

A1CD2

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : A1CD2
Mat.-No./ Genisys-No. : 04528182190

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 : Danger

Hazard statements : H315 Causes skin irritation.
H317 May cause an allergic skin reaction.
H318 Causes serious eye damage.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P264 Wash skin thoroughly after handling.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves/ eye protection/ face protection.
P285 In case of inadequate ventilation wear respiratory protection.
Response:
P302 + P352 IF ON SKIN: Wash with plenty of soap and water.
P304 + P341 IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for

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breathing.

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

P310 Immediately call a POISON CENTER or doctor/ physician.
P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.

P362 Take off contaminated clothing and wash before reuse.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**R1 (B / C)****GHS Classification**

Skin irritation, Category 2

H315: Causes skin irritation.

Serious eye damage, Category 1

H318: Causes serious eye damage.

Respiratory sensitisation, Category 1

H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin sensitisation, Category 1

H317: May cause an allergic skin reaction.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
tetradonium bromide	1119-97-7	>= 1 - < 5
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	>= 1 - < 5
Brij 35	9002-92-0	>= 1 - < 5
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3	>= 0.1 - < 1

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.
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 skin irritation persists, call a physician.
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

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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 : Clean mouth with water and drink afterwards plenty of water.
 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.
 Rinse mouth with water.
- 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 : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
- 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.
- 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.
 Refer to protective measures listed in sections 7 and 8.
- 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.

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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 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.
To prevent leaks or spillages from spreading, provide a suitable liquid retention system.

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.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**R1 (B / C)****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

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.
When using do not smoke.
Wash hands before breaks and at the end of workday.

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SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES**R1 (B / C)**

Appearance	: liquid
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
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.
Conditions to avoid	: No data available
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

SECTION 11. TOXICOLOGICAL INFORMATION**R1 (B / C)****Information on likely routes of exposure****Acute toxicity**

Not classified based on available information.

Product:

Acute oral toxicity	: Acute toxicity estimate : > 5,000 mg/kg Method: Calculation method
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Acute inhalation toxicity : Acute toxicity estimate : > 10 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: Calculation method

Components:**tetradonium bromide:**

Acute oral toxicity : LD50 Oral (Rat): 3,900 mg/kg

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Acute oral toxicity : LD50 Oral (Rat): > 2,000 mg/kg
Test substance: anhydrous substance

LD50 Oral (Rabbit): 2,300 mg/kg

Acute inhalation toxicity : LC50 (Rat): 1 - 5 mg/l
Exposure time: 6 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Test substance: anhydrous substance

Acute toxicity estimate : 1.5 mg/l

Test atmosphere: dust/mist

Method: Expert judgement

Brij 35:

Acute oral toxicity : LD50 Oral (Rat): 1,000 mg/kg

Skin corrosion/irritation

Causes skin irritation.

Product:

Remarks: May cause skin irritation in susceptible persons.

Components:**tetradonium bromide:**

Result: Causes burns.

Brij 35:

Result: Irritating to skin.

2-methyl-2H-isothiazol-3-one hydrochloride:

Result: Causes burns.

Serious eye damage/eye irritation

Causes serious eye damage.

Product:

Remarks: May cause irreversible eye damage.

Components:**Brij 35:**

Result: Risk of serious damage to eyes.

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Respiratory or skin sensitisation

Skin sensitisation: May cause an allergic skin reaction.

Respiratory sensitisation: May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Components:**2-methyl-2H-isothiazol-3-one hydrochloride:**

Assessment: May cause sensitisation by skin contact.

Germ cell mutagenicity

Not classified based on available information.

Components:**Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):**

Genotoxicity in vitro : Test Type: Ames test

Remarks: In vitro tests did not show mutagenic effects

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.

Components:**tetradonium bromide:**

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

Brij 35:

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:**tetradonium bromide:**

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

Brij 35:

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

Aspiration toxicity

Not classified based on available information.

Components:**Brij 35:**

No data available

Further information**Components:****tetradonium bromide:**

Remarks: Other dangerous properties can not be excluded.

SECTION 12. ECOLOGICAL INFORMATION***R1 (B / C)*****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:**tetradonium bromide:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Toxicity to fish : LC50 (Poecilia reticulata (guppy)): ca. 320 mg/l
Exposure time: 96 h
Test substance: anhydrous substance

LC50 (Leuciscus idus (Golden orfe)): > 500 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia (water flea)): > 100 mg/l
Exposure time: 24 h

Toxicity to algae : ErC50 (Desmodesmus subspicatus (green algae)): > 100 mg/l
Exposure time: 72 h

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Toxicity to bacteria : EC50 (Pseudomonas putida): 56 mg/l
Exposure time: 8 h
Test substance: anhydrous substance

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

Brij 35:

Toxicity to daphnia and other aquatic invertebrates : LC50 (Daphnia magna (Water flea)): 6.46 mg/l
Exposure time: 48 h

Ecotoxicology Assessment
Acute aquatic toxicity : Toxic to aquatic life.

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

2-methyl-2H-isothiazol-3-one hydrochloride:

Ecotoxicology Assessment
Acute aquatic toxicity : This product has no known ecotoxicological effects.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

Persistence and degradability
Components:
Edetic acid disodium salt dihydrate (EDTA-2Na-2H₂O):

Biodegradability : Biodegradation: 3 %
Testing period: 30 d
Method: Directive 67/548/EEC Annex V, C.4.C.
Remarks: According to the results of tests of biodegradability this product is not readily biodegradable.

Biochemical Oxygen Demand (BOD) : 10 mg/g
Incubation time: 5 d

Bioaccumulative potential
Components:
tetradonium bromide:

Bioaccumulation : Remarks: Bioaccumulation is unlikely.

Partition coefficient: n-octanol/water : log Pow: 2.2

Brij 35:

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Bioaccumulation : Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): 220
Exposure time: 72 h

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).

Components:**Brij 35:**

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

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SECTION 15. REGULATORY INFORMATION**R1 (B / C)****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Sodium phosphate dibasic dihydrate	10028-24-7	5000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

This material does not contain any components with a section 304 EHS RQ.

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

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 SOCM 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 phosphate dibasic dihydrate	10028-24-7	1 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

Sodium phosphate dibasic dihydrate	10028-24-7	1 %
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This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

Massachusetts Right To Know

Sodium phosphate dibasic dihydrate	10028-24-7	1 - 5 %
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Pennsylvania Right To Know

water	7732-18-5	90 - 100 %
tetradonium bromide	1119-97-7	1 - 5 %
Sodium phosphate dibasic dihydrate	10028-24-7	1 - 5 %

New Jersey Right To Know

water	7732-18-5	90 - 100 %
tetradonium bromide	1119-97-7	1 - 5 %
Edetic acid disodium salt dihydrate (EDTA-2Na-2H ₂ O)	6381-92-6	1 - 5 %

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Brij 35

9002-92-0

1 - 5 %

Sodium phosphate dibasic dihydrate

10028-24-7

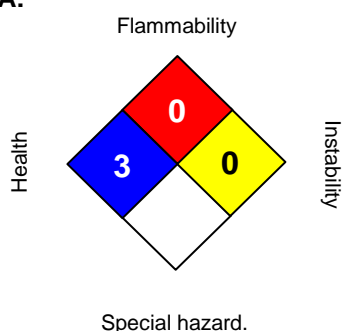
1 - 5 %

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.

SECTION 16. OTHER INFORMATION**Further information****R1 (B / C)**

NFPA:

**HMIS III:**

HEALTH	3
FLAMMABILITY	0
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.