

SAFETY DATA SHEET

SIEMENS

Atellica™ IM Creatine Kinase MB Master Curve Material (CKMB MCM)

SDS #: 10995534

Section 1. Identification

Product identifier : Atellica™ IM Creatine Kinase MB Master Curve Material (CKMB MCM)
Product code : 10995534
Product type : Solid.

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

Not applicable.

Manufactured/supplied : Siemens Healthcare Diagnostics Inc.
 511 Benedict Avenue
 Tarrytown, NY 10591-5097 USA
 1-877-229-3711
 (800) 424-9300 (CHEMTREC) (24/365)

Section 2. Hazards identification

OSHA/HCS status : While this material is not considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200), this SDS contains valuable information critical to the safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

Classification of the substance or mixture : Not classified.

Additional information : Potentially biohazardous material.
 Not available.

GHS label elements

Signal word : No signal word.

Hazard statements : No known significant effects or critical hazards.

Precautionary statements

Prevention : Not applicable.

Response : Not applicable.

Storage : Not applicable.

Disposal : Not applicable.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Ingredient name	%	CAS number
Gentamicin, sulfate (salt)	0.13	1405-41-0

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

- | | |
|---------------------|---|
| Eye contact | : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs. |
| Inhalation | : Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours. |
| Skin contact | : Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. |
| Ingestion | : Wash out mouth with water. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur. |

Most important symptoms/effects, acute and delayed

Potential acute health effects

- | | |
|---------------------|---|
| Eye contact | : No known significant effects or critical hazards. |
| Inhalation | : No known significant effects or critical hazards. |
| Skin contact | : No known significant effects or critical hazards. |
| Ingestion | : No known significant effects or critical hazards. |

Over-exposure signs/symptoms

- | | |
|---------------------|---------------------|
| Eye contact | : No specific data. |
| Inhalation | : No specific data. |
| Skin contact | : No specific data. |
| Ingestion | : No specific data. |

Indication of immediate medical attention and special treatment needed, if necessary

- | | |
|-----------------------------------|---|
| Notes to physician | : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours. |
| Specific treatments | : No specific treatment. |
| Protection of first-aiders | : No action shall be taken involving any personal risk or without suitable training. |

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

- | | |
|---------------------------------------|---|
| Suitable extinguishing media | : In case of fire, use water spray (fog), foam or dry chemical. |
| Unsuitable extinguishing media | : None known. |

- | | |
|---|---|
| Specific hazards arising from the chemical | : No specific fire or explosion hazard. |
|---|---|

- | | |
|---|---|
| Hazardous thermal decomposition products | : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
sulfur oxides
halogenated compounds
metal oxide/oxides |
|---|---|

Section 5. Fire-fighting measures

- Special protective actions for fire-fighters** : Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.
- Special protective equipment for fire-fighters** : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

- For non-emergency personnel** : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.
- For emergency responders** : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".
- Environmental precautions** : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

- Small spill** : Move containers from spill area. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor.
- Large spill** : Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

- Protective measures** : Put on appropriate personal protective equipment (see Section 8).
- Advice on general occupational hygiene** : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.
- Conditions for safe storage, including any incompatibilities** : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

None.

- Appropriate engineering controls** : Good general ventilation should be sufficient to control worker exposure to airborne contaminants.
- Environmental exposure controls** : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Section 8. Exposure controls/personal protection

Individual protection measures

- Hygiene measures** : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
- Eye/face protection** : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
- Skin protection**
- Hand protection** : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
- Body protection** : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Other skin protection** : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
- Respiratory protection** : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9. Physical and chemical properties

- Physical state** : Solid.
- Color** : Yellow.
- Odor** : Odorless.
- pH** : Not applicable.
- Flash point** : Not available.
- Flammability (solid, gas)** : ☒ Not relevant/applicable due to nature of the product.
- Relative density** : ☒ Not relevant/applicable due to nature of the product.
- Solubility in water** : ☒ Not relevant/applicable due to nature of the product.
- Partition coefficient: n-octanol/water** : Not available.
- Auto-ignition temperature** : Not available.
- Viscosity** : Not available.

Section 10. Stability and reactivity

- Reactivity** : No specific test data related to reactivity available for this product or its ingredients.
- Chemical stability** : The product is stable.
- Possibility of hazardous reactions** : Under normal conditions of storage and use, hazardous reactions will not occur.
- Conditions to avoid** : No specific data.
- Incompatible materials** : No specific data.
- Hazardous decomposition products** : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Gentamicin, sulfate (salt)	LD50 Oral	Rat	>5 g/kg	-

Irritation/Corrosion

Not available.

Sensitization

Not available.

Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive toxicity

Not available.

Teratogenicity

Not available.

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on the likely routes of exposure : Not available.

Potential acute health effects

Eye contact : No known significant effects or critical hazards.
Inhalation : No known significant effects or critical hazards.
Skin contact : No known significant effects or critical hazards.
Ingestion : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : No specific data.
Inhalation : No specific data.
Skin contact : No specific data.
Ingestion : No specific data.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Long term exposure

Potential immediate effects : Not available.
Potential delayed effects : Not available.

Section 11. Toxicological information

Potential chronic health effects

Not available.

General	: No known significant effects or critical hazards.
Carcinogenicity	: No known significant effects or critical hazards.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
Developmental effects	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	120108 mg/kg

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Gentamicin, sulfate (salt)	Acute EC50 21.2 ppm Fresh water Acute LC50 >955 ppm Fresh water	Daphnia - Daphnia magna Fish - Oncorhynchus mykiss	48 hours 96 hours

Persistence and degradability

Not available.

Bioaccumulative potential

Not available.

Mobility in soil

Soil/water partition coefficient (K_{oc})	: Not available.
--	------------------

Other adverse effects	: No known significant effects or critical hazards.
------------------------------	---

Section 13. Disposal considerations

Disposal methods	: The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.
-------------------------	--

Section 14. Transport information

DOT Classification

UN number Not regulated.

UN proper shipping name -

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

TDG Classification

UN number Not regulated.

UN proper shipping name -

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

ADR/RID

UN number Not regulated.

UN proper shipping name -

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

IMDG

UN number Not regulated.

Section 14. Transport information

UN proper shipping name -

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

IATA

UN number Not regulated.

UN proper shipping name -

Transport hazard class(es) -

Packing group -

Environmental hazards No.

Additional information -

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption:** Not determined
United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

Section 15. Regulatory information

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Classification : Not applicable.

Composition/information on ingredients

No products were found.

State regulations

Massachusetts : None of the components are listed.

New York : None of the components are listed.

New Jersey : None of the components are listed.

Pennsylvania : None of the components are listed.

California Prop. 65

WARNING: This product contains less than 1% of a chemical known to the State of California to cause birth defects or other reproductive harm.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
gentamicin, sulfate (salt)	No.	Yes.	No.	No.

International regulations

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule I Chemicals

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals

Section 16. Other information

History

Date of issue/Date of revision : 8/30/2017

Version : 1

Key to abbreviations

: ATE = Acute Toxicity Estimate
 BCF = Bioconcentration Factor
 GHS = Globally Harmonized System of Classification and Labelling of Chemicals
 IATA = International Air Transport Association
 IBC = Intermediate Bulk Container
 IMDG = International Maritime Dangerous Goods
 LogPow = logarithm of the octanol/water partition coefficient
 MARPOL = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
 UN = United Nations

 Indicates information that has changed from previously issued version.