

Calibrator for automated systemsVersion
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015**SECTION 1. IDENTIFICATION**

Product name : Calibrator for automated systems

Product code : 10759350190

Manufacturer or supplier's detailsCompany name of supplier : Roche Diagnostics
-Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone

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 in accordance with 29 CFR 1910.1200**

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 elements

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 ingredients

Chemical name	CAS-No.	Concentration (% w/w)
pentaerythritol	115-77-5	≥ 10 - < 20
Methanaminium, N,N,N-trimethyl-, chloride (1:1)	75-57-0	≥ 0.1 - < 1

SECTION 4. FIRST AID MEASURES

Calibrator for automated systemsVersion
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

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.

SECTION 5. FIRE-FIGHTING MEASURES

Suitable extinguishing media	:	Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Specific hazards during fire fighting	:	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 fire-fighters	:	Wear self-contained breathing apparatus for firefighting if necessary.

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.

Calibrator for automated systems

Version
1.3

Revision Date:
06-07-2017

Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

SECTION 7. HANDLING AND STORAGE

- Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.
- 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.
- Technical measures/Precautions : See label, package insert or internal guidelines
- Materials to avoid : No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Cfas USA F1-oSw

Ingredients with workplace control parameters

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

Hazardous components without workplace control parameters

Ingredients	CAS-No.
Methanaminium, N,N,N-trimethyl-, chloride (1:1)	75-57-0

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Protective gloves

Calibrator for automated systemsVersion
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

Remarks	: Wear appropriate protective gloves to prevent skin contact. Replace torn or punctured gloves promptly.
Eye protection	: Safety glasses
Skin and body protection	: Protective suit
Hygiene measures	: Handle in accordance with good industrial hygiene and safety practice.

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

Appearance	: solid, (lyophilized)
Color	: light yellow
Odor	: characteristic
Odor Threshold	: Not applicable
pH	: 6.9 Concentration: 100 g/l (as aqueous solution)
Melting point/range	: No data available
Boiling point/boiling range	: No data available
Flash point	: does not flash
Evaporation rate	: No data available
Flammability (solid, gas)	: Sustains combustion
Flammability (liquids)	: Sustains combustion
Self-ignition	: No data available
Autoignition temperature	: No data available
Upper explosion limit	: No data available
Lower explosion limit	: No data available
Vapor pressure	: No data available
Relative vapor density	: Not applicable
Relative density	: No data available
Solubility(ies)	

Calibrator for automated systemsVersion
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

Water solubility	:	soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	Not applicable
Viscosity, kinematic	:	Not applicable
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	:	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

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

Not classified based on available information.

Ingredients:**pentaerythritol:**

Acute oral toxicity	:	LD50 Oral (Mouse): 25,500 mg/kg LD50 Oral (Rat): > 5,100 mg/kg Method: OECD Test Guideline 401
Acute inhalation toxicity	:	LC0 (Rat): 11 mg/l Exposure time: 6 h Test atmosphere: dust/mist
Acute dermal toxicity	:	LD50 (Rabbit): > 10,000 mg/kg Method: OECD Test Guideline 402

Methanaminium, N,N,N-trimethyl-, chloride (1:1):

Calibrator for automated systemsVersion
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

Acute oral toxicity : LD50 Oral (Rat): 47 mg/kg
Method: OECD Test Guideline 401
GLP: no

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

LD50 Dermal (Rabbit): > 200 - < 500 mg/kg
Method: OECD Test Guideline 402
GLP: yes

Skin corrosion/irritation

Not classified based on available information.

Ingredients:**pentaerythritol:**

Species: Rabbit
Result: No skin irritation

Serious eye damage/eye irritation

Not classified based on available information.

Ingredients:**pentaerythritol:**

Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Ingredients:**pentaerythritol:**

Species: Mouse
Method: OECD Test Guideline 429
Result: Did not cause sensitization on laboratory animals.

Germ cell mutagenicity

Not classified based on available information.

Ingredients:**pentaerythritol:**

Genotoxicity in vitro : Test Type: Ames test
Species: Salmonella typhimurium
Method: OECD Test Guideline 471
Result: negative

: Species: Chinese hamster cells
Concentration: 1,4

Calibrator for automated systemsVersion
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015Method: OECD Test Guideline 473
Result: negative: Species: mouse lymphoma cells
Method: OECD Test Guideline 476
Result: negative: Test Type: Ames test
Species: Escherichia coli
Method: OECD Test Guideline 471
Result: negative**Carcinogenicity**

Not classified based on available information.

Ingredients:**pentaerythritol:**Species: Rat
Application Route: Oral
Group: yes
NOAEL: 1,000 mg/kg bw/day
Result: negative**IARC**

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No ingredient 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 ingredient 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.

Ingredients:**Methanaminium, N,N,N-trimethyl-, chloride (1:1):**

Assessment: Causes damage to organs.

STOT-repeated exposure

Not classified based on available information.

Repeated dose toxicity**Ingredients:****pentaerythritol:**

Species: Rat

Calibrator for automated systems

Version
1.3

Revision Date:
06-07-2017

Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

NOAEL: 100 mg/kg
Application Route: Oral
Group: yes
Symptoms: Diarrhea
Remarks: No significant adverse effects were reported

Methanaminium, N,N,N-trimethyl-, chloride (1:1):

Species: Rat
NOAEL: 5 mg/kg
Application Route: Oral
Method: OECD Test Guideline 421
GLP: yes

Aspiration toxicity

Not classified based on available information.

Further information**Ingredients:****Methanaminium, N,N,N-trimethyl-, chloride (1:1):**

Remarks: Other dangerous properties can not be excluded.

SECTION 12. ECOLOGICAL INFORMATION***Cfas USA F1-oSw*****Ecotoxicity****Ingredients:****pentaerythritol:**

Toxicity to fish : LC50 (Leuciscus idus (Golden orfe)): > 5,000 mg/l
Exposure time: 48 h

LC50 (Oryzias latipes (Orange-red killifish)): > 100 mg/l
Exposure time: 96 h

NOEC (Oncorhynchus mykiss (rainbow trout)): 56 mg/l
Exposure time: 96 h

LC50 (Brachydanio rerio (zebrafish)): > 1,000 mg/l
Exposure time: 96 h
Method: OECD Test Guideline 203

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 38,900 mg/l
Exposure time: 24 h

NOEC (Daphnia magna (Water flea)): 1,000 mg/l
Exposure time: 24 h

EC50 (Daphnia magna (Water flea)): 3,560 mg/l
Exposure time: 48 h

Calibrator for automated systems

Version
1.3

Revision Date:
06-07-2017

Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

Method: OECD Test Guideline 202

Toxicity to algae : EbC50 (Desmodesmus subspicatus (Scenedesmus subspicatus)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

ErC50 (Desmodesmus subspicatus (Scenedesmus subspicatus)): > 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

NOEC (Desmodesmus subspicatus (Scenedesmus subspicatus)): 100 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

EC50 (Scenedesmus quadricauda (Green algae)): > 1,000 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201

Toxicity to microorganisms : (Pseudomonas putida): > 500 mg/l
Exposure time: 0.5 h

Methanaminium, N,N,N-trimethyl-, chloride (1:1):

Toxicity to fish : LC50 (Pimephales promelas (fathead minnow)): 462 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 0.16 mg/l
Exposure time: 11 d
GLP: yes

NOEC (Daphnia magna (Water flea)): 0.03 mg/l
Exposure time: 11 d
GLP: yes

LC50 (Daphnia magna (Water flea)): 1.86 mg/l
Exposure time: 48 h
GLP: yes

Toxicity to algae : ErC50 (Pseudokirchneriella subcapitata (green algae)): 115 mg/l
Exposure time: 72 h
Method: OECD Test Guideline 201
GLP: yes

Ecotoxicology Assessment

Chronic aquatic toxicity : Toxic to aquatic life with long lasting effects.

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

Other organisms relevant to the environment : No data available

Calibrator for automated systemsVersion
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015**Persistence and degradability****Ingredients:****pentaerythritol:**

Biodegradability : Result: Inherently biodegradable.
Biodegradation: 99 %
Exposure time: 28 d
Method: OECD Test Guideline 301

Methanaminium, N,N,N-trimethyl-, chloride (1:1):

Biodegradability : Remarks: Expected to be biodegradable

Bioaccumulative potential**Ingredients:****pentaerythritol:**

Partition coefficient: n- : log Pow: -1.7 (22 °C)
octanol/water

Methanaminium, N,N,N-trimethyl-, chloride (1:1):

Partition coefficient: n- : Remarks: No data available
octanol/water

Mobility in soil

No data available

Other adverse effects

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.

SECTION 14. TRANSPORT INFORMATION**International Regulations****UNRTDG**

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

Calibrator for automated systems
Version
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015**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

Domestic regulation**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**Cfas USA F1-oSw****EPCRA - Emergency Planning and Community Right-to-Know****CERCLA Reportable Quantity**

Ingredients	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Copper(II) sulfate, pentahydrate	7758-99-8	10	*

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 304 Extremely Hazardous Substances Reportable Quantity

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

*: Calculated RQ exceeds reasonably attainable upper limit.

SARA 302 Extremely Hazardous Substances Threshold Planning Quantity

This material does not contain any components with a section 302 EHS TPQ.

SARA 311/312 Hazards : No SARA Hazards

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 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).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (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 I 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 heptahydrate	7782-63-0	0.0064 %
-------------------------------	-----------	----------

Calibrator for automated systems
Version
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

Copper(II) sulfate, 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 heptahydrate	7782-63-0	0.0064 %
Copper(II) sulfate, pentahydrate	7758-99-8	0.0024 %

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

pentaerythritol	115-77-5
-----------------	----------

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned
pentaerythritol	115-77-5
1-Piperazineethanesulfonic acid, 4-(2-hydroxyethyl)-	7365-45-9
Albumins, blood serum	9048-46-8
Whole Chicken egg, lyo.	Not Assigned

California Prop. 65

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

Carbonic acid, lithium salt (1:2)	554-13-2
-----------------------------------	----------

The ingredients of this product are reported in the following inventories:

DSL : This product contains the following components that are not on the Canadian DSL nor NDSL.

Human serum /-plasma / -hemolysate, lyophilized

Whole Chicken egg, lyo.

Dextrose

Lipoproteins from blood plasma

Pyridoxal 5-Phosphate, Monohydrate

Creatine monohydrate

Ficoll 70

Creatine kinase

Alanine aminotransferase

Acid phosphatase

Alkaline phosphatase

Aspartate aminotransferase

.alpha.-Amylase

Calibrator for automated systems
Version
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

Fructose biphosphate aldolase

Triacylglycerol lipase

.gamma.-Glutamyltransferase

Dehydrogenase, glutamate

Bovine Serum Albumin

AICS	: Not in compliance with the inventory
NZIoC	: On the inventory, or in compliance with the inventory
ENCS	: Not in compliance with the inventory
ISHL	: Not in compliance with the inventory
KECI	: Not in compliance with the inventory
PICCS	: Not in compliance with the inventory
IECSC	: Not in compliance with the inventory
TCSI	: Not in compliance with the inventory
TSCA	: Not On TSCA Inventory

TSCA list

No substances are subject to a Significant New Use Rule.

No substances are subject to TSCA 12(b) export notification requirements.

Cfas USA F1-oSw**GHS label elements**

Not a hazardous substance or mixture.

SECTION 16. OTHER INFORMATION
Full text of other abbreviations

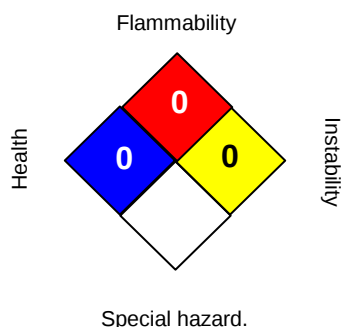
AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; ELx - Loading rate associated with x% response; EmS - Emergency Schedule; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; IARC -

Calibrator for automated systems

Version
1.3Revision Date:
06-07-2017Date of last issue: 06-02-2016
Date of first issue: 11-05-2015

International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International Maritime Organization; ISHL - Industrial Safety and Health Law (Japan); ISO - International Organisation for Standardization; KECI - Korea Existing Chemicals Inventory; LC50 - Lethal Concentration to 50 % of a test population; LD50 - Lethal Dose to 50% of a test population (Median Lethal Dose); MARPOL - International Convention for the Prevention of Pollution from Ships; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; NZIoC - New Zealand Inventory of Chemicals; OECD - Organization for Economic Co-operation and Development; OPPTS - Office of Chemical Safety and Pollution Prevention; PBT - Persistent, Bioaccumulative and Toxic substance; PICCS - Philippines Inventory of Chemicals and Chemical Substances; (Q)SAR - (Quantitative) Structure Activity Relationship; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information

Cfas USA F1-oSw**NFPA:****HMIS® IV:**

HEALTH	/	0
FLAMMABILITY		0
PHYSICAL HAZARD		0

HMIS® ratings are based on a 0-4 rating scale, with 0 representing minimal hazards or risks, and 4 representing significant hazards or risks. The "*" represents a chronic hazard, while the "/" represents the absence of a chronic hazard.

Revision Date : 06-07-2017

The information provided in this Material 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.

US / Z8 / 1611