1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING

Product identifier
Product Name: KADIAN CAP 100MG BULK

Other means of identification
Product Code: 306699
Synonyms: Roxanol, Duramorph, Kadian

Recommended use of the chemical and restrictions on use
Recommended Use: Pharmaceutical

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Details of the supplier of the safety data sheet
Manufacturer
Allergan plc
5 Giralda Farms
Madison, NJ USA 07940
+1-800-272-5525

E-mail address: SDS@Allergan.com

Emergency telephone number
Emergency Telephone: Call CHEMTREC Day or Night
Within USA or Canada: 1-800-424-9300
Outside USA and Canada: +1-703-741-5970 (collect calls accepted)

2. HAZARDS IDENTIFICATION

Classification

OSHA Regulatory Status
This chemical is considered hazardous by the 2012 OSHA Hazard Communication Standard (29 CFR 1910.1200)

Acute toxicity - Oral: Category 4
Respiratory sensitization: Category 1
Skin sensitization: Category 1
Germ cell mutagenicity: Category 2
Carcinogenicity: Category 1A
Reproductive toxicity: Category 2
Effects on or via lactation: Yes

Label elements

Emergency Overview

Danger

Hazard statements
H302 - Harmful if swallowed
H317 - May cause an allergic skin reaction
H334 - May cause allergy or asthma symptoms or breathing difficulties if inhaled
H341 - Suspected of causing genetic defects
3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS No.</th>
<th>EINECS</th>
<th>Weight-%</th>
</tr>
</thead>
<tbody>
<tr>
<td>#2 CAP GREEN/GREEN</td>
<td>EZ99-01-30</td>
<td>N/A</td>
<td>60 - 100*</td>
</tr>
</tbody>
</table>
4. FIRST AID MEASURES

First aid measures

Eye contact Rinse immediately with plenty of water and seek medical advice.

Skin Contact Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.

Inhalation Remove to fresh air.

Ingestion Consult a physician if necessary.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Unsuitable extinguishing media None known.

Specific hazards arising from the chemical Fire may produce irritating, corrosive and/or toxic gases.

Explosion data Sensitivity to Mechanical Impact Not impact sensitive.
Sensitivity to Static Discharge Fine dust dispersed in air, in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard.

Protective equipment and precautions for firefighters As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.

Environmental precautions See Section 12 for additional ecological information.

Methods for containment Prevent further leakage or spillage if safe to do so.

Methods for cleaning up Use personal protective equipment as required. Cover powder spill with plastic sheet or tarp to minimize spreading and keep powder dry. Take up mechanically, placing in appropriate containers for disposal. Avoid creating dust. Clean contaminated surface thoroughly.

7. HANDLING AND STORAGE

Advice on safe handling Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.

Storage Conditions Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.
Control parameters

Exposure Guidelines

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH TLV</th>
<th>OSHA PEL</th>
<th>NIOSH IDLH</th>
<th>Allergan OEL (ug/m³)</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>STEL: 1000 ppm</td>
<td>TWA: 1000 ppm</td>
<td>IDLH: 3300 ppm</td>
<td>N/A</td>
</tr>
<tr>
<td>(vacated) TWA: 1900 mg/m³</td>
<td>TWA: 1000 ppm</td>
<td>TWA: 1000 ppm</td>
<td>TWA: 1900 mg/m³</td>
<td></td>
</tr>
<tr>
<td>MORPHINE SULFATE USP (FOR GEN MORPHINE) 64-31-3</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>53 ug/m³</td>
</tr>
<tr>
<td>TWA: 2 mg/m³ particulate matter containing no asbestos and &lt;1% crystalline silica, respirable particulate matter</td>
<td>(vacated) TWA: 2 mg/m³ respirable dust &lt;1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more; use Quartz limit</td>
<td>IDLH: 1000 mg/m³ TWA: 2 mg/m³ containing no Asbestos and &lt;1% Quartz respirable dust</td>
<td>N/A</td>
<td></td>
</tr>
<tr>
<td>CONFECTIONERS SUGAR 6X WITH CORN STARCH 57-50-1</td>
<td>TWA: 10 mg/m³</td>
<td>TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction (vacated) TWA: 15 mg/m³ total dust TWA: 5 mg/m³ respirable fraction</td>
<td>TWA: 10 mg/m³ total dust TWA: 5 mg/m³ respirable dust</td>
<td>N/A</td>
</tr>
</tbody>
</table>

NIOSH IDLH Immediately Dangerous to Life or Health

Other Information

Vacated limits revoked by the Court of Appeals decision in AFL-CIO v. OSHA, 965 F.2d 962 (11th Cir., 1992).

Appropriate engineering controls

Engineering Controls

The health hazard risks of handling this material are dependent on factors, such as physical form and quantity. Site specific risk assessments should be conducted to determine the appropriate exposure control measures. 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 as low as reasonably achievable.

Individual protection measures, such as personal protective equipment

Eye/face protection

No eye protection is normally needed during medical administration of this product. During operations in which dusts of the product may be generated, safety glasses should be considered.

Skin and body protection

During medical administration of this product, medical latex or nitrile gloves should be worn to avoid absorption of the product. Use appropriate protective clothing for the task (e.g., lab coat, etc.).

Respiratory protection

Respiratory protection is generally not needed during routine conditions of use of this product. If respiratory protection is needed, use only respiratory protection authorized under appropriate regional regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties
10. STABILITY AND REACTIVITY

Reactivity
Not defined As Reactive substance

Chemical stability
Stable under normal conditions.

Possibility of Hazardous Reactions
None under normal processing.

Conditions to avoid
Aerosol formation.

Incompatible materials
None known based on information supplied.

Hazardous Decomposition Products
None known based on information supplied.

11. TOXICOLOGICAL INFORMATION

Information on likely routes of exposure

Acute toxicity

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Inhalation</th>
<th>Eye contact</th>
<th>Skin Contact</th>
<th>Ingestion</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP</td>
<td>Avoid breathing vapors or mists.</td>
<td>See Symptoms for more information.</td>
<td>Avoid contact with skin.</td>
<td>See Symptoms for more information.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Oral LD50</th>
<th>Dermal LD50</th>
<th>Inhalation LC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP</td>
<td>= 7060 mg/kg ( Rat )</td>
<td>N/A</td>
<td>= 124.7 mg/L ( Rat ) 4 h</td>
</tr>
<tr>
<td>MORPHINE SULFATE</td>
<td>461</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>
_Delayed and immediate effects as well as chronic effects from short and long-term exposure_

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Germ cell mutagenicity</th>
<th>Carcinogenicity</th>
<th>Reproductive toxicity</th>
<th>Effects on or via lactation</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP</td>
<td>Not mutagenic in the standard battery of tests.</td>
<td>This product is categorized as a Group I by the IARC because of the major metabolite of ethanol, acetaldehyde is carcinogenic in experimental animals.</td>
<td>Studies have shown developmental toxicity, but only at high doses.</td>
<td>No information available</td>
</tr>
<tr>
<td>MORPHINE SULFATE USP(FOR GEN MORPHINE)</td>
<td>No information available.</td>
<td>No information available.</td>
<td>Suspected Reproductive Toxicant.</td>
<td>No information available</td>
</tr>
</tbody>
</table>

_Numerical measures of toxicity - Product Information_

**Unknown Acute Toxicity**

86.19% of the mixture consists of ingredient(s) of unknown toxicity

The following values are calculated based on chapter 3.1 of the GHS document.

- ATEmix (oral) 1249 mg/kg
- ATEmix (inhalation-dust/mist) 289.4 mg/l

**12. ECOLOGICAL INFORMATION**

_Ecotoxicity_

85.67% of the mixture consists of component(s) of unknown hazards to the aquatic environment

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Algae/aquatic plants</th>
<th>Fish</th>
<th>Crustacea</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>N/A</td>
<td>100: 96 h Pimephales promelas mg/L LC50 static 13400 - 15100: 96 h Pimephales promelas mg/l LC50 flow-through 12.0 - 16.0: 96 h Oncorhynchus mykiss mL/L LC50 static</td>
<td>9268 - 14221: 48 h Daphnia magna mg/L LC50 10800: 24 h Daphnia magna mg/L EC50 2: 48 h Daphnia magna mg/L EC50 Static</td>
</tr>
<tr>
<td>TALC USP(1656) 14807-96-6</td>
<td>N/A</td>
<td>100: 96 h Brachydanio rerio g/L LC50 semi-static</td>
<td>N/A</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Persistence and degradability</th>
<th>Bioaccumulation</th>
<th>Mobility</th>
<th>Partition coefficient</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>-0.32</td>
</tr>
<tr>
<td>MORPHINE SULFATE USP(FOR GEN MORPHINE) 64-31-3</td>
<td>NOT READILY BIODEGRADABLE</td>
<td>N/A</td>
<td>High Mobility in soil</td>
<td>.89</td>
</tr>
</tbody>
</table>

_Other adverse effects_ No information available

**13. DISPOSAL CONSIDERATIONS**

_Waste treatment methods_

_Disposal of wastes_ Disposal should be in accordance with applicable regional, national and local laws and regulations.

_Contaminated packaging_ Do not reuse container. Dispose of contents/containers in accordance with local regulations.

_US EPA Waste Number_ U088
This product contains one or more substances that are listed with the State of California as a hazardous waste.

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Hazardous Waste Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>Toxic Ignitable</td>
</tr>
</tbody>
</table>

### 14. TRANSPORT INFORMATION

- **DOT**: Not regulated
- **TDG**: Not regulated
- **ICAO (air)**: Not regulated
- **IATA**: Not regulated
- **IMDG**: Not regulated
- **ADR**: Not regulated
- **ADN**: Not regulated

### 15. REGULATORY INFORMATION

#### International Inventories
- **TSCA**: Not Listed
- **DSL/NDSL**: Not Listed
- **EINECS/ELINCS**: Not Listed

#### Legend:
- TSCA - United States Toxic Substances Control Act Section 8(b) Inventory
- DSL/NDSL - Canadian Domestic Substances List/Non-Domestic Substances List
- EINECS/ELINCS - European Inventory of Existing Chemical Substances/European List of Notified Chemical Substances

#### US Federal Regulations

**Carcinogenicity**

The table below indicates whether each agency has listed any ingredient as a carcinogen. This product contains one or more substances which are classified by IARC as carcinogenic to humans (Group 1), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>ACGIH</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>A3</td>
<td>Group 1</td>
<td>Known</td>
<td>X</td>
</tr>
<tr>
<td>TALC USP(1656) 14807-98-6</td>
<td>-</td>
<td>Group 3</td>
<td>-</td>
<td>X</td>
</tr>
</tbody>
</table>

**SARA 313**

Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

**SARA 311/312 Hazard Categories**

- Acute health hazard: No
- Chronic Health Hazard: No
- Fire hazard: No
- Sudden release of pressure hazard: No
- Reactive Hazard: No
CWA (Clean Water Act)
This product contains the following substances which are regulated pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42)

CERCLA
This material, as supplied, contains one or more substances regulated as a hazardous substance under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302)

US State Regulations

California Proposition 65
This product contains the following Proposition 65 chemicals

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>California Proposition 65</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP - 64-17-5</td>
<td>Carcinogen</td>
</tr>
<tr>
<td></td>
<td>Developmental</td>
</tr>
</tbody>
</table>

U.S. State Right-to-Know Regulations

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>New Jersey</th>
<th>Massachusetts</th>
<th>Pennsylvania</th>
</tr>
</thead>
<tbody>
<tr>
<td>ALCOHOL USP 64-17-5</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>TALC USP(1656) 14807-96-6</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>DIETHYL PHTHALATE 84-66-2</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

16. OTHER INFORMATION

Revision Date: 02-Oct-2018
Revision Note: No information available
Disclaimer
The information provided in this Material Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.

End of Safety Data Sheet