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 at least 24 hours following exposure. Use UVA sun blocking glasses.

5. FIRE-FIGHTING MEASURES
Fire and Explosion If fire is uncontrollable or exposed to direct flame, evacuate for a radius of 1500 feet.
Hazards
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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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 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/PERSOAL 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 Green color, oval shaped soft gelatin capsules
Colour
Physical Form Reactivity: Stable.
Stability Chemical stability: Stable under normal conditions.
Conditions to Avoid. Conditions to avoid: Heat, flames and sparks
Hazardous decomposition products: Carbon monoxide (CO). Carbon dioxide (CO₂).

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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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.

Eye Effects
Eye Contact: May cause eye irritation.
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.

Target Organ Effects
Blood. Eyes. Immune system.

Sensitisation
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

Genetic Toxicity
Chronic Effects on Humans may affect genetic material (mutagenic)

Carcinogenicity
Classified 2 (Some evidence.) by NTP. 3 (Not classifiable for human.) by IARC.
MUTAGENIC EFFECTS: Mutagenic for mammalian somatic cells. Mutagenic for bacteria and/or yeast

Reproductive Effects
Birth defects or other reproductive harm.

Pharmacological Effects
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)

12. ECOLOGICAL INFORMATION

Summary
As supplied, the preparation is not expected to present significant adverse environmental effects. Local regulations and procedures should be consulted prior to environmental release.

Ecotoxicity
Not expected to present significant adverse environmental effects

Products of Biodegradation:
Possibly hazardous short term degradation products are not likely. However, long term degradation products may arise.

Toxicity of the Products of Biodegradation:
The products of degradation are less toxic than the product itself.

Special Remarks on the Products of Biodegradation:
Not available.

13. DISPOSAL CONSIDERATIONS

Disposal
Contact a licensed professional waste disposal service to dispose of this material.

Recommendations
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.

Regulatory Requirements
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:

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:

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.

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.