

MATERIAL SAFETY DATA SHEET

Alubra™ PG 100

FMC BioPolymer

MSDS Ref. No.: 4070808

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Revision No.: 1

This document has been prepared to meet the requirements of the U.S. OSHA Hazard Communication Standard, 29 CFR 1910.1200 and Canada's Workplace Hazardous Materials Information System (WHMIS) requirements.

1. PRODUCT AND COMPANY IDENTIFICATION

PRODUCT NAME: Alubra™ PG 100

SYNONYMS: Sodium Octadecy Fumarate; 2-Butenedioic acid (2E)-, monooctadecyl ester, sodium salt

GENERAL USE: Pharmaceutical Excipient

**Finished and processed in the
United States
Made in India**

FMC BioPolymer
1735 Market Street
Philadelphia, PA 19103
(800) 526-3649 (General Information)
msdsinfo@fmc.com (Email - General Information)

FMC Europe NV
Avenue Mounier 83
1200 Brussels, Belgium
353 21 435 4133 (General Information - Cork,
Ireland)

EMERGENCY TELEPHONE NUMBERS

(302) 451-0100 (FMC Plant - Newark, Delaware)

(303) 595-9048 (Medical - U.S. - Call Collect)

For leak, fire, spill, or accident emergencies, call:
(800) 424-9300 (CHEMTREC - U.S.A. & Canada)
(703) 527-3887 (CHEMTREC - Collect - All Other Countries)

2. HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:

- Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed.
- Powder becomes slippery when wet.

POTENTIAL HEALTH EFFECTS: May cause eye and skin irritation. Effects from overexposure may result from either swallowing, inhaling or coming into contact with the eyes or skin.

3. COMPOSITION / INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Wt.%	EC No.	EC Class
Sodium stearyl fumarate	4070-80-8	100	223-781-1	Not classified

4. FIRST AID MEASURES

EYES: Flush with water for at least 15 minutes. If irritation occurs and persists, obtain medical attention.

SKIN: Wash with plenty of soap and water.

INGESTION: Drink plenty of water. Never give anything by mouth to an unconscious person. If any discomfort persists, obtain medical attention.

INHALATION: Remove to fresh air. If breathing difficulty or discomfort occurs and persists, obtain medical attention.

NOTES TO MEDICAL DOCTOR: This product is expected to have low oral, dermal and inhalation toxicity. It may be irritating to the eyes, skin, respiratory tract and mucous membranes.

5. FIRE FIGHTING MEASURES

EXTINGUISHING MEDIA: Water

FIRE / EXPLOSION HAZARDS: The accumulation of excessive dust on overhead structures may produce explosive concentrations when disturbed and dispersed. According to NFPA 68, (Explosion Venting Guide), the Hazard Class of Dust Deflagrations for microcrystalline cellulose is St-1, the lowest hazard class.

FIRE FIGHTING PROCEDURES: For fires involving this material, do not enter any enclosed or confined fire space without wearing full protective clothing and self-contained breathing apparatus (SCBA) approved for firefighting. This is necessary to protect against the hazards of heat, products of combustion and oxygen deficiency. Do not breathe smoke, gases or vapors generated.

FLAMMABLE LIMITS: Not applicable

6. ACCIDENTAL RELEASE MEASURES

RELEASE NOTES: Powder becomes slippery when wet. Maintain good housekeeping practices to minimize accumulation of settled dust, especially on overhead surfaces. Sweep up the spilled material and dispose of in accordance with the waste disposal method outlined in Section 13, "Disposal Considerations".

7. HANDLING AND STORAGE

HANDLING AND STORAGE: Use local exhaust or general dilution ventilation to control exposure to dust. Always use safe lifting techniques when manually moving containers, especially when handling containers weighing more than 50 pounds (22.7 kg). To protect quality, store in a tight container in a dry place. Avoid exposure to excessive heat.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

PERSONAL PROTECTIVE EQUIPMENT

EYES AND FACE: Whenever airborne dust concentrations are high, appropriate protective eyewear, such as mono-goggles, should be worn to prevent eye contact.

RESPIRATORY: Whenever dust in the worker's breathing zone cannot be controlled with ventilation or other engineering means, workers should wear respirators or dust masks approved by NIOSH/MSHA, EU CEN or comparable certification organization to protect them against airborne dust.

PROTECTIVE CLOTHING: No special clothing is required.

GLOVES: No special gloves are required.

9. PHYSICAL AND CHEMICAL PROPERTIES

ODOR:	Not available
APPEARANCE:	Solid
AUTOIGNITION TEMPERATURE:	Not applicable
BOILING POINT:	Not applicable
COEFFICIENT OF OIL / WATER:	(Octanol/Water) Not available
EVAPORATION RATE:	(Butyl acetate = 1) Not applicable

FLASH POINT:	Not applicable
MELTING POINT:	Decomposes
MOLECULAR WEIGHT:	390.54 36.46
pH:	Not available
SOLUBILITY IN WATER:	Not available
SPECIFIC GRAVITY:	Not available
VAPOR DENSITY:	Not available
VAPOR PRESSURE:	Not applicable

10. STABILITY AND REACTIVITY

CONDITIONS TO AVOID:	None known
STABILITY:	Stable
HAZARDOUS DECOMPOSITION PRODUCTS:	None known.

11. TOXICOLOGICAL INFORMATION

EYE EFFECTS: Expected to be irritating to the eyes.

SKIN EFFECTS: Expected to be mildly irritating to the skin.

DERMAL LD₅₀: No data available for the product.

ORAL LD₅₀: No data available for the product.

INHALATION LC₅₀: No data available for the product.

SENSITIZATION: No data available for the product.

ACUTE EFFECTS FROM OVEREXPOSURE: No data available for the formulation. This product may be irritating to the eyes and skin. It is expected to have low oral and dermal toxicity.

CHRONIC EFFECTS FROM OVEREXPOSURE: No data available for the product.

CARCINOGENICITY:

NTP: Not listed
IARC: Not listed
OSHA: Not listed
OTHER: Not Listed (ACGIH)

12. ECOLOGICAL INFORMATION

ENVIRONMENTAL DATA: No data available for the formulation.

ECOTOXICOLOGICAL INFORMATION: No data available for the formulation.

13. DISPOSAL CONSIDERATIONS

DISPOSAL METHOD: No special disposal methods are suggested. It is the user's responsibility to comply with all applicable local, state, and federal laws, rules, regulations and standards.

14. TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION (DOT)

ADDITIONAL INFORMATION: This material is not regulated in transportation.

INTERNATIONAL MARITIME DANGEROUS GOODS (IMDG)

ADDITIONAL INFORMATION: Not regulated as a hazardous material

ADR - EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD

ADDITIONAL INFORMATION: Not regulated as a hazardous material

**INTERNATIONAL CIVIL AVIATION ORGANIZATION (ICAO) /
INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA)**

ADDITIONAL INFORMATION:

Not regulated as a hazardous material

OTHER INFORMATION:

CANADIAN TRANSPORT (TDG):

This material is not regulated when transported by road in Canada.

15. REGULATORY INFORMATION

UNITED STATES

SARA TITLE III (SUPERFUND AMENDMENTS AND REAUTHORIZATION ACT)

SECTION 302 EXTREMELY HAZARDOUS SUBSTANCES (40 CFR 355, APPENDIX A):

Not applicable

SECTION 311 HAZARD CATEGORIES (40 CFR 370):

None

SECTION 312 THRESHOLD PLANNING QUANTITY (40 CFR 370):

The Threshold Planning Quantity (TPQ) for this product, if treated as a mixture, is 10,000 lbs; however, this product contains the following ingredients with a TPQ of less than 10,000 lbs.:

None

SECTION 313 REPORTABLE INGREDIENTS (40 CFR 372):

This product does not contain any toxic chemicals subject to the reporting requirements of Section 313, Title III of the SARA (Superfund Amendments and Reauthorization Act) of 1986.

CERCLA (COMPREHENSIVE ENVIRONMENTAL RESPONSE COMPENSATION AND LIABILITY ACT)

CERCLA DESIGNATION & REPORTABLE QUANTITIES (RQ) (40 CFR 302.4):

Not applicable

CANADA

WHMIS (WORKPLACE HAZARDOUS MATERIALS INFORMATION SYSTEM):

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations. Not a controlled product under the Canadian Workplace Hazardous Materials Information System (WHMIS).

16. OTHER INFORMATION

HMIS

Health	1
Flammability	1
Physical Hazard	0
Personal Protection (PPE)	E

Protection = E (Safety glasses, gloves, dust respirator)

HMIS = Hazardous Materials Identification System

Degree of Hazard Code:

- 4 = Severe
- 3 = Serious
- 2 = Moderate
- 1 = Slight
- 0 = Minimal

NFPA

Health	1
Flammability	1
Reactivity	0
Special	None

No special requirements

NFPA (National Fire Protection Association)

Degree of Hazard Code:

- 4 = Extreme
- 3 = High
- 2 = Moderate
- 1 = Slight
- 0 = Insignificant

REVISION SUMMARY:

New MSDS.

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