Amnesteem® (Isotretinoin Capsules)

SAFETY DATA SHEET

North America GHS

According to Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules and Regulations & the Hazardous Products Regulation (February 11, 2015) & NORMA Oficial Mexicana NOM-018-STPS-2015

1. IDENTIFICATION

Product identifier

Product Name: Amnesteem® (Isotretinoin Capsules)

Synonyms: Isotretinoin Capsules, 10 mg; Isotretinoin Capsules, 20 mg; Isotretinoin Capsules, 30 mg; Isotretinoin Capsules, 40 mg; Amnesteem® (Isotretinoin Capsules, USP)

Other means of identification

Other Information: No other information

Recommended use of the chemical and restrictions on use

Recommended Use: Pharmaceutical. Use only as directed.

The intent of this safety data sheet (SDS) is to provide safety information for occupational handling of this product. This information may not be relevant for medical use of this product. Patients/ consumers should consult the package insert/ product label/ physician/ pharmacist for information regarding the usage of this product. For information on the ingredients used in this product, refer to the appropriate SDS for each ingredient.

Uses advised against: No information available.

Details of the supplier of the safety data sheet

Mylan Inc.
Robert J. Coury Global Center
1000 Mylan Blvd.
Canonsburg, PA 15317, USA
+1.724.514.1800

Contact e-mail: SDScontact@viatris.com

For any suspected reports of adverse events, product quality complaints or medical/product information questions, please email: druginfo@viatris.com

Emergency telephone number

Emergency Telephone: 24 hr. Emergency Contact ChemTel
International: +1-813-248-0585
US & Canada: 1-800-255-3924
Mexico: 800-099-0731

Other Contact Information

FDA Adverse Events Reporting Number: For reporting adverse health events call: +1 877-446-3679

2. HAZARDS IDENTIFICATION

Pharmaceutical Agent – Handling of this product in its final form presents minimal occupational exposure risk

Patients/Consumers: Please refer to the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii) and in Canada's Hazardous Products Act

Classification

Not classified

Label elements

Not classified

Other Hazards

No information available.

Unknown acute toxicity

No information available

3. COMPOSITION/INFORMATION ON INGREDIENTS

This product is a drug, as defined by the US Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and by Canada's Food and Drugs Act. It is in solid, final form for direct administration to the patient. Therefore, is it exempt from the US 2012 Hazard Communication Standard, as defined in the 29 CFR 1910.1200(b)(6)(vii) and in Canada's Hazardous Products Act

4. FIRST AID MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Description of first aid measures

Overdose: Refer to information on package labeling and packaging. In case of overdose, get medical help or contact a Poison Control Center right away.
General advice: Show this safety data sheet to the doctor in attendance.
Inhalation: IF INHALED: Remove to fresh air and keep at rest in a position comfortable for breathing. Get medical attention immediately if symptoms occur.
Skin contact: Wash off immediately with soap and plenty of water. If skin irritation or rash occurs: Get medical advice/attention.
Eye contact: In case of eye contact, immediately flush eyes with plenty of water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
Ingestion: Do not induce vomiting without medical advice. Rinse mouth thoroughly with water. Get medical attention if symptoms occur.
Self-protection of the first aider: First aider: Pay attention to self-protection. Do not breathe dust/fume/gas/mist/vapors/spray. Avoid contact with skin, eyes or clothing. Use personal protective equipment as required.

Most important symptoms and effects, both acute and delayed

Symptoms: Impairment of vision. Rashes. Gastrointestinal discomfort. May cause adverse cardiovascular effects.
Chronic symptoms: May cause adverse reproductive effects - such as birth defect, miscarriages, or infertility.

Indication of any immediate medical attention and special treatment needed

Treat symptomatically. In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

5. FIRE-FIGHTING MEASURES

Extinguishing media

Suitable Extinguishing Media: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.
Unsuitable extinguishing media: None known.

Specific hazards arising from the chemical

Fire hazard: Not flammable.
Explosive hazard: Not an explosive.
Reactivity: Hazardous reactions will not occur under normal conditions.
Hazardous combustion products: Carbon oxides.

Advice for firefighters

Precautionary measures in case of fire: Standard procedure for chemical fires.
Firefighting instructions: Use water spray or fog; do not use straight streams.
Protection of Firefighters: Firefighters should wear self-contained breathing apparatus and full firefighting turnout gear.
Other Information: Refer to Section 9 for flammability properties.

6. ACCIDENTAL RELEASE MEASURES

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Personal precautions, protective equipment and emergency procedures

Personal precautions: Avoid contact with skin, eyes or clothing. Do not breathe dust/fume/gas/mist/vapors/spray. Use personal protective equipment as required.

For non-emergency personnel

Personal Protective Equipment: Use personal protective equipment as required.
Emergency procedures: Evacuate personnel to safe areas.

For emergency responders

Personal Protective Equipment: Use personal protective equipment as required.
Emergency procedures: Evacuate personnel to safe areas. Ventilate the area. Eliminate all ignition sources if safe to do so.

Environmental precautions

Do not flush into surface water or sanitary sewer system. Should not be released into the environment. See Section 12 for additional Ecological Information.

Methods and material for containment and cleaning up

Methods for containment: Prevent further leakage or spillage if safe to do so.

Methods for cleaning up: Use appropriate personal protective equipment (PPE). Carefully shovel or sweep up spilled material and place in suitable container. Avoid generating dust. For spills:. Soak up with inert absorbent material. Use clean non-sparking tools to collect absorbed material. Avoid breathing dust or spray mist.
Prevention of secondary hazards: Clean contaminated objects and areas thoroughly observing environmental regulations.

Reference to other sections

See section 8 for more information. See section 13 for more information.

7. HANDLING AND STORAGE

Precautions for safe handling

Patients/Consumers: Patients should adhere to the instructions provided within the product information insert or product label for appropriate consumer-specific information about this product when used according to the physician's directions.
Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice. Avoid contact with skin, eyes or clothing. Do not eat, drink or smoke when using this product. Remove contaminated clothing and shoes.

Conditions for safe storage, including any incompatibilities

Storage Conditions: Keep at temperatures between 20 and 25 °C (68 and 77 °F). Keep containers tightly closed in a dry, cool and well-ventilated place. Protect from light. Keep out of reach of children. Store locked up.
Specific end use(s): Pharmaceutical. Use only as directed. Refer to product insert for usage instructions and product information.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

This is a pharmaceutical product in its final form. The risk of harmful exposure in the workplace is limited; however, the following guidance may be used as needed.

Control parameters

Exposure Limits: No information available

Exposure controls

Appropriate engineering controls: Site-specific risk assessments should be conducted to determine the appropriate exposure control measures. If applicable, use process enclosures, local exhaust ventilation, or other engineering controls to maintain airborne levels below recommended exposure limits.

Individual protection measures, such as personal protective equipment

Hand protection: Wear suitable gloves.
Eye/face protection: Safety glasses with side shields are recommended for medical or industrial exposures.
Skin and body protection: Wear suitable protective clothing.
Respiratory protection: Use appropriate respiratory protection.
General hygiene considerations: Do not eat, drink or smoke when using this product. Wash hands before breaks and immediately after handling the product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Physical state:	Solid
Appearance:	Capsules
Color:	red brown; red brown and cream; orange brown; White to light yellow
Odor:	No data available
Odor threshold:	No data available
pH:	No data available
Melting point / freezing point:	No data available
Boiling point / boiling range:	No data available
Flash point:	No data available
Evaporation rate:	No data available
Flammability (solid, gas):	No data available
Upper flammability limit:	No data available
Lower flammability limit:	No data available
Vapor pressure:	No data available
Vapor density:	No data available
Relative density:	No data available
Water solubility:	No data available
Solubility in other solvents:	No data available
Partition coefficient:	No data available
Autoignition temperature:	No data available
Decomposition temperature:	No data available
Kinematic viscosity:	No data available
Dynamic viscosity:	No data available
Explosive properties:	No data available

Oxidizing properties: No data available

Other Information

VOC Content (%): No data available

10. STABILITY AND REACTIVITY

Reactivity

Hazardous reactions will not occur under normal conditions.

Chemical stability

Stable under normal conditions.

Possibility of hazardous reactions

None under normal processing.

Conditions to avoid

Extremes of temperature and direct sunlight.

Incompatible materials

Strong oxidizing agents, strong acids, and strong bases.

Hazardous decomposition products

Decomposition will not occur under normal conditions.

11. TOXICOLOGICAL INFORMATION

Information on toxicological effects

Information on likely routes of exposure

Inhalation: Not an expected route of exposure.

Ingestion: Based on available data, the classification criteria are not met.

Eye contact: Not an expected route of exposure.

Skin contact: Not an expected route of exposure.

Symptoms related to the physical, chemical and toxicological characteristics

Symptoms: Impairment of vision. Rashes. Gastrointestinal discomfort. May cause adverse cardiovascular effects.

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

Skin corrosion/irritation: Not applicable.

Serious eye damage/eye irritation: Not applicable.

Respiratory or skin sensitization: Not applicable.

Germ cell mutagenicity: Based on available data, the classification criteria are not met.

Carcinogenicity: Based on available data, the classification criteria are not met.

Reproductive toxicity: Contains a known or suspected reproductive toxin.

STOT - single exposure: Based on available data, the classification criteria are not met.

STOT - repeated exposure: Based on available data, the classification criteria are not met.

Aspiration hazard: Based on available data, the classification criteria are not met.

Numerical measures of toxicity

Acute toxicity: No information available

12. ECOLOGICAL INFORMATION

Ecotoxicity

Toxic to aquatic life with long lasting effects.

Persistence and degradability

No information available.

Bioaccumulation

No information available.

Mobility

No information available.

Other adverse effects

No information available.

13. DISPOSAL CONSIDERATIONS

Waste treatment methods

Dispose of contents/container in accordance with local, regional, national, and international regulations as applicable. Dispose of waste in accordance with environmental legislation. Do not flush into surface water or sanitary sewer system.

14. TRANSPORT INFORMATION

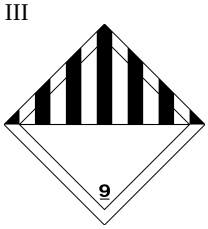
Transportation requirements can vary based on numerous factors such as regional regulations and shipment volume. It is the responsibility of the transporting organization to ensure compliance with all applicable laws and regulations regarding the transportation of this product.

DOT Not regulated

TDG

Marine pollutants exemption may apply. See 1.45.1 of the TRANSPORTATION OF DANGEROUS GOODS REGULATIONS code.

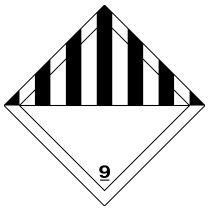
UN/ID no UN 3077
Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Isotretinoin)
Hazard Class 9
Packing Group III



Special Provisions TDG - 16; TDG - 99

IATA

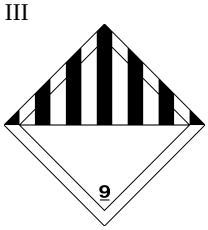
UN/ID no UN 3077
Proper shipping name Environmentally hazardous substances, solid, n.o.s. (contains Isotretinoin)
Hazard Class 9
Packing Group III



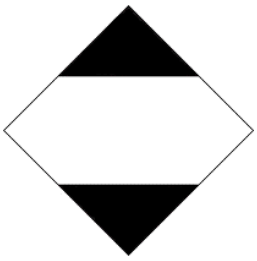
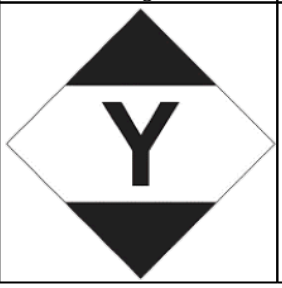
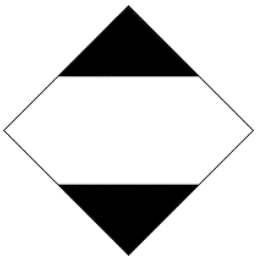
Special Provisions IATA - A97; IATA - A158; IATA - A179; IATA - 197

IMDG

UN/ID no UN 3077
Proper shipping name ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (contains Isotretinoin)
Hazard Class 9
Packing Group III



Special Provisions IMDG - 274; IMDG - 335; IMDG - 375; IMDG - 966; IMDG - 967; IMDG - 969

	DOT	TDG	IATA	IMDG
Limited Quantity **	Not Regulated	5 kg	30 kg G	5 kg
				

**Limited quantities provide the maximum quantity per inner packaging or article for carrying dangerous goods as limited quantities in accordance with the regulations.

	DOT	TDG	IATA	IMDG
Excepted Quantity - Inner Packaging #	Not Regulated	30 g	30 g	30 g
Excepted Quantity - Outer	Not Regulated	1000 g	1000 g	1000 g

Packaging #				

Dangerous goods regulations may not be applicable to a shipment that satisfies the quantity limits and other excepted quantity regulations.

15. REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

International Regulations

Ozone-depleting substances (ODS): Not applicable
Persistent Organic Pollutants: Not applicable
The Rotterdam Convention: Not applicable

US Federal Regulations

SARA 313: Section 313 of Title III of the Superfund Amendments and Reauthorization Act of 1986 (SARA). This product does not contain any chemicals which are subject to the reporting requirements of the Act and Title 40 of the Code of Federal Regulations, Part 372.

CWA (Clean Water Act)

This product does not contain any substances regulated as pollutants pursuant to the Clean Water Act (40 CFR 122.21 and 40 CFR 122.42).

CERCLA

This material, as supplied, does not contain any substances regulated as hazardous substances under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) (40 CFR 302) or the Superfund Amendments and Reauthorization Act (SARA) (40 CFR 355). There may be specific reporting requirements at the local, regional, or state level pertaining to releases of this material.

U.S. State Right-to-Know Regulations

US State Regulations:

Chemical name	New Jersey	Massachusetts	Pennsylvania
Soybean Oil 8001-22-7	-	-	X
Hydrogenated vegetable oil 68334-28-1	-	-	X
Isotretinoin 4759-48-2	-	X	-

Canada

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations (CPR) and the SDS contains all the information required by the CPR.

16. OTHER INFORMATION

Revision Date: 22-September-2025

Other Information: This document has been prepared in accordance with standards for workplace safety. The precautionary statements and warning included might not apply in all cases. Your needs may vary depending on the potential for exposure in your workplace.

Key or legend to abbreviations and acronyms used in the safety data sheet:

Legend, Section 8: EXPOSURE CONTROLS/PERSONAL PROTECTION
TWA: TWA (time-weighted average)
STEL: STEL (Short Term Exposure Limit)

Party responsible for the preparation of this document:
Viatris Global Environmental, Health, and Safety Department - Occupational Toxicology
Phone number: +1 304-559-2595

This SDS has been prepared for occupational exposure and intended to address some end-user concerns; however, patients/consumers are also strongly encouraged to review the product information insert or product label for consumer-specific information about this product. Patients/Consumers: Refer to the package insert or product label for appropriate consumer-specific information about this product when used according to manufacturer's directions. 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 completeness of the information 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.

Viatris GEHS NA GHS SDS