
 MBI NUTRACEUTICALS	STANDARD OPERATING PROCEDURE CONFIDENTIAL	SOP NUMBER/RELEASE GP-021 / 2
	TITLE: EMPLOYEE PRACTICES	PAGE NUMBER 1 of 5

SOP COVER PAGE

REVIEWED BY:	Signed:		Date:	
	Kimberly Griffin, QC Manager			
APPROVED BY:	Signed:		Date:	
	Trent Jensen, Vice President			
APPROVED BY:	Signed:		Date:	
	Jeff Jensen, Vice President			
EFFECTIVE DATE:	2/20/2023	SUPERSEDES VERSION:	GP-021 Release 1 2/10/2020	
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1. PURPOSE

- 1.1. This Standard Operating Procedure (SOP) describes employee practices for hygiene, dress, and procedures for protection against product contamination.

2. SCOPE

- 2.1. This procedure covers the minimum requirements for all employees with access to production, packaging, or storage areas to minimize risk of contamination to processes, ingredients, and finished products.

3. RESPONSIBILITIES


- 3.1. Management and Quality Assurance Personnel:
 - 3.1.1. Train and enforce the requirements of this SOP with all employees, contractors, or visitors who enter any production, packaging, or storage areas.
- 3.2. MBI Nutraceuticals employees, contractors, and visitors:
 - 3.2.1. Comply with the Good Manufacturing Practices described in this SOP.

4. REFERENCES


- 4.1. U.S. Department of Health and Human Services, FDA 21 CFR Part 211.28
- 4.2. U.S. Department of Health and Human Services, FDA 21 CFR Part 111
- 4.3. Centers for Disease Control Handwashing Protocol

5. PROCEDURE

- 5.1. Personal Hygiene
 - 5.1.1. Training on employee personal hygiene practices should be included in the mandatory annual cGMP training program. This training should cover basic knowledge of microbiological organisms and stress the employee's responsibility to protect product quality and safety through proper hygienic practices.
 - 5.1.2. Employees personal hygiene practices should include the following:
 - 5.1.2.1. Maintain personal cleanliness through regular bathing.
 - 5.1.2.2. Maintain oral hygiene through teeth brushing.
 - 5.1.2.3. Use deodorant or antiperspirant to avoid unpleasant body odors.
 - 5.1.2.4. Don't use heavily scented perfumes, colognes, or lotions that can cause allergic reactions, migraines, or respiratory problems for other employees.
 - 5.1.2.5. Maintain clean and trimmed fingernails.
 - 5.1.2.6. Wash hands after eating and using the restroom, see section 4.3 on hand washing.
- 5.2. Disease Control
 - 5.2.1. Any person (employee, visitor, or contractor) with an infectious or communicable illness, open lesions (including boils, sores, or infected wounds), or any abnormal source of microbial contamination, must be excluded from any operations that could result in product contamination.

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- 5.2.2. Instructions on reporting health conditions that could result in product contamination to supervisors should be included in the mandatory annual cGMP training program.
- 5.2.3. Health conditions that should be reported include, but are not limited to the following:
 - 5.2.3.1. Open lesions
 - 5.2.3.2. Boils
 - 5.2.3.3. Sores
 - 5.2.3.4. Infected wounds
 - 5.2.3.5. Fever
 - 5.2.3.6. Diarrhea
 - 5.2.3.7. Vomiting
- 5.2.4. When a supervisor learns or observes that an employee has a health condition that could threaten the safety of products, the supervisor must not permit that person to enter any production-related, packaging, or product storage areas.
- 5.2.5. Employees with such health conditions will not be permitted to enter any production-related, packaging, or product storage areas until the health condition no longer exists. Employees may be required to show written permission to return to work from a qualified medical expert.
- 5.3. Dress Code and Outer Garments
 - 5.3.1. Employees who handle component materials, finished products, or packaging or equipment that come in contact with products should wear white company-issued lab coats over street clothes.
 - 5.3.2. The lab coats should be designed to prevent foreign objects from falling into products and components. They should have snap-type closures, elastic sleeve cuffs, and no pockets above waist level. Employees should not clip pens, pencils, thermometers, phones, or other items on their garments above waist level.
 - 5.3.3. Lab coats should be maintained clean at all times. They should not be worn outside of the work area where there is a possibility of contamination. Lab coats should not be worn in parking lots, or anywhere outside of the production building.
 - 5.3.4. Lab coats should be removed before entering the toilet areas, cafeteria or break rooms. Storage locations are provided outside these areas for hanging outer garments.
 - 5.3.5. Lab coats are not to be taken home.
 - 5.3.6. Shorts and capri pants are not allowed in the warehouse, production, packaging, or laboratory areas. Only full length pants that cover the entire legs can be worn.
 - 5.3.7. Employees are issued dedicated shoes. These shoes are not to be worn outside or taken home. The inside of the entire plant is the controlled zone.
 - 5.3.8. All maintenance and warehouse employees should wear a lab coat while working in the plant. These employees also comply with dedicated shoe requirements. Shoe coverings are provided if short term outside use is needed.

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5.4. Hand Washing

- 5.4.1. All employees must wash their hands thoroughly using liquid soap and hot water before starting work, after breaks, after using restrooms, after leaving production areas, or whenever hands become contaminated.
- 5.4.2. Following is the Centers for Disease Control Handwashing Protocol:
 - 5.4.2.1. Wet your hands with clean, running water (warm or cold), turn off the tap, and apply soap.
 - 5.4.2.2. Lather your hands by rubbing them together with the soap. Lather the backs of your hands, between your fingers, and under your nails.
 - 5.4.2.3. Scrub your hands for at least 20 seconds. Need a timer? Hum the “Happy Birthday” song from beginning to end twice.
 - 5.4.2.4. Rinse your hands well under clean, running water.
 - 5.4.2.5. Dry your hands using a clean towel or air dry them.

5.5. Gloves

- 5.5.1. Gloves approved for food contact use should be worn by all employees who handle components, products, or equipment that contacts components or products.
- 5.5.2. Gloves must be kept clean and intact. Gloves should be replaced whenever they become damaged or contaminated.

5.6. Jewelry


- 5.6.1. Employees who work in production areas may not wear jewelry such as necklaces, chains, bracelets, watches, rings with stones, etc. Facial adornments such as appliques, stones, exposed body piercings, false fingernails, and fingernail polish are also forbidden.
- 5.6.2. Medical alert necklaces may be worn, if concealed and not removed while in production areas. Medical alert bracelets may interfere with proper handwashing and should be avoided.
- 5.6.3. Wearing one plain wedding band without a stone on the left ring finger is permitted, provided it is covered with an approved sanitary glove. Rings with stones are never permitted.
- 5.6.4. Visitors may wear a glove over a wedding ring that cannot be removed while in the warehouse.

5.7. Hair Restraints

- 5.7.1. Employees must wear company-issued hairnets in the warehouse, production, mixing, packaging, or any other areas where product-contact equipment are handled.
- 5.7.2. Hairnets must be worn over the ears in a manner that covers all hair. If necessary, two hairnets may be worn to cover all hair.
- 5.7.3. Caps, hats, and beanies must be covered with a hairnet.
- 5.7.4. All facial hair must be covered with a beard net or hairnet.

5.8. Personal Effects


- 5.8.1. Personal items such as coats, pocketbooks, bags, lunch boxes, food or drink items, etc. are not permitted in any production or packaging areas of the plant. Employees should leave these items in their lockers or in the locker room. Food and drinks are not allowed in personal lockers and should be stored in the lunchroom.
- 5.8.2. Nothing should be stored on top of lockers.

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- 5.8.3. Use of cosmetics and skin preparations are not allowed in the warehouse, production, or packaging areas.
- 5.8.4. Management may inspect all personal lockers.
- 5.9. Consumption of Food and Other Items
 - 5.9.1. Employees are not permitted to consume food, candy, or drinks (including water) in production and warehouse areas. The chewing of gum is also forbidden in these areas. Food and drinks must be consumed only in designated areas.
 - 5.9.2. The Hallway leading into the warehouse or into the GMP area has a designated water station shelf. All bottles/ containers must have a lid and spill proof. No open containers are allowed.
 - 5.9.3. Tobacco products, toothpicks, throat lozenges, and medicines are not allowed in production, packaging, and warehouse areas.

6. HISTORY


RELEASE NO.	EFFECTIVE DATE	REASON/JUSTIFICATION FOR CHANGE
1	02/10/2020	New
2	2/20/2023	Specific designated area for closed drink containers added to section 5.9.2

 MBI NUTRACEUTICALS	STANDARD OPERATING PROCEDURE CONFIDENTIAL		SOP NUMBER/RELEASE GP-002 / 3
	TITLE: PERSONAL PROTECTIVE EQUIPMENT		PAGE NUMBER 1 of 3

SOP COVER PAGE

AUTHOR:	Signed: _____		Date: _____
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	Trent Jensen, Production Manager		
REVIEWED BY:	Signed: _____		Date: _____
	Jeff Jensen, Packaging Manager		
APPROVED BY:	Signed: _____		Date: _____
	Ned Jensen, President		
EFFECTIVE DATE:	05/30/2019	SUPERSEDES VERSION:	GP-002 Release 2
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TITLE: PERSONAL PROTECTIVE EQUIPMENT			PAGE NUMBER 2 of 3

1. PURPOSE

1.1. This Standard Operating Procedure (SOP) defines the requirements for use of personal protective equipment (PPE) while in the production, packaging, manufacturing, laboratory or similar areas at the MBI Nutraceuticals facility. Proper PPE practice is designed to provide a safe working environment and to minimize employee exposure to hazardous materials and/or situations.

2. SCOPE

2.1. This GMP SOP defines the PPE requirements for head, eye, face, ear, hand, foot, and respiration while performing daily operations at the MBI Nutraceuticals facility.

3. RESPONSIBILITIES

3.1. All MBI personnel:

3.1.1. Perform operations while adhering to appropriate PPE practice standards described within this SOP.

3.1.2. Evaluate the need for PPE in collaboration with management.

3.2. Management:

3.2.1. Purchase PPE

3.2.2. Ensure PPE is sufficiently available to all personnel.

3.2.3. Provide adequate PPE to all personnel to minimize employee exposure to workplace hazards.

3.2.4. Ensure appropriate PPE is being used during daily operations in the facility

3.2.5. Identify appropriate PPE for specific areas.

3.2.6. Post appropriate signs designating specific PPE requirements as necessary.

4. REFERENCES

4.1. None

5. SPECIAL REQUIREMENTS

5.1. None

6. DEFINITIONS

6.1. SDS- Safety Data Sheet

6.2. PPE- Personal protective equipment (gloves, lab coat or body covering, safety glasses)

7. MATERIALS AND EQUIPMENT

7.1. PPE: gloves, lab coat, safety glasses


7.2. Fume hood

8. SAFETY REQUIREMENTS

8.1. When handling chemicals, refer to the appropriate SDS for PPE recommendations.

9. PROCEDURE


9.1. Clothing

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- 9.1.1. Wear appropriate clothing and follow specific gowning requirements for all designated work areas.
- 9.1.2. Aprons and acid suits must be worn when a risk of splashing caustic solutions is present.
- 9.1.3. For the laboratory, refer to SOP GP-001 for specific clothing requirements.
- 9.2. Respiratory protection
 - 9.2.1. Respirators must be worn as required and posted by management.
 - 9.2.2. When doing tasks which involve exposure to dust, particulate matter, or strong fumes, an employee may opt to wear a dust mask or respirator for their protection and/or comfort.
- 9.3. Head protection
 - 9.3.1. Hard hats must be worn as required and posted by management.
 - 9.3.2. When working around low overhangs, or with items which may fall from overhead, an employee may opt to wear a hard hat for their protection and/or comfort.
- 9.4. Eye and face protection
 - 9.4.1. Safety glasses, goggles, or face shields must be worn when performing high-risk procedures when working with volatile substances, and when splatters or splashes of acids or bases may occur. Non-laboratory personnel will need laboratory supervision in dealing with any lab chemicals or tasks.
- 9.5. Hand protection
 - 9.5.1. Hand protection must be used when performing tasks with potential injury to hands and/or arms.
 - 9.5.2. Corrosive resistant gloves must be worn when working with caustic or acidic solutions.
 - 9.5.3. Appropriate gloves must be worn when handling hazardous materials.
- 9.6. Foot protection
 - 9.6.1. Closed-toed shoes must be worn at all times when working in any area within the manufacturing facility, such as production or packaging areas), or as required and posted by management.

10. HISTORY


RELEASE NO.	EFFECTIVE DATE	REASON/JUSTIFICATION FOR CHANGE
1	06/01/05	New
2	10/15/2010	Updated SOP format, including cover page and release history. Added section to conform to SOP template section headings. Minor grammar corrections. Expanded scope to include all areas at MBi where PPE may be required. Changed references for EH&S group to Management. Added reference to Laboratory Safety SOP. Changed requirement for steel-toed shoes to closed-toed shoes. Steel-toed shoes required where posted.
3	03/13/2019	Updated personnel. Formatting changes.

	MBi NUTRACEUTICALS	STANDARD OPERATING PROCEDURE CONFIDENTIAL	SOP NUMBER/RELEASE EQ-006 / 6
TITLE: GENERAL CLEANING PROCEDURE FOR EQUIPMENT			PAGE NUMBER 1 of 4

SOP COVER PAGE

AUTHOR:	Signed: _____ Date: _____		
	Kimberly Griffin, QA Manager		
APPROVED BY:	Signed: _____ Date: _____		
	Trent Jensen, VP/Production		
APPROVED BY:	Signed: _____ Date: _____		
	Jeff Jensen, VP/Business Development		
EFFECTIVE DATE:	2/20/2023	SUPERSEDES VERSION:	EQ-006 Release 5 1/27/22
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1. PURPOSE

- 1.1. This Standard Operating Procedure (SOP) defines general procedures for equipment and utensil cleaning.

2. SCOPE

- 2.1. This SOP is limited to the general cleaning procedure for manufacturing equipment and utensils at MBI. Equipment with specific cleaning procedures will have those procedures outlined in their Cleaning and Operation SOP and are not covered in the scope of this SOP.

3. RESPONSIBILITIES


- 3.1. Manufacturing Supervisor:
 - 3.1.1. Acts as oversight for developing, revising, and maintaining this SOP
 - 3.1.2. Ensures that employees that clean equipment are trained on this SOP
 - 3.1.3. Ensures all employees compliance with this SOP
- 3.2. Manufacturing Employees:
 - 3.2.1. Comply with the procedures of this SOP
 - 3.2.2. Provide input for developing, revising, and maintaining this SOP
 - 3.2.3. Ensure compliance of all employees to this SOP
- 3.3. Warehouse Manager:
 - 3.3.1. Acts as oversight for developing, revising, and maintaining this SOP
 - 3.3.2. Maintains service and cleanliness of equipment
 - 3.3.3. Ensures compliance of all employees to this SOP

4. REFERENCES

- 4.1. Standard Operating Procedures for specific equipment cleaning
- 4.2. SOP EQ-034 Hygiene Ensure Luminometer
- 4.3. Utah Department of Agriculture, Quaternary Ammonium, Why Use Test Strips?
<https://ag.utah.gov/wp-content/uploads/2021/02/Sanitizers-Quaternary-Ammonium.pdf>

5. MATERIALS AND EQUIPMENT

- 5.1. Liquid Soap (Such as Dawn)
- 5.2. Rag
- 5.3. Liquid WAXIE Solution 910 FINALE FS No Rinse Sanitizer
- 5.4. Scouring pads (Scotch-Brite or similar)
- 5.5. Hygiene Ensure monitor
- 5.6. Hygiene Ultrasnap ATP surface swab
- 5.7. Yellow 5 gallon buckets


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6. SAFETY REQUIREMENTS

- 6.1. Employees that clean equipment must wear at a minimum: hair coverings, facial hair cover (if applicable), lab coat or similar body cover suit and gloves.

7. PROCEDURE

- 7.1. Equipment used in manufacturing or packing products shall be cleaned directly after use. If the equipment is not used for longer periods of time, they should be cleaned again to eliminate dust that may have accumulated on it since it was last used, and to allow it to pass Hygiene surface swab testing, if applicable.
- 7.2. Yellow 5 gallon buckets are designated for sanitation purposes only.
- 7.3. To clean manufacturing and production equipment with soap and water:
- 7.3.1. Using scouring pads and hot soapy water, cover all surfaces of the equipment and scrub.
 - 7.3.2. Rinse the equipment thoroughly with water.
 - 7.3.3. Visually inspect the equipment. The equipment surfaces should be free of soap residue, bubbles, film, rouge, discoloring, rust, or foreign material. Equipment should be visually clean, and extra care taken to inspect hard to view areas.
 - 7.3.4. If the equipment fails visual inspection, repeat steps 7.2.1 to 7.2.3. The equipment may not be used until it passes visual inspection.
- 7.4. To sanitize equipment with WAXIE 910 No Rinse Sanitizer following cleaning:
- 7.4.1. Waxie Solution Station dispenser is used to dispense the correct amount of Waxie 910 concentrate and water. A minimum of once per quarter, the dispensed solution should be tested to confirm that the correct amount of ammonium is in the solution.
 - 7.4.1.1. Tear off a two-inch strip of Hydrion QT-40 paper, and immerse in the prepared Waxie 910 solution for ten seconds. Compare the test strip to the color guide on the package.
 - 7.4.1.2. Record the concentration on the Waxie 910/Bleach log page.
 - 7.4.1.3. The concentration should be about 200 ppm. If it is higher than that, the solution should be diluted and retested until the test strip reads 200 ppm. If the concentration is measuring lower than 200 ppm, additional concentrate should be added until the solution measures at 200 ppm.
 - 7.4.1.4. If the Waxie Solution Station is dispensing the solution at an incorrect concentration, then Waxie customer service should be called to request maintenance.
 - 7.4.1.5. While the Waxie Solution Station is dispensing the solution at an incorrect concentration, the solution should be tested and corrected according to the directions in 7.3.1.3 every time it is prepared.
 - 7.4.1.6. After the Waxie Solution Station has been serviced for a malfunction affecting the Waxie 910 concentration, the ammonium concentration should be tested weekly until three consecutive 200 ppm measurements are taken, prior to resuming monthly or quarterly testing.
 - 7.4.2. Spray or submerge the equipment thoroughly with WAXIE 910.

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- 7.4.3. Allow the surface to remain in contact with the sanitizer for 10 minutes. Let air dry.
- 7.4.4. If applicable, test surfaces of the equipment with Hygiena Ensure Luminometer, according to the procedure in SOP EQ-034.
- 7.4.5. If the equipment fails the Hygiena test, repeat steps 7.2 and 7.3.2 through 7.3.4. The equipment may not be used until it passes Hygiena testing.
- 7.5. Large drums and kettles should be nested, covered, or inverted to prevent dust accumulation on interior surfaces until immediately before use.
- 7.6. Verification of equipment cleaning and sanitization is recorded in the batch record prior to equipment use with a product.
- 7.7. Packaging personnel should sign off on the packaging record that accompanies the equipment that the equipment has been cleaned prior to use.
- 7.8. General Production Area Housekeeping
 - 7.8.1. Only one batch of product shall be in the packing or manufacturing area at any given time.
 - 7.8.2. All labels, closures, and products relating to that batch must be put away properly before another batch of product can be brought to the area.

8. RECORDS, REPORTS, AND FORMS

- 8.1. Packaging Cleaning and Use Log Books
- 8.2. Batch Production Records
- 8.3. Hygiena Suretrend Software
- 8.4. Waxie 910/Bleach Log: (H:) / Lab / Documents / Charts / Waxie910_Bleach ppm log.doc

9. HISTORY


RELEASE NO.	EFFECTIVE DATE	REASON/JUSTIFICATION FOR CHANGE
1	08/01/05	New
2	03/15/2006	Format SOP and update for consistency
3	03/04/2010	Added special instructions for protecting critical surfaces from contamination when not in use, including wrapping surfaces in plastic and nesting, covering, or inverting drums and kettles.
4	04/03/2019	9.4 & 9.10 Replace Bleach with WAXIE 910 QUATERNARY. Addition of Hygiena Ensure Luminometer testing.
5	1/27/22	Removed unnecessary definitions. Updated cleaning procedure to reflect current practice. Removed high pressure steam cleaner, and DI water for cleaning. Added steps for testing Waxie 910 concentration, logging.
6	2/20/2023	Update QA Manager. Added Yellow 5 gallon buckets to the material list and procedure.

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	TITLE: PREVENTIVE MAINTENANCE		PAGE NUMBER 1 of 4

SOP COVER PAGE

APPROVED BY:	Signed:		Date:
	Kimberly Griffin, Quality Manager		
APPROVED BY:	Signed:		Date:
	Jeff Jensen, VP / Business Development		
APPROVED BY:	Signed:		Date:
	Trent Jensen, VP / Production		
EFFECTIVE DATE:	1/16/2023	SUPERSEDES VERSION:	New Document
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REVIEW DATE:		Signature:	

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1. PURPOSE

- 1.1. Establish and conduct the Preventative Maintenance program in order to ensure appropriate functioning of the facility and equipment at MBI Nutraceuticals. Both preventive and routine maintenance are needed to ensure safe and efficient equipment.

2. SCOPE

- 2.1. This SOP describes the methods and responsibility for the preventive maintenance for the MBI facility and equipment. Preventive Maintenance shall be documented, planned, and carried out in a manner that minimizes the risk of contamination.

3. RESPONSIBILITIES

3.1. Maintenance Manager:

- 3.1.1 Acts as oversight for developing, revising and maintaining this SOP
- 3.1.2 Ensures that employees that operate equipment are trained on this SOP
- 3.1.3 Ensures all employees compliance with this SOP

3.2. Manufacturing/ Maintenance Employees:

- 3.2.1 Comply with the procedures in this SOP
- 3.2.2 Provide input for developing, revising and maintaining this SOP
- 3.2.3 Ensure compliance of all employees to this SOP

4. REFERENCES


- 4.1. SOP EQ-039 Chemical Control Program
- 4.2. SOP GP-002 Personal Protective Equipment
- 4.3. Equipment Master List

5. MATERIALS AND EQUIPMENT

- 5.1. Provide a list of materials and equipment used if applicable.

6. SAFETY REQUIREMENTS

- 6.1. Employees performing preventive maintenance must wear at a minimum the following: hair coverings, facial hair cover (if applicable), lab coat or dedicated uniform and safety glasses. SOP GP-002 Personal Protective Equipment

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7. PROCEDURE

7.1. Preventive Maintenance:

7.1.1 The maintenance mechanic notifies the area manager about any potential or immediate repair needed to the equipment or facility.

7.1.2 Maintenance shall provide routine maintenance of the facility or equipment based on the PM Schedule. The Preventive Maintenance Schedule shall cover the following: facility exterior and interior equipment, manufacturing equipment.

7.1.3 Preventive Maintenance will be logged in the corresponding binder found in the Maintenance Cabinet.

7.2. Emergency Repairs:

7.2.1 Emergency repairs shall be documented on an incident report, and records maintained.

7.2.2 The Maintenance Manager must document the completion of any work on the Incident Log found in lab archives.

7.2.3 Upon completion of repairs, remove all tools and debris from any maintenance activity and inform the area manager in order to initiate appropriate sanitation.

7.2.4 The Manager or Supervisor must ensure appropriate and effective clean up measures are taken once all Maintenance or Service Contractor activity is completed and prior to the commencement of plant operations.

7.2.5 The Production Manager must be contacted immediately anytime tools can not be accounted for to make a determination on next steps.


7.3. Equipment Lubrication & Paints:

7.3.1 Equipment located over product or product conveyors shall be lubricated with food grade lubricants. Be sure fitted drip trays are located under necessary equipment to collect lubricant that may drip from the machinery.

7.3.2 Non toxic paint shall be used in a food handling or contact zone and not on any product contact surface.

7.3.3 MSDS for food grade lubricants must be kept on file.

7.3.4 If non-food grade lubricants are used in the facility, they must be physically separated from food grade lubricants and stored in a locked cabinet.

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7.3.5 All oils, lubricants, and cleaners used in the facility must be approved, properly labeled, and stored, procedures located in SOP EQ-039 Chemical Control Program

7.4. Temporary Repairs:

7.4.1 Temporary repairs are not to be utilized within general processing facilities. The use of plastic, tape, string, cardboard, or other non-permanent materials as a means to repair or alter the facility or equipment must be avoided.


7.4.2 Temporary repairs need to be controlled and monitored on a daily basis.

8. **RECORDS, REPORTS, AND FORMS**

- 8.1. Preventive Maintenance Form and Log
- 8.2. Incident Report and Log (Lab Archive)

9. **HISTORY**


RELEASE No.	EFFECTIVE DATE	REASON/JUSTIFICATION FOR CHANGE
1	1/16/2023	New Document
2		

	MBI NUTRACEUTICALS	STANDARD OPERATING PROCEDURE CONFIDENTIAL	SOP NUMBER/RELEASE FA-002 / 7
TITLE: SANITATION PROGRAM			PAGE NUMBER 1 of 5

SOP COVER PAGE

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If the SOP is reviewed and there are no changes (i.e. if it is not revised) then a signature and date (below) indicate the review has occurred. If a revision is required, a new version is released and the signature/date (below) do not need to be completed.			
Review Date:		Signature:	
Review Date:		Signature:	
Review Date:		Signature:	

Approval of this page indicates approval of all pages in this procedure.

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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

5. MATERIALS AND EQUIPMENT

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

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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. Eating or drinking is permitted only in the break room and office areas. Food and drinks are not permitted in manufacturing or packaging areas.
- 7.1.8. Keep all doors leading to the outside closed, other than during receiving or shipping.
- 7.1.9. Smoking is not permitted in the building at any time.
- 7.1.10. All areas must be kept orderly and free from accumulated waste and debris.
- 7.1.11. All building areas should be maintained in a clean and orderly manner.
- 7.1.12. 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.

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- 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. Acceptably cleaned and sanitized equipment must be segregated from dirty equipment until used.
- 7.8. Large drums and kettles should be nested, covered, or inverted to prevent dust accumulation on critical surfaces until immediately before use.
- 7.9. Enter the equipment cleaning and sanitizing information in the Cleaning and Use Logs.
- 7.10. Cleaning records shall be kept with the batch record.
- 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.

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8. RECORDS, REPORTS, AND FORMS

- 8.1. Batch records
- 8.2. Facility Sanitation Logbook
- 8.3. Lab Archives

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.
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