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First issue: June 27, 2009 Revised: Nov. 11, 2011

CeolusTM UF-702, MSDS No.060EU



MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Product Name : Microcrystalline Cellulose

CeolusTM UF-702

: MCC Synonym(s)

: Excipient for pharmaceutical General Use Product Description: Powder of carbohydrate

MSDS Number 060EU

MANUFACTURER

Company Name : Asahi Kasei Chemicals Corporation

Address : Functional Additives Division, Ceolus Marketing Department

1-105 Kanda Jinbocho, Chiyoda-ku, Tokyo 101-8101 Japan

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EMERGENCY TELEPHONE NUMBER:

Asahi Kasei Chemicals Corporation (Ceolus Marketing Dept.)

Telephone No.: +81-90-5202-0970 Mobile phone No.: +81-90-5202-0970

2. HAZARDS IDENTIFICATION

ENVIRONMENT

Inherently biodegradable

PHYSICAL AND CHEMICAL HAZARDS

Combustible powder material. May form flammable / explosive dust-air mixture.

HUMAN HEALTH

Inhalation: Very low hazard in normal use. Dust may be slightly irritating. Eye: Very low hazard in normal use. Dust may cause mechanical irritation.

Skin: Very low hazard in normal use. May cause skin irritation to hypersensitive persons. Ingestion: Very low hazard in normal use. Large doses may results in abnormal symptoms.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name : Microcrystalline Cellulose

CAS Registry Number: 9004-34-6 EINECS Number: 232-674-9

EU Symbols: Not classified as dangerous

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EU Risk Phrases: Not classified as dangerous

EU Safety Advise Phrases: Not classified as dangerous

Chemical Formula : $(C_6H_{10}O_5)_x$

Ingredients (Impurities) & Composition

Microcrystalline Cellulose : 93.0 % or more

4. FIRST AID MEASURES

INHALATION:

Remove to fresh air. If breathing is difficult, give oxygen or get medical attention.

EYE:

Flush eyes with water for at least 15 minutes. Get medical attention, if irritation persists.

SKIN:

Wash with soap and water. Get medical attention, if irritation persists.

INGESTION:

Microcrystalline Cellulose, which is generally recognized as safe by FDA, is very safe to eat.

However, if ingestion of large quantities results in abnormal symptoms, get medical attention.

PROTECTION TO FIRST-AIDERS:

Not specifically.

5. FIRE FIGHTING MEASURES

FLAMMABLE PROPERTIES:

Combustible at elevated temperatures. Contact with strong oxidizers may cause fire.

Dusts at sufficient concentrations can form explosive mixtures with air.

Auto-ignition temperature: 420°C.

Lower explosion limit: $150 \text{ g/m}^3 \text{ (PH-101, D}_{50} = 40 \text{ }\mu\text{m})$

EXTINGUISHING MEDIA:

Generally use extinguishing media such as water, carbon dioxide, dry chemical powder, and foam.

FIRE FIGHTING INSTRUCTIONS:

Evacuate area and fight fire from a safe distance. Wear full fire-fighting turn-out gear (full bunker gear) and respiratory protection (self-contained breathing apparatus) as in an ordinary type of fire.

6. ACCIDENTAL RELEASE MEASURES

Wear appropriate personal protection. (See Section 8.)

LAND SPILL:

Sweep up material and place in a disposal container. Reduce airborne dust and prevent scattering by moistening with water.

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WATER SPILL:

Pick up spill for recovery or disposal and place in a closed container.

7. HANDLING AND STORAGE

HANDLING:

Handle without making air-suspended dust. May form flammable dust-air mixture. Be careful to prevent quality deterioration due to exposure to light, heat, or moisture.

STORAGE:

Store indoors and avoid exposure to direct sunlight, excessive heat and humidity. Storage at room temperature is recommended. Store in a tightly-closed container after opening to avoid moisture absorption. To avoid transfer of odors, refrain from storing near odiferous materials.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMIT VALUES: Cellulose

OSHA Permissible Exposure Limit (PEL):

total dust: 15 mg/m³ TWA, respirable fraction: 5 mg/m³ TWA.

ACGIH Threshold Limit Value (TLV):

 $10 \text{ mg/m}^3 \text{ TWA}$

EXPOSURE CONTROLS

Occupational Exposure Controls

Engineering controls:

Provide local exhaust ventilation, or other engineering controls to control airborne levels below recommended exposure limits. Make available in the work area emergency shower and eye wash, and clarify their locations.

Personal Protection

Respiratory Protection: If airborne concentrations are expected to exceed exposure limits, A air

purifying respirator may be worn.

Eye Protection : Wear safety glasses or safety goggles, if necessary.

Skin Protection : Wear protective gloves, if necessary.

Environmental Exposure Controls

Not specifically

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9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance : White, free flowing powder

Odour : Odorless

pH : 5.0-7.0 as an 11% solid dispersion

Melting Point/Melting Range : Not applicable Decomposition Temperature : 260 - 300°C

Flash Point : Not applicable Auto Ignition Temperature: 420°C Flammability : Flammable

Lower explosion limit: 150 g/m³ (PH-101, $D_{50} = 50 \mu m$)

 $70 \text{ g/m}^3 \text{ (PH-M06, D}_{50} = 14 \text{ } \mu\text{m})$

Relative Density : 1.56 g/cm³ (True density)

Approximately 0.2-0.5 g/cm³ (Bulk density)

Solubility : Insoluble in water and in most of organic solvent.

Partly soluble in NaOH ag.soln.

10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID:

Direct sunlight High temperatures

STABILITY:

Chemically stable when used under normal conditions.

MATERIALS TO AVOID:

Moisture

Oxidizing materials

HAZARDOUS REACTIONS/DECOMPOSITION PRODUCTS

Carbon monoxide and carbon dioxide may form when heated to decomposition.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Ingestion: Oral (Rat): LD50 >5g/kg

Skin absorption: Dermal (Rabbit): LD50 >2g/kg

Inhalation: (Rat): LC50 >5mg/L/4 hours Eye Irritation: Minimally irritating(rabbit).

Skin Irritation: No irritation to human skin. May cause skin irritation to hypersensitive persons.

Primary irritation index (P.I.I.): 0 (Rabbit)

Chronic Toxicity; Microcrystalline Cellulose is regarded as GRAS (generally recognized as safe) by FDA.

Mutagenicity: negative (non-mutagenic) in the Ames test.

Carcinogenicity:

IARC: Not listed

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NTP: Not listed ACGIH: Not listed

12. ECOLOGICAL INFORMATION

ECOTOXICITY

Practically nontoxic to fish: Rainbow trout LC50 (96hr) > 100%, saturated solution (Microcrystalline cellulose, Avicel PH-101)

PERSISTENCE AND BIODEGRADABILITY

Inherently biodegradable.

BIOACCUMULATIVE POTENTIAL

Not available

13. DISPOSAL CONSIDERATIONS

Comply with all EU, national and local regulations.

Do not dump this product into sewers, on the ground or into any body of water.

14. TRANSPORT INFORMATION:

NOTE: Avoid exposure to direct sunlight, high temperature, and moisture.

Be careful not to allow moisture absorption and contamination.

ADR,RID,IMDG,ICAO/IATA

UN Class

UN Number

Not applicable

Not applicable

15. REGULATORY INFORMATION

No labeling requirements under Directives 67/548/EEC and EC 1272/2008.

Additional Regulatory Information: Microcrystalline Cellulose meets the standards set forth in the European Pharmacopeia.

Please refer to any other EU, national and local regulations.

16. OTHER INFORMATION

REFERENCES:

Sigma Aldrich Library of Chemical Safety Data FMC Corporation's MSDS

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