Cyclosporin Sample Pretreatment Reagent

SECTION 1. IDENTIFICATION

Product name : Cyclosporin Sample Pretreatment Reagent

Mat.-No./ Genisys-No. : 20766364122

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
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Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number:

In case of emergencies: : CHEMTREC 1-800-424-9300 (U.S. or Canada)
1-703-527-3887 (International)

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

SECTION 2. HAZARDS IDENTIFICATION

GHS Classification

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.

GHS Label element

Hazard pictograms :

Signal word : Warning

Hazard statements : H226 Flammable liquid and vapour.

Precautionary statements : **Prevention:**
P210 Keep away from heat/sparks/open flames/hot surfaces. - No smoking.
P233 Keep container tightly closed.
P240 Ground/bond container and receiving equipment.
P241 Use explosion-proof electrical/ ventilating/ lighting/ equipment.
P242 Use only non-sparking tools.
P243 Take precautionary measures against static discharge.
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.
Response:
P303 + P361 + P353 IF ON SKIN (or hair): Remove/ Take off immediately all contaminated clothing. Rinse skin with water/ shower.
P370 + P378 In case of fire: Use dry sand, dry chemical or

alcohol-resistant foam for extinction.
Storage:
P403 + P235 Store in a well-ventilated place. Keep cool.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

R1

GHS Classification

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

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
ethane-1,2-diol	107-21-1	>= 30 - < 50
methanol	67-56-1	>= 20 - < 30

SECTION 4. 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.

Most important symptoms and effects, both acute and delayed : No information available.

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

SECTION 5. FIREFIGHTING MEASURES

Suitable extinguishing media	:	Alcohol-resistant foam Carbon dioxide (CO2) Dry chemical
Unsuitable extinguishing media	:	High volume water jet
Specific hazards during firefighting	:	Do not allow run-off from fire fighting to enter drains or water courses.
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.
Special protective equipment for firefighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures	:	Use personal protective equipment. 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.
Environmental precautions	:	Prevent product from entering drains. Prevent further leakage or spillage if safe to do so. Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	:	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).

SECTION 7. HANDLING AND STORAGE

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.

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.

Conditions for safe storage : 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.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

R1

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
ethane-1,2-diol	107-21-1	C	50 ppm 125 mg/m3	OSHA P0
		C (Aerosol only)	100 mg/m3	ACGIH
methanol	67-56-1	TWA	200 ppm	ACGIH
		STEL	250 ppm	ACGIH
		TWA	200 ppm 260 mg/m3	NIOSH REL
		ST	250 ppm 325 mg/m3	NIOSH REL
		TWA	200 ppm 260 mg/m3	OSHA Z-1
		TWA	200 ppm 260 mg/m3	OSHA P0
		STEL	250 ppm 325 mg/m3	OSHA P0

Biological occupational exposure limits

Components	CAS-No.	Control parameters	Biological specimen	Sampling time	Permissible concentration	Basis
Methanol	67-56-1	Methanol	Urine	End of shift (As soon as possible after exposure ceases)	15 mg/l	ACGIH BEI

Personal protective equipment

Respiratory protection : In the case of vapour formation use a respirator with an

approved filter.

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.
Eye protection	:	Eye wash bottle with pure water Tightly fitting safety goggles
Skin and body protection	:	impervious clothing Choose body protection according to the amount and concentration of the dangerous substance at the work place.
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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

R1

Appearance	:	liquid
Melting point/range	:	No data available
Boiling point/boiling range	:	No data available
Flash point	:	34 °C
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Solubility(ies)		
Water solubility	:	completely miscible
Auto-ignition temperature	:	No data available
Thermal decomposition	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

SECTION 10. STABILITY AND REACTIVITY

Reactivity	:	No dangerous reaction known under conditions of normal use.
Chemical stability	:	Stable under normal conditions.
Possibility of hazardous reactions	:	No decomposition if stored and applied as directed. Vapours may form explosive mixture with air.
Conditions to avoid	:	Heat, flames and sparks.
Incompatible materials	:	No data available
Hazardous decomposition products	:	No data available

SECTION 11. TOXICOLOGICAL INFORMATION

R1

Information on likely routes of exposure

Acute toxicity

Not classified based on available information.

Components:

methanol:

Acute oral toxicity	:	LD50 Oral (Mouse): 7,300 mg/kg LD50 Oral (Rat): 5,600 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., 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.

IARC	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.
ACGIH	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by ACGIH.
OSHA	No component of this product present at levels greater than or equal to 0.1% is identified as a carcinogen or potential carcinogen by OSHA.
NTP	No component of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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.

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:

methanol:
No aspiration toxicity classification

Further information

Product:

Remarks: Solvents may degrease the skin.

SECTION 12. ECOLOGICAL INFORMATION

R1

Ecotoxicity

Product:

Ecotoxicology Assessment Toxicity Data on Soil	:	Not expected to adsorb on soil.
Other organisms relevant to the environment	:	No data available

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)): > 10,000 mg/l Exposure time: 48 h
Toxicity to algae	:	EC0 (Scenedesmus quadricauda (Green algae)): 8,000 mg/l Exposure time: 7 d
Toxicity to bacteria	:	(Bacteria): 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

Persistence and degradability

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 %

Bioaccumulative potential

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

Mobility in soil

No data available

Other adverse effects

No data available

Product:

Regulation	40 CFR Protection of Environment; Part 82 Protection of Stratospheric Ozone - CAA Section 602 Class I Substances
Remarks	This product neither contains, nor was manufactured with a Class I or Class II ODS as defined by the U.S. Clean Air Act Section 602 (40 CFR 82, Subpt. A, App.A + B).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

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

SECTION 14. TRANSPORT INFORMATION

International Regulation

IATA-DGR

UN/ID No.	:	UN NA 1993
Proper shipping name	:	Flammable liquid, n.o.s. (Methanol solution)
Class	:	3
Packing group	:	III
Labels	:	Flammable liquids
Packing instruction (cargo aircraft)	:	366
Packing instruction (passenger aircraft)	:	355

IMDG-Code

UN number	:	UN 1993
Proper shipping name	:	Flammable liquid, n.o.s. (Methanol solution)
Class	:	3
Packing group	:	III
Labels	:	3
EmS Code	:	F-E, S-E

Marine pollutant : no

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Not applicable for product as supplied.

National Regulations

49 CFR

UN/ID/NA number : UN NA 1993
Proper shipping name : Flammable liquids, n.o.s. (Methanol solution)
Class : 3
Packing group : III
Labels : Class 3 - Flammable Liquid
ERG Code : 128
Marine pollutant : no

SECTION 15. REGULATORY INFORMATION

R1

EPCRA - Emergency Planning and Community Right-to-Know Act

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Ethylene Glykol	107-21-1	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium azide	26628-22-8	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 : No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : The following components are subject to reporting levels established by SARA Title III, Section 313:

ethane-1,2-diol	107-21-1	38 %
methanol	67-56-1	27 %

Clean Air Act

The following chemical(s) are listed as HAP under the U.S. Clean Air Act, Section 12 (40 CFR 61):

ethane-1,2-diol	107-21-1	38 %
methanol	67-56-1	27 %

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 112(r) for Accidental Release Prevention (40 CFR 68.130, Subpart F).
The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489):

ethane-1,2-diol	107-21-1	38 %

methanol	67-56-1	27 %

Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

Copper(II)sufate-pentahydrate	7758-99-8	0 %

The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Copper(II)sufate-pentahydrate	7758-99-8	0 %

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

ethane-1,2-diol	107-21-1	30 - 50 %
methanol	67-56-1	20 - 30 %
sodium azide	26628-22-8	0 - 0.1 %

Pennsylvania Right To Know

ethane-1,2-diol	107-21-1	30 - 50 %
water	7732-18-5	30 - 50 %
methanol	67-56-1	20 - 30 %
sodium azide	26628-22-8	0 - 0.1 %

New Jersey Right To Know

ethane-1,2-diol	107-21-1	30 - 50 %
water	7732-18-5	30 - 50 %
methanol	67-56-1	20 - 30 %

California Prop 65 WARNING: This product contains a chemical known to the State of California to cause birth defects or other reproductive harm.

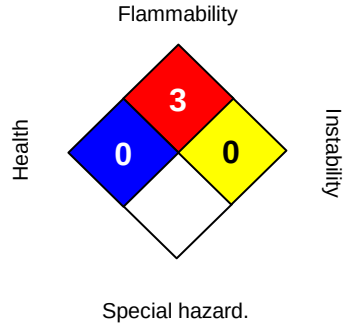
methanol	67-56-1
streptomycin sulphate	3810-74-0

SECTION 16. OTHER INFORMATION

Further information

R1

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	3
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

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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.