

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

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

1.1 Product identifier

Trade name : Cell-Free DNA Collection Tube
Product code : 07785674001

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

Recommended restrictions : For professional users only.
on use

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)621-759-4223
E-mail address : info.dia-sds@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

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)

Eye irritation, Category 2 H319: Causes serious eye irritation.
Skin sensitisation, Category 1 H317: May cause an allergic skin reaction.
Specific target organ toxicity - repeated exposure, Category 2 H373: May cause damage to organs through prolonged or repeated exposure.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

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Hazard pictograms

:



Signal word

:

Warning

Hazard statements

:

H317 May cause an allergic skin reaction.
H319 Causes serious eye irritation.
H373 May cause damage to organs through prolonged or repeated exposure.

Precautionary statements

:

Prevention:

P260 Do not breathe mist or vapours.
P280 Wear protective gloves/ eye protection/ face protection.

Response:

P314 Get medical advice/ attention if you feel unwell.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P337 + P313 If eye irritation persists: Get medical advice/ attention.
P362 + P364 Take off contaminated clothing and wash it before reuse.

Hazardous components which must be listed on the label:

65501-24-8	Tripotassium hydrogen ethylenediaminetetraacetate
39236-46-9	N,N''-methylenebis[N'-[3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]urea]

2.3 Other hazards

This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

Ecological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

Toxicological information: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

Chemical name	CAS-No. EC-No. Index-No.	Classification	Concentration (% w/w)
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SAFETY DATA SHEET

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Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

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	Registration number		
Tripotassium hydrogen ethylene-diaminetetraacetate	65501-24-8 241-543-5	Acute Tox. 4; H332 Eye Irrit. 2; H319 STOT RE 2; H373 (Respiratory system) Acute toxicity estimate Acute inhalation toxicity (dust/mist): 1,6 mg/l	>= 20,0 - < 30,0
N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)]urea]	39236-46-9 254-372-6 01-2119983788-11	Skin Sens. 1B; H317 Aquatic Chronic 3; H412	>= 10,0 - < 20,0

For explanation of abbreviations see section 16.

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.
Consult a physician after significant exposure.
If unconscious, place in recovery position and seek medical advice.
- 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.
Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

- Risks : May cause an allergic skin reaction.
Causes serious eye irritation.
May cause damage to organs through prolonged or repeated exposure.

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.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



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Version
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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 : Do not allow run-off from fire fighting to enter drains or water courses.

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

5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

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

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Ensure adequate ventilation.
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.
If the product contaminates rivers and lakes or drains inform respective authorities.

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".

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

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SECTION 7: Handling and storage

7.1 Precautions for safe handling

- Advice on safe handling : Avoid formation of aerosol.
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.
Provide sufficient air exchange and/or exhaust in work rooms.
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 : When using do not eat or drink. When using do not smoke.
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. Containers which are opened must be carefully re-sealed 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
- Storage class (TRGS 510) : 12
- 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

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Engineering measures

No data available

Personal protective equipment

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

Eye/face protection	:	Use eye protection according to EN 166. Eye wash bottle with pure water Tightly fitting safety goggles Wear face-shield and protective suit for abnormal processing problems.
Hand protection	:	In case of contact through splashing: Material : Nitrile rubber Break through time : > 30 min Glove thickness : > 0,11 mm In case of full contact: Material : butyl-rubber Break through time : > 480 min Glove thickness : > 0,4 mm
Remarks	:	The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it. This recommendation is only valid for the product mentioned in the safety data sheet and provided by us and for the application specified by us. Please observe the instructions regarding permeability and breakthrough time which are provided by the supplier of the gloves. Also take into consideration the specific local conditions under which the product is used, such as the danger of cuts, abrasion, and the contact time. The suitability for a specific workplace 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.
Respiratory protection	:	In the case of vapour formation use a respirator with an approved filter.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Physical state	:	liquid
Colour	:	light yellow
Odour	:	No data available
Odour Threshold	:	No data available
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

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Date of first issue: 01.10.2015

Flammability : Does not sustain combustion.

Upper explosion limit / Upper flammability limit : No data available

Lower explosion limit / Lower flammability limit : No data available

Flash point : does not flash

Auto-ignition temperature : No data available

Decomposition temperature : No data available

pH : ca. 6,8 - 7,4

Viscosity

Viscosity, dynamic : No data available

Viscosity, kinematic : No data available

Solubility(ies)

Water solubility : completely miscible

Solubility in other solvents : No data available

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

Vapour pressure : No data available

Relative density : No data available

Density : 1,15 - 1,23 g/cm³

Relative vapour density : No data available

Particle characteristics

Particle Size Distribution : Not applicable

9.2 Other information

Explosives : Not explosive

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

Flammability (liquids) : Does not sustain combustion.

Self-ignition : No data available

Evaporation rate : No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

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

Conditions to avoid : No data available

10.5 Incompatible materials

Materials to avoid : No data available

10.6 Hazardous decomposition products

No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity

Not classified based on available information.

Product:

Acute inhalation toxicity : Acute toxicity estimate: > 5 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:

Tripotassium hydrogen ethylenediaminetetraacetate:

Acute oral toxicity : LD50 Oral (Rat): 2.800 mg/kg
Method: OECD Test Guideline 401
The value is given in analogy to the following substances:
Disodium dihydrogen ethylenediaminetetraacetate

Acute inhalation toxicity : LC50: 1,6 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Remarks: Expert judgement
Based on data from similar materials

Acute toxicity estimate: 1,6 mg/l
Test atmosphere: dust/mist
Method: ATE value derived from LD50/LC50 value

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Acute oral toxicity : LD50 (Rat): 5.200 mg/kg

Acute inhalation toxicity : LC50: > 5,5 mg/l
Exposure time: 1 h
Test atmosphere: dust/mist
Assessment: The substance or mixture has no acute inhalation toxicity
Remarks: No mortality observed at this dose.

Acute dermal toxicity : LD50 Dermal (Rabbit): > 5.000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Product:

Remarks : May cause skin irritation and/or dermatitis.

Components:

Tripotassium hydrogen ethylenediaminetetraacetate:

Species : Rabbit
Method : OECD Test Guideline 404
Result : No skin irritation
Remarks : Based on data from similar materials

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Result : No skin irritation

Serious eye damage/eye irritation

Causes serious eye irritation.

Product:

Remarks : May cause irreversible eye damage.

Components:

Tripotassium hydrogen ethylenediaminetetraacetate:

Result : Irritating to eyes.

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Result : No eye irritation

Respiratory or skin sensitisation

Skin sensitisation

May cause an allergic skin reaction.

Respiratory sensitisation

Not classified based on available information.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

Product:

Remarks : Causes sensitisation.

Components:

Tripotassium hydrogen ethylenediaminetetraacetate:

Test Type : Maximisation Test
Species : Guinea pig
Assessment : Does not cause skin sensitisation.
Method : OECD Test Guideline 406
Result : negative
Remarks : Based on data from similar materials

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Test Type : Local lymph node assay (LLNA)
Species : Mouse
Assessment : The product is a skin sensitiser, sub-category 1B.
Method : OECD Test Guideline 442A
GLP : No information available.

Test Type : Maximisation Test
Species : Guinea pig
Assessment : The product is a skin sensitiser, sub-category 1B.
Method : OECD Test Guideline 406
GLP : no

Germ cell mutagenicity

Not classified based on available information.

Components:

Tripotassium hydrogen ethylenediaminetetraacetate:

Genotoxicity in vitro : Test Type: In vitro mammalian cell gene mutation test
Test system: mouse lymphoma cells
Method: OECD Test Guideline 476
Result: negative
Remarks: Based on data from similar materials

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Result: negative
Remarks: Based on data from similar materials

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
Remarks: Based on data from similar materials

Test Type: Microbial mutagenesis assay (Ames test)

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

Test system: Escherichia coli
Metabolic activation: with and without metabolic activation
Method: OECD Test Guideline 471
Result: negative
Remarks: Based on data from similar materials

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

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

Test Type: Chromosome aberration test in vitro
Test system: Chinese hamster ovary cells
Metabolic activation: with and without metabolic activation
Result: negative

Genotoxicity in vivo : Test Type: In vivo micronucleus test
Species: Mouse
Application Route: Oral
Result: negative

Test Type: in vivo assay
Species: Rat
Application Route: Oral
Result: negative

Carcinogenicity

Not classified based on available information.

Components:

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

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 based on available information.

Components:

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Effects on foetal development : Test Type: Embryo-foetal development
Species: Rat
Application Route: Oral
Dose: 300 milligram per kilogram
Embryo-foetal toxicity: NOAEL F1: 300
Result: No teratogenic effects

Test Type: Embryo-foetal development
Species: Mouse
Application Route: Oral
Dose: 300 milligram per kilogram

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

Embryo-foetal toxicity: NOAEL F1: 300
Result: No teratogenic effects

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

May cause damage to organs through prolonged or repeated exposure.

Components:

Tripotassium hydrogen ethylenediaminetetraacetate:

Exposure routes	: Inhalation
Target Organs	: Respiratory system
Assessment	: May cause damage to organs through prolonged or repeated exposure.
Remarks	: Based on data from similar materials

Repeated dose toxicity

Components:

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Species	: Rat
NOAEL	: 200 mg/kg
LOAEL	: 500 mg/kg
Application Route	: Oral

Species	: Rabbit
NOAEL	: 200 mg/kg
Application Route	: Dermal

Aspiration toxicity

Not classified based on available information.

11.2 Information on other hazards

Endocrine disrupting properties

Product:

Assessment	: The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.
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SECTION 12: Ecological information

12.1 Toxicity

Components:

Tripotassium hydrogen ethylenediaminetetraacetate:

Toxicity to fish	: LC50 (Lepomis macrochirus (Bluegill sunfish)): 792 mg/l
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SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

Exposure time: 96 h
Test Type: static test
Remarks: Based on data from similar materials

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Toxicity to fish : LC0 (Lepomis macrochirus (Bluegill sunfish)): 220 mg/l
Exposure time: 96 h
Test Type: static test
Method: OPPTS 850.1500
GLP: No information available.

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 58 mg/l
Exposure time: 48 h
Test Type: flow-through test

Toxicity to algae/aquatic plants : ErC50 (Pseudokirchneriella subcapitata (green algae)): 5,78 mg/l
End point: Growth inhibition
Exposure time: 72 h
Method: Regulation (EC) No. 440/2008, Annex, C.3
GLP: yes
Remarks: Based on data from similar materials

NOEC (Pseudokirchneriella subcapitata (green algae)): 1,6 mg/l
End point: Growth inhibition
Exposure time: 72 h
Method: Regulation (EC) No. 440/2008, Annex, C.3
GLP: yes
Remarks: Based on data from similar materials

Toxicity to microorganisms : EC50 (Bacteria): 567 mg/l
End point: Respiration inhibition
Exposure time: 3 h
Method: OECD Test Guideline 209
GLP: yes
Remarks: Based on data from similar materials
nominal concentration

12.2 Persistence and degradability

Components:

Tripotassium hydrogen ethylenediaminetetraacetate:

Biodegradability : Result: Inherently biodegradable.
Test substance: anhydrous substance

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Biodegradability : Test Type: aerobic
Inoculum: activated sludge, non-adapted
Result: Not readily biodegradable.
Biodegradation: 42,7 %
Exposure time: 25 d
Method: OECD Test Guideline 301B

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

GLP: No information available.

12.3 Bioaccumulative potential

Components:

Tripotassium hydrogen ethylenediaminetetraacetate:

Bioaccumulation : Remarks: No data available

Partition coefficient: n-octanol/water : log Pow: -4,3 (25 °C)

N,N''-methylenebis[N'-(3-(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl)urea]:

Bioaccumulation : Remarks: Due to the distribution coefficient n-octanol/water, accumulation in organisms is not expected.

Partition coefficient: n-octanol/water : log Pow: 0,9 (20 °C)

12.4 Mobility in soil

No data available

12.5 Results of PBT and vPvB assessment

Product:

Assessment : This substance/mixture contains no components considered to be either persistent, bioaccumulative and toxic (PBT), or very persistent and very bioaccumulative (vPvB) at levels of 0.1% or higher.

12.6 Endocrine disrupting properties

Product:

Assessment : The substance/mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 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.

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : The product should not be allowed to enter drains, water courses or the soil.
Do not contaminate ponds, waterways or ditches with chemi-

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
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cal or used container.
Send to a licensed waste management company.

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

14.1 UN number or ID number

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.2 UN proper shipping name

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.3 Transport hazard class(es)

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA : Not regulated as a dangerous good

14.4 Packing group

ADR : Not regulated as a dangerous good
RID : Not regulated as a dangerous good
IMDG : Not regulated as a dangerous good
IATA (Cargo) : Not regulated as a dangerous good
IATA (Passenger) : 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 Maritime transport in bulk according to IMO instruments

Remarks : Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
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SECTION 15: Regulatory information

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

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

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

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

Regulation (EU) 2019/1021 on persistent organic pollutants (recast) : Not applicable

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

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

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 hazard class (Germany) : WGK 3 highly hazardous to water
Classification according to AwSV, Annex 1 (5.2)

TA Luft List (Germany) : 5.2.1 Total dust:
others: 13,2 %
IMIDAZOLIDINYL UREA
Glycine

5.2.2 Inorganic substances in powdered form:
Not applicable

5.2.4 Inorganic substances in gaseous form:
Not applicable

5.2.5 Organic Substances:
Not applicable

5.2.7.1.1 Carcinogenic substance:
Not applicable

5.2.7.1.1 Quartz fine dust PM4:
Not applicable

5.2.7.1.1 Formaldehyde:
Not applicable

5.2.7.1.2 Germ cell mutagens:
Not applicable

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cell-Free DNA Collection Tube

Version
2.5

Revision Date:
30.06.2023

Date of last issue: 30.08.2021
Date of first issue: 01.10.2015

5.2.7.1.3 Substances toxic to reproduction:

Not applicable

5.2.7.2 Poorly degradable, easily enrichable and highly toxic organic substances:

Not applicable

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

Other regulations:

Take note of Directive 94/33/EC on the protection of young people at work or stricter national regulations, where applicable.

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.

Tripotassium hydrogen ethylenediaminetetraacetate

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 : Not 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 : Product contains substance(s) not listed on TSCA inventory.

TECI : Not in compliance with the inventory

15.2 Chemical safety assessment

Chemical Safety Assessments for all substances in this product are either Complete or Not applicable.

SECTION 16: Other information

Full text of H-Statements

H317 : May cause an allergic skin reaction.
H319 : Causes serious eye irritation.
H332 : Harmful if inhaled.
H373 : May cause damage to organs through prolonged or repeated exposure if inhaled.

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

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H412 : Harmful to aquatic life with long lasting effects.

Full text of other abbreviations

Acute Tox. : Acute toxicity
Aquatic Chronic : Long-term (chronic) aquatic hazard
Eye Irrit. : Eye irritation
Skin Sens. : Skin sensitisation
STOT RE : Specific target organ toxicity - repeated exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - Agreement concerning the International Carriage of Dangerous Goods by Road; AIIIC - Australian Inventory of Industrial Chemicals; 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 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; TECI - Thailand Existing Chemicals 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

Classification of the mixture:

Eye Irrit. 2 H319
Skin Sens. 1 H317
STOT RE 2 H373

Classification procedure:

Calculation method
Calculation method
Calculation method

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

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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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