



**SQUARE PHARMACEUTICALS LTD
DHAKA UNIT**

SAFETY DATA SHEET

PART I: What is the material and what do I need to know in an emergency?

1. IDENTIFICATION OF THE SUBSTANCE/MIXTURE

IDENTIFICATION of the SUBSTANCE or PREPARATION:

Trade Name: Mirtazapine Orally Disintegrating Tablets USP

Generic Name: Mirtazapine USP

Chemical Name API (IUPAC): 1,2,3,4,10,14b-hexahydro-2-methylpyrazino [2,1-a]pyrido[2,3-c]benzazepine

Chemical Formula of API: C₁₇H₁₉N₃

Legal Category: Prescription Only Medicine (POM).

Therapeutic Class: Antidepressant.

Therapeutic action and Use: Mirtazapine orally disintegrating tablets, USP are indicated for the treatment of major depressive disorder.

Relevant Use of the Product: Human Pharmaceuticals

How Supplied:

Mirtazapine ODT USP, 15 mg: NDC 72578-103-84 in unit-dose blister cartons of 30 (5 x 6) unit-dose tablets

Mirtazapine ODT USP, 30 mg: NDC 72578-104-84 in unit-dose blister cartons of 30 (5 x 6) unit-dose tablets

Mirtazapine ODT USP, 30 mg: NDC 72578-105-84 in unit-dose blister cartons of 30 (5 x 6) unit-dose tablets

COMPANY/UNDERTAKING IDENTIFICATION:

SQUARE PHARMACEUTICALS LTD.

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2. HAZARDS IDENTIFICATION

GLOBAL HARMONIZATION AND EU CLP REGULATION (EC) 1272/2008 LABELING AND CLASSIFICATION:

According to Article 1, item 5 (a) of CLP Regulation (EC) 1272/2008, medicinal products in the finished state for human use, as defined in 2001/83/EC, are exempted from classification and other criteria of 1272/2008.

EU LABELING/CLASSIFICATION: According to Article 1 of European Union Council Directive 92/32/EEC, medical products in the finished state for human use (as defined by European Union Council Directives 67/548/EEC and 87/21/EEC) are not subject to the regulations and administrative provisions of European Union Council Directive 92/32/EEC



**SQUARE PHARMACEUTICALS LTD
DHAKA UNIT**

SAFETY DATA SHEET

EMERGENCY OVERVIEW: Product Description: This product is supplied as tablets which are off-white colored, round shaped, beveled edged, uncoated tablets (15, 30 and 45 mg).

Health Hazards: In the workplace, exposure via inhalation and skin contact may cause irritation. Dusts from tablets can cause mechanical irritation to the eyes. Non-therapeutic ingestion may be harmful. In therapeutic use, the most common adverse effects reported include constipation, weight gain, dizziness, nausea, increased appetite, dry mouth, somnolence, dizziness, peripheral edema, disturbance in thinking, serum triglyceride increase, and lack or loss of strength and energy, weakness. A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported (see Section 11. (Toxicological Information) for more information on this syndrome. Therapeutic use can cause other serious central nervous system effects, adverse effects on cardiovascular and blood systems. May cause harm to the fetus during pregnancy, based on animal data. Limited evidence of carcinogenic potential, based on animal data. These effects may be possible as a result of workplace exposure. Refer to Section 11 (Toxicological Information) for additional information on adverse effects.

Flammability Hazards: This product requires substantial pre-heating before ignition occurs. When involved in a fire, this product may decompose and produce irritating vapors and toxic compounds (including carbon, magnesium, silicon, titanium and nitrogen oxides).

Reactivity Hazards: This product is not reactive.

Environmental Hazards: Release to the environment may have adverse effect.

Emergency Recommendations: Emergency responders must wear personal protective equipment suitable for the situation to which they are responding.

3. COMPOSITION AND INFORMATION ON INGREDIENTS

Composition:

| Active Ingredient | Content | |
|----------------------|---------|---|
| Mirtazapine USP | 15 mg | Each orally disintegrating tablet contains Mirtazapine USP 15 mg |
| | 30 mg | Each orally disintegrating tablet contains Mirtazapine USP 30 mg |
| | 45 mg | Each orally disintegrating tablet contains Mirtazapine USP 45 mg |
| Inactive ingredients | 15 mg | Mannitol USP (Pearlitol 50C), Microcrystalline Cellulose NF (M 101), Crospovidone NF (Polyplasdone XL), Povidone USP (K 29/32), Mannitol USP (Pearlitol 200 SD), Microcrystalline Cellulose NF (M 102), Aspartame NF, Orange Flavour 501071 AP0551, Anhydrous Citric Acid USP, Colloidal Silicon Dioxide NF, Magnesium Stearate NF and Sodium Stearyl Fumarate NF |
| | 30 mg | |
| | 45 mg | |

PART II: What should I do if a hazardous situation occurs?

4. FIRST AID MEASURES

DESCRIPTION OF FIRST AID MEASURES: Contaminated individuals must be taken for medical attention if any adverse effects occur. Remove contaminated clothing and shoes. Take a copy of this SDS to health professional with victim. Wash clothing and thoroughly clean shoes before reuse.

Skin Exposure: If skin contact with this product occurs, flush affected area with water. Minimum flushing is for 20 minutes. The contaminated individual must seek medical attention if any adverse effects occur after flushing.

Eye Exposure: If dusts from product enter the eyes, open contaminated individual's eyes while under gently running water. Use sufficient force to open eyelids. Have contaminated individual "roll" eyes. Minimum flushing is for 20 minutes. Contaminated individual must seek medical attention if adverse effect occurs or continues after flushing.

Inhalation: If dusts are inhaled, remove victim to fresh air. The contaminated individual must seek medical attention if any adverse effects occur.

Ingestion: If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, seek immediate medical attention. If alert, victim should drink up to three glasses of water. Do not induce vomiting. Never induce vomiting or give diluents (milk or water) to someone who is unconscious.



SQUARE PHARMACEUTICALS LTD DHAKA UNIT

SAFETY DATA SHEET

having convulsions, or unable to swallow. If victim is convulsing, maintain an open airway and obtain emergency medical attention.

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: In therapeutic use, pre-existing cardiovascular disease, central nervous and blood system disorders (including leukopenia/neutropenia, agranulocytosis), susceptibility to dehydration, depression, or suicidal tendencies may be aggravated. Workplace exposure may also aggravate these conditions. Persons who may have hypersensitivity reactions to benzodiazepines or other disorders described in Section 11 (Toxicological Information) may experience aggravation upon exposure.

INDICATION OF IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT IF NEEDED: Treat symptoms and eliminate exposure. Persons developing hypersensitivity reactions should receive immediate medical attention. Ensure an adequate airway, oxygenation, and ventilation. Monitor cardiac rhythm and vital signs. General supportive and symptomatic measures are also recommended. Induction of emesis is not recommended. Gastric lavage with a large-bore orogastric tube with appropriate airway protection, if needed, may be indicated if performed soon after ingestion, or in symptomatic patients. Activated charcoal should be administered. There is no experience with the use of forced diuresis, dialysis, hemoperfusion or exchange transfusion in the treatment of Mirtazapine acute oral exposure. No specific antidotes for Mirtazapine are known.

5. FIRE AND EXPLOSION DATA

FLASH POINT: Not available.

AUTOIGNITION TEMPERATURE: Not available.

FLAMMABLE LIMITS (in air by volume, %): Not applicable.

FIRE EXTINGUISHING MEDIA: Unless incompatibilities exist for surrounding materials, carbon dioxide, water spray, 'ABC' type chemical extinguishers, foam, dry chemical and halon extinguishers can be used to fight fires involving this product.

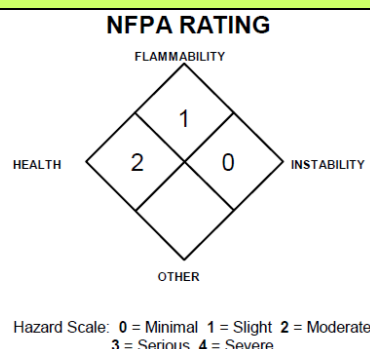
UNSUITABLE FIRE EXTINGUISHING MEDIA: None known.

SPECIAL HAZARDS ARISING FROM THE SUBSTANCE: This product must be substantially pre-heated before ignition can occur. When involved in a fire, this material may decompose and produce irritating vapors and toxic compounds (including carbon, magnesium, silicon, titanium and nitrogen oxides).

Explosion Sensitivity to Mechanical Impact: Not applicable.

Explosion Sensitivity to Static Discharge: Not sensitive.

SPECIAL PROTECTIVE ACTIONS FOR FIRE-FIGHTERS: Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. All personal protective gear and contaminated fire-response equipment should be decontaminated with soapy water and thoroughly rinsed before being returned to service. Move fire-exposed containers if it can be done without risk to firefighters. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.



6. ACCIDENTAL RELEASE MEASURE

PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES: Spill kits, clearly labeled, should be kept in or near preparation and administrative areas. It is suggested that kits include a respirator, chemical splash goggles, two pairs of gloves, two sheets (12" x 12") of absorbent material, 250-mL and 1-liter spill control pillows, a small scoop to collect glass fragments (if applicable) and two large waste disposal bags. Absorbents should be able to be incinerated. Avoid generating airborne dusts of this product during spill response procedures as described below.

PROTECTIVE EQUIPMENT:

Small Spills/Spills in Hoods: Personnel wearing nitrile or other appropriate gloves, lab coat or other protective clothing and eye protection should immediately clean incidental spills (e.g. a single container).

Large Spills: For large spills (e.g., a pallet of containers), proper protective equipment, including double nitrile or appropriate gloves, and protective clothing (i.e., disposable Tyvek coveralls). When there is any danger of airborne dusts being generated, use a full-face respirator equipped with a High Efficiency Particulate (HEPA) filter. Self-Contained Breathing Apparatus (SCBA) can be used instead of an air-purifying respirator.

METHODS FOR CLEAN-UP AND CONTAINMENT:

Cleanup of Small Spills: Pick-up or wipe-up spilled tablets with damp absorbent sheets to prevent generation of dusts. Decontaminate the spill area (three times) using a bleach and detergent solution and then rinse with clean water.

Large Spills: Restrict access to the spill areas. Gently wet down area and carefully sweep up spilled product, avoiding the generation of airborne dusts. The dispersion of particles into surrounding air and the possibility of inhalation is a serious matter and should be treated as such. Do not apply chemical in-activators as they may produce hazardous by-products. Thoroughly clean all contaminated surfaces three times using a bleach and detergent solution and then rinse with clean water.



**SQUARE PHARMACEUTICALS LTD
DHAKA UNIT**

SAFETY DATA SHEET

All Spills: Use procedures described above and then place all spill residues in an appropriate, labeled container and seal. Move to a secure area. Dispose of in accordance with Federal, State, and local hazardous waste disposal regulations (see Section 13, Disposal Considerations). For spills on water, contain, minimize dispersion and collect. Dispose of recovered product and report spill per regulatory requirements. Disposal of this product has requirements under DEA regulations as a narcotic substance.

ENVIRONMENTAL PRECAUTIONS: Prevent product from entering sewer or confined spaces, waterways, soil or public waters. Do not flush to sewer. For spills on water, contain, minimize dispersion and collect.

REFERENCE TO OTHER SECTIONS: Review Sections 2, 8, 11 and 12 before proceeding with cleanup. See Section 13, Disposal Considerations for more information.

PART III: How can I prevent hazardous situations from occurring?

7. HANDLING AND STORAGE

PRECAUTIONS FOR SAFE HANDLING: All employees who handle this product should be thoroughly trained to handle it safely. As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat or drink while handling this product. After handling this product, wash face and hands thoroughly prior to eating, drinking, smoking or applying cosmetics. Ensure this material is used with adequate ventilation. Appropriate personal protective equipment must be worn (see Section 8, Exposure Controls - Personal Protection). Open containers slowly on a stable surface in areas that have been designated for use of this material. Minimize all exposures to this product. Avoid generation of dusts. Areas in which this product is used should be wiped down, so that this particulates do not accumulate.

CONDITIONS FOR SAFE STORAGE: Containers of this product must be properly labeled. Store containers in a cool, dry location, away from direct sunlight and sources of intense heat. Recommended Storage Temperature: Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature]. Protect from light and moisture. Use immediately upon opening individual tablet blister. Store away from incompatible materials (see Section 10, Stability and Reactivity). Product should be stored in secondary containers. Keep containers tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged. Have appropriate extinguishing equipment in the storage area (e.g., sprinkler system, portable fire extinguishers). Empty containers may contain residual material; therefore, empty containers should be handled with care and disposed of properly.

SPECIFIC END USE(S): This product is a human pharmaceutical.

PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT: When cleaning non-disposable equipment, wear nitrile or other appropriate gloves (double gloving is recommended), goggles, and lab coat. Prevent dispersion of particulates by wetting or dampening surfaces prior to clean up of equipment. If applicable, wash equipment using a bleach and detergent solution and then rinse with clean water.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

EXPOSURE LIMITS/CONTROL PARAMETERS:

Ventilation and Engineering Controls: General: Use with adequate ventilation. Follow standard operating procedures and requirements for handling this product. Ensure eyewash stations and deluge showers are available and accessible in areas where this product is used. Wear appropriate personal protect equipment consistent with the recommendations of this SDS. Prevent accumulation of product on work surfaces by routinely cleaning areas appropriately.

PROTECTIVE EQUIPMENT: *The following information on appropriate Personal Protective Equipment is provided to assist employers in complying with OSHA regulations found in 29 CFR Subpart I (beginning at 1910.132, including U.S. Federal OSHA Respiratory Protection (29 CFR 1910.134), OSHA Eye Protection 29 CFR 1910.133, OSHA Hand Protection 29 CFR 1910.138, OSHA Foot Protection 29 CFR 1910.136 and OSHA Body Protection 29 CFR 1910.132), equivalent standards of Canada (including CSA Respiratory Standard Z94.4-02, Z94.3-M1982, Industrial Eye and Face Protectors and CSA Standard Z195-02, Protective Footwear), or standards of EU member states (including EN 529:2005 for respiratory PPE, CEN/TR 15419:2006 for hand protection, and CR 13464:1999 for face/eye protection). Please reference applicable regulations and standards for relevant details.*

Respiratory Protection: Maintain airborne contaminant concentrations below exposure limits listed above, if applicable. For materials



**SQUARE PHARMACEUTICALS LTD
DHAKA UNIT**

SAFETY DATA SHEET

without listed exposure limits, minimize respiratory exposure. If necessary, use only respiratory protection authorized under appropriate regulations. Oxygen levels below 19.5% are considered IDLH by U.S. OSHA. In such atmospheres, use of a full-facepiece pressure/demand SCBA or a full facepiece, supplied air respirator with auxiliary self-contained air supply is required under U.S. OSHA's Respiratory Protection Standard (1910.134-1998).

Eye Protection: Wear splash goggles or safety glasses as appropriate for the task. If necessary, refer to appropriate regulations.

9. PHYSICAL AND CHEMICAL PROPERTIES

| Parameters | Mirtazapine Orally Disintegrating Tablets USP 15 mg | Mirtazapine Orally Disintegrating Tablets USP 30 mg | Mirtazapine Orally Disintegrating Tablets USP 45 mg |
|-------------------|--|--|--|
| Appearance | White to off-white colored, round shaped, beveled edged, uncoated tablets, debossed with '677' on upper face and plain on the other side. The tablet should be free from all physical defects. | White to off-white colored, round shaped, beveled edged, uncoated tablets, debossed with '676' on upper face and plain on the other side. The tablet should be free from all physical defects. | White to off-white colored, round shaped, beveled edged, uncoated tablets, debossed with '679' on upper face and plain on the other side. The tablet should be free from all physical defects. |
| Color | White to off-white | White to off-white | White to off-white |

10. STABILITY AND REACTIVITY DATA

CHEMICAL STABILITY: Stable under normal conditions.

DECOMPOSITION PRODUCTS: *Combustion:* Products of thermal decomposition may include carbon, magnesium, silicon, titanium and nitrogen oxides. *Hydrolysis:* None known.

MATERIALS WITH WHICH SUBSTANCE IS INCOMPATIBLE: Incompatible with strong oxidizing agents, and strong acids.

POSSIBILITY OF HAZARDOUS REACTION/POLYMERIZATION: Will not occur.

CONDITIONS TO AVOID: Exposure to or contact with extreme temperatures, incompatible chemicals.

PART IV Is there any other useful information about this material?

11. TOXICOLOGICAL INFORMATION

SYMPTOMS OF EXPOSURE BY ROUTE OF EXPOSURE: The main route of occupational exposure to this product is via inhalation of dusts and skin contact. The anticipated symptoms of exposure, by route of exposure are described further in this section.

Inhalation: Inhalation of dusts generated by damaged tablets of this product may slightly irritate the nose, throat, and lungs. No other health effects from inhalation known.

Contact with Skin or Eyes: It is anticipated that dusts generated by product may irritate contaminated skin or eyes. Symptoms of skin contact may include itching and redness. Symptoms of eye contact can include redness, pain, and watering (mechanical irritation).

Skin Absorption: No specific data is available on absorption through intact skin; all skin contact should be avoided.

Ingestion: Accidental ingestion of this product (i.e., through poor hygiene practices) may be harmful, causing adverse central nervous system effects. Other effects may occur as described under 'Other Potential Health Effects'.

Injection: Not a potential route of exposure for tablets.

OTHER POTENTIAL HEALTH EFFECTS: In therapeutic use, the most common adverse effects reported include constipation, weight gain, dizziness, nausea, increased appetite, dry mouth, somnolence, dizziness, peripheral edema, disturbance in thinking, serum triglyceride increase, and lack or loss of strength and energy, weakness. A potentially fatal symptom complex sometimes referred to as Neuroleptic Malignant Syndrome (NMS) has been reported in association with administration of antidepressant drugs, including Mirtazapine. Clinical manifestations of NMS are high fever, muscle rigidity, altered mental status and evidence of autonomic instability (irregular pulse or blood pressure, rapid heart rate, excessive sweating and irregular heartbeat). Additional signs may include elevated creatinine phosphokinase (indicating stress or injury to muscle of heart or brain), breakdown of muscle tissue, and acute renal failure. These effects may be possible as a result of workplace exposure.

| HAZARDOUS MATERIAL IDENTIFICATION SYSTEM | | | |
|--|---------------|-------|---------------|
| HEALTH HAZARD | (BLUE) | 2* | |
| FLAMMABILITY HAZARD | (RED) | 1 | |
| PHYSICAL HAZARD | (YELLOW) | 0 | |
| PROTECTIVE EQUIPMENT | | | |
| EYES | RESPIRATORY | HANDS | BODY |
| | SEE SECTION 8 | | SEE SECTION 8 |
| For Routine Industrial Use and Handling Applications | | | |

Hazard Scale: 0 = Minimal 1 = Slight 2 = Moderate
3 = Serious 4 = Severe * = Chronic hazard



**SQUARE PHARMACEUTICALS LTD
DHAKA UNIT**

SAFETY DATA SHEET

Body systems adversely affected during therapeutic use are provided below.

- Blood and Lymphatic System
- Body as a Whole
- Cardiovascular System
- Central Nervous system
- Ears
- Eyes
- Gastrointestinal System
- Hypersensitivity Reactions
- Metabolic System
- Musculoskeletal System
- Psychiatric Disorder
- Reproductive System
- Respiratory System
- Skin
- Urinary System

HEALTH EFFECTS OR RISKS FROM EXPOSURE:

Acute: Dusts from product may cause irritation if inhaled and mechanical irritation to the eyes. Accidental ingestion may be harmful. Chronic: May cause fetal harm. Limited evidence of carcinogenic potential, based on animal data. Chronic exposure may result in addition and adverse effects on the body systems described under 'Other Potential Health Effects'.

TARGET ORGANS: It is anticipated that for Occupational Exposure the target organs are: Acute: Skin, eyes, respiratory system. Chronic: Fetal harm, carcinogenic potential. In therapeutic use this product may have an impact on the body systems listed under 'Other Potential Health Effects'.

12. ECOLOGICAL INFORMATION

ALL WORK PRACTICES MUST BE AIMED AT ELIMINATING ENVIRONMENTAL CONTAMINATION.

Estimated values for the active ingredient are available from the U.S. Environmental Protection Agency's EPISuite™; however, this information is not provided in this SDS.

MOBILITY: Currently, there is no specific information available on the potential mobility of this product.

PERSISTENCE AND BIODEGRADABILITY: Currently, there is no specific information on persistence and biodegradability for this product. Some biodegradation is expected.

BIO-ACCUMULATION POTENTIAL: Currently, no specific information is available on the bioconcentration potential of this product.

ECOTOXICITY: This material may be harmful to contaminated plant and animal life, especially in large quantities. All releases to terrestrial, atmospheric and aquatic environments should be avoided. The following aquatic toxicity data are available for the active ingredient.

MIRTAZAPINE:

LC50 (Fishes) 96 hours = 6.96 mg/L

EC50 (*Daphnia* water flea) 48 hours = 19.9 mg/L

RESULTS OF PBT AND vPvB ASSESSMENT: No Data Available. PBT and vPvB assessments are part of the chemical safety report required for some substances in European Union Regulation (EC) 1907/2006, Article 14.

OTHER ADVERSE EFFECTS: The components of this product are not listed as having ozone depletion potential.

ENVIRONMENTAL EXPOSURE CONTROLS: Controls should be engineered to prevent release to the environment, including procedures to prevent spills, atmospheric release and release to waterways.

13. DISPOSAL CONSIDERATION

WASTE TREATMENT/DISPOSAL METHODS: Waste disposal must be in accordance with appropriate Federal, State, and local regulations. This product, if unaltered by use, may be disposed of by treatment at a permitted facility or as advised by your local hazardous waste regulatory authority. All protective clothing, gloves, and disposable materials used in the preparation or handling of this drug should be disposed of in accordance with established hazardous waste disposal procedures. It is the responsibility of the generator to determine at the time of disposal whether the product meets the criteria of a hazardous waste per regulations of the area in which the waste is generated and/or disposed. Incineration is recommended for the product and disposable equipment. Shipment of wastes must be done with appropriately permitted and registered transporters. Reusable equipment should be cleaned with soap and water and thoroughly rinsed.

DISPOSAL CONTAINERS: Waste materials must be placed in and shipped in appropriate 5-gallon or 55-gallon poly or metal waste pails or drums. Permeable cardboard containers are not appropriate and should not be used. Ensure that any required marking or labeling of the containers be done to all applicable regulations.

PRECAUTIONS TO BE FOLLOWED DURING WASTE HANDLING: Wear proper protective equipment when handling waste materials.



**SQUARE PHARMACEUTICALS LTD
DHAKA UNIT**

SAFETY DATA SHEET

Note: Because of being a controlled substance in the United States, the local Drug Enforcement Administration office must be notified for authority and instructions for disposal.

EWC WASTE CODE: Wastes from Human or Animal Health Care or Related Research: 18 01 08: Medicines Other Than Those Mentioned in 18 01 07.

14. TRANSPORTATION INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION: This product is NOT classified as dangerous goods, per U.S. DOT regulations, under 49 CFR 172.101.

TRANSPORT CANADA TRANSPORTATION OF DANGEROUS GOODS REGULATIONS: This product does not meet the criteria of classification of Dangerous Goods, per regulations of Transport Canada.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): This product does not meet the criteria as Dangerous Goods, per rules of IATA.

INTERNATIONAL MARITIME ORGANIZATION (IMO) DESIGNATION: This product is NOT classified as Dangerous Goods by the International Maritime Organization.

EUROPEAN AGREEMENT CONCERNING THE INTERNATIONAL CARRIAGE OF DANGEROUS GOODS BY ROAD (ADR): This product does not meet the criteria as Dangerous Goods of the United Nations Economic Commission for Europe.

TRANSPORT IN BULK ACCORDING TO THE IBC CODE: Not applicable.

ENVIRONMENTAL HAZARDS: This product does not meet the criteria of environmentally hazardous according to the criteria of the UN Model Regulations (as reflected in the IMDG Code, ADR, RID, and ADN) and is not specifically listed in Annex III under MARPOL 73/78.

15. REGULATORY INFORMATION

ADDITIONAL U.S. REGULATIONS:

U.S. SARA Reporting Requirements: The components of this product are not subject to the reporting requirements of Sections 302, 304, and 313 of Title III of the Superfund Amendments and Reauthorization Act.

U.S. SARA Threshold Planning Quantity (TPQ): There are no specific Threshold Planning Quantities for the components of this product. The default Federal SDS submission and inventory requirement filing threshold of 10,000 lb (4,540 kg) may apply, per 40 CFR 370.20.

U.S. SARA Hazard Categories (Section 311/312, 40 CFR 370-21): ACUTE: Yes; CHRONIC: Yes; FIRE: No; REACTIVE: No; SUDDEN RELEASE: No

U.S. CERCLA Reportable Quantity (RQ): Not applicable.

U.S. TSCA Inventory Status: This product is regulated under Food and Drug Administration (FDA) standards; this product is not subject to requirements under TSCA.

Other U.S. Federal Regulations: Under the Hazard Communication Standard (HCS), Section (b)(5)(ii) drugs are subject to labeling requirements by the FDA under the Federal Food, Drug and Cosmetic Act and are exempt from labeling provisions of the HCS; this section of the HCS exempts only labeling requirements and not requirements for a Safety Data Sheet for drugs.

California Safe Drinking Water and Toxic Enforcement Act (Proposition 65): No component is on the California Proposition 65 lists.

16. OTHER INFORMATION

SDS Creation Date: 09 November 2022

SDS Version Number: 1

The information above is believed to be accurate and represents the best information currently available to us. However, we make no warranty of merchantability or any other warranty, express or implied, with respect to such information, and we assume no liability resulting from its use. Users should make their own investigations to determine the suitability of the information for their particular purposes. In no event shall SQUARE Pharmaceuticals Ltd. be liable for any claims, losses, or damages of any third party or for lost profits or any special, indirect, incidental, consequential or exemplary damages, howsoever arising, even if SQUARE Pharmaceuticals Ltd. has been advised of the possibility of such damages.

End of Safety Data
