

SAFETY DATA SHEET

 Date: 11/10/2015

Generic Name: Levocetirizine Dihydrochloride Tablets

 Brand Equivalent: XYZAL®

SECTION 1: IDENTIFICATION	
Product Name	Levocetirizine Dihydrochloride Tablets, 5 mg
Active substance	Levocetirizine Dihydrochloride
Synonyms	N/A
Formula	C ₂₁ H ₂₇ Cl ₃ N ₂ O ₃
Intended Use	Antihistaminic
Chemical Name	R-(+)-2-[2- [4- [(4-chlorophenyl) phenyl methyl] piperazin -1-yl] ethoxy] acetic acid Dihydrochloride
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
Physical hazards	Not hazardous.
Health hazards	Not hazardous
Label Elements	Not hazardous in accordance with the GHS and OSHA Hazcom 2012

3. Composition/Information on ingredients		
Components	CAS-No	Concentration (%w/w)
Levocetirizine Dihydrochloride	130018-87-0	4.902
Microcrystalline Cellulose, NF (Avicel PH102)	9004-34-6	*
Lactose Monohydrate, NF (Super Tab 11 SD)	64044-51-5	*
Colloidal Silicon Dioxide, NF (Aerosil 200)	112945-52-5	*
Magnesium Stearate, NF	557-04-0	*
Opadry White YS-1-18202-A / Sheffcoat white 4		*

* Proprietary, In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES	
Eye contact	Immediately flush eyes with water while lifting the upper and lower lids. Get medical attention if irritation persists.
Skin contact	First aid is not generally required for skin contact. Wash skin with soap and water. If irritation develops, get medical attention. Launder clothing before reuse.
Inhalation	Remove victim to fresh air. If irritation occurs or symptoms develop, get medical attention.
Ingestion	In the case of unintended ingestion, rinse mouth with water. DO not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to a person who is unconscious or convulsing. Get medical attention if any adverse effects occur or for over dose.
Most important symptoms/effects, acute and delayed	May cause mild eye irritation. Swallowing may cause sleepiness, fatigue, drymouth and pharyngitis.
Indication of immediate medical attention and special treatment needed	Immediate medical attention is recommended for large unintended ingestion.

5. FIRE-FIGHTING MEASURES	
Suitable extinguishing media	Water spray, dry chemical, carbon dioxide, or foam as appropriate for surrounding fire and materials.
Specific hazards arising from the chemical	This product is not a fire hazard but may burn under fire conditions after the water has evaporated.
Special protective equipment and precautions for firefighters	Fire fighters should wear positive pressure self –contained breathing apparatus and full protective clothing for all fires involving chemicals. Cool fire exposed containers with water.

6. ACCIDENTAL RELEASE MEASURES	
Personal precautions, protective equipment and emergency procedures	Wear appropriate protective clothing and equipment as described in section 8. Caution-Spilled liquid may present a slip hazard.
Environmental Precautions	Prevent spill from entering sewers and water courses. Report releases as required by local and national authorities.
Methods and materials for containment and cleaning up	Collect liquid with an inert absorbent and place in appropriate container for disposal. Clean area thoroughly.

7. HANDLING AND STORAGE	
Precautions for safe handling	Avoid contact with eyes, skin and clothing. wash thoroughly with soap and water after handling.
Conditions for safe storage, including any incompatibilities	Store as indicated on product packaging in a secure location. Keep only in original package. Store at 20°C -25°C. Protect from light and moisture. Store away from food stuffs.

8. Exposure controls/Personal protection	
Appropriate engineering controls	Use with adequate general or local exhaust ventilation to keep exposures below occupational exposure limits.
Respiratory Protection	Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).
Eye protection	None required for normal use. Chemical Safety goggles recommended for bulk handling.
Skin Protection	None required for normal use. Impervious gloves recommended for bulk handling.
Other	None known

9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
<i>Appearance</i>	
Physical State	solid
Color	pink
Form	film coated tablets
<i>Odour</i>	
Odour	Not available
Odor Threshold	Not available
pH	Not available
<i>Other information</i>	
Bulk density	Not available
Evaporation rate	Not available
Molecular formula	Not applicable
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not applicable
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	very slightly soluble
Specific Gravity/ Relative Density	Not available
Viscosity, dynamic	Not available
Viscosity, kinematic	Not available
% Volatile	Not available
<i>Thermal/Stability properties</i>	
Autoignition temperature	Not available
Boiling Point	Not available
Thermal decomposition	Not available
Explosive Limits, LEL	Not available
Explosive limits, UEL	Not available
Explosiveness	Not available
Flammability	Not available
Flash point	Not available
Melting Point	Not available
Oxidizing Potential	Not available
<i>Vapor Properties</i>	
Vapor Density	Not available
Vapor Pressure	Not available
Saturated Vapor Concentration	Not available

10. Stability and Reactivity	
stability	
Chemical Stability	Stable
Reactivity	Not reactive under normal conditions of use
conditions to Avoid	None known
Incompatible materials	Avoid oxidizing agents
Hazardous Reactions	None known.

11. Toxicological Information	
Inhalation	Inhalation of mists may cause irritation of the mucous membranes and upper respiratory tract.
Ingestion	Swallowing may cause sleepiness, fatigue, dry mouth and pharyngitis.
Skin contact	Contact may cause slight irritation
Eye contact	Contact may cause slight irritation with redness and tearing
Chronic effects	None currently known.
Sensitization	Components are not known to be sensitizers.
Carcinogenicity	Not carcinogenic
Reproductive Toxicity	None of the components are reproductive toxins

12. Ecological Information	
Ecotoxicity	No ecotoxicity data noted for the ingredient(s).
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	Not available
Mobility in soil	Not available
Other adverse effects	Not available

13. Disposal considerations	
Advice On Disposal And Packaging	Disposal should be in accordance with applicable regional, national and local laws and regulations. Local regulations may be more stringent than regional or national requirements. This information presented only applies to the material as supplied.

14. Transport Information	
DOT	Not regulated
TDG	Not regulated
IMDG	Not regulated
IATA	Not regulated
Special precautions	None known

15. Regulatory Information	
CERCLA	This product is not subject to CERCLA release reporting. Many states have more stringent release reporting requirements. Report spills as required under federal, state and local regulations
SARA Hazard category	Not hazardous

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	<i>11/10/2015</i>
Revision	01
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