

SAFETY DATA SHEET

according to Regulation (EC) No. 1907/2006



CK-MB 100Tests, cobas c/Integra

Version
1.4

Revision Date:
28.11.2016

Date of last issue: 23.10.2016
Date of first issue: 22.01.2016

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

1.1 Product identifier

Commercial Product Name : CK-MB 100Tests, cobas c/Integra
Mat.-No./ Genisys-No. : 07190808190

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

Recommended restrictions on use : For professional users only.

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

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)

Hazard pictograms :



Signal word : Danger

Hazard statements : H360D May damage the unborn child.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

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Response:

P308 + P313 IF exposed or concerned: Get medical advice/attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

2.3 Other hazards

See SECTION 3

SECTION 3: Composition/information on ingredients

R1 (B)

Classification (REGULATION (EC) No 1272/2008)

Reproductive toxicity, Category 1B H360D: May damage the unborn child.

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

Toxic to Reproduction Category 2 R61: May cause harm to the unborn child.

Hazardous components

Chemical name	CAS-No. EC-No. Registration number	Classification	Concentration (% w/w)
imidazole	288-32-4 206-019-2 01-2119485825-24	Acute Tox. 4; H302 Skin Corr. 1C; H314 Eye Dam. 1; H318 Repr. 1B; H360D	>= 0,3 - < 1

For explanation of abbreviations see section 16.

R2 (C)

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

For explanation of abbreviations see section 16.

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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 : 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.
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

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.
- Unsuitable extinguishing media : High volume water jet

5.2 Special hazards arising from the substance or mixture

- Specific hazards during fire-fighting : Do not allow run-off from fire fighting to enter drains or water courses.

5.3 Advice for firefighters

- Special protective equipment for firefighters : Wear self-contained breathing apparatus for firefighting if necessary.
- Further information : Collect contaminated fire extinguishing water separately. This

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must not be discharged into drains.
Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions : Use personal protective equipment.
Refer to protective measures listed in sections 7 and 8.

6.2 Environmental precautions

Environmental precautions : Prevent product from entering drains.
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 : Soak up with inert absorbent material (e.g. sand, silica gel, acid binder, universal binder, sawdust).
Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

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

SECTION 7: Handling and storage

7.1 Precautions for safe handling

Advice on safe handling : 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.
Dispose of rinse water in accordance with local and national regulations.

Advice on protection against fire and explosion : Normal measures for preventive fire protection.

Hygiene measures : When using do not eat or drink. When using do not smoke.
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. Observe label precautions. 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) : 6.1D, Non-combustible, acute toxic Cat.3 / toxic hazardous

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materials or hazardous materials causing chronic effects

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

R1 (B)

Contains no substances with occupational exposure limit values.

R2 (C)

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

Respiratory protection : In the case of vapour formation use a respirator with an approved filter.

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SECTION 9: Physical and chemical properties

9.1 Information on basic physical and chemical properties

R1 (B)

Appearance	: liquid
Colour	: colourless
Odour	: very faint
Odour Threshold	: No data available
pH	: 6,6
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)	: The product is not flammable., Does not sustain 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	: 1,0084 g/cm ³
Solubility(ies)	
Water solubility	: completely miscible
Solubility in other solvents	: No data available
Partition coefficient: n-octanol/water	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Viscosity	
Viscosity, dynamic	: No data available
Viscosity, kinematic	: No data available
Oxidizing properties	: The substance or mixture is not classified as oxidizing.

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R2 (C)

Appearance	:	liquid
Colour	:	colourless
Odour	:	very faint
Odour Threshold	:	No data available
pH	:	9,3
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)	:	Does not sustain 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	:	1,04 g/cm ³
Solubility(ies)		
Water solubility	:	completely miscible
Solubility in other solvents	:	No data available
Partition coefficient: n-octanol/water	:	No data available
Auto-ignition temperature	:	No data available
Decomposition temperature	:	No data available
Viscosity		
Viscosity, dynamic	:	No data available
Viscosity, kinematic	:	No data available
Oxidizing properties	:	The substance or mixture is not classified as oxidizing.

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9.2 Other information

R1 (B)

No data available

R2 (C)

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 decomposition if stored and applied as directed.

10.4 Conditions to avoid

No data available

10.5 Incompatible materials

No data available

10.6 Hazardous decomposition products

No data available

SECTION 11: Toxicological information

11.1 Information on toxicological effects

R1 (B)

Acute toxicity

Not classified based on available information.

Components:

imidazole:

Acute oral toxicity : LD50 Oral (Rat): 970 mg/kg

Skin corrosion/irritation

Not classified based on available information.

Components:

imidazole:

Result: Causes burns.

Remarks: Extremely corrosive and destructive to tissue.

Serious eye damage/eye irritation

Not classified based on available information.

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Components:

imidazole:

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

May damage the unborn child.

Components:

imidazole:

Reproductive toxicity - Assessment : May damage the unborn child., Known human reproductive toxicant

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.

R2 (C)

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.

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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

R1 (B)

Components:

imidazole:

- | | | |
|---|---|---|
| Toxicity to fish | : | LC50 (Leuciscus idus (Golden orfe)): ca. 280 mg/l
Exposure time: 48 h |
| Toxicity to daphnia and other aquatic invertebrates | : | EC50 (Daphnia magna (Water flea)): 341,5 mg/l
Exposure time: 48 h |
| Toxicity to algae | : | EC50 (Scenedesmus quadricauda (Green algae)): 133 mg/l
Exposure time: 72 h |
| Toxicity to microorganisms | : | EC50 (Pseudomonas putida): 1.200 mg/l
Exposure time: 17 h |

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 |

R2 (C)

No data available

12.2 Persistence and degradability

R1 (B)

Components:

imidazole:

- | | | |
|------------------|---|------------------------|
| Biodegradability | : | Biodegradation: > 90 % |
|------------------|---|------------------------|

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Exposure time: 18 d
Method: OECD Test Guideline 301A
GLP: yes

Biodegradation: 83 %
Exposure time: 8 d
Method: OECD Test Guideline 302

R2 (C)

No data available

12.3 Bioaccumulative potential

R1 (B)

Components:

imidazole:

Partition coefficient: n- : log Pow: -0,02
octanol/water

R2 (C)

No data available

12.4 Mobility in soil

R1 (B)

No data available

R2 (C)

No data available

12.5 Results of PBT and vPvB assessment

R1 (B)

Not relevant

R2 (C)

Not relevant

12.6 Other adverse effects

R1 (B)

Components:

imidazole:

Additional ecological infor- : No data available
mation

R2 (C)

No data available

SECTION 13: Disposal considerations

13.1 Waste treatment methods

Product : Do not contaminate ponds, waterways or ditches with chemical or used container.

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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

14.1 UN number

Not regulated as a dangerous good

14.2 UN proper shipping name

Not regulated as a dangerous good

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, ADN, IMDG-Code, ICAO/IATA-DGR

14.7 Transport in bulk according to Annex II of Marpol 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)

R1 (B)

Labelling (REGULATION (EC) No 1272/2008)

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Hazard pictograms :



Signal word :

Danger

Hazard statements :

H360D May damage the unborn child.

Precautionary statements :

Prevention:

P201 Obtain special instructions before use.

P202 Do not handle until all safety precautions have been read and understood.

P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:

P308 + P313 IF exposed or concerned: Get medical advice/ attention.

Storage:

P405 Store locked up.

Disposal:

P501 Dispose of contents/ container to an approved waste disposal plant.

Hazardous components which must be listed on the label:

288-32-4 imidazole

R2 (C)

Labelling (REGULATION (EC) No 1272/2008)

Not a hazardous substance or mixture.

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 other abbreviations

Acute Tox. : Acute toxicity
Eye Dam. : Serious eye damage
Repr. : Reproductive toxicity
Skin Corr. : Skin corrosion

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 -

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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.

DE / EN / 1605