

SAFETY DATA SHEET

1. IDENTIFICATION

Product identifier: FM CONT ICAPS AREDS II

Synonyms: 6G5

Manufacturer Name: Perrigo Company

Address: 515 Eastern Avenue
Allegan, MI 49010 USA

Telephone number: 269-673-8451

Emergency phone number: 888-464-2986 (U.S. calls)
+1 760-4767-3962 Code 333304 (International calls)

Distributor Name: Alcon Laboratories, Inc

Address: 6201 S. Freeway
Fort Worth, TX 76134

Recommended use: Dietary Supplement

Restrictions on use: Use only as directed.

2. HAZARD(S) IDENTIFICATION

Classification:

Physical	Health
Not hazardous	Not Hazardous

Label Elements

Not hazardous in accordance with the GHS and OSHA Hazcom 2012.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical name	CAS No.	Concentration
Ascorbic Acid	50-81-7	Proprietary
DL Alpha Tocopherol	10191-41-0	Proprietary
Gelatin	9000-70-8	Proprietary
Soybean Oil	8001-22-7	Proprietary
Glycerol	56-81-5	Proprietary
Lutein	127-40-2	Proprietary
Water	7732-18-5	Proprietary
Yellow Beeswax	8006-40-4	Proprietary
Zinc Oxide	1314-13-2	<2%
Silicon Dioxide	7631-86-9	Proprietary
Caramel Powder	8028-89-5	Proprietary
Copper Gluconate	527-09-3	Proprietary
Lecithin	85711-58-6	Proprietary
Zeaxanthin	144-68-3	Proprietary

The exact percentage (concentration) of composition has been withheld as a trade secret.

4. FIRST-AID MEASURES

Inhalation: Remove victim to fresh air. If irritation occurs, get medical attention.

Skin contact: In the case of contact with crushed or broken capsules, remove contaminated clothing. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.

Eye contact: Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.

Ingestion: In the case of unintended ingestion, rinse mouth with water. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if any adverse effects occur.

Most important symptoms/effects, acute and delayed: Capsule contents may cause eye irritation. Inhalation of dust or mists from broken capsules may cause upper respiratory tract irritation.

Indication of immediate medical attention and special treatment, if necessary: Immediate medical attention is not required.

5. FIRE-FIGHTING MEASURES

Extinguishing media: Use water spray, carbon dioxide, dry chemical or foam to extinguish a fire.

Specific hazards arising from the chemical: Capsules are not a fire hazard but may burn under fire conditions.

Special protective equipment and precautions for fire-fighters: Firefighters should wear positive pressure self-contained breathing apparatus and full protective clothing for all fires involving chemicals.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment, and emergency procedures: Wear appropriate protective clothing and equipment as described in Section 8.

Environmental Precautions: Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.

Methods and materials for containment and cleaning up: Collect using methods that avoid the generation of dust and damage to capsules (scoop up carefully) and place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE

Precautions for safe handling: Avoid the generation of dust or mists. If capsules are damaged, avoid contact with eyes, skin and clothing and avoid breathing dust.

Conditions for safe storage, including any incompatibilities: Store as indicated on product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure guidelines:

Ascorbic Acid	
DL Alpha Tocopherol	None Established
Gelatin	None Established
Soybean Oil (as vegetable oil mists)	5 mg/m ³ TWA (respirable) 15 mg/m ³ TWA (total dust) OSHA PEL
Glycerol	5 mg/m ³ TWA (respirable) 15 mg/m ³ TWA (total dust) OSHA PEL
Lutein	
Yellow beeswax	None Established
Zinc Oxide	2 mg/m ³ (respirable) TWA, 10 mg/m ³ (respirable) STEL ACGIH TLV 5 mg/m ³ (respirable), 15 mg/m ³ (total dust) TWA OSHA PEL
Silicon Dioxide	80 mg/m ³ / %SiO ₂ TWA OSHA PEL
Caramel Powder	None Established
Copper Gluconate	10 mg/m ³ TWA ACGIH TLV 5 mg/m ³ (respirable); 15 mg/m ³ (total dust) TWA OSHA PEL
Lecithin	None Established
Zeaxanthin	10 mg/m ³ TWA total dust ACGIH TLV

Appropriate engineering controls: Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits.

Individual protection measures:

Respiratory protection: None needed under normal use conditions. If exposure limits are exceeded, a NIOSH approved particulate respirator is recommended. Selection of respiratory protection depends on the contaminant type, form and concentration. Select in accordance with OSHA 1910.134 and good Industrial Hygiene practice.

Skin protection: None normally required.

Eye protection: Safety glasses or goggles recommended for handling damaged capsules.

Other: None known.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance (physical state, color, etc.): Dark brown oblong softgel capsule

Odor: None

Odor threshold: Not applicable	pH: Not applicable
Melting point/freezing point: Not applicable	Boiling Point: Not applicable
Flash point: Not applicable	Evaporation rate: Not applicable
Flammability (solid, gas): Not flammable	VOC: Not applicable
Flammable limits: LEL: Not applicable	UEL: Not applicable
Vapor pressure: Not applicable	Vapor density: Not applicable
Relative density: Not available	Solubility(ies): Not available
Partition coefficient: n-octanol/water: Not available	Auto-ignition temperature: Not available
Decomposition temperature: Not available	Viscosity: Not applicable

10. STABILITY AND REACTIVITY

Reactivity: Not reactive under normal conditions of use.

Chemical stability: Stable.

Possibility of hazardous reactions: None known.

Conditions to avoid: None known.

Incompatible materials: Avoid oxidizing agents.

Hazardous decomposition products: Thermal decomposition may yield carbon oxides.

11. TOXICOLOGICAL INFORMATION

Acute effects of exposure:

Inhalation: Inhalation of dust or mists from damaged capsules may cause irritation of the mucous membranes and upper respiratory tract.

Ingestion: Swallowing amounts above the recommended dosage may cause gastrointestinal upset.

Skin contact: Contact with damaged capsules may cause slight irritation.

Eye contact: Contact with damaged capsules may cause slight irritation with redness and tearing.

Chronic Effects: None known.

Sensitization: Components are not known to be sensitizers.

Germ Cell Mutagenicity: None of the components have been shown to cause germ cell mutagenicity.

Reproductive Toxicity: None of the components have been shown to cause reproductive toxicity.

Carcinogenicity: None of the components are listed as carcinogens or suspected carcinogens by IARC, NTP, ACGIH or OSHA.

Acute Toxicity Values: Components are not acutely toxic.

12. ECOLOGICAL INFORMATION

Ecotoxicity values: This product is classified as harmful to aquatic organisms with long-term effects

Zinc Oxide: LC50 pimephales promelas 0.33 – 0.78 mg/L/96 hr; EC50 daphnia magna 1.1 – 13.4 mg/L/48 hr

Persistence and degradability: No data is available

Bioaccumulative potential: No data is available

Mobility in soil: No data is available.

Other adverse effects: None known.

13. DISPOSAL CONSIDERATIONS

Dispose in accordance with all local, state and federal regulations. No specific disposal method is recommended.

14. TRANSPORT INFORMATION

	UN Number	Proper shipping name	Hazard Class	Packing Group	Environmental Hazard
DOT		Not Regulated			
TDG		Not Regulated			
IMDG		Not Regulated			
IATA		Not Regulated			

Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code): Not applicable – product is transported only in packaged form.

Special precautions: None known.

15. REGULATORY INFORMATION

Safety, health, and environmental regulations specific for the product in question.

CERCLA: This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations.

SARA Hazard Category (311/312): Not Hazardous

EPA SARA 313: This product contains the following chemicals regulated under SARA Title III, section 313:

Zinc compounds <2%

Copper Compounds <1%

EPA TSCA Inventory: This product is a drug and not subject to TSCA.

CANADA:

Canadian CEPA: This product is a drug and not subject to CEPA regulations.

Canadian WHMIS Classification: Drugs are exempt from WHMIS

This product has been classified under the CPR and this SDS discloses information elements required by the CPR.

16. OTHER INFORMATION

NFPA Rating: Health = 1	Flammability = 1	Instability = 0
HMIS Rating: Health = 1	Flammability = 1	Physical Hazard = 0

SDS Revision History: New SDS

Date of preparation: 4/9/2015

Disclaimer: This SDS has been prepared for occupational exposure. Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. Although reasonable care has been taken in the preparation of this document, we extend no warranties and make no representations as to the accuracy of the information contained therein, and assume no responsibility regarding the suitability of this information for the user's intended purposes or for the consequence of its use. Each individual should make a determination as to the suitability of the information for their particular purpose(s).