

SOM**ETHICON
MATERIAL SAFETY DATA SHEET****Code:** **ETHICON ID #1518****Date Issued:** 12/27/89**Issued by:** Workplace Safety and Environmental Affairs Department
201-218-2702**SECTION I - IDENTIFICATION OF MATERIALS**

Chemical Name/Composition: Bone Wax
Trade Name & Synonyms: ETHICON Bone Wax
Chemical Family: Insect Wax / Mineral Wax Blend

SECTION II - SIGNIFICANT COMPONENTS AND CONTAMINANTS

<u>Components</u>	<u>CAS Number (ETHICON ID#)</u>	<u>%</u>	<u>Exposure Limits (Reference)</u>
Beeswax	8012-89-3 (ETHICON ID #1432)	72.63	None Established by OSHA or ACGIH
Paraffin Wax	8002-74-2 (ETHICON ID #3898)	14.87	2 mg/m ³ - ACGIH - TLV (8 hr.) (fume)
Isopropyl Palmitate	142-91-6 (ETHICON ID #2058)	12.5	None Established by OSHA or ACGIH

Note: None of the above components are listed on the NTP, IARC, or ACGH carcinogen list

ACGIH	• American Conference of Governmental Industrial Hygienists
IARC	• International Agency for Research on Cancer
NTP	• National Toxicology Program
OSHA	• Occupational Safety and Health Administration
PEL	• Permissible Exposure Limit
STEL	• Short-Term Exposure Limit

SECTION III - PHYSICAL DATA**Appearance and Odor:**

Homogenous cream to light yellow waxy solid with a very slight waxy odor

Boiling Point: NAP **Melting Point:** 61-64°

Specific Gravity: 0.9 for beeswax / paraffin wax blend

Odor Threshold: NAV*

Vapor Press: NAP **Evap. Rate:** (mm of Mercury) NAP

pH: NAP

Vapor Density (Air=1): NAP

Solub. in Water: Insoluble

BONE WAX**SECTION IV - FIRE AND EXPLOSION HAZARD DATA****Flashpoint (Specify Method):** 400°F (C.O.C.)**Upper Explosive Limit (UEL):** NAP**Lower Explosive Limit (LEL):** NAP**Auto Ignition Temperature:** NAP**Fire Extinguishing Media:** (Data from beeswax / mineral wax blend)
Use dry chemical**Special Fire Fighting Procedures/Unusual Fire and Explosion Hazards:** (Data from beeswax/mineral blend)

No special firefighting procedures.

No unusual fire and explosion hazards.

Thermal decomposition of bone wax may give off hydrocarbon compounds, carbon monoxide and carbon dioxide.

Note:

NAV - Not Available

NAP - Not Applicable

SECTION V - HEALTH HAZARD DATA**Toxicity:**

Since Bone wax is a combination of waxes and isopropyl palmitate, potential acute and chronic health hazards will be similar to the individual components.

Health Hazards**Variability Among Individuals**

Individuals may show varying sensitivity.

Effects of Overexposure (Signs and symptoms of exposure)

None expected during normal conditions of use.

Health Hazards (from review of paraffin, beeswax, isopropyl palmitate MSDSs)**Eyes**

Product contacting the eyes may cause eye irritation, primarily from mechanical action.

Skin

Prolonged or repeated skin contact may cause irritation or dermatitis in certain sensitive individuals.

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BONE WAX**SECTION V - HEALTH HAZARD DATA**

(continued)

Inhalation

Inhalation is not expected during normal use of this product. However, if the product is in a particulate form, the hazards are expected to be similar to a nuisance dust (i.e., nose, throat and pulmonary irritation).

Pre-existing Medical Conditions Which May Be Aggravated By Exposure

Skin contact may aggravate existing dermatitis.

SECTION VI - EMERGENCY AND FIRST AID PROCEDURES**Eye Contact**

If product gets into eyes, flush with clear water for 15 minutes or until irritation subsides. If irritation persists, call a physician.

Skin Contact

In case of skin contact, wash skin thoroughly with soap and water.

Inhalation

If particulate is inhaled, remove from exposure. If breathing is irregular, call a physician immediately.

Ingestion

If ingested, call a physician immediately.

SECTION VII - REACTIVITY**General Reactivity**

This product is stable and will not react violently with water. Hazardous polymerization will not occur. Avoid contact with strong oxidants.

SECTION VIII - ENVIRONMENTAL INFORMATION**Steps To Be Taken In Case Material Is Released or Spilled**

If molten, allow to solidify. Sweep up spilled material and place in disposal container. No specific handling required. Observe applicable local, state or federal regulations for waste material disposal.

BONE WAX

SECTION IX - PROTECTION AND PRECAUTIONS

Ventilation

If in a particulate form, use adequate ventilation to keep dust levels below nuisance dust exposure levels (i.e., 10 mg/m³).

Respiratory Protection

If in a particulate form, use respiratory protection as required.

Protective Gloves

Sensitive individuals may require gloves to avoid prolonged or repeated skin contact.

Eye Protection

Use safety glasses, goggles or face shield when particulates are generated.

Other Protective Equipment

None needed.

Work Practices/Engineering Controls

None needed.

Personal Hygiene

Routine personal hygiene.

MSDS/1/26-29

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ETHICON*

BONE WAX

DESCRIPTION

ETHICON* Bone Wax is a sterile mixture of beeswax, paraffin, and isopropyl palmitate, a wax-softening agent. It is opaque and has a waxy odor.

ACTIONS

ETHICON Bone Wax achieves local hemostasis of bone by acting as a mechanical (tamponade) barrier. It does not act biochemically and is minimally resorbable.

INDICATIONS

ETHICON Bone Wax may be used for the control of bleeding from bone surfaces.

CONTRAINDICATIONS

Bone Wax should not be used where rapid osseous regeneration and fusion are desired.

WARNINGS

ETHICON Bone Wax should not be resterilized or subjected to excessive heat. Bone Wax may inhibit osteogenesis and may act as a physical barrier to the reparative process.

Do not use if package is opened or damaged. Discard opened, unused bone wax.

PRECAUTIONS

Bone Wax should be used sparingly. Excess Bone Wax should be removed from the operative site. The package should be opened just prior to use to minimize the possibility of contamination and excessive drying.

ADVERSE REACTION

Mild inflammatory reactions have been reported in tissues immediately adjacent to the site of implantation. Studies have suggested that Bone Wax as a foreign body may impair the ability of cancellous bone to clear bacteria.¹ In animal models, the local accumulation of foreign body giant cells has been observed and histologic examination has revealed the appearance of macrophages and occasionally polymorphonuclear leukocytes and lymphocytes.

DOSAGE ADMINISTRATION

Bone Wax should be used immediately after removal from the package. Using aseptic technique, Bone Wax should be warmed to desired consistency by manipulation with the fingers or by immersion of the unopened foil packet in a warm sterile solution.

HOW SUPPLIED

ETHICON Bone Wax is available sterile in individual foil envelopes, each containing 2.5 grams, and packaged in an individually sealed overwrap packet.

ETHICON, INC.

a *Johnson & Johnson* company

Somerville, New Jersey 08876-0151

¹Johnson, Peter, M.D. and Fromm, David, M.D., EFFECTS OF BONE WAX BACTERIAL CLEARANCE SURGERY, 89(2) 206-209 (1981).

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