

Insulin Calset

Version 1.3

Revision Date 09-18-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : Insulin Calset

Mat.-No./ Genisys-No. : 12017504122

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

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.

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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

Cal 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.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
hydroxyl-2-pyridone	822-89-9	>= 1 - < 5
2-methyl-2H-isothiazol-3-one hydrochloride	26172-54-3	>= 0.1 - < 1

Cal 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.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
hydroxyl-2-pyridone	822-89-9	>= 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.

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- 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. 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.

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SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Cal 1****Components with workplace control parameters**

Contains no substances with occupational exposure limit values.

Cal 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**Cal 1**

Appearance : solid

Colour : white

Odour : odourless

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

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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.

Cal 2

Appearance	: solid
Colour	: white
Odour	: odourless
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.

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	: No data available
Incompatible materials	: No data available

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Hazardous decomposition products : No hazardous decomposition products are known.

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:**hydroxyl-2-pyridone:**

Acute oral toxicity : LD50 Oral (Rat): 1,765 mg/kg

Acute dermal toxicity : LD50 Dermal (Rat): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**hydroxyl-2-pyridone:**

Remarks: May cause skin irritation in susceptible persons.

2-methyl-2H-isothiazol-3-one hydrochloride:

Result: Causes burns.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**hydroxyl-2-pyridone:**

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:**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.

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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:**hydroxyl-2-pyridone:**

Exposure routes: Inhalation

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:**hydroxyl-2-pyridone:**

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

Aspiration toxicity

Not classified based on available information.

Components:**hydroxyl-2-pyridone:**

No aspiration toxicity classification

Cal 2**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:**hydroxyl-2-pyridone:**

Acute oral toxicity : LD50 Oral (Rat): 1,765 mg/kg

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Acute dermal toxicity : LD50 Dermal (Rat): > 2,000 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:**hydroxyl-2-pyridone:**

Remarks: May cause skin irritation in susceptible persons.

2-methyl-2H-isothiazol-3-one hydrochloride:

Result: Causes burns.

Serious eye damage/eye irritation

Not classified based on available information.

Components:**hydroxyl-2-pyridone:**

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:**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.

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STOT - single exposure

Not classified based on available information.

Components:

hydroxyl-2-pyridone:

Exposure routes: Inhalation

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Not classified based on available information.

Components:

hydroxyl-2-pyridone:

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

Aspiration toxicity

Not classified based on available information.

Components:

hydroxyl-2-pyridone:

No aspiration toxicity classification

SECTION 12. ECOLOGICAL INFORMATION

Cal 1

Ecotoxicity

Product:

Ecotoxicology Assessment

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

Other organisms relevant to the environment : No data available

Components:

hydroxyl-2-pyridone:

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 70.7 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): > 97.8 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 78.6 mg/l
Exposure time: 48 h

Ecotoxicology Assessment Acute aquatic toxicity : Toxic to aquatic life.

Chronic aquatic toxicity : This product has no known ecotoxicological effects.

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

Other organisms relevant to : No data available

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the environment

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:****hydroxyl-2-pyridone:**Biodegradability : Biodegradation: 94 %
Testing period: 29 d
Method: OECD Test Guideline 301
Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

Impact on Sewage Treatment : Do not discharge product into the aquatic environment without pretreatment (biological treatment plant).

Bioaccumulative potential**Components:****hydroxyl-2-pyridone:**

Partition coefficient: n-octanol/water : log Pow: -0.64

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).

Components:**hydroxyl-2-pyridone:**

Additional ecological information : No data available

Cal 2**Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to : No data available

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the environment

Components:**hydroxyl-2-pyridone:**

Toxicity to fish : LC50 (Oncorhynchus mykiss (rainbow trout)): 70.7 mg/l
Exposure time: 96 h

LC50 (Lepomis macrochirus (Bluegill sunfish)): > 97.8 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates : EC50 (Daphnia magna (Water flea)): 78.6 mg/l
Exposure time: 48 h

Ecotoxicology Assessment
Acute aquatic toxicity

: Toxic to aquatic life.

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

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:****hydroxyl-2-pyridone:**

Biodegradability : Biodegradation: 94 %
Testing period: 29 d
Method: OECD Test Guideline 301
Remarks: According to the results of tests of biodegradability this product is considered as being readily biodegradable.

Impact on Sewage Treatment : Do not discharge product into the aquatic environment without pretreatment (biological treatment plant).

Bioaccumulative potential**Components:****hydroxyl-2-pyridone:**

Partition coefficient: n-octanol/water : log Pow: -0.64

Mobility in soil

No data available

Other adverse effects

No data available

Product:

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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:**hydroxyl-2-pyridone:**

Additional ecological information : No data available

SECTION 13. DISPOSAL CONSIDERATIONS**Disposal methods**

Waste from residues : 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***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.

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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 SOCM 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

Albumins, blood serum	9048-46-8	70 - 90 %
sodium chloride	7647-14-5	10 - 20 %

New Jersey Right To Know

Albumins, blood serum	9048-46-8	70 - 90 %
sodium chloride	7647-14-5	10 - 20 %
hydroxyl-2-pyridone	822-89-9	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).

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This product does not contain any chemicals listed under the U.S. Clean Air Act Section 111 SOCOMI 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

Albumins, blood serum	9048-46-8	70 - 90 %
sodium chloride	7647-14-5	10 - 20 %

New Jersey Right To Know

Albumins, blood serum	9048-46-8	70 - 90 %
sodium chloride	7647-14-5	10 - 20 %
hydroxyl-2-pyridone	822-89-9	1 - 5 %

California Prop 65

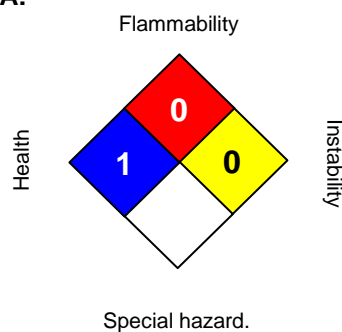
: This product does not contain any chemicals known to State of California to cause cancer, birth defects, or any other reproductive harm.

SECTION 16. OTHER INFORMATION

Further information

Cal 1

NFPA:



HMIS III:

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

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

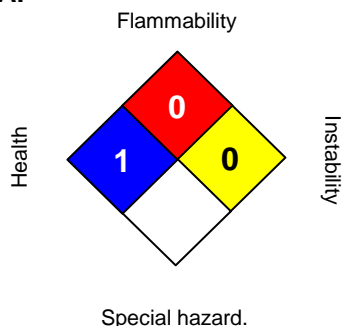
Cal 2

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NFPA:**HMIS III:**

HEALTH	2
FLAMMABILITY	0
PHYSICAL HAZARD	0

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.