

Elecsys EBV VCA IgGVersion
3.1Revision Date:
29.08.2024Date of last issue: 29.08.2024
Date of first issue: 08.02.2021**Cover letter for product:**Trade name : Elecsys EBV VCA IgG
Product code : 08355355190

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

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

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

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements :

Prevention:

P261 Avoid breathing mist or 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 reuse.

Disposal:

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

Other hazards which do not result in classification

None known.



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

Not assigned by regulation

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Product name : Cal 1

Manufacturer or supplier's details

Company : Roche Diagnostics Deutschland GmbH

Address : Sandhoferstrasse 116
68305 Mannheim
Deutschland

Telephone : +496217590

Emergency telephone number:
Im Notfall: : Werkschutzzentrale Roche +49(0)621-759-2203
Diagnostics GmbH

Giftnotruf: : Mainz +49(0)6131-19240

E-mail address : info.dia-sds@roche.com

Telefax : +496217592890

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 dust.
P272 Contaminated work clothing should not be allowed out of
the workplace.
P280 Wear protective gloves.

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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 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
Chemical nature : Handle as potentially infectious.

Components

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

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

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

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 : Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides

Specific extinguishing methods : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for 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.
Avoid dust formation.
Avoid breathing dust.

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

Advice on protection against fire and explosion : Avoid dust formation.
Provide appropriate exhaust ventilation at places where dust is formed.

Advice on safe handling : Avoid formation of respirable particles.
Do not breathe vapours/dust.

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Avoid exposure - obtain special instructions before use.
Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin 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.
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

Contains no substances with occupational exposure limit values.

Engineering measures : No data available

Personal protective equipment

Hand protection

Material : Protective gloves

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 : Dust impervious protective suit
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : solid, (lyophilised)

Colour : white, light yellow

Odour : none

Odour Threshold : Not applicable

pH : Not applicable

Melting point/range : No data available

Boiling point/boiling range : No data available

Flash point : does not flash

Evaporation rate : No data available

Flammability (solid, gas) : Sustains combustion

Flammability (liquids) : Sustains combustion

Self-ignition : No data available

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Vapour pressure : No data available

Relative vapour density : Not applicable

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Relative density	:	No data available
Solubility(ies)	:	
Water solubility	:	completely soluble
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	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available
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 moisture
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h

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Method: Calculation methodAcute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method**Components:****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.

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

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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)-oneTest 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: negativeTest 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

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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.

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

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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.

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

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

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

No data available

Other adverse effects**Product:**Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).
The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**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

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

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated (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,

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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. Human serum /-plasma / -hemolysate, lyophilized hydroxyl-2-pyridone
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

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

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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.

AU / EN / 2304

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Product name : Cal 2

Manufacturer or supplier's details

Company : Roche Diagnostics Deutschland GmbH

Address : Sandhoferstrasse 116
68305 Mannheim
Deutschland

Telephone : +496217590

Emergency telephone number:
Im Notfall: : Werkschutzzentrale Roche +49(0)621-759-2203
Diagnostics GmbH

Giftnotruf: : Mainz +49(0)6131-19240

E-mail address : info.dia-sds@roche.com

Telefax : +496217592890

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 dust.
P272 Contaminated work clothing should not be allowed out of
the workplace.
P280 Wear protective gloves.

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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 reuse.

Disposal:

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

Other hazards which do not result in classification

None known.

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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.

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

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

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 : Carbon oxides
Nitrogen oxides (NO_x)
Sulphur oxides

Specific extinguishing methods : Collect contaminated fire extinguishing water separately. This must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

Special protective equipment for 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.
Avoid dust formation.
Avoid breathing dust.

Environmental precautions : Prevent product from entering drains.
Prevent further leakage or spillage if safe to do so.

Methods and materials for containment and cleaning up : Keep in suitable, closed containers for disposal.

SECTION 7. HANDLING AND STORAGE

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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.
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
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Personal protective equipment

Hand protection

Material : Protective gloves

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 : Dust impervious protective suit
Choose body protection according to the amount and concentration of the dangerous substance at the work place.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

- Appearance : solid, (lyophilised)
- Colour : white, light yellow
- Odour : none
- Odour Threshold : Not applicable
- pH : Not applicable
- Melting point/range : No data available
- Boiling point/boiling range : No data available
- Flash point : does not flash
- Evaporation rate : No data available
- Flammability (solid, gas) : Sustains combustion
- Flammability (liquids) : Sustains combustion
- Self-ignition : No data available
- Upper explosion limit / Upper flammability limit : No data available
- Lower explosion limit / Lower flammability limit : No data available
- Vapour pressure : No data available
- Relative vapour density : Not applicable

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Relative density	:	No data available
Solubility(ies)		
Water solubility	:	completely soluble
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	:	Not applicable
Viscosity, kinematic	:	Not applicable
Explosive properties	:	No data available
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 moisture
Incompatible materials	:	Strong oxidizing agents
Hazardous decomposition products	:	No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified due to lack of data.

Product:

Acute oral toxicity	:	Acute toxicity estimate: > 2,000 mg/kg Method: Calculation method
Acute inhalation toxicity	:	Acute toxicity estimate: > 5 mg/l Exposure time: 4 h

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Method: Calculation methodAcute dermal toxicity : Acute toxicity estimate: > 2,000 mg/kg
Method: Calculation method**Components:****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.

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

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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)-oneTest 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: negativeTest 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

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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.

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

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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.

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

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

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

No data available

Other adverse effects**Product:**Additional ecological information : An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
Harmful to aquatic life with long lasting effects.**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).
The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.
Can be disposed as waste water, when in compliance with local regulations.Contaminated packaging : Empty remaining contents.
Dispose of as unused product.
Empty containers should be taken to an approved waste handling site for recycling or disposal.
Do not re-use empty containers.**SECTION 14. TRANSPORT INFORMATION****International Regulations****UNRTDG**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

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

Standard for the Uniform Scheduling of Medicines and Poisons : No poison schedule number allocated (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,

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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. Human serum /-plasma / -hemolysate, lyophilized hydroxyl-2-pyridone
NZIoC	:	Not in compliance with the inventory
ENCS	:	Not in compliance with the inventory
ISHL	:	Not in compliance with the inventory
KECI	:	Not in compliance with the inventory
PICCS	:	Not in compliance with the inventory
IECSC	:	Not in compliance with the inventory
TCSI	:	Not in compliance with the inventory
TSCA	:	Product contains substance(s) not listed on TSCA inventory.
TECI	:	Not in compliance with the inventory

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

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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 : R1

Manufacturer or supplier's details

Company : Roche Diagnostics Deutschland GmbH

Address : Sandhoferstrasse 116
68305 Mannheim
Deutschland

Telephone : +496217590

Emergency telephone number:
Im Notfall: : Werkschutzzentrale Roche +49(0)621-759-2203
Diagnostics GmbH

Giftnotruf: : Mainz +49(0)6131-19240

E-mail address : info.dia-sds@roche.com

Telefax : +496217592890

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.

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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 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 : May cause an allergic skin reaction.

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delayed

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

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 : Carbon oxides
Gaseous hydrogen chloride (HCl).
Sodium oxides
- 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.

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For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin 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

Material : Protective gloves

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 should be discussed with the producers of the protective gloves.

Eye protection : Eye wash bottle with pure water

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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 : 6.4 - 6.6 (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 (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 : 1.019 g/cm³

Solubility(ies)
Water solubility : completely miscible

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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	:	No data available
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 decomposition if stored and applied as directed.

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

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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.

Product:

Remarks : Causes sensitisation.

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

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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.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****N-Methylisothiazolone hydrochloride:**

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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

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

Mobility in soil

No data available

Other adverse effects

No data available

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

- 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
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

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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.

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

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

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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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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

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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 : R2

Manufacturer or supplier's details

Company : Roche Diagnostics Deutschland GmbH

Address : Sandhoferstrasse 116
68305 Mannheim
Deutschland

Telephone : +496217590

Emergency telephone number:
Im Notfall: : Werkschutzzentrale Roche +49(0)621-759-2203
Diagnostics GmbH

Giftnotruf: : Mainz +49(0)6131-19240

E-mail address : info.dia-sds@roche.com

Telefax : +496217592890

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.

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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 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 : May cause an allergic skin reaction.

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delayed

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

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 : Carbon oxides
Gaseous hydrogen chloride (HCl).
Sodium oxides
- 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.

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For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin 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

Material : Protective gloves

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 should be discussed with the producers of the protective gloves.

Eye protection : Eye wash bottle with pure water

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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 : 6.4 - 6.6 (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 (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 : 1.018 g/cm³

Solubility(ies)
Water solubility : completely miscible

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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	:	No data available
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 decomposition if stored and applied as directed.

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

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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.

Product:

Remarks : Causes sensitisation.

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

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Date of first issue: 08.02.2021**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.

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Components:****N-Methylisothiazolone hydrochloride:**

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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

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

Mobility in soil

No data available

Other adverse effects

No data available

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SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

SECTION 14. TRANSPORT INFORMATION

International Regulations

UNRTDG

- 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
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

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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.

Bovine Serum Albumin
MAB / PAB
hydroxyl-2-pyridone
rec. Antigen-Conjugat
Streptavidin Poly

NZIoC : Not in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

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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 - (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

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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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SECTION 1: IDENTIFICATION

Product name : SA Coat-Beads

Manufacturer or supplier's details

Company : Roche Diagnostics Deutschland GmbH

Address : Sandhoferstrasse 116
68305 Mannheim
Deutschland

Telephone : +496217590

Emergency telephone number:
Im Notfall: : Werkschutzzentrale Roche +49(0)621-759-2203
Diagnostics GmbH

Giftnotruf: : Mainz +49(0)6131-19240

E-mail address : info.dia-sds@roche.com

Telefax : +496217592890

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.

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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 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)
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 : 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 : May cause an allergic skin reaction.

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and effects, both acute and delayed

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 : Carbon oxides
Nitrogen oxides (NOx)
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.
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.

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- 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 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.

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:

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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 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, Beads

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

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

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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.

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.

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Conditions to avoid	:	No data available
Incompatible materials	:	No data available
Hazardous decomposition products	:	No decomposition if stored and applied as directed. In case of fire hazardous decomposition products may be produced such as: Carbon oxides Nitrogen oxides (NOx) Sulphur oxides

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 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)

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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.

Components:

Sucrose:

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

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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.

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

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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
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

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Aspiration toxicity

Not classified due to lack of data.

Components:

Sucrose:

No data available

Further information

Components:

Sucrose:

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
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 : ErC50 (Pseudokirchneriella subcapitata (green algae)): 0.289

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plants 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

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.

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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
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

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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 : No poison schedule number allocated (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
Beads
Impurity

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

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SECTION 16: ANY OTHER RELEVANT INFORMATION

Revision Date : 29.08.2024

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

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