

CK-MB CalSet

Version 1.1

Revision Date 12-10-2013

Print Date 01-17-2014

SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

Product name : CK-MB CalSet

Mat.-No./ Genisys-No. : 05957664190

Chemical nature : Handle as potentially infectious.

Manufacturer or supplier's details

Company : Roche Diagnostics

Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone number : +49(0)621-759-2012 oder +49(0)621-759-4848 oder
+49(0)8856-60-2629

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

Physical state	solid
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GHS Classification

Not a hazardous substance or mixture.

GHS Label element

Not a hazardous substance or mixture.

Potential Health Effects

Aggravated Medical Condition : None known.

Symptoms of Overexposure : No information available.

Carcinogenicity:

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SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**Cal 1**

Substance / Mixture : Preparation

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No.	Concentration [%]
sucrose	57-50-1	≥ 20 - < 30
L-malic acid	97-67-6	≥ 1 - < 5

Cal 2

Substance / Mixture : Preparation

Chemical nature : Handle as potentially infectious.

Hazardous components

Chemical Name	CAS-No.	Concentration [%]
sucrose	57-50-1	≥ 20 - < 30
L-malic acid	97-67-6	≥ 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 skin irritation persists, call a physician.
If on skin, rinse well with water.
If on clothes, remove clothes.

In case of eye contact : Immediately flush eye(s) with plenty of water.
Remove contact lenses.
Protect unharmed eye.
Keep eye wide open while rinsing.
If eye irritation persists, consult a specialist.

If swallowed : Clean mouth with water and drink afterwards plenty of water.
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.

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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.

Unsuitable extinguishing media : High volume water jet

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 fire fighting if necessary.

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures : Use personal protective equipment.
Avoid dust formation.
Avoid breathing dust.

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

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

SECTION 7. HANDLING AND STORAGE

Advice on safe handling : Avoid contact with skin and eyes.
For personal protection see section 8.
Smoking, eating and drinking should be prohibited in the application area.
Dispose of rinse water in accordance with local and national regulations.

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

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION***Cal 1***

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Components with workplace control parameters

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1

Cal 2**Components with workplace control parameters**

Components	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
sucrose	57-50-1	TWA	10 mg/m ³	ACGIH
		TWA (Respirable)	5 mg/m ³	NIOSH REL
		TWA (total)	10 mg/m ³	NIOSH REL
		TWA (total dust)	15 mg/m ³	OSHA Z-1
		TWA (respirable fraction)	5 mg/m ³	OSHA Z-1

Personal protective equipment

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

: Eye wash bottle with pure water
Tightly fitting safety goggles

Skin and body protection

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

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Hygiene measures : When using do not eat or drink.
When using do not smoke.
Wash hands before breaks and at the end of workday.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES***Cal 1***

Appearance : solid
Colour : light yellow
Odour : none
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 : completely 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 : light yellow
Odour : none
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 : completely soluble
Auto-ignition temperature : no data available

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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.
No decomposition if stored and applied as directed.
Conditions to avoid : no data available
Incompatible materials : no data available
Hazardous decomposition products : no data available

SECTION 11. TOXICOLOGICAL INFORMATION***Cal 1*****Acute toxicity****Product:**

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Components:**sucrose:**

Acute oral toxicity : LD50 Oral rat: 29,700 mg/kg

LD50 Oral mouse: 14,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate : > 30 mg/l
Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate : > 5,001 mg/kg
Method: Expert judgement

Skin corrosion/irritation**Product:**

Remarks: May cause skin irritation and/or dermatitis.

Components:

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L-malic acid:

Result: Irritating to skin.

Serious eye damage/eye irritation

Product:

Remarks: Product dust may be irritating to eyes, skin and respiratory system.

Components:

L-malic acid:

Result: Eye irritation

Respiratory or skin sensitisation

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT - single exposure

Components:

sucrose:

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

L-malic acid:

Exposure routes: inhalation (dust/mist/fume)

Assessment: May cause respiratory irritation.

STOT - repeated exposure

Components:

sucrose:

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

L-malic acid:

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

Aspiration toxicity

Components:

sucrose:

no data available

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L-malic acid:
no data available

Further information**Components:****sucrose:**

Remarks: Health injuries are not known or expected under normal use.

Cal 2**Acute toxicity****Product:**

Acute oral toxicity : Acute toxicity estimate : > 5,000 mg/kg
Method: Calculation method

Components:**sucrose:**

Acute oral toxicity : LD50 Oral rat: 29,700 mg/kg

LD50 Oral mouse: 14,000 mg/kg

Acute inhalation toxicity : Acute toxicity estimate : > 30 mg/l
Method: Expert judgement

Acute dermal toxicity : Acute toxicity estimate : > 5,001 mg/kg
Method: Expert judgement

Skin corrosion/irritation**Product:**

Remarks: May cause skin irritation and/or dermatitis.

Components:**L-malic acid:**

Result: Irritating to skin.

Serious eye damage/eye irritation**Product:**

Remarks: Product dust may be irritating to eyes, skin and respiratory system.

Components:**L-malic acid:**

Result: Eye irritation

Respiratory or skin sensitisation

no data available

Germ cell mutagenicity

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no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT - single exposure**Components:****sucrose:**

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

L-malic acid:

Exposure routes: inhalation (dust/mist/fume)

Assessment: May cause respiratory irritation.

STOT - repeated exposure**Components:****sucrose:**

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

L-malic acid:

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

Aspiration toxicity**Components:****sucrose:**

no data available

L-malic acid:

no data available

Further information**Components:****sucrose:**

Remarks: Health injuries are not known or expected under normal use.

SECTION 12. ECOLOGICAL INFORMATION***Cal 1*****Ecotoxicity****Product:**

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Ecotoxicology Assessment

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

Other organisms relevant to the environment : no data available

Components:**sucrose :**Toxicity to fish : LC50 : > 100 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

Ecotoxicology Assessment

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

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

L-malic acid :

Ecotoxicology Assessment

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

Other organisms relevant to the environment : no data available

Persistence and degradability

no data available

Bioaccumulative potential**Components:****sucrose :**

Partition coefficient: n-octanol/water : log Pow: -3.67

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
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).

Remarks

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

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Ecotoxicology Assessment

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

Other organisms relevant to the environment : no data available

Components:**sucrose :**Toxicity to fish : LC50 : > 100 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity) : > 1 mg/l

Ecotoxicology Assessment

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

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

L-malic acid :

Ecotoxicology Assessment

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

Other organisms relevant to the environment : no data available

Persistence and degradability

no data available

Bioaccumulative potential**Components:****sucrose :**

Partition coefficient: n-octanol/water : log Pow: -3.67

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
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).

Remarks

SECTION 13. DISPOSAL CONSIDERATIONS

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Disposal methods

- Waste from residues : Special treatment as infectious material is mandatory in compliance with local regulations (disinfection and incineration).
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.

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

Special precautions for user

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

SECTION 15. REGULATORY INFORMATION**Cal 1**

- OSHA Hazards** : Moderate skin irritant, Moderate eye irritant, Moderate respiratory irritant

- WHMIS Classification** : D2B: Toxic Material Causing Other Toxic Effects

EPCRA - Emergency Planning and Community Right-to-Know Act

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- SARA 302** : SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.
- SARA 313** : 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):

tris(2-hydroxyethyl)ammonium chloride	637-39-8	5.677 %
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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.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations**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	50 - 70 %
sucrose	57-50-1	20 - 30 %
tris(2-hydroxyethyl)ammonium chloride	637-39-8	5 - 10 %
L-malic acid	97-67-6	1 - 5 %

New Jersey Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	50 - 70 %
sucrose	57-50-1	20 - 30 %
tris(2-hydroxyethyl)ammonium chloride	637-39-8	5 - 10 %
L-malic acid	97-67-6	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.

Inventories

AICS (Australia), DSL (Canada), IECSC (China), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

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Cal 2

OSHA Hazards : Moderate skin irritant, Moderate eye irritant, Moderate respiratory irritant

WHMIS Classification : D2B: Toxic Material Causing Other Toxic Effects

EPCRA - Emergency Planning and Community Right-to-Know Act

SARA 302 : SARA 302: No chemicals in this material are subject to the reporting requirements of SARA Title III, Section 302.

SARA 313 : 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):

tris(2-hydroxyethyl)ammonium chloride	637-39-8	5.677 %
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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.

This product does not contain any toxic pollutants listed under the U.S. Clean Water Act Section 307

US State Regulations**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	50 - 70 %
sucrose	57-50-1	20 - 30 %
tris(2-hydroxyethyl)ammonium chloride	637-39-8	5 - 10 %
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New Jersey Right To Know

Human serum /-plasma / -hemolysate, lyophilized	Not Assigned	50 - 70 %
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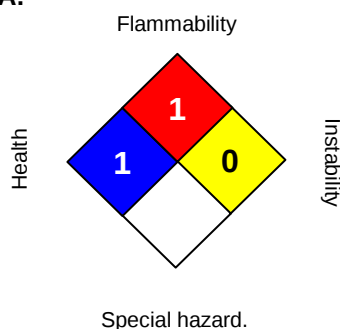
tris(2-hydroxyethyl)ammonium chloride
L-malic acid

637-39-8 5 - 10 %
97-67-6 1 - 5 %

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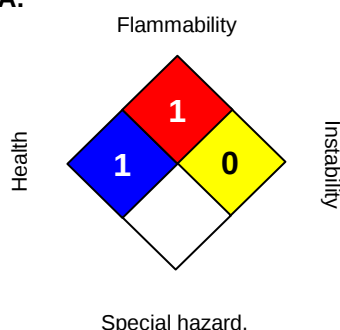
Inventories

AICS (Australia), DSL (Canada), IECSC (China), ENCS (Japan), ISHL (Japan), KECI (Korea), NZIoC (New Zealand), PICCS (Philippines), TSCA (USA)

SECTION 16. OTHER INFORMATION**Further information****Cal 1****NFPA:****HMIS III:**

HEALTH	2
FLAMMABILITY	1
PHYSICAL HAZARD	0

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

Cal 2**NFPA:****HMIS III:**

HEALTH	2
FLAMMABILITY	1
PHYSICAL HAZARD	0

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

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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