

SAFETY DATA SHEET

Date: 07/07/2016

Generic Name: Omeprazole and Sodium bicarbonate capsules

Brand Equivalent: Zegerid®

SECTION 1: IDENTIFICATION	
Product Name	Omeprazole and Sodium bicarbonate capsules, 20 mg/ 1100 mg & 40 mg/1100 mg
Active substance	Omeprazole and Sodium bicarbonate
Synonyms	N/A
Formula	C ₁₇ H ₁₉ N ₃ O ₃ S
Intended Use	Treatment of oesophageal reflux disease
Chemical Name	5-methoxy-2-[[[4-methoxy-3, 5dimethyl-2-pyridinyl) methyl] sulfinyl]-1 <i>H</i> -benzimidazole
How Supplied	40 mg/1100 mg: White to Off white powder filled in size "00" hard gelatin capsules with Opaque light blue colored cap and Opaque white colored body imprinted "SG" on cap and "364" on body with black ink. 20 mg/ 1100 mg: White to Off white powder filled in size "00" hard gelatin capsules with Opaque white colored cap and Opaque white colored body imprinted "SG" on cap and "363" on body with black ink.
Manufacturer Name & Address	ScieGen Pharmaceuticals, Inc. 89 Arkay drive, Hauppauge, NY 11788.
Telephone No.	631-434-2723

2. HAZARDS IDENTIFICATION	
EMERGENCY OVERVIEW:	
PHYSICAL DESCRIPTION:	This product is a white to off-white powder packaged in a capsule.
HEALTH HAZARD:	This product can cause irritation to the eyes or skin. This product may be harmful if swallowed or inhaled. If vapors, mists or particulates of this product are inhaled, irritation of the nose or throat could occur
FIRE HAZARD:	This product requires considerable pre-heating before ignition.
REACTIVITY HAZARD:	This product is stable under ordinary conditions of use and storage.
ENVIRONMENTAL HAZARD:	This product does not normally present a significant hazard to aquatic or terrestrial life.

3. Composition/Information on ingredients		
Components	CAS-No	Concentration (%w/w)
Omeprazole , USP	73590-58-6	1.69% for 20 mg/1100 mg 3.32% for 40 mg/1100 mg
Sodium Bicarbonate, USP #1	144-55-8	*
Croscarmellose Sodium, NF (VIVASOL [®] GF)	74811-65-7	*
Sodium Stearyl Fumarate, NF (Pruv [®])	4070-80-8	*
Empty Hard Gelatin Capsule Size	Mixture	*

* 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	Contact can cause eye or skin irritation. Prolonged skin contact can result in dermatitis. Prolonged eye exposure may include redness, pain, and tearing.
Skin contact	No component of this product is reported to be absorbed through intact skin.
Inhalation	Vapors, mists, sprays or dusts of this product can cause irritation to the respiratory tract.
INGESTION	Exposures above clinical dosage could result in adverse effects. Minor occupational exposures are not expected to be harmful.

5. FIRE-FIGHTING MEASURES	
Extinguishing Media (suitable)	water spray, foam, dry chemical or CO ₂ .
Extinguishing Media (unsuitable)	-
UNUSUAL FIRE AND EXPLOSION HAZARDS:	When involved in a fire, this material can decompose and produce irritating fumes and toxic gases (e.g., Carbon monoxide and Carbon dioxide).
Special Protective Actions For Fire-Fighters:	Incipient fire responders should wear eye protection. Structural firefighters must wear Self-Contained Breathing Apparatus and full protective equipment. Move containers from fire area if it can be done without risk to personnel. If possible, prevent runoff water from entering storm drains, bodies of water, or other environmentally sensitive areas.

6. ACCIDENTAL RELEASE MEASURES	
SPILL AND LEAK RESPONSE	Trained personnel using pre-planned procedures should respond to uncontrolled releases. Proper protective equipment should be used. In case of a spill, clear the affected area and protect people
RESPONSE TO INCIDENTAL RELEASES	Personnel who have received basic chemical safety training can generally handle small scale releases, such as 1 container of this product. Respond to incidental chemical releases by wearing gloves, goggles, and appropriate body protection.
RESPONSE TO NON-INCIDENTAL RELEASES	Respond to non-incident chemical releases of this product, such as the simultaneous puncturing of several containers, by clearing the impacted area and contacting appropriate emergency personnel. Clean up should only be done by qualified personnel. Responders should wear the level of protection appropriate to the type of chemical released, the volume of the material spilled, and the location where the incident has occurred. Minimum Personal Protective Equipment should be Level C: triple-gloves, chemical resistant apron, boots, and splash goggles and air purifying respirator equipped with a HEPA filter. Level B protection should be used when oxygen levels are below 19.5% or are unknown.
RESPONSE EQUIPMENT AND PROCEDURES:	Sweep-up spilled product. If necessary, moisten with water to suppress dust. Decontaminate the area thoroughly. Prevent spill rinsate from contamination of storm drains, sewers, soil or groundwater. Place all spill residues in a suitable container and seal. Dispose of in accordance with applicable U.S. Federal, State, or local procedures or appropriate standards of Canada (see Section 13, Disposal Considerations).

7. HANDLING AND STORAGE	
WORK PRACTICES AND HYGIENE PRACTICES:	As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash thoroughly after using this product. Do not eat or drink while using this material. Avoid generating dusts, mists or sprays of this product. Remove contaminated clothing immediately.
STORAGE AND HANDLING PRACTICES:	All employees who handle this material should be trained to use it safely. Open containers carefully on a stable surface. Empty containers can contain residual material; therefore, empty containers should be handled with care. Store containers in a cool, dry location, away from direct sunlight, sources of intense heat, or where freezing is possible. Store away from incompatible materials (see Section 10, Stability and Reactivity). Keep container tightly closed when not in use. Inspect all incoming containers before storage, to ensure containers are properly labeled and not damaged.
PROTECTIVE PRACTICES DURING MAINTENANCE OF CONTAMINATED EQUIPMENT	Follow practices indicated in Section 6 (Accidental Release Measures). Make certain that application equipment is locked and tagged-out safely if necessary. Collect all reinstates and dispose of according to applicable U.S. Federal, State, or local procedures or appropriate Canadian standards
Specific use(s)	This is a human pharmaceutical.

8. Exposure controls/Personal protection	
Exposure Controls	<p>The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.</p> <p>Prevent entry into drains. See Section 6 for environmental precautions.</p>
Occupational exposure controls	<p>The recommended personal protective equipment (PPE) is based on preventing the potential adverse health effects from exposure to the active pharmaceutical ingredient (API). The risk of exposure to the API in the formulation/product needs to be taken into consideration.</p> <p>Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.</p> <p>The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.</p>
Eye protection:	<p>Use safety glasses to protect against direct contact with the product if the risk assessment does not support the selection of other protection.</p>
Skin and body Protection	<p>For specific industrial applications, body protection is not normally needed. Use body protection appropriate for task (e.g., Tyvek suit, rubber apron). If a hazard of injury to the feet exists due to falling objects, rolling objects, where objects can pierce the soles of the feet or where employee s feet can be exposed to electrical hazards, use foot protection, as described in U.S. OSHA 29 CFR 1910.136.</p>
Respiratory protection	<p>As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment. Consult a qualified safety and health professional for additional guidance, as needed.</p>
General hygiene considerations	<p>Handle in accordance with good industrial hygiene and safety practice.</p>



9. PHYSICAL AND CHEMICAL PROPERTIES	
General Information	
<i>Appearance</i>	
Physical State	capsules
Color	refer section 1
<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	C ₁₇ H ₁₉ N ₃ O ₃ S
Hydrolysis/Photolysis	Not available
Hygroscopicity	Not available
Molecular Weight	Not available
Log Octanol/Water Partition Coeff [log Kow]	Not available
Surface Tension	Not available
pKa	Not available
Particle Size	Not available
Solubility, Water	Not available
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	
Reactivity	No known reactivity hazard under normal conditions.
Chemical Stability	Stable under normal conditions
Conditions to Avoid	No conditions producing hazardous situations known.
Incompatible materials	Acids , decomposes
Hazardous Decomposition products	No hazardous decomposition products are known.
Hazardous Reactions	None known.

11. Toxicological Information	
Routes of Entry	Ingestion, Inhalation, Eye contact, Skin contact
Eye Irritation	May cause eye irritation. May cause conjunctivitis.
Inhalation	May cause effects as described under single exposure.(STOT)
Skin Contact	May cause skin irritation.
Ingestion	Low acute oral toxicity.
Mutagenicity	The substance is not considered to be genotoxic.
Acute Toxicity Study	There is no data available
Repeated Dose Toxicity	There is no data available
Genetic Toxicity	There is no data available
Carcinogenicity	The substance is not considered to be carcinogenic.
Reproductive Toxicity	There is no evidence of a teratogenic potential or any other adverse effects on reproductive function.
Sensitization	May cause an allergic skin reaction. Omeprazole: It is an extreme skin sensitizer in animal tests. Many cases of occupational skin sensitisation have been reported.
Pharmacokinetics/Toxicokinetics	There is no data available
Other Toxicity Information	There is no data available

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	
PREPARING WASTES FOR DISPOSAL:	Industrial Use: Waste disposal must be in accordance with appropriate U.S. Federal, State, and local regulations or with regulations of Canada
EPA WASTE NUMBER	No component of this product is listed by RCRA. The specific RCRA codes depend on the exact nature of the discarded material.

14. Transport Information	
U.S. D.O.T	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.
IATA	This product does not meet the criteria as Dangerous Goods, per rules of IATA.
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); components are not specifically listed in Annex III under MARPOL 73/78.



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15. Regulatory Information	
Safety, health and environmental regulations/legislation specific for the substance or mixture	
ANSI LABEL PRECAUTIONS	Caution! Harmful if swallowed or inhaled. Eye, skin and respiratory tract irritant. Do not breathe fumes, dusts, vapors or mist. Do not swallow or take internally. Wash thoroughly after handling.
ENVIRONMENTAL HAZARDS	Do not discharge effluent containing this product into streams, ponds, estuaries, oceans or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

U.S. SARA SECTION 311/312 FOR PRODUCT: Acute health effects; chronic health effects.

U.S. TSCA INVENTORY STATUS: The components of this product are listed on the TSCA Inventory.

OTHER U.S. FEDERAL REGULATIONS: Not applicable.

CALIFORNIA SAFE DRINKING WATER AND TOXIC ENFORCEMENT ACT (PROPOSITION 65):

This material is not found on either the Proposition 65 Carcinogen List or the Adverse Reproductive Effects List.

16. Other information	
Recommended Restrictions for Use:	Not available
Prepared on	07/07/2016
Revision	01
Disclaimer	The above information is believed to be correct but should only be used as a guide. ScieGen Pharmaceuticals, Inc. disclaims any express or implied warranty as to the accuracy of the above information and shall not be held liable for any direct, incidental or consequential damages resulting from reliance on the above information.