

SAFETY DATA SHEET

1. Identification

Product identifier Methoxsalen Capsules, 10 Mg
Other means of identification Not available.
Recommended use Medicinal Product.

This safety data sheet is written to provide health, safety and environmental information for people handling this formulated product in the workplace. It is not intended to provide information relevant to medicinal use of the product. In this instance patients should consult prescribing information/package insert/product label or consult their pharmacist or physician. For health and safety information for individual ingredients used during manufacturing, refer to the appropriate safety data sheet for each ingredient.

Recommended restrictions No other uses are advised.

Manufacturer/Importer/Supplier/Distributor information

Company name Valeant Pharmaceuticals International, Inc.
Address 2150 St. Elzéar Blvd. West
 Laval, Quebec H7L 4AB
 Canada
Telephone Customer Support 1-800-321-4576
E-mail Not available.
Emergency phone number 3E Emergency Response 1-866-951-9833
 Hotline

2. Hazard(s) identification

Classified hazards

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Label elements

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

Hazard(s) not otherwise classified (HNOC)

Exempt from requirements - product regulated as a medicinal product, cosmetic product or medical device.

3. Composition/information on ingredients

Mixtures

Chemical name	Common name and synonyms	CAS number	%
METHOXSALEN		298-81-7	1.72
D&C YELLOW #10		8004-92-0	*
FD & C YELLOW NO. 6		2783-94-0	*
FD&C BLUE 1		3844-45-9	*
GELATIN		9000-70-8	*
GLYCERIN		56-81-5	*
METHYL PARABEN		99-76-3	*
POLYETHYLENE GLYCOL 400		25322-68-3	*
PROPYL PARABEN		94-13-3	*
SORBITOL		50-70-4	*
WATER		7732-18-5	*

*Designates that a specific chemical identity and/or percentage of composition has been withheld as a trade secret.

4. First-aid measures

Inhalation	Move to fresh air. If breathing is difficult, trained personnel should give oxygen. Call a physician if symptoms develop or persist. Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Immediately flush skin with plenty of water. Take off contaminated clothing and wash before reuse. Get medical attention if symptoms occur.
Eye contact	Rinse thoroughly with plenty of water for at least 15 minutes and consult a physician.
Ingestion	If swallowed, rinse mouth with water (only if the person is conscious). If ingestion of a large amount does occur, call a poison control center immediately. Do not induce vomiting without advice from poison control center.
Most important symptoms/effects, acute and delayed	Rash. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis.
Indication of immediate medical attention and special treatment needed	No specific antidotes are recommended. Treat according to locally accepted protocols. For additional guidance, refer to the current prescribing information or to the local poison control information center.
General information	In the case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). Ensure that medical personnel are aware of the material(s) involved, and take precautions to protect themselves.

5. Fire-fighting measures

Suitable extinguishing media	Water. Foam. Dry chemical powder. Carbon dioxide (CO ₂).
Unsuitable extinguishing media	None known.
Specific hazards arising from the chemical	During fire, gases hazardous to health may be formed.
Special protective equipment and precautions for firefighters	Self-contained breathing apparatus and full protective clothing must be worn in case of fire.
Fire fighting equipment/instructions	Move containers from fire area if you can do so without risk.
Specific methods	Use standard firefighting procedures and consider the hazards of other involved materials.
General fire hazards	No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Keep people away from and upwind of spill/leak. Keep out of low areas. Wear appropriate protective equipment and clothing during clean-up. Avoid inhalation of dust. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. Local authorities should be advised if significant spillages cannot be contained. For personal protection, see section 8 of the SDS.
Methods and materials for containment and cleaning up	<p>Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). This product is miscible in water. Stop the flow of material, if this is without risk.</p> <p>Large Spills: Wet down with water and dike for later disposal. Prevent entry into waterways, sewer, basements or confined areas. Following product recovery, flush area with water.</p> <p>Small Spills: Sweep up or vacuum up spillage and collect in suitable container for disposal.</p> <p>Never return spills to original containers for re-use. For waste disposal, see section 13 of the SDS.</p>
Environmental precautions	Avoid discharge into drains, water courses or onto the ground.

7. Handling and storage

Precautions for safe handling	Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin, and clothing. Do not taste or swallow. When using, do not eat, drink or smoke. Should be handled in closed systems, if possible. Use only outdoors or in a well-ventilated area. Wear appropriate personal protective equipment. Wash hands thoroughly after handling. Observe good industrial hygiene practices.
Conditions for safe storage, including any incompatibilities	Store in original tightly closed container. Store in a well-ventilated place. Refrigeration recommended. Store away from incompatible materials (see Section 10 of the SDS).

8. Exposure controls/personal protection

Occupational exposure limits

US. OSHA Table Z-1 Limits for Air Contaminants (29 CFR 1910.1000)

Components	Type	Value	Form
GLYCERIN (CAS 56-81-5)	PEL	5 mg/m ³ 15 mg/m ³	Respirable fraction. Total dust.

US. Workplace Environmental Exposure Level (WEEL) Guides

Components	Type	Value	Form
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)	TWA	10 mg/m ³	Particulate.

Biological limit values No biological exposure limits noted for the ingredient(s).

Exposure guidelines

Appropriate engineering controls No special controls required during normal clinical use.
When handling bulk product General ventilation normally adequate.

Individual protection measures, such as personal protective equipment

Eye/face protection No eye protection required under conditions of intended use.
When handling bulk product: If contact is likely, safety glasses with side shields are recommended. No eye protection required under conditions of intended use. When handling bulk product:

Skin protection

Hand protection No hand protection required under conditions of intended use.
When handling bulk product: For prolonged or repeated skin contact use suitable protective gloves. No hand protection required under conditions of intended use. When handling bulk product:

Other

No special precautions needed under conditions of intended use.
When handling bulk product: Wear suitable protective clothing as protection against splashing or contamination. No special precautions needed under conditions of intended use. When handling bulk product:

Respiratory protection No respiratory protection required under conditions of intended use.
When handling bulk product: Use a NIOSH/MSHA approved respirator if there is a risk of exposure to dust/fume at levels exceeding the exposure limits. No personal respiratory protective equipment normally required. No respiratory protection required under conditions of intended use. When handling bulk product:

Thermal hazards None known.

General hygiene considerations Always observe good personal hygiene measures, such as washing after handling the material and before eating, drinking, and/or smoking. Routinely wash work clothing and protective equipment to remove contaminants. For advice on suitable monitoring methods, seek guidance from a qualified environment, health and safety professional.

9. Physical and chemical properties

Appearance Green gelatin capsule with clear-to-amber liquid fill.

Physical state Solid.

Form Capsule

Color Green

Odor Not available.

Odor threshold Not available.

pH Not available.

Melting point/freezing point Not available.

Initial boiling point and boiling range 134.6 °F (57 °C)

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower (%) Not available.

Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	> 1
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Slightly soluble
Partition coefficient (n-octanol/water)	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Strong oxidizing agents.
Hazardous decomposition products	None known. Irritating and/or toxic fumes and gases may be emitted upon the product's decomposition.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Under normal conditions of intended use, this material is not expected to be an inhalation hazard.
Skin contact	Health injuries are not known or expected under normal use.
Eye contact	Health injuries are not known or expected under normal use.
Ingestion	Health injuries are not known or expected under normal use. Expected to be a low ingestion hazard. However, ingestion is not likely to be a primary route of occupational exposure.

Symptoms related to the physical, chemical and toxicological characteristics	Rash. Severe eye irritation. Symptoms may include stinging, tearing, redness, swelling, and blurred vision. Skin irritation. May cause redness and pain. May cause an allergic skin reaction. Dermatitis.
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Information on toxicological effects

Acute toxicity	Toxic if inhaled. Toxic if swallowed. May cause an allergic skin reaction.
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Components	Species	Test Results
FD & C YELLOW NO. 6 (CAS 2783-94-0)		
Acute		
<i>Oral</i>		
LD50	Mouse	> 6 g/kg
	Rat	> 10 g/kg
<i>Other</i>		
LD50	Mouse	4200 mg/kg
	Rat	3800 mg/kg
METHOXSALEN (CAS 298-81-7)		
Acute		
<i>Oral</i>		
LD50	Mouse	423 mg/kg
	Rat	791 mg/kg

Components	Species	Test Results
METHYL PARABEN (CAS 99-76-3)		
Acute		
<i>Oral</i>		
LD50	Dog	3000 mg/kg
	Guinea pig	3 g/kg
	Mouse	8 g/kg
	Rabbit	6 g/kg
<i>Other</i>		
LD50	Mouse	0.96 g/kg
	Rat	> 0.5 g/kg
PROPYL PARABEN (CAS 94-13-3)		
Acute		
<i>Oral</i>		
LD50	Mouse	6 g/kg
	Rabbit	6 g/kg
<i>Other</i>		
LD50	Mouse	0.4 g/kg
SORBITOL (CAS 50-70-4)		
Acute		
<i>Oral</i>		
LD50	Mouse	17800 mg/kg
<i>Other</i>		
LD50	Mouse	9480 mg/kg
	Rat	7100 mg/kg

* Estimates for product may be based on additional component data not shown.

Skin corrosion/irritation Causes skin irritation.

Serious eye damage/eye irritation Causes serious eye irritation.

Respiratory or skin sensitization

Respiratory sensitization Not available.

Skin sensitization May cause an allergic skin reaction.

Germ cell mutagenicity No data available to indicate product or any components present at greater than 0.1% are mutagenic or genotoxic.

Carcinogenicity Carcinogenic effects are not expected as a result of occupational exposure.

IARC Monographs. Overall Evaluation of Carcinogenicity

FD & C YELLOW NO. 6 (CAS 2783-94-0) 3 Not classifiable as to carcinogenicity to humans.

FD&C BLUE 1 (CAS 3844-45-9) 3 Not classifiable as to carcinogenicity to humans.

METHOXSALEN (CAS 298-81-7) 1 Carcinogenic to humans.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

METHOXSALEN (CAS 298-81-7) Known To Be Human Carcinogen.

Reproductive toxicity This product is not expected to cause reproductive or developmental effects.

Specific target organ toxicity - single exposure Not classified.

Specific target organ toxicity - repeated exposure Not classified.

Aspiration hazard Not available.

Chronic effects Prolonged exposure may cause chronic effects.

Further information Caution - Pharmaceutical agent. Occupational exposure to the substance or mixture may cause adverse effects.

12. Ecological information

Ecotoxicity

The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Components	Species	Test Results
FD&C BLUE 1 (CAS 3844-45-9)		
Aquatic		
Fish	LC50	Coho salmon, silver salmon (Oncorhynchus kisutch)
		332 mg/l, 96 hours
GLYCERIN (CAS 56-81-5)		
Aquatic		
Fish	LC50	Rainbow trout, donaldson trout (Oncorhynchus mykiss)
		51000 - 57000 mg/l, 96 hours
POLYETHYLENE GLYCOL 400 (CAS 25322-68-3)		
Aquatic		
Fish	LC50	Atlantic salmon (Salmo salar)
		> 1000 mg/l, 96 hours

* Estimates for product may be based on additional component data not shown.

Persistence and degradability

Bioaccumulative potential

Partition coefficient n-octanol / water (log Kow)

GLYCERIN	-1.76
PROPYL PARABEN	3.04
SORBITOL	-2.2

Mobility in soil

Mobility in general

Other adverse effects Not available.

13. Disposal considerations

Disposal instructions

Collect and reclaim or dispose in sealed containers at licensed waste disposal site. Do not discharge into drains, water courses or onto the ground. Dispose in accordance with all applicable regulations.

Local disposal regulations

Dispose in accordance with all applicable regulations.

Hazardous waste code

The waste code should be assigned in discussion between the user, the producer and the waste disposal company.

Waste from residues / unused products

Dispose of in accordance with local regulations. Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions). Avoid discharge into water courses or onto the ground.

Contaminated packaging

Empty containers should be taken to an approved waste handling site for recycling or disposal. Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code Not applicable.

15. Regulatory information

US federal regulations

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1050)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

Hazard categories	Immediate Hazard - Yes
	Delayed Hazard - Yes
	Fire Hazard - No
	Pressure Hazard - No
	Reactivity Hazard - No

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous chemical	No
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SARA 313 (TRI reporting)

Not regulated.

Other federal regulations**Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List**

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act (SDWA)	Not regulated.
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US state regulations**US. California Controlled Substances. CA Department of Justice (California Health and Safety Code Section 11100)**

Not listed.

US. Massachusetts RTK - Substance List

FD&C BLUE 1 (CAS 3844-45-9)

GLYCERIN (CAS 56-81-5)

US. New Jersey Worker and Community Right-to-Know Act

GLYCERIN (CAS 56-81-5)

US. Pennsylvania Worker and Community Right-to-Know Law

GLYCERIN (CAS 56-81-5)

METHOXSALEN (CAS 298-81-7)

US. Rhode Island RTK

Not regulated.

US. California Proposition 65

WARNING: This product contains a chemical known to the State of California to cause cancer.

US - California Proposition 65 - CRT: Listed date/Carcinogenic substance

METHOXSALEN (CAS 298-81-7)

Listed: February 27, 1987

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	Yes
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	No
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	Yes
Korea	Existing Chemicals List (ECL)	Yes
New Zealand	New Zealand Inventory	No
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No

Country(s) or region	Inventory name	On inventory (yes/no)*
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	Yes

*A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)
A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 10-01-2014

Version # 01

Disclaimer Valeant cannot anticipate all conditions under which this information and its product, or the products of other manufacturers in combination with its product, may be used. It is the user's responsibility to ensure safe conditions for handling, storage and disposal of the product, and to assume liability for loss, injury, damage or expense due to improper use. The information in the sheet was written based on the best knowledge and experience currently available.