

Safety Data Sheet

Material Name: Primary Human Skeletal Muscle Derived Cells (SkMDC)

SDS ID: CM-002-EU
In Compliance with Regulation
(EC) 1907/2006 (REACH) as
Amended

Section 1 - IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING

1.1 Product Identifier:

Primary Human Skeletal Muscle Derived Cells (SkMDC)

Synonyms

SkMDC

Substance Registration Number(s)

This material is imported in amounts <1 ton/year. The substances in this product are not subject to REACH registration requirements.

1.2 Relevant Identified Uses of the Substance or Mixture and Uses Advised Against Identified Uses

Research use only

Uses Advised Against

None known.

Manufacturer's Part Number: SK-1111

1.3 Details of the supplier of the safety data sheet

Cook MyoSite, Inc.
105 Delta Drive
Pittsburgh, PA, U.S.A 15238
Mfg Contact: researchsales@cookmedical.com

Phone: +1-412-963-7380

1.4 Emergency Telephone Number

+45 56868686

Section 2 - HAZARDS IDENTIFICATION

2.1 Classification of the Substance or Mixture

Classification according to Regulation (EC) No 1272/2008

No classification is assigned, based on classification criteria. Review the entire data sheet for any additional information which did not result in a GHS classification.

Classification according to Directives 67/548/EEC and/or 1999/45/EC

No classification is assigned based on classification criteria.

2.2 Label Elements

Labeling according to Regulation (EC) 1272/2008:

None needed according to classification criteria.

Symbol(s)

None needed according to classification criteria.

Signal Word

None needed according to classification criteria.

Hazard Statement(s)

None allocated.

Precautionary Statement(s)

Prevention

None allocated.

Response

None allocated.

Storage

Store at temperatures not exceeding -80°C.

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Disposal

None allocated.

Labelling according to Directive 67/548/EEC and/or 1999/45/EC

None needed according to classification criteria.

2.3 Other Hazards

No additional information is available.

Section 3 - COMPOSITION / INFORMATION ON INGREDIENTS

CAS EC No Registration No	Component Synonyms	67/548 EEC (DSD)	1272/2008 (CLP)	Percent
67-68-5 200-664-3 --	Dimethyl sulfoxide			7-13

Section 4 - FIRST AID MEASURES

4.1 Description of First Aid Measures

Inhalation

IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER or doctor/physician if you feel unwell.

Skin

Wash thoroughly after handling. Wear protective clothing to minimize skin contact. Wash contaminated clothing before reuse.

Eyes

Flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Call a POISON CENTER or doctor/physician.

Ingestion

If swallowed, get medical attention.

4.2 Most Important Symptoms and Effects, both Acute and Delayed

Acute

No information on significant adverse effects.

Delayed

No information on significant adverse effects.

4.3 Indication of any Immediate Medical Attention and Special Treatment Needed

No special instructions.

Section 5 - FIRE FIGHTING MEASURES

5.1 Extinguishing Media

Use carbon dioxide, regular dry chemical, regular foam or water.

Unsuitable Extinguishing Media

None known.

5.2 Special Hazards Arising from the Substance or Mixture

Negligible fire hazard.

Thermal Decomposition Products

Combustion: oxides of carbon, oxides of sulfur

5.3 Advice for Firefighters

Fire Fighting Measures

No data available.

Protective Equipment and Precautions for Firefighters

Wear full protective fire fighting gear including self contained breathing apparatus (SCBA) for protection against possible exposure.

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Section 6 - ACCIDENTAL RELEASE MEASURES

6.1 Personal Precautions, Protective Equipment and Emergency Procedures

Wear personal protective clothing and equipment, see Section 8.

6.2 Environmental Precautions

Prevent entry into sewers, drains, ditches, underground or confined spaces and waterways.

6.3 Methods and Material for Containment and Cleaning up

Collect spilled material in appropriate container for disposal. Bleach and wash with water. Dispose in accordance with all applicable regulations.

6.4 Reference to Other Sections

See Section 7 for Handling and Storage. See Section 8 for Personal Protective Equipment. See Section 13 for Disposal Guidance.

Section 7 - HANDLING AND STORAGE

7.1 Precautions for Safe Handling

Products contain human source material. Treat as potentially infectious. Handle at Biological Safety Level 2 to minimize exposure to potentially infectious agents. Each donor tissue, prior to cell isolation, is tested for the presence of HIV-1, Hepatitis B and Hepatitis C virus. Testing cannot offer complete assurance that the tested virus are absent. Avoid contact with skin and eyes. Wash thoroughly after handling. Wear protective gloves/clothing and eye/face protection.

7.2 Conditions for Safe Storage, Including any Incompatibilities

Keep frozen. Store at temperatures not exceeding -80°C. Do not reuse containers. Discard all empty containers.

7.3 Specific End Use(s)

Research use only

Section 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control Parameters

Component Exposure Limits

Dimethyl sulfoxide (67-68-5)

Austria:	50 ppm TWA; 160 mg/m3 TWA skin notation
Denmark:	50 ppm TWA; 160 mg/m3 TWA
Estonia:	50 ppm TWA; 150 mg/m3 TWA 150 ppm STEL; 500 mg/m3 STEL Skin notation
Finland:	50 ppm TWA Potential for cutaneous absorption
Germany (DFG):	50 ppm TWA MAK; 160 mg/m3 TWA MAK 100 ppm Peak; 320 mg/m3 Peak skin notation
Lithuania:	50 ppm TWA; 150 mg/m3 TWA 150 ppm STEL; 500 mg/m3 STEL Skin notation
Slovenia:	160 mg/m3 TWA Potential for cutaneous absorption
Sweden:	50 ppm LLV; 150 mg/m3 LLV 150 ppm STV; 500 mg/m3 STV Skin notation

Derived No Effect Levels (DNELs)

No DNELs available.

Predicted No Effect Concentrations (PNECs)

No PNECs available.

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8.2 Exposure Controls

Appropriate Engineering Controls

Use process enclosures, local exhaust ventilation, or other engineering controls to keep airborne levels to a minimum. Ensure compliance with applicable exposure limits.

Personal Protective Equipment

Eye / Face Protection

Wear splash resistant safety goggles with a faceshield.

Skin Protection

Lab coat or apron. Protective clothing must be changed when it shows signs of contamination.

Glove Recommendations

Wear appropriate gloves.

Respiratory Protection

Approved respirators should be worn when airborne concentrations are expected to exceed occupation exposure limits.

Environmental Exposure Controls

Prevent entry into sewers, drains, ditches, underground or confined spaces and waterways.

Section 9 - PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on Basic Physical and Chemical Properties

Physical State:	Solid	Appearance:	cloudy
Color:	amber	Physical Form:	Frozen Solid
Odor:	odorless to slight odor	Odor Threshold:	Not available
pH:	7.0-7.6	Melting Point:	Not available
Boiling Point:	Not available	Flash Point:	Not available
Evaporation Rate:	Not available	LEL:	Not available
UEL:	Not available	Vapor Pressure:	Not available
Vapor Density (air = 1):	Not available	Density:	1 g/cm ³
Specific Gravity (water = 1):	Not available	Water Solubility:	soluble
Log KOW:	Not available	Coeff. Water/Oil Dist:	Not available
KOC:	Not available	Viscosity:	Med-Ideal
Flammability (solid, gas):	Not flammable		

9.2 Other Information

No additional information.

Section 10 - STABILITY AND REACTIVITY

10.1 Reactivity

No reactivity hazard is expected.

10.2 Chemical Stability

Stable below -60°C.

10.3 Possibility of Hazardous Reactions

Hazardous polymerization will not occur.

10.4 Conditions to Avoid

Avoid contact with heat. Avoid elevated temperatures above -60°C.

10.5 Incompatible Materials

acid chlorides, strong acids, strong oxidizing materials, strong reducing agents

10.6 Hazardous Decomposition Products

Thermal Decomposition Products

Combustion: oxides of carbon, oxides of sulfur

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Section 11 - TOXICOLOGICAL INFORMATION

11.1 Information on Toxicological Effects

Acute and Chronic Toxicity

Component Analysis - LD50/LC50

The components of this material have been reviewed in various sources and no selected endpoints have been identified.

Irritation / Corrosivity

No information available for the product.

Respiratory Sensitization

No data available.

Skin Sensitization

No data available.

Germ Cell Mutagenicity

No data available.

Carcinogenicity

Component Carcinogenicity

None of this product's components are listed by IARC or DFG.

Reproductive Toxicity

None known.

Specific Target Organ Toxicity - Single Exposure

None known.

Specific Target Organ Toxicity - Repeated Exposure

None known.

Aspiration Hazard

No data available.

Section 12 - ECOLOGICAL INFORMATION

12.1 Toxicity

No data available.

Component Analysis - Aquatic Toxicity

Dimethyl sulfoxide (67-68-5)

Fish: 96 Hr LC50 Pimephales promelas: 34000 mg/L; 96 Hr LC50 Oncorhynchus mykiss: 33 - 37 g/L [static]; 96 Hr LC50 Lepomis macrochirus: >40 g/L [static]; 96 Hr LC50 Cyprinus carpio: 41.7 g/L

12.2 Persistence and Degradability

No information available.

12.3 Bioaccumulative Potential

No information available.

12.4 Mobility in Soil

No information available.

12.5 Results of PBT and vPvB Assessment

No information available.

EU - Interim Strategy for Management of PBT and vPvB Substances (PBT Assessments)

No components of this material are listed.

12.6 Other Adverse Effects

No information available.

Section 13 - DISPOSAL CONSIDERATIONS

13.1 Waste Treatment Methods

Dispose in accordance with all applicable local regulations. Dispose in a puncture-resistant biohazard container.

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Section 14 - TRANSPORT INFORMATION

Transportation

Not regulated.

International Bulk Chemical Code

This material does not contain any chemicals required by the IBC Code to be identified as dangerous chemicals in bulk.

Section 15 - REGULATORY INFORMATION

15.1 Safety, Health and Environmental Regulations / Legislation Specific for the Substance or Mixture

EU - REACH (1907/2006) - Annex XIV List of Substances Subject to Authorisation

No components of this material are listed.

EU - REACH (1907/2006) - Article 59(1) Candidate List of Substances Subject to Authorisation

No components of this material are listed.

EU - REACH (1907/2006) - Annex XVII Restrictions of Certain Dangerous Substances, Mixtures and Articles

No components of this material are listed.

Germany Regulations

Germany Water Classification

Dimethyl sulfoxide (67-68-5)

ID Number 5050, hazard class 1 - low hazard to waters

Denmark Regulations

Environmental Protection Agency List of Undesirable Substances

No components of this material are listed.

Substance Analysis - Inventory

Component	CAS	EEC
Dimethyl sulfoxide	67-68-5	EIN

15.2 Chemical Safety Assessment

No chemical safety assessment has been carried out for the substance/mixture.

Section 16 - OTHER INFORMATION

16.1 Indication of changes

New MSDS: 1.0000

16.2 Key / Legend to abbreviations and acronyms used in the safety data sheet

ACGIH - American Conference of Governmental Industrial Hygienists; CA - Canada; CAS - Chemical Abstracts Service; DOT - Department of Transportation; CLP - Classification, Labelling and Packaging; DFG - Deutsche Forschungsgemeinschaft; DSD - Dangerous Substances Directive (67/548/EEC); EC50 - Effective Concentration, 50%; EEC - European Economic Community; EPA - Environmental Protection Agency; EINECS - European Inventory of Existing Commercial Chemical Substances; LC50 - Lethal Concentration, 50%; LD50 - Lethal Dose, 50%; NIOSH - National Institute for Occupational Safety and Health; NTP - National Toxicology Program; OSHA - Occupational Safety and Health Administration; REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals; SARA = Superfund Amendments and Reauthorization Act.; STEL - Short-term Exposure Limit; TDG - Transportation of Dangerous Goods; TWA - Time Weighted Average; WHMIS - Workplace Hazardous Materials Information System

16.3 Key literature references and sources for data

Available upon request

16.4 Methods used for classification of mixture according to Regulation (EC) No 1272/2008

Available upon request

16.5 Full text of R phrases in Section 3

None

16.6 Training Advice

Read the Safety Data Sheet before handling product.

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16.7 Other Information

The information set forth in this Safety Data Sheet does not purport to be all-inclusive and should be used only as a guide. While the information and recommendations set forth herein are believed to be accurate, the company makes no warranty regarding such information and recommendations and disclaims all liability from reliance thereon.

End of Sheet CM-002-EU