

**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  
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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****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	$\geq 1$ - $< 5$

**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/m <sup>3</sup>	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/m <sup>3</sup>	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.
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**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

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**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

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**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 hNOEC (Pimephales promelas (fathead minnow)): 52,930 mg/l  
Exposure time: 96 hToxicity to daphnia and other : EC50 (Daphnia magna (Water flea)): 34,400 mg/l  
aquatic invertebrates Exposure time: 48 h

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

Toxicity to fish (Chronic : > 1 mg/l  
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.



**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

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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.

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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).  
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 SOCM

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

propane-1,2-diol	57-55-6	2.9647 %
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**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 SOCM I Intermediate or Final VOC's (40 CFR 60.489):

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

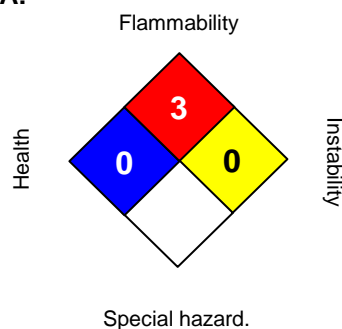
Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	70 - 90 %
4-(2-hydroxyethyl)piperazin-1-ylethanesulphonic acid	7365-45-9	5 - 10 %
propane-1,2-diol	57-55-6	1 - 5 %

**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:**

<b>HEALTH</b>	<b>0</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

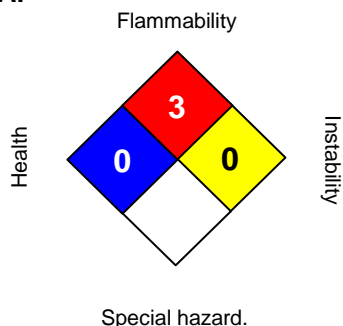
**Cal 2**

**Folate III CalSet**

Version 1.4

Revision Date 09-18-2014

Print Date 12-06-2014

**NFPA:****HMIS III:**

<b>HEALTH</b>	<b>0</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

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.