ETHICON, INC -- DERMABOND TOPICAL SKIN ADHESIVE

MSDS Safety Information

MSDS Date: 09/04/1998
MSDS Num: CLLQF
Product ID: DERMABOND TOPICAL SKIN ADHESIVE
MFN: 01
Responsible Party
Cage: 10614
Name: ETHICON, INC
Address: ROUTE 22
Box: 158
City: SOMERVILLE NJ 08876-0151
Info Phone Number: 732-562-7117
Emergency Phone Number: 800-255-2500
Review Ind: Y
Published: Y

Contractor Summary

Cage: 10614
Name: ETHICON, INC
Address: ROUTE 22
Box: 158
City: SOMERVILLE NJ 08876-0151
Phone: 732-562-7117

Ingredients

Name: 2-OCTYL CYANOACRYLATE
Percent by Wt: 94.

Name: PLASTICIZER
Percent by Wt: 6.

Health Hazards Data

Route Of Entry Inds - Inhalation: NO
Ingestion: NO
Carcinogenicity Inds - NTP: NO
IARC: NO
OSHA: NO

Effects of Exposure: EYE: IRRITATING TO THE EYES; R36. SKIN: UNKNOWN.

   INGESTION: DERMABOND POLYMERIZES RAPIDLY ON CONTACT WITH ORAL MUCOSA MAKING
   INGESTION OF THE LIQUID ADHESIVE UNLIKELY. INHALTION: DERMABOND POLYMERIZES
   RAPIDLY ON CONTACT WITH ORAL AND NASAL MUCOSA MAKING INHALTION OF THE LIQUID
   ADHESIVE EXTREMELY UNLIKELY.

Explanation Of Carcinogenicity: DERMABOND IS NOT CARCINOGENIC.

Signs And Symptoms Of Overexposure: DERMABOND HAS NOT BEEN ASSOCIATED WITH
   ADVERSE HEALTH EFFECTS. REACTIONS FOR LOWER HOMOLOGUE INDUSTRIAL
   CYANOACRYLATES ARE TYPICALLY RESTRICTED TO LOCAL SELF-LIMITED IRRITATION OF
   ATTACHED AND IMMEDIATELY SURROUNDING TISSUES.

Medical Cond Aggravated By Exposure: ADVERSE REACTION MAY OCCUR IN INDIVIDUALS
   WHO ARE HYPERSENSITIVE TO CYANOACRYLATE OR FORMALDEHYDE WHEN EXPOSED TO
   DERMABOND.

First Aid: EYE: RINSE IMMEDIATELY WITH PLENTY OF WATER AND SEEK MEDICAL
   ADVICE; S26 IF RESIDUAL ADHESIVE REMAINS, APPLY TOPICAL OPHTHALMIC OINTMENT TO
   HELP LOOSEN THE BOND AND CONTACT AN OPHTHALMOLOGIST. SKIN: IF UNINTENDED
   BONDING OF INTACT SKIN OCCURS, PEEL OFF THE ADHESIVE BUT DO NOT PULL SKIN
   APART. PETROLEUM JELLY OR ACETONE MAY HELP LOOSEN THE BOND. OTHER AGENTS SUCH
   AS H2O, SALINE, BETADINE, OR SOAP ARE NOT EXPECTED TO IMMEDIATELY LOOSEN THE
BOND. INGESTION HIGHLY UNLIKELY. IT IS ALMOST IMPOSSIBLE TO SWALLOW DERMABOND. IT WILL SOLIDIFY AND ADHERE WITHIN THE MOUTH. SEEK MEDICAL ATTENTION. SEE SUPPLEMENTAL DATA

Handling and Disposal

Spill Release Procedures: THE LIQUID ADHESIVE WILL POLYMERIZE ONCE EXPRESSED THROUGH THE APPLICATOR OR OTHERWISE RELEASED FROM ITS PRIMARY CONTAINER. THE POLYMERIZED ADHESIVE IS NON-TOXIC AND MAY BE DISPOSED OF WITH THE APPLICATOR IN NON-HAZARDOUS SOLID WASTE. ANY LIQUID ADHESIVE MAY BE POLYMERIZED WITH WATER AND PICKED UP WITH AN INERT ABSORBENT MATERIAL.
Waste Disposal Methods: ENSURE COMPLIANCE WITH LOCAL, STATE AND FEDERAL NON-HAZARDOUS SOLID WASTE REGULATIONS.
Handling And Storage Precautions: DERMABOND IS ORIGINALLY STERILIZED BY DRY HEAT AND ETHYLENE OXIDE GAS. DO NOT RESTERILIZE. DO NOT USE IF PACKAGE IS OPENED OR DAMAGED. DISCARD ANY UNUSED MATERIAL FOLLOWING COMPLETION OF MEDICAL PROCEDURE. RECOMMENDED STORAGE CONDITIONS ARE BELOW 30C/86F AWAY FROM MOISTURE AND DIRECT HEAT;S15.
Other Precautions: CONTD FROM STORAGE: KEEP CONTAINER IN A WELL-VENTILATED PLACE;S9. DO NOT USE AFTER EXPIRATION DATE. CONSULT PACKAGE INSERT FOR INSTRUCTIONS FOR USE.

Fire and Explosion Hazard Information

Flash Point Method: TCC
Flash Point Text: 150-200F
Extinguishing Media: CARBON DIOXIDE, DRY CHEMICAL POWDER, FOAM.
Fire Fighting Procedures: WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING.
Unusual Fire/Explosion Hazard: EMITS TOXIC FUMES UNDER COMBUSTION.
Control Measures

Respiratory Protection: RESPIRATION PROTECTION IS NOT ANTICIPATED FOR THIS PRODUCT'S NORMAL APPLICATION OR USE.
Ventilation: USE IN WELL-VENTILATED AREA.
Protective Gloves: NITRILE OR POLYETHYLENE GLOVES; S37.
Eye Protection: WEAR EYE/FACE PROTECTION; S39.
Other Protective Equipment: WEAR SUITABLE PROTECTIVE CLOTHING; S36.
Work Hygienic Practices: CONSULT PACKAGE INSERT FOR INSTRUCTIONS FOR USE.
Supplemental Safety and Health: CONT INGESTION: IF THE POLYMERIZED MATERIAL IS SWALLOWED, NO ADVERSE EFFECTS ARE EXPECTED. HOWEVER, CONTACT A PHYSICIAN IF GASTRIC DISTRESS IS NOTED.

Physical/Chemical Properties

HCC: N1
B.P. Text: 184-194F
Vapor Pres: <0.2MMHG
Spec Gravity: 0.985
Solubility in Water: ~ZERO
Appearance and Odor: VIOLET; SLIGHT ODOR. CONTAINED IN A CRUSHABLE GLASS AMPULE.

Reactivity Data

Stability Indicator: YES
Stability Condition To Avoid: AVOID EXCESSIVE HEAT AND HUMIDITY, AND EXPOSURE TO DIRECT SUNLIGHT.
Materials To Avoid: DERMABOND WILL POLYMERIZE ON CONTACT WITH ANY BASIC OR ALKALINE SUBSTRATE.
Hazardous Decomposition Products: SMALL AMOUNTS OF FORMALDEHYDE MAY BE GENERATED.
Hazardous Polymerization Indicator: NO
Conditions To Avoid Polymerization: PER MSDS HAZARDOUS POLYMERIZATION WILL NOT OCCUR.

Toxicological Information

Toxicological Information: DERMABOND HAS BEEN TESTED ACCORDING TO INTERNATIONAL STANDARD ISO 10993 FOR BIOLOGICAL EVALUATION OF MEDICAL DEVICES AND FDA OFFICE OF DEVICE EVALUATION'S BIOCOMPATIBILITY TESTING GUIDANCE (G95-1, MAY 1995) FOR TOPICAL DEVICES IN CONTACT WITH SKIN FOR LESS THAN 30 DAYS. THE RESULTS OF ALL TESTING PERFORMED IN ACCORDANCE WITH THESE GUIDANCES INDICATE DERMABOND IS NON-TOXIC.

Ecological Information

Ecological: DISPOSAL OF DERMABOND IN NORMAL OR MEDICAL WASTE WILL BE TO LANDFILLS OR INCINRATION AND IS NOT CONSIDERED A SIGNIFICANT ENVIRONMENTAL RELEASE. PRODUCT THAT IS APPLIED TO PATIENTS AS A TOPICAL SKIN ADHESIVE WILL EVENTUALLY GO TO NON-HAZARDOUS SOLID WASTE. ECOTOXICOLOGICAL INFORMATION: UNKNOWN.

MSDS Transport Information


Regulatory Information

Federal Regulatory Information: PREMARKET APPROVAL APPLICATION P960052 FOR

Other Information

Other Information: REFERENCE DOCUMENTATION: SEE PACKAGE INSERT FOR INSTRUCTIONS FOR USE.

Transportation Information

Responsible Party Cage: 10614
Trans ID NO: 158836
Product ID: DERMABOND TOPICAL SKIN ADHESIVE
MSDS Prepared Date: 09/04/1998
Review Date: 09/10/2001
MFN: 1
Multiple KIT Number: 0
Unit Of Issue: CY
Type Of Container: CYLINDER

Detail DOT Information

DOT PSN Code: ZZZ
DOT Proper Shipping Name: NOT REGULATED BY THIS MODE OF TRANSPORTATION

Detail IMO Information

IMO PSN Code: ZZZ
IMO Proper Shipping Name: NOT REGULATED FOR THIS MODE OF TRANSPORTATION

Detail IATA Information

IATA PSN Code: ZZZ
IATA Proper Shipping Name: NOT REGULATED BY THIS MODE OF TRANSPORTATION

Detail AFI Information

AFI PSN Code: ZZZ
AFI Proper Shipping Name: NOT REGULATED BY THIS MODE OF TRANSPORTATION

HAZCOM Label

Product ID: DERMABOND TOPICAL SKIN ADHESIVE
Cage: 10614
Company Name: ETHICON, INC
Street: ROUTE 22
PO Box: 158
City: SOMERVILLE NJ
Zipcode: 08876-0151
Health Emergency Phone: 800-255-2500
Label Required IND: Y
Date Of Label Review: 09/10/2001
Status Code: A
Origination Code: F
Eye Protection IND: YES
Signal Word: CAUTION
Health Hazard: None
Contact Hazard: Slight
Fire Hazard: None
Reactivity Hazard: None

Hazard And Precautions: EYE: IRRITATING TO THE EYES; R36. SKIN: UNKNOWN.

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