## Vapour-permeable Adhesive Film Dressing

Semipermeable Adhesive Dressing

**Definition** Vapour-permeable Adhesive Film Dressing is a sterile, extensible, waterproof, water-vapour permeable polyurethane film of low reflectance, evenly coated with a synthetic adhesive mass. It is transparent. The adhesive surface is covered with a suitable protector and does not offset when the protector is removed. There may be a coloured non-adherent strip or other suitable device on at least one edge to facilitate handling.

The dressing is supplied sterile in single pieces.

**Film identification** Prepare a 10% w/v solution in *tetrahydrofuran* of part of the residual film obtained in the test for Weight of film. Apply a few drops to a sodium chloride plate and allow the solvent to evaporate. The *infrared absorption spectrum* of the resulting film, Appendix II A, is concordant with the *reference spectrum* of polyurethane.

**Adhesiveness** Complies with the tests, Appendix XX H.

**Extensibility** Complies with the test, Appendix XX G, except that the load required to produce a 20% extension under the specified conditions is not more than 2 N per cm width (about 0.2 kgf per cm width).

**Waterproofness** Complies with the test, Appendix XX K.

**Water-vapour permeability** Not less than 500 g $m^{-2}$ per 24 hours, Appendix XX J1.

**Weight of adhesive mass** Not less than 20 g $m^{-2}$ when determined by the method described under Weight of film. Calculate the weight of adhesive mass from the expression $(W-f)/A$.

**Weight of film** Not less than 25 g $m^{-2}$ when determined by the following method. Measure the area of a sample weighing 10 g ($W$). Soak it in *toluene* or *propan-2-ol* for about 60 seconds, remove from the solvent and immediately wipe the adhesive from it using absorbent cotton soaked in the solvent. Wash the film by agitating it in clean solvent for about 30 seconds and dry the residual film to constant weight at 40°. Calculate the weight per unit area of the film from the expression $f/A$ where $f$ is the weight of the residual film and $A$ is the area of the unextracted sample.

**Sterility** Complies with the *test for sterility*, Appendix XVI A, using about 10 $cm^2$ as the minimum quantity for each culture.

## Vapour-permeable Waterproof Plastic Wound Dressing

Semipermeable Waterproof Plastic Wound Dressing

**Definition** Vapour-permeable Waterproof Plastic Wound Dressing consists of an absorbent pad attached to a piece of vapour-permeable waterproof plastic adhesive tape so that a suitable adhesive margin is left. The pad and adhesive margin are covered with a suitable protector which, when removed, does not detach the pad from the tape.

The pad may be impregnated with a suitable antiseptic, as specified in the general requirements for Surgical Dressings. It may be dyed with a suitable yellow dye.

The tape consists of an extensible plastic film spread evenly with an adhesive mass and is waterproof but is permeable to water vapour and air. The film may be coloured with a suitable pigment.

**Assembly; Dimensions of adhesive margin** The pad is substantially the same shape as the dressing, attached as centrally as possible to the tape, leaving a margin of not less than 3 mm or not less than 10% of the overall dimensions, whichever is the greater. The width of the margin on any one side is not less than half the width of the margin on the opposite side.

The corners of the dressing may be trimmed; any such trimming is disregarded when defining the shape and dimensions of the dressing.

**Tape**

**Adhesiveness** Complies with the tests, Appendix XX H.

**Extensibility** Complies with the test, Appendix XX G.

**Waterproofness** Complies with the test, Appendix XX K.

**Water-vapour permeability** Not less than 500 g $m^{-2}$ per 24 hours, Appendix XX J1.

**Weight of adhesive mass** Not less than 25 g $m^{-2}$, Appendix XX D3, using Method III of Appendix XX D2.

**Weight of film** Not less than 65 g $m^{-2}$, Appendix XX D2, Method III.

**Absorbent pad**

**Content of antiseptic** If present, complies with the appropriate requirement, Appendix XX P.

**Dimensions** Not less than 33% of the overall dimensions of the dressing.

**Weight per unit area** Not less than 34 g $m^{-2}$, Appendix XX D1, Method II.

**Labelling** The label on the unit container, the label on the shelf container and the label on the outer transit container state, where applicable, that the pad has been dyed.

## Silicone Foam Cavity Wound Dressing

**Definition** Silicone Foam Cavity Wound Dressing is a soft and slightly absorbent wound dressing of low adherence prepared from fluid silicone elastomer base and tin(II) 2-ethylhexanoate. It is prepared by mixing thoroughly for 15 seconds fluid silicone elastomer base (100 parts by volume) and tin(II) 2-ethylhexanoate (6 parts by volume), immediately before use, and allowing to expand to about four times its volume within the wound.

**Fluid silicone elastomer base**

**Characteristics** A pale brown, viscous fluid.

**Identification** A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of silicone elastomer base.

B. The residue obtained on ignition in a platinum crucible yields the reaction characteristic of *silicates*, Appendix VI.

**Relative density** 1.055 to 1.105, Appendix V G.

**Viscosity** 2.0 to 6.0 Pa s, Appendix V H, Method IV.

**Tin(II) 2-ethylhexanoate**

**Characteristics** A straw-coloured liquid.

**Identification** A. The *infrared absorption spectrum*, Appendix II A, is concordant with the *reference spectrum* of tin(II) 2-ethylhexanoate.
B. Dissolve 0.1 g in 20 ml of *1,2-dichloroethane* and extract with 20 ml of 0.1M *hydrochloric acid*. To 5 ml of the extract add 5M *sodium hydroxide* dropwise until a white precipitate is produced. The precipitate dissolves on further addition of 5M *sodium hydroxide*.

**Content of tin(II)** 25.0 to 30.0% when determined by the following method. Boil 200 ml of *water* with 100 ml of *hydrochloric acid* for 10 minutes and pass a current of carbon dioxide continuously through the mixture until the assay is complete. Add 0.5 g of the substance being examined and boil for 5 minutes. Cool to room temperature, add 0.5 g of *potassium iodide* and titrate with 0.0167M *potassium iodate VS* using *starch mucilage* as indicator. Each ml of 0.0167M *potassium iodate VS* is equivalent to 5.935 mg of Sn.

**Dressing**

*The dressing, prepared as directed on the label immediately before examination, complies with the following requirements.*

**Characteristics** Soft and slightly absorbent solid.

**Acidity or alkalinity** To 15 g, previously cut into pieces not greater than 50 mg in weight, add 150 ml of *water*, macerate for 2 hours in a closed vessel, decant the liquid, carefully squeezing out the residual liquid with a glass rod, mix and filter. To 25 ml add 0.15 ml of *phenolphthalein solution*; to another 25 ml add 0.05 ml of *methyl orange solution*. Neither solution shows a pink colour.

**Apparent density** Not more than 190 kg $m^{-3}$ when determined by Method 2 of British Standard 4443: Part 1:1979 (Methods of test for flexible cellular materials).

**Water-vapour permeability** Not less than 600 g $m^{-2}$ per 24 hours, Appendix XX J2. Prepare the material for testing in the following manner using two glass plates (100 mm × 200 mm × 3 mm) and a glass rod 7.0 mm in diameter, bent to form a U-shape, with side arms 200 mm in length and 75 mm in base width. Lay the rod horizontally on one of the glass plates. To 20 g of the silicone elastomer base in a suitable container add 1.2 g of the tin(II) 2-ethylhexanoate and mix thoroughly for 15 seconds. Immediately pour this mixture on to the glass plate within the area of the central cavity close to the closed end of the U-shaped rod and place the other glass plate on top of the U-shaped rod spacer. Clamp the plates into position, stand the assembly on its edge with the open end of the U-shaped rod uppermost and allow the foam to expand and cure for 5 minutes. Carefully remove the glass plates and the U-tube spacer. Allow the resultant foam sheet to stand for 24 hours and then cut circular test discs 54 to 56 mm in diameter.

**Extractable tin** Not more than 6 ppm of Sn when determined by the following method. To 5 g, previously cut into pieces not more than 50 mg in weight, add 50 ml of a 0.9% w/v solution of *sodium chloride* and shake for 4 hours. Filter and determine by *atomic absorption spectrophotometry*, Appendix II D, measuring at 235.5 nm and using a nitrous oxide—acetylene flame.

**Cadmium, copper, lead and zinc** Not more than 5 ppm of each metal when determined by the method described in the test for Extractable tin, but using an air—acetylene flame and measuring at 228.8 nm for Cd, at 324.7 nm for Cu, at 217.0 nm for Pb and at 213.9 nm for Zn.

**Water-soluble substances** Not more than 1.5%, Appendix XX M, with the following modification. Cut the dressing into pieces not more than 50 mg in weight.

**Storage** The components of the dressing should be kept in well-closed containers and stored at a temperature not exceeding 25°.

**Labelling** The label on the package states (1) the directions for preparing the dressing; (2) the conditions under which the components should be stored.

## Sodium Fusidate Gauze Dressing

**Definition** Sodium Fusidate Gauze Dressing consists of cotton fabric of leno weave with two picks in each shed which has been impregnated with Sodium Fusidate Ointment.

The dressing is supplied sterile in single pieces.

**Fabric**

**Fibre identification** The separated fabric, obtained in the test for Weight per unit area, complies with the tests for *cotton*, Appendix XX A.

**Threads per 10 cm** Warp, not less than 74; weft, not less than 80, Appendix XX C1, Method I, when determined on the impregnated fabric.

**Weight per unit area** Not less than 39 g $m^{-2}$ when determined by the following method. Determine the area of 1.5 g of the dressing. Separate the dressing from the facing material using forceps, leaving behind any ointment adhering to the facing material, transfer it to an apparatus for the *continuous extraction of drugs*, Appendix XI F, and extract with 150 ml of *ether* for 6 hours. Reserve the ether solution for the test for Ether-soluble substances. Remove the extracted fabric from the apparatus and dry it to constant weight at 105°. Calculate the weight per unit area of the fabric in g $m^{-2}$.

**Ointment**

**Content of sodium fusidate, $C_{31}H_{47}NaO_6$** 90.0 to 110.0% of the prescribed or stated amount.

**Identification** A. Cut 100 $cm^2$ of the dressing and facing material into pieces of suitable size (about 4 $cm^2$) and extract with 15 ml of n-*hexane*. Shake the hexane solution with 3 ml of *water* and allow to separate. Remove the aqueous layer, mix it with 5 ml of 0.2M *orthophosphoric acid* and extract with two 5-ml quantities of *chloroform*. Dry the combined chloroform extracts with *anhydrous sodium sulphate*, evaporate to dryness and dissolve the residue in 0.6 ml of *chloroform IR*. The *infrared absorption spectrum* of the resulting solution, Appendix II A, is concordant with the *reference spectrum* of fusidic acid.
B. In the Assay the principal peak in the chromatogram obtained with solution (2) has the same retention time as the peak due to fusidic acid in the chromatogram obtained with solution (1).