



# SAFETY DATA SHEET

Revision Date 02-Oct-2018

Version 10

## 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

H350 - May cause cancer  
 H361 - Suspected of damaging fertility or the unborn child  
 H362 - May cause harm to breast-fed children



**Appearance** No information available      **Physical state** Solid      **Odor** No information available

**Chemical Name**  
**MORPHINE SULFATE USP(FOR GEN MORPHINE)**

**Symptoms**  
 Respiratory depression including fatal cases may occur with overexposure to Morphine. Most common adverse reactions (>10%): Constipation, nausea, and somnolence.

**Chemical Name**  
**MORPHINE SULFATE USP(FOR GEN MORPHINE)**

**Medical Conditions Aggravated by Exposure**  
 Significant respiratory disease, acute or severe bronchial asthma, known or suspected paralytic tissue, hypersensitivity to morphine.

#### Precautionary statements

P301 + P312 - IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell  
 P330 - Rinse mouth  
 P285 - In case of inadequate ventilation wear respiratory protection  
 P304 + P341 - IF INHALED: If breathing is difficult, remove victim to fresh air and keep at rest in a position comfortable for breathing  
 P342 + P311 - If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician  
 P261 - Avoid breathing dust/fume/gas/mist/vapors/spray  
 P272 - Contaminated work clothing should not be allowed out of the workplace  
 P302 + P352 - IF ON SKIN: Wash with plenty of soap and water  
 P333 + P313 - If skin irritation or rash occurs: Get medical advice/attention  
 P321 - Specific treatment (see supplemental first aid instructions on this label)  
 P363 - Wash contaminated clothing before reuse  
 P202 - Do not handle until all safety precautions have been read and understood  
 P281 - Use personal protective equipment as required  
 P405 - Store locked up  
 P501 - Dispose of contents/ container to an approved waste disposal plant  
 P280 - Wear protective gloves/protective clothing/eye protection/face protection  
 P201 - Obtain special instructions before use  
 P260 - Do not breathe dust/fume/gas/mist/vapors/spray  
 P263 - Avoid contact during pregnancy/while nursing  
 P264 - Wash face, hands and any exposed skin thoroughly after handling  
 P270 - Do not eat, drink or smoke when using this product  
 P308 + P313 - IF exposed or concerned: Get medical advice/attention

#### Other Information

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

Over the counter drugs in their solid form are considered exempt under the criteria of the Federal OSHA Hazard Communication Standard 20 CFR 1910.1200. However, in an industrial setting where a component's occupational exposure limit may be surpassed, than can be considered hazardous

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS No.	EINECS	Weight-%
#2 CAP GREEN/GREEN	EZ99-01-30	N/A	60 - 100*

ALCOHOL USP	64-17-5	200-578-6	3 - 7*
MORPHINE SULFATE USP(FOR GEN MORPHINE)	64-31-3	200-582-8	1 - 5*
TALC USP(1656)	14807-96-6	238-877-9	1 - 5*
CONFECTIONERS SUGAR 6XWITH CORN STARCH	57-50-1	200-334-9	1 - 5*

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

#### 4. FIRST AID MEASURES

##### First aid measures

<b>Eye contact</b>	Rinse immediately with plenty of water and seek medical advice.
<b>Skin Contact</b>	Wash off immediately with soap and plenty of water while removing all contaminated clothes and shoes.
<b>Inhalation</b>	Remove to fresh air.
<b>Ingestion</b>	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

<b>Sensitivity to Mechanical Impact</b>	Not impact sensitive.
<b>Sensitivity to Static Discharge</b>	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

<b>Personal precautions</b>	Use personal protection recommended in Section 8. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing.
<b>Environmental precautions</b>	See Section 12 for additional ecological information.
<b>Methods for containment</b>	Prevent further leakage or spillage if safe to do so.
<b>Methods for cleaning up</b>	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

<b>Advice on safe handling</b>	Avoid contact with skin, eyes or clothing. Avoid generation of dust. Do not eat, drink or smoke when using this product.
<b>Storage Conditions</b>	Keep containers tightly closed in a dry, cool and well-ventilated place. Store away from incompatible materials.

**Incompatible materials** None known based on information supplied.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Control parameters

#### **Exposure Guidelines**

Chemical Name	ACGIH TLV	OSHA PEL	NIOSH IDLH	Allergan OEL (ug/m <sup>3</sup> )
ALCOHOL USP 64-17-5	STEL: 1000 ppm	TWA: 1000 ppm TWA: 1900 mg/m <sup>3</sup> (vacated) TWA: 1000 ppm (vacated) TWA: 1900 mg/m <sup>3</sup>	IDLH: 3300 ppm TWA: 1000 ppm TWA: 1900 mg/m <sup>3</sup>	N/A
MORPHINE SULFATE USP(FOR GEN MORPHINE) 64-31-3	N/A	N/A	N/A	53 ug/m <sup>3</sup>
TALC USP(1656) 14807-96-6	TWA: 2 mg/m <sup>3</sup> particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter	(vacated) TWA: 2 mg/m <sup>3</sup> respirable dust <1% Crystalline silica, containing no Asbestos TWA: 20 mppcf if 1% Quartz or more;use Quartz limit	IDLH: 1000 mg/m <sup>3</sup> TWA: 2 mg/m <sup>3</sup> containing no Asbestos and <1% Quartz respirable dust	N/A
CONFECTIONERS SUGAR 6XWITH CORN STARCH 57-50-1	TWA: 10 mg/m <sup>3</sup>	TWA: 15 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable fraction (vacated) TWA: 15 mg/m <sup>3</sup> total dust (vacated) TWA: 5 mg/m <sup>3</sup> respirable fraction	TWA: 10 mg/m <sup>3</sup> total dust TWA: 5 mg/m <sup>3</sup> respirable dust	N/A

*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

<b>Physical state</b>	Solid	<b>Appearance</b>	No information available
<b>Color</b>	No information available	<b>Odor</b>	No information available
<b>Odor threshold</b>	No information available		

<b><u>Property</u></b>	<b><u>Values</u></b>
<b>pH</b>	No information available
<b>Melting point/freezing point</b>	255 °C / 491 °F
<b>Boiling point / boiling range</b>	109 °C / 228 °F
<b>Flash point</b>	No information available
<b>Evaporation rate</b>	No information available
<b>Flammability (solid, gas)</b>	No information available
<b>Flammability Limit in Air</b>	
<b>Upper flammability limit:</b>	No information available
<b>Lower flammability limit:</b>	No information available
<b>Vapor pressure</b>	No information available
<b>Vapor density</b>	No information available
<b>Specific Gravity</b>	No information available
<b>Water solubility</b>	No information available
<b>Solubility in other solvents</b>	No information available
<b>Partition coefficient</b>	No information available
<b>Autoignition temperature</b>	No information available
<b>Decomposition temperature</b>	No information available
<b>Explosive properties</b>	No information available
<b>Oxidizing properties</b>	No information available

**Other Information**

<b>Molecular weight</b>	758.83
<b>VOC Content (%)</b>	No information available
<b>Density</b>	No information available
<b>Bulk density</b>	No information available

**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**

Chemical Name	Inhalation	Eye contact	Skin Contact	Ingestion
ALCOHOL USP	Avoid breathing vapors or mists.	See Symptoms for more information.	Avoid contact with skin.	See Symptoms for more information.

Chemical Name	Oral LD50	Dermal LD50	Inhalation LC50
ALCOHOL USP	= 7060 mg/kg ( Rat )	N/A	= 124.7 mg/L ( Rat ) 4 h
MORPHINE SULFATE	461	N/A	N/A

USP(FOR GEN MORPHINE)			
CONFECTIONERS SUGAR 6XWITH CORN STARCH	= 29700 mg/kg ( Rat )	N/A	N/A

#### Delayed and immediate effects as well as chronic effects from short and long-term exposure

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

#### 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 components(s) of unknown hazards to the aquatic environment

Chemical Name	Algae/aquatic plants	Fish	Crustacea
ALCOHOL USP 64-17-5	N/A	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	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
TALC USP(1656) 14807-96-6	N/A	100: 96 h Brachydanio rerio g/L LC50 semi-static	N/A

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

**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

Chemical Name	RCRA	RCRA - Basis for Listing	RCRA - D Series Wastes	RCRA - U Series Wastes
DIETHYL PHTHALATE 84-66-2	U088	Included in waste stream: F039	-	U088

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

Chemical Name	California Hazardous Waste Status
ALCOHOL USP 64-17-5	Toxic Ignitable

#### 14. TRANSPORT INFORMATION

<b>DOT</b>	Not regulated
<b>TDG</b>	Not regulated
<b>ICAO (air)</b>	Not regulated
<b>IATA</b>	Not regulated
<b>IMDG</b>	Not regulated
<b>ADR</b>	Not regulated
<b>ADN</b>	Not regulated

#### 15. REGULATORY INFORMATION

##### International Inventories

<b>TSCA</b>	Not Listed
<b>DSL/NDSL</b>	Not Listed
<b>EINECS/ELINCS</b>	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 I), probably carcinogenic to humans (Group 2A) or possibly carcinogenic to humans (Group 2B).

Chemical Name	ACGIH	IARC	NTP	OSHA
ALCOHOL USP 64-17-5	A3	Group 1	Known	X
TALC USP(1656) 14807-96-6	-	Group 3	-	X

##### 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

<b>Acute health hazard</b>	No
<b>Chronic Health Hazard</b>	No
<b>Fire hazard</b>	No
<b>Sudden release of pressure hazard</b>	No
<b>Reactive Hazard</b>	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

Chemical Name	California Proposition 65
ALCOHOL USP - 64-17-5	Carcinogen Developmental

**U.S. State Right-to-Know Regulations**

Chemical Name	New Jersey	Massachusetts	Pennsylvania
ALCOHOL USP 64-17-5	X	X	X
TALC USP(1656) 14807-96-6	X	X	X
DIETHYL PHTHALATE 84-66-2	X	X	X

**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**