

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

IRON2

Version
1.8

Revision Date:
20.02.2015

Date of last issue: 12.08.2014
Date of first issue: 22.10.2012

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

1.1 Product identifier

Commercial Product Name : IRON2
Mat.-No./ Genisys-No. : 03183696122

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
E-mail address : mannheim.umweltschutz@roche.com
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

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 : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P280 Wear protective gloves/ protective clothing/
eye protection/ face protection.

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Response:

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

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

P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

Additional Labelling:

EUH210 Safety data sheet available on request.

EUH208 Contains 1-[1,3-bis(hydroxymethyl)-2,5-dioximidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea, 78491-02-8. May produce an allergic reaction.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

R1 (A) / (Pos. B)/F1

Classification (REGULATION (EC) No 1272/2008)

Skin corrosion, Category 1A

H314: Causes severe skin burns and eye damage.

Chronic aquatic toxicity, Category 3

H412: Harmful to aquatic life with long lasting effects.

Classification (67/548/EEC, 1999/45/EC)

Corrosive

R35: Causes severe burns.

Hazardous components

| Chemical Name | CAS-No. EC-No. Registration number | Classification (67/548/EEC) | Classification (REGULATION (EC) No 1272/2008) | Concentration (%) |
|---|---|---|---|----------------------|
| Isotridecyl(PEG-Ether) _{n,n=8} | 9043-30-5 500-027-2 | Xn; R22 Xi; R41 | Acute Tox. 4; H302 Eye Dam. 1; H318 Aquatic Chronic 2; H411 | >= 5 - < 10 |
| Citric acid monohydrate | 5949-29-1 201-069-1 | Xi; Xi; R36 | Eye Irrit. 2; H319 | >= 3 - < 10 |
| thiourea | 62-56-6 200-543-5 | Carc.Cat.3; R40 Repr.Cat.3; R63 Xn; R22 N; R51-R53 | Acute Tox. 4; H302 Carc. 2; H351 Repr. 2; H361d Aquatic Chronic 2; H411 | >= 0,3 - < 1 |

For explanation of abbreviations see section 16.

R2 (B) / (Pos. C)

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Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture.

Hazardous components

Remarks : No hazardous ingredients

SECTION 4: First aid measures

4.1 Description of first aid measures

- General advice : Move out of dangerous area.
Consult a physician.
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 : Immediate medical treatment is necessary as untreated wounds from corrosion of the skin heal slowly and with difficulty.
If on skin, rinse well with water.
If on clothes, remove clothes.
- In case of eye contact : Small amounts splashed into eyes can cause irreversible tissue damage and blindness.
In the case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
Continue rinsing eyes during transport to hospital.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do NOT induce vomiting.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
Take victim immediately to hospital.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

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.

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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.

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.
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".

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.

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Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.
Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.

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) : 8B, Non-combustible, corrosive hazardous materials

Other data : 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

R1 (A) / (Pos. B)/F1

Contains no substances with occupational exposure limit values.

R2 (B) / (Pos. C)

Contains no substances with occupational exposure limit values.

8.2 Exposure controls

Personal protective equipment

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

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Wear face-shield and protective suit for abnormal processing problems.

Hand protection

Material : Protective gloves

Remarks : The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC 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

R1 (A) / (Pos. B)/F1

Appearance : liquid

Colour : colourless

Odour : No data available

Odour Threshold : No data available

pH : 1,6

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.

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available

Relative vapour density : No data available

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Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : completely miscible

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

Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : No data available

R2 (B) / (Pos. C)

Appearance : liquid

Colour : No data available
Odour : No data available
Odour Threshold : No data available
pH : No data available
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.

Upper explosion limit : No data available

Lower explosion limit : No data available

Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : completely miscible

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

Auto-ignition temperature : No data available
Decomposition temperature : No data available

Viscosity : No data available
Explosive properties : No data available
Oxidizing properties : The substance or mixture is not classified as oxidizing.

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9.2 Other information

R1 (A) / (Pos. B)/F1

No data available

R2 (B) / (Pos. C)

No data available

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 data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

R1 (A) / (Pos. B)/F1

Acute toxicity

Not classified based on available information.

Components:

Isotridecyl(PEG-Ether)_{n,n=8}:

Acute oral toxicity : LD50 Oral (Rat): > 500 mg/kg

Acute dermal toxicity : LD50 Dermal (Rat): > 2.000 mg/kg

Citric acid monohydrate:

Acute oral toxicity : LD50 (Mouse): 5.400 mg/kg

LD50 (Rat): > 6.730 mg/kg

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LD50 (Rabbit): > 7.000 mg/kg

thiourea:

Acute oral toxicity : LD50 Oral (Rat): 1.750 mg/kg

Acute dermal toxicity : LD50 Dermal (Rabbit): > 2.800 mg/kg

Skin corrosion/irritation

Causes severe burns.

Components:

Isotridecyl(PEG-Ether)_{n,n=8}:

Remarks: May cause skin irritation in susceptible persons.

Citric acid monohydrate:

Remarks: Extremely corrosive and destructive to tissue.

thiourea:

Remarks: This information is not available.

Serious eye damage/eye irritation

Causes serious eye damage.

Components:

Isotridecyl(PEG-Ether)_{n,n=8}:

Result: Risk of serious damage to eyes.

Remarks: May cause irreversible eye damage.

Citric acid monohydrate:

Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

thiourea:

Remarks: This information is not available.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:

Citric acid monohydrate:

Assessment: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Components:

thiourea:

Carcinogenicity - Assessment : Limited evidence of a carcinogenic effect.

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Reproductive toxicity

Not classified based on available information.

Components:

thiourea:

Reproductive toxicity - Assessment : Suspected of damaging the unborn child.

STOT - single exposure

Not classified based on available information.

Components:

Isotridecyl(PEG-Ether)_{n,n=8}:

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

Citric acid monohydrate:

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

thiourea:

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

STOT - repeated exposure

Not classified based on available information.

Components:

Isotridecyl(PEG-Ether)_{n,n=8}:

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

Citric acid monohydrate:

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

Aspiration toxicity

Not classified based on available information.

Components:

Isotridecyl(PEG-Ether)_{n,n=8}:

No data available

Citric acid monohydrate:

No data available

thiourea:

No data available

R2 (B) / (Pos. C)

Acute toxicity

Not classified based on available information.

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Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

R1 (A) / (Pos. B)/F1

Components:

Isotridecyl(PEG-Ether)_{n,n=8}:

Toxicity to fish : LC50 (Danio rerio (zebra fish)): 1,1 mg/l
Exposure time: 96 h

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Citric acid monohydrate:

Toxicity to fish : LC0 (Carassius auratus (goldfish)): 625 mg/l

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 120 mg/l
Exposure time: 72 h

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

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thiourea:

- Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): 10.000 mg/l
Exposure time: 48 h
- Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 35 mg/l
Exposure time: 48 h
- Toxicity to algae : (Desmodesmus subspicatus (green algae)): 3,8 - 10 mg/l
Exposure time: 72 h
- Ecotoxicology Assessment
Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.
- Toxicity Data on Soil : Not expected to adsorb on soil.
- Other organisms relevant to the environment : No data available

R2 (B) / (Pos. C)

No data available

12.2 Persistence and degradability

R1 (A) / (Pos. B)/F1

Components:

Isotridecyl(PEG-Ether)_{n,n=8}:

- Biodegradability : Biodegradation: > 90 %
Method: OECD Test Guideline 302
Remarks: Readily biodegradable, according to appropriate OECD test.

Citric acid monohydrate:

- Biodegradability : Remarks: Expected to be ultimately biodegradable

thiourea:

- Biodegradability : Biodegradation: 0 %
Exposure time: 34 d
Method: OECD Test Guideline 301C

R2 (B) / (Pos. C)

No data available

12.3 Bioaccumulative potential

R1 (A) / (Pos. B)/F1

Components:

Citric acid monohydrate:

- Partition coefficient: n-octanol/water : log Pow: 1,72

thiourea:

- Partition coefficient: n- : log Pow: -0,92 (20 °C)

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octanol/water

Method: OECD Test Guideline 107

R2 (B) / (Pos. C)

No data available

12.4 Mobility in soil

R1 (A) / (Pos. B)/F1

No data available

R2 (B) / (Pos. C)

No data available

12.5 Results of PBT and vPvB assessment

R1 (A) / (Pos. B)/F1

Not relevant

R2 (B) / (Pos. C)

Not relevant

12.6 Other adverse effects

R1 (A) / (Pos. B)/F1

No data available

R2 (B) / (Pos. C)

No data available

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 chemical 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

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

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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, ADNR,
IMDG-Code, ICAO/IATA-DGR
No data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 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 II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances
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 contaminating class : WGK 2 water endangering
(Germany)

R1 (A) / (Pos. B)/F1

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H314 Causes severe skin burns and eye damage.
H412 Harmful to aquatic life with long lasting effects.

Precautionary statements : **Prevention:**
P273 Avoid release to the environment.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P301 + P330 + P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.

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- P303 + P361 + P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
- P304 + P340 + P310 IF INHALED: Remove person to fresh air and keep comfortable for breathing. Immediately call a POISON CENTER or doctor/ physician.
- P305 + P351 + P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

R2 (B) / (Pos. C)

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

Additional Labelling:

- EUH210 Safety data sheet available on request.
- EUH208 Contains 1-[1,3-bis(hydroxymethyl)-2,5-dioxoimidazolidin-4-yl]-1,3-bis(hydroxymethyl)urea, 78491-02-8. May produce an allergic reaction.

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 R-Phrases

- R22 : Harmful if swallowed.
- R22 : Also harmful if swallowed.
- R36 : Irritating to eyes.
- R40 : Limited evidence of a carcinogenic effect.
- R41 : Risk of serious damage to eyes.
- R51 : Toxic to aquatic organisms.
- R53 : May cause long-term adverse effects in the aquatic environment.
- R63 : Possible risk of harm to the unborn child.

Full text of H-Statements

- H302 : Harmful if swallowed.
- H318 : Causes serious eye damage.
- H319 : Causes serious eye irritation.
- H351 : Suspected of causing cancer.
- H361d : Suspected of damaging the unborn child.
- H411 : Toxic to aquatic life with long lasting effects.

Full text of other abbreviations

- Acute Tox. : Acute toxicity
- Aquatic Chronic : Chronic aquatic toxicity
- Carc. : Carcinogenicity
- Eye Dam. : Serious eye damage
- Eye Irrit. : Eye irritation
- Repr. : Reproductive toxicity

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The Roche logo, consisting of the word "Roche" in a bold, sans-serif font, enclosed within a hexagonal border.

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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