

# SAFETY DATA SHEET-

## Methoxsalen Capsules USP 10mg[Soft Gelatin]

### 1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND OF THE COMPANY/UNDERTAKING.

**Material** Methoxsalen Capsules USP 10mg  
**Company Name** Strides Arcolab Ltd,  
 Opp to IIM,  
 Bilekahalli, Arekare main Road,  
 Bangalore-560076

### 2. COMPOSITION / INFORMATION ON INGREDIENTS

Ingredients	CAS RN	Percentage
Methoxsalen	298-81-7	100

### 3. HAZARDS IDENTIFICATION

**Fire and Explosion** Slightly flammable to flammable in presence of heat. Slightly explosive in presence of open flames and sparks

**Health** Caution - METHOXSALEN IS A POTENT DRUG.  
 Methoxsalen with UV radiation should be used only by physicians who have special competence in the diagnosis and treatment of psoriasis and vitiligo and who have special training and experience in photochemotherapy. Psoralen and ultraviolet radiation therapy should be under constant supervision of such a physician. For the treatment of patients with psoriasis, photochemotherapy should be restricted to patients with severe, recalcitrant, disabling psoriasis which is not adequately responsive to other forms of therapy, and only when the diagnosis is certain. Because of the possibilities of ocular damage, aging of the skin, and skin cancer (including melanoma), the patient should be fully informed by the physician of the risks inherent in this therapy. When methoxsalen is used in combination with photopheresis, refer to the UVAR\* System Operator's Manual for specific warnings, cautions, indications, and instructions related to photopheresis.

**Over exposure effects** Can cause severe burns in conjunction with UVA light, either artificial or sunlight. Irritation to mucous membranes, headache and drowsiness if inhaled beyond normal.

**Protection of first-aiders** Use personal protective equipment. Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

### 4. FIRST-AID MEASURES

**Ingestion** Check for and remove any dentures. If swallowed give person 2 to 4 glasses of water and induce vomiting, preferably within 2 hours of ingestion. Keep person in a darkened room for at least 24 hours.

**Inhalation** Remove from exposure area, treat symptomatically and get medical attention if symptoms persist.

**Skin Contact** Rinse area( DO Not Rub In) with cold water. Apply sunscreen if possible. Stay out of the UVA light for at least 24 hours.

**Eye Contact** Check for and remove any contact lenses. Wash eyes thoroughly with water immediately after contact. Individual must stay out of UVA light for atleast 24 hours following exposure. Use UVA sun blocking glasses.

### 5. FIRE-FIGHTING MEASURES

**Fire and Explosion Hazards** If fire is uncontrollable or exposed to direct flame, evacuate for a radius of 1500 feet.

**Extinguishing Media** Suitable: Water spray. Carbon dioxide, dry chemical powder, or appropriate foam.

**Special Firefighting** SMALL FIRE: Use DRY chemical powder. LARGE FIRE: Use water spray, fog or

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**Procedures** foam. Do not use water jet.

### 6. ACCIDENTAL RELEASE MEASURES

**Personal Precautions** Use personal protective equipment. Avoid contact with the skin and the eyes. Avoid dust formation. Ensure adequate ventilation. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

**Environmental Precautions** Prevent further leakage or spillage if safe to do so.

**Clean-up Methods** Contain and collect spillage with non-combustible absorbent material, (e.g. sand, earth, diatomaceous earth, vermiculite) and place in container for disposal according to local/national regulations

**Decontamination Procedures** No specific decontamination or detoxification procedures have been identified for this product. Waste must be disposed of in accordance with federal, state and local environmental control regulations.

### 7. HANDLING AND STORAGE

**HANDLING**  
**General Requirements** Wear personal protective equipment. Avoid contact with skin, eyes and clothing. Avoid dust formation. Use only in area provided with appropriate exhaust ventilation. Do not eat, drink or smoke when using this product. Remove and wash contaminated clothing before re-use.

**STORAGE** Keep containers tightly closed in a dry, cool and well-ventilated place. Keep out of the reach of children. Keep in properly labeled containers.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

**Exposure limits** National occupational exposure limits

**Derived No Effect Level** No information available

**Predicted No Effect Concentration** No information available

#### ENGINEERING CONTROLS

**Exposure Controls** Ensure adequate ventilation, especially in confined areas.

#### PERSONAL PROTECTIVE EQUIPMENT

**Eye Protection** Safety glasses with side-shields.

**Hand protection** Protective gloves.

**Skin and body protection** Impervious clothing.

**Respiratory protection** No special protective equipment required.

**Thermal hazards** No information available

**Hygiene measures** When using, do not eat, drink or smoke. Remove and wash contaminated clothing before re-use. Provide regular cleaning of equipment, work area and clothing. Wash hands before breaks and immediately after handling the product. Keep away from food, drink and animal feeding stuffs.

### 9. PHYSICAL AND CHEMICAL PROPERTIES

#### Appearance

**Colour** Green color, oval shaped soft gelatin capsules

#### Physical Form

**Stability** Reactivity: Stable.

**Conditions to Avoid.** Chemical stability: Stable under normal conditions.

Conditions to avoid: Heat, flames and sparks

Hazardous decomposition products: Carbon monoxide (CO). Carbon dioxide (CO<sub>2</sub>).

### 11. TOXICOLOGICAL INFORMATION

**Oral Toxicity** Harmful if swallowed.

**Inhalation Toxicity** May be harmful if inhaled. Material may be irritating to mucous membranes and upper respiratory tract.

**Skin Effects** Skin Contact: May cause skin irritation.

Skin Absorption: May be harmful if absorbed through the skin.

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<b>Eye Effects</b>	<p>Skin Burning: Serious burns from either UVA or sunlight (even through window glass) can result if the recommended dosage of the drug and/or exposure schedules are not maintained.</p> <p>Eye Contact: May cause eye irritation.</p> <p>CATARACTOGENICITY: It has been found that the concentration of methoxsalen in the lens is proportional to the serum level. If the lens is exposed to UVA during the time methoxsalen is present in the lens, photochemical action may lead to irreversible binding of methoxsalen to proteins and the DNA components of the lens. However, if the lens is shielded from UVA, the methoxsalen will diffuse out of the lens in a 24 hour period. Patients should be told emphatically to wear UVA-absorbing, wraparound sunglasses for the twenty-four (24) hour period following ingestion of methoxsalen, whether exposed to direct or indirect sunlight in the open or through a window glass.</p>
<b>Target Organ Effects Sensitisation</b>	<p>Blood. Eyes. Immune system.</p> <p>Causes photosensitivity. Exposure to light can result in allergic reactions resulting in dermatologic lesions, which can vary from sunburn like responses to edematous, vesiculated lesions, or bullae</p>
<b>Genetic Toxicity Carcinogenicity</b>	<p>Chronic Effects on Humans may affect genetic material (mutagenic)</p> <p>Classified 2 (Some evidence.) by NTP. 3 (Not classifiable for human.) by IARC.</p> <p>MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast</p>
<b>Reproductive Effects Pharmacological Effects</b>	<p>Birth defects or other reproductive harm.</p> <p>Methoxsalen, upon photoactivation, conjugates and forms covalent bonds with DNA which leads to the formation of both monofunctional (addition to a single strand of DNA) and bifunctional adducts (crosslinking of psoralen to both strands of DNA)</p>

## 12. ECOLOGICAL INFORMATION

<b>Summary</b>	As supplied, the preparation is not expected to present significant adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.
<b>Ecotoxicity</b>	Not expected to present significant adverse environmental effects
<b>Products of Biodegradation:</b>	Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.
<b>Toxicity of the Products of Biodegradation:</b>	The products of degradation are less toxic than the product itself.
<b>Special Remarks on the Products of Biodegradation:</b>	Not available.

## 13. DISPOSAL CONSIDERATIONS

<b>Disposal Recommendations</b>	<p>Contact a licensed professional waste disposal service to dispose of this material.</p> <p>Dissolve or mix the material with a combustible solvent and burn in a chemical incinerator equipped with an afterburner and scrubber. Observe all federal, state, and local environmental regulations.</p>
<b>Regulatory Requirements</b>	Observe all federal, state, and local environmental regulations.

## 14. TRANSPORT INFORMATION

RID/ADR	Non-hazardous for road transport.
IMDG	Non-hazardous for sea transport.
IATA	Non-hazardous for air transport.

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### 15. REGULATORY INFORMATION

**Federal and State Regulations:**

California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer, birth defects or other reproductive harm, which would require a warning under the statute: Methoxsalen

California prop. 65: This product contains the following ingredients for which the State of California has found to cause cancer which would require a warning under the statute: Methoxsalen California Director's List of Hazardous

Substances: Methoxsalen TSCA 8(b) inventory: Methoxsalen

**Other Regulations:**

OSHA: Hazardous by definition of Hazard Communication Standard (29 CFR 1910.1200). EINECS: This product is on the European Inventory of Existing Commercial Chemical Substances.

**Other Classifications:**

**WHMIS (Canada):** Not controlled under WHMIS (Canada).

**DSCL (EEC):**

R22- Harmful if swallowed. R34- Causes burns. R43- May cause sensitization by skin contact. R45- May cause cancer. R46- May cause heritable genetic damage. S22- Do not breathe dust. S26- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice. S36/37/39- Wear suitable protective clothing, gloves and eye/face protection. S46- If swallowed, seek medical advice immediately and show this container or label. S53- Avoid exposure - obtain special instructions before use.

**HMIS (U.S.A.):**

Health Hazard: 3

Fire Hazard: 1

Reactivity: 0

Personal Protection: j

**National Fire Protection Association (U.S.A.):**

Health: 3

Flammability: 1

Reactivity: 0

**Protective Equipment:**

Gloves. Synthetic apron. Vapor and dust respirator. Be sure to use an approved/certified respirator or equivalent.

Splash

### 16. OTHER INFORMATION

**References:** Not available.

**Other Special Considerations:** Not available.

Disclaimer

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information given is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and is not to be considered a warranty or quality specification. The information relates only to the specific material designated and may not be valid for such material used in combination with any other materials or in any process, unless specified in the text.