

Creatine Kinase (CK), 100mgVersion
1.3Revision Date:
06-01-2016Date of last issue: 04-21-2016
Date of first issue: 07-30-2015**SECTION 1. IDENTIFICATION**

Product name : Creatine Kinase (CK), 100mg
Product code : 10127566001

Manufacturer or supplier's details

Company name of supplier : Roche Diagnostics

Address : 9115 Hague Road
46250 Indianapolis IN

Telephone : 1-800-428-5074

Emergency telephone:

In case of emergencies: : CHEMTREC

1-800-424-9300 (U.S. or Ca-
nada)
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**

Not a hazardous substance or mixture.

GHS label elements

Not a hazardous substance or mixture.

Other hazards

None known.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

Substance / Mixture : Mixture

Substance name : Creatine Kinase (CK),lyo

Hazardous ingredients

Chemical name	CAS-No.	Concentration (% w/w)
Creatine Kinase (CK)	9001-15-4	>= 90 - <= 100

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.

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| 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.
If symptoms persist, call a physician.
Rinse mouth with water. |
| Most important symptoms and effects, both acute and delayed | : | None known. |
| Notes to physician | : | The first aid procedure should be established in consultation with the doctor responsible for industrial medicine. |
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SECTION 5. FIRE-FIGHTING MEASURES

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| Suitable extinguishing media | : | Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Specific hazards during fire fighting | : | No information available. |
| Hazardous combustion products | : | No hazardous combustion products are known |
| Further information | : | Standard procedure for chemical fires.
Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Special protective equipment for fire-fighters | : | Wear self-contained breathing apparatus for firefighting if necessary. |
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SECTION 6. ACCIDENTAL RELEASE MEASURES

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| 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. |
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SECTION 7. HANDLING AND STORAGE

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| Advice on protection against fire and explosion | : | Provide appropriate exhaust ventilation at places where dust is formed. |
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- 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.
- Technical measures/Precautions : See label, package insert or internal guidelines
- Materials to avoid : No materials to be especially mentioned.

SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION**Ingredients with workplace control parameters**

Ingredients	CAS-No.	Value type (Form of exposure)	Control parameters / Permissible concentration	Basis
Creatine Kinase (CK)	9001-15-4	IOEL	0.00006 mg/m ³	Roche Industrial Hygiene Committee (RIHC)

Engineering measures : No data available

Personal protective equipment

Respiratory protection : No personal respiratory protective equipment normally required.

Hand protection

Material : Protective gloves

Remarks : Wear appropriate protective gloves to prevent skin contact.
Replace torn or punctured gloves promptly.

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

Appearance : solid, (lyophilized)

Color : white, light pink, light yellow

Odor : none

Odor Threshold : Not applicable

pH : ca. 8

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Melting point/range	:	(as aqueous solution) 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
Flammability (liquids)	:	Sustains combustion
Upper explosion limit	:	No data available
Lower explosion limit	:	No data available
Vapor pressure	:	No data available
Relative vapor 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
Autoignition temperature	:	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.

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	:	Exposure to moisture.
Incompatible materials	:	Strong oxidizing agents

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

SECTION 11. TOXICOLOGICAL INFORMATION**Acute toxicity**

Not classified based on available information.

Product:

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

Ingredients:**Creatine Kinase (CK):**

Acute oral toxicity : Acute toxicity estimate: > 5,001 mg/kg
Method: Expert judgment

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

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

Skin corrosion/irritation

Not classified based on available information.

Serious eye damage/eye irritation

Not classified based on available information.

Respiratory or skin sensitization**Skin sensitization**

Not classified based on available information.

Respiratory sensitization

Not classified based on available information.

Germ cell mutagenicity

Not classified based on available information.

Carcinogenicity

Not classified based on available information.

IARC

No ingredient of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

OSHA

No ingredient 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 ingredient of this product present at levels greater than or equal to 0.1% is identified as a known or anticipated carcinogen by NTP.

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Not classified based on available information.

STOT-single exposure

Not classified based on available information.

Ingredients:**Creatine Kinase (CK):**

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

STOT-repeated exposure

Not classified based on available information.

Ingredients:**Creatine Kinase (CK):**

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

Aspiration toxicity

Not classified based on available information.

Ingredients:**Creatine Kinase (CK):**

No data available

Further information**Ingredients:****Creatine Kinase (CK):**

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

SECTION 12. ECOLOGICAL INFORMATION**Ecotoxicity****Product:****Ecotoxicology Assessment**

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

Other organisms relevant to the environment : No data available

Ingredients:**Creatine Kinase (CK):**Toxicity to fish : LC50: > 100 mg/l
Exposure time: 96 h

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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

Persistence and degradability

No data available

Bioaccumulative potential

Ingredients:

Creatine Kinase (CK):

Partition coefficient: n-octanol/water : Remarks: No data available

Mobility in soil

No data available

Other adverse effects

Product:

Ozone-Depletion Potential : 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 : 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

UNRTDG

Not regulated as a dangerous good

IATA-DGR

Not regulated as a dangerous good

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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.

Domestic regulation**49 CFR**

Not regulated as a dangerous good

SECTION 15. REGULATORY INFORMATION**EPCRA - Emergency Planning and Community Right-to-Know****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 311/312 Hazards : No SARA Hazards**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 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).

This product does not contain any hazardous air pollutants (HAP), as defined by the U.S. Clean Air Act Section 112 (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):

Glycine	56-40-6	9 %
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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

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Glycine	56-40-6	5 - 10 %

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New Jersey Right To Know

Creatine Kinase (CK)	9001-15-4	90 - 100 %
Glycine	56-40-6	5 - 10 %

The ingredients of this product are reported in the following inventories:

CH INV	On the inventory, or in compliance with the inventory
DSL	This product contains the following components that are not on the Canadian DSL nor NDSL. Creatine Kinase (CK)
AICS	Not in compliance with the inventory Creatine Kinase (CK)
NZIoC	On the inventory, or in compliance with the inventory
ENCS	Not in compliance with the inventory Creatine Kinase (CK) 1,4-Dithiothreitol (DTT)
ISHL	Not in compliance with the inventory Creatine Kinase (CK) 1,4-Dithiothreitol (DTT)
KECI	Not in compliance with the inventory Creatine Kinase (CK) 1,4-Dithiothreitol (DTT)
PICCS	Not in compliance with the inventory Creatine Kinase (CK)
IECSC	On the inventory, or in compliance with the inventory

TSCA list

No substances are subject to a Significant New Use Rule.

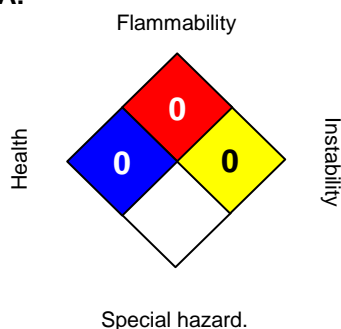
No substances are subject to TSCA 12(b) export notification requirements.

SECTION 16. OTHER INFORMATION
Full text of other abbreviations

AICS - Australian Inventory of Chemical Substances; ASTM - American Society for the Testing of Materials; bw - Body weight; CERCLA - Comprehensive Environmental Response, Compensation, and Liability Act; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DOT - Department of Transportation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; EHS - Extremely Hazardous Substance; 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; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; HMIS - Hazardous Materials Identification System; 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

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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; MSHA - Mine Safety and Health Administration; n.o.s. - Not Otherwise Specified; NFPA - National Fire Protection Association; NO(A)EC - No Observed (Adverse) Effect Concentration; NO(A)EL - No Observed (Adverse) Effect Level; NOELR - No Observable Effect Loading Rate; NTP - National Toxicology Program; 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; RCRA - Resource Conservation and Recovery Act; REACH - Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals; RQ - Reportable Quantity; SADT - Self-Accelerating Decomposition Temperature; SARA - Superfund Amendments and Reauthorization Act; SDS - Safety Data Sheet; TCSI - Taiwan Chemical Substance Inventory; TSCA - Toxic Substances Control Act (United States); UN - United Nations; UNRTDG - United Nations Recommendations on the Transport of Dangerous Goods; vPvB - Very Persistent and Very Bioaccumulative

Further information
NFPA:

HMIS III:

HEALTH	0
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 Material 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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