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## **SECTION 1. PRODUCT AND COMPANY IDENTIFICATION**

Product name : Cell Conditioning Solution (CC2),1 Liter

Mat.-No./ Genisys-No. : 05279798001

Manufacturer or supplier's details

Company : Roche Diagnostics Limited

Charles Avenue

Address : Burgess Hill

RH15 9RY West Sussex

Telephone : +44 1444 256000 Telefax : +44 1444 256239

Emergency telephone : +49(0)621-759-2012 oder +49(0)621-759-4848 oder

number +49(0)8856-60-2629

Emergency telephone number:

In case of emergencies: : Health, Safety & +44 1444 256500 or +44 7802

(Roche Diagnostics Ltd.) Environment 260498

- +44 1444 256561 or +44 7710

Product Safety / Vigilance 391653

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Toxicology 24Hr help-line: : NPIS: +44 844 892 0111 Health Advice 24Hr help-line: NHS Direct: +44 845 4647

NHS 24: +44 8454 242424

Recommended use of the chemical and restrictions on use

Restrictions on use : For professional users only.

#### **SECTION 2. HAZARDS IDENTIFICATION**

Physical state liquid

**GHS Classification** 

Eye irritation : Category 2A

GHS Label element

Hazard pictograms

Signal word : Warning

Hazard statements : H319 Causes serious eye irritation.

Precautionary statements : Prevention:

P264 Wash skin thoroughly after handling. P280 Wear eye protection/ face protection.



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#### Response:

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

easy to do. Continue rinsing.

P337 + P313 If eye irritation persists: Get medical advice/

attention.

#### **Potential Health Effects**

Carcinogenicity:

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.

#### **SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**

Substance / Mixture : Preparation

#### **Hazardous components**

Chemical Name	CAS-No.	Concentration [%]
ethane-1,2-diol	107-21-1	>= 5 - < 10
sodium dodecyl sulphate	151-21-3	>= 1 - < 5
Citric acid monohydrate	5949-29-1	>= 1 - < 5
disodium disulphite	7681-57-4	>= 1 - < 5

#### **SECTION 4. 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.

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 skin irritation persists, call a physician.

If on skin, rinse well with water. If on clothes, remove clothes.

In case of eye contact : Immediately flush eye(s) with plenty of water.



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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.

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 : Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Unsuitable extinguishing

media

: High volume water jet

Specific hazards during

firefighting

: No information available.

Further information : Standard procedure for chemical fires.

Use extinguishing measures that are appropriate to local

circumstances and the surrounding environment.

Special protective equipment

for firefighters

: Wear self contained breathing apparatus for fire fighting if

necessary.

#### **SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures Environmental precautions Use personal protective equipment.

Refer to protective measures listed in sections 7 and 8.

autions : 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

Soak up with inert absorbent material (e.g. sand, silica gel,

acid binder, universal binder, sawdust).

Keep in suitable, closed containers for disposal.

## **SECTION 7. HANDLING AND STORAGE**

Advice on safe handling : Do not breathe vapours/dust.

Avoid exposure - obtain special instructions before use.

Avoid contact with skin and eyes. For personal protection see section 8.

Smoking, eating and drinking should be prohibited in the



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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.

Conditions for safe storage : Keep container tightly closed in a dry and well-ventilated

place.

Electrical installations / working materials must comply with

the technological safety standards.

Materials to avoid :

#### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

## 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	С	50 ppm 125 mg/m3	OSHA P0
disodium disulphite	7681-57-4	STEL	5 mg/m3	ACGIH
		TWA	5 mg/m3	NIOSH REL
		TWA	5 mg/m3	OSHA P0

#### Personal protective equipment

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

Wear face-shield and protective suit for abnormal processing

problems.

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 : When using do not eat or drink.



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When using do not smoke.

Wash hands before breaks and at the end of workday.

#### **SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**

Appearance : liquid

pH : 6

Melting point/range : no data available
Boiling point/boiling range : no data available

Flash point

does not flash

Flammability (solid, gas) : The product is not flammable.

Upper explosion limit : no data available
Lower explosion limit : no data available
Auto-ignition temperature : no data available
Thermal decomposition : no data available

## **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.

Conditions to avoid : no data available

Incompatible materials : no data available

Hazardous decomposition

products

: no data available

#### **SECTION 11. TOXICOLOGICAL INFORMATION**

## **Acute toxicity**

#### **Product:**

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg

Method: Calculation method

Acute inhalation toxicity : Acute toxicity estimate : 33.71 mg/l

Exposure time: 4 h
Test atmosphere: vapour
Method: Calculation method



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Acute dermal toxicity : Acute toxicity estimate : > 5,000 mg/kg

Method: Calculation method

**Components:** 

sodium dodecyl sulphate:

Acute oral toxicity : LD50 Oral rat: 1,288 mg/kg

Acute inhalation toxicity : LC50 rat: >3900 mg/m3

Exposure time: 1 h

Acute dermal toxicity : LD50 Dermal rabbit: 580 mg/kg

Citric acid monohydrate:

Acute oral toxicity : LD50 mouse: 5,400 mg/kg

LD50 rat: > 6,730 mg/kg

LD50 rabbit: > 7,000 mg/kg

disodium disulphite:

Acute oral toxicity : LD50 Oral rat: 1,131 mg/kg

Acute dermal toxicity : LD50 Dermal rat: > 2,000 mg/kg

#### Skin corrosion/irritation

#### **Product:**

Remarks: May cause skin irritation and/or dermatitis.

#### **Components:**

# sodium dodecyl sulphate:

Result: Irritating to skin.

# Citric acid monohydrate:

Remarks: Extremely corrosive and destructive to tissue.

## disodium disulphite:

Remarks: May cause skin irritation in susceptible persons.

## Serious eye damage/eye irritation

## **Product:**

Remarks: May cause irreversible eye damage.

## **Components:**

## sodium dodecyl sulphate:

Result: Irritating to eyes.

## Citric acid monohydrate:



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Result: Irritating to eyes.

Remarks: May cause irreversible eye damage.

#### disodium disulphite:

Result: Risk of serious damage to eyes. Remarks: May cause irreversible eye damage.

# Respiratory or skin sensitisation

#### **Product:**

Remarks: Causes sensitisation.

## **Components:**

# Citric acid monohydrate:

Classification: Did not cause sensitisation on laboratory animals.

### Germ cell mutagenicity

no data available

## Carcinogenicity

## **Components:**

## sodium dodecyl sulphate:

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

no data available

## STOT - single exposure

## **Components:**

# sodium dodecyl sulphate:

Assessment: May cause respiratory irritation.

## Citric acid monohydrate:

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

# disodium disulphite:

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

# STOT - repeated exposure

# Components:

### Citric acid monohydrate:

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



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#### disodium disulphite:

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

## **Aspiration toxicity**

# **Components:**

Citric acid monohydrate:

no data available

#### disodium disulphite:

no data available

#### **SECTION 12. ECOLOGICAL INFORMATION**

## **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.



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Other organisms relevant to

the environment

sodium dodecyl sulphate:

: no data available

Toxicity to fish : LC0 (Leuciscus idus (Golden orfe)): 26 mg/l

LC50 (Lepomis macrochirus (Bluegill sunfish)): 4.5 mg/l

Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): 3.6 mg/l

Exposure time: 96 h

Toxicity to daphnia and other

aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 6 mg/l

Exposure time: 48 h

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 0.46 mg/l

Exposure time: 0.5 h

**Ecotoxicology Assessment** 

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

Other organisms relevant to

the environment

Citric acid monohydrate:

: no data available

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** 

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

disodium disulphite :

: no data available

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): > 150 mg/l

Exposure time: 96 h

LC50 (Oncorhynchus mykiss (rainbow trout)): < 220 mg/l

Exposure time: 96 h

Toxicity to daphnia and other

aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 89 mg/l

Exposure time: 24 h

Toxicity to algae : IC50 (Desmodesmus subspicatus (green algae)): 48 mg/l

Exposure time: 72 h

Toxicity to bacteria : EC50 (Pseudomonas putida): 56 mg/l

Exposure time: 17 h

**Ecotoxicology Assessment** 

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



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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

sodium dodecyl sulphate:

Biodegradability : Biodegradation: 90 %

Exposure time: 28 d

Method: OECD Test Guideline 301

Remarks: Readily biodegradable, according to appropriate

OECD test.

Citric acid monohydrate:

Biodegradability : Remarks: Expected to be ultimately biodegradable

**Bioaccumulative potential** 

**Components:** 

ethane-1,2-diol:

Partition coefficient: n-: log Pow: -1.36

octanol/water

sodium dodecyl sulphate:

Bioaccumulation : Species: Cyprinus carpio (Carp)

Exposure time: 3 d

Bioconcentration factor (BCF): 3.9 - 5.3

Partition coefficient: n-

octanol/water

octanol/water

: log Pow: 1.6

Citric acid monohydrate:

Partition coefficient: n-

: log Pow: 1.72

disodium disulphite:

Partition coefficient: n-

: log Pow: -3.7 (25 °C)

octanol/water

Mobility in soil

no data available

Other adverse effects

no data available

**Product:** 

Remarks

40 CFR Protection of Environment: Part 82 Protection of Regulation

> Stratospheric Ozone - CAA Section 602 Class I Substances 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).

Components:

sodium dodecyl sulphate:



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Additional ecological

information

: no data available

#### **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.

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**

#### International regulation

IATA-DGR

Not regulated as a dangerous good

**IMDG-Code** 

Not regulated as a dangerous good

## 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

Not regulated as a dangerous good

Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR,

IMDG-Code, ICAO/IATA-DGR

# **SECTION 15. REGULATORY INFORMATION**

OSHA Hazards : Harmful by ingestion., Toxic by skin absorption, Moderate skin

irritant, Severe eye irritant, Moderate respiratory irritant

WHMIS Classification : D1B: Toxic Material Causing Immediate and Serious Toxic

**Effects** 

Toxic Material Causing Other Toxic Effects

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



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## **CERCLA Reportable Quantity**

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

SARA 302 : 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 7 %

#### 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 7 %

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 7 %

#### **Clean Water Act**

This product does not contain any Hazardous Substances listed under the U.S. CleanWater Act, Section 311, Table 116.4A.

This product does not contain any Hazardous Chemicals listed under the U.S. CleanWater Act, Section 311, Table 117.3.

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

# **US State Regulations**

#### **Massachusetts Right To Know**

ethane-1,2-diol	107-21-1	5 - 10 %
disodium disulphite	7681-57-4	1 - 5 %

## Pennsylvania Right To Know

water	7732-18-5	70 - 90 %
ethane-1,2-diol	107-21-1	5 - 10 %
disodium disulphite	7681-57-4	1 - 5 %

## **New Jersey Right To Know**

water	7732-18-5	70 - 90 %
ethane-1,2-diol	107-21-1	5 - 10 %
sodium dodecyl sulphate	151-21-3	1 - 5 %
Citric acid monohydrate	5949-29-1	1 - 5 %
disodium disulphite	7681-57-4	1 - 5 %

California Prop 65 : This product does not contain any chemicals known to State of

California to cause cancer, birth defects, or any other

reproductive harm.

## Inventories

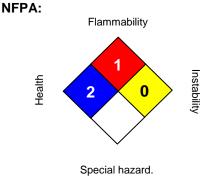


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AICS (Australia), DSL (Canada), IECSC (China), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

#### **SECTION 16. OTHER INFORMATION**

#### **Further information**



## HMIS III:

HEALTH	2
FLAMMABILITY	1
PHYSICAL HAZARD	0

0 = not significant, 1 = Slight,

2 = Moderate, 3 = High 4 = Extreme, \* = Chronic

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.