1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

MATERIAL NAME: CONDYLOX TOPICAL SOLUTION 0.5%
List Number: 4675

MANUFACTURER: Abbott Laboratories for Oclassen Pharmaceuticals, Inc.,
a subsidiary of Watson Pharmaceuticals, Inc.
311 Bonnie Circle
Corona, CA 91720

EMERGENCY TELEPHONE NUMBER: 1-800-441-4987
CHEMTREC TELEPHONE NUMBER: 1-800-424-9300

2. COMPOSITION/INFORMATION ON INGREDIENTS

INGREDIENT NAME: Podophyllotoxin *
CAS/RTECS NUMBERS: 518-28-5 / LV2500000
OSHA-PEL 8HR TWA: N/L
STEL: N/L
CEILING: N/L
ACGIH-TLV 8HR TWA: N/L
STEL: N/L
CEILING: N/L
OTHER 8HR TWA: 1 mcg/m3 - skin (Abbott Laboratories)
LIMITS STEL: N/A
CEILING: N/A
* Hazardous per OSHA criteria

2. COMPOSITION/INFORMATION ON INGREDIENTS, continued

INGREDIENT NAME: Ethanol *
CAS/RTECS NUMBERS: 64-17-5 / KQ6300000
OSHA-PEL 8HR TWA: 1000 ppm (1900 mg/m3)
STEL: N/L
CEILING: N/L
ACGIH-TLV 8HR TWA: 1000 ppm (1880 mg/m3)
STEL: N/L
CEILING: N/L
OTHER 8HR TWA: N/A
LIMITS STEL: N/A
CEILING: N/A
* Hazardous per OSHA criteria

INGREDIENT NAME: Lactic Acid *
CAS/RTECS NUMBERS: N/A / N/A
OSHA-PEL 8HR TWA: 15 mg/m3 total dust, 5 mg/m3 respirable fraction.**
STEL: N/L
CEILING: N/L
ACGIH-TLV 8HR TWA: 10 mg/m3 total dust, 5 mg/m3 respirable fraction.**
STEL: N/L
CEILING: N/L
OTHER 8HR TWA: N/A
LIMITS STEL: N/A
CEILING: N/A
* Hazardous per OSHA criteria.
**As nuisance particulate.

INGREDIENT NAME: Sodium Lactate
CAS/RTECS NUMBERS: N/A
OSHA-PEL 8HR TWA: 15 mg/m3 total dust, 5 mg/m3 respirable fraction.**
STEL: N/L
CEILING: N/L
ACGIH-TLV 8HR TWA: 10 mg/m3 total dust, 5 mg/m3 respirable fraction.**
STEL: N/L
CEILING: N/L
OTHER 8HR TWA: N/A
LIMITS STEL: N/A
CEILING: N/A
** As nuisance particulate.

3. HAZARDS INFORMATION

EMERGENCY OVERVIEW: This product is used to remove warts. It is a skin irritant and corrosive to the eyes. Target organs include the eyes and possible the fetus, hematopoietic system, gastrointestinal tract, liver and dividing cells. It has the potential to cause allergic reactions.

ROUTE(S) OF ENTRY: Skin: N/D
Inhalation: Yes
Ingestion: No

INGESTION RATING: None

SKIN ABSORPTION RATING: N/D

INHALATION RATING: N/D

CORROSIVENESS RATING: Corrosive to eyes

SKIN CONTACT RATING: Irritant

SKIN SENSITIZATION RATING: N/D

EYE CONTACT RATING: Corrosive to eyes

TARGET ORGANS: Eyes and skin, possibly fetus, hematopoietic system, gastrointestinal tract, liver.

CARCINOGENICITY RATING: NTP: N/L IARC: N/L OSHA: N/L
ACGIH: N/L
None

SIGNS AND SYMPTOMS: N/D. Direct contact with the eyes would be irritating and possibly cause permament damage. Skin irritation would be expected from repeated skin contact. Signs of toxicity included coughing, vomiting, diarrhea, abdominal pain, cyanosis, respiratory stimulation, rapid heart rate, weakness, ataxia, flaccid paralysis and coma. Liver dysfunction, electroencephalogram changes, hypokalemia, glucosuria and granulocytopenia have been reported.

3. HAZARDS INFORMATION, continued

MEDICAL CONDITIONS AGGRAVATED BY EXPOSURE: N/D. Hypersensitivity to podophyllotoxin. Data suggest liver dysfunction, blood disorders, pregnancy, eye ailments, and hematopoietic and gastrointestinal disorders.

4. FIRST AID MEASURES

EYES: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care as necessary.

SKIN: Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care as necessary.

INGESTION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care as necessary.

INHALATION: Remove from source of exposure. If signs of toxicity occur, seek medical attention. No known antidote. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING PROCEDURES

FLASH POINT: N/D
FLASH POINT METHOD: N/A
LOWER EXPLOSIVE LIMIT(%): N/D
UPPER EXPLOSIVE LIMIT(%): N/D
AUTOIGNITION TEMPERATURE: N/D

FIRE & EXPLOSION HAZARDS: None known.

EXTINGUISHING MEDIA: Use media appropriate for primary cause of fire.

FIRE FIGHTING INSTRUCTIONS: None known.

6. ACCIDENTAL RELEASE MEASURES

SPILL OR RELEASE PROCEDURES: Wipe up material and dispose of as directed in Section 13. Wash surfaces containing residue with large quantities of water.

7. HANDLING AND STORAGE

HANDLING: N/D

STORAGE: N/D

SPECIAL PRECAUTIONS: N/D

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS: N/A

RESPIRATORY PROTECTION: N/A

SKIN PROTECTION: N/A

EYE PROTECTION: N/A

OTHER PROTECTION: N/A. Use good clinical and hygiene practices.

9. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE/PHYSICAL STATE: Clear colorless liquid.
ODOR: N/D
BOILING POINT: N/A
MELTING/FREEZING POINT: N/A
VAPOR PRESSURE (mm Hg): N/A
VAPOR DENSITY (Air=1): N/A
EVAPORATION RATE: N/A
BULK DENSITY: N/D
SPECIFIC GRAVITY: N/A
SOLUBILITY: N/D

9. PHYSICAL AND CHEMICAL PROPERTIES, continued

pH: N/A
VISCOSITY: N/A

10. STABILITY AND REACTIVITY

CHEMICAL STABILITY: N/D

INCOMPATIBILITIES: N/D

HAZARDOUS DECOMPOSITION PRODUCTS: N/D

HAZARDOUS POLYMERIZATION: N/D

11. TOXICOLOGICAL INFORMATION

ORAL TOXICITY: N/D. LD50 for podophyllotoxin = 90-100 mg/kg in mice. LD50 for ethanol = 5560-13,700 mg/kg in animals. LD50 for lactic acid = 1810-5000 mg/kg in animals.

DERMAL TOXICITY: N/D. LD50 for podophyllotoxin = 200-500 mg/kg in rats and rabbits. LD50 for other ingredients > 2000 mg/kg in animals.

INHALATION TOXICITY: N/D. LC50 for ethanol = 20,000 ppm/10 hours in rats.

CORROSIVENESS: N/D

DERMAL IRRITATION: N/D. 5 mg of lactic acid applied to skin for 24 hours produced severe dermal irritation in rabbits.

OCULAR IRRITATION: N/D. Lactic acid reported to cause severe eye irritation and necrosis. Podophyllotoxin and ethanol produced moderate to severe irritation to the cornea, iris and conjunctivitis without permanent injury in rabbits.

DERMAL SENSITIZATION: N/D. Podophyllotoxin reported to be negative in the maximization test in guinea pigs but positive results reported in cats and rabbits.

11. TOXICOLOGICAL INFORMATION, continued

SPECIAL TARGET ORGAN EFFECTS: N/D. Podophyllotoxin arrests cell division in mitosis by inhibiting the polymerization of microtubule subunits (i.e., a mitotic spindle poison). As a result, podophyllotoxin has an embryolethal effect when administered to animals early in pregnancy. Parenteral use has resulted in bone marrow and gastrointestinal toxicity. Podophyllum resin is a well known abortifacient. There are reports that dermal application of the resin containing podophyllotoxin has produced intrauterine death. Use of the resin as a laxative during pregnancy has also caused birth defects. Systemic toxicity may result from dermal exposure. Chronic ethanol consumption has been linked to liver, kidney and brain damage, and fetal alchol syndrome.

CARCINOGENICITY INFORMATION: N/D

12. ECOLOGICAL INFORMATION

ECOLOGICAL INFORMATION: N/D

13. DISPOSAL CONSIDERATIONS

WASTE DISPOSAL METHODS: All waste must be packaged, labeled, transported and disposed of in conformance with applicable local, state, and federal laws and regulations and in accordance with good engineering practices. This material is a RCRA hazardous waste.

14. TRANSPORTATION INFORMATION

DOT STATUS: Regulated
PROPER SHIPPING NAME: Flammable liquid, n.o.s. (contains ethanol) [final product in consumer package can be shipped as Consumer Commodity - Class 9]
HAZARD CLASS: 3
UN NUMBER: UN 1993
PACKING GROUP: II
REPORTABLE QUANTITY: N/A

14. TRANSPORTATION INFORMATION, continued

IATA/ICA0 STATUS: Regulated
PROPER SHIPPING NAME: Flammable Liquid, N.O.S. (contains ethanol) [final product in consumer package can be shipped as Consumer Commodity - Class 9]
HAZARD CLASS: 3
UN NUMBER: UN 1993
PACKING GROUP: II
REPORTABLE QUANTITY: N/A

IMO STATUS: Regulated
PROPER SHIPPING NAME: N/A
HAZARD CLASS: N/A
UN NUMBER: N/A
PACKING GROUP: N/A
REPORTABLE QUANTITY: N/A
FLASH POINT: N/D

15. REGULATORY INFORMATION

TSCA STATUS: Exempt

CERCLA STATUS: N/L

SARA STATUS: N/L

RCRA STATUS: This would be a RCRA D001 Waste.

PROP 65 (CA): N/D

16. OTHER INFORMATION

LEGEND: N/A = Not Applicable
N/D = Not Determined
N/L = Not Listed
L = Listed
C = Ceiling
S = Short-term
(R) = Registered Trademark of Abbott Laboratories
(TM) = Registered Trademark of Abbott Laboratories

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