

ETHICON, INC -- DERMABOND TOPICAL SKIN ADHESIVE --

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===== Product Identification =====

Product ID:DERMABOND TOPICAL SKIN ADHESIVE

MSDS Date:09/04/1998

FSC:NIIN:Submitter:D RV

Status Code:A

MSDS Number: CLLQF

=== Responsible Party ===

Company Name:ETHICON, INC

Address:ROUTE 22

Box:158

City:SOMERVILLE

State:NJ

ZIP:08876-0151

Country:US

Info Phone Num:732-562-7117

Emergency Phone Num:800-255-2500

CAGE:10614

=== Contractor Identification ===

Company Name:ETHICON, INC

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===== Composition/Information on Ingredients =====

Ingred Name:2-OCTYL CYANOACRYLATE

= Wt:94.

Ingred Name:PLASTICIZER

= Wt:6.

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===== Hazards Identification =====

Routes of Entry: Inhalation:NO Skin:UNKNOWN Ingestion:NO

Reports of Carcinogenicity:NTP:NO IARC:NO OSHA:NO

Health Hazards Acute and Chronic: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 INHLATION OF THE LIQUID ADHESIVE EXTREMELY UNLIKELY.

Explanation of Carcinogenicity:DERMABOND IS NOT CARCINOGENIC.

Effects 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 IMMEDIA TELY SURROUNDING TISSUES.

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

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===== First Aid Measures =====

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

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===== Fire Fighting Measures =====

Flash Point Method:TCC
Flash Point: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.

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===== Accidental Release Measures =====

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.

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===== Handling and Storage =====

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.

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===== Exposure Controls/Personal Protection =====

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
Boiling Pt: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.

===== Stability and Reactivity Data =====

Stability Indicator/Materials to Avoid:YES
DERMABOND WILL POLYMERIZE ON CONTACT WITH ANY BASIC OR ALKALINE
SUBSTRATE.
Stability Condition to Avoid:AVOID EXCESSIVE HEAT AND HUMIDITY, AND
EXPOSURE TO DIRECT SUNLIGHT.
Hazardous Decomposition Products:SMALL AMOUNTS OF FORMALDEHYDE MAY BE
GENERATED.
Conditions to Avoid Polymerization:PER MSDS HAZARDOUS POLYMERIZATION
WILL NOT OCCUR.

===== Toxicological Information =====

Toxicological Information:DERMABOND HAS BEEN TESTES ACCORDING TO
INTERNATIONAL STANDARD ISO 10993 FOR BIOLOGICAL EVALUATION OF
MEDICAL DEVICES AND FDA OFFICE OF DEVICE EVALUATION'S
BIOCOMPATABILITY 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 QUIDANCES INDICATE
DERMABOND IS NON-TOXIC.

===== Ecological Information =====

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

===== Disposal Considerations =====

Waste Disposal Methods:ENSURE COMPLIANCE WITH LOCAL, STATE AND FEDERAL
NON-HAZARDOUS SOLID WASTE REGULATIONS.

===== MSDS Transport Information =====

Transport Information:PROPER SHIPPING NAME:2-OCTYL CYANOARYLATE. HAZARD
CLASS:9. DOT IDENTIFICATION NUMBER: UN3082. DOT SHIPPING LABEL:
OTHER REGULATED SUBSTANCE, LIQUID,N.O.S. PACKAGING EXCEPTION: 49
CFR173.4 AND 49CFR173 .155. PACKAGING REQUIREMENT: PGIII. FRIGHT
CLASSIFICATION: 100-56940

===== Regulatory Information =====

Federal Regulatory Information:PREMARKET APPROVAL APPLICATION P960052
FOR DERMABOND TOPICAL SKIN ADHESIVE APPROVED 8/25/98. CANADIAN

REGULATORY INFORMATION: REGISTERED FOR SALE IN CANADA. EUROPEAN
(ECC) REGULATORY INFORMATION: DERM ABOND IS CE MARKED AS AUTHORIZED
BY THE BRITISH STANDARDS INSTITUTION, NOTIFIED BODY NUMBER 0086.
(CERTIFICATE NUMBER CE 0168, FIRST ISSUED AUGUST 20,1997.

===== Other Information =====

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