

Control D Level 2 Bio

Version 2.0	Revision Date: 22.06.2019	Date of last issue: 01.02.2019 Date of first issue: 06.08.2014
----------------	------------------------------	---

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Control D Level 2 Bio
Product code : 07368186001

1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended restrictions on use : For professional users only.

1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH
-
Sandhoferstrasse 116
68305 Mannheim
Deutschland
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-2012, +49(0)621-759-4848
+49(0)8856-60-2629
E-mail address : mannheim.umweltschutz@roche.com

1.4 Emergency telephone number

In case of emergencies: : Central Works Security +49(0)621-759-2203
Roche Diagnostics GmbH
Centre for detoxification: : Mainz +49(0)6131-19240
Munich +49(0)89-19240


SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

The product is a kit consisting of individual ingredients. The classification of the ingredients can be obtained from section 3. Section Label elements contains the resulting labelling for the kit.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms : 

Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

Precautionary statements :

Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Response:

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.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

Cal D Level 2

Classification (REGULATION (EC) No 1272/2008)

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

Components

Chemical name	CAS-No. EC-No. Index-No. Registration number	Classification	Concentration (% w/w)
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3 247-499-3 01-2120764168-47-XXXX	Acute Tox. 3; H301 Acute Tox. 2; H330 Acute Tox. 3; H311 Skin Corr. 1A; H314 Eye Dam. 1; H318 Skin Sens. 1A; H317 Aquatic Acute 1; H400 Aquatic Chronic 1; H410 M-Factor (Acute aquatic toxicity): 1 M-Factor (Chronic aquatic toxicity): 1	>= 0,1 - < 0,25

For explanation of abbreviations see section 16.

Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

SECTION 4: First aid measures

4.1 Description of 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.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

- Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : No information available.

5.3 Advice for firefighters

- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
- Further information : Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local cir-

Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

cumstances and the surrounding environment.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

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.

6.3 Methods and material for containment and cleaning up

Methods for 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.

6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

SECTION 7: Handling and storage

7.1 Precautions for safe handling

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.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

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

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : 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

Control D Level 2 Bio

Version 2.0	Revision Date: 22.06.2019	Date of last issue: 01.02.2019 Date of first issue: 06.08.2014
----------------	------------------------------	---

Storage class (TRGS 510) : 12, Non Combustible Liquids

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

7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

Cal D Level 2

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

No data available

Personal protective equipment

Eye protection : Eye wash bottle with pure water
Tightly fitting safety goggles

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.

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

9.1 Information on basic physical and chemical properties

Cal D Level 2

Appearance : liquid

Control D Level 2 Bio

Version 2.0	Revision Date: 22.06.2019	Date of last issue: 01.02.2019 Date of first issue: 06.08.2014
----------------	------------------------------	---

Colour	:	No data available
Odour	:	No data available
Odour Threshold	:	No data available
pH	:	4,3
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Upper explosion limit / Upper flammability limit	:	No data available
Lower explosion limit / Lower flammability limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	No data available
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

9.2 Other information

Cal D Level 2

Self-ignition	:	No data available
---------------	---	-------------------

Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

SECTION 10: Stability and reactivity

10.1 Reactivity

No dangerous reaction known under conditions of normal use.

10.2 Chemical stability

Stable under normal conditions.

10.3 Possibility of hazardous reactions

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

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Cal D Level 2

Acute toxicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

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

Acute inhalation toxicity : LC50 (Rat): 0,11 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Assessment: Corrosive to the respiratory tract.

Acute dermal toxicity : LD50 Dermal (Rat): 242 mg/kg
Method: OECD Test Guideline 402

Skin corrosion/irritation

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

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

Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Test Type : Local lymph node assay (LLNA)
Assessment : May cause sensitisation by skin contact.
Method : OECD Test Guideline 429
Result : The product is a skin sensitiser, sub-category 1A.

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

Germ cell mutagenicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Genotoxicity in vitro : Test Type: 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

Genotoxicity in vivo : Test Type: Micronucleus test
Species: Mouse (male and female)
Application Route: Oral
Method: OECD Test Guideline 474
Result: negative

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

Carcinogenicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Remarks : No data available

Reproductive toxicity

Not classified based on available information.

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

Effects on foetal development : Species: Rat
Application Route: Oral
Dose: 40 mg/kg/d
Result: No effects on foetal development

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Repeated dose toxicity

Components:

2-methyl-2H-isothiazol-3-one 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.

Species : Dog
NOAEL : 40,9 mg/kg bw/day
Application Route : Oral
Exposure time : 90 d
Method : OECD Test Guideline 409

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

Cal D Level 2

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

Components:

2-methyl-2H-isothiazol-3-one 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

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

NOEC (Daphnia magna (Water flea)): 0,9 mg/l
Exposure time: 48 h
Test Type: static test
Method: OECD Test Guideline 202

EC50 (Daphnia magna (Water flea)): 0,998 mg/l
Exposure time: 48 h
Test Type: flow-through 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

NOEC (Pseudokirchneriella subcapitata (green algae)): 0,047 mg/l
Exposure time: 72 h
Test Type: static test
Method: OECD Test Guideline 201

M-Factor (Acute aquatic toxicity) : 1

Toxicity to fish (Chronic toxicity) : NOEC: 2,38 mg/l
Exposure time: 98 d
Species: Oncorhynchus mykiss (rainbow trout)
Method: OECD Test Guideline 210

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity) : NOEC: 0,0442 mg/l
Exposure time: 21 d
Species: Daphnia magna (Water flea)
Method: OECD Test Guideline 211

M-Factor (Chronic aquatic toxicity) : 1

12.2 Persistence and degradability

Cal D Level 2

Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

Components:

2-methyl-2H-isothiazol-3-one hydrochloride:

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

12.3 Bioaccumulative potential

Cal D Level 2

Components:

2-methyl-2H-isothiazol-3-one 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

12.4 Mobility in soil

Cal D Level 2

No data available

12.5 Results of PBT and vPvB assessment

Cal D Level 2

Not relevant

12.6 Other adverse effects

Cal D Level 2

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : 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.

Control D Level 2 Bio

Version 2.0	Revision Date: 22.06.2019	Date of last issue: 01.02.2019 Date of first issue: 06.08.2014
----------------	------------------------------	---

SECTION 14: Transport information

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

14.3 Transport hazard class(es)

Not regulated as a dangerous good

14.4 Packing group

Not regulated as a dangerous good

14.5 Environmental hazards

Not regulated as a dangerous good

14.6 Special precautions for user

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

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code

Remarks : Not applicable

SECTION 15: Regulatory information

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

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.

Not applicable

Water contaminating class : WGK 1 slightly hazardous to water (Germany)

Cal D Level 2

REACH - Candidate List of Substances of Very High Concern for Authorisation (Article 59) : Not applicable

REACH - List of substances subject to authorisation (Annex XIV) : Not applicable

Regulation (EC) No 1005/2009 on substances that deplete the ozone layer : Not applicable

Regulation (EC) No 850/2004 on persistent organic pollutants : Not applicable

Regulation (EC) No 649/2012 of the European Parliament and the Council concerning the export and import of dangerous chemicals : Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

REACH - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles (Annex XVII) : Conditions of restriction for the following entries should be considered: Number on list 3

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

DSL : All components of this product are on the Canadian DSL

AICS : On the inventory, or in compliance with the inventory

NZIoC : On the inventory, or in compliance with the inventory

ENCS : Not in compliance with the inventory

ISHL : Not in compliance with the inventory

KECI : On the inventory, or in compliance with the inventory

PICCS : On the inventory, or in compliance with the inventory

IECSC : On the inventory, or in compliance with the inventory

TCSI : On the inventory, or in compliance with the inventory

TSCA : All substances listed as active on the TSCA inventory

Volatile organic compounds : Directive 2010/75/EU of 24 November 2010 on industrial emissions (integrated pollution prevention and control)
Remarks: Not applicable

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Warning

Hazard statements : H317 May cause an allergic skin reaction.

Precautionary statements :

Prevention:

P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.

Response:

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

II

Hazardous components which must be listed on the label:

II 26172-54-3 2-methyl-2H-isothiazol-3-one hydrochloride

15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

SECTION 16: Other information

Full text of H-Statements

H301 : Toxic if swallowed.
H311 : Toxic in contact with skin.
H314 : Causes severe skin burns and eye damage.
H317 : May cause an allergic skin reaction.
H318 : Causes serious eye damage.
H330 : Fatal if inhaled.
H400 : Very toxic to aquatic life.
H410 : Very toxic to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Acute : Short-term (acute) aquatic hazard
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Dam. : Serious eye damage
Skin Corr. : Skin corrosion
Skin Sens. : Skin sensitisation

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; 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; 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; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; RID - Regulations concerning the International

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Control D Level 2 Bio

Version
2.0

Revision Date:
22.06.2019

Date of last issue: 01.02.2019
Date of first issue: 06.08.2014

Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; SVHC - Substance of Very High Concern; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

Further information

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.

DE / EN / 1810