

Standard Operating Procedure

Title: Factory Cleaning Procedure



- Handling chemicals, i.e. Formaldehyde - see [SOP EHS-005](#)
- Using IPA/Solvent – **gloves** must also be worn.
- Washing walls and ceilings
- **Every Cleaner should be trained in [Emergency Procedures \(Form-585\)](#)**

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Procedure

1. The General Rules and GMP Requirements

1. The rules and GMP requirements apply equally to Contract Cleaners and Operations staff.
2. All cleaners should undergo Induction conducted Site and be supervised while working in the Plant.
3. Clean uniforms, factory shoes and hats must be worn as applicable in the particular areas. (All cleaners working in the Production areas must be familiar with the requirements of [SOP MAN-005](#))
4. Solutions, buckets, mops, etc., used for cleaning must be changed/renewed **daily** or whenever they become badly soiled, so as not to spread the soil. This is to be done by the Cleaners during the cleaning process.
5. **No food or drink can be taken into the factory.**
6. Rubbish should be collected in either bins or bags and disposed of cleanly in the correct bins. (Any filled product **MUST** go into the "FILLED PRODUCT" security disposal bin. Other security waste to be placed into the "NON-FILLED" security disposal bin. Any tablets picked up from the floor are to be collected and placed in a container on the area Manager's desk for reconciliation. If a tablet that is currently being packed is picked up from the floor, place the tablet in the rejects floor bin and contact the area Manager.
7. **Nothing should be picked up from the floor and returned to packing lines.**
8. No container that comes in contact with product should be placed directly on the floor.
9. If Production is continuing in an area to be cleaned, advise the [authorised person](#) and work effectively in small areas, **avoid creating large, wet, slippery areas.**
10. Special cleaning should be arranged with the Production Managers preferably when sections of the plant are closed down.
11. All problems should be reported to the Cleaning Supervisor who will liaise with Cleaning Coordinator or Quality Assurance Manager.
12. All cleaning equipment and bulk solutions must be stored neatly in specific cleaners' rooms.
13. The Cleaners' rooms are to be kept in a neat, tidy, clean state.

2. Areas of the Plant and Hygiene Classes

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There are some sections of the Plant, which are cleaned on a periodic basis; on request; or after rebuilding or major maintenance, e.g. Duct-work; pipes/drains, lights; windows.

This work will be requested by the Cleaning Coordinator or delegate when a need is perceived and a practical time agreed.

Note During special building or [equipment installation](#) activities, the Building Contractor or Project Manager will be responsible for protecting the plant, (floors, etc.) from the building debris. They will also ensure it is moved off-site.

4. Cleaning Aids

4.1. Buckets

There are three types of bucket systems used within Site. These are the single, double bucket system and the triple bucket system.

4.1.1. Single Buckets

These are roller wringer buckets. The buckets are colour coded to each environmental grade of the factory and are dedicated to these areas. **Green** buckets for E areas, **Blue** for D and **Yellow** for C.

4.1.2. Double and Triple bucket systems

This is a trolley holding two large buckets. Over one bucket is suspended a mop squeezer, and this is considered the "dirty" bucket. The other bucket, ("clean" bucket) accommodates the clean floor [cleaning/disinfecting solution](#). The buckets should be cleaned on a daily basis and the mop head and solution changed on a daily basis. The mop should remain in the clean bucket when not in use.

These buckets are the only type that should be used within the sterile area and should be dedicated to that particular area of the cleanroom.

4.2. Mops

Cotton mops with a plastic or anodised aluminium handle are used in the E, D and C areas and are also colour coded same as the mop buckets for their respective areas.

Cotton or natural fibre string mops should not be used within a sterile cleanroom. An open cell hydrophilic mop head with a plastic or anodised aluminium handle should be used. These should be dedicated solely to Sterile use on the floors, using a two-bucket system (one for wringing and one for rinsing). The mops should be inspected daily by cleaning staff for any signs of shedding. These should be processed daily, to obtain a guaranteed cleanliness level and sterilised before each use.

The mops are supplied by in a sterile state. They are made of fabric and are very low in [particulate and residue contamination](#). They are used once and after use, the mop is put into a plastic bag and placed in the dirty Sterile garment basket on the 'dirty' side of the change room. They are then cleaned and returned to site, again in a sterile state, to the Sterile Garment Storage Room, located in the Work-In-Progress area of the Warehouse.

4.3. Squeegees, Dustpans

Their use is necessary especially for broken glass, but not ideal as dust may be generated.

4.4. Vacuum Cleaners

These are preferred for picking up dust from the floor or from containers. Dry vacuums must be equipped with HEPA filtration and approved by the Cleaning Coordinator.

Wet vacuum cleaners (to cope with major spills) are available in the site in case of large liquid spills.

4.5. Buffers, Waxers and Floor Polishers

Floors in Production **BLUE** areas, and Laboratory and Canteen areas to be sealed and then coated with Equinox Top Coat (see section 6.3 below), then polished by machine. Spray bottles (Duraseal Auto Burnish) and nylon hand pads or stainless steel pads may be needed for 'spots'. **Do not use IPA as this damages the finish.** These should not be used inside

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6.3.1. Duraseal Base Coat

After stripping floor, apply two thin coats. First coat vertically and second coat horizontally. Allow thirty minutes drying time between coats.

NOTE: You must then leave thirty (30) minutes after last base coat before applying the top coat. **Do not buff polish between coats.**

Equipment

1 x poly cotton mop with White handle
1 White wring bucket.

6.3.2. Duraseal Auto Burnish

Spray floor one metre in front of buffing machine at intervals of 3 metres. Using a fine mist, spray then buff directly over area you have just sprayed Auto Burnish. Return to area you have just passed over and dry buff.

Equipment

1 Straight line buff
1 Trigger spray bottle with Auto Burnish

Chemical

Duraseal Auto Burnish
Dilution 20/1 48mL x 1L spray bottle.

6.3.3. Equinox Top Coat & Duraseal Top Coat

After applying base coat, apply thin coats of Top Coat allowing ten minutes drying time between coats. You must apply coats in a dragging motion. Avoid lifting the mop. Apply coats to floor until it becomes glazed. **Do not buff between coats and do not buff floor for twelve hours after applying last coat.**

Equipment

1 poly cotton mop with White handle
1 White wring bucket.

7. Cleaning Procedures for Sterile Rooms

7.1. Daily Schedule

General Areas

General areas are areas that surround the point of manufacture or production. These are not termed as critical areas because they do not come in direct contact with the finished product. Critical areas (EGA), are as mentioned earlier, cleaned by the Sterile Operators.

Floors

The floors in the [Sterile areas](#) need to be cleaned daily. The floor should be initially cleaned using an in-house vacuum system (where available) to remove glass, granulate or regrind. Once the debris has been removed from the floor, a sterile solution of "Target" (brand) should be applied using a sterile mop, this should be applied liberally to the surface. (See Website for chemical brand names).

Trolleys

These should be designated to the sterile area only, these should be wiped down using disposable wipes. Using 70% IPA, start from the top and work down.

Rubbish

Remove all rubbish at the end of each cleaning session, this will help prevent any cross-contamination.

7.2. Weekly Schedule

General Areas

Walls

Using a WallWipr™ (brand) wipe down the walls, working from the ceiling line down to the floor with Target 2.5% mixed with a sterile pre-filtered water solution. Squeegee off any residue.

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Note: IPA has an expiry date of one month and is displayed on the label on the bottle. It must not be used after the expiry date.

Target and Biogard (brands) are diluted using Distilled Water only. Target is the preferred disinfectant, though Biogard may be used due to unavailability of Target.

7.4. Rubbish Removal

At Site, several different classes of rubbish exist that must be disposed of separately by different means.

7.4.1. Filled Product Security Waste

This type of waste is placed in specially labelled bins "**Filled Product Security Waste**". It is then placed in a yellow disposal bin held in the rubbish holding area for disposal by shredding.

CLEANERS are responsible for emptying these labelled bins from the Laboratory areas on a DAILY basis.

7.4.2. Non-Filled Product Security Waste

This type of waste includes empty product containers and product labels. It is to be placed in the bins labelled "**Security Waste**". These bins are taken to the WIP area in the Warehouse for shredding.

CLEANERS are responsible for emptying these labelled bins from the Laboratory areas on a DAILY basis.

7.4.3. General Waste

This type of waste collection includes most rubbish from Offices, floors, Cafeteria, etc. It is to be bundled into plastic bags and placed in a disposal bin in the rubbish holding area.

Removal of this rubbish from the Laboratory, Offices and Canteen into the disposal bins is the responsibility of the **CLEANERS**.

Canteen rubbish is the responsibility of the Caterers and must not be taken through the Production area for disposal.

7.4.4. Glass containers and broken glass

The items are to be kept SEPARATE from soft paper, etc. to avoid accidents, then placed into boxes and/or plastic bins before transferring to the general waste disposal bin.

CLEANERS are responsible for emptying these labelled bins from the Laboratory areas.

8. Tacky Mats

Tacky mats are to be changed by the Cleaners on a DAILY basis after cleaning has been completed. If required in high use areas, the mat can be changed by Production or Laboratory staff in addition to the daily change.

9. Security of Building

Much of the cleaning is done outside normal hours. While this allows free access to areas, it is important that buildings and offices are not left open when unattended.

External doors should be locked outside normal hours and NEVER chocked open.

All doors should be left in the same locked/unlocked state at the conclusion of cleaning as they were when the cleaner entered them.

10. Weekly Recording and Environmental Auditing

A Daily Cleaning Log, which is controlled by the Cleaning service, should be completed every day for all areas. The details of the areas to be covered are outlined in the Daily Cleaning Logs. The