

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

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

1.1 Product identifier

Commercial Product Name : HE4 CalSet
Mat.-No./ Genisys-No. : 05950945190

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
E-mail address : mannheim.umweltschutz@roche.com
Telephone : +496217590
Telefax : +496217592890
Responsible Department : +49(0)621-759-2012+49(0)621-759-4848+49(0)8856-60-2629

1.4 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 May produce an allergic reaction.

Contains: 2-methyl-2H-isothiazol-3-one hydrochloride, 26172-54-3

2.3 Other hazards

None known.

HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

SECTION 3: Composition/information on ingredients***Cal 1/CalCheck F1*****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

Remarks : No hazardous ingredients

Cal 2/CalCheck F2**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

Remarks : No hazardous ingredients

SECTION 4: First aid measures**4.1 Description of 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. |

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

If symptoms persist, call a physician.
Rinse mouth with water.

4.2 Most important symptoms and effects, both acute and delayed

None known.

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.

5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting : 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 : Avoid dust formation.

6.2 Environmental precautions

Environmental precautions : 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 : Pick up and arrange disposal without creating dust.
Sweep up and shovel.
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

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

HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

SECTION 7: Handling and storage**7.1 Precautions for safe handling**

- Advice on safe handling : For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
- Advice on protection against fire and explosion : Provide appropriate exhaust ventilation at places where dust is formed.
- Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

7.2 Conditions for safe storage, including any incompatibilities

- Requirements for storage areas and containers : Electrical installations / working materials must comply with the technological safety standards.
- Further information on storage conditions : See label, package insert or internal guidelines
- Advice on common storage : No materials to be especially mentioned.
- 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

SECTION 8: Exposure controls/personal protection**8.1 Control parameters*****Cal 1/CalCheck F1***

Contains no substances with occupational exposure limit values.

Cal 2/CalCheck F2

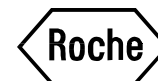
Contains no substances with occupational exposure limit values.

8.2 Exposure controls**Personal protective equipment**

- Eye protection : Safety glasses
- Hand protection
- Material : Protective gloves

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

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 : Protective suit

Respiratory protection : No personal respiratory protective equipment normally required.

SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

Cal 1/CalCheck F1

Appearance : (lyophilised)

Colour : white
light yellow

Odour : none

Odour Threshold : No data available
pH : 7,0 (25 °C)(as aqueous solution)

Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : does not flash

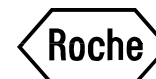
Evaporation rate : No data available
Flammability (solid, gas) : Sustains combustion

Upper explosion limit : No data available
Lower explosion limit : No data available
Vapour pressure : No data available
Relative vapour density : No data available
Relative density : No data available
Density : No data available
Solubility(ies)
Water solubility : completely soluble

Partition coefficient: n-octanol/water : No data available
Auto-ignition temperature : No data available

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

Thermal decomposition	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

Cal 2/CalCheck F2

Appearance	: (lyophilised)
Colour	: white light yellow
Odour	: none
Odour Threshold	: No data available
pH	: 7,0 (25 °C)(as aqueous solution)
Melting point/freezing point	: No data available
Initial boiling point and 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	: No data available
Relative density	: No data available
Density	: No data available
Solubility(ies)	
Water solubility	: completely soluble
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Thermal decomposition	: No data available
Viscosity	: No data available
Explosive properties	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

9.2 Other information

Cal 1/CalCheck F1

No data available

Cal 2/CalCheck F2

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

No data available

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.

Stable under recommended storage conditions.

No hazards to be specially mentioned.

10.4 Conditions to avoid

Conditions to avoid : Exposure to moisture.
Heat, flames and sparks.

10.5 Incompatible materials

Materials to avoid : Strong oxidizing agents

10.6 Hazardous decomposition products

Hazardous decomposition products : No decomposition if stored and applied as directed.

SECTION 11: Toxicological information

11.1 Information on toxicological effects

Cal 1/CalCheck F1

Acute toxicity

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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.

HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

Carcinogenicity

Not classified based on available information.

Reproductive toxicity

Not classified based on available information.

STOT - single exposure

Not classified based on available information.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

Cal 2/CalCheck F2**Acute toxicity**

Not classified based on available information.

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

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.

STOT - repeated exposure

Not classified based on available information.

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information**12.1 Toxicity****Cal 1/CalCheck F1**

No data available

Cal 2/CalCheck F2

HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

No data available

12.2 Persistence and degradability

Cal 1/CalCheck F1

No data available

Cal 2/CalCheck F2

No data available

12.3 Bioaccumulative potential

Cal 1/CalCheck F1

No data available

Cal 2/CalCheck F2

No data available

12.4 Mobility in soil

Cal 1/CalCheck F1

No data available

Cal 2/CalCheck F2

No data available

12.5 Results of PBT and vPvB assessment

Cal 1/CalCheck F1

Not relevant

Cal 2/CalCheck F2

Not relevant

12.6 Other adverse effects

Cal 1/CalCheck F1

No data available

Cal 2/CalCheck F2

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

- | | |
|------------------------|---|
| Product | : 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. |

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

SECTION 14: Transport information

14.1 UN number

ADR

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.2 Proper shipping name

ADR

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.3 Transport hazard class

ADR

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.4 Packing group

ADR

Not dangerous goods

IMDG

Not dangerous goods

IATA_C

Not dangerous goods

IATA_P

Not dangerous goods

14.5 Environmental hazards

ADR

Not dangerous goods

IMDG

Not dangerous goods

IATA

Not dangerous goods

14.6 Special precautions for user

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

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



HE4 CalSet

Version 1.3

Revision Date 16.05.2014

Print Date 13.08.2014

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)

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

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.