SAFETY DATA SHEETS

This SDS packet was issued with item:

078859526

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

078391632 078919991 078920368 078920369

FMOM No.: 2112C-5MM-0.05 **DATE:** 10/03/08

PRODUCT NAME: Doxycycline Hyclate F/C Tablets

POTENCY: 100mg

BATCH SIZE: 5,000,000 Tablets

DOXYCYCLINE HYCLATE: CAS #564-25-0, CAS #24390-14-5

Signs and Symptoms of Overexposure:	Possible allergic reaction to dust if inhaled, ingested, or in contact with skin.
Acute:	Eye, skin and/or respiratory tract irritation.
Chronic:	Possible hypersensitization
Emergency and First Aid Procedures:	Remove from exposure. Remove contaminated clothing. Persons developing serious hypersensitivity reactions must receive immediate medical attention. Upon eye or skin contact, flush affected area with copious quantities of water. Obtain medical attention.
1. Inhalation:	May cause irritation of respiratory tract. Avoid inhalation. Remove to fresh air.
2. Eyes:	May cause irritation. Flush with copious quantities of water.
3. Skin:	May cause irritation. Flush with copious quantities of water.
4. Ingestion:	May cause irritation. Flush out mouth with water.

DOCUSATE SODIUM 85% and SODIUM BENZOATE 15%): CAS #577-11-7

ACUTE EFFECTS:	Harmful if swallowed. May be harmful if inhaled. May be harmful if absorbed through the skin. Causes eye and skin irritation. Material is irritating to mucous membranes and upper respiratory tract. To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

FIRST AID:	In case of contact, immediately flush eyes with copious amounts of water for at least 15 minutes. In case of contact, immediately wash skin with soap and copious amounts of water. If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen. call a physician. Wash contaminated clothing before reuse.
Extinguishing Media:	Water spray. Carbon Dioxide, Dry Chemical Powder, Alcohol or Polymer Foam.
Fire Fighting Procedures:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Unusual Fire and Explosion Hazard:	Emits toxic fumes under fire conditions.

<u>COLLOIDAL SILICON DIOXIDE (CAB-O-SIL):</u> CAS #112945-52-5

Primary Route(s) of Entry:	Inhalation. Non-toxic LD_{50} = Greater than 5000 mg/kg (oral) Cab-o-sil is not considered a potential carcinogen by IARC, NTP, or OSHA.
Signs and Symptoms of Overexposure	
1. Chronic:	None known
2. Acute:	None known other than possible temporary discomfort due to inhalation of dust concentration above the permissible exposure limit.
Emergency and First Aid Procedures	
1. Eyes:	Flush Eyes with plenty of water.
2. Inhalation:	Move victim to fresh air.

CORN STARCH (Purity 21): CAS #9005-25-8

Acute Overexposure:	NONE
Chronic Overexposure:	NONE
Emergency and First Aid Procedures	
Eyes:	Flush with water.
Skin:	N/A
Inhalation:	N/A
Ingestion:	N/A

CROSCARMELLOSE SODIUM (AC-DI-SOL): CAS #74811-65-7

Hazards Identification:	
Emergency Overview:	Accumulation of overhead settled dust my form explosive concentrations in air when disturbed and dispersed.
Potential Health Effects:	Minimally irritating to the eyes and skin.
First Aid Measures:	
1. Eyes:	Flush with water for at least 15 minutes. If irritation occurs and persists, obtain medical attention.
2. Skin:	Wash with plenty of soap and water. Get medical attention of irritation occurs and persists.
3. Inhalation:	Remove to fresh air. If breathing difficulty or discomfort occurs and persists, obtain medical attention.
4. Ingestion:	Drink plenty of water. Never give anything by mouth to an unconscious person. If any discomfort persists, obtain medical attention.
Notes to Medical Doctor:	AC-DI-SOL Croscarmellose Sodium has a very low toxicity. Treatment is symptomatic and supportive only.

Fire Fighting Measures:	
Unusual Fire and Explosion Hazard:	Accumulation of overhead settled dust may form explosive concentrations in air when disturbed and dispersed. The propagation of flame through air-floated dusts takes place usually following a small explosion, which shakes down accumulated dust.
Special 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.
Exposure Controls/ Personal Protection:	
1. Respiratory:	Whenever dust in the worker's breathing zone cannot be controlled with ventilation, workers should wear respirators which are approved by NIOSH/MSHA (or equivalent agency) for protection against airborne dust.
2. Eyes:	Whenever airborne dust concentrations are high, appropriate protective eyewear, such as monogoggles, should be worn to prevent eye contact.
3. Gloves:	Not required.
4. Special Clothing & Equipment:	Not required.
5. Exposure Limits:	None known.

TECHNOLOGICAL INFORMATION

Eye Contact:	Minimally irritating (Rabbit). FMC study number I82-603.
Skin Contact:	Minimally irritating. Primary Irritation Index (Rabbit) = 0.1/8.0 FMC Study Number I82-602. Non-sensitizing (Guinea Pig). F'MC Study Number I91-1186.
Skin Absorption:	Dermal LD_{50} (Rabbit) > 2 g/kg. FMC Study Number I82-601.
Inhalation:	No mortality in rats at maximum a concentration. 4 hour LC_{50} > 0.13 mg/l. FMC Study Number I82-604.
Ingestion:	Oral LD_{50} (Rat) > 5050 mg/kg. FMC Study Number I80-433.
Acute Effects for Overexposure:	No significant hazard in animal toxicity tests.
Chronic Effects from Overexposure:	AC-DI-SOL SD-711 was negative (nonmutagenic) in the Ames test (FMC Study Number I87-960) and did not induce chromosome aberrations in rats (FMC Study Number I87-979), A 90 day animal study showed no adverse effects when administered in the diet (FMC Study Number I80-434). No adverse human effects known.

<u>MICROCRYSTALLINE CELLULOSE (AVICEL):</u> CAS #9004-34-6

Route(s) of Exposure

1. Inhalation:	No significant hazard. No mortality in rats at maximum attainable concentration. 4 Hour LC_{50} > 5.05 - 5.49mg/l. FMC Study Numbers 182-622 and 182-627 (1983).
2. Skin Contact:	Nonirritant. Primary Irritation Index (Rabbit) = 0/8.0. FMC Study Number 182-625 (1982).
3. Eye Contact:	Minimally irritating (Rabbit). FMC Study Numbers 182-621 and 182-626 (1982).
4. Skin Absorption:	No significant hazard. Dermal LD_{50} (Rabbit) > 2g/kg. FMC Study Numbers 182-620 and 182-624 (1982).
5. Ingestion:	No significant hazard. Oral LD_{50} (Rat) > 5g/gl. FMC Study Number 182-623 (1982).

Emergency and First Aid Procedures

1. Eyes:	Flush with clean water for at least fifteen minutes. If irritation occurs and persists, obtain medical attention.
2. Skin:	Wash with soap and water. If irritation occurs and persist, obtain medical attention.
3. Inhalation:	Remove victim to fresh air. If breathing is difficult or if any discomfort persists, obtain medical attention.
4. Ingestion:	Drink plenty of water. If any discomfort persists, obtain medical attention.

MAGNESIUM STEARATE: CAS # 557-04-0

Exposure/Health Effects:

1. Inhalation:	Symptoms from excessive inhalation of dust may include coughing and difficult breathing.
2. Eyes:	May cause mechanical irritation.
3. Skin:	No information found. Not expected to be a hazard.
4. Ingestion:	Low level of toxicity by ingestion.
5. Chronic Exposure:	Grossly excessive and chronic inhalation of the dust may cause a progressive chemical pneumonitis.
6. Aggravation of Pre-existing Condition:	Persons with pre-existing skin disorders, impaired respiratory function, of a history of pulmonary disease should not be exposed to dusts.

OPADRY CLEAR YS-1-7006: (CAS # NOT DETERMINED)

Signs and Symptoms of Over Exposure:	None.
Primary Route of Entry:	Inhalation

Emergency and First Aid Procedures

1. Eyes:	In case of accidental eye contact flush eyes with water if irritation persists obtain medical attention.

TITANIUM DIOXIDE: CAS # 13463-67-7

Sign and Symptoms of Overexposure:	Acute exposure may irritate the throat and air passages, sometimes causing cough and phlegm. Chronic exposure repeated heavy exposures may cause bronchitis, with cough and phlegm. If exposure continues, emphysema may develop. Lung scaring may also result.
Emergency and First Aid Procedures:	Not listed with NTP, IARC or OSHA as known or suspected carcinogen. No specific first aid procedures are necessary for accidental exposure to this product.
Medical Conditions Aggravated by Exposure:	Persons suffering from chronic respiratory diseases may be at increased risk.

FD&C YELLOW #6 LAKE: CAS # 15790-07-5

Signs and Symptoms of Overexposure:	
ACUTE:	NO EFFECTS.
CHRONIC:	N/A.
Emergency and First Aid Procedures:	
1. Eyes:	N/A
2. Skin:	N/A
3. Inhalation:	N/A
4. Ingestion:	N/A

<u>FD&C BLUE NO. 2 LAKE:</u> CAS # 16521-38-3

Effects Of Overexposure:	May cause transient eye, nose, and throat irritation.
Route Of Entry:	Inhalation

First Aid Procedures:

1. Eye Contact:	Flush with water for at least 15 minutes
2. Skin Contact:	Wash with mild soap and water.
3. Inhalation:	Remove victim to fresh air. If breathing is difficult, administer oxygen.

As in all cases of overexposure, if irritation persists, seek medical attention.

SAFETY DATA SHEET

Doxycycline Hyclate Tablets, 100mg

Section 1. Identification

GHS product identifier : Doxycycline Hyclate Tablets, 100mg

Chemical name : 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrate

Synonyms : Not available.

Product code : Not available.

Chemical family : Not available.

Product type : Regulated prescription drug.

Container information : Not available.

Identified uses

To treat or prevent infections that are proven or strongly suspected to be caused by bacteria.

Supplier's details : West-Ward Pharmaceutical Corp.
465 Industrial Way West
Eatontown NJ 07724 USA

Emergency telephone number (with hours of operation) : CHEMTREC, U.S. : 1-800-424-9300 International: +1-703-527-3887
24/7

Section 2. Hazards identification

OSHA/HCS status : This material is considered hazardous by the OSHA Hazard Communication Standard (29 CFR 1910.1200).

Classification of the substance or mixture : ACUTE TOXICITY (oral) - Category 4
SKIN CORROSION/IRRITATION - Category 2
SERIOUS EYE DAMAGE/ EYE IRRITATION - Category 2A
CARCINOGENICITY - Category 2
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

GHS label elements

Hazard pictograms :

Signal word : Warning

Hazard statements : Harmful if swallowed.
Causes serious eye irritation.
Causes skin irritation.
Suspected of causing cancer.
May cause respiratory irritation.

Precautionary statements

Section 2. Hazards identification

General : Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.

Prevention : Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required. Wear protective gloves. Wear eye or face protection. Use only outdoors or in a well-ventilated area. Avoid breathing dust. Do not eat, drink or smoke when using this product. Wash hands thoroughly after handling.

Response : IF exposed or concerned: Get medical attention. IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing. Call a POISON CENTER or physician if you feel unwell. IF SWALLOWED: Call a POISON CENTER or physician if you feel unwell. Rinse mouth. IF ON SKIN: Wash with plenty of soap and water. Take off contaminated clothing. Wash contaminated clothing before reuse. If skin irritation occurs: Get medical attention. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical attention.

Storage : Store locked up.

Disposal : Dispose of contents and container in accordance with all local, regional, national and international regulations.

Hazards not otherwise classified : None known.

Section 3. Composition/information on ingredients

Substance/mixture : Mixture

Chemical name : 4-(Dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrate

Other means of identification : Not available.

CAS number/other identifiers

CAS number : Not applicable.

Product code : Not available.

Ingredient name	%	CAS number
2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, hydrochloride, (4S,4aR,5S,5aR,6R,12aS)-, compd. with ethanol, hydrate (2:2:1:1)	30 - 60	24390-14-5
Cellulose	30 - 60	9004-34-6
Magnesium distearate	1 - 5	557-04-0
Croscarmellose sodium	5 - 10	74811-65-7
Starch	1 - 5	9005-25-8
Docusate Sodium	1 - 5	577-11-7
Sodium Benzoate	0.1 - 1	532-32-1
Silicon dioxide	1 - 5	7631-86-9
Opadry Clear YS-1-7006	1 - 5	842143-59-3
Titanium dioxide	0.1 - 1	13463-67-7
Aluminium, 6-hydroxy-5-[(4-sulfophenyl)azo]-2-naphthalenesulfonic acid complex	0.1 - 1	15790-07-5
Aluminium, 2-(1,3-dihydro-3-oxo-5-sulfo-2H-indol-2-ylidene)-2,3-dihydro-3-oxo-1H-indole-5-sulfonic acid complex	0.1 - 1	16521-38-3

Any concentration shown as a range is to protect confidentiality or is due to batch variation.

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment and hence require reporting in this section.

Occupational exposure limits, if available, are listed in Section 8.

Section 4. First aid measures

Description of necessary first aid measures

Eye contact : Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 20 minutes. Get medical attention.

Inhalation : Remove victim to fresh air and keep at rest in a position comfortable for breathing. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention. If necessary, call a poison center or physician. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband. In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Skin contact : Flush contaminated skin with plenty of water. Continue to rinse for at least 20 minutes. Get medical attention. Wash clothing before reuse. Clean shoes thoroughly before reuse.

Ingestion : Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention. If necessary, call a poison center or physician. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.

Most important symptoms/effects, acute and delayed

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : May cause respiratory irritation. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact : Causes skin irritation.

Ingestion : Harmful if swallowed. Irritating to mouth, throat and stomach.

Over-exposure signs/symptoms

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : Adverse symptoms may include the following:
respiratory tract irritation
coughing

Skin contact : Adverse symptoms may include the following:
irritation
redness

Ingestion : No known significant effects or critical hazards.

Indication of immediate medical attention and special treatment needed, if necessary

Notes to physician : In case of inhalation of decomposition products in a fire, symptoms may be delayed. The exposed person may need to be kept under medical surveillance for 48 hours.

Section 4. First aid measures

Specific treatments : No specific treatment.

Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. If it is suspected that fumes are still present, the rescuer should wear an appropriate mask or self-contained breathing apparatus. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

See toxicological information (Section 11)

Section 5. Fire-fighting measures

Extinguishing media

Suitable extinguishing media : Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media : None known.

Specific hazards arising from the chemical : No specific fire or explosion hazard.

Hazardous thermal decomposition products : Decomposition products may include the following materials:
carbon dioxide
carbon monoxide
nitrogen oxides
Sulfur oxides
halogenated compounds
metal oxide/oxides

Special protective actions for fire-fighters : No special measures are required.

Special protective equipment for fire-fighters : Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6. Accidental release measures

Personal precautions, protective equipment and emergency procedures

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment.

For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

Methods and materials for containment and cleaning up

Spill : Move containers from spill area. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Avoid dust generation. Do not dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed, labeled waste container. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7. Handling and storage

Precautions for safe handling

Protective measures : Put on appropriate personal protective equipment (see Section 8). Avoid exposure - obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Do not get in eyes or on skin or clothing. Do not ingest. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Empty containers retain product residue and can be hazardous. Do not reuse container.

Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. See also Section 8 for additional information on hygiene measures.

Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Store locked up. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination.

Section 8. Exposure controls/personal protection

Control parameters

Occupational exposure limits

Ingredient name	Exposure limits
Titanium dioxide	**OSHA PEL (United States, 2/2013).** TWA: 15 mg/m³ 8 hours. Form: Total dust **OSHA PEL 1989 (United States, 3/1989).** TWA: 10 mg/m³ 8 hours. Form: Total dust **ACGIH TLV (United States, 6/2013).** TWA: 10 mg/m³ 8 hours.

Appropriate engineering controls : Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits.

Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation.

Individual protection measures

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: chemical splash goggles.

Skin protection

Section 8. Exposure controls/personal protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Use a properly fitted, particulate filter respirator complying with an approved standard if a risk assessment indicates this is necessary. Respirator selection must be based on known or anticipated exposure levels, the hazards of the product and the safe working limits of the selected respirator.

Section 9. Physical and chemical properties

Appearance

Physical state : Solid.

Color : Not available.

Odor : Not available.

Odor threshold : Not available.

pH : Not available.

Melting point : Not available.

Boiling point : Not available.

Flash point : Not applicable.

Evaporation rate : Not available.

Flammability (solid, gas) : Not available.

Lower and upper explosive (flammable) limits : Not available.

Vapor pressure : Not available.

Vapor density : Not available.

Relative density : Not available.

Solubility : Not available.

Partition coefficient: n-octanol/water : Not available.

Auto-ignition temperature : Not available.

Decomposition temperature : Not available.

Viscosity : Not available.

Section 10. Stability and reactivity

Reactivity : No specific test data related to reactivity available for this product or its ingredients.

Chemical stability : The product is stable.

Possibility of hazardous reactions : Under normal conditions of storage and use, hazardous reactions will not occur.

Conditions to avoid : No specific data.

Incompatible materials : Reactive or incompatible with the following materials: oxidizing materials.

Hazardous decomposition products : Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11. Toxicological information

Information on toxicological effects

Acute toxicity

Product/ingredient name	Result	Species	Dose	Exposure
Docusate Sodium	LD50 Dermal LD50 Oral	Rabbit Rat	>10 g/kg 1900 mg/kg	- -

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Docusate Sodium	Eyes - Mild irritant Skin - Moderate irritant Eyes - Severe irritant	Rabbit Rabbit Rabbit	- - -	250 µg 24 hours 10 mg 1%	- - -
Titanium dioxide	Skin - Mild irritant	Human	-	72 hours 300 µg Intermittent	-

Sensitization

There is no data available.

Carcinogenicity

Classification

Product/ingredient name	OSHA	IARC	NTP
Titanium dioxide	-	2B	-

Specific target organ toxicity (single exposure)

Name	Category	Route of exposure	Target organs
2-Naphthacenecarboxamide, 4-(dimethylamino)-1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, hydrochloride, (4S,4aR,5S,5aR,6R,12aS)-, compd. with ethanol, hydrate (2:2:1:1)	Category 3	Not applicable.	Respiratory tract irritation

Specific target organ toxicity (repeated exposure)

There is no data available.

Aspiration hazard

There is no data available.

Information on the likely routes of exposure : Dermal contact. Ingestion.

Section 11. Toxicological information

Potential acute health effects

Eye contact : Causes serious eye irritation.

Inhalation : May cause respiratory irritation. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.

Skin contact : Causes skin irritation.

Ingestion : Harmful if swallowed. Irritating to mouth, throat and stomach.

Symptoms related to the physical, chemical and toxicological characteristics

Eye contact : Adverse symptoms may include the following:
pain or irritation
watering
redness

Inhalation : Adverse symptoms may include the following:
respiratory tract irritation
coughing

Skin contact : Adverse symptoms may include the following:
irritation
redness

Ingestion : No known significant effects or critical hazards.

Delayed and immediate effects and also chronic effects from short and long term exposure

Short term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Long term exposure

Potential immediate effects : No known significant effects or critical hazards.

Potential delayed effects : No known significant effects or critical hazards.

Potential chronic health effects

General : No known significant effects or critical hazards.

Carcinogenicity : Suspected of causing cancer. Risk of cancer depends on duration and level of exposure.

Mutagenicity : No known significant effects or critical hazards.

Teratogenicity : No known significant effects or critical hazards.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : No known significant effects or critical hazards.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	1000 mg/kg

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
Docusate Sodium	Acute EC50 43 mg/L Fresh water	Daphnia - Daphnia magna	48 hours
	Acute LC50 24000 µg/l Fresh water	Fish - Oncorhynchus mykiss - Fingerling	96 hours
Titanium dioxide	Acute EC50 5.83 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours
	Acute LC50 3 mg/L Fresh water	Crustaceans - Ceriodaphnia dubia - Neonate	48 hours
	Acute LC50 5.5 ppm Fresh water	Daphnia - Daphnia magna - Juvenile (Fledgling, Hatchling, Weanling)	48 hours
	Acute LC50 1000 mg/L Fresh water	Fish - Pimephales promelas	96 hours
	Chronic NOEC 0.984 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata - Exponential growth phase	72 hours

Persistence and degradability

There is no data available.

Bioaccumulative potential

Product/ingredient name	$LogP_{ow}$	BCF	Potential
Docusate Sodium	-	9.33	low
Titanium dioxide	-	352	low

Mobility in soil

Soil/water partition coefficient (K_{OC}) : Not available.

Other adverse effects : No known significant effects or critical hazards.

Section 13. Disposal considerations

Disposal methods : The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling empty containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Section 14. Transport information

	DOT Classification	IMDG	IATA
UN number	Not regulated.	Not regulated.	Not regulated.
UN proper shipping name	-	-	-
Transport hazard class(es)	-	-	-
Packing group	-	-	-
Environmental hazards	No.	No.	No.
Additional information	-	-	-

AERG : Not applicable.

Special precautions for user : **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code : Not available.

Section 15. Regulatory information

U.S. Federal regulations : **TSCA 8(a) CDR Exempt/Partial exemption**: Not determined

United States inventory (TSCA 8b): Not determined.

Clean Air Act Section 112 (b) Hazardous Air Pollutants (HAPs) : Not listed

Clean Air Act Section 602 Class I Substances : Not listed

Clean Air Act Section 602 Class II Substances : Not listed

DEA List I Chemicals (Precursor Chemicals) : Not listed

DEA List II Chemicals (Essential Chemicals) : Not listed

SARA 302/304

Composition/information on ingredients

No products were found.

SARA 304 RQ : Not applicable.

SARA 311/312

Section 15. Regulatory information

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
2-Naphthacenecarboxamide, 4-(dimethylamino) -1,4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, hydrochloride, (4S,4aR,5S,5aR,6R,12aS)-, compd. with ethanol, hydrate (2:2:1:1)	30 - 60	No.	No.	No.	Yes.	No.
Docusate Sodium	1 - 5	No.	No.	No.	Yes.	No.
Titanium dioxide	0.1 - 1	No.	No.	No.	No.	Yes.

State regulations

Massachusetts : The following components are listed: Cellulose; Starch; Silicon dioxide; Titanium dioxide

New York : None of the components are listed.

New Jersey : The following components are listed: Cellulose; Titanium dioxide

Pennsylvania : The following components are listed: Cellulose; Starch; Silicon dioxide; Titanium dioxide

California Prop. 65

WARNING: This product contains a chemical known to the State of California to cause cancer and birth defects or other reproductive harm.

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
2-Naphthacenecarboxamide, 4-(dimethylamino)-1, 4,4a,5,5a,6,11,12a-octahydro-3,5,10,12,12a-pentahydroxy-6-methyl-1,11-dioxo-, hydrochloride, (4S,4aR,5S,5aR,6R,12aS)-, compd. with ethanol, hydrate (2:2:1:1)	No.	Yes.	No.	No.
Titanium dioxide	Yes.	No.	No.	No.

International regulations

International lists : **Australia inventory (AICS)**: Not determined.
China inventory (IECSC): Not determined.
Japan inventory: Not determined.
Korea inventory: Not determined.
Malaysia Inventory (EHS Register): Not determined.
New Zealand Inventory of Chemicals (NZIoC): Not determined.
Philippines inventory (PICCS): Not determined.
Taiwan inventory (CSNN): Not determined.

Chemical Weapons Convention List Schedule I Chemicals : Not listed

Chemical Weapons Convention List Schedule II Chemicals : Not listed

Chemical Weapons Convention List Schedule III Chemicals : Not listed

Section 16. Other information

History

Date of issue mm/dd/yyyy : 02/15/2014

Version : 1

Revised Section(s) : Not applicable.

Prepared by : KMK Regulatory Services Inc.

Key to abbreviations : ATE = Acute Toxicity Estimate
BCF = Bioconcentration Factor
GHS = Globally Harmonized System of Classification and Labelling of Chemicals
IATA = International Air Transport Association
IBC = Intermediate Bulk Container
IMDG = International Maritime Dangerous Goods
LogPow = logarithm of the octanol/water partition coefficient
MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)
UN = United Nations

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein.
Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.