

MATERIAL SAFETY DATA INFORMATION  
23-MAY-1989

\*\*\*\*\* SECTION I \*\*\*\*\*

MANUFACTURER/SOURCE OF INFORMATION: ALCON LABORATORIES, INC.\*  
EMERGENCY TEL: 817-551-4444  
ADDRESS: 6201 SOUTH FREEWAY, FORT WORTH, TEXAS 76134  
CHEMICAL NAME AND SYNONYMS:  
AVITENE; MICROFIBRILLAR COLLAGEN HEMOSTAT; MCH  
CAS NO.: AP0000328  
NIOSH/RTECS NO.: N/A  
MOLECULAR FORMULA: N/A  
PRODUCT CODE NO: N/A  
CERCLA HAZARD RATINGS (SCALE 0-3):  
HEALTH-N/A FIRE-N/A REACTIVITY-N/A PERSISTENCE-N/A

\*\*\*\*\* SECTION II (COMPONENTS AND CONTAMINANTS) \*\*\*\*\*

PERCENTAGE: 100% COMPONENT: BOVINE COLLAGEN

\*\*\*\*\* SECTION III (PHYSICAL DATA) \*\*\*\*\*

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

\*\*\*\*\* SECTION IV (FIRE AND EXPLOSION HAZARD DATA) \*\*\*\*\*

FIRE AND EXPLOSION HAZARD: THIS MATERIAL SHOULD NOT PRESENT A FIRE OR EXPLOSION  
HAZARD.

FLASH POINT: N/A UPPER EXPLOSION LIMIT: N/A  
LOWER EXPLOSION LIMIT: N/A

FIREFIGHTING MEDIA: USE MEDIA APPROPRIATE FOR THE SURROUNDING CONDITIONS.

FIREFIGHTING: WEAR SELF-CONTAINED BREATHING APPARATUS AND PROTECTIVE CLOTHING  
TO PREVENT CONTACT WITH SKIN AND EYES.

TOXIC GASES PRODUCED: CARBON DIOXIDE, CARBON MONOXIDE

\*\*\*\*\* SECTION V (HEALTH EFFECTS AND FIRST AID) \*\*\*\*\*

\*TOXICITY:

PRECAUTIONS: ONLY THAT AMOUNT OF AVITENE (MCH) NECESSARY TO PRODUCE HEMOSTASIS  
SHOULD BE USED. AFTER SEVERAL MINUTES, EXCESS MATERIAL SHOULD BE  
REMOVED; THIS IS USUALLY POSSIBLE WITHOUT THE RE-INITIATION OF  
ACTIVE BLEEDING. FAILURE TO REMOVE EXCESS MCH MAY RESULT IN BOWEL  
ADHESION OR MECHANICAL PRESSURE SUFFICIENT TO COMPROMISE THE  
URETER. IN OTOLARYNGOLOGICAL SURGERY, PRECAUTIONS AGAINST ASPIRA-  
TION SHOULD INCLUDE REMOVAL OF ALL EXCESS DRY MATERIAL AND  
THOROUGH IRRIGATION OF THE PHARYNX. MCH CONTAINS A LOW, BUT  
DETECTABLE, LEVEL OF INTERCALATED BOVINE SERUM PROTEIN WHICH REACTS  
IMMUNOLOGICALLY AS DOES BEEF SERUM ALBUMIN. INCREASES IN ANTI-BSA  
TITER HAVE BEEN OBSERVED FOLLOWING TREATMENT WITH MCH. ABOUT TWO-  
THIRDS OF INDIVIDUALS EXHIBIT ANTIBODY TITERS BECAUSE OF INGESTION  
OF FOOD PRODUCTS OF BOVINE ORIGIN. INTRADERMAL SKIN TESTS HAVE

OCCASIONALLY SHOWN A WEAK POSITIVE REACTION TO BSA OR MCH BUT THESE HAVE NOT BEEN CORRELATED WITH IGG TITERS TO BSA. TESTS HAVE FAILED TO DEMONSTRATE CLINICALLY SIGNIFICANT ELICITATION OF ANTIBODIES OF THE IGE CLASS AGAINST BSA FOLLOWING MCH THERAPY. CARE SHOULD BE EXERCISED TO AVOID SPILLAGE ON NONBLEEDING SURFACES PARTICULARLY IN ABDOMINAL OR THORACIC VISCERA. IT HAS BEEN SUGGESTED THAT FRAGMENTS OF MCH MAY PASS THROUGH FILTERS OF BLOOD SCAVENGING SYSTEMS. THEREFORE THE REINTRODUCTION OF BLOOD FROM OPERATIVE SITES TREATED WITH MCH SHOULD BE AVOIDED. TERATOLOGY STUDIES IN RATS AND RABBITS HAVE REVEALED NO HARM TO ANIMAL FETUS. THERE ARE NO WELL-CONTROLLED STUDIES IN PREGNANT WOMEN; THEREFORE, MCH SHOULD BE USED IN PREGNANT WOMEN ONLY WHEN CLEARLY NEEDED. AVITENE (MCH) SHOULD NOT BE USED IN CONJUNCTION WITH AUTOLOGOUS BLOOD SALVAGE CIRCUITS.

CARCINOGENICITY: NOT KNOWN.

INHALATION--

.ACUTE EXPOSURE: MAY BE HARMFUL BY INHALATION.

.CHRONIC EXPOSURE: NO EFFECTS LISTED

.FIRST AID: REMOVE TO FRESH AIR. IF BREATHING BECOMES DIFFICULT, CALL A PHYSICIAN.

SKIN CONTACT--

.ACUTE EXPOSURE: MAY BE HARMFUL BY SKIN ABSORPTION.

.CHRONIC EXPOSURE: NO EFFECTS LISTED

.FIRST AID: FLUSH SKIN WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES, REMOVE CONTAMINATED CLOTHING AND SHOES AND CALL A PHYSICIAN.

EYE CONTACT--

.ACUTE EXPOSURE: NO EFFECTS LISTED.

.CHRONIC EXPOSURE: NO EFFECTS LISTED.

.FIRST AID: FLUSH EYES WITH COPIOUS AMOUNTS OF WATER FOR AT LEAST 15 MINUTES. ASSURE ADEQUATE FLUSHING BY SEPARATING THE EYELIDS WITH FINGERS.

INGESTION--

.ACUTE EXPOSURE: MAY BE HARMFUL BY INGESTION.

.CHRONIC EXPOSURE: NO EFFECTS LISTED

.FIRST AID: IF SWALLOWED, WASH OUT MOUTH WITH WATER PROVIDED PERSON IS CONSCIOUS. CALL A PHYSICIAN.

\*\*\*\*\* SECTION VI (REACTIVITY DATA) \*\*\*\*\*

REACTIVITY: STABLE

INCOMPATIBILITIES: NONE KNOWN

DECOMPOSITION: WHEN HEATED TO DECOMPOSITION, MATERIAL EMITS TOXIC FUMES.

POLYMERIZATION: WILL NOT OCCUR

\*CONDITION TO AVOID: THIS MATERIAL IS STABLE FROM A SAFETY POINT OF VIEW.

\*\*\*\*\* SECTION VII (SPILL OR LEAK PROCEDURES) \*\*\*\*\*

SPILL: WEAR RESPIRATOR, CHEMICAL SAFETY GOGGLES, RUBBER BOOTS AND HEAVY RUBBER GLOVES. SWEEP UP, PLACE IN A BAG AND HOLD FOR WASTE DISPOSAL. AVOID RAISING DUST. VENTILATE AREA AND WASH SPILL SITE AFTER MATERIAL PICKUP IS COMPLETE.

DISPOSAL: DISPOSAL SHOULD BE MADE IN ACCORDANCE WITH EXISTING DISPOSAL PRACTICES EMPLOYED FOR INFECTIOUS WASTE AT YOUR INSTITUTION. OBSERVE ALL FEDERAL, STATE, AND LOCAL LAWS. THIS PRODUCT DOES

NOT MEET THE DEFINITION OF HAZARDOUS WASTE AS DEFINED IN 40CFR,  
PART 261.11.

\*\*\*\*\* SECTION VIII (SPECIAL PROTECTION INFORMATION) \*\*\*\*\*

VENTILATION: MECHANICAL EXHAUST REQUIRED

FIREFIGHTING: SELF-CONTAINED BREATHING APPARATUS SHOULD BE USED WHEN  
FIGHTING FIRES INVOLVING A CHEMICAL.

CLOTHING: WEAR PROTECTIVE CLOTHING AS NECESSARY TO PREVENT CONTACT WITH  
SKIN.

GLOVES: COMPATIBLE CHEMICAL-RESISTANT

EYE PROTECTION: CHEMICAL SAFETY GOGGLES

RESPIRATORY PROTECTION: NIOSH/MSHA-APPROVED

\*\*\*\*\* SECTION IX (STORAGE AND HANDLING PRECAUTIONS) \*\*\*\*\*

SPECIAL PRECAUTIONS: STORE IN A TIGHT CONTAINER AS DEFINED IN THE UNITED  
STATES PHARMACOPEIA. THIS MATERIAL SHOULD BE HANDLED  
AND STORED PER LABEL AND OTHER INSTRUCTIONS TO ENSURE  
PRODUCT INTEGRITY.

OTHER PRECAUTIONS: AVOID CONTACT WITH EYES, SKIN, OR CLOTHING. AVOID  
BREATHING DUST OR MIST. WASH THOROUGHLY AFTER HANDLING.  
DO NOT PERMIT EATING, DRINKING, OR SMOKING NEAR MATERIAL.

\*\*\*\*\* SECTION X (TRANSPORTATION AND SHIPPING INFORMATION) \*\*\*\*\*

THIS PRODUCT DOES NOT POSE AN UNREASONABLE RISK TO HEALTH AND SAFETY OR  
PROPERTY WHEN TRANSPORTED IN COMMERCE. THE HAZARD CLASS DEFINITIONS OF  
49CFR, PART 173 ARE NOT APPLICABLE TO THIS PRODUCT.

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THE ABOVE INFORMATION IS BELIEVED TO BE CORRECT BUT DOES NOT PURPORT TO BE ALL  
INCLUSIVE AND SHOULD BE USED ONLY AS A GUIDE. USERS SHOULD MAKE INDEPENDENT  
DETERMINATIONS OF THE SUITABILITY AND COMPLETENESS OF INFORMATION FROM ALL  
SOURCES TO ASSURE PROPER USE AND DISPOSAL OF THESE MATERIALS AND THE SAFETY  
AND HEALTH OF EMPLOYEES AND CUSTOMERS.  
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APPROVED:  
R&D: R.H./E.D./J.H.

REVISED:  
R&D: T.K.

DATE: 3/31/89

DATE: 5/22/89

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