

# Standard Operating Procedure

## Title: Preparation of Disinfectant Solutions for use in Sterile and Production

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- 4.2. Bottles with the **Red** nozzle will be labelled specifically for use in each Sterile airlock to avoid using bottles with the White nozzles in a Grade C area.
    - 4.2.1. Bottles with the **RED** nozzle that are used in the Sterile Airlocks are **NOT TO BE TAKEN INTO THE STERILE AREA** and be re-filled. When empty, the Sterile Operator should contact a Production Operator to re-fill the bottles using the IPA vessel.
  - 4.3. **WHITE** spray nozzles are to be used **INSIDE STERILE ONLY**, Environmental Grade B.
  - 4.4. If a **White** spray nozzle, with bottle is found outside environmental grade B, the Production Operator should be notified and the bottle discarded. **Under NO circumstances can the bottle be reused.**
  - 4.5. Clean Room Garments are to send the White nozzle spray bottles to the site Warehouse already rinsed with Distilled Water, dried and sterilised via Ethylene oxide.
  - 4.6. Production personnel will then issue the White nozzle spray bottles from the site Warehouse to Production for use in Sterile.
  - 4.7. If dirt or foreign matter is found inside the Alcohol spray bottle, or the outside is badly soiled by paint or ink - discard the spray bottle.

### 5. Disinfectants

Disinfectants used on critical surfaces or gloves in Sterile areas are to be supplied Sterile filtered. Therefore **ALL 70% IPA SOLUTIONS USED IN THE STERILE FILLING AREAS MUST BE FILTERED THROUGH A STERILE, STERILISING FILTER.**

### 6. Containers for Disinfectants

Containers for Disinfectants **should not be topped up**. Before filling Bioprep containers, they must be rinsed with Distilled Water until there are no traces of soap and Distilled Water must be pumped through the pump until it runs clear.

Microshield uses a new bottle but the pump must be cleaned the same way as the Bioprep pump. Before filling 70% IPA spray bottles, they should be emptied of all remaining alcohol and any alcohol in the nozzle must be pumped out.

### 7. Preparation of Sterile Filtered 70% IPA (% volume/volume)

- 7.1. Weigh one new 20L drum of IPA on the moveable Floor Scale. Note the following in the 70% IPA Preparation Logbook:
  - The area where the IPA is issued
  - The full drum weight
  - The Product Code of the IPA
  - The date of preparation and the Manufacturer's batch number from the drum.
  - The logbook covers the IPA preparation areas:
- 7.2. Close the valves, release pressure from the vessel using the spring loaded release valve. Remove the pressure gauge and empty the contents of the IPA drum into the 40L Pressure vessel.
- 7.3. Weigh the empty new drum of IPA and calculate the amount of IPA filled into the Pressure vessel. The drum normally contains 20L of IPA = 15.6Kg of IPA,

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- Manufacture date
- Expiry date
- Production area name.

7.17. The sample is to be placed on to the designated shelf of the Micro. The Micro. Lab. is to test the sample as per procedure.

### 8. Sterile Operators filling procedure for WHITE nozzle spray bottles

- 8.1. Firstly check that the Expiry Date labelled on the vessel is one (1) month from the date of preparation.
- 8.2. Remove the old Expiry Date sticker on the white nozzle spray bottle and replace it with a new Expiry Date sticker. Use the 'For Sterile Use Only' Expiry Date stickers. The expiry date on the vessel is the date you will need to write on the expiry sticker for the spray bottle.
- 8.3. Empty the spray bottle of any remaining 70% IPA prior to refilling. Also, activate the pump a few times to empty the nozzle. 1/3 fill the spray bottle with the fresh 70% IPA, swirl the bottle ensuring all the internal surface has been rinsed and dispose the 70% IPA. This is to clean the internal surface of the spray bottle before refilling with the fresh 70% IPA.
- 8.4. Fill the White nozzle spray bottle with sterile filtered 70% IPA from the vessel inside Sterile. Make sure that the nozzle on the IPA bottle is on "SPRAY" position after the bottle has been filled.
- 8.5. When the vessel is empty, contact a Production Services operator to re-fill the vessel.

### 9. Filling Procedure for Red Nozzle Spray Bottles (Grade C, D & Class I)

- 9.1. Firstly, check that the Expiry Date labelled on the vessel is one (1) month from the date of preparation.
- 9.2. Remove the old Expiry Date sticker on the Red nozzle spray bottle and replace it with a new Expiry Date sticker. The Expiry Date on the vessel is the date to be written on the Expiry Date sticker for the spray bottle.
- 9.3. Empty the spray bottle of any remaining 70% IPA prior to refilling. Also, activate the pump a few times to empty the nozzle. 1/3 fill the spray bottle with the fresh 70% IPA, swirl the bottle ensuring all the internal surface has been rinsed and dispose the 70% IPA. This is to clean the internal surface of the spray bottle before refilling with the fresh 70% IPA.
- 9.4. Fill the Red nozzle spray bottle with sterile filtered 70% IPA from the vessel .
- 9.5. Make sure that the nozzle on the IPA bottle is on "SPRAY" position after the bottle has been filled.

### 10. 70% IPA is used as follows:

- 10.1. In Spray Bottles both inside and outside the Sterile Area airlock.
- 10.2. For Disinfection of equipment, machine parts, etc. in the Airlock before being taken into the Sterile Area.
- 10.3. By Sterile Area Operators: Gloves are to be sprayed regularly with 70% IPA – approximately every 10 minutes, before entering any LAL area and before and after handling equipment.