

SAFETY DATA SHEET

Isosorbide Mononitrate ER Tablets, 30mg and 60mg



Section 1. Identification

GHS product identifier	: Isosorbide Mononitrate ER Tablets, 30mg and 60mg
Chemical name	: 1,4:3,6-Dianhydro-, D-glucitol 5-nitrate
Synonyms	: Not available.
Product code	: Not available.
Chemical family	: Not available.
Product type	: Regulated prescription drug.
Container information	: Not available.

Identified uses

Prevention of angina pectoris due to coronary artery disease.

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	: CARCINOGENICITY - Category 2 TOXIC TO REPRODUCTION (Fertility) - Category 2 TOXIC TO REPRODUCTION (Unborn child) - Category 2

GHS label elements

Hazard pictograms



Signal word	: Warning
Hazard statements	: Suspected of damaging fertility or the unborn child. Suspected of causing cancer.

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.
Prevention	: Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Use personal protective equipment as required.
Response	: IF exposed or concerned: Get medical attention.
Storage	: Store locked up.



Section 2. Hazards identification

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 : 1,4:3,6-Dianhydro-, D-glucitol 5-nitrate
Other means of identification : Not available.

CAS number/other identifiers

CAS number : Not applicable.
Product code : Not available.

Ingredient name	%	CAS number
Isosorbide mononitrate	30 - 60	16051-77-7
Methocel	30 - 60	79484-92-7
Lactose	10 - 30	63-42-3
Synthetic Paraffin Wax Powder	10 - 30	308069-08-1
Carnauba wax	1 - 5	8015-86-9
Magnesium distearate	1 - 5	557-04-0
Silicon dioxide	0.1 - 1	7631-86-9
Diammonium hydrogenorthophosphate	0.1 - 1	7783-28-0
Opadry Clear YS-1-7006	1 - 5	842143-59-3
Titanium dioxide	0.1 - 1	13463-67-7
Diiron trioxide	0.1 - 1	1309-37-1
iron hydroxide oxide yellow	0.1 - 1	51274-00-1

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 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 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.

Section 4. First aid measures

- 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. 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** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Over-exposure signs/symptoms

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Skin contact** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Ingestion** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

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. 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.

Section 5. Fire-fighting measures

- 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
phosphorus oxides
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. Avoid exposure during pregnancy. 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. If during normal use the material presents a respiratory hazard, use only with adequate ventilation or wear appropriate respirator. 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.

Section 7. Handling and storage

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, 6/2010). TWA: 15 mg/m ³ 8 hours. Form: Total dust ACGIH TLV (United States, 3/2012). TWA: 10 mg/m ³ 8 hours.
Diiron trioxide	NIOSH REL (United States, 1/2013). TWA: 5 mg/m ³ , (as Fe) 10 hours. Form: Dust and fumes ACGIH TLV (United States, 3/2012). TWA: 5 mg/m ³ 8 hours. Form: Respirable fraction OSHA PEL (United States, 6/2010). TWA: 10 mg/m ³ 8 hours.

Appropriate engineering controls : 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: safety glasses with side-shields.

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.

Section 8. Exposure controls/personal protection

- 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 and acids.
- 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
Isosorbide mononitrate	LD50 Oral	Rat	2010 mg/kg	-

Irritation/Corrosion

Product/ingredient name	Result	Species	Score	Exposure	Observation
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	-
Diiron trioxide	-	3	-

Specific target organ toxicity (single exposure)

There is no data available.

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** : No known significant effects or critical hazards.
- Inhalation** : Exposure to decomposition products may cause a health hazard. Serious effects may be delayed following exposure.
- Skin contact** : No known significant effects or critical hazards.
- Ingestion** : No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

- Eye contact** : No known significant effects or critical hazards.
- Inhalation** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Skin contact** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations
- Ingestion** : Adverse symptoms may include the following:
reduced fetal weight
increase in fetal deaths
skeletal malformations

Section 11. Toxicological information

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 : Suspected of damaging the unborn child.

Developmental effects : No known significant effects or critical hazards.

Fertility effects : Suspected of damaging fertility.

Numerical measures of toxicity

Acute toxicity estimates

Route	ATE value
Oral	2680 mg/kg

Section 12. Ecological information

Toxicity

Product/ingredient name	Result	Species	Exposure
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
Isosorbide mononitrate	-0.15	-	low
Titanium dioxide	-	352	low

Mobility in soil

Section 12. Ecological information

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 : Not listed

(b) Hazardous Air Pollutants (HAPs)

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

Composition/information on ingredients

Name	%	Fire hazard	Sudden release of pressure	Reactive	Immediate (acute) health hazard	Delayed (chronic) health hazard
Isosorbide mononitrate Titanium dioxide	30 - 60 0.1 - 1	Yes. No.	No. No.	No. No.	No. No.	Yes. Yes.

SARA 313

	Product name	CAS number	%
Form R - Reporting requirements	Diammonium hydrogenorthophosphate	7783-28-0	0.1 - 1
Supplier notification	Diammonium hydrogenorthophosphate	7783-28-0	0.1 - 1

SARA 313 notifications must not be detached from the SDS and any copying and redistribution of the SDS shall include copying and redistribution of the notice attached to copies of the SDS subsequently redistributed.

State regulations

Massachusetts : The following components are listed: Silicon dioxide; Titanium dioxide; Diiron trioxide

New York : None of the components are listed.

New Jersey : The following components are listed: Titanium dioxide; Diiron trioxide

Pennsylvania : The following components are listed: Silicon dioxide; Titanium dioxide; Diiron trioxide

California Prop. 65

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

Section 15. Regulatory information

Ingredient name	Cancer	Reproductive	No significant risk level	Maximum acceptable dosage level
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.