MATERIAL SAFETY DATA SHEET

MANUFACTURER'S NAME: DAVOL, INC. (FORMERLY MEDCHEM PRODUCTS, INC.)
EMERGENCY TEL: (617) 932-5900
ADDRESS: 160 NEW BOSTON STREET, WOBURN, MA 01801

CHEMICAL NAME AND SYNONYMS: AVITENE®, MICROFIBRILLAR COLLAGEN HEMOSTAT, MCH
CAS NUMBER: N/A
NIOSH/TECS NUMBER: N/A
CERCLA HAZARD RATINGS (SCALE 0-3)
  HEALTH - N/A  FIRE - N/A  REACTIVITY - N/A  PERSISTENCE - N/A

PERCENTAGE: 100% COMPONENT: U.S. BOVINE COLLAGEN

HAZARD DESCRIPTION: THIS MATERIAL IS AN ABSORBABLE TOPICAL HEMOSTATIC AGENT PREPARED AS A DRY, STERILE, FIBROUS, WATER INSOLUBLE PARTIAL HYDROCHLORIC ACID SALT OF PURIFIED EDIBLE BOVINE COLLAGEN.

BOILING POINT: N/A MELTING POINT: N/A
SPECIFIC GRAVITY: N/A VAPOR PRESSURE: N/A
EVAPORATION RATE: N/A SOLUBILITY IN WATER: INSOLUBLE
VAPOR DENSITY: N/A

FIRE AND EXPLOSION HAZARD DATA:
FLASH POINT: N/A UPPER EXPLOSION LIMIT: N/A
LOWER EXPLOSION LIMIT: N/A
FIRE FIGHTING MEDIA: USE MEDIA APPROPRIATE FOR SURROUNDING CONDITIONS.
FIRE FIGHTING: USE EQUIPMENT APPROPRIATE FOR SURROUNDING CONDITIONS.
TOXIC GASES PRODUCED: CARBON DIOXIDE, CARBON MONOXIDE

TOXICITY:
PRECAUTIONS: AVITENE® (MCH) IS EDIBLE. PROVOCATIVE SKIN TESTS ON HUMAN VOLUNTEERS AND EXPERIENCE IN CLINICAL USE OF THIS PRODUCT FOR OVER 20 YEARS INDICATE THAT THERE IS NO SIGNIFICANT IMMUNOLOGICAL RESPONSE FROM EXPOSURE TO IT. WHEN INTRODUCED INTO INTERNAL WOUNDS IT IS ABSORBED IN APPROXIMATELY SIX WEEKS, PRODUCING MINIMAL TISSUE REACTION.
CARCINOGENICITY: NOT KNOWN.

INHALATION
ACUTE EXPOSURE: MAY PRODUCE BRONCHIAL IRRITATION.
CHRONIC EXPOSURE: NO EFFECTS HAVE BEEN OBSERVED.
FIRST AID: PROVIDE FRESH AIR.

SKIN CONTACT
ACUTE EXPOSURE: HARMLESS
CHRONIC EXPOSURE: NO ILL EFFECTS OBSERVED.
FIRST AID: NOT REQUIRED

EYE CONTACT
ACUTE EXPOSURE: CONJUNCTIVAL IRRITATION AS WITH ANY INERT PARTICULATE FOREIGN BODY.
CHRONIC EXPOSURE: NO EFFECTS OBSERVED.
FIRST AID: FLUSH EYES WITH OVER-THE-COUNTER EYE DROPS, OR COPIOUS AMOUNTS OF WATER.
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SECTION VI (REACTIVITY DATA)

REACTIVITY:
STABLE

INCOMPATIBILITIES:
NONE KNOWN

DECOMPOSITION:
WHEN HEATED TO DECOMPOSITION (128°C) MATERIAL EMITS PUNGENT ODOR WHICH IS NOT HARMFUL.

POLYMERIZATION:
WILL NOT OCCUR.

CONDITIONS TO AVOID:
NONE

SECTION VII (SPILL OR LEAK PROCEDURES)

SPILL:
SPILLS MAY OCCUR IN PACKAGE FILL PROCESS. A SURGICAL MASK WILL PREVENT INHALATION OF FLOATING PARTICLES. OTHERWISE THERE IS NO DANGER FROM INHALATION OR OTHER CONTACT WITH FLOATING FIBERS.

DISPOSAL:
DISPOSAL OF EXCESS MATERIAL SHOULD BE MADE IN ACCORDANCE WITH EXISTING PRACTICES FOR NON-TOXIC WASTE.

SECTION VIII (SPECIAL PROTECTION INFORMATION DURING MANUFACTURE)

VENTILATION:
FILL OPERATIONS ARE CARRIED OUT IN CLASS 10,000 CLEAN ROOM WITH FILTERED AIR CIRCULATION. NO OTHER PRECAUTIONS FOR PROTECTION OF OPERATING PERSONNEL ARE REQUIRED.

FIRE FIGHTING:
EXISTING CHEMICAL FIRE FIGHTING PROCEDURES ARE ADEQUATE.

CLOTHING:
GOWNS AND SURGICAL MASKS ARE WORN TO PROTECT THE PRODUCT. NO OTHER PRECAUTIONS ARE NEEDED.

GLOVES:
STERILE GLOVES ARE WORN TO PROTECT THE PRODUCT.

EYE PROTECTION:
NOT REQUIRED.

SECTION IX (STORAGE AND HANDLING PRECAUTIONS)

SPECIAL PRECAUTIONS:
STORAGE IN TIGHT CONTAINER AS DEFINED IN UNITED STATES PHARMACOPEIA.

STORAGE CONDITIONS:
AMBIENT TEMPERATURE AND HUMIDITY (SHOULD NOT EXCEED 30°C / 86°F, 65% RH)

OTHER PRECAUTIONS:
DO NOT USE IF POUCH SEAL IS NOT INTACT. AVOID BREATHING SUSPENDED MCH FIBERS.

APPROVED:

[Signature]

MASSI TAMMIETRO
DIRECTOR QUALITY ASSURANCE
DAVOL, INC.

JULY, 1997