



## MATERIAL SAFETY DATA SHEET

While we believe the information provided herein is accurate and current, Monarch Pharmaceuticals makes no representations or warranties, either expressed or implied, and assumes no responsibility for any damage or injuries of any kind, which may result from use or reliance upon this information.

<b>SECTION I</b>	<b>MATERIAL IDENTIFICATION</b>
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**PRODUCT NAME:** Skelaxin® Tablets **DATE OF ISSUE:** 03/11/04

**FORMULA:** 5-[(3,5-dimethylphenoxy)methyl]-2-oxazolidinone

**NDC#:** 60793-136-01 (800mg, 100's) **REVISION:** 05/15/07  
 60793-136-05 (800mg, 500's)

**SYNONYMS:** Metaxalone

<b>MANUFACTURING DIVISION:</b> King Pharmaceuticals, Inc.	<b>ADDRESS</b> 501 Fifth Street Bristol, TN 37620	<b>PHONE #</b> 800-776-3637
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<b>SECTION II</b>	<b>INGREDIENT (S)</b>
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### EXPOSURE LIMITS/GUIDELINES

CAS#	INGREDIENT NAME	OSHA PEL	ACGIH TLV	OTHER	LISTED AS CARCINOGEN
1665-48-1	Metaxalone	N/D	N/D	N/D	No

<b>SECTION III</b>	<b>PHYSICAL AND CHEMICAL DATA</b>
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<b>PHYSICAL STATE:</b> Tablet	<b>APPEARANCE:</b> 400mg, round, pale rose, inscribed 8662 on scored side, C on other side.
<b>SPECIFIC GRAVITY:</b> N/D	800mg, oval, pink tablet, inscribed 8667 on scored side, S on the other
<b>CHARACTERISTIC ODOR:</b> Odorless	
<b>SOLUBILITY IN WATER:</b> Slightly soluble	<b>pH:</b> N/D

<b>SECTION IV</b>	<b>FIRE AND EXPLOSION DATA</b>
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**FLASH POINT AND METHOD:** Not flammable.

**EXTINGUISHING MEDIUM:** Water spray, Foam, Halon, Carbon Dioxide, Dry Chemical or any 'ABC' Class

**SPECIAL FIRE FIGHTING PROCEDURES:** Incipient fire responders should wear eye protection. Structural firefighters must wear self-contained breathing apparatus (SCBA) and full protective equipment.

**HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS:** When involved in a fire, products of thermal decomposition may include irritating fumes and toxic gases (e.g., carbon oxides, nitrogen oxides). This product can burn when strongly heated.

**SECTION V****CHEMICAL REACTIVITY DATA**

**STABILITY:** Stable

**INCOMPATIBILITY:** This product is generally compatible with other common materials in a medical facility. Acids, caustics, strong oxidizers and other chemicals that could affect its performance, should be avoided.

**HAZARDOUS POLYMERIZATION:** Will not occur.

**HAZARDOUS DECOMPOSITION OF BYPRODUCTS:** N/D

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

**SECTION VI****HEALTH HAZARD INFORMATION****ROUTE OF ENTRY:**

**Eyes:** Eye contact with this product may be irritating (i.e., foreign object). Symptoms of eye contact may include redness, pain, and watering.

**Skin:** Skin contact with this product may be mildly irritating. Symptoms of skin contact may include redness and itching. Repeated skin contact may cause dermatitis (dry, red skin). This product is not known to be absorbed through the skin.

**Ingestion:** Ingestion is not anticipated to be a significant route of occupational overexposure for this product. If this product is swallowed (i.e., through poor hygiene practices), it may slightly irritate the mouth and throat. Severe ingestion overexposure of this product may cause nausea, vomiting, and diarrhea. Symptoms may include those described for "Other Potential Health Effects".

**Injection:** Though not anticipated to be a significant route of overexposure for this product, injection (via punctures or lacerations by contaminated objects) may cause redness at the site of injection. Symptoms may include those described for "Other Potential Health Effects".

**Inhalation:** Inhalation of airborne dusts of this product may mildly irritate the mucous membranes and upper respiratory tract. Symptoms of such overexposure may include coughing and congestion. Severe inhalation overexposure may cause symptoms such as those described for "Other Potential Health Effects".

**HEALTH HAZARD: Health Effects or Risks from Exposure: An Explanation in Lay Terms:**

**Acute:** Contact with this product may irritate the nose, throat, eyes, skin and other contaminated tissues. Severe ingestion overexposure of Acetaminophen (a component of this product) can cause diarrhea, increased sweating, loss of appetite, nausea, vomiting, pain, tenderness, and/or swelling in the upper abdominal area, and stomach cramps. Persons who are hypersensitive to Metaxalone may suffer an allergic reaction upon exposure to Skelaxin.

**Chronic:** Persons who are hypersensitive to Metaxalone may suffer an allergic reaction upon exposure to Skelaxin.

**Target Organs:** Acute/Skin, Brain, Blood ; Chronic/Skin, Liver

**Other Potential Health Effects:** Skelaxin is a muscle relaxant. Symptoms described in patients given therapeutic doses of this substance include blurred vision, clumsiness, unsteadiness, drowsiness, dizziness, lightheadedness, faintness, headache, nervousness, and irritability. In addition, persons who are hypersensitive to Metaxalone may suffer an allergic reaction upon exposure to Skelaxin.

**TOXICITY INFORMATION:****Metaxalone:**

LD50 (oral, rat) =775mg/kg

LD50 (intraperitoneal, rat) =515mg/kg

**Metaxalone(continued):**

LD50 (oral, Mouse) =1690 mg/kg: Behavioral:

muscle weakness, rigidity (including catalepsy);

Sense Organs and Special Senses (Eye): mydriasis (pupillary dilation)

**Metaxalone(continued):**

LD50 (intraperitoneal, mouse) = 490mg/kg

**Suspected Cancer Agent:** The components of this product are not found on the following lists: Federal OSHA Z List, NTP, IARC, and CAL/OSHA and therefore are neither considered to be nor suspected to be cancer-causing agents by these agencies.

**Irritancy of Product:** This product may be mildly irritating to the eyes and slightly irritating to the skin.

**Sensitization to the Product:** Persons who are hypersensitive to Metaxalone may suffer an allergic reaction upon exposure to Skelaxin.

**Reproductive Toxicity Information:** The effects of Skelaxin in human pregnancy are unknown.

**Mutagenicity:** This product is not reported to produce mutagenic effects in humans.

**Embryotoxicity:** This product is not reported to produce embryotoxic effects in humans.

**Teratogenicity:** This product is not reported to cause teratogenic effects in humans.

**Reproductive Toxicity:** This product is not reported to cause reproductive effects in humans.

A mutagen is a chemical that causes permanent changes to genetic material (DNA) such that the changes will propagate through generational lines. An embryotoxin is a chemical that causes damage to a developing embryo (i.e. within the first eight weeks of pregnancy in humans), but the damage does not propagate across generational lines. A teratogen is a chemical that causes damage to a developing fetus, but the damage does not propagate across generational lines. A reproductive toxin is any substance that interferes in any way with the reproductive process.

**ACGIH Biological Exposure Indices:** Currently, there are no ACGIH Biological Exposure Indices (BEIs) determined for the components of this product.

**(For further information see current package insert)**

## SECTION VII

## FIRST AID INFORMATION

**EYES:** If this product contaminates the eyes, open victim's eyes while under gently running water. Use sufficient force to open eyelids. Have victim "roll" eyes. Minimum flushing is for 15 minutes.

**SKIN:** If this product contaminates the skin, immediately begin decontamination with running water. Remove exposed or contaminated clothing, taking care not to contaminate eyes. The minimum recommended flushing time is 15 minutes.

**INHALATION:** If airborne particulates of this product are inhaled, remove victim to fresh air. If necessary, use artificial respiration to support vital functions. Remove or cover gross contamination to avoid exposure to rescuers.

**INGESTION:** Ingestion is not anticipated to be a significant route of overexposure. If this product is swallowed, CALL PHYSICIAN OR POISON CONTROL CENTER FOR MOST CURRENT INFORMATION. If professional advice is not available, DO NOT induce vomiting. Victim should drink milk, egg whites, or large quantities of water. Never induce vomiting or give diluents (milk or water) to someone who is unconscious, having convulsions, or unable to swallow.

**REGULATED EXPOSURE LIMITS:** N/D

**Medical Conditions Aggravated By Exposure:** Epilepsy, kidney disease, liver disease, and porphyria may be aggravated by acute or chronic overexposures to this product.

**Recommendations to Physicians:** Treat symptoms and eliminate overexposure. General supportive measures should be employed, along with intravenous fluids, and an adequate airway maintained.

**PERSONS ACCIDENTALLY OVEREXPOSED TO SKELAXIN MUST RECEIVE MEDICAL ATTENTION IF ANY ADVERSE EFFECTS OCCUR!** Take a copy of the label and MSDS to health professional with victim.

## SECTION VIII

## SPECIAL PROTECTION INFORMATION

**RESPIRATORY PROTECTION:** Respiratory protection is not generally needed during routine use of this product. Use only respiratory protection authorized in the U.S. Federal OSHA Respiratory Protection Standard (29 CFR 1910.134), equivalent U.S. State standards, Canadian CSA Standard Z94.4-93, the European Standard EN166, equivalent standards of EC member states, or the Australian standard 1716-Respiratory Protective Devices and Australian Standard 1715-Selection, Use, and Maintenance of Respiratory Protective Devices. Use supplied air respiration protection if oxygen levels are below 19.5% or are unknown.

**PROTECTIVE GLOVES:** Wear latex or rubber gloves for routine industrial use. Use triple gloves for spill response. If necessary, refer to Australian Standard 2161-Industrial Safety Gloves and Mittens for further information.

**VENTILATION:** Use with adequate ventilation to ensure exposure levels are maintained. Follow standard medical product handling procedures.

**EYE PROTECTION:** Splash goggles or safety glasses. If necessary, refer to U.S. OSHA 29 CFR 1910.133, or the European Standard EN166, or the Australian Standard 1337-Eye Protection for Industrial Applications and Australian Standard 1336-Recommended Practices for Eye Protection in the Industrial Environment for further information.

**OTHER PROTECTIVE CLOTHING OR EQUIPMENT:** Use body protection appropriate for task (e.g., coveralls, Tyvek® suit). If necessary, refer to Australian Standard 3765-Clothing for Protection Against Hazardous Chemicals for further information. Ensure eyewash/safety shower stations are available near areas where this product is used.

## SECTION IX

## SPILL, LEAK, AND DISPOSAL PROCEDURES

**ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:** Prevent exposure, responders should wear gloves, goggles, and suitable body protection during the cleanup of small spills. Small releases can be cleaned up using a damp sponge. In the case of a large spill (in which airborne dusts can be generated), clear the affected area, protect people, and respond with trained personnel. Minimum Personal Protective Equipment should be Level C: triple-gloves (rubber gloves and nitrile gloves over latex gloves), Chemical resistant suit and boots, hardhat, and Air-Purifying respirator with organic vapor cartridge). Self-Contained Breathing Apparatus (SCBA) must be selected if release occurs in confined or poorly ventilated areas or in situations in which the level of oxygen is below 19.5%. Sweep up spilled material, avoiding the generation of airborne particulates. Rinse area with soap and water solution and follow with a water rinse. Close off sewers and take other measures to protect human health and the environment as necessary. Decontaminate the area thoroughly. Place all spill residue in an appropriate container and seal.

**WASTE DISPOSAL METHOD:** Dispose of as a medical waste in accordance with local, state and federal regulations or the authority having jurisdiction. 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 gowns, 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. Incineration is recommended. Reusable equipment should be cleaned with soap and water.

## SECTION X

## SPECIAL PRECAUTIONS

**STORE AS STATED IN PRODUCT LABELING:** This material should be handled and stored per label instructions to ensure product integrity. Store at controlled room temperature, between 15-30 deg C (59-86 deg F).

**OTHER PRECAUTIONS:** N/D

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N/D=Not determined

N/A=Not applicable

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company regarding the most current MSDS available.