# SAFETY DATA SHEET

**Doxycycline Hyclate Capsules, 50mg, & 100mg**

WEST-WARD

## Section 1. Identification

**GHS product identifier** : Doxycycline Hyclate Capsules, 50mg, & 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
SPECIFIC TARGET ORGAN TOXICITY (SINGLE EXPOSURE) (Respiratory tract irritation) - Category 3

Percentage of the mixture consisting of ingredient(s) of unknown toxicity: 75%

**GHS label elements**

**Hazard pictograms** :

**Signal word** : Warning

**Hazard statements** : Harmful if swallowed.
Causes serious eye irritation.
Causes skin irritation.
May cause respiratory irritation.

**Precautionary statements**

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

## Section 2. Hazards identification

**Prevention** : 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 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) | 10 - 30 | 24390-14-5 |
| D-Glucose, 4-O-β-D-galactopyranosyl-, hydrate (1:1) | 60 - 100 | 10039-26-6 |
| Cellulose | 10 - 30 | 9004-34-6 |
| Magnesium distearate | 1 - 5 | 557-04-0 |

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

# Section 4. First aid measures

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.

**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
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). Do not ingest. Avoid contact with eyes, skin and clothing. 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.

# Section 7. Handling and storage

**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

None.

**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

**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**

There is no data available.

**Irritation/Corrosion**

There is no data available.

# Section 11. Toxicological information

### Sensitization

There is no data available.

### Carcinogenicity

There is no data available.

### 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.

### 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

# Section 11. Toxicological information

**General** : No known significant effects or critical hazards.

**Carcinogenicity** : No known significant effects or critical hazards.

**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 | 416.7 mg/kg |

# Section 12. Ecological information

## Toxicity

There is no data available.

## Persistence and degradability

There is no data available.

## Bioaccumulative potential

There is no data available.

## 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) | 10 - 30 | No. | No. | No. | Yes. | No. |

## State regulations

**Massachusetts** : The following components are listed: Cellulose

**New York** : None of the components are listed.

**New Jersey** : The following components are listed: Cellulose

**Pennsylvania** : The following components are listed: Cellulose

## California Prop. 65

**WARNING:** This product contains a chemical known to the State of California to cause 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. |

## International regulations

**International lists** : **Australia inventory (AICS)**: All components are listed or exempted.
**China inventory (IECSC)**: Not determined.
**Japan inventory**: Not determined.
**Korea inventory**: All components are listed or exempted.
**Malaysia Inventory (EHS Register)**: Not determined.
**New Zealand Inventory of Chemicals (NZIoC)**: All components are listed or exempted.
**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<br>BCF = Bioconcentration Factor<br>GHS = Globally Harmonized System of Classification and Labelling of Chemicals<br>IATA = International Air Transport Association<br>IBC = Intermediate Bulk Container<br>IMDG = International Maritime Dangerous Goods<br>LogPow = logarithm of the octanol/water partition coefficient<br>MARPOL 73/78 = International Convention for the Prevention of Pollution From Ships, 1973 as modified by the Protocol of 1978. ("Marpol" = marine pollution)<br>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.**