

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006

Roche

Cyclosporin Sample Pretreatment Reagent

Version
1.6

Revision Date:
22.02.2015

Date of last issue: 01.08.2014
Date of first issue: 14.09.2012

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

1.1 Product identifier

Commercial Product Name : Cyclosporin Sample Pretreatment Reagent
Mat.-No./ Genisys-No. : 20766364122

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
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 : H226 Flammable liquid and vapour.
H301 Toxic if swallowed.
H312 + H332 Harmful in contact with skin or if inhaled
H370 Causes damage to organs.

Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open

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P260 flames/hot surfaces. - No smoking.
Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.

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

P308 + P311 IF exposed or concerned: Call a POISON CENTER or doctor/ physician.

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

P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

R1

Classification (REGULATION (EC) No 1272/2008)

Flammable liquids, Category 3 H226: Flammable liquid and vapour.

Acute toxicity, Category 3 H301: Toxic if swallowed.

Acute toxicity, Category 4 H332: Harmful if inhaled.

Acute toxicity, Category 4 H312: Harmful in contact with skin.

Specific target organ toxicity - single exposure, Category 1 H370: Causes damage to organs.

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

Flammable R10: Flammable.

Toxic R23/24/25: Toxic by inhalation, in contact with skin and if swallowed.

R39/23/24/25: Toxic: danger of very serious irreversible effects through inhalation, in contact with skin and if swallowed.

Hazardous components

| Chemical Name | CAS-No. EC-No. Registration number | Classification (67/548/EEC) | Classification (REGULATION (EC) No 1272/2008) | Concentration (%) |
|-----------------|---|---|--|----------------------|
| ethane-1,2-diol | 107-21-1 203-473-3 | Xn; R22 | Acute Tox. 4; H302 | >= 30 - < 50 |
| methanol | 67-56-1 200-659-6 | F; R11 T; R23/24/25- R39/23/24/25 | Flam. Liq. 2; H225 Acute Tox. 3; H301 Acute Tox. 3; H331 Acute Tox. 3; H311 | >= 25 - < 30 |

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STOT SE 1; H370

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.
Consult a physician.
Show this safety data sheet to the doctor in attendance.
Symptoms of poisoning may appear several hours later.
Do not leave the victim unattended.
- If inhaled : 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.
If on clothes, remove clothes.
- In case of eye contact : Flush eyes with water as a precaution.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.
- If swallowed : Keep respiratory tract clear.
Do not give milk or alcoholic beverages.
Never give anything by mouth to an unconscious person.
If symptoms persist, call a physician.
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.

SECTION 5: Firefighting measures

5.1 Extinguishing media

- Suitable extinguishing media : Alcohol-resistant foam
Carbon dioxide (CO₂)
Dry chemical
- Unsuitable extinguishing media : High volume water jet

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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.
For safety reasons in case of fire, cans should be stored separately in closed containments.
Use a water spray to cool fully closed containers.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Remove all sources of ignition.
Evacuate personnel to safe areas.
Refer to protective measures listed in sections 7 and 8.
Beware of vapours accumulating to form explosive concentrations. Vapours can accumulate in low areas.

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 : Contain spillage, and then collect with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local / national regulations (see section 13).

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 : 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 ap-

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plication area.

Take precautionary measures against static discharges.

Provide sufficient air exchange and/or exhaust in work rooms.

Open drum carefully as content may be under pressure.

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

Advice on protection against fire and explosion : Do not spray on a naked flame or any incandescent material. Take necessary action to avoid static electricity discharge (which might cause ignition of organic vapours). Keep away from open flames, hot surfaces and sources of ignition.

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

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Prevent unauthorized access. No smoking. 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. Observe label precautions. 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) : 3, Flammable liquids

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

Occupational Exposure Limits

| Components | CAS-No. | Value type (Form of exposure) | Control parameters | Basis |
|---------------------|---|-------------------------------|---------------------------------|-------------|
| ethane-1,2-diol | 107-21-1 | TWA | 20 ppm 52 mg/m ³ | 2000/39/EC |
| Further information | Identifies the possibility of significant uptake through the skin, Indicative | | | |
| | | STEL | 40 ppm 104 mg/m ³ | 2000/39/EC |
| Further information | Identifies the possibility of significant uptake through the skin, Indicative | | | |
| | | AGW (Vapour and aerosols) | 10 ppm 26 mg/m ³ | DE TRGS 900 |
| Peak-limit: excu- | 2;(l) | | | |

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| | | | | |
|---|--|-----|----------------------|----------------|
| sion factor (category) | | | | |
| Further information | Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., European Union (The EU has established a limit value: deviations in value and peak limit are possible), Sum of vapor and aerosols., Skin absorption, When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child | | | |
| methanol | 67-56-1 | TWA | 200 ppm 260 mg/m3 | 2006/15/EC |
| Further information | Identifies the possibility of significant uptake through the skin, Indicative | | | |
| | | AGW | 200 ppm 270 mg/m3 | DE TRGS 900 |
| Peak-limit: excursion factor (category) | 4;(II) | | | |
| Further information | Senate commission for the review of compounds at the work place dangerous for the health (MAK-commission)., European Union (The EU has established a limit value: deviations in value and peak limit are possible), Skin absorption, When there is compliance with the OEL and biological tolerance values, there is no risk of harming the unborn child | | | |

Biological occupational exposure limits

| Substance name | CAS-No. | Control parameters | Sampling time | Basis |
|----------------|---------|---------------------------|---|----------|
| Methanol | 67-56-1 | Methanol: 30 mg/l (Urine) | Immediately after exposition or after working hours, In case of long-term exposition: after more than one shift | TRGS 903 |

8.2 Exposure controls

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 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.

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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

| | |
|--|--|
| 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 | : 34 °C |
| Evaporation rate | : No data available |
| Flammability (solid, gas) | : No data available |
| 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. |

9.2 Other information

R1

No data available

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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.
Vapours may form explosive mixture with air.

10.4 Conditions to avoid

Conditions to avoid : Heat, flames and sparks.

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

Acute toxicity

Toxic if swallowed.
Harmful in contact with skin or if inhaled

Components:

methanol:

Acute oral toxicity : LD50 Oral (Mouse): 7.300 mg/kg
LD50 Oral (Rat): 5.628 mg/kg
Acute inhalation toxicity : LC50 (Rat): 85,26 mg/l
Exposure time: 4 h
LC50 (Rat): 64000 ppm
Exposure time: 4 h
Acute dermal toxicity : LD50 Dermal (Rabbit): 15.800 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

methanol:

Remarks: The product may be absorbed through the skin.

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May irritate skin.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

methanol:

Remarks: Contact with eyes may cause irritation.

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

Components:

methanol:

Species: Guinea pig

Result: Did not cause sensitisation on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Components:

methanol:

Genotoxicity in vitro : Test Type: Ames test
Result: negative

Genotoxicity in vivo : Result: negative

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Causes damage to organs.

Components:

methanol:

Target Organs: Eyes

Assessment: Causes damage to organs.

STOT - repeated exposure

Not classified based on available information.

Components:

methanol:

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

Aspiration toxicity

Not classified based on available information.

Components:

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methanol:

No aspiration toxicity classification

Further information

SECTION 12: Ecological information

12.1 Toxicity

R1

Components:

ethane-1,2-diol:

| | |
|---|--|
| Toxicity to fish | : LC50 (Leuciscus idus (Golden orfe)): > 100 mg/l Exposure time: 96 h LC50 (Carassius auratus (goldfish)): > 100 mg/l Exposure time: 96 h Method: OECD Test Guideline 203 LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l Exposure time: 96 h |
| Toxicity to daphnia and other aquatic invertebrates | : LC50 (Daphnia magna (Water flea)): > 10.000 mg/l Exposure time: 48 h Method: OECD Test Guideline 202 |
| Toxicity to algae | : EC0 (Scenedesmus quadricauda (Green algae)): > 10.000 mg/l Exposure time: 7 d |
| Toxicity to bacteria | : EC0 (Pseudomonas putida): > 10.000 mg/l Exposure time: 16 h |
| 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 |

methanol:

| | |
|---|--|
| Toxicity to fish | : LC50 (Lepomis macrochirus (Bluegill sunfish)): 15.400 mg/l Exposure time: 96 h LC50 (Oncorhynchus mykiss (rainbow trout)): 8.000 mg/l Exposure time: 48 h LC50 (Leuciscus idus (Golden orfe)): > 10.000 mg/l |
| Toxicity to daphnia and other aquatic invertebrates | : EC50 (Daphnia magna (Water flea)): 6.100 mg/l Exposure time: 48 h |

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| | |
|---|---|
| Toxicity to algae | : EC0 (Scenedesmus quadricauda (Green algae)): 8.000 mg/l Exposure time: 7 d |
| Toxicity to bacteria | : (Pseudomonas putida): 6.600 mg/l Exposure time: 16 h |
| Ecotoxicology Assessment Toxicity Data on Soil | : Not expected to adsorb on soil. |
| Other organisms relevant to the environment | : No data available |

12.2 Persistence and degradability

R1

Components:

ethane-1,2-diol:

| | |
|------------------|---|
| Biodegradability | : Biodegradation: 100 % Exposure time: 28 d Method: OECD Test Guideline 302 |
|------------------|---|

methanol:

| | |
|------------------|---|
| Biodegradability | : Result: Readily biodegradable Biodegradation: 99 % Exposure time: 30 d Method: OECD Test Guideline 301 |
|------------------|---|

| | |
|---------------------------------|---|
| Biochemical Oxygen Demand (BOD) | : Biochemical oxygen demand 600 - 1.120 mg/g Incubation time: 5 d |
|---------------------------------|---|

| | |
|------------------------------|--------------|
| Chemical Oxygen Demand (COD) | : 1.420 mg/g |
|------------------------------|--------------|

| | |
|------|--------------|
| ThOD | : 1.500 mg/g |
|------|--------------|

| | |
|----------|--------|
| BOD/ThOD | : 76 % |
|----------|--------|

12.3 Bioaccumulative potential

R1

Components:

ethane-1,2-diol:

| | |
|--|------------------|
| Partition coefficient: n-octanol/water | : log Pow: -1,36 |
|--|------------------|

methanol:

| | |
|-----------------|------------------------------------|
| Bioaccumulation | : Remarks: Does not bioaccumulate. |
|-----------------|------------------------------------|

| | |
|--|-----------------|
| Partition coefficient: n-octanol/water | : log Pow: -0,7 |
|--|-----------------|

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12.4 Mobility in soil

R1

No data available

12.5 Results of PBT and vPvB assessment

R1

Not relevant

12.6 Other adverse effects

R1

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. Do not burn, or use a cutting torch on, the empty drum. |

SECTION 14: Transport information

14.1 UN number

- | | | |
|------|---|------------|
| ADR | : | UN NA 1993 |
| IMDG | : | UN NA 1993 |
| IATA | : | UN NA 1993 |

14.2 UN proper shipping name

- | | | |
|------|---|---|
| ADR | : | Flammable liquid, n.o.s. (Methanol solution) |
| IMDG | : | Flammable liquid, n.o.s. (Methanol solution) |
| IATA | : | Flammable liquid, n.o.s. (Methanol solution) |

14.3 Transport hazard class(es)

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ADR : 3

IMDG : 3

IATA : 3

14.4 Packing group

ADR

Packing group : III
Classification Code : F1
Labels : 3
Tunnel restriction code : D/E

IMDG

Packing group : III
Labels : 3
EmS Code : F-E, S-E

IATA

Packing instruction (cargo aircraft) : 366
Packing instruction (passenger aircraft) : 355
Packing instruction (LQ) : Y344
Packing group : III
Labels : Flammable liquids

14.5 Environmental hazards

ADR

Environmentally hazardous : no

IMDG

Marine pollutant : no

14.6 Special precautions for user

Remarks : 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

| | | Quantity 1 | Quantity 2 |
|---|------------|------------|------------|
| 2 | Toxic | 50 t | 200 t |
| 6 | Flammable. | 5.000 t | 50.000 t |

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

| | | | |
|----|---|------|-------|
| H3 | STOT SPECIFIC TARGET ORGAN TOXICITY – SINGLE EXPOSURE | 50 t | 200 t |
|----|---|------|-------|

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P5c FLAMMABLE LIQUIDS 5.000 t 50.000 t

Water contaminating class : WGK 1 slightly water endangering
(Germany)

R1

Labelling (REGULATION (EC) No 1272/2008)

Hazard pictograms :



Signal word : Danger

Hazard statements : H226 Flammable liquid and vapour.
H301 Toxic if swallowed.
H312 + H332 Harmful in contact with skin or if inhaled
H370 Causes damage to organs.

Precautionary statements : **Prevention:**
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P260 Do not breathe dust/ fume/ gas/ mist/ vapours/ spray.
P280 Wear protective gloves/ eye protection/ face protection.
Response:
P301 + P310 + P330 IF SWALLOWED: Immediately call a POISON CENTER or doctor/ physician. Rinse mouth.
P308 + P311 IF exposed or concerned: Call a POISON CENTER or doctor/ physician.
P370 + P378 In case of fire: Use dry sand, dry chemical or alcohol-resistant foam to extinguish.

Hazardous components which must be listed on the label:

67-56-1 methanol

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

R11 : Highly flammable.
R22 : Harmful if swallowed.
R23/24/25 : Toxic by inhalation, in contact with skin and if swallowed.
R39/23/24/25 : Toxic: danger of very serious irreversible effects through inha-

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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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lation, in contact with skin and if swallowed.

Full text of H-Statements

| | |
|------|---------------------------------------|
| H225 | : Highly flammable liquid and vapour. |
| H301 | : Toxic if swallowed. |
| H302 | : Harmful if swallowed. |
| H311 | : Toxic in contact with skin. |
| H331 | : Toxic if inhaled. |
| H370 | : Causes damage to organs. |

Full text of other abbreviations

| | |
|------------|--|
| Acute Tox. | : Acute toxicity |
| Flam. Liq. | : Flammable liquids |
| STOT SE | : Specific target organ toxicity - single exposure |

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