

ETHYLENE OXIDE DECONTAMINATION

IN PORTABLE BAGS

May 1977 Revision

## CONTENTS

|                |                                         |
|----------------|-----------------------------------------|
| 1.0 . . . . .  | Purpose                                 |
| 2.0 . . . . .  | Scope                                   |
| 3.0 . . . . .  | History of Effectiveness to April, 1977 |
| 4.0 . . . . .  | E.O. Bag Utilization Recommendations    |
| 5.0 . . . . .  | Equipment                               |
| 6.0 . . . . .  | Decontamination Cycle                   |
| 7.0 . . . . .  | Safety Precautions                      |
| 8.0 . . . . .  | Care and Maintenance                    |
| 9.0 . . . . .  | E.O. Bag Availability/Ordering          |
| 10.0 . . . . . | Approximate Costs                       |
| 11.0 . . . . . | Miscellaneous Notes                     |
| 12.0 . . . . . | Attachments                             |

KOREAN Talc  
4  
P 5

## 1.0 Purpose

To describe the system and procedures to be followed in order to decontaminate batches of JOHNSON'S\* Baby Powder and Prickly Heat Powder which do not meet the microbial limits as defined by the Baby Products Company.

## 2.0 Scope

This procedure is applicable to all Johnson & Johnson locations which cannot produce powder consistently within the microbial limits and which do not have the availability of autoclave facilities.

## 3.0 History of Effectiveness to April, 1977

### 3.1 South Africa

Johnson & Johnson South Africa developed the basic bag and its initial operating conditions. They used the bag on batches of finished powder which did not comply with the specified microbial limits. Utilization of the E.O. bag with the more than 100+ batches of powder which had not complied initially (out of the many batches produced since use of the bag started in 1975) resulted in a reduction of the total microbial count to below the specified limit of 100 microorganisms per gram in every instance.

- NOTES: A. All production used the relatively "clean" Korean Talc.
- B. The 100+ batches with high counts prior to decontamination were only slightly above the limit of 100 microorganisms per gram in most instances. Consequently not much of a reduction in count by use of the E.O. Bag was required to reduce the microbial content of these batches to the acceptable limit.

C. South Africa no longer uses the E.O. Bag because they now have installed their own autoclave facility.

### 3.2 Kenya/Tanzania

Kenya, Tanzania and several other countries use talc from India. Although this talc is analytically acceptable, it frequently contains total microbial counts in the high thousands per gram and will also in many instances contain pathogens.

#### 3.2.2 Raw Talc

A total of 22 bags (100 kg. each) of talc were run thru an E.O. Cycle in groups of 11 bags each time (2 cycles total). Though initial counts (as high as 8,000+/gram) were reduced, the counts still remained significantly above the acceptable limit of 100 microorganisms per gram in most instances. Additionally, pathogens were present in approximately 40% of the bags prior to use of the E.O. Bag and most still contained pathogens after being run thru the E.O. cycle (even with cycles in excess of 12 hours).

#### 3.2.3 Finished Powder

As of the end of March a total of 55 cycles (42 Baby Powder and 13 Prickly Heat Powder) had been decontaminated by using the E.O. bag. The talc source was India and the readings taken of the finished powders prior to E.O. decontamination frequently gave readings in the high thousands per gram, with pathogens present in approximately 50% of the samples tested.

| <u>Hrs. Per<br/>Cycle</u> | <u>No. of<br/>Cycles</u> | <u>% With Count Re-<br/>duced to below<br/>100 Micro./gm.</u> | <u>%With No<br/>Pathogens<br/>Detected</u> |
|---------------------------|--------------------------|---------------------------------------------------------------|--------------------------------------------|
| 4 - 6                     | 19                       | 63%                                                           | 95%                                        |
| 6 - 8                     | 13                       | 54%                                                           | 100%                                       |
| 8 - 10                    | 0                        | -                                                             | -                                          |
| 10+                       | 23                       | 87%                                                           | 100%                                       |

### 3.3 Zambia

#### 3.3.1

Zambia uses talc from India. Microbial analyses have shown that this talc contains high total counts and frequently contains pathogens.

#### 3.3.2 Raw Talc

No attempts to decontaminate - based upon negative experiences by Kenya with Raw Talc.

#### 3.3.3 Finished Powder

Ten (10) batches were cycled and then evaluated microbially thru March. All ten batches had been decontaminated to acceptable levels by use of a cycle similar to the one used in Kenya.

### 4.0 E. O. Bag Utilization Recommendations

#### 4.1 Utilization With Raw Talc

- 4.1.1 No history on Talc with initial relatively low (though out of specification) microbial counts (i.e. occasional batches of Italian or Korean Raw Talc with counts slightly above 100 microorganisms per gram).
- 4.1.2 Reliance upon the E.O. Bag to decontaminate effectively batches of raw talc with high initial counts (i.e. Indian Talc) is not advisable at this time.
- 4.1.3 Future experimentation might develop an extended cycle at high concentrations of gas which would be effective with raw talc containing high initial counts.

#### 4.2 Utilization With Finished Powders

- 4.2.1 Based upon somewhat limited experience, use of the E.O. Bag is advisable in attempting to decontaminate batches of Finished Powder to a microbially acceptable level.

NOTE: This applies only where no autoclave facilities are available to do the decontamination.

- 4.2.2 The cycle time should be at least ten (10) hours when applying the recommended attached total procedures.
- 4.2.3 Every finished batch of Powder should be retested prior to release since use of the E.O. Bag will not always assure microbial acceptability.
- 4.2.4 Future experimentation might develop a more effective and/or shorter cycle.

## 5.0 Equipment

- 5.1 Decontamination Plant Layout  
(See attachment 1 and photographs).
- 5.2 Teflon Decontamination Bag 5' x 4' x 4'.
- 5.3 Pressure Gauge - 0 to 10 P.S.I.
- 5.4 Vacuum Gauge - 0 to 30 inches Mercury.
- 5.5 Vacuum Pump\* - size will determine evacuation time
  - \*Kenya uses 0.5 HP pump
  - \*S. Africa used 5.0 HP pump
- 5.6 Gas Cylinder containing 12% Ethylene Oxide and 88% Freon 12 mixture.
- 5.7 Gas Valves\* - suitable to allow bypass of gauge during filling.  
(See Attachments 4 and 5)
  - \*Kenya uses Four Saunders valves  $\frac{1}{2}$  inch b.s.p. aluminum body, p.t.f.e.l. diaphragm
- 5.8 Connecting Tubing - 6 mm copper tubing used throughout. Hose clamps\* at the bag with rubber tubing\*\* from the copper to the bag connections.
  - \*The rubber tubing and the clamps provide mechanical rigidity at the joint.
  - \*\*The copper should be inserted into the bag connection in such a manner as to prevent gas contact with the rubber.

### 5.9 Evaporation Coil

5.9.1 Coil\* made of copper and immersed in hot water ( $80^{\circ}\text{C} \pm 10^{\circ}\text{C}$ ) during feeding of E.O. into the bags.

5.9.2 The copper is rolled into 5 coils (250 mm diameter) so as to fit into the bucket.

\*Purpose of the coil is to assure that no liquid gas enters the bag.

5.10 Bag connections (see drawing attachment 2).

5.11 Manifold (see drawing attachment 3).

5.12 Use 0.5 inch Plywood Boards of the following sizes for inside the bag support:

Bottom - 53" x 48"  
Top - 49" x 44"

2 Sides - 51" x 43"  
2 Ends - 42.5" x 41.5"

### 6.0 Decontamination Cycle/Procedures

6.1 Place opened teflon bag on a pallet and then place the bottom plywood board the two side boards and the rear board in place inside the bag.

6.2 Fill the bag to capacity with finished product.

6.3 Lubricate the inside of the zipper with petroleum jelly.

6.4 Place the top and front boards in place, close the zipper and then lubricate the outside of the zipper with paraffin wax.

6.5 Connect the bag to the vacuum pump, make sure that the E.O. gas inlet valve is closed and then open the suction valve.

6.6 Switch on the vacuum pump.

6.7 When the vacuum gauge reads approximately 5 inches mercury below atmospheric, close the suction valve and immediately switch off the pump.

6.8 Disconnect the vacuum pump and vacuum gauge.

6.9 Place the gas cylinder on a scale and record the gross weight.

6.10 Connect the cylinder and the copper tube coil to the teflon bag.

- 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  $80^{\circ}\text{C} \pm 10^{\circ}\text{C}$ .

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 Precautions) and record the total cycle time.

## 7.0 Safety Precautions

7.1 Ethylene Oxide is a highly toxic irritant which can blister the skin. The first warning of E.O. in the air would be irritation of the eyes and nose. Therefore, the E.O. Bag operation must be conducted in a facility open to the outside so as to facilitate the evacuation of gas and to prevent accumulation in any building in the event of leaks.

7.2 When setting up the cycle and when venting the bag, gloves and goggles should be worn to protect the hands and eyes.

### 7.3 First Aid

In cases of severe exposure to Ethylene Oxide a doctor should be summoned immediately. For dealing with minor cases or before the doctor arrives the following suggestions may be useful:

**Eyes:** Ethylene Oxide can be highly damaging to the eyes. If they come into contact with either the liquid or the vapor they should be bathed with large quantities of water for about fifteen minutes. The eyelids should be held apart during irrigation, to ensure contact to the water with all tissues of the surface of the eyes and lids. Should eye irritation continue to persist, the eyes should be irrigated for a second period of fifteen minutes and a doctor, preferably an eye specialist should be called.

**Skin Contact:** All clothing contaminated with Ethylene Oxide should be removed immediately. All areas of skin affected should be thoroughly soaked with soap and water.

#### 7.4 Flammability

The standard E.O. mixtures with halocarbon or CO<sub>2</sub> (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 becomes 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.

## 8.0 Care and Maintenance

### 8.1 Bag Cleaning

The bag should be sponged down in a warm solution of detergent (i.e. Teepol from Shell) and then thoroughly rinsed in clean water and hung up to dry. This procedure should be carried out at the conclusion of every cycle.

### 8.2 Zipper Maintenance

Failure of the zipper is usually the first serious maintenance problem to occur. Since the bag is rendered useless once the zipper fails, the following instructions should be carefully followed.

8.2.1 Prior to or during the beginning of each cycle you should lubricate the inside of the zipper with petroleum jelly and the outside with a paraffin wax.

8.2.2 Never overfill the bag or force the zipper.

8.2.3 Never bend or tread on the zipper.

### 8.3 Burst Pressure

Be careful to not overinflate the bag. Working pressure is approximately 1.0 P.S.I.G. and burst pressure is 3.0 P.S.I.G.

8.4 A properly maintained bag should last for at least 100 cycles.

## 9.0 E. O. Bag Availability/Ordering

This equipment (bag and set of fittings) is not a standard stock item. Long lead times (at least six months) are needed. Hence if you are planning to order or replace any equipment you should confirm your intentions as soon as possible. This will minimize delays in delivery. The very limited inventory is handled thru Mr. Eric Davies (Senior Purchasing Agent) in the United Kingdom (Pontllanfraith). Please place all orders thru Mr. Davies and kindly notify International Quality Assurance so that any new developments can be properly communicated.

10.0 Approximate Costs

(Based upon early 1976 prices)

- 10.1 Decontamination Bags = Approximately \$250.00 F.O.B. U.K.
- 10.2 Set of Fittings (Valves, Gauges, Tubing, Clamps, etc.)  
= Approximately \$60.00 F.O.B. U.K.
- 10.3 Based on approximately 6.0 kg. per cycle, each cycle should cost approximately \$15.00 Gas Usage.

11.0 Miscellaneous Notes

- 11.1 The contents of this manual are based for the most part upon extensive and very helpful input from the Johnson & Johnson Companies in South Africa, Kenya and the United Kingdom.
- 11.2 South Africa noted a perfume loss of from 5 - 20% after use of the E.O. Bag.
- 11.3 Johnson & Johnson Zambia is considering the development of a steel decontamination chamber. This method might prove to be more reliable from a maintenance and from an effectiveness (can use more pressure) point of view.
- 11.4 Powder run thru the E.O. Bag cycle has been tested satisfactorily for Primary Irritation and Sensatization characteristics.
- 11.5 As mentioned previously, the E.O. Bag should be used only if there is a contamination problem and no autoclave facilities are available. When using the bag, all procedures (particularly those for safety) should be followed closely.