

# SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



## Insulin Calset

Version  
1.8

Revision Date:  
16.03.2016

Date of last issue: 16.10.2015  
Date of first issue: 26.06.2013

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

#### 1.1 Product identifier

Commercial Product Name : Insulin Calset  
Mat.-No./ Genisys-No. : 12017504122

#### 1.2 Relevant identified uses of the substance or mixture and uses advised against

Recommended restrictions : For professional users only.  
on use

#### 1.3 Details of the supplier of the safety data sheet

Company : Roche Diagnostics Deutschland GmbH  
-  
Sandhoferstrasse 116  
68305 Mannheim  
Telephone : +496217590  
Telefax : +496217592890  
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629  
E-mail address : mannheim.umweltschutz@roche.com

#### 1.4 Emergency telephone number

Emergency telephone number:  
In case of emergencies: : Central Works Security +49(0)621-759-2203  
Roche Diagnostics GmbH  
  
Centre for detoxification: : Mainz +49(0)6131-19240  
Munich +49(0)89-19240

### SECTION 2: Hazards identification

#### 2.1 Classification of the substance or mixture

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.

#### 2.2 Label elements

##### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

##### Additional Labelling:

EUH210 Safety data sheet available on request.

EUH208 Contains 2-methyl-2H-isothiazol-3-one hydrochloride, 26172-54-3. May produce an allergic reaction.

#### 2.3 Other hazards

See SECTION 3

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### SECTION 3: Composition/information on ingredients

#### Cal 1

##### Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

##### Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture.

##### Hazardous components

Chemical name	CAS-No. EC-No. Registration number	Classification	Concentration (% w/w)
hydroxyl-2-pyridone	822-89-9 212-506-0	Acute Tox. 4; H302 Eye Irrit. 2; H319 STOT SE 3; H335	$\geq 1 - < 3$

For explanation of abbreviations see section 16.

#### Cal 2

##### Classification (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

##### Classification (67/548/EEC, 1999/45/EC)

Not a hazardous substance or mixture.

##### Hazardous components

Chemical name	CAS-No. EC-No. Registration number	Classification	Concentration (% w/w)
hydroxyl-2-pyridone	822-89-9 212-506-0	Acute Tox. 4; H302 Eye Irrit. 2; H319 STOT SE 3; H335	$\geq 1 - < 3$

For explanation of abbreviations see section 16.

### SECTION 4: First aid measures

#### 4.1 Description of first aid measures

- General advice : Move out of dangerous area.  
Show this safety data sheet to the doctor in attendance.  
Do not leave the victim unattended.
- If inhaled : Call a physician or poison control centre immediately.  
Move to fresh air.  
If unconscious place in recovery position and seek medical advice.
- 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.

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Remove contact lenses.  
Protect unharmed eye.  
Keep eye wide open while rinsing.  
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.  
Take victim immediately to hospital.  
Rinse mouth with water.

### 4.2 Most important symptoms and effects, both acute and delayed

Symptoms : No information available.

### 4.3 Indication of any immediate medical attention and special treatment needed

Treatment : The first aid procedure should be established in consultation with the doctor responsible for industrial medicine.

## SECTION 5: Firefighting measures

### 5.1 Extinguishing media

Suitable extinguishing media : Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media : High volume water jet

### 5.2 Special hazards arising from the substance or mixture

Specific hazards during fire-fighting : No information available.

### 5.3 Advice for firefighters

Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.

Further information : Standard procedure for chemical fires.  
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

## SECTION 6: Accidental release measures

### 6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.  
Avoid dust formation.  
Avoid breathing dust.  
Ensure adequate ventilation.

### 6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.

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Prevent further leakage or spillage if safe to do so.  
Local authorities should be advised if significant spillages cannot be contained.

### 6.3 Methods and material for containment and cleaning up

Methods for cleaning up : Keep in suitable, closed containers for disposal.

### 6.4 Reference to other sections

Treat recovered material as described in the section "Disposal considerations".

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## SECTION 7: Handling and storage

### 7.1 Precautions for safe handling

Advice on safe handling : Avoid formation of respirable particles.  
Do not breathe vapours/dust.  
Avoid exposure - obtain special instructions before use.  
Avoid contact with skin and eyes.  
For personal protection see section 8.  
Smoking, eating and drinking should be prohibited in the application area.  
Provide sufficient air exchange and/or exhaust in work rooms.  
Dispose of rinse water in accordance with local and national regulations.  
Persons susceptible to skin sensitisation problems or asthma, allergies, chronic or recurrent respiratory disease should not be employed in any process in which this mixture is being used.

Advice on protection against fire and explosion : Avoid dust formation. Provide appropriate exhaust ventilation at places where dust is formed.

Hygiene measures : Wash hands before breaks and at the end of workday.

### 7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers : Keep container tightly closed in a dry and well-ventilated place. Electrical installations / working materials must comply with the technological safety standards.

Further information on storage conditions : See label, package insert or internal guidelines

Storage class (TRGS 510) : 11, Combustible Solids

Other data : No decomposition if stored and applied as directed.

### 7.3 Specific end use(s)

Specific use(s) : Laboratory chemicals

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## SECTION 8: Exposure controls/personal protection

### 8.1 Control parameters

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### **Cal 1**

Contains no substances with occupational exposure limit values.

### **Cal 2**

Contains no substances with occupational exposure limit values.

## **8.2 Exposure controls**

### **Engineering measures**

No data available

### **Personal protective equipment**

Eye protection : Eye wash bottle with pure water  
Tightly fitting safety goggles

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.

Skin and body protection : Choose body protection according to the amount and concentration of the dangerous substance at the work place.

Respiratory protection : In the case of dust or aerosol formation use respirator with an approved filter.  
Effective dust mask

## **SECTION 9: Physical and chemical properties**

### **9.1 Information on basic physical and chemical properties**

#### **Cal 1**

Appearance : solid

Colour : white

Odour : odourless

Odour Threshold : Not applicable

pH : Not applicable

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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
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Relative self-ignition temperature for solids	:	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.

### Cal 2

Appearance	:	solid
Colour	:	white
Odour	:	odourless
Odour Threshold	:	Not applicable
pH	:	Not applicable
Melting point/range	:	No data available

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Boiling point/boiling range	:	No data available
Flash point	:	does not flash
Evaporation rate	:	No data available
Flammability (solid, gas)	:	Sustains combustion
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapour pressure	:	No data available
Relative vapour density	:	Not applicable
Relative density	:	No data available
Solubility(ies)		
Water solubility	:	soluble
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Relative self-ignition temperature for solids	:	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.

### 9.2 Other information

#### **Cal 1**

No data available

#### **Cal 2**

No data available

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### SECTION 10: Stability and reactivity

#### 10.1 Reactivity

No dangerous reaction known under conditions of normal use.

#### 10.2 Chemical stability

Stable under normal conditions.

#### 10.3 Possibility of hazardous reactions

Hazardous reactions : No dangerous reaction known under conditions of normal use.

No decomposition if stored and applied as directed.

#### 10.4 Conditions to avoid

Conditions to avoid : No data available

#### 10.5 Incompatible materials

Materials to avoid : No data available

#### 10.6 Hazardous decomposition products

No hazardous decomposition products are known.

### SECTION 11: Toxicological information

#### 11.1 Information on toxicological effects

##### **Cal 1**

##### **Acute toxicity**

Not classified based on available information.

##### **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.

##### **Serious eye damage/eye irritation**

Not classified based on available information.

##### **Components:**

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

Result: Irritating to eyes.



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Remarks: May cause irreversible eye damage.

### 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.

#### 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.

## Cal 2

#### Acute toxicity

Not classified based on available information.

#### 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:

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Remarks: May cause skin irritation in susceptible persons.

### 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

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.

#### 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.

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## SECTION 12: Ecological information

### 12.1 Toxicity

#### *Cal 1*

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### 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 : EC50 (Daphnia magna (Water flea)): 78,6 mg/l  
aquatic invertebrates 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  
the environment

### **Cal 2**

#### 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 : EC50 (Daphnia magna (Water flea)): 78,6 mg/l  
aquatic invertebrates 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  
the environment

## **12.2 Persistence and degradability**

### **Cal 1**

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### Components:

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

- Biodegradability : Biodegradation: 94 %  
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).

### **Cal 2**

### Components:

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

- Biodegradability : Biodegradation: 94 %  
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).

## 12.3 Bioaccumulative potential

### **Cal 1**

### Components:

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

- Partition coefficient: n-octanol/water : log Pow: -0,64

### **Cal 2**

### Components:

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

- Partition coefficient: n-octanol/water : log Pow: -0,64

## 12.4 Mobility in soil

### **Cal 1**

No data available

### **Cal 2**

No data available

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### 12.5 Results of PBT and vPvB assessment

#### **Cal 1**

Not relevant

#### **Cal 2**

Not relevant

### 12.6 Other adverse effects

#### **Cal 1**

##### **Components:**

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

Additional ecological information : No data available

#### **Cal 2**

##### **Components:**

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

Additional ecological information : No data available

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## SECTION 13: Disposal considerations

### 13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.  
Send to a licensed waste management company.  
Can be disposed as waste water, when in compliance with local regulations.

Contaminated packaging : Empty remaining contents.  
Dispose of as unused product.  
Empty containers should be taken to an approved waste handling site for recycling or disposal.  
Do not re-use empty containers.

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## SECTION 14: Transport information

### 14.1 UN number

Not regulated as a dangerous good

### 14.2 UN proper shipping name

Not regulated as a dangerous good

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### 14.3 Transport hazard class(es)

Not regulated as a dangerous good

### 14.4 Packing group

Not regulated as a dangerous good

### 14.5 Environmental hazards

Not regulated as a dangerous good

### 14.6 Special precautions for user

Remarks : Not dangerous goods in the meaning of ADR/RID, ADNR, IMDG-Code, ICAO/IATA-DGR

### 14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

Remarks : Not applicable

## SECTION 15: Regulatory information

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

Seveso II - Directive 2003/105/EC amending Council Directive 96/82/EC on the control of major-accident hazards involving dangerous substances  
Not applicable

Seveso III: Directive 2012/18/EU of the European Parliament and of the Council on the control of major-accident hazards involving dangerous substances.  
Not applicable

Water contaminating class : WGK 1 slightly water endangering  
(Germany)

### Cal 1

#### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

#### Additional Labelling:

EUH210 Safety data sheet available on request.

EUH208 Contains 2-methyl-2H-isothiazol-3-one hydrochloride, 26172-54-3. May produce an allergic reaction.

### Cal 2

#### Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

#### Additional Labelling:

EUH210 Safety data sheet available on request.

EUH208 Contains 2-methyl-2H-isothiazol-3-one hydrochloride, 26172-54-3. May produce

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an allergic reaction.

### 15.2 Chemical safety assessment

A Chemical Safety Assessment is not required for this substance when it is used in the specified applications.

## SECTION 16: Other information

### Full text of H-Statements

H302 : Harmful if swallowed.  
H319 : Causes serious eye irritation.

### Full text of other abbreviations

Acute Tox. : Acute toxicity  
Eye Irrit. : Eye irritation  
STOT SE : Specific target organ toxicity - single exposure

ADN - European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways; ADR - European Agreement concerning the International Carriage of Dangerous Goods by Road; AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CLP - Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECHA - European Chemicals Agency; EC-Number - European Community number; ECx - Concentration associated with x% response; 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; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - 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; n.o.s. - Not Otherwise Specified; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; 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; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RID - Regulations concerning the International Carriage of Dangerous Goods by Rail; SADT - Self-Accelerating Decomposition Temperature; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TRGS - Technical Rule for Hazardous Substances; TSCA - Toxic Substances Control Act (United States); UN - United Nations; vPvB - Very Persistent and Very Bioaccumulative

### Further information

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.

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