

**Calibrator for automated systems**

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

**SECTION 1. IDENTIFICATION**

Product name : Calibrator for automated systems

Mat.-No./ Genisys-No. : 10759350360

Chemical nature : Handle as potentially infectious.

**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**

Not a hazardous substance or mixture.

**Other hazards**

None known.

**SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS*****Cfas USA F1-oSw*****GHS Classification**

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

**Hazardous components**

Chemical Name	CAS-No.	Concentration (%)
pentaerythritol	115-77-5	>= 10 - < 20
tetramethylammonium chloride	75-57-0	>= 0.1 - < 1

**SECTION 4. FIRST AID MEASURES**

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General advice	: 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.
In case of eye contact	: Immediately flush eye(s) with plenty of water. Remove contact lenses. Protect unharmed eye. 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. 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.

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**SECTION 5. FIREFIGHTING MEASURES**

Suitable extinguishing media	: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
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 firefighting if necessary.

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**SECTION 6. ACCIDENTAL RELEASE MEASURES**

Personal precautions, protective equipment and emergency procedures	: Avoid dust formation.
Environmental precautions	: Local authorities should be advised if significant spillages cannot be contained.
Methods and materials for containment and cleaning up	: Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

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### SECTION 7. HANDLING AND STORAGE

- Advice on safe handling : For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.
- Conditions for safe storage : Electrical installations / working materials must comply with the technological safety standards.
- Materials to avoid : No materials to be especially mentioned.

### SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

#### *Cfas USA F1-oSw*

##### Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
pentaerythritol	115-77-5	TWA	10 mg/m <sup>3</sup>	ACGIH
		TWA (Respirable)	5 mg/m <sup>3</sup>	NIOSH REL
		TWA (total)	10 mg/m <sup>3</sup>	NIOSH REL
		TWA (total dust)	15 mg/m <sup>3</sup>	OSHA Z-1
		TWA (respirable fraction)	5 mg/m <sup>3</sup>	OSHA Z-1
		TWA (Total dust)	10 mg/m <sup>3</sup>	OSHA P0
		TWA (respirable dust fraction)	5 mg/m <sup>3</sup>	OSHA P0

##### Personal protective equipment

- Respiratory protection : No personal respiratory protective equipment normally required.

##### 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 : Safety glasses

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Skin and body protection	: Protective suit
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.

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**SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES*****Cfas USA F1-oSw***

Appearance	: (lyophilised)
Colour	: light yellow
Odour	: characteristic
pH	: 6.9, Concentration: 100 g/l
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Flammability (solid, gas)	: Sustains combustion
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Solubility(ies) Water solubility	: soluble
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

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**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	: Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	: No data available
Incompatible materials	: No data available
Hazardous decomposition products	: No data available

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**SECTION 11. TOXICOLOGICAL INFORMATION*****Cfas USA F1-oSw*****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

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

**Components:****pentaerythritol:**

Acute oral toxicity : LD50 Oral (Mouse): 18,500 mg/kg  
LD50 Oral (Rat): 18,500 mg/kg  
LD50 Oral (Rabbit): 18,500 mg/kg

Acute inhalation toxicity : Acute toxicity estimate : > 30 mg/l  
Method: Expert judgement

Acute dermal toxicity : LD50 (Rabbit): > 10,000 mg/kg

**tetramethylammonium chloride:**

Acute oral toxicity : LD50 Oral (Rat): 50 mg/kg  
Symptoms: Spasm, Dizziness

LD50 Oral (Rat): 80 mg/kg  
Symptoms: Spasm

Acute dermal toxicity : LD50 Dermal (Rat): 537 mg/kg

**Skin corrosion/irritation**

Not classified based on available information.

**Components:****pentaerythritol:**

Remarks: This information is not available.

**Serious eye damage/eye irritation**

Not classified based on available information.

**Components:****pentaerythritol:**

Remarks: This information is not available.

**Respiratory or skin sensitisation**

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

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**Germ cell mutagenicity**

Not classified based on available information.

**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:****tetramethylammonium chloride:**

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

**STOT - repeated exposure**

Not classified based on available information.

**Aspiration toxicity**

Not classified based on available information.

**Components:****tetramethylammonium chloride:**

No data available

**Further information****Components:****tetramethylammonium chloride:**

Remarks: Other dangerous properties can not be excluded.

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**SECTION 12. ECOLOGICAL INFORMATION*****Cfas USA F1-oSw***

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**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

**Components:****pentaerythritol:**Toxicity to fish : LC50: > 100 mg/l  
Exposure time: 96 hToxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 38,900 mg/l  
Exposure time: 24 h

Toxicity to fish (Chronic toxicity) : &gt; 1 mg/l

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

**tetramethylammonium chloride:**Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 462 mg/l  
Exposure time: 96 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:****pentaerythritol:**Biodegradability : Biodegradation: 99 %  
Exposure time: 28 d  
Method: OECD Test Guideline 301**tetramethylammonium chloride:**

Biodegradability : Remarks: Expected to be biodegradable

**Bioaccumulative potential**

No data available

**Mobility in soil**

No data available

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**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:****pentaerythritol:**

Additional ecological information

: No data available

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**SECTION 13. DISPOSAL CONSIDERATIONS****Disposal methods**

Waste from residues

: Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).  
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging

: Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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**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*****Cfas USA F1-oSw*****EPCRA - Emergency Planning and Community Right-to-Know Act****CERCLA Reportable Quantity**



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Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Copper(II)sufate-pentahydrate	7758-99-8	10	*

\*: 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** : 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).

The following chemical(s) are listed under the U.S. Clean Air Act Section 111 SOCM

Intermediate or Final VOC's (40 CFR 60.489):

pentaerythritol	115-77-5	16.267 %
Sodium acetate trihydrate	6131-90-4	1.94 %

**Clean Water Act**

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

iron (II) sulfate (1:1) heptahydrate	7782-63-0	0.0064 %
Copper(II)sufate-pentahydrate	7758-99-8	0.0024 %

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

iron (II) sulfate (1:1) heptahydrate	7782-63-0	0.0064 %
Copper(II)sufate-pentahydrate	7758-99-8	0.0024 %

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

**Massachusetts Right To Know**

pentaerythritol	115-77-5	10 - 20 %
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**Pennsylvania Right To Know**

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	50 - 70 %
pentaerythritol	115-77-5	10 - 20 %
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	5 - 10 %
Albumins, blood serum	9048-46-8	5 - 10 %
non hazardous compounds	Not Assigned	5 - 10 %

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### New Jersey Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	50 - 70 %
pentaerythritol	115-77-5	10 - 20 %
4-(2-hydroxyethyl)piperazin-1- ylethanesulphonic acid	7365-45-9	5 - 10 %
Albumins, blood serum	9048-46-8	5 - 10 %
non hazardous compounds	Not Assigned	5 - 10 %

### California Prop 65

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

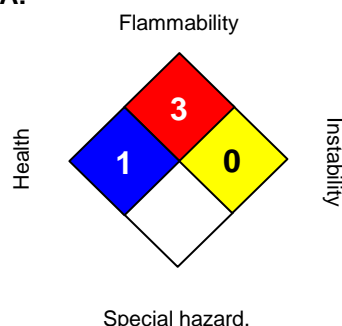
lithium carbonate	554-13-2
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## SECTION 16. OTHER INFORMATION

### Further information

#### Cfas USA F1-oSw

##### NFPA:



##### HMIS III:

<b>HEALTH</b>	<b>1</b>
<b>FLAMMABILITY</b>	<b>3</b>
<b>PHYSICAL HAZARD</b>	<b>0</b>

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.