

DI-CUP® 40C

1. PRODUCT AND COMPANY IDENTIFICATION

Company

Arkema Inc. 900 First Avenue

King of Prussia, Pennsylvania 19406

Functional Additives

Customer Service Telephone Number: (800) 331-7654

(Monday through Friday, 8:00 AM to 5:00 PM EST)

Emergency Information

Transportation: CHEMTREC: (800) 424-9300

(24 hrs., 7 days a week)

Medical: Rocky Mountain Poison Center: (866) 767-5089

(24 hrs., 7 days a week)

Product Information

Product name: DI-CUP® 40C

Synonyms: Dicumyl peroxide on a carrier of calcium carbonate

Molecular formula: [C6H5C(CH3)2O]2
Chemical family: Dicumyl peroxide
Product use: initiator/catalyst

2. HAZARDS IDENTIFICATION

Emergency Overview

Color: off-white Physical state: solid Form: powder

Odor: pungent, unpleasant

*Classification of the substance or mixture:

Flammable solids, Category 2, H228 Organic peroxides, Type G Skin irritation, Category 2, H315 Eye irritation, Category 2B, H320 Reproductive toxicity, Category 1B, H360 Chronic aquatic toxicity, Category 2, H411

^{*}For the full text of the H-Statements mentioned in this Section, see Section 16.



DI-CUP® 40C

GHS-Labelling

Hazard pictograms:









Signal word: Danger

Hazard statements:

H228 : Flammable solid.

H315 + H320 : Causes skin and eye irritation. H360 : May damage fertility or the unborn child. H411 : Toxic to aquatic life with long lasting effects.

Supplemental Hazard Statements:

May form combustible dust concentrations in air.

Organic peroxide.

Hazardous decomposition may occur.

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SAFETY DATA SHEET

DI-CUP® 40C

Precautionary statements:

Prevention:

P201: Obtain special instructions before use.

P202 : Do not handle until all safety precautions have been read and understood.

P210 : Keep away from heat/sparks/open flames/hot surfaces. No smoking.

P240: Ground/bond container and receiving equipment.

P241: Use explosion-proof electrical/ ventilating/ lighting equipment.

P264: Wash skin thoroughly after handling. P273: Avoid release to the environment.

P280: Wear protective gloves or eye protection or face protection.

P281: Use personal protective equipment as required.

Response:

P302 + P352: IF ON SKIN: Wash with plenty of soap and water.

P305 + P351 + P338 : IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P308 + P313 : IF exposed or concerned: Get medical advice/ attention. P332 + P313 : If skin irritation occurs: Get medical advice/ attention.

P337 + P313 : If eye irritation persists: Get medical advice/ attention. P362 : Take off contaminated clothing and wash before reuse.

P370 + P378 : In case of fire: Use dry sand, dry chemical or alcohol-resistant foam for extinction.

P391: Collect spillage.

Storage:

P405: Store locked up.

Disposal:

P501: Dispose of contents or container to an approved waste disposal plant.

Supplemental information:

Potential Health Effects:

Mechanical irritation effects from dust exposure are possible at ambient temperature.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS-No.	Wt/Wt	GHS Classification**
Carbonic acid calcium salt (1:1)	471-34-1	>= 58 - <= 65 %	Not classified



DI-CUP® 40C

Peroxide, bis(1-methyl-1-phenylethyl)	80-43-3	>= 35 - <= 42 %	H242, H315, H320, H360, H411
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^{**}For the full text of the H-Statements mentioned in this Section, see Section 16.

4. FIRST AID MEASURES

4.1. Description of necessary first-aid measures:

Inhalation:

If inhaled, remove victim to fresh air.

Skin:

In case of contact, immediately flush skin with plenty of water. Get medical attention. Remove contaminated clothing and shoes. Wash clothing before reuse. Thoroughly clean shoes before reuse.

Eves:

Immediately flush eye(s) with plenty of water. Get medical attention.

Ingestion:

If swallowed, DO NOT induce vomiting. Get medical attention. Never give anything by mouth to an unconscious person.

4.2. Most important symptoms/effects, acute and delayed:

For most important symptoms and effects (acute and delayed), see Section 2 (Hazard Statements and Supplemental Information if applicable) and Section 11 (Toxicology Information) of this SDS.

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

Unless otherwise noted in Notes to Physician, no specific treatment noted; treat symptomatically.

5. FIREFIGHTING MEASURES

Extinguishing media (suitable):

Water spray, Foam, Dry chemical, Carbon dioxide (CO2)

Extinguishing media (unsuitable):

High volume water jet

Protective equipment:

Fire fighters and others who may be exposed to products of combustion should wear full fire fighting turn out gear (full Bunker Gear) and self-contained breathing apparatus (pressure demand / NIOSH approved or equivalent).



DI-CUP® 40C

Further firefighting advice:

Do not use a solid stream of water.

A solid stream of water can cause a dust explosion.

Fight fire with large amounts of water from a safe distance.

Cool closed containers exposed to fire with water spray.

Closed containers of this material may explode when subjected to heat from surrounding fire.

After a fire, wait until the material has cooled to room temperature before initiating clean-up activities.

Do not allow run-off from fire fighting to enter drains or water courses.

Fire fighting equipment should be thoroughly decontaminated after use.

Fire and explosion hazards:

Contact with incompatible materials or exposure to temperatures exceeding the SADT may result in a self accelerating decomposition reaction with release of flammable vapors which may autoignite. Dust clouds generated during handling and/or storage can form explosive mixtures with air. Dust explosion characteristics vary with the particle size, particle shape, moisture content, contaminants, and other variables. Note: Check that all equipment is properly grounded and installed to satisfy electrical classification requirements. As with any dry material, pouring this material or allowing it to free-fall or to be conveyed through chutes or pipes can accumulate and generate electrostatic sparks, potentially causing ignition of the material itself, or of any flammable materials which may come into contact with the material or its container.

When burned, the following hazardous products of combustion can occur:

Carbon oxides
Aromatic derivatives
Hazardous organic compounds

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, Emergency procedures, Methods and materials for containment/clean-up:

Prevent further leakage or spillage if you can do so without risk. Evacuate area of all unnecessary personnel. Ventilate the area. Eliminate all ignition sources. Avoid dust formation and dispersal of dust in the air. Wet down (dampen) the spilled material with water. Sweep or scoop up using non-sparking tools and place into suitable properly labeled containers for prompt disposal. The sweepings should be wetted down further with water. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Implement workplace practices such that dusts are not allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits.

Protective equipment:

Appropriate personal protective equipment is set forth in Section 8.



DI-CUP® 40C

7. HANDLING AND STORAGE

Handling

General information on handling:

Contact with materials to avoid or exposure to temperatures exceeding the SADT may result in a self-accelerating decomposition reaction with release of flammable vapors which may autoignite.

Do not taste or swallow.

Do not get in eyes, on skin, or on clothing.

Keep away from heat, sparks and flames.

Do not breathe dust.

Wash thoroughly after handling.

Keep container tightly closed and away from combustible materials.

Prevent product contamination.

No smoking.

Use only with adequate ventilation.

Keep only in the original container.

Prevent dust accumulation.

Implement routine housekeeping practices to ensure that dusts do not accumulate on surfaces.

Check that all equipment is properly grounded and installed to satisfy electrical classification requirements.

Dry powders can build static electricity charges when subjected to the friction of transfer and mixing operations.

Avoid creating dust in handling, transfer or clean up.

RESIDUAL DUSTS MAY EXPLODE ON IGNITION.

DO NOT CUT, DRILL, GRIND, OR WELD ON OR NEAR THIS CONTAINER.

Container hazardous when empty.

Follow label warnings even after container is emptied.

Improper disposal or reuse of this container may be dangerous and/or illegal.

Emptied container retains product residue.

Storage

General information on storage conditions:

Keep in a dry, cool place. Keep container closed when not in use. Store in original container. Store in upright position only. Segregated or detached storage is preferred. Store out of direct sunlight in a cool well-ventilated place. Store away from combustibles and materials to avoid. Store in closed containers, in a secure area to prevent container damage and subsequent spillage. Store in well ventilated area away from heat and sources of ignition such as flame, sparks and static electricity. Ensure that all storage and handling equipment is properly grounded and installed to satisfy electrical classification requirements. Static electricity may accumulate when transferring material. All metal and groundable storage containers, including but not limited to drums, cylinders, Returnable Intermodal Bulk Containers (RIBCs) and Class C Flexible Intermodal Bulk Containers (FIBCs) must be bonded and grounded during filling and emptying operations. Observe all federal, state and local regulations and National Fire Protection Association (NFPA) Codes, which pertain to the specific local conditions of storage and use, including NFPA 654.

Refer also to National Fire Protection Association (NFPA) Code 400, Hazardous Materials Code. Observe all federal, state and local regulations and National Fire Protection Association (NFPA) Codes which pertain to the specific local conditions of storage and use, including OSHA 29 CFR 1910.106 and NFPA 30, 70, 77, and 497.

Storage stability - Remarks:

Follow the recommended storage temperatures provided in this Section in order to maintain stability and oxygen content.

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SAFETY DATA SHEET

DI-CUP® 40C

Storage incompatibility - General:

Store away from excessive heat, sources of ignition, and reactive materials.

Store separate from:

Strong acids

Strong oxidizing agents

Reducing agents

Accelerators

Friedel - Crafts reaction catalyst

Brass

Copper

Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Temperature tolerance - Do not store above:

86 °F (30 °C)

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Airborne Exposure Guidelines:

Carbonic acid calcium salt (1:1) (471-34-1)

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Form: Respirable fraction.

PEL: 5 mg/m3

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Form: Total dust PEL: 15 mg/m3

Only those components with exposure limits are printed in this section. Limits with skin contact designation above have skin contact effect. Air sampling alone is insufficient to accurately quantitate exposure. Measures to prevent significant cutaneous absorption may be required. Limits with a sensitizer designation above mean that exposure to this material may cause allergic reactions.

Engineering controls:

Investigate engineering techniques to reduce exposures below airborne exposure limits or to otherwise reduce exposures. Provide ventilation if necessary to minimize exposures or to control exposure levels to below airborne exposure limits (if applicable see above). If practical, use local mechanical exhaust ventilation at sources of air contamination such as open process equipment.

Check that all dust control equipment such as local exhaust ventilation, material transport systems, and airmaterial separation devices involved in handling this product contain explosion relief vents or an explosion suppression system or an oxygen-deficient environment. Isolation devices may be appropriate to prevent propagation from one unit to another. Ensure that dust-handling systems are designed in a manner to prevent the escape of dust into the work area (i.e., there is no leakage from the equipment). Consult ACGIH ventilation



DI-CUP® 40C

manual, NFPA Standard 91 and NFPA Standard 654 for design of exhaust system and safe handling.

Respiratory protection:

Do not breathe dust. Where airborne exposure is likely or airborne exposure limits are exceeded (if applicable, see above), use NIOSH approved respiratory protection equipment appropriate to the material and/or its components. Full facepiece equipment is recommended and, if used, replaces need for face shield and/or chemical goggles. Consult respirator manufacturer to determine appropriate type equipment for a given application. Observe respirator use limitations specified by NIOSH or the manufacturer. For emergency and other conditions where there may be a potential for significant exposure or where exposure limit may be significantly exceeded, use an approved full face positive-pressure, self-contained breathing apparatus or positive-pressure airline with auxiliary self-contained air supply. Respiratory protection programs must comply with 29 CFR § 1910.134.

Skin protection:

Wear appropriate chemical resistant protective clothing and chemical resistant gloves to prevent skin contact. Consult glove manufacturer to determine appropriate type glove material for given application. Rinse immediately if skin is contaminated. Wash contaminated clothing and clean protective equipment before reuse. Provide a safety shower at any location where skin contact can occur. Wash thoroughly after handling.

Eye protection:

Where there is potential for eye contact, wear chemical goggles and have eye flushing equipment immediately available.

9. PHYSICAL AND CHEMICAL PROPERTIES

Color: off-white

Physical state: solid

Form: powder

Odor: pungent, unpleasant

Odor threshold: No data available

Flash point Not applicable

Auto-ignition

temperature:

No data available.

Lower flammable limit

(LFL):

Not determined

Upper flammable limit

(UFL):

Not determined

pH: Not applicable

Density: No data available.

Specific Gravity (Relative No data available



DI-CUP® 40C

density):

Vapor pressure: No data available.

Vapor density: 5.8 kg/m3

Boiling point/boiling

range:

Decomposes before boiling.

Melting point/range: No data available

Freezing point: No data available

Evaporation rate: No data available

Solubility in water: Negligible

Burning rate: 2.9 mm/s (Method: The Manual of Tests and Criteria - Part 33.2.1) Wetted zone

stops the fire for at least 4 minutes.

Viscosity, dynamic: No data available

Oil/water partition

coefficient:

No data available.

Self-Accelerating Decomposition Temperature (SADT): 196 °F (91 °C) 40 pound container Expressed as pure peroxide

Thermal decomposition: No data available

Active oxygen content: 2.36 %

Flammability: See GHS Classification in Section 2 if applicable

10. STABILITY AND REACTIVITY

Stability:

This material is chemically unstable and should only be handled under specified conditions. See HANDLING AND STORAGE section of this MSDS for specified conditions.

Hazardous reactions:

Hazardous polymerization does not occur.

Materials to avoid:

Strong acids Strong oxidizing agents Reducing agents Accelerators

Friedel - Crafts reaction catalyst

Brass

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SAFETY DATA SHEET

DI-CUP® 40C

Copper

Iron

For all Organic Peroxides, compatible materials of contact are stainless steel 304 or 316 (preferred), high-density polyethylene (HDPE), polytetrafluoroethylene or glass linings.

Conditions / hazards to avoid:

See HANDLING AND STORAGE section of this MSDS for specified conditions. SADT - Self Accelerating Decomposition Temperature. Lowest temperature at which the tested package size will undergo a self-accelerating decomposition reaction. This reaction will generate flammable vapors which may autoignite. The length of time to generate a decomposition reaction, after the SADT has been reached or exceeded, is dependent upon how much the SADT has been exceeded and the length of time needed for the reaction exotherm (heat spike from increasing decomposition rate) to initiate a rapid decomposition reaction. Typically, SADT is inversely proportional to package size. Larger packages will have a lower SADT due to smaller ratio to heat transfer area to volume of product.

Hazardous decomposition products:

Temperatures at or above SADT can result in the release of hazardous decomposition products which are flammable and may autoignite.

Thermal decomposition giving flammable and toxic products:

Carbon oxides

Aromatic derivatives

Hazardous organic compounds

11. TOXICOLOGICAL INFORMATION

Data on this material and/or its components are summarized below.

Data for Carbonic acid calcium salt (1:1) (471-34-1)

Acute toxicity

Oral:

No deaths occurred. (rat) LD0 > 2,000 mg/kg.

Dermal:

No deaths occurred. (rat) LD0 > 2,000 mg/kg.

Inhalation:

No deaths occurred. (rat) 4 h LC0 > 3 mg/l. (dust/mist, Maximum concentration technically possible)

Skin Irritation:

Not irritating. (rabbit) (4 h)

Eye Irritation:

Causes mild eye irritation. (rabbit)

Skin Sensitization:

Not a sensitizer. LLNA: Local Lymph Node Assay. (mouse) No skin allergy was observed.

Repeated dose toxicity

Repeated oral administration to rat, mouse / No adverse systemic effects reported.



DI-CUP® 40C

Genotoxicity

Assessment in Vitro:

No genetic changes were observed in laboratory tests using: bacteria, animal cells, human cells

Developmental toxicity

Exposure during pregnancy. Oral (sheep) / bone effects in lambs (at doses that produce effects in mothers, blood chemistry changes)

Exposure during pregnancy. Oral (rat) / No birth defects were observed.

Reproductive effects

Reproductive/Developmental Effects Screening Assay. Oral (rat) / No toxicity to reproduction

Human experience

General:

Dust contact with the eyes can lead to mechanical irritation. Contact with dust can cause mechanical irritation or drying of the skin.

Human experience

Inhalation:

Upper respiratory tract: Local irritation, coughing. (dust) (severity of effects depends on extent of exposure)

Human experience

Ingestion:

Kidney: failure, weakness, nausea. (effects of excessive exposure)

Data for Peroxide, bis(1-methyl-1-phenylethyl) (80-43-3)

Acute toxicity

Oral:

No deaths occurred. (rat) LD0 > 2,000 mg/kg.

Dermal:

No deaths occurred. (rat) LD0 > 2,000 mg/kg.

Inhalation:

No deaths occurred. (rat, rabbit) 6 h LC0 >= 0.224 mg/l. (40 %) (dust/mist, maximum achieved concentration)

Skin Irritation:

Practically non-irritating. (rabbit) (4 h)

Eye Irritation:

Not irritating. (rabbit)

Skin Sensitization:

Not a sensitizer. LLNA: Local Lymph Node Assay. (mouse) No skin allergy was observed.

Repeated dose toxicity

Subchronic oral administration to rat / affected organ(s): liver, kidney / signs: changes in organ weights,



DI-CUP® 40C

clinical chemistry changes

Genotoxicity

Assessment in Vitro:

No genetic changes were observed in laboratory tests using: bacteria, animal cells

Developmental toxicity

Exposure during pregnancy. oral (rat) / Birth defects were observed. (levels produced toxic effects in the mothers and offspring)

Human experience

Inhalation:

Respiratory tract: Dust and/or vapor are reported to cause irritation when proper industrial hygiene controls/procedures are not used.

Nose: irritation, nosebleeds, appearance of visible blood vessels in the nose. (repeated or prolonged exposure) (based on reports of occupational exposure to workers)

Human experience

Skin contact:

Irritant but not a sensitizer.

Human experience

Eye contact:

Dust and/or vapor are reported to cause irritation when proper industrial hygiene controls/procedures are not used. (based on reports of occupational exposure to workers)

12. ECOLOGICAL INFORMATION

Chemical Fate and Pathway

Data on this material and/or its components are summarized below.

Data for Peroxide, bis(1-methyl-1-phenylethyl) (80-43-3)

Biodegradation:

Not readily biodegradable. (28 d) biodegradation 44 %

Bioaccumulation:

56 d = 137 - 1,470 (Carp)

Octanol Water Partition Coefficient:

log Pow: = 5.6, at 77 °F (25 °C)

Photodegradation:

Air reaction with OH radicals Half-life direct photolysis: 23 h

Mobility and Distribution in the Environment:

Strong adsorption / Log Koc = 3.56



DI-CUP® 40C

Ecotoxicology

Data on this material and/or its components are summarized below.

Data for Carbonic acid calcium salt (1:1) (471-34-1)

Aquatic toxicity data:

No effect up to the limit of solubility. Oncorhynchus mykiss (rainbow trout) 96 h LC50 > 100 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Aquatic invertebrates:

No effect up to the limit of solubility. Daphnia magna (Water flea) 48 h EC50 > 100 mg/l (Nominal concentration, Water accommodated fraction was tested.)

Algae:

No effect up to the limit of solubility. Desmodesmus subspicatus (green algae) 72 h EC50 > 14 mg/l (Water accommodated fraction was tested.)

Microorganisms:

Respiration inhibition / Activated sludge 3 h EC50 > 1,000 mg/l

Chronic toxicity to aquatic plants:

No effect up to the limit of solubility. Desmodesmus subspicatus (green algae) 72 h NOEC = 14 mg/l (Water accommodated fraction was tested.)

Data for Peroxide, bis(1-methyl-1-phenylethyl) (80-43-3)

Aquatic invertebrates:

No effect up to the limit of solubility. Daphnia magna (Water flea) 48 h EC50 > 100 mg/l (Nominal concentration)

Algae:

No effect up to the limit of solubility. Pseudokirchneriella subcapitata (algae) 72 h EC50 > 20 mg/l (Nominal concentration)

Microorganisms:

Respiration inhibition / Activated sludge 30 min NOEC > 1,000 mg/l

Chronic toxicity to aquatic invertebrates:

Toxic. Reproduction Test / Daphnia magna (Water flea) 21 d NOEC r = 0.117 mg/l

Chronic toxicity to aquatic plants:

Practically nontoxic. Pseudokirchneriella subcapitata (green algae) 72 h NOEC r = 10 mg/l

13. DISPOSAL CONSIDERATIONS

Waste disposal:

Disposal via incineration is recommended. Dispose of in accordance with federal, state and local regulations. Consult a regulatory specialist to determine appropriate state or local reporting requirements, for assistance in waste characterization and/or hazardous waste disposal and other requirements listed in pertinent environmental permits. Note: Chemical additions to, processing of, or otherwise altering this material may make this waste management information incomplete, inaccurate, or otherwise inappropriate. Furthermore, state and local waste

DI-CUP® 40C

disposal requirements may be more restrictive or otherwise different from federal laws and regulations.

Take appropriate measures to prevent release to the environment.

14. TRANSPORT INFORMATION

US Department of Transportation (DOT)

UN Number 1325

Proper shipping name Flammable solids, organic, n.o.s. **Technical name** (Dicumyl peroxide, <= 52%)

Class 4.1 Packaging group Ш Marine pollutant ves

International Maritime Dangerous Goods Code (IMDG)

UN Number

Proper shipping name FLAMMABLE SOLID, ORGANIC, N.O.S.

Technical name (DICUMYL PEROXIDE, <= 52%)

Class 4.1 **Packaging group** Ш Marine pollutant yes

Japan. ISHL - Inventory of Chemical Substances

15. REGULATORY INFORMATION

Chemical Inventory Status

US. Toxic Substances Control Act **TSCA** The components of this product are all on

the TSCA Inventory.

All components of this product are on the Canadian Domestic Substances List (DSL) DSL

ISHL (JP)

Canadian DSL

Conforms to

China. Inventory of Existing Chemical Substances in IECSC (CN) Conforms to

China (IECSC)

Japan. ENCS - Existing and New Chemical ENCS (JP) Conforms to

Substances Inventory

Korea. Korean Existing Chemicals Inventory (KECI) KECI (KR) Conforms to

Philippines Inventory of Chemicals and Chemical PICCS (PH) Conforms to

Substances (PICCS)

Australia Inventory of Chemical Substances (AICS) **AICS** Conforms to

Product code: 103208 Version 4.0 Issued on: 03/01/2021 Page: 14 / 16



DI-CUP® 40C

United States - Federal Regulations

SARA Title III - Section 302 Extremely Hazardous Chemicals:

The components in this product are either not SARA Section 302 regulated or regulated but present in negligible concentrations.

SARA Title III - Section 311/312 Hazard Categories:

Acute Health Hazard, Chronic Health Hazard, Fire Hazard, Reactivity Hazard

SARA Title III - Section 313 Toxic Chemicals:

This material does not contain any chemical components with known CAS numbers that exceed the threshold (De Minimis) reporting levels established by SARA Title III, Section 313.

Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) - Reportable Quantity (RQ):

The components in this product are either not CERCLA regulated, regulated but present in negligible concentrations, or regulated with no assigned reportable quantity.

United States - State Regulations

New Jersey Right to Know

<u>Chemical name</u>	<u>CAS-No.</u>
Carbonic acid calcium salt (1:1)	471-34-1

Pennsylvania Right to Know

Chemical name	CAS-No.
Carbonic acid calcium salt (1:1)	471-34-1

Peroxide, bis(1-methyl-1-phenylethyl) 80-43-3

California Prop. 65

This product does not contain any chemicals known to the State of California to cause cancer, birth defects, or any other reproductive defects.

16. OTHER INFORMATION



DI-CUP® 40C

Full text of H-Statements referred to under sections 2 and 3.

H228 Flammable solid.

H242 Heating may cause a fire.H315 Causes skin irritation.H320 Causes eye irritation.

H360 May damage fertility or the unborn child.H411 Toxic to aquatic life with long lasting effects.

Miscellaneous:

Other information: Refer to National Fire Protection Association (NFPA) Code 654,

Standard for the Prevention of Fire and Dust Explosions from the Manufacturing, Processing, and Handling of Combustible Particulate

Solids, for safe handling.

Latest Revision(s):

 Reference number:
 200008780

 Date of Revision:
 03/01/2021

 Date Printed:
 03/02/2021

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Arkema has implemented a Medical Policy regarding the use of Arkema products in Medical Devices applications that are in contact with the body or circulating bodily fluids (http://www.arkema.com/en/social-responsibility/responsible-product-management/medical-device-policy/index.html) Arkema has designated Medical grades to be used for such Medical Device applications. Products that have not been designated as Medical grades are not authorized by Arkema for use in Medical Device applications that are in contact with the body or circulating bodily fluids. In addition, Arkema strictly prohibits the use of any Arkema products in Medical Device applications that are implanted in the body or in contact with bodily fluids or tissues for greater than 30 days. The Arkema trademarks and the Arkema name shall not be used in conjunction with customers' medical devices, including without limitation, permanent or temporary implantable devices, and customers shall not represent to anyone else, that Arkema allows, endorses or permits the use of Arkema products in such medical devices.

It is the sole responsibility of the manufacturer of the medical device to determine the suitability (including biocompatibility) of all raw materials, products and components, including any medical grade Arkema products, in order to ensure that the final end-use product is safe for its end use; performs or functions as intended; and complies with all applicable legal and regulatory requirements (FDA or other national drug agencies). It is the sole responsibility of the manufacturer of the medical device to conduct all necessary tests and inspections and to evaluate the medical device under actual end-use requirements and to adequately advise and warn purchasers, users, and/or learned intermediaries (such as physicians) of pertinent risks and fulfill any postmarket surveillance obligations. Any decision regarding the appropriateness of a particular Arkema material in a particular medical device should be based on the judgment of the manufacturer, seller, the competent authority, and the treating physician.