

Precinorm CK-MB

Version 1.3

Revision Date 09-19-2014

Print Date 12-06-2014

SECTION 1. IDENTIFICATION

Product name : Precinorm CK-MB

Mat.-No./ Genisys-No. : 11447378122

Manufacturer or supplier's detailsCompany 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

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS**F1****GHS Classification**

Not a hazardous substance or mixture.

Hazardous components

Chemical Name	CAS-No.	Concentration (%)
sucrose	57-50-1	>= 10 - < 20
L-malic acid	97-67-6	>= 5 - < 10

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

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	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.
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 firefighting 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. If the product contaminates rivers and lakes or drains inform respective authorities.

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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**F1****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
		TWA (Total dust)	15 mg/m ³	OSHA P0
		TWA (respirable dust fraction)	5 mg/m ³	OSHA P0

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

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Eye protection	: discussed with the producers of the protective gloves. : 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.
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**F1**

Appearance	: lyophilised cake
Colour	: light yellow
pH	: 6.2 - 6.6, (25 °C)(as aqueous solution)
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.

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	: Heat, flames and sparks. Exposure to moisture.

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Incompatible materials : Strong oxidizing agents
Bases
Alkali metals
Reducing agents

Hazardous decomposition products : No data available

SECTION 11. TOXICOLOGICAL INFORMATION***F1*****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:**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

Not classified based on available information.

Product:

Remarks: May cause skin irritation and/or dermatitis.

Components:**L-malic acid:**

Result: Irritating to skin.

Serious eye damage/eye irritation

Not classified based on available information.

Product:

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

Components:**L-malic acid:**

Result: Eye irritation

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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.

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:**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

Not classified based on available information.

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

Not classified based on available information.

Components:

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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***F1*****Ecotoxicity****Product:**

Ecotoxicology Assessment

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

Other organisms relevant to : No data available
the environment**Components:****sucrose:**Toxicity to fish : LC50: > 100 mg/l
Exposure time: 96 hToxicity to fish (Chronic : > 1 mg/l
toxicity)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 : No data available
the environment**L-malic acid:**

Ecotoxicology Assessment

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

Other organisms relevant to : No data available
the environment**Persistence and degradability**

No data available

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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

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 : Do not contaminate ponds, waterways or ditches with chemical or used container.
Send to a licensed waste management company.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

SECTION 15. REGULATORY INFORMATION**F1**

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EPCRA - Emergency Planning and Community Right-to-Know Act**CERCLA Reportable Quantity**

Components	CAS-No.	Component RQ (lbs)	Calculated product RQ (lbs)
Zinc Chloride	7646-85-7	1000	*

*: Calculated RQ exceeds reasonably attainable upper limit.

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).

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	9.77 %
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Clean Water Act

The following Hazardous Substances are listed under the U.S. CleanWater Act, Section 311, Table 116.4A:

zinc chloride	7646-85-7	0.007 %
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The following Hazardous Chemicals are listed under the U.S. CleanWater Act, Section 311, Table 117.3:

zinc chloride	7646-85-7	0.007 %
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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	50 - 70 %
sucrose	57-50-1	10 - 20 %
tris(2-hydroxyethyl)ammonium chloride	637-39-8	5 - 10 %
acetylcysteine	616-91-1	5 - 10 %
L-malic acid	97-67-6	5 - 10 %

New Jersey Right To Know

Albumins, blood serum	9048-46-8	50 - 70 %
sucrose	57-50-1	10 - 20 %
tris(2-hydroxyethyl)ammonium chloride	637-39-8	5 - 10 %
acetylcysteine	616-91-1	5 - 10 %
L-malic acid	97-67-6	5 - 10 %

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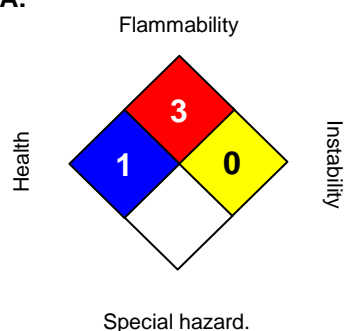
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California Prop 65

: 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****F1****NFPA:****HMIS III:**

HEALTH	2
FLAMMABILITY	3
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.