MATERIAL SAFETY DATA SHEET

Pinnacle Biologics, Inc.
2801 Lakeside Drive, Suite 209
Bannockburn, IL 60015
Telephone: 847-283-7690
Fax: 847-283-7695

MSDS No.: PHOTOFRIN® 01
Date: July 18, 2007

I. PRODUCT IDENTIFICATION

PRODUCT NAME:	PHOTOFRIN® sterile porfimer sodium
SYNONYMS:	Polyporphyrin oligomer containing ester and ether linkage; PHOTOFRIN® II; CL 184, 116
USE/SIZE:	Photosensitizing agent for photodynamic therapy
PRODUCT No.:	MRD Formulations (CL 184,116)
CAS No.:	[87806-31-3]
TRADE NAMES:	PHOTOFRIN® porfimer sodium

II. HAZARDOUS INGREDIENTS AND IDENTIFICATION

CHEMICAL AND COMMON NAMES:	Porfimer sodium CAS No. 87806-31-3
WARNING:	Handle with extreme care. May be phototoxic. May cause eye and skin irritation, especially under brightly lit conditions.

POTENTIAL HEALTH EFFECTS:

SKIN:	May cause skin irritation under brightly lit conditions.
INGESTION:	None known or expected.
EYE:	May cause severe eye irritation under brightly lit conditions.
INHALATION:	None known or expected

TARGET ORGAN EFFECTS (Subchronic/Chronic):
Blood and blood forming systems, liver skin, spleen, bile duct, and adrenal glands (based on animal data).

CARCINOGENIC EFFECTS:	No data applicable.
REPRODUCTIVE/TERATOGENIC EFFECTS:	No data applicable.

CARCINOGENICITY STATUS:	Not listed in (NTP), (IARC), or (OSHA).
MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE:	None known.

III. PHYSICAL PROPERTIES

APPEARANCE AND ODOR:	Dark red to reddish-brown cake or crystalline lyophilized powder. Aqueous solutions are dark red to reddish-brown and practically opaque.
BOILING POINT:	Not applicable.
MELTING POINT:	Decomposes (color change to black at 225-240° C, did not melt at up to 300°C).
SPECIFIC GRAVITY/DENSITY:	No data available.
VAPOR PRESSURE:	$\leq 2X10^{-}$ torr @20°C
VAPOR DENSITY:	Not applicable.
SOLUBILITY, AQUEOUS (WATER):	Soluble to greater than 25mg/mL at neutral pH; reprecipitates out of solution when pH is lowered to <5.
SOLUBILITY, OTHER SOLVENTS:	No data available
pH:	7.2-7.9 (aqueous solution. approx. 13-18 mg/mL) 7.0-8.1 (reconstituted to 2.5 mg/mL in 5% dextrose in water)
DECOMPOSITION TEMPERATURE:	No data available; color change to black at 225-240°C did not melt at up to 300°C.
VISCOSITY:	Not applicable

IV. FIRE AND EXPLOSION HAZARD DATA

FLASH POINT: Not Applicable	FLAMMABLE LIMITS: Lower and upper limits are not applicable.
AUTOIGNITION TEMPERATURE:	Not applicable.
EXTINGUISHING MEDIA:	Water, carbon dioxide, dry chemical, foam.
HAZARDOUS COMBUSTION PRODUCTS:	Toxic emissions may be given off in a fire. See decomposition products in Section V-Stability and Reactivity.

SPECIAL FIREFIGHTING PROCEDURES:	Wear NIOSH/MSHA approved positive pressure, self contained breathing appartus and full protective turn out gear. Use caution in approaching fire. Use water to keep fire exposed containers cool.

V. REACTIVITY DATA

STABLILITY:	Lyophilized powder will retain potency at room temperature (15-25°C) for 36 months. Aqueous solutions will lose potency at room temperature; but are stable for >30 months at -20°C.
POLYMERIZATION:	Will not occur.
INCOMPATIBLE MATERIALS:	No data available.
HAZARDOUS DECOMPOSITION PRODUCTS:	Emits toxic fumes of CO, CO_2 and NO_x.

VI. SUMMARY OF TOXICITY AND HEALTH HAZARD DATA

ACUTE/SUBCHRONIC/CHRONIC DATA:

PHOTOFRIN® was not an eye or skin irritant in the standard Draize test (no attempt to evaluate the effect bright light on this protocol was made). There are no acute LD50 data available for PHOTOFRIN® by industrially-relevant routes of exposure.

When hematoporphyrin derivative (a less purified version of PHOTOFRIN®) was administered intraperitoneally (IP) to dark-housed mice, a 24-hr LD50 of 275mg/kg was reported; the corresponding LD50 for PHOTOFRIN® 130 mg/kg IP. If mice were exposed to low level of light for 5 hours after IP administration of the compound, the LD50's dropped to 7.5 and 4mg/kg for the hematoporphyrin derivative and PHOTOFRIN® respectively. In mice exposed to a 12-hr cycle of low light 2.5-14 footcandles (ft-c) for 14 days, one of 10 animals died after a 125 mg/kg intravenous (IV) injection of PHOTOFRIN®. Reddening and swelling of the skin and other signs of toxicity were seen at doses $\geq$ 50 mg/kg (IV); 25 mg/kg was a no-effect level. Under brightly lit conditions (120 ft-c for 3 hr, then 4-19 ft-c on a 12-hr cycle) redness, swelling, and/or other signs of phototoxicity were observed at all levels down to 4.8 mg/kg PHOTOFRIN®. IV. In both the IP and IV studies, death was attributed to a shock like syndrome. Acute studies in rats gave similar light and dose-related phototoxic effects.

In repeat-dose intravenous studies of PHOTOFRIN® porfimer sodium in rats under normal laboratory lighting conditions, effects were seen in the blood and blood forming systems, the liver, spleen, and bile duct (places where normal porphyrins are accumulated and/or used). These effects were seen to be reversible when administration of PHOTOFRIN® was stopped. In subchronic studies in dogs, effects were seen in the blood and blood forming systems, the liver, spleen, and adrenal glands (a recovery phase was not included in the dog study). No studies of the effect of long-term administration with bright light have been conducted.

REPRODUCTIVE/TERATOGENIC EFFECTS DATA:

While PHOTOFRIN® was toxic to pregnant rats and rabbits and their offspring (increased fetal resorptions and lowered fetal body weight), it was not teratogenic (did not cause birth defects).

MUTAGENICITY:

PHOTOFRIN® was negative with and without light in five different *in vitro* test systems (Ames test. CHO/HGRPT mammalian point mutation assay. Na+/K+ ATPase mammalian point mutation, cell transformation and *in vitro* cytogenetics). It was also negative in the mouse micronucleus assay, an *in vitro* test. PHOTOFRIN® was marginally positive in one *in vitro* test system (sister chromatid exchange (SCE), but only in the presence of light. The less purified preparation (hematoporphyrin derivative) is reported in the literature to have caused an increase in the number of DNA strand breaks in bacteria and mammalian cells *in vitro* with light activation. The hematoporphyrin derivative with light activation also produced increases in chromosomal aberrations and weak induction of sister chromatid exchanges.

CARCINOGENICITY:

No long-term toxicity studies have been conducted in laboratory animals.

VII. EMERGENCY AND FIRST AID PROCEDURES

EYES: Immediately flush eyes with plenty of cool, low-pressure water for at least 20 minutes. Contact a physician if irritation occurs. Remain in subdued light until examined by medical personnel.

SKIN: Promptly wash with soap and cool running water. Remove contaminated clothing. Contaminated clothing should be washed before reuse. Contact a physician if irritation occurs.

INHALATION: Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

INGESTION: Do not induce vomiting except as directed by medical personnel. Never give anything by mouth to an unconscious person. Never induce vomiting in an unconscious person. Call a physician.

VIII. SPECIAL PROTECTION INFORMATION

EXPOSURE GUIDELINES:

INGREDIENT NAME	OSHA PEL/STEL	ACGIH TLV/STEL	AHPC-TWA
Porfimer Solution	Not Established	Not Established	Not Established

VENTILATION: Use closed-system handling, laboratory bench hood or local exhaust ventilation to control dust of mist.

RESPIRATOR: When engineering controls are not adequate to contain dust/mist, wear an approved air-purifying respirator with high-efficiency cartridges or a supplied-air respirator.

GLOVES: Rubber gloves and long sleeves should be worn to prevent contact with the skin.

EYE PROTECTION: The use of Safety Glasses/Goggles is required.

OTHER PROTECTION: Minimize excess handling. Keep container closed when not in use. Wash hands, face and exposed body parts at lunch breaks, and at end of shift.

IX. SPILL OR LEAK PROCEDURES

STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED:

Review Section II – Hazards Identification, and Section VIII – Exposure Controls/ Personal Protection before proceeding with the clean up. Shut off the source of spill or leak if it is safe to do so. Scoop or shovel spilled material into a suitable open head drum. Secure the drum, cover and move; clean spill area thoroughly.

TREATMENT AND DISPOSAL:

Decontaminate or dispose of all protective clothing and equipment. Dispose of in accordance with recommendations in Section XII – Disposal Considerations.

REPORTING REQUIREMENTS:

The United States Environmental Protection Agency (USEPA) has not established a Reportable Quantity (RQ) for releases of this material. State and Local regulations vary and may impose additional reporting requirements.

X. STORAGE AND HANDLING

Maintain good housekeeping and personal hygiene procedures. Aqueous solutions must be stored at or BELOW 20°C.

XI. ECOLOGICAL INFORMATION

ECOTOXICOLOGICAL INFORMATION:

n-OCTANOL/WATER Partition Coefficient (P_{ow}) of PHOTOFRIN® at 24°C was as follows:

Ph	P_{ow}	Log P_{ow}
7.0	0.031 ± 0.001	-1.5 ± 0.2
9.0	0.006 ± 0.002	-2.3 ± 0.2

Microbial Inhibition: PHOTOFRIN® was evaluated for potential inhibitory effects on the growth of pure cultures of bacteria, fungi, and blue-green algae. No inhibition was observed for the test organisms at any of the concentrations (3.91, 15.6, 62.5, 250 and 1000mg/L of PHOTOFRIN® porfimer sodium, under the study conditions utilized.

Environmental Concentration Lethal to 50%: The no observed effect level (NOEL) in Daphnia magna is 994 mg/L at 24 and 48 hr which classifies PHOTOFRIN® porfimer sodium as practically non-toxic, under the study conditions utilized.

CHEMICAL FATE INFORMATION: No data available.

XII. DISPOSAL

DISPOSAL RECOMMENDATIONS:

Dispose of in accordance with all Federal, State, and local regulations.
Incineration at a permitted facility is recommended.

RCRA WASTE#:

This is not a RCRA regulated hazardous waste.

XIII. TRANSPORT INFORMATION

U.S. DEPARTMENT OF TRANSPORTATION (DOT): Non-Regulated.

INTERNATIONAL AIR TRANSPORT ASSOCIATION (IATA): Non- Regulated.

XIV. REGULATORY INFORMATION

USEPA: Not Regulated.

OSHA: OSHA has not developed a Permissible Exposure Limit (PEL) for Porfimer Sodium (See Section VIII).

SARA TITLE III: Not Applicable

XV. OTHER INFORMATION

HAZARD RATINGS*:

NFPA:		**HMIS:**	
Health:	3	Health:	3
Flammablity:	0	Flammablity:	0
Reactivity:	0	Reactivity:	0
Special Hazards:	Phototoxic	Special Hazards:	Phototoxic

*A hazard ratings has not been developed by NFPA or HMIS for this product. The hazard ratings provided in this MSDS are based on NFPA and HMIS hazard evaluation criteria, as well as, professional judgement. This information is intended solely for the use of individuals trained in these hazard rating systems.

XVI. APPENDIX

The information and recommendations contained hererin are based upon tests believed to be reliable. However, Pinnacle Biologics, Inc. does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFTEY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform with actual conditions of usage may be requried. Pinnacle Biologics, Inc. assumes no responsibility for results obtained or for incidental or consequential damages arising from the use of these data. No freedom from infringement of any patent, copyright or trademark is to be inferred.