



Material Safety Data Sheet

Product code: NDC64067-216-0
Revision date: 12-09-2009

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

Supplier:
Therakos
1001 US Highway 202 North
Raritan, NJ 08869-0606

E-mail address Therakos.com

Emergency telephone number: 877-865-6850
Regional Emergency Telephone Number: In Australia:
61 2 9413 6297

Product name: UVADEX
Product code: NDC64067-216-0
Synonyms: Methoxsalen 8-Methoxypsoralen (8-MOP)
Identified use: In conjunction with Extracorporeal Photopheresis (Not for direct injection)

2. HAZARDS IDENTIFICATION

General hazard information: Not classified as hazardous.
If a rare sensitivity reaction occurs, contact your physician immediately.

Indication of danger: Not dangerous goods

Most important hazards

Risk Phrase None for finished product.

Carcinogenicity rating:

Johnson & Johnson: None.
European Union: None.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Components	CAS Number	Weight %	Synonyms	EINECS-No.	Classification
Propylene glycol	57-55-6	5		200-338-0	
Methoxsalen	298-81-7	0.002		206-066-9	Xi;R41-43 T;R45-46 Xn;R22

4. FIRST AID MEASURES

Eye contact: In the case of contact with eyes, rinse immediately with plenty of water for 15 minutes and seek medical attention.

Skin contact: Wash contaminated areas thoroughly with soap and water. In the case of skin irritation or allergic reactions see a physician.

Ingestion: If ingested, seek medical attention immediately and show the label.

Inhalation: Move to fresh air immediately. If experiencing difficulty breathing, seek medical attention.

5. FIRE-FIGHTING MEASURES

Suitable extinguishing media: Use any extinguishing media which is suitable for the surrounding fire.

Extinguishing media which must not be used for safety reasons: None.

Special exposure hazards arising from the substance or preparation itself, combustion products, resulting gases: None reasonably foreseeable.

Special protective equipment for firefighters: Wear a self-contained breathing apparatus and full protective gear.

Combustion products or resulting gases: None.

6. ACCIDENTAL RELEASE MEASURES

Personal precautions: Ensure adequate ventilation.

Environmental precautions: No special environmental precautions required.

Methods for cleaning up: Wipe up with absorbent material (e.g. cloth, fleece).

7. HANDLING AND STORAGE

Handling:

Technical measures/precautions: No special technical protective measures required.

Safe handling advice: None under normal processing.

Storage:

Technical measures/storage conditions: This product should be stored between 59°F (15°C) and 86°F (30°C) Store in a light-resistant container.

Incompatible products: Strong oxidizing agents

Specific use(s): None under normal use.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Components	CAS Number	Weight %	J&J - OEL (TWA - 8 hr)	J&J - OEL (STEL)	J&J - OEL (Ceiling)	J&J - PBOEL
Methoxsalen	298-81-7	0.002	10 µg/m ³			Category 3A Repro

Components	Australia	Hong Kong	Japan	India	Korea	Malaysia	China
Propylene glycol (5%) 57-55-6	TWA = 10 mg/m ³ TWA = 150 ppm TWA = 474 mg/m ³						

Components	New Zealand	Philippines	Singapore	Taiwan	Thailand	ACGIH OEL	Indonesia
Propylene glycol (5%) 57-55-6	TWA = 10 mg/m ³ TWA = 150 ppm TWA = 474 mg/m ³						

Engineering controls: Effective local exhaust ventilation.

Eye protection: Eye and face protection recommended when manufacturing product.

Hand protection: Latex gloves

Respiratory protection: None normally required for routine use, unless sprays or mists are generated during use.

Skin and body protection Skin protection recommended when manufacturing product.

9. PHYSICAL AND CHEMICAL PROPERTIES

General Information

Physical state: Liquid

Appearance: Aqueous solution

Color: Colorless to light-yellow.

Odor: Odorless

Important Health Safety and Environmental Information

Flash point: Not applicable. **Boiling point/range:** No information available.

pH: 4.5 **Voc content (%):** 0.05 g/L (95% Ethanol)

Other information

Explosivity: None.

10. STABILITY AND REACTIVITY

Chemical stability: Stable.

Materials to avoid: Stay away from strong oxidizing agents.

Conditions to avoid: Exposure to sunlight.

Hazardous polymerization: Hazardous polymerization does not occur.

11. TOXICOLOGICAL INFORMATION

Acute toxicity

Eye contact	Not available. Not expected to cause eye irritation.
Skin contact	Not available. May cause sensitization of susceptible persons by skin contact
Ingestion	No effects expected.
Inhalation	Not available. Not expected to be toxic if inhaled.

Components	LD50 Oral	LD50 Dermal	LC50 (mg/m ³) Inhalation	LC50 (ppm) Inhalation
Propylene glycol (5%) 57-55-6	= 20000 mg/kg Rat	= 20800 mg/kg Rabbit		
Methoxsalen (0.002%) 298-81-7	= 791 mg/kg Rat 423 mg/kg Mouse			

Sub-Chronic/Chronic Toxicity

No repeat dose data available.

Specific effects

Target Organ(s)	No significant organ toxicity expected.
Reproductive effects	This product contains a material that may cause adverse reproductive effects.*
Developmental effects	Contains ingredients which may cause harm to the unborn child.
Carcinogenic effects	Contains ingredients which may cause cancer.

Components	ACGIH	IARC	OSHA	NTP
Methoxsalen (0.002%) 298-81-7		1		K

Genotoxic effects Not available.

12. ECOLOGICAL INFORMATION

Ecotoxicity

Ecotoxicity effects:	This product has no known eco-toxicological effects.
Aquatic toxicity effects:	This product has no known aquatic toxicological effects.

13. DISPOSAL CONSIDERATIONS

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Waste from residues / unused products:

Waste disposal must be in accordance with appropriate US, Federal, State and International regulations. 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.

Contaminated packaging:

Do not re-use empty containers.

14. TRANSPORT INFORMATION

Product not regulated by DOT, IATA/ICAO, IMO/IMDG, ADR/RID, or TDG.

15. REGULATORY INFORMATION

Indication of danger: Not dangerous goods

R -phrase(s)

None for finished product.

S -phrase(s)

None.

Components	Australia (AICS) List:	New Zealand	Japan Inventory of Existing & New Chemical Substances (ENCS)	China Inventory List:	Philippines (PICCS) List:	Korea Inventory (KECL) List:
Propylene glycol (5%) 57-55-6	X	X	2-234	X	X	KE-29267
Methoxsalen (0.002%) 298-81-7	X		9-2281			KE-23294

Components	Japan Industrial Safety & Health Law (ISHL) Listing	Japan Pharmacopoeia List:	Japan class ii specified chemical substance -:	Japan designated chemical substance -:	Japan ISHL Prohibited Substances Data	Japan Deleterious Substances - Main Law List
Propylene glycol (5%) 57-55-6	2-(8)-321 2-(8)-323	X				
Methoxsalen (0.002%) 298-81-7	8-(4)-751	X				

Components	Australia Hazardous Substances List	China Banned or Severely Restricted Toxic Chemicals List	Korea Non-Toxic Chemicals List	Korea Restricted Substances Data	Phillipines Priority Chemical List (PCL)
Propylene glycol (5%) 57-55-6	X				

16. OTHER INFORMATION

This data sheet contains changes from the previous version in section(s):

None.

Additional advice:

Australian Poisons Information Centre
24 Hour Service: - 13 11 26
Police or Fire Brigade: - 0000 (exchange): - 1100

Literary reference:

The values set up in the table for Content % are derived from the 28th Adaption of Annex I and Chips III for calculating the formulation. C represents concentration.

MSDS Format:

Asian Pacific Format

This Material Safety Data Sheet was prepared in accordance with Regulation JIS Z7250 of the Occupational Safety and Health Regulation.

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End of Safety Data Sheet