Safety Data Sheet

Section 1: Identification

Product identifier

Product Name • Visudyne® (verteporfin for injection)

Product Code • 301875600150; NDC 0187-5600-15

Relevant identified uses of the substance or mixture and uses advised against

Recommended use • Visudyne® (verteporfin for injection) is a light activated drug used in photodynamic therapy.

Details of the supplier of the safety data sheet

Manufacturer • Valeant Pharmaceuticals North America, LLC
400 Somerset Corporate Blvd.
Bridgewater, NJ 08807
United States
valeant.com

Telephone (General) • 1-800-321-4576

Emergency telephone number

Manufacturer • 1-800-535-5053 - US - Infotrac
Manufacturer • +1 352-323-3500 - International - Infotrac

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 consumer use of the product.

Section 2: Hazard Identification

United States (US)
According to: OSHA 29 CFR 1910.1200 HCS

Classification of the substance or mixture

OSHA HCS 2012 • Skin Irritation 2
Eye Irritation 2A
Reproductive Toxicity 2
Effects on or via Lactation
Germ Cell Mutagenicity 2
Hazards Not Otherwise Classified - Health Hazards - Photosensitizer

Label elements

OSHA HCS 2012

WARNING

Hazard statements • Photosensitizer
Causes skin irritation
Causes serious eye irritation
May cause harm to breast-fed children
Suspected of damaging fertility or the unborn child.
Suspected of causing genetic defects.

Precautionary statements

**Prevention** • Do not handle until all safety precautions have been read and understood.
Avoid contact during pregnancy/while nursing.
Wash thoroughly after handling.
Wear protective gloves/protective clothing/eye protection/face protection.

**Response** • IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
If skin irritation occurs: Get medical advice/attention.
Take off contaminated clothing and wash before reuse.
If exposed, avoid exposure to sun or bright light.

**Storage/Disposal** • Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Other hazards

OSHA HCS 2012 • No data available

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### Section 3 - Composition/Information on Ingredients

#### Substances

- Material does not meet the criteria of a substance according to United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

#### Mixtures

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>Identifiers</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ascorbyl palmitate</td>
<td>CAS:137-66-6</td>
<td>&lt; 0.1%</td>
</tr>
<tr>
<td></td>
<td>EINECS:205-305-4</td>
<td></td>
</tr>
<tr>
<td>Butylated hydroxytoluene</td>
<td>CAS:128-37-0</td>
<td>&lt; 0.01%</td>
</tr>
<tr>
<td></td>
<td>EINECS:204-881-4</td>
<td></td>
</tr>
<tr>
<td>Dimyristoyl phosphatidylcholine</td>
<td>CAS:18656-38-7</td>
<td>&lt; 10%</td>
</tr>
<tr>
<td></td>
<td>EINECS:242-481-1</td>
<td></td>
</tr>
<tr>
<td>Egg phosphatidylglycerol</td>
<td>CAS:93685-90-6</td>
<td>&lt; 10%</td>
</tr>
<tr>
<td></td>
<td>EINECS:297-639-2</td>
<td></td>
</tr>
<tr>
<td>Lactose monohydrate</td>
<td>CAS:64044-51-5</td>
<td>&gt; 80%</td>
</tr>
<tr>
<td>Verteporfin</td>
<td>CAS:129497-78-5</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

The exact percentage of composition has been withheld as a trade secret.

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### Section 4: First-Aid Measures

#### Description of first aid measures

**Inhalation** • Remove source of exposure. Seek medical attention if irritation or signs of toxicity occur. Providesymptomatic or supportive care as necessary.

**Skin** • After contact with skin, take off immediately all contaminated clothing and wash immediately with plenty of (to be specified by manufacturer). If irritation develops and persists, get medical attention.
Eye

- If eye contact occurs, rinse eyes under gently running water for at least 15 minutes. Use sufficient force to open eyelids and roll eyes while flushing. Seek medical attention if irritation persists or signs of toxicity occur. Provide symptomatic or supportive care as necessary.

Ingestion

- Remove source of exposure. Seek medical attention if irritation or signs of toxicity occur. Provide symptomatic or supportive care as necessary. If signs/symptoms develop, get medical attention.

Most important symptoms and effects, both acute and delayed

- Skin and eye contact should be avoided due to the potential for photosensitivity reactions upon exposure to light. If exposed, they should protect all parts of their skin and their eyes by wearing protective clothing and dark sunglasses. UV sunscreens are not effective in protecting against photosensitivity reactions because photoactivation of the residual drug in the skin can be caused by visible light.

Indication of any immediate medical attention and special treatment needed

Notes to Physician

- Treat according to accepted protocols. For additional guidance, refer to the current prescribing information.

Other information

- Have the product container or label with you when calling a poison control center or doctor, or going for treatment. Additional details are provided on the product packaging and/or in the product insert.

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Section 5: Fire-Fighting Measures

Extinguishing media

Suitable Extinguishing Media

- Water spray, carbon dioxide, dry chemical powder or appropriate foam for surrounding fire.

Unsuitable Extinguishing Media

- No data available

Firefighting Procedures

- As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and appropriate protective clothing.

Special hazards arising from the substance or mixture

Unusual Fire and Explosion Hazards

- No data available

Hazardous Combustion Products

- During a fire, irritating and highly toxic gases may be generated by thermal decomposition or combustion.

Advice for firefighters

- No data available

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Section 6 - Accidental Release Measures

Personal precautions, protective equipment and emergency procedures

Personal Precautions

- Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Skin and eye contact should be avoided due to the potential for photosensitivity reactions upon exposure to light. Use of rubber gloves and eye protection is recommended.

Emergency Procedures

- Keep unauthorized personnel away.

Environmental precautions

- LARGE SPILLS: Prevent entry into waterways, sewers, basements or confined areas.

Methods and material for containment and cleaning up

Containment/Clean-up Measures

- For breakage or spill of material prior to reconstitution, dampen powder with water then wipe up with damp cloth.
For liquid spill after reconstitution, wipe up spill and place in liquid-tight container for disposal. Wear personal protective equipment to avoid contact with skin and eyes.

Other Information

- In the event of a release of bulk material, the user should determine if the release qualifies as reportable according to local, state, and federal regulations.

Section 7 - Handling and Storage

Precautions for safe handling

Handling

- No special handling is required. Refer to Section 8. Use only in accordance with product literature. Use of impervious gloves is recommended if there is a potential for skin contact.

Conditions for safe storage, including any incompatibilities

Storage

- Keep tightly closed. Store at controlled room temperature 20-25°C/68-77°F (excursions permitted to 15-30°C/59-86°F), to maintain product integrity. Use before date marked on carton and/or container.

Section 8 - Exposure Controls/Personal Protection

Control parameters

Exposure Limits/Guidelines

- No regulatory limits for ribavirin have been established. Good industrial hygiene practices should be followed to reduce exposures as much as possible.

<table>
<thead>
<tr>
<th>Result</th>
<th>ACGIH</th>
<th>Canada Quebec</th>
<th>NIOSH</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butylated hydroxytoluene (128-37-0)</td>
<td>STELs Not established</td>
<td>10 mg/m3 STEV</td>
<td>Not established</td>
</tr>
<tr>
<td></td>
<td>TWAs 2 mg/m3 TWA (inhalable fraction and vapor)</td>
<td>Not established</td>
<td>10 mg/m3 TWA</td>
</tr>
</tbody>
</table>

Exposure Control Notations

ACGIH

- Butylated hydroxytoluene (128-37-0): Carcinogens: (A4 - Not Classifiable as a Human Carcinogen)

Exposure Limits Supplemental

ACGIH

- Butylated hydroxytoluene (128-37-0): TLV Basis - Critical Effects: (upper respiratory tract irritation)

Exposure controls

Engineering Measures/Controls

- Use chemical fume hood, process enclosures, local exhaust ventilation or other engineering controls to minimize airborne levels.

Personal Protective Equipment

Respiratory

- In case of insufficient ventilation, wear suitable respiratory equipment. Use NIOSH approved respiratory protection (US requirements)

Eye/Face

- Wear eye/face protection

Hands

- Wear protective gloves

Skin/Body

- Avoid contact with skin

Environmental Exposure Controls

- No special controls are required under conditions of intended use. In the event of a bulk spill, prevent spilled material from entering storm sewers or drains, waterways, and contact with the soil.

Section 9 - Physical and Chemical Properties
Information on Physical and Chemical Properties

<table>
<thead>
<tr>
<th>Material Description</th>
<th>Physical Form</th>
<th>Appearance/Description</th>
<th>dark green lyophilized cake.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Color</td>
<td>Dark green.</td>
<td>Odor</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Odor Threshold</td>
<td>Not relevant</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**General Properties**

<table>
<thead>
<tr>
<th>Physical Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Boiling Point</td>
<td>No data available</td>
</tr>
<tr>
<td>Decomposition Temperature</td>
<td>&gt; 290 °C (&gt; 554 °F)</td>
</tr>
<tr>
<td>Melting Point/Freezing Point</td>
<td>&gt; 240 °C (&gt; 464 °F)</td>
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<tr>
<td>Specific Gravity/Relative Density</td>
<td>No data available</td>
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<tr>
<td>Water Solubility</td>
<td>Soluble</td>
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<tr>
<td>Viscosity</td>
<td>Not relevant</td>
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</table>

**Volatility**

<table>
<thead>
<tr>
<th>Physical Property</th>
<th>Value</th>
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</thead>
<tbody>
<tr>
<td>Flash Point</td>
<td>Not relevant</td>
</tr>
<tr>
<td>LEL</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Flammability (solid, gas)</td>
<td>Not relevant</td>
</tr>
<tr>
<td>Octanol/Water Partition coefficient</td>
<td>No data available</td>
</tr>
</tbody>
</table>

**Section 10: Stability and Reactivity**

**Reactivity**

- Stable under normal temperatures and pressures.

**Chemical stability**

- No data available

**Possibility of hazardous reactions**

- No data available

**Conditions to avoid**

- Light exposure. Will slowly degrade once reconstituted. Avoid exposure to extreme heat or cold.

**Incompatible materials**

- No data available

**Hazardous decomposition products**

- No data available

**Section 11 - Toxicological Information**

**Information on toxicological effects**

<table>
<thead>
<tr>
<th>Components</th>
<th>Verteporfin (1.8%)</th>
<th>Acute Toxicity: Intravenous-Woman TDLo • 150 mg/kg; <strong>Cardiac</strong>: Cardiomyopathy including infarction; <strong>Cardiac</strong>: Arrhythmias (including changes in conduction); Biochemical: Enzyme inhibition, induction, or change in blood or tissue levels: Multiple enzyme effects</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>129497-78-5</td>
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</tr>
</tbody>
</table>

**GHS Properties Classification**

<table>
<thead>
<tr>
<th>Preparat Date: 14/June/2016</th>
<th>Revision Date: 14/June/2016</th>
<th>Format: GHS Language: English (US)</th>
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</thead>
<tbody>
<tr>
<td>OSHA HCS 2012</td>
<td></td>
<td>Page 5 of 9</td>
</tr>
</tbody>
</table>
### Potential Health Effects

#### Inhalation

**Acute (Immediate)**
- May cause irritation.

**Chronic (Delayed)**
- No data available

#### Skin

**Acute (Immediate)**
- May cause irritation.

**Chronic (Delayed)**
- No data available

#### Eye

**Acute (Immediate)**
- May cause irritation.

**Chronic (Delayed)**
- No data available

#### Ingestion

**Acute (Immediate)**
- Not expected to be an exposure route. However, may cause gastric and intestinal irritation if ingested.

**Chronic (Delayed)**
- No data available

#### Mutagenic Effects

- Photodynamic therapy (PDT) as a class has been reported to result in DNA damage including DNA strand breaks, alkali-labile sites, DNA degradation, and DNA-protein cross links which may result in chromosomal aberrations, sister chromatid exchanges (SCE), and mutations. In addition, other photodynamic therapeutic agents have been shown to increase the incidence of SCE in Chinese hamster ovary (CHO) cells irradiated with visible light and in Chinese hamster lung fibroblasts irradiated with near UV light, increase mutations and DNA-protein cross-linking in mouse L5178 cells, and increase DNA-strand breaks in malignant human cervical carcinoma cells, but not in normal cells. Verteporfin was not evaluated in these latter systems. It is not known how the potential for DNA damage with PDT agents translates into human risk.

#### Carcinogenic Effects

<table>
<thead>
<tr>
<th>CAS</th>
<th>IARC</th>
<th>NTP</th>
</tr>
</thead>
<tbody>
<tr>
<td>128-37-0</td>
<td>Group 3-Not Classifiable</td>
<td>Evidence of Carcinogenicity</td>
</tr>
</tbody>
</table>

#### Reproductive Effects

- There are no data with the use of VISUDYNE in pregnant women to inform a drug-associated risk. Intravenous administration of verteporfin to pregnant rats during the period of organogenesis produced an increase in the incidence of anophthalmia/microphthalmia and wavy ribs at exposures approximately 40-fold the human exposure at the recommended clinical dose. Verteporfin did not produce adverse fetal effect in rats or rabbits at exposures 6-to 20-fold the human exposure at the recommended clinical dose. Lactation: Verteporfin and its diacid metabolite have been found in human breast milk following an intravenous infusion at the recommended human dose of 6 mg/m2. Verteporfin was present in breast milk at
levels up to 66% of the corresponding plasma levels and declined below the limit of quantification (2 ng/mL) within 24 hours. The diacid metabolite had lower peak concentrations but persisted up to at least 48 hours.

Other information

- PHOTOSENSITIZER: Verteporfin is photoactivated by certain wavelengths of light (which are among those naturally found in the spectrum of sunlight). This may cause Visudyne to be hazardous to persons exposed to it, and then exposed to certain wavelengths of light outside of a controlled clinical setting. Following exposure, care should be taken to avoid direct sunlight or bright indoor light for 5 days.

Section 12 - Ecological Information

Toxicity

- This material has not been tested for environmental effects.

Persistence and degradability

- No data available

Bioaccumulative potential

- No data available

Mobility in Soil

- No data available

Other adverse effects

Section 13 - Disposal Considerations

Waste treatment methods

Product waste

- Waste characterizations and compliance with applicable laws are the responsibility solely of the waste generator.

Packaging waste

- Dispose of content and/or container in accordance with local, regional, national, and/or international regulations.

Section 14 - Transport Information

<table>
<thead>
<tr>
<th>UN number</th>
<th>UN proper shipping name</th>
<th>Transport hazard class(es)</th>
<th>Packing group</th>
<th>Environmental hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>DOT</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>TDG</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>IMO/IMDG</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>IATA/ICAO</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
<td>Not Applicable</td>
</tr>
</tbody>
</table>

Special precautions for user

- No data available

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

- No data available

Section 15 - Regulatory Information
Safety, health and environmental regulations/legislation specific for the substance or mixture

SARA Hazard Classifications  • No data available

<table>
<thead>
<tr>
<th>Component</th>
<th>CAS</th>
<th>Canada DSL</th>
<th>EU EINECS</th>
<th>TSCA</th>
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<tbody>
<tr>
<td>Butylated hydroxytoluene</td>
<td>128-37-0</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Verteporfin</td>
<td>129497-78-5</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Lactose monohydrate</td>
<td>64044-51-5</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Dimyristoyl phosphatidylcholine</td>
<td>18656-38-7</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Egg phosphatidylglycerol</td>
<td>93685-90-6</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Ascorbyl palmitate</td>
<td>137-66-6</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Canada

Labor
Canada - WHMIS - Classifications of Substances
- Butylated hydroxytoluene 128-37-0 Not Listed
- Lactose monohydrate 64044-51-5 Not Listed
- Ascorbyl palmitate 137-66-6
  Uncontrolled product according to WHMIS classification criteria (listed under Scorbic palmitate)
- Verteporfin 129497-78-5 Not Listed
- Egg phosphatidylglycerol 93685-90-6 Not Listed
- Dimyristoyl phosphatidylcholine 18656-38-7 Not Listed

Canada - WHMIS - Ingredient Disclosure List
- Butylated hydroxytoluene 128-37-0 1 %
- Lactose monohydrate 64044-51-5 Not Listed
- Ascorbyl palmitate 137-66-6 Not Listed
- Verteporfin 129497-78-5 Not Listed
- Egg phosphatidylglycerol 93685-90-6 Not Listed
- Dimyristoyl phosphatidylcholine 18656-38-7 Not Listed

United States - California

Environment
U.S. - California - Proposition 65 - Carcinogens List
- Butylated hydroxytoluene 128-37-0 Not Listed
- Lactose monohydrate 64044-51-5 Not Listed
- Ascorbyl palmitate 137-66-6 Not Listed
- Verteporfin 129497-78-5 Not Listed
- Egg phosphatidylglycerol 93685-90-6 Not Listed
- Dimyristoyl phosphatidylcholine 18656-38-7 Not Listed

U.S. - California - Proposition 65 - Developmental Toxicity
- Butylated hydroxytoluene 128-37-0 Not Listed
- Lactose monohydrate 64044-51-5 Not Listed
- Ascorbyl palmitate 137-66-6 Not Listed
- Verteporfin 129497-78-5 Not Listed
<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS Number</th>
<th>Prop 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Egg phosphatidylglycerol</td>
<td>93685-90-6</td>
<td>Not Listed</td>
</tr>
<tr>
<td>Dimyristoyl phosphatidylcholine</td>
<td>18656-38-7</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**U.S. - California - Proposition 65 - Reproductive Toxicity - Female**

- Butylated hydroxytoluene           | 128-37-0   | Not Listed     |
- Lactose monohydrate                | 64044-51-5 | Not Listed     |
- Ascorbyl palmitate                 | 137-66-6   | Not Listed     |
- Verteporfin                        | 129497-78-5| Not Listed     |
- Egg phosphatidylglycerol           | 93685-90-6 | Not Listed     |
- Dimyristoyl phosphatidylcholine    | 18656-38-7 | Not Listed     |

**U.S. - California - Proposition 65 - Reproductive Toxicity - Male**

- Butylated hydroxytoluene           | 128-37-0   | Not Listed     |
- Lactose monohydrate                | 64044-51-5 | Not Listed     |
- Ascorbyl palmitate                 | 137-66-6   | Not Listed     |
- Verteporfin                        | 129497-78-5| Not Listed     |
- Egg phosphatidylglycerol           | 93685-90-6 | Not Listed     |
- Dimyristoyl phosphatidylcholine    | 18656-38-7 | Not Listed     |

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**Section 16 - Other Information**

**Revision Date**
- 14/June/2016

**Last Revision Date**
- 14/June/2016

**Preparation Date**
- 14/June/2016

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