-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
- 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-methylisothiazol-3(2H)-one

Persistence and degradability**Components:****N-Methylisothiazolone hydrochloride:**

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

Bioaccumulative potential**Components:****N-Methylisothiazolone hydrochloride:**

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

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Mobility in soil

No data available

Other adverse effects

No data available

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

- UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable

IATA-DGR

- UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

- UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable

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Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable

National Regulations

ADG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Hazchem Code : Not applicable

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Standard for the Uniform Scheduling of Medicines and Poisons : Schedule 6 (Please use the original publication of the SUSMP to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

The components 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
Antigen / Protein, recombinant
Cobinamide Dicyanide

NZIoC : Not in compliance with the inventory

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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

SECTION 16: ANY OTHER RELEVANT INFORMATION

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Date format : dd.mm.yyyy

Full text of other abbreviations

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; 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 -

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(Quantitative) Structure Activity Relationship; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of Dangerous Goods; TECI - 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; WHMIS - Workplace Hazardous Materials Information System

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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Date of first issue: 18.04.2018**SECTION 1: IDENTIFICATION**

Product name : R2

Manufacturer or supplier's detailsCompany : Roche Diagnostics Australia
Pty LimitedAddress : 2 Julius Avenue
North Ryde, NSW 2113, Australia
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION**GHS Classification**

Skin sensitisation : 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 vapours.

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

P280 Wear protective gloves.

Response:

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

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

P362 + P364 Take off contaminated clothing and wash it before

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reuse.

Disposal:

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
N-Methylisothiazolone hydrochloride	26172-54-3	>= 0.0015 -< 0.1
D-Biotin	58-85-5	< 10

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : 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 : Flush eyes with water as a precaution.
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.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
- Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

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-
- Unsuitable extinguishing media : High volume water jet
- Specific hazards during firefighting : No information available.
- Hazardous combustion products : Oxides of phosphorus
- Specific extinguishing methods : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Special protective equipment for firefighters : 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.
If the product contaminates rivers and lakes or drains inform respective authorities.
- 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 vapours/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

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regulations.

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

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

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

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
D-Biotin	58-85-5	IOEL	0.4 mg/m ³	Roche Industrial Hygiene Committee (RIHC)

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 : Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local

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conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

- 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : liquid
- Colour : No data available
- Odour : none
- Odour Threshold : No data available
- pH : 6.0 - 8.0
Concentration: 100 %
- 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) : Does not sustain combustion.
- Flammability (liquids) : The product is not flammable., Does not sustain combustion.
- Self-ignition : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower : No data available

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flammability limit

Vapour pressure : No data available

Relative vapour density : No data available

Relative density : No data available

Density : 1.012 g/cm³

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

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

Auto-ignition 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.

Particle characteristics

Particle Size Distribution : Not applicable

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 decomposition if stored and applied as directed.

Conditions to avoid : No data available

Incompatible materials : Strong oxidizing agents

Not applicable

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Hazardous decomposition products : No hazardous decomposition products are known.
No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Components**N-Methylisothiazolone hydrochloride:**

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-methylisothiazol-3(2H)-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-methylisothiazol-3(2H)-one

D-Biotin:

Acute oral toxicity : LD50 Oral (Rat): > 20,000 mg/kg
LD50 Oral (Mouse): > 10,000 mg/kg

Skin corrosion/irritation

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components**N-Methylisothiazolone hydrochloride:**

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

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

Serious eye damage/eye irritation

Not classified due to lack of data.

Product:

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

Components**N-Methylisothiazolone hydrochloride:**

Result : Risk of serious damage to eyes.

D-Biotin:

Species : Rabbit
Result : No eye irritation
Exposure time : 72 h
Method : OECD Test Guideline 405

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified due to lack of data.

Product:

Remarks : Causes sensitisation.

Components**N-Methylisothiazolone hydrochloride:**

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

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Test Type : Maximisation 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-methylisothiazol-3(2H)-one

D-Biotin:

Test Type : Maximisation Test
Species : Guinea pig
Method : OECD Test Guideline 406
Result : Did not cause sensitisation on laboratory animals.

Chronic toxicity**Germ cell mutagenicity**

Not classified due to lack of data.

Components**N-Methylisothiazolone hydrochloride:**

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-methylisothiazol-3(2H)-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-methylisothiazol-3(2H)-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-methylisothiazol-3(2H)-one

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D-Biotin:Genotoxicity in vitro : Test Type: Ames test
Result: negative**Carcinogenicity**

Not classified due to lack of data.

Components**D-Biotin:**

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

Reproductive toxicity

Not classified due to lack of data.

Components**N-Methylisothiazolone hydrochloride:**Effects on foetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg bw/day
Result: No effects on foetal development
The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-one**STOT - single exposure**

Not classified due to lack of data.

Components**D-Biotin:**

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

STOT - repeated exposure

Not classified due to lack of data.

Components**D-Biotin:**

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

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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-methylisothiazol-3(2H)-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-methylisothiazol-3(2H)-one

Aspiration toxicity

Not classified due to lack of data.

Components**D-Biotin:**

No data available

Further information**Product:**

Remarks : No data available

ComponentsD-Biotin:

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.

Other organisms relevant to the environment : No data available

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- 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-methylisothiazol-3(2H)-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
- 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-methylisothiazol-3(2H)-one

D-Biotin:

- Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): 500 mg/l
Exposure time: 48 h
Method: OECD Test Guideline 203
- Toxicity to microorganisms : (activated sludge): 100 mg/l

Ecotoxicology Assessment

- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

Persistence and degradability**Components:****N-Methylisothiazolone hydrochloride:**

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

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Biodegradability : Result: Not readily biodegradable.
Biodegradation: 38 %
Exposure time: 28 d
Method: OECD Test Guideline 301C

Bioaccumulative potential**Components:****N-Methylisothiazolone hydrochloride:**

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

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

D-Biotin:

Partition coefficient: n-octanol/water : log Pow: 0.39

Mobility in soil

No data available

Other adverse effects**Product:**

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : Do not dispose of waste into sewer.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Do not re-use empty containers.

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

UN number : Not applicable
Proper shipping name : Not applicable

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Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
 Proper shipping name : Not applicable
 Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 Packing instruction (cargo aircraft) : Not applicable
 Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
 Proper shipping name : Not applicable
 Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 EmS Code : Not applicable
 Marine pollutant : Not applicable

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

Not applicable

National Regulations

ADG

UN number : Not applicable
 Proper shipping name : Not applicable
 Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 Hazchem Code : Not applicable

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : Schedule 6 (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)

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Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

The components 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
HBK, B12-e-DADOO-DDS-Bi

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

SECTION 16: ANY OTHER RELEVANT INFORMATION

Revision Date : 22.12.2025

Date format : dd.mm.yyyy

Full text of other abbreviations

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Date of first issue: 18.04.2018**SECTION 1: IDENTIFICATION**

Product name : SA Coat-Beads

Manufacturer or supplier's detailsCompany : Roche Diagnostics Australia
Pty LimitedAddress : 2 Julius Avenue
North Ryde, NSW 2113, Australia
Australia

Telephone : +61 2 9860 2222

Emergency telephone number:

Emergency contact: : National Support Centre: Tel. 1800 645 619
Follow Voice Prompts

E-mail address : australia.qra@roche.com

Telefax : +61 2 9860 2111

Recommended use of the chemical and restrictions on useRecommended use : Laboratory chemicals
Refer to product literature for further details.**SECTION 2. HAZARDS IDENTIFICATION****GHS Classification**

Skin sensitisation : 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 vapours.

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

P280 Wear protective gloves.

Response:

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

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

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P362 + P364 Take off contaminated clothing and wash it before reuse.

Disposal:

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

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Components

Chemical name	CAS-No.	Concentration (% w/w)
Sucrose	57-50-1	< 10
N-Methylisothiazolone hydrochloride	26172-54-3	>= 0.0015 -< 0.1

SECTION 4. FIRST AID MEASURES

- General advice : Move out of dangerous area.
Show this safety data sheet to the doctor in attendance.
Do not leave the victim unattended.
- If inhaled : 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 : Flush eyes with water as a precaution.
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.
- Most important symptoms and effects, both acute and delayed : May cause an allergic skin reaction.
- Notes to physician : Treat symptomatically.

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media : Use extinguishing measures that are appropriate to local

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circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

Specific hazards during firefighting : No information available.

Hazardous combustion products : Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides

Specific extinguishing methods : 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 firefighters : 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.
If the product contaminates rivers and lakes or drains inform respective authorities.

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 vapours/dust.
Avoid exposure - obtain special instructions before use.

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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 sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

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

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Sucrose	57-50-1	TWA	10 mg/m ³	AU OEL
		TWA	10 mg/m ³	ACGIH

Engineering measures : No data available

Personal protective equipment

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

Use respiratory protection unless adequate local exhaust ventilation is provided or exposure assessment demonstrates that exposures are within recommended exposure guidelines.

Filter type : Particulates type

Hand protection

In case of contact through splashing:

Material : Nitrile rubber

Break through time : > 30 min

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Glove thickness : > 0.11 mm

In case of full contact:

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

Remarks : Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. The suitability for a specific workplace should be discussed with the producers of the protective gloves.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid, Contains microparticles

Colour : clear, colourless, red brown

Odour : odourless

Odour Threshold : No data available

pH : 7.1 - 7.4

Melting point/ range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

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Flammability (solid, gas)	:	The product is not flammable., Does not sustain combustion.
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
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Density	:	1.01 g/cm ³ (20 °C)
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Explosive properties	:	Not explosive Expert judgement
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.
Particle characteristics		
Particle Size Distribution	:	Not applicable

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.

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Possibility of hazardous reactions : No decomposition if stored and applied as directed.

Conditions to avoid : No data available

Incompatible materials : Not applicable

Hazardous decomposition products : No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Components**Sucrose:**

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

N-Methylisothiazolone hydrochloride:Acute oral toxicity : LD50 Oral (Rat, female): 175 mg/kg
Method: OECD Test Guideline 425Acute 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-methylisothiazol-3(2H)-oneAcute 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-methylisothiazol-3(2H)-one**Skin corrosion/irritation**

Not classified due to lack of data.

Product:

Remarks : May cause skin irritation and/or dermatitis.

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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.

Product:

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

Components**N-Methylisothiazolone hydrochloride:**

Result : Risk of serious damage to eyes.

Respiratory or skin sensitisation**Skin sensitisation**

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified due to lack of data.

Product:

Remarks : Causes sensitisation.

Components**N-Methylisothiazolone hydrochloride:**

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

Test Type : Maximisation 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-methylisothiazol-3(2H)-one

Chronic toxicity**Germ cell mutagenicity**

Not classified due to lack of data.

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

N-Methylisothiazolone hydrochloride:

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-methylisothiazol-3(2H)-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-methylisothiazol-3(2H)-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-methylisothiazol-3(2H)-one

Carcinogenicity

Not classified due to lack of data.

Components**Sucrose:**

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

Reproductive toxicity

Not classified due to lack of data.

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

STOT - single exposure

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.

Components**Sucrose:**

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.

Product:

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

Components**Sucrose:**

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

Repeated dose toxicity**Components****N-Methylisothiazolone hydrochloride:**

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-methylisothiazol-3(2H)-one

Species : Dog

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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-methylisothiazol-3(2H)-one

Aspiration toxicity

Not classified due to lack of data.

Components**Sucrose:**

No data available

Further information**Product:**

Remarks : No data available

ComponentsSucrose:

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:**Sucrose:****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**N-Methylisothiazolone hydrochloride:**

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

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The value is given in analogy to the following substances: 2-methylisothiazol-3(2H)-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

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-methylisothiazol-3(2H)-one

Persistence and degradability

Components:

N-Methylisothiazolone hydrochloride:

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

Bioaccumulative potential

Components:

Sucrose:

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

N-Methylisothiazolone hydrochloride:

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

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

Mobility in soil

No data available

Other adverse effects

Product:

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Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues : Do not dispose of waste into sewer.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.

Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Do not re-use empty containers.

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Environmentally hazardous : no

IATA-DGR

UN/ID No. : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
Packing instruction (cargo aircraft) : Not applicable
Packing instruction (passenger aircraft) : Not applicable

IMDG-Code

UN number : Not applicable
Proper shipping name : Not applicable
Class : Not applicable
Subsidiary risk : Not applicable
Packing group : Not applicable
Labels : Not applicable
EmS Code : Not applicable
Marine pollutant : Not applicable

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

Not applicable

National Regulations

ADG

UN number : Not applicable
 Proper shipping name : Not applicable
 Class : Not applicable
 Subsidiary risk : Not applicable
 Packing group : Not applicable
 Labels : Not applicable
 Hazchem Code : Not applicable

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

Therapeutic Goods (Poisons Standard) Instrument : No poison schedule number allocated (Please use the original publication to check for specific uses, specific conditions or threshold limits that might apply for this chemical)
 Prohibition/Licensing Requirements : There is no applicable prohibition, authorisation and restricted use requirements, including for carcinogens referred to in Schedule 10 of the model WHS Act and Regulations.

The components 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

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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

SECTION 16: ANY OTHER RELEVANT INFORMATION

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Full text of other abbreviations

ACGIH : USA. ACGIH Threshold Limit Values (TLV)
AU OEL : Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA : 8-hour, time-weighted average
AU OEL / TWA : Exposure standard - time weighted average

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; 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; 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; n.o.s. - Not Otherwise Specified; Nch - Chilean Norm; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NOErC - No Observed Effect Concentration based on growth rate; NOEyC - No Observed Effect Concentration based on yield; NOM - Official Mexican Norm; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TDG - Transportation of

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Dangerous Goods; TECI - 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; WHMIS - Workplace Hazardous Materials Information System

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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