# **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
<u>GHS label elements</u> Hazard pictograms	:

Signal word Hazard statements

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

#### Precautionary statements





## Section 2. Hazards identification

<ul> <li>Read label before use. Keep out of reach of children. If medical advice is needed, have product container or label at hand.</li> </ul>
: 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.
: 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.
: Store locked up.
: Dispose of contents and container in accordance with all local, regional, national and international regulations.
: 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-penta 6-methyl-1,11-dioxo-2-naphthacenecarboxamide monohydrate	hydroxy-
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)		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	<ul> <li>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.</li> </ul>
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 e	ffects
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/sy	r <u>mptoms</u>
Eye contact	: Adverse symptoms may include the following: pain or irritation watering redness
Inhalation	<ul> <li>Adverse symptoms may include the following: respiratory tract irritation coughing</li> </ul>
Skin contact	: Adverse symptoms may include the following: irritation redness
Ingestion	: No known significant effects or critical hazards.
Indication of immediate I	nedical attention and special treatment needed, if necessary
Notos to physician	the approximation of decomposition products in a fire, symptome may be delayed

Notes to physician: In case of inhalation of decomposition products in a fire, symptoms may be delayed.<br/>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<br/>sewers, water courses, basements or confined areas. Avoid dust generation. Do not<br/>dry sweep. Vacuum dust with equipment fitted with a HEPA filter and place in a closed,<br/>labeled waste container. Dispose of via a licensed waste disposal contractor. Note:<br/>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/m <sup>3</sup> 8 hours. Form: Total dust OSHA PEL 1989 (United States, 3/1989). TWA: 10 mg/m <sup>3</sup> 8 hours. Form: Total dust ACGIH TLV (United States, 6/2013). TWA: 10 mg/m <sup>3</sup> 8 hours.
Appropriate engineering controls	:	or mist, use process enclosures, local ex	er operations generate dust, fumes, gas, vapor khaust ventilation or other engineering controls taminants below any recommended or statutory
Environmental exposure controls	:	Emissions from ventilation or work proce they comply with the requirements of env	ess equipment should be checked to ensure vironmental protection legislation.
Individual protection meas	ures		
Hygiene measures	:	eating, smoking and using the lavatory a Appropriate techniques should be used t	to remove potentially contaminated clothing. sing. Ensure that eyewash stations and safety
Eye/face protection	:	assessment indicates this is necessary t gases or dusts. If contact is possible, th	ved standard should be used when a risk o avoid exposure to liquid splashes, mists, e following protection should be worn, unless e 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

<u>Appearance</u>		
Physical state	:	Solid.
Color	:	Not available.
Odor	:	Not available.
Odor threshold	:	Not available.
рН	:	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	1	Not available.
Solubility	1	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

Hazardous decomposition products	: Under normal conditions of storage and use, hazardous decomposition products should not be produced.
Incompatible materials	: Reactive or incompatible with the following materials: oxidizing materials.
Conditions to avoid	: No specific data.
Possibility of hazardous reactions	: Under normal conditions of storage and use, hazardous reactions will not occur.
Chemical stability	: The product is stable.
Reactivity	: No specific test data related to reactivity available for this product or its ingredients.

### Section 11. Toxicological information

### Information on toxicological effects

#### Acute toxicity

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

#### Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
Docusate Sodium	Eyes - Mild irritant	Rabbit	-	250 µg	-
	Skin - Moderate irritant	Rabbit	-	24 hours 10 mg	-
	Eyes - Severe irritant	Rabbit	-	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		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	<ul> <li>May cause respiratory irritation. Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.</li> </ul>
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 ef	<u>ects</u>
General	: No known significant effects or critical hazards.
Carcinogenicity	: Suspected of causing cancer. Risk of cancer depends on duration and level exposure.
Mutagenicity	: No known significant effects or critical hazards.
Teratogenicity	: No known significant effects or critical hazards.
<b>Developmental effects</b>	: No known significant effects or critical hazards.
Fertility effects	: No known significant effects or critical hazards.

#### Numerical measures of toxicity

Acute toxicity estimates			
Ī	Route	ATE value	
	Oral	1000 mg/kg	





## Section 12. Ecological information

### <u>Toxicity</u>

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 -	72 hours	
		Exponential growth phase		
	Acute LC50 3 mg/L Fresh water	Crustaceans - Ceriodaphnia dubia -	48 hours	
		Neonate		
	Acute LC50 5.5 ppm Fresh water	Daphnia - Daphnia magna - Juvenile	48 hours	
		(Fledgling, Hatchling, Weanling)		
	Acute LC50 1000 mg/L Fresh water	Fish - Pimephales promelas	96 hours	
	Chronic NOEC 0.984 mg/L Fresh water	Algae - Pseudokirchneriella subcapitata -	72 hours	
		Exponential growth phase		

### Persistence and degradability

There is no data available.

### **Bioaccumulative potential**

Product/ingredient name	LogPow	BCF	Potential
Docusate Sodium	-	9.33	low
Titanium dioxide		352	low

### Mobility in soil

Soil/water partition coefficient (Koc)

: 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	ΙΑΤΑ
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 : Not available. to Annex II of MARPOL 73/78 and the IBC Code

### 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	1	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 SARA 311/312 : Not applicable.





## 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 Titanium dioxide	1 - 5 0.1 - 1	No. No.	No. No.	No. No.	Yes. No.	No. Yes.

#### **State regulations**

- Massachusetts
- The following components are listed: Cellulose; Starch; Silicon dioxide; Titanium dioxide
  None of the components are listed.
- New York 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		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	<ul> <li>Australia inventory (AICS): Not determined.</li> <li>China inventory (IECSC): Not determined.</li> <li>Japan inventory: Not determined.</li> <li>Korea inventory: Not determined.</li> <li>Malaysia Inventory (EHS Register): Not determined.</li> <li>New Zealand Inventory of Chemicals (NZIoC): Not determined.</li> <li>Philippines inventory (PICCS): Not determined.</li> <li>Taiwan inventory (CSNN): Not determined.</li> </ul>
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 Version Revised Section(s)	:	02/15/2014 1 Not applicable.
Prepared by	4	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 = Internediate 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.

