Please replace pages 6 and 7 of your Instruction Manual titled "ETHYLENE OXIDE DECONTAMINATION IN PORTABLE BAG" (May 1977) Revision) with the attached.

6.11 Open the inlet valve to the bag.

6.12 Be certain that the pressure gauge is isolated by closing the nearest valve to that gauge.

6.13 Place the copper coils into a container of water already heated to 80 C ± 10 C.

NOTE: Check frequently to assure that the copper tube outlet from the evaporator to the bag remains warm during transfer. This eliminates the possibility of E.O. entering the bag in liquid form.

6.14 Open the two valves at the cylinder and release 6 kg. of gas into the teflon bag. During this feed the pressure should not exceed 1.0 P.S.I.G. (The pressure should be checked frequently during filling since the burst strength of the bag is 3.0 P.S.I.G.).

6.15 Record the time when 6 kg. has been fed into the bag and then close all valves and disconnect the pipe at the point nearest to the bag.

6.16 Let the pressurized bag stand for a minimum of 10 hours.

6.17 Vent bag into the open air by releasing the zipper (See Safety requirements) and record the total cycle time.

7.0 SAFETY REQUIREMENTS

7.1 Ethylene Oxide is a highly toxic irritant which may cause immediate damage to the eyes and skin upon contact with liquid ETO and to the respiratory system if high concentration of the gas are inhaled. Exposure to the gas has also been associated with changes in the chromosomes of human lymphocyte (white blood) cells. Although no adverse long-term health effect have been determined, some may possibly exist. Therefore, J&J has developed a guideline for occupational exposure to ETO limiting exposure to 1 ppm (8 hour time weighted average) and 10 ppm peak which needs to be rigidly followed for all operations where exposures to ETO occur. This guideline can be obtained from Corporate Health and Safety in New Brunswick by contacting the Director of Industrial Hygiene, Corporate Health and Safety Affairs, Tel: 201-524-4982.

7.2 ETO bag operations must be located outdoors and should preferably be physically separated from the main building. Regardless, it should be located at least 50 feet from any building air intake or opening.

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7.3 Entry into the bag sterilizer area must be restricted to authorized personnel only.

7.4 A full-face gas mask equipped with ETC canister must be worn by the operator while gassing the bag and following the sterilization cycle when the bag is vented and unzipped. The bag should then be laid open to allow the ETO gas to dissipate from the product for 2-3 hours before the product is handled manually or moved indoors.

7.5 Respiratory protection must be used when disconnecting and changing ETO cylinders.

7.6 In case of severe exposure, a doctor should be summoned. To administer first aid: for eyes, wash immediately with large quantities of water for at least five minutes; remove contaminated clothing immediately; follow other safety precautions specified in the Corporate ETO guideline manual.

7.4 Flammability

The standard E.O. mixtures with halocarbon or CO2 (i.e. 88/12) are non-flammable when mixed with any proportions of air. However, if the E.O. concentration exceeds 12% by weight then the mixture become flammable. It is very important therefore that these mixtures be withdrawn from the cylinders as liquid and that they are then completely vaporized before entering the E.O. Bag. Hence, by careful use and monitoring of the vaporization equipment (warm copper tube always between evaporator and bag) the concentration should never exceed the flammability limit.

7.5 Handling and Storage of Cylinders

A. Cylinders should be stored upright in a dry, ventilated place, kept if possible, below 20 C.

B. Cylinders must be kept well away from naked flames or red hot surfaces. No part of the cylinder should be subjected to a temperature higher than 50 C.

C. Care must be taken when handling cylinders. A cylinder barrow or trolley should be used to move them.

D. When returning an empty cylinder, replace any valve outlet and protective cap supplied with the cylinder. Do not permit air to enter the cylinder.

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