

SAFETY DATA SHEETS

This SDS packet was issued with item:

078947020

N/A

Imipramine Tablets USP 10 mg, 25 mg and 50 mg (active strengths)

Safety Data Sheet

According To Federal Register / Vol. 77, No. 58 / Monday, March 26, 2012 / Rules And Regulations
Date of Issue: 08/11/2020

Version: 1.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Imipramine Tablets USP 10 mg, 25 mg and 50 mg (active strengths)

Additional information: This *Safety Data Sheet* applies only in industrial settings when the product is not being handled in its final form (tablet), ready for direct administration to the patient. When the product is in final form, packaged according to the US Food, Drug, and Cosmetic Act ready for administration to the patient, it is considered exempt from the US 2012 Hazard Communication Standard and this *Safety Data Sheet* does not apply.

1.2. Intended Use of the Product

Use of the Substance/Mixture: Regulated prescription drug (tablet)

1.3. Name, Address, and Telephone of the Responsible Party

Company

Oxford Pharmaceuticals, LLC

301 Leaf Lake Parkway

Birmingham, AL 35211

T 205-434-9649

www.oxford-rx.com

1.4. Emergency Telephone Number

Emergency Number : ChemTel LLC
(800)255-3924 (North America)
+1 (813)248-0585 (International)

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Acute Tox. 4 (Oral) H302

STOT RE 1 H372

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H302 - Harmful if swallowed.
H372 - Causes damage to organs through prolonged or repeated exposure.

Precautionary Statements (GHS-US)

: P260 - Do not breathe vapors, mist, or spray.
P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
P270 - Do not eat, drink or smoke when using this product.
P301+P312 - If swallowed: Call a poison center or doctor if you feel unwell.
P314 - Get medical advice/attention if you feel unwell.
P330 - Rinse mouth.
P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Product is in tablet form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source, it may cause a dust explosion. Exposure may aggravate pre-existing eye, skin, or respiratory conditions.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

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3.2. Mixture

Name	Product Identifier	%	GHS US classification
Proprietary compound 1*	(CAS-No.) Trade Secret	10 - 35	Acute Tox. 4 (Oral), H302
Proprietary compound 2*	(CAS-No.) Trade Secret	17 -24	Comb. Dust
Proprietary compound 3*	(CAS-No.) Trade Secret	1 - 5	STOT RE 1, H372
Proprietary compound 4*	(CAS-No.) Trade Secret	2 - 4	Not classified
Proprietary compound 5*	(CAS-No.) Trade Secret	0.7 - 1	Comb. Dust
Proprietary compound 6*	(CAS-No.) Trade Secret	0.5 - 1.5	STOT SE 3, H335 Comb. Dust
Proprietary compound 7*	(CAS-No.) Trade Secret	≤ 0.05	Acute Tox. 3 (Oral), H301 Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Aquatic Acute 1, H400
Proprietary compound 8*	(CAS-No.) Trade Secret	0.00006 – 0.04	Carc. 1A, H350 STOT SE 3, H335 STOT RE 1, H372

Full text of H-phrases: see section 16

*The specific chemical identity of the composition have been withheld as a trade secret [29 CFR 1910.1200].

SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Obtain medical attention if irritation develops or persists. Drench affected area with water for at least 15 minutes.

First-aid Measures After Eye Contact: Rinse cautiously with water for at least 5 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Obtain medical attention if irritation develops or persists.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Causes damage to organs through prolonged or repeated exposure. Harmful if swallowed.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: Contains Crystalline Silica (Proprietary compound 8): As quartz and titanium dioxide is bound in a polymer matrix, it is not expected to be available as an airborne hazard under normal condition of use. If dust is released into the air, repeated exposure to respirable (airborne) crystalline silica and titanium dioxide dust may cause respiratory irritation, lung damage in the form of silicosis, kidney failure and cancer. Causes damage to organs through prolonged or repeated exposure.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is in tablet form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source, it may cause a dust explosion.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

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Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Carbon oxides (CO, CO₂). Nitrogen oxides. Hydrogen chloride gas. Smoke.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe dust. Do not get in eyes, on skin, or on clothing.

6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain solid spills with appropriate barriers and prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Recover the product by vacuuming, shoveling or sweeping. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: Product is in tablet form, but contains substances that are combustible dusts. If these substances in their powder form are allowed to accumulate, dispersed in sufficient quantities in air, and in the presence of an ignition source, it may cause a dust explosion.

Precautions for Safe Handling: Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work. Do not breathe dust. Avoid contact with eyes, skin and clothing. Handle empty containers with care because they may still present a hazard. Do not get in eyes, on skin, or on clothing.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Oxidizers.

7.3. Specific End Use(s)

Regulated prescription drug (tablet)

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

Proprietary compound 2		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	10 mg/m ³ (total dust) 5 mg/m ³ (respirable dust)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust) 5 mg/m ³ (respirable fraction)
Proprietary compound 3		
USA ACGIH	ACGIH TWA (mg/m ³)	2 mg/m ³ (particulate matter containing no asbestos and <1% crystalline silica, respirable particulate matter)
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen containing no asbestos fibers
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	2 mg/m ³ (containing no Asbestos and <1% Proprietary compound 8-respirable dust)

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USA IDLH	US IDLH (mg/m ³)	1000 mg/m ³ (containing no asbestos and <1% Proprietary compound 8)
Proprietary compound 4		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³
USA ACGIH	ACGIH chemical category	Not Classifiable as a Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	2.4 mg/m ³ (CIB 63-fine) 0.3 mg/m ³ (CIB 63-ultrafine, including engineered nanoscale)
USA IDLH	US IDLH (mg/m ³)	5000 mg/m ³
USA OSHA	OSHA PEL (TWA) (mg/m ³)	15 mg/m ³ (total dust)
Proprietary compound 5		
USA ACGIH	ACGIH TWA (mg/m ³)	10 mg/m ³ (inhalable particulate matter (Stearates)) 3 mg/m ³ (respirable particulate matter (Stearates))
Proprietary compound 6		
USA AIHA	WEEL TWA (mg/m ³)	10 mg/m ³ (molecular weight>200-aerosol)
Proprietary compound 8		
USA ACGIH	ACGIH TWA (mg/m ³)	0.025 mg/m ³ (respirable particulate matter)
USA ACGIH	ACGIH chemical category	A2 - Suspected Human Carcinogen
USA NIOSH	NIOSH REL (TWA) (mg/m ³)	0.05 mg/m ³ (respirable dust)
USA IDLH	US IDLH (mg/m ³)	50 mg/m ³ (respirable dust)
USA OSHA	OSHA PEL (TWA) (mg/m ³)	50 µg/m ³ (Respirable crystalline silica)
Proprietary compound 7		
USA AIHA	WEEL TWA (mg/m ³)	2.5 mg/m ³
USA AIHA	WEEL TWA (ppm)	0.5 ppm (OARS publication)

8.2. Exposure Controls

Appropriate Engineering Controls

: Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

Personal Protective Equipment

: Gloves. Protective clothing. Protective goggles.



Materials for Protective Clothing

: Chemically resistant materials and fabrics.

Hand Protection

: Wear protective gloves.

Eye and Face Protection

: Chemical safety goggles.

Skin and Body Protection

: Wear suitable protective clothing.

Respiratory Protection

: If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.

Other Information

: When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State	: Solid
Appearance	: No data available
Odor	: No data available
Odor Threshold	: No data available
pH	: No data available
Evaporation Rate	: No data available
Melting Point	: No data available
Freezing Point	: No data available
Boiling Point	: No data available
Flash Point	: No data available
Auto-ignition Temperature	: No data available

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Decomposition Temperature	: No data available
Flammability (solid, gas)	: No data available
Vapor Pressure	: No data available
Relative Vapor Density at 20°C	: No data available
Relative Density	: No data available
Solubility	: No data available
Partition Coefficient: N-Octanol/Water	: No data available
Viscosity	: No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

- 10.1. **Reactivity:** Hazardous reactions will not occur under normal conditions.
- 10.2. **Chemical Stability:** Stable under recommended handling and storage conditions (see section 7).
- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. **Incompatible Materials:** Oxidizers.
- 10.6. **Hazardous Decomposition Products:** Not expected to decompose under ambient conditions.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity (Oral): Harmful if swallowed.

Acute Toxicity (Dermal): Not classified

Acute Toxicity (Inhalation): Not classified

Imipramine Tablets USP 10 mg, 25 mg and 50 mg (active strengths)	
ATE (Oral)	759.75 mg/kg body weight
Proprietary compound 1	
LD50 Oral Rat	305 mg/kg
Proprietary compound 2	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rabbit	> 2000 mg/kg
LC50 Inhalation Rat	> 5800 mg/m ³ (Exposure time: 4 h)
Proprietary compound 4	
LD50 Oral Rat	> 10000 mg/kg
Proprietary compound 5	
LD50 Oral Rat	> 2000 mg/kg
Proprietary compound 6	
LD50 Oral Rat	47000 mg/kg
LD50 Dermal Rabbit	> 20 g/kg
Proprietary compound 8	
LD50 Oral Rat	> 5000 mg/kg
LD50 Dermal Rat	> 5000 mg/kg
Proprietary compound 7	
LD50 Oral Rat	335 mg/kg
LD50 Dermal Rat	> 2000 mg/kg
ATE (Oral)	100.00 mg/kg body weight

Skin Corrosion/Irritation: Not classified

Serious Eye Damage/Irritation: Not classified

Respiratory or Skin Sensitization: Not classified

Germ Cell Mutagenicity: Not classified

Carcinogenicity: Not classified

Proprietary compound 3	
IARC group	3
National Toxicology Program (NTP) Status	Evidence of Carcinogenicity.
Proprietary compound 4	

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IARC group	2B
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.
Proprietary compound 8	
IARC group	1
National Toxicology Program (NTP) Status	Known Human Carcinogens.
OSHA Hazard Communication Carcinogen List	In OSHA Hazard Communication Carcinogen list.

Reproductive Toxicity: Not classified

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Causes damage to organs through prolonged or repeated exposure.

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

Symptoms/Injuries After Skin Contact: Prolonged exposure may cause skin irritation.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: This material is harmful orally and can cause adverse health effects or death in significant amounts.

Chronic Symptoms: Contains Crystalline Silica (Proprietary compound 8): As quartz and titanium dioxide is bound in a polymer matrix, it is not expected to be available as an airborne hazard under normal condition of use. If dust is released into the air, repeated exposure to respirable (airborne) crystalline silica and titanium dioxide dust may cause respiratory irritation, lung damage in the form of silicosis, kidney failure and cancer. Causes damage to organs through prolonged or repeated exposure.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

Proprietary compound 3	
LC50 Fish 1	> 100 g/l (Exposure time: 96 h - Species: Brachydanio rerio [semi-static])
Proprietary compound 7	
EC50 Daphnia 1	800 mg/l

12.2. Persistence and Degradability

Imipramine Tablets USP 10 mg, 25 mg and 50 mg (active strengths)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Imipramine Tablets USP 10 mg, 25 mg and 50 mg (active strengths)	
Bioaccumulative Potential	Not established.
Proprietary compound 3	
BCF Fish 1	(no known bioaccumulation)

12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

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

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

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SARA Section 311/312 Hazard Classes	
Health hazard - Specific target organ toxicity (single or repeated exposure)	
Health hazard - Acute toxicity (any route of exposure)	

Proprietary compound 1	Listed on the United States TSCA (Toxic Substances Control Act) inventory
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Proprietary compound 2	Listed on the United States TSCA (Toxic Substances Control Act) inventory
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

Proprietary compound 3	Listed on the United States TSCA (Toxic Substances Control Act) inventory
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Proprietary compound 4	Listed on the United States TSCA (Toxic Substances Control Act) inventory
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Proprietary compound 5	Listed on the United States TSCA (Toxic Substances Control Act) inventory
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Proprietary compound 6	Listed on the United States TSCA (Toxic Substances Control Act) inventory
EPA TSCA Regulatory Flag	XU - XU - indicates a substance exempt from reporting under the Chemical Data Reporting Rule, (40 CFR 711).

Proprietary compound 8	Listed on the United States TSCA (Toxic Substances Control Act) inventory
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Proprietary compound 7	Listed on the United States TSCA (Toxic Substances Control Act) inventory
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15.2. US State Regulations


Proprietary compound 2	U.S. - Massachusetts - Right To Know List
	U.S. - New Jersey - Right to Know Hazardous Substance List
	U.S. - Pennsylvania - RTK (Right to Know) List

Proprietary compound 3	U.S. - Massachusetts - Right To Know List
	U.S. - New Jersey - Right to Know Hazardous Substance List
	U.S. - Pennsylvania - RTK (Right to Know) List

Proprietary compound 4	U.S. - Massachusetts - Right To Know List
	U.S. - New Jersey - Right to Know Hazardous Substance List
	U.S. - Pennsylvania - RTK (Right to Know) List

Proprietary compound 8	U.S. - Massachusetts - Right To Know List
	U.S. - New Jersey - Right to Know Hazardous Substance List
	U.S. - Pennsylvania - RTK (Right to Know) List

Proprietary compound 7	U.S. - New Jersey - Right to Know Hazardous Substance List
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California Proposition 65  **WARNING:** This product can expose you to Proprietary compound 8, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Chemical Name (CAS No.)	Carcinogenicity	Developmental Toxicity	Female Reproductive Toxicity	Male Reproductive Toxicity
Proprietary compound 4	X			
Proprietary compound 8	X			

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision

: 08/11/2020

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Other Information

: This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 3 (Oral)	Acute toxicity (oral) Category 3
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Aquatic Acute 1	Hazardous to the aquatic environment - Acute Hazard Category 1
Carc. 1A	Carcinogenicity Category 1A
Comb. Dust	Combustible Dust
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Skin Irrit. 2	Skin corrosion/irritation Category 2
STOT RE 1	Specific target organ toxicity (repeated exposure) Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H301	Toxic if swallowed
H302	Harmful if swallowed
H315	Causes skin irritation
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H350	May cause cancer
H372	Causes damage to organs through prolonged or repeated exposure
H400	Very toxic to aquatic life

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

SDS US (GHS HazCom)