according to Regulation (EC) No. 1907/2006 (REACH)

Creatine Kinase R2 - Material number: 00017

1. Identification of the substance/preparation and of the company/undertaking

Date of print: 2022-08-18 Date of first version: 2011-07-29

Identification of the substance or preparation

Name of product: Creatine Kinase Reagent R2

as part of the kits: 01 00017 XX XX XXXX (The positions X code different packages.)

Use of the substance / preparation

Reagent for in-vitro diagnostics in human samples

Company / undertaking identification

Company name: DiaSystem Scandinavia AB

Street/POB-No.: Bultvägen 4
State/city/postal code: S-553 02 Jönköping
World Wide Web: http://www.diasystem.se
Email: info@diasystem.se
Telephone: +46 (0) 36 12 62 20
Telefax: +46 (0) 36 18 77 30

Dept. responsible for information:

DiaSystem, Telephone: +46 (0) 36 12 62 20

Emergency telephone

Giftinformationscentralen, Telephone +46 112

2. Hazards identification

Classification according to directive 67/548/EEC or 1999/45/EC:

This preparation is classified as not hazardous.

Critical hazard to man and environment:

Product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.

3. Composition/information on ingredients

Chemical characterization (preparation)

aqueous solution, contains phosphates

Dangerous ingredients:

CAS-No.	EINECS / ELINCS	Chemical name	Content	Classificatio	n	
288-32-4	206-019-2	Imidazole	< 2 %	C; R34. Re	pr. Cat. 3; R63.	Xn; R22

Additional information: Contains Sodium azide (0,95 g/L) as preservative.

4. First aid measures

After skin contact: Change contaminated clothing. Remove residues with water.

After eye contact: Immediately flush eyes with plenty of flowing water for 10 to 15 minutes holding eyelids apart.

In case of troubles or persistent symptoms, consult an ophthalmologist.

After swallowing: Rinse mouth thoroughly with water. Induce vomiting.

Have victim drink large quantities of water, with active charcoal if possible. Seek medical attention.

Creatine Kinase - page 1 of 5 01 00017/1 2011-07

according to Regulation (EC) No. 1907/2006 (REACH)

Creatine Kinase R2 - Material number: 00017

5. Fire fighting measures

Suitable extinguishing media:

Product is non-combustible. Extinguishing materials should therefore be selected according to surroundings.

Date of print: 2022-08-18 Date of first version: 2011-07-29

Special exposure hazards arising from the preparation itself, combustion products, resulting gases:

Can be released in case of fire: Nitrogen oxides (NOx), phosphorus oxides, carbon monoxide and carbon

dioxide.

Special protective equipment for fire-fighters:

Wear self-contained breathing apparatus.

Additional information: Do not allow fire water to penetrate into surface or ground water.

6. Accidental release measures

Personal precautions: Avoid contact with skin and eyes.

Environmental precautions: Do not allow to penetrate into soil, waterbodies or drains.

Methods for cleaning up: Soak up with absorbent materials such as sand, siliceus earth, acid- or universal binder.

Store in special closed containers and dispose of according to ordinance. Wash spill area with plenty of

water.

7. Handling and storage

Handling

Information for safe handling:

Avoid contact with skin and eyes.

Keep all containers, equipment and working place clean.

Product contains bovine material. Even though tests on infectious diseases ended negative, this product

should be handled as potentially infectious biomaterial.

Storage

Requirements for storerooms and containers:

Keep containers tightly closed and at a temperature between 2 °C and 8 °C.

Protect from light.

Storage class: 12

8. Exposure controls / Personal protection equipment

Exposure controls

See information in chapter 7, section storage.

Occupational exposure controls

Respiratory protection: Provide adequate ventilation.

Hand protection: Protective gloves according to EN 374.

Glove material: Nitrile rubber Breakthrough time: >480 min.

 $Observe\ glove\ manufacturer's\ instructions\ concerning\ penetrability\ and\ breakthrough\ time.$

Eye protection: Tightly sealed safety glasses according to EN 166.

Skin protection: Lab apron
General protection and hygiene measures:

Change contaminated clothing.

Wash hands before breaks and at the end of work.

Creatine Kinase - page 2 of 5 01 00017/1 2011-07

Date of print: 2022-08-18 Date of first version: 2011-07-29

according to Regulation (EC) No. 1907/2006 (REACH)

Creatine Kinase R2 - Material number: 00017

9. Physical and chemical properties

Appearance

Physical state: liquid

Colour: colourless, clear
Odour: odourless

Important health, safety and environmental information

Flash point / flash point range: not combustible

Density: at 20 °C: 1,039 g/mL

PH value: at 25 °C: 9,0

Solubility in water: fully miscible

10. Stability and reactivity

Conditions to avoid: Protect against heat /sun rays.

Materials to avoid: Acids, alkalis

Hazardous decomposition products:

Can be released in case of fire: Nitrogen oxides (NOx), phosphorus oxides, carbon monoxide and carbon

dioxide.

Additional information: Product is stable under normal storage conditions.

11. Toxicological information

Toxicological Tests:

After eye contact: mild irritant

General remarks

Contains Sodium azide (0,95 g/L):

After resorption of toxic quantities: headache, dizziness, nausea, coughing, vomiting, spasms, breathing paralysis, CNS disorders, low blood pressure, cardiovascular failure, unconsciousness, collapse.

Product contains bovine material. All donor animals were sourced from BSE-free herds. The cattle received ante- and post mortem health inspection by a veterinarian, and they were apparently free from infectious and contagious material. However, the material should be treated as potentially infectious.

12. Ecological information

Ecotoxicity

Aquatoxicity: Contains phosphates: May contribute to the eutrophication of water supplies.

Water Hazard Class: 1 = mild water pollutant

Additional ecological information

General information: Do not allow to enter ground water, sewage or drains.

13. Disposal considerations

Product

Waste key number 160506* = Laboratory chemicals consisting of or containing dangerous substances

including mixtures of laboratory chemicals.
* = Evidence for disposal must be provided.

Recommendation: Special waste. Waste disposal according to official state regulations.

according to Regulation (EC) No. 1907/2006 (REACH)

Creatine Kinase R2 - Material number: 00017

Contaminated packaging

Waste key number 150102 = Plastic packaging.

Recommendation: Waste disposal according to official state regulations.

Cleaned containers may be recycled.

14. Transport information

Overland transport (ADR/RID)

Product designation: Not restricted

Transport by sea (IMDG)

Proper shipping name: Not restricted

Air transport (IATA)

Proper shipping name: Not restricted

Additional information

Not a hazardous material with respect to transportation regulations.

15. Regulatory information

Classification

Code letter and hazard symbol:

not applicable
R phrase(s):
not applicable
s phrase(s):
not applicable

National regulations

National regulations - Germany

Storage class: 12

Water Hazard Class: 1 = mild water pollutant

National regulations - EC member states

Volatile organic compounds (VOC):

0 % by weight

National regulations - USA

Hazard rating systems NFPA Hazard Rating:



Health: 1 (Slight)
Fire: 0 (Minimal)
Reactivity: 0 (Minimal)
HMIS Version III Rating:
Health: 1 (Slight)
Flammability: 0 (Minimal)

Flammability: 0 (Minimal) Physical Hazard: 0 (Minimal) Personal Protection: B



Date of print: 2022-08-18 Date of first version: 2011-07-29

16. Other information

Further remarks

R phrase(s): R 22 = Harmful if swallowed.

R 34 = Causes burns.

R 63 = Possible risk of harm to the unborn child.

Reason of change: Changes in section 1: Emergency No.

Group that issues data sheet

Contact person: see chapter 1, department responsible for information.

The information in this data sheet has been established to our best knowledge and was up-to-date at time of revision. It does not represent a guarantee for the properties of the product described in terms of the legal warranty regulations.

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