Safety Data Sheet

1. PRODUCT AND COMPANY IDENTIFICATION

Product name	:	Microcrystalline Cellulose Ceolus ® KG(KG-802, KG-1000)
Synonym(s)	:	MCC
SDS Reference No.	:	017
General use	:	Excipient for pharmaceuticals
SUPPLYER		Importer
MANUFACTURER		
Company name	:	ASAHI KASEI CORPORATION
Department in charge and address	:	Functional Additives Division, Ceolus Marketing Department Jimbo-cho Mitsui Building, 1-105, Jimbo-cho, Kanda, Chiyoda-ku, Tokyo, JAPAN 101-8101 Telephone No.: +81-3-3296-3361 Functional Additives Division, Ceolus R&D Department, 834 Kawashima-machi, Nobeoka-shi, Miyazaki, JAPAN 882-0017 Telephone No.: +81-982-22-6207
EMERGENCY TELEPHONE NUMBER	:	Functional Additive Division, Ceolus R&D Department Telephone No.: +81-982-22-6207 Mobile phone No.:+81-80-1536-9359
Recommended use and restriction on use	:	Excipient for pharmaceuticals

2. HAZARDS IDENTIFICATION

GHS Classification

Physicochemial hazards : Not classified or not applicable.

Health hazards

Acute toxicity (oral)	: Not classified
Acute toxicity (dermal)	: Not classified
Acute toxicity (inhalation: dust, mist)	: Not classified
Skin corrosion/irritation	: Not classified
Specific target organ toxicity - repeated exposure	: Not classified

Other than listed above are “classification not possible” or “not applicable”.

GHS labeling elements : Not required.

Important hazard statements

Health hazards	:	Very low level of hazards, but symptoms may appear by inhalation, ingestion or dermal absorption depending on personnel. Similarly skin irritation may be caused in persons with hypersensitivity.
Environmental effects	:	No data available.
Physicochemical hazards	:	Flammable. Low possibility of dust explosion, but dust explosion may be caused if the product is mixed with air at appropriate rate (similar to flour or starch).

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical/mixture	: Single product
Chemical name	: Microcrystalline cellulose
Other name	: MCC, Crystalline Cellulose
Component and content	:

Component	Microcrystalline cellulose

Concentration or concentration range (wt%)	More than 93.0 (containing less than 7.0 of moisture)
Chemical formula	$(C_6H_{10}O_5)_n$
Chemical substances control law in Japan	8-568
Industrial safety and health law in Japan	8-568
CAS No.	9004-34-6

4. FIRST AID MEASURES

INHALATION : Remove victim to fresh air and keep at rest. Get medical advice/attention. If breathing is difficult, give oxygen inhalation.

SKN : Wash with plenty of water and soap. If skin irritation occurs, get medical advice.

EYES : Rinse immediately with clean water at least 15 minutes. If eye irritation occurs, get medical attention/advice.

INGESTION : Microcrystalline cellulose is assessed as GRAS (generally recognized as safe) by FDA in the US. Therefore the product is considered to be safe. However, if abnormality is noted after ingestion of a large volume, get medical attention/advice.

PROTECTION OF FIRST-AID RESPONDERS : Wear protective equipment such as dust mask as required.

5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA : Not specified. Use water, carbon dioxide, dry chemical powder, foam extinguisher, etc., as used in the general fire.

PROHIBITED EXTINGUISHING MEDIA : Not specified.

SPECIFIC HAZARD ARISING FROM THE FIRE : Hazardous gas such as carbon monoxide is included in combustion gas.

SPECIFIC FIRE-FIGHTING PROCEDURES : Move the combustion source away from the fire if safe to do. Fight fire from upwind position. Avoid stirring burned objects and spreading the dust.

PROTECTION OF FIRE-FIGHTING PERSONNEL : Wear appropriate protective equipment (gloves, glasses, mask) when fighting fire.

6. ACCIDENTIAL RELEASE MEASURES

PERSONAL SAFETY, PRECAUTIONS, PROTECTIVE EQUIPMENT, AND EMERGENCY MEASURES

: Wear appropriate protective equipment (glasses, mask) and prevent inhalation of dust. Beware of wet slippery floor.

ENVIROMENTAL PRECAUTIONS : Avoid environmental impacts caused by releasing product to rivers, etc.

METHODS AND MATERIALS FOR CONTAINMENT AND CLEAN UP

: Small leakage: Sweep up and collect with electric vacuum cleaner, broom, etc., and dispose of as general waste.

PREVENTIVE MEASURES FOR SECONDARY HAZARDS : Incinerate with subdivided portions because flame may arise if large amount of the waste is put in incinerator. Avoid spreading dust when placing the waste in incinerator because deflagration may occur.

7. HANDLING AND STORAGE

HANDLING

Engineering measures	: Handle in well-ventilated place and use local exhaust, etc., depending on the situation.
Safety handling precautions	: Handle without generating aerosol or dust.
Contact avoidance	: Avoid contact with strong oxidizer because the product is organic mixture.
Hygienic measures	: Wash the hands thoroughly after handling.

STORAGE

Safe storage conditions	: The product deteriorates by light, heat, moisture, etc. Protect from direct sunlight, high temperature and humidity, and store indoors. Avoid transfer of odor or storing in the same place with materials with strong odor.
Safe container/packaging materials	: Store in a plastic bag, etc., after opening the package to prevent moisture absorption.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ADMINISTRATIVE LEVEL : Not established.

ALLOWABLE EXPOSURE LIMIT

Recommendation of The Japan Society for Occupational Health (2012)	: Allowable concentration as Class 3 dust As general dust, 8 mg/m^3 (total dust), 2 mg/m^3 (respirable dust)	
ACGIH (1994-1995)	: 10 mg/m^3 (TWA)	Data of cellulose itself
OSHA	: 15 mg/m^3 (TWA, total dust)	Data of cellulose itself
	5 mg/m^3 (TWA, respirable fraction)	Data of cellulose itself
Facility measures	: Handle without generating dust, especially indoors. Install local exhaust, etc., depending on the situation. It is preferable to install hand- and eye-washing facilities near the handling area and indicate the location clearly.	

PROTECTIVE EQUIPMENT

Respiratory protection	: Use dust mask as required.
Hand protection	: Wear gloves as required.
Eye protection	: Wear safety glasses or goggles as required.
Skin and body protection	: Not specified.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	
Physical state	: Solid
Shape	: Free flowing powder
Color	: White
Odor	: Odorless
pH	: 5.0-7.5 as an 11% solid dispersion
Temperature at which the physical state change	
Melting point, freezing point	: Not applicable
Decomposition temperature	: 310-350oC (microcrystalline cellulose PH-101)
Flash point	: Not applicable
Ignition point	: 310-350oC (microcrystalline cellulose PH-101)
Explosive limits	
Lower limit	: 100 g/m^3 (microcrystalline cellulose KG-802)
Upper limit	: No data available.
Specific gravity (relative density)	: 1.56 g/cm^3 (true density), Approximately 0.10-0.25g/ cm^3 (bulk density)
Solubility	
Water	: Insoluble in water and in most of organic solvent.

Other solvent : Partially soluble in NaOH aq.soln.

10. STABILITY AND REACTIVITY

STABILITY : Chemically stable. Hazardous reaction will not occur by air, light or moisture.

POSSIBILITY OF HAZARDOUS REACTION : May produce heat and ignite in contact with strong oxidizers.

CONDITIONS TO AVOID : High temperature equal to or above ignition point.

INCOMPATIBLE SUBSTANCE : Strong oxidizer and such highly reactive substances.

HAZARDOUS DECOMPOSITION PRODUCTS : Carbon dioxide is produced by combustion. Carbon monoxide may be produced by incomplete combustion.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

- Oral : LD_{50} (rat) of microcrystalline cellulose is reported as >5g/kg.
- Dermal : LD_{50} (rabbit) of microcrystalline cellulose is reported as >2g/kg.
- Inhalation (dust) : Based on the test result of 4-hour LC_{50} (rat) > 5 mg/L.

Skin corrosion/irritation : No irritation to human skin. May cause skin irritation to hypersensitive persons. Primary irritation index (P.I.I.): 0 (Rabbit)

Serious eye damage/eye irritation : Minimally irritating(rabbit).

Respiratory sensitization or skin sensitization : No data available.

Germ cell mutagenicity : Negative (non-mutagenic) in Ames test.

Carcinogenicity : No data available.

Reproductive toxicity : No data available.

Specific target organ toxicity-single exposure : No data available.

Specific target organ toxicity-repeated exposure : No abnormality was noted in blood and histopathological observation in a repeated administration of microcrystalline cellulose in the rat at 2000 mg/kg/day for 90 days. Therefore it is classified as "Not classified".

Aspiration hazard: : No data available.

12. ECOLOGICAL INFORMATION

ECOTOXICITY:

- Acute aquatic hazard (short-term) : Practically nontoxic to fish: Rainbow trout LC_{50} (96hr) > 100%, saturated solution(Microcrystalline cellulose, Avicel PH-101)
- Chronic aquatic hazard (long-term) : No data available.

PERSISTENCE/ DEGRADABILITY : Inherently biodegradable.

BIOACCUMULATION POTENTIAL : No data available.

MOBILITY IN SOIL : No data available.

HAZARDOUS TO THE OZONE LAYER : No data available.

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13. DISPOSAL CONSIDERATIONS

RESIDUAL CONTENTS	: Incinerate in incinerator little by little or contract an agency for industrial waste disposal licensed by the prefectural governor. Before disposing of the empty container, remove content completely.
CONTAMINATED CONTAINER AND PACKAGING	: Recycle the container after cleaning or dispose of correctly according to the related laws and standards of the local public organization.

14. TRANSPORT INFORMATION

International regulations:

U.N. Class	: Not applicable
U.N. number	: Not applicable
Marine pollutant	: Not applicable
Marine pollutant for bulk transport by MARPOL 73/78 Annex II and IBC code	: Not applicable
IMDG (International Maritime Dangerous Good Code) code	: Not applicable to classification criteria.
IATA-DGR (International Air Transport Association's Dangerous Good Regulations)	: Not applicable to classification criteria.

Regulations in Japan

Marine regulations	: Not regulated.
Air regulations	: Not regulated.
Land regulation	: Not regulated.
Special safety precautions and conditions during transport	: Confirm no damage of the container or leakage of the product. Do not transport with strong odor materials and avoid transfer of odor.
Emergency response guide number	: None

15. REGULATORY INFORMATION

16. OTHER INFORMATION

The descriptions herein this safety data sheet (SDS) is based on the currently available data and information, and may be revised by the new knowledge. The precautions herein are for normal handling. If you use this product under the special conditions, take safety measures appropriate for the special use and usage.

If you intend to use this product for purposes other than recommended uses, please contact us in advance as the envisaged uses might not be suitable to the product.
The contents herein are carefully reviewed but no guarantee is given for its integrity or accuracy.

The contents in this SDS were just translated in English from the SDS, written in Japanese for domestic use. **This shall be used only as a reference to prepare of SDSs in compliant with relevant local laws and regulations.**

Reference

JECFA in WHO Food Additives Series vol.40, 1998(Acute toxicity)
Test Data of Huntingdon Life Sciences Ltd. Report No:95/ ASH253/ 1331(Germ cell mutagenicity)