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SOP COVER PAGE

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1. PURPOSE

- 1.1. This Standard Operating Procedure (SOP) defines the requirements for basic sanitation. This written program provides assurance that basic levels of cleanliness of the facility are maintained.

2. SCOPE

- 2.1. This Good Manufacturing Practices (GMP) SOP covers basic facility sanitation. See GP-021 Employee Practices for employee health and hygiene policies. See EQ-006 General Equipment Cleaning, EQ-023 Packaging Equipment Cleaning and specific equipment SOPs for basic equipment cleaning procedures. See EQ-039 Chemical Control Program for approved chemicals.

3. RESPONSIBILITIES


- 3.1. All GMP personnel are required to maintain their respective areas according to the procedures in this SOP.
- 3.2. Sanitation personnel are responsible for performing the tasks in the cleaning logbooks according to the procedures in this SOP.

4. REFERENCES

- 4.1. GP-021 Employee Practices
- 4.2. EQ-006 General Equipment Cleaning
- 4.3. EQ-041 Preventive Maintenance
- 4.4. EQ-039 Chemical Control Program
- 4.5. EQ-023 Packaging Equipment Cleaning and Operations
- 4.6. Lab Archives
- 4.7. MBI Cleaning and Holding Validation Report (H:\Lab)

5. MATERIALS AND EQUIPMENT

- 5.1. Soap for handwashing (Waxie Luxury Foam Soap, or similar)
- 5.2. Sanitizer solution (Waxie 910 Quaternary)
- 5.3. Sanitizer for Organic Certified Equipment (Isopropyl Alcohol)
- 5.4. General purpose cleaner (Waxie Solution Station 710 Multi Disinfectant Cleaner, or similar)
- 5.5. Windows and mirrors (Waxie 543 Green Glass Surface Cleaner)
- 5.6. Equipment Degreaser (Waxie 920 Brk-Away)
- 5.7. Floors (Crete Clean Plus)
- 5.8. Dishwashing soap, Equipment and Utensils (Dawn)
- 5.9. Sponges
- 5.10. Mops
- 5.11. Automatic floor scrubber
- 5.12. Garbage containers and bags
- 5.13. Yellow 5 gallon buckets
- 5.14. Sanitized Sticker

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6. SAFETY REQUIREMENTS

- 6.1. All cleaners and chemicals should be used as directed per the Chemical Control Program, product labels and safety data sheets (SDS). Personal protective equipment (PPE) should be used when required or recommended.

7. PROCEDURE


7.1. General Sanitation

- 7.1.1. Note: All Waxie products are to be dispensed by the appropriate dispensers. These dispensers mix concentrates at levels that are safe but also effective for cleaning and killing pathogens.


Dilution Ratio:

Waxie 710 Multi Purpose Disinfectant Cleaner	1:256 (0.5 oz/gl)
Waxie 910 Finale FS No Rinse Sanitizer	1:512 (¼ oz/gl)
Waxie 920 Brk-Away FS Cleaner/ Degreaser	1:32
Waxie 543 Waxie -Green Glass Surface Cleaner	1:60 (2.1 oz/gl)
CreteClean Plus with ScarGuard	1 oz / 1 gl

- 7.1.2. QC will control and perform daily testing and logging on the Waxie 910 No Rinse Sanitizer and the bleach diluted products. Only the Quality Unit can approve and release the Sanitizer.
- 7.1.3. The bottles will be controlled by an ID # assigned and signed off by the QC employee conducting the testing.
- 7.1.4. The sanitizer bottles will be turned in at the end of the work day to the QC department and prepared for the following business day.
- 7.1.5. The chemical dispenser will be tested by QC daily.
- 7.1.6. All testing and logging will be documented in Lab Archives.
- 7.1.7. Isopropyl Alcohol is the only approved organic equipment sanitizer. This product is safe and also effective for cleaning and killing pathogens.
 - 7.1.7.1. A QC employee will ensure the Isopropyl Alcohol is replenished in the designated spray bottles.
 - 7.1.7.2. Each time the spray bottle is replenished with Isopropyl Alcohol, a QC employee will initial and date the spray bottle.
 - 7.1.7.3. Employees are trained on the Organic sanitation procedures
- 7.1.8. Eating or drinking is permitted only in the break room and office areas. Food and drinks are not permitted in manufacturing or packaging areas.
- 7.1.9. Keep all doors leading to the outside closed, other than during receiving or shipping.
- 7.1.10. Smoking is not permitted in the building at any time.
- 7.1.11. All areas must be kept orderly and free from accumulated waste and debris.
- 7.1.12. All building areas should be maintained in a clean and orderly manner.

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- 7.1.13. Dogs, cats, and other animals are not permitted on the premises at any time.
- 7.2. Bathroom and office areas (cleaned weekly or as necessary)
 - 7.2.1. All restroom floors, toilets, and sinks must be cleaned with disinfectant. Toilet paper, paper towels, and liquid soap dispensers should be checked and replenished.
 - 7.2.2. Completed tasks must be documented in the appropriate cleaning log.
- 7.3. Lunchroom
 - 7.3.1. Tables should be cleaned after use.
 - 7.3.2. Each employee is responsible for cleaning or disposing of his or her own dishes and utensils after use.
 - 7.3.3. No food or open drinks may be left in the lunchroom overnight, other than in the refrigerator.
 - 7.3.4. No food, drinks, used cups, or utensils may be left overnight in the lunchroom sink.
 - 7.3.5. Garbage containers should be emptied when full, or as needed. Soiled garbage bags must be replaced with new bags. Soiled garbage cans must be cleaned and disinfected.
 - 7.3.6. At the end of the week, or as required, the warehouse area should be swept and mopped using a Crete Clean Plus..
 - 7.3.7. All food, other than factory-sealed containers, should be removed and discarded from the refrigerator periodically.
- 7.4. Semiannual maintenance
 - 7.4.1. Air filters for air-conditioning and heating ducts must be replaced every six months, or when required. (Maintenance PM)
- 7.5. Maintenance performed as-required
 - 7.5.1. Warehouse floors should be swept and mopped using an automatic floor scrubber. A regular mop and bucket should be used in hard to reach areas. All areas should be cleaned with CreteClean Plus floor cleaner..
 - 7.5.2. All offices should be swept and mopped with disinfectant.
 - 7.5.3. Window frames, walls, ceiling vents, light fixtures, and door jambs should be cleaned with a sponge and mop or similar using a disinfectant solution.
- 7.6. Yellow 5 gallon buckets are designated for sanitation purposes only.
- 7.7. Sanitized Utensils
 - 7.7.1. Acceptably cleaned and sanitized utensils must be segregated from dirty utensils until used.
 - 7.7.2. Sanitized utensils will be stored in the "Cleaned and Sanitized" Cabinet.
 - 7.7.3. In addition to regular utensil cleaning, the cabinet as well as all utensils will be cleaned and sanitized monthly and documented on the Utensil Cabinet Sanitation Log by the Sanitation Supervisor located inside the cabinet (see EQ-006 General Cleaning Procedure).
- 7.8. Pails, Drums and Totes
 - 7.8.1. Acceptably cleaned and sanitized pails, drums and totes must be segregated from dirty equipment.

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- 7.8.2. The Sanitation Supervisor upon completion of cleaning will place a sanitized sticker on each receptacle stating the date it was cleaned and by who.
- 7.8.3. Sanitized pails, drums and totes will be stored in the warehouse on clean and sanitized plastic pallets.
- 7.8.4. Pails, large drums and totes will be nested, covered, or inverted to prevent dust accumulation on critical surfaces until immediately before use.
- 7.8.5. All equipment cleaning records shall be kept with the batch record MMR Folder.


- 7.9. The Quality Control Lab has validated that the clean and sanitized equipment can be stored up to one month in either the warehouse or cabinet. Covered receptacles can be stored up to 90 days after cleaning. Surface ATP swabs, allergen swabs and pathogenic bacterial swabs were performed during this validation according to SOPs EQ-034, QC-042 and QC-037. To ensure validation of cleaning, more stringent swabbing procedures were utilized. (See reference 4.7)
- 7.10. Pails, drums and totes that have passed the allotted time will be recleaned, sanitized and stickered with a new date by the Sanitation Supervisor.
- 7.11. General Production Area Housekeeping
 - 7.11.1. Only one batch of product shall be in the packing and manufacturing area at any given time.
 - 7.11.2. All labels, closures, and products relating to that batch must be put away in an appropriate storage area before another batch of product can be brought to the area.

8. RECORDS, REPORTS, AND FORMS

- 8.1. Batch records
- 8.2. Facility Sanitation Logbook
- 8.3. Lab Archives
- 8.4. Utensil Cabinet Sanitation Log

9. HISTORY

RELEASE NO.	EFFECTIVE DATE	REASON/JUSTIFICATION FOR CHANGE
1	06/01/05	New
2	03/26/2007	Addition of specific language to employee personnel hygiene section.
3	02/29/2008	Change 7.9 heading from "Weekly Sanitation" to "As Required"
4	09/20/2010	Updated SOP format with cover page, updated materials and equipment section to reflect use of multiple cleaners, added safety requirements and definitions. Updated semi-annual requirement for A/C and heat duct filters.
5	6/11/19	Updated cleaners used in premises cleaning.
6	1/27/22	Removed employee hygiene section that is covered more thoroughly in different SOP. Added references. Updated logging procedures.

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7	2/20/2023	Updated reference section with EQ-041 Preventive Maintenance and EQ-039 Chemical Control Program. Updated materials list and added yellow gallon buckets used for sanitation purposes. Added Dilution Ratio for chemicals. Added Section 7.1.2 QC Sanitizer Testing
8	4/30/2024	Added 7.7 Section Sanitized Utensils, Added 7.8 Section pails, drums and totes. Added 7.9 QC Validation of storage and 7.10 Reclean of receptacles after the allotted time and sanitation sticker application.. Added reference MBI Cleaning and Holding Validation report.
9	8/28/2024	Added Section 7.1.7 Isopropyl Alcohol Sanitizer procedure Added 7.1 closed lid vessel addendum