

Version 1.2 Revision Date 11-18-2013 Print Date 02-21-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : CONFIRM CD79a RabbitMono

Mat.-No./ Genisys-No. : 05640296001

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

Emergency Overview

Physical state	liquid
Colour	yellow
Odour	none

GHS Classification

Not a hazardous substance or mixture.

GHS Label element

Not a hazardous substance or mixture.

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



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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

No hazardous ingredients

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 on skin, rinse well with water.

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.

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 : High volume water jet



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media

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.

: 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

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

Contains no substances with occupational exposure limit values.



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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

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 : Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : liquid
Colour : yellow
Odour : none
pH : 7.3

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

Density : 1.02 g/cm3

Solubility(ies)

Water solubility : completely miscible

Auto-ignition temperature : no data available

Thermal decomposition : Hazardous decomposition products formed under fire

conditions.



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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

: Reacts with the following substances:

Oxidizing agents

No decomposition if stored and applied as directed.

Conditions to avoid : Exposure to light.

Incompatible materials : Oxidizing agents

Hazardous decomposition

products

: Hazardous decomposition products formed under fire

conditions.

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 : 30.24 mg/l

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

Skin corrosion/irritation

Product:

Remarks: May cause skin irritation and/or dermatitis.

Serious eye damage/eye irritation

Product:

Remarks: Vapours may cause irritation to the eyes, respiratory system and the skin.

Respiratory or skin sensitisation

Product:

Remarks: Causes sensitisation.



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Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT - single exposure

no data available

STOT - repeated exposure

no data available

Aspiration toxicity

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

Persistence and degradability

no data available

Bioaccumulative potential

no data available

Mobility in soil

no data available

Other adverse effects

no data available

Product:

Remarks

Regulation 40 CFR Protection of Environment; Part 82 Protection of

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).

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods



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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.

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 : No OSHA Hazards

WHMIS Classification : Not Rated

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

CERCLA Reportable Quantity

Components	CAS-No.	Component RQ	Calculated product RQ
		(lbs)	(lbs)
Sodium hydroxide	1310-73-2	1000	

SARA 302: No chemicals in this material are subject to the

reporting requirements of SARA Title III, Section 302.



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SARA 313 : SARA 313: This material does not contain any chemical

components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA

Title III, Section 313.

Clean Air Act

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 12 (40 CFR 61).

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).

This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

Clean Water Act

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

sodium hydroxide 1310-73-2 0.0657 %

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

sodium hydroxide

1310-73-2 0.0657 %

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

No components are subject to the Massachusetts Right to Know Act.

Pennsylvania Right To Know

water 7732-18-5 90 - 100 % sodium hydroxide 1310-73-2 0 - 0.1 %

New Jersey Right To Know

 water
 7732-18-5
 90 - 100 %

 Caseins
 9000-71-9
 1 - 5 %

 Dipotassium hydrogen phosphate 3 hydrate
 16788-57-1
 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

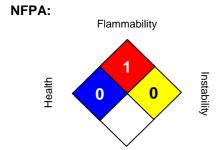
AICS (Australia), DSL (Canada), IECSC (China), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIOC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16. OTHER INFORMATION



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Further information



Special hazard.

HMIS III:

HEALTH	0
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.