HCG+ß CalSet

Version 1.3 Revision Date 09-18-2014 Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name	:	HCG+ß CalSet
Mat.-No./ Genisys-No.	:	03302652190
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

Hazard pictograms :

Signal word : Danger

Hazard statements : H317 May cause an allergic skin reaction.
H334 May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statements : **Prevention:**
P261 Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
P272 Contaminated work clothing should not be allowed out of the workplace.
P280 Wear protective gloves.
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 breathing.

P333 + P313 If skin irritation or rash occurs: Get medical advice/ attention.
P342 + P311 If experiencing respiratory symptoms: Call a POISON CENTER or doctor/ physician.
P363 Wash contaminated clothing before reuse.
Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Bottle 1

GHS Classification

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.

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Citric acid monohydrate	5949-29-1	>= 1 - < 5
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3	>= 0.1 - < 1

Bottle 2

GHS Classification

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.

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
Citric acid monohydrate	5949-29-1	>= 1 - < 5
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3	>= 0.1 - < 1

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	:	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.
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	:	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.

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.

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

Bottle 1

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

Bottle 2

Components with workplace control parameters

Contains no substances with occupational exposure limit values.

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

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Bottle 1

Appearance	:	(lyophilised)
Colour	:	white light yellow
Odour	:	none
pH	:	5.4 - 5.8, (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.

Bottle 2

Appearance : (lyophilised)

Colour : white

light yellow

Odour : none

pH : 5.4 - 5.8, (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.

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

Bottle 1

Information on likely routes of exposure

Acute toxicity

Not classified based on available information.

Components:

Citric acid monohydrate:

Acute oral toxicity : LD50 (Mouse): 5,400 mg/kg

LD50 (Rat): > 6,730 mg/kg

LD50 (Rabbit): > 7,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Citric acid monohydrate:
Remarks: Extremely corrosive and destructive to tissue.

2-methyl-2H-isothiazol-3-one hydrochloride:
Result: Causes burns.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Citric acid monohydrate:
Result: Irritating to eyes.
Remarks: May cause irreversible eye damage.

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:

Citric acid monohydrate:
Assessment: Did not cause sensitisation on laboratory animals.

2-methyl-2H-isothiazol-3-one hydrochloride:
Assessment: May cause sensitisation by skin contact.

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:

Citric acid monohydrate:
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:

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

Aspiration toxicity

Not classified based on available information.

Components:

Citric acid monohydrate:
No data available

Bottle 2

Information on likely routes of exposure

Acute toxicity

Not classified based on available information.

Components:

Citric acid monohydrate:

Acute oral toxicity	:	LD50 (Mouse): 5,400 mg/kg
		LD50 (Rat): > 6,730 mg/kg
		LD50 (Rabbit): > 7,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

Citric acid monohydrate:
Remarks: Extremely corrosive and destructive to tissue.

2-methyl-2H-isothiazol-3-one hydrochloride:
Result: Causes burns.

Serious eye damage/eye irritation

Not classified based on available information.

Components:

Citric acid monohydrate:
Result: Irritating to eyes.
Remarks: May cause irreversible eye damage.

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:

Citric acid monohydrate:
Assessment: Did not cause sensitisation on laboratory animals.

2-methyl-2H-isothiazol-3-one hydrochloride:
Assessment: May cause sensitisation by skin contact.

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:

Citric acid monohydrate:
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:

Citric acid monohydrate:
Assessment: The substance or mixture is not classified as specific target organ toxicant,

repeated exposure.

Aspiration toxicity

Not classified based on available information.

Components:

Citric acid monohydrate:
No data available

SECTION 12. ECOLOGICAL INFORMATION

Bottle 1

Ecotoxicity

Components:

Citric acid monohydrate:

Toxicity to fish	:	LC0 (Carassius auratus (goldfish)): 625 mg/l
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 120 mg/l Exposure time: 72 h
Ecotoxicology Assessment 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:

Citric acid monohydrate:

Biodegradability	:	Remarks: Expected to be ultimately biodegradable

Bioaccumulative potential

Components:

Citric acid monohydrate:

Partition coefficient: n-octanol/water	:	log Pow: 1.72

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).

Bottle 2

Ecotoxicity

Components:

Citric acid monohydrate:

Toxicity to fish	:	LC0 (Carassius auratus (goldfish)): 625 mg/l
Toxicity to daphnia and other aquatic invertebrates	:	EC50 (Daphnia magna (Water flea)): 120 mg/l Exposure time: 72 h
Ecotoxicology Assessment 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:

Citric acid monohydrate:

Biodegradability	:	Remarks: Expected to be ultimately biodegradable

Bioaccumulative potential

Components:

Citric acid monohydrate:

Partition coefficient: n-octanol/water	:	log Pow: 1.72

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).

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 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

Bottle 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).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

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.
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 %
Sodium citrate	6132-04-3	10 - 20 %

New Jersey Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	70 - 90 %
Sodium citrate	6132-04-3	10 - 20 %
Citric acid monohydrate	5949-29-1	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.

Bottle 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).
This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCMI Intermediate or Final VOC's (40 CFR 60.489).

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.
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 %
Sodium citrate	6132-04-3	10 - 20 %

New Jersey Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	70 - 90 %
Sodium citrate	6132-04-3	10 - 20 %
Citric acid monohydrate	5949-29-1	1 - 5 %

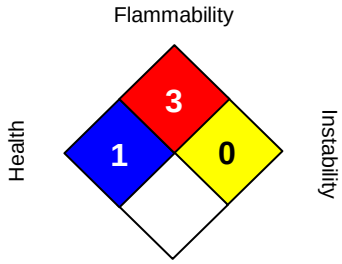
California Prop 65 : This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION

Further information

Bottle 1

NFPA:



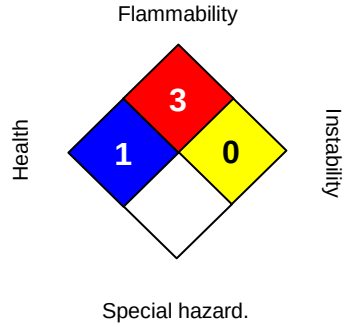
HMIS III:

HEALTH	2
FLAMMABILITY	3
PHYSICAL HAZARD	0

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

Bottle 2

NFPA:



HMIS III:

HEALTH	2
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.