

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : Folate III CalSet
 Mat.-No./ Genisys-No. : 04874072190
 Chemical nature : Handle as potentially infectious.

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics
 -
 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

Cal 1

GHS Classification

Not a hazardous substance or mixture.

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
propane-1,2-diol	57-55-6	>= 1 - < 5

Cal 2

GHS Classification

Not a hazardous substance or mixture.

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
propane-1,2-diol	57-55-6	>= 1 - < 5

SECTION 4. FIRST AID MEASURES

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 : 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.

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.

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 : Avoid dust formation.

Environmental precautions : Prevent product from entering drains.
If the product contaminates rivers and lakes or drains inform

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

respective authorities.

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.

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 : Containers which are opened must be carefully resealed and kept upright to prevent leakage.
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

Cal 1

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
propane-1,2-diol	57-55-6	TWA	10 mg/m3	US WEEL

Cal 2

Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
propane-1,2-diol	57-55-6	TWA	10 mg/m3	US WEEL

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

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

	contact time. The suitability for a specific workplace should be discussed with the producers of the protective gloves.
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

Cal 1

Appearance	: (lyophilised)
Colour	: white
	light yellow
Odour	: none
pH	: 7.0 - 7.2, (25 °C)(as aqueous solution)
Flash point	: does not flash
Flammability (solid, gas)	: Sustains combustion
Solubility(ies)	
Water solubility	: completely soluble
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

Cal 2

Appearance	: (lyophilised)
Colour	: white
	light yellow
Odour	: none
pH	: 7.0 - 7.2, (25 °C)(as aqueous solution)
Flash point	: does not flash
Flammability (solid, gas)	: Sustains combustion
Solubility(ies)	
Water solubility	: completely soluble
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.
------------	---

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Chemical stability	: Stable under normal conditions.
Possibility of hazardous reactions	: No dangerous reaction known under conditions of normal use.
	Stable under recommended storage conditions. No hazards to be specially mentioned.
Conditions to avoid	: Exposure to moisture.
Incompatible materials	: Strong oxidizing agents
Hazardous decomposition products	: No decomposition if stored and applied as directed.

SECTION 11. TOXICOLOGICAL INFORMATION***Cal 1*****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
---------------------	---

Components:**propane-1,2-diol:**

Acute oral toxicity	: LD50 (Rat): 20,000 mg/kg LD50 (Mouse): 20,300 mg/kg
Acute inhalation toxicity	: Acute toxicity estimate : > 30 mg/l Method: Expert judgement
Acute dermal toxicity	: LD50 (Rabbit): 20,800 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**propane-1,2-diol:**

Remarks: This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**propane-1,2-diol:**

Remarks: This information is not available.

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Respiratory or skin sensitisation

Skin sensitisation: Not classified based on available information.

Respiratory sensitisation: Not classified based on available information.

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:

propane-1,2-diol:

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:

propane-1,2-diol:

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

Aspiration toxicity

Not classified based on available information.

Components:

propane-1,2-diol:

No data available

Cal 2

Information on likely routes of exposure

Acute toxicity

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Not classified based on available information.

Product:

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

Components:**propane-1,2-diol:**

Acute oral toxicity : LD50 (Rat): 20,000 mg/kg

LD50 (Mouse): 20,300 mg/kg

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

Acute dermal toxicity : LD50 (Rabbit): 20,800 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**propane-1,2-diol:**

Remarks: This information is not available.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**propane-1,2-diol:**

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.

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.

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

Components:**propane-1,2-diol:**

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:**propane-1,2-diol:**

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

Aspiration toxicity

Not classified based on available information.

Components:**propane-1,2-diol:**

No data available

SECTION 12. ECOLOGICAL INFORMATION***Cal 1*****Ecotoxicity****Components:****propane-1,2-diol:**

Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): > 1,000 mg/l
Exposure time: 24 h

NOEC (Pimephales promelas (fathead minnow)): 52,930 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 34,400 mg/l
Exposure time: 48 h

Toxicity to algae : EC50 (Chlorella pyrenoidosa (aglae)): 92,000 mg/l

Toxicity to fish (Chronic toxicity) : > 1 mg/l

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 26,800 mg/l
Exposure time: 0.5 h

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

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

Other organisms relevant to the environment : No data available

Persistence and degradability

Components:

propane-1,2-diol:

Biodegradability : Zahn-Wellens Test
 Result: Readily biodegradable.
 Biodegradation: 98 %
 Exposure time: 5 d
 Method: OECD Test Guideline 302

Bioaccumulative potential

Components:

propane-1,2-diol:

Partition coefficient: n-octanol/water : log Pow: -0.92

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).

Additional ecological information

: An environmental hazard cannot be excluded in the event of unprofessional handling or disposal.
 Harmful to aquatic life with long lasting effects.

Cal 2

Ecotoxicity

Components:

propane-1,2-diol:

Toxicity to fish : LC0 (Oncorhynchus mykiss (rainbow trout)): > 1,000 mg/l
 Exposure time: 24 h

NOEC (Pimephales promelas (fathead minnow)): 52,930 mg/l
 Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates

: EC50 (Daphnia magna (Water flea)): 34,400 mg/l
 Exposure time: 48 h

Toxicity to algae

: EC50 (Chlorella pyrenoidosa (aglae)): 92,000 mg/l

Toxicity to fish (Chronic

: > 1 mg/l

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

toxicity)

Toxicity to bacteria : EC50 (Photobacterium phosphoreum): 26,800 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 : No data available

Persistence and degradability

Components:

propane-1,2-diol:

Biodegradability : Zahn-Wellens Test
Result: Readily biodegradable.
Biodegradation: 98 %
Exposure time: 5 d
Method: OECD Test Guideline 302

Bioaccumulative potential

Components:

propane-1,2-diol:

Partition coefficient: n-
octanol/water : log Pow: -0.92

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).

Additional ecological
information : An environmental hazard cannot be excluded in the event of
unprofessional handling or disposal.
Harmful to aquatic life with long lasting 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).
The product should not be allowed to enter drains, water
courses or the soil.

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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 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

SECTION 15. REGULATORY INFORMATION

Cal 1

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

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).

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):

propane-1,2-diol	57-55-6	2.9647 %
------------------	---------	----------

Clean Water Act

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

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

Dinatriumhydrogenphos	7782-85-6	0.1789 %
phat-heptahydrat		
reinst/usp		

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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

Massachusetts Right To Know

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	70 - 90 %
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	5 - 10 %
sodium chloride	7647-14-5	5 - 10 %
propane-1,2-diol	57-55-6	1 - 5 %
Dinatriumhydrogenphosphat-heptahydrat reinst/usp	7782-85-6	0.1 - 1 %

New Jersey Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	70 - 90 %
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	5 - 10 %
sodium chloride	7647-14-5	5 - 10 %
propane-1,2-diol	57-55-6	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.

Cal 2

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

CERCLA Reportable Quantity

This material does not contain any components with a CERCLA RQ.

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).

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):

propane-1,2-diol	57-55-6	3.3132 %
------------------	---------	----------

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.

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

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

Massachusetts Right To Know

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

Pennsylvania Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	70 - 90 %
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	5 - 10 %
propane-1,2-diol	57-55-6	1 - 5 %

New Jersey Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	70 - 90 %
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	5 - 10 %
propane-1,2-diol	57-55-6	1 - 5 %

California Prop 65

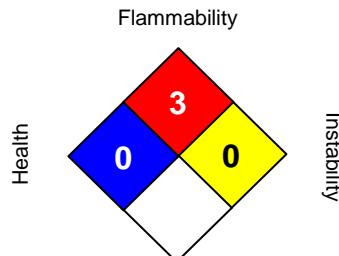
: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION

Further information

Cal 1

NFPA:



HMIS III:

HEALTH	0
FLAMMABILITY	3
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

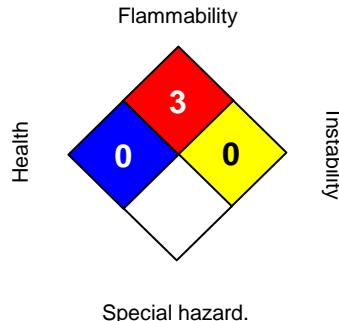
Cal 2

Folate III CalSet

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

NFPA:**HMIS III:**

HEALTH	0
FLAMMABILITY	3
PHYSICAL HAZARD	0

0 = not significant, 1 =Slight,
2 = Moderate, 3 = High
4 = Extreme, * = Chronic

Revision Date

: 09-18-2014

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.