SAFETY DATA SHEET

Section 1: Identification	
Material **Recommended use**	**Varenicline tartrate tablets 0.5 mg and 1 mg** Pharmaceutical product used for Smoking cessation
Manufacturer	**Hetero Labs Limited, Unit-III** **22-110, IDA,** Unit III, Jeedimetla, Hyderabad-500055, India.
Distributor	**Camber Pharmaceuticals, Inc.**, Piscataway, NJ 08854
Section 2: Hazard(s) Identification	
Classification of the Substance or Mixture **GHS - Classification**	Not classified as hazardous
EU Classification:	EU Indication of danger: Not classified
Label Elements **Signal Word:**	Not required
Other Hazards **Australian Hazard Classification (NOHSC):**	No data available Non-Hazardous Substance. Non-Dangerous Goods
Section 3: Composition/Information on Ingredients	
Ingredients	CAS
Varenicline tartrate	375815-87-5
Magnesium stearate	557-04-0
Microcrystalline cellulose	9004-34-6
Anhydrous dibasic calcium phosphate	7757-93-9
Croscarmellose Sodium	74811-65-7
Ferric oxide	1309-33-7
Silicon Dioxide	7631-86-9
Opadry pink	NA
Opadry yellow	NA
Opadry clear	NA

Section 4: First-Aid Measures	
Eye Contact	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately
Skin Contact	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
Ingestion	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately
Inhalation	Remove to fresh air and keep patient at rest. Seek medical attention immediately
Indication of the Immediate Medical Attention and Special Treatment Needed **Notes to Physician**	None
Section 5: Fire-Fighting Measures	
Extinguishing Media	Extinguish fires with CO_2, extinguishing powder, foam, or water.
Special Hazards Arising from the Substance or Mixture **Hazardous Combustion Products**	Formation of toxic gases is possible during heating or fire
Fire / Explosion Hazards	Not applicable
Advice for Fire-Fighters	During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus
Section 6: Accidental Release Measures	
Personal Precautions, Protective Equipment and Emergency Procedures	Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.
Environmental Precautions	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release
Methods and Material for Containment and Cleaning Up **Measures for Cleaning /Collecting**	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly
Section 7: Handling and Storage	
Precautions for Safe Handling	Minimize dust generation and accumulation. If tablets or capsules are crushed and/or broken, avoid breathing dust and avoid contact with eyes, skin, and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases

	to the environment should be avoided. Refer to Section 12 - Ecological Information, for information on potential effects on the environment. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls
Conditions for Safe Storage, Including any Incompatibilities **Storage Conditions** **Specific end use(s)**	Store as directed by product packaging. Pharmaceutical drug product
Section 8: Exposure Controls/Personal Protection	
Engineering Controls	Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep air borne contamination levels below the exposure limits listed above in this section.
Personal Protective Equipment	Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).
Hands	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations
Eyes	Wear safety glasses or goggles if eye contact is possible
Skin	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations
Respiratory protection	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL
Section 9: Physical and Chemical Properties	
Physical Form	Film-coated tablets
Colour	0.5 mg – Pink; 1 mg -Yellow

Description	Varenicline tablets are supplied for oral administration in two strengths and are supplied in the following package configurations: Varenicline tablets 0.5 mg: Pink, capsular, biconvex, film coated tablets debossed with “H” on one side and “V23” on the other side. Bottle of 56 Tablets NDC 31722-678-56 Starting Month Box: 0.5 mg x 11 tablets and 1 mg x 42 tablets NDC 31722-690-31 Varenicline tablets 1 mg: Yellow, capsular, biconvex, film coated tablets debossed with “H” on one side and “V24” on the other side. Bottle of 56 Tablets NDC 31722-679-56 Continuing Month Box: 1 mg x 56 tablets NDC 31722-679-31 Store at 20º to 25ºC (68º to 77ºF); excursions permitted to 15º to 30ºC (59º to 86ºF) [see USP Controlled Room Temperature].
Section 10: Stability and Reactivity	
Reactivity	No data available
Chemical Stability	Stable under normal conditions of use
Possibility of Hazardous Reactions **Oxidizing Properties** **Conditions to Avoid** **Incompatible Materials** **Hazardous Decomposition Products**	 No data available None known As a precautionary measure, keep away from strong oxidizers No data available
Section 11: Toxicological Information	
Information on Toxicological Effects **General Information**	The information included in this section describes the potential hazards of the individual ingredients.
Short Term	Active ingredient may be harmful if swallowed. May cause minor irritation if tablets are crushed or broken

Long Term	Animal studies indicate that this material may cause adverse effects on the liver
Known Clinical Effects	Adverse effects associated with therapeutic use include nausea, sleep disturbances, constipation, flatulence, vomiting. Additionally, behavioral changes, agitation, depressive mood, suicidal behavior, abnormal dreams, and effects on cardiovascular system may occur

Acute Toxicity: (Species, Route, End Point, Dose)

Varenicline tartrate

Rat Oral LDmin.(hydrochloride salt) 300 mg/kg
Rat Dermal LD50 > 2000mg/kg

Irritation / Sensitization: (Study Type, Species, Severity)

Varenicline tartrate

Eye Irritation Rabbit Mild
Skin Irritation Rabbit Mild
Skin Sensitization - M & K Guinea Pig Negative

Repeated Dose Toxicity: (Duration, Species, Route, Dose, End Point, Target Organ)

Varenicline tartrate

3 Month(s)	Monkey	Oral 0.2 mg/kg/day	NOAEL	No effects at maximum dose
9 Month(s)	Monkey	Oral 0.2 mg/kg/day	NOAEL	No effects at maximum dose
3 Month(s)	Rat	Oral 10 mg/kg/day	NOAEL	Gastrointestinal system, Liver
6 Month(s)	Rat	Oral 10 mg/kg/day	NOAEL	Gastrointestinal system
9 Month(s)	Monkey	Oral 0.4 mg/kg/day	NOAEL	Gastrointestinal system

Reproduction & Developmental Toxicity: (Study Type, Species, Route, Dose, End Point, Effect(s))

Varenicline tartrate

Fertility & Embryonic Development-Females Rat Oral 15 mg/kg/day NOAEL No effects at maximum dose
Fertility & Embryonic Development - Males Rat Oral 15 mg/kg/day NOAEL No effects at maximum dose
Embryo/Fetal Development Rat Oral 0.3 mg/kg/day NOAEL Maternal Toxicity, Not Teratogenic
Embryo/Fetal Development Rabbit Oral 10 mg/kg/day NOAEL Maternal Toxicity, Fetotoxicity
Prenatal & Postnatal Development Rat Oral 0.3, 3 mg/kg/day NOAEL Maternal Toxicity, Developmental toxicity

Genetic Toxicity: (Study Type, Cell Type/Organism, Result)

Varenicline tartrate

Bacterial Mutagenicity (Ames) Salmonella , E. coli Negative
In Vitro Chromosome Aberration Chinese Hamster Ovary (CHO) cells Negative
In Vitro Chromosome Aberration Human Lymphocytes Negative
In Vivo Micronucleus Rat Bone Marrow Negative

Varenicline tartrate

2 Year(s) Rat Male Oral 1 mg/kg/day NOAEL Tumors
2 Year(s) Mouse Oral 20 mg/kg/day NOEL Not carcinogenic

Carcinogen Status: None of the components of this formulation are listed as a carcinogen by IARC, NTP or OSHA.
Colloidal silicon dioxide
IARC Group 3 (Not Classifiable)

Section 12: Ecological Information

Environmental Overview	This mixture contains material that is toxic to aquatic life. Releases to the environment should be avoided.

Toxicity:
Aquatic Toxicity: (Species, Method, End Point, Duration, Result)
Varenicline tartrate
Oncorhynchus mykiss (Rainbow Trout) OECD LC50 96 Hours 48 mg/L
Pseudokirchneriella subcapitata (Green Alga) OECD EC50 72 Hours 2.9 mg/L
Daphnia magna (Water Flea) OECD EC50 48 Hours 0.24 mg/L
Aquatic Toxicity Comments:
A greater than (>) symbol indicates that acute ecotoxicity was not observed at the maximum solubility. Since the substance is insoluble in aqueous solutions above this concentration, an acute ecotoxicity value (i.e. LC/EC50) is not achievable.

Bacterial Inhibition: (Inoculum, Method, End Point, Result)
Varenicline tartrate
Trichoderma viride (Fungus) MIC > 1000 mg/L
Bacillus subtilis (Bacterium) MIC > 1000 mg/L

Persistence and Degradability:
Biodegradation: (Method, Inoculum, Biodeg Study, Result, Endpoint, Duration, Classification)
Varenicline tartrate
OECD Activated sludge Ultimate (CO_2 Evolution) 15.7% After 28 Day(s) Not Ready
Bio-accumulative Potential:
Partition Coefficient: (Method, pH, Endpoint, Value)
Varenicline tartrate
Measured 6-8 Log D -0.817
Mobility in Soil: No data available

Section 13: Disposal Considerations

Waste Treatment Methods	Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural wastewater and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

Section 14: Transport Information

The following refers to all modes of transportation unless specified below.

Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.

Section 15: Regulatory Information

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture
Canada - WHMIS: Classifications
WHMIS hazard class:
None required
This product has been classified in accordance with the hazard criteria of the CPR and the MSDS contains all of the information required by the CPR.

Varenicline tartrate	
CERCLA/SARA 313 Emission reporting	Not Listed
California Proposition 65	Not Listed
EU EINECS/ELINCS List	Not Listed

Section 16: Other Information

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Version: 00

Further information

Revision date: New issue

Revision note: New issue

The information and recommendations in this safety data sheet are, to the best of our knowledge, accurate as of the date of issue. Nothing herein shall be deemed to create any warranty, express or implied. It is the responsibility of the user to determine the applicability of this information and the suitability of the material or product for any particular purpose.

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