

SAFETY DATA SHEET

Dronabinol Capsules, USP CIII

1. IDENTIFICATION

Manufacturer:

Ascent Pharmaceuticals Inc
550 S.Research Place
Central Islip, NY 11722

Emergency Phone:

1-855-221-1622

Product Name: Dronabinol Capsules, USP 2.5 mg, 5 mg and 10 mg

Synonym(s): Not found.

Chemical Name: ((6aR, 10aR)-6a,7,8,10a-Tetrahydro-6,6,9-trimethyl-3-pentyl-6Hdibenzo[b,d]-pyran-1-ol

Trade Name(s): Dronabinol Capsules, USP, 2.5 mg, 5 mg and 10 mg.

Molecular formula and weight: C₂₁H₃₀O₂ and 314.47

2.HAZARDS IDENTIFICATION

Health Hazards: Reproductive toxicity Category 2

Symbol(s):



Signal Word: Warning

Hazard Statement(s):

H361 Suspected of damaging fertility or the unborn child.

P201- Obtain special instructions before use.

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

P280- Wear protective gloves/protective clothing/eye protection/face protection.



P308 + P313- IF exposed or concerned: Get medical advice/attention.

P405- Store locked up.

P501- Dispose of contents/container in accordance with local/provincial/federal regulations.

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>CAS</u>	<u>Concentration %</u>
Dronabinol	[1972-08-3]	1 to 4 % (approx.)
Excipients	NA	96-99 % (approx.)

*The formula also contains Sesame Oil (60-70%); Gelatin (20-30%); Glycerin (5-10%); Purified Water (0.5-5%); Titanium Dioxide (0.01-2%); Coloring Agents (0.001-0.5%).

4. FIRST AID MEASURES

Inhalation: In case of accidental inhalation, remove to fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration. Get medical attention if symptoms appear.

Eye Contact: If exposure occurs to crushed or broken capsules immediately flush eyes with plenty of water for at least 15 minutes. Get medical attention if irritation occurs.

Skin Contact: If exposure occurs to crushed Capsules, wash with soap and water. Get medical attention if irritation develops. Take off contaminated clothing and wash before reuse.

Ingestion: If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately

Protection of First-aiders: Use personal protective equipment.

Signs and Symptoms: Clinical data suggests the following: variable central nervous system effects, palpitation, flushing, cardiac changes, gastrointestinal pain, nausea, vomiting, dizziness, anxiety, confusion, euphoria



Medical Conditions Aggravated by Exposure: Any pre-existing ailments in cardiovascular system, Pregnancy.

Notes to Physician: Treat supportively and symptomatically.

5.FIRE-FIGHTING MEASURES

Extinguisher Media: Use extinguishing agent suitable for type of surrounding fire. Fire water contaminated with this material must be contained and prevented from being discharged to any water way, sewer or drain.

Firefighting Procedures: As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.

Fire and Explosion Hazards: None known under normal conditions of product handling.

Hazardous Decomposition Products: Gases hazardous to health may be formed.

6.ACCIDENTAL RELEASE MEASURES

The following are recommended for manufacturing or other situations where exposure may occur.

Personal Precautions: Not necessary for small spills. For large spills, immediately contact emergency personnel. Keep unnecessary personnel away. Use suitable protective equipment.

Methods for cleaning up: Sweep up or vacuum up spillage and collect in suitable container for disposal. Should not be released into the environment. Do not flush to sewer. All clean-up operations should be witnessed by more than one individual. The amount of material collected should be assessed and documented.

7.HANDLING AND STORAGE

Handling: Special handling and storage requirements must be observed to assure compliance with Drug Enforcement Administration regulations. All employees who handle this material should be thoroughly trained to handle it safely. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.



Storage Conditions: Store according to label and/or product insert information. Store away from oxidizers, acids, and bases.

8.EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Limit Dronabinol – Not applicable.

Note: ACGIH has established TLVs for other components of this product as follows:

- Glycerol: 10 mg/m³ (total mist)
- Titanium Dioxide: 10 mg/m³

Capsules are not considered hazardous under normal handling procedures and the following are recommended for manufacturing or other situations where exposure may occur.

Engineering Controls: Good general ventilation should be used. Ventilation rates should be matched to conditions. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits. If exposure limits have not been established, maintain airborne levels to an acceptable level.

Personal Protective Equipment:

Eye/Face Protection: Wear safety glasses with side shields wherever the potential exists for direct exposure to capsules.

Skin Protection: Use disposable chemical resistant gloves

Respiratory Protection: None required with normal handling of finished product. Use a NIOSH approved respirator or an alternate approved dust mask should be used.

Additional Exposure Precautions: None required with normal handling of finished product. Use disposable outer garments or chemical resistant garments of equal or greater protection, when there is potential for direct contact with crushed or leaking capsules. Protect exposed skin.



9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance:

2.5 mg: Brown to dark brown round capsules containing clear to light yellow liquid, printed with "A" in white ink

5 mg : White to off white round capsules containing clear to light yellow liquid, printed with "A" in black ink.

10 mg: Pink round capsules containing clear to light yellow liquid, printed with "A" in black ink.

Physical State: Solid (Capsule)

Boiling Point: Not available

Melting range: Not available

pH: Not available.

Evaporation Rate: Not available

Solubility: Not available

Vapor Density: Not available.

Vapor Pressure: Not available.

10. STABILITY AND REACTIVITY

Reactivity: Data not available

Stability: The product is stable under normal conditions.

Incompatibilities: Strong oxidizing agents, acids, and bases.

Hazardous Polymerization: Irritating and/or toxic fumes and gases may be emitted upon the products decomposition.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity:

Active Ingredient:

LD50 Oral (rat): 666 mg/kg

LD50 Oral (mice): 482 mg/kg



Carcinogenicity: Not listed as a carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.

12.ECOLOGICAL INFORMATION

General information: The information presented below pertains to the individual ingredients, and not to the mixture(s) or final formulations.

Ecotoxicity: No data available.

Acute toxicity (Aquatic invertebrates): No data available.

Bioaccumulation: No data available.

Mobility: No data available.

13.DISPOSAL CONSIDERATIONS

Waste Disposal: Dispose of waste must be in accordance with all applicable Federal, State and local laws. Notify site Drug Enforcement Agency compliance officer and local DEA office for appropriate disposal procedures. Processing, use or contamination of this product may change the waste management options. State and local disposal regulations may differ from federal disposal regulations.

14.TRANSPORT INFORMATION

Regulatory Organizations:

DOT: Not Regulated

IATA: Not Regulated

15.REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible Ascent and Company usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.



U.S. Regulations

Drug Enforcement Administration: Schedule III.

TSCA - No

CERCLA - Not on this list

SARA 302 - Not on this list

SARA 313 : Not on this list

OSHA Substance Specific – Not on this list

16.OTHER INFORMATION

SDS Sections Revised: New SDS

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS MATERIAL SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute or product literature which may accompany the finished product.

GLOSSARY:

CAS Number = Chemical Abstract Service Registry Number

CERCLA = Comprehensive Environmental Response Compensation and Liability Act (of 1980)

DOT = Department of Transportation

ECG = Electrocardiography

IARC = International Agency for Research on Cancer

ICAO/IATA = International Civil Aviation Organization/ International Air Transport Association

IMO = International Maritime Organization

MSDS = Material Safety Data Sheet

NA = Not Applicable

NIOSH = National Institute for Occupational Safety and Health

NTP = National Toxicology Program

OSHA = Occupational Safety and Health Administration

SARA = Superfund Amendments and Reauthorization Act

SSRI's = Selective serotonin reuptake inhibitor

TSCA = Toxic Substances Control Act

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