

Company Procedure

Title: Repackaging Cleaning Procedure Number: R13-PR-100-034

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1.0 Purpose

The purpose of this procedure is to ensure the Repackaging facility and warehouses are sanitized as outlined in 21 CFR 211.56.

2.0 Scope

This procedure applies to each production line, all hoppers, all filling stations, the production floor, the ceiling and warehouses.

3.0 Responsibility

Supervisors – oversee daily cleaning of production lines and production floor, bi-weekly floor cleaning and quarterly cleaning.

Expeditors – cleaning and trash removal at RCF.

Housekeeping – daily restroom and facility cleaning at Repackaging.

Pest Control - handled by an outside approved vendor.

4.0 Safety Considerations

Safety is a condition of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

Items to be used on the production floor for cleaning are:

- Air hose
- Dawn detergent (3 mils per 10 gallons of water; adjust accordingly)
- Clean rags
- Box wrench set
- Screw drivers
- Allen wrenches
- Isopropyl alcohol
- Steam cleaner
- Pressure washer

Items to be used by Housekeeping are:

- Broom & dust pan
- Trash bags
- Toilet scrubber & plunger
- Cleaning rags & paper towels



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6.0 Procedure

A. Daily cleanup for Auto Lines

1. Auto #1 Clean Up

a. Non-critical Contact Points

- i. Starting at the top of the machine, use compresses air to blow off all salt inside and outside of the scales.
- ii. Empty each bucket of the scales by turning on the control panel and pressing the zero buttons.
- iii. Use compressed air to blow salt off the machine from top to bottom.
- iv. Wipe down the gripper arms, turret and suction cups with a damp rag.
- v. Clean seal bars and change seal tape if needed.
- vi. Wipe down all doors, the bottom of machine, the discharge belt and the pouch magazine feeder with a damp rag.
- vii. Use compressed air to blow off the long conveyor, and then wipe down with a damp rag.
- viii. Use compressed air to blow off the taper, wipe down with a damp rag, then change tape rolls if needed.
- ix. Clean up all nonconforming pouches and dispose of salt following the guidelines listed in the *Rework and Reprocessing of Salt (R12-PR-100-007)* procedure.
- x. All floor space around the machine and work areas must be swept and free of debris

b. Critical Contact Points

- i. Remove fill funnel and wash for 3–5 minutes with 2 ½ gallons of water with .75 mils of Dawn detergent, rinse for 2-3 minutes with hot water, and spray with Isopropyl Alcohol.
- ii. Clean storage container with diluted Dawn detergent, rinse with water and spray down with Isopropyl Alcohol.
- iii. Put funnel into clean storage container.
- iv. While Hopper #3 is drained of salt, it will be blown out and sprayed with Isopropyl alcohol and left to air dry.

When clean up is complete, the shift Production Supervisor and Operator must inspect all areas of the machine and sign *Daily Clean Up for Auto #1 (R12-PR-100-F017a)*. The form should be filed in the Cleaning Log book. An ID sign should be posted stating the condition of the machine. RED- Not Clean, Green- Cleaned for USP, and Blue- Cleaned for tech grade.

2. Auto #2 Clean Up

a. Non-critical Contact Points



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- i. Starting at the top of the AMS system, use compressed air to blow off all salt and debris from the top of the machine.
- ii. Use compressed air to blow out the cup area and the area where the chain is located.
- iii. Use compressed air to blow salt off the machine from top to bottom.
- iv. Wipe down the gripper arms, turret and suction cups with a damp rag.
- v. Clean seal bars and change seal tape if needed.
- vi. Wipe down all doors, the bottom of machine, the discharge belt and the pouch magazine feeder with a damp rag.
- vii. Use compressed air to blow off Alpha Check Weigher and then wipe down with a damp rag.
- viii. Use compressed air to blow off the long conveyor, and then wipe down with a damp rag.
- ix. Use compressed air to blow off the taper, wipe down with a damp rag, then change tape rolls if needed.
- x. Clean up all nonconforming pouches and dispose of salt following the guidelines listed in the *Rework and Reprocessing of Salt (R12-PR-100-007)* procedure.
- xi. All floor space around the machine and work areas must be swept and free of debris.

b. Critical Contact Points

- i. Remove fill funnel and wash for 3-5 minutes with 2 ½ gallons of water with .75 mils of Dawn detergent, rinse for 2-3 minutes with hot water, and spray with Isopropyl Alcohol.
- ii. Clean storage container with diluted Dawn detergent, rinse with water and spray down with Isopropyl Alcohol.
- iii. Put funnel into clean storage container.
- iv. While Hopper #5 is drained of salt, it will be blown out and sprayed with Isopropyl alcohol and left to air dry.

When clean up is complete, the shift Production Supervisor and Operator must inspect all areas of the machine and sign *Daily Clean Up for Auto #2 (R12-PR-100-F017b)*. The form should be filed in the Cleaning Log book. An ID sign should be posted stating the condition of the machine. RED- Not Clean, Green- Cleaned for USP, and Blue- Cleaned for tech grade.

3. Auto #3 Clean Up

a. Non-critical Contact Points

- i. Starting at the top of the AMS system, use compressed air to blow off all salt and debris from the top of the machine.
- ii. Use compressed air to blow out the scales.
- iii. Use compressed air to blow salt off the machine from top to bottom.
- iv. Wipe down the contact fingers and suction cups with a damp rag.
- v. Clean seal bars and change seal tape if needed.

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- vi. Wipe down all doors, the bottom of machine, the conveyor belt and the pouch magazine feeder with a damp rag.
- vii. Use compressed air to blow off the taper, wipe down with a damp rag, then change tape rolls if needed.
- viii. Clean up all nonconforming pouches and dispose of salt following the guidelines listed in the *Rework and Reprocessing of Salt (R12-PR-100-007)* procedure.
- ix. All floor space around the machine and work areas must be swept and free of debris.

b. Critical Contact Points

- i. Remove fill funnel and wash for 3-5 minutes with 2 ½ gallons of water with .75 mils of Dawn detergent, rinse for 2-3 minutes with hot water, and spray with Isopropyl Alcohol.
- ii. Clean storage container with diluted Dawn detergent, rinse with water and spray down with Isopropyl Alcohol.
- iii. Put funnel into clean storage container.
- iv. While Hopper #4 is drained of salt, it will be blown out and sprayed with Isopropyl alcohol and left to air dry.

When clean up is complete, the shift Production Supervisor and Operator must inspect all areas of the machine and sign *Daily Clean Up for Auto Line #3 (R12-PR-100-F017c)*. The form should be filed in the Cleaning Log book. An ID sign should be posted stating the condition of the machine. RED- Not Clean, Green- Cleaned for USP, and Blue- Cleaned for tech grade.

4. Auto #4 Clean Up

a. Non-critical Contact Points

- i. Starting at the top of the machine, use compresses air to blow off all salt inside and outside of the scales.
- ii. Empty each bucket of the scales by turning on the control panel and pressing the zero buttons
- iii. Use compressed air to blow salt off the machine from top to bottom.
- iv. Wipe down the gripper arms, turret and suction cups with a damp rag.
- v. Clean seal bars and change seal tape if needed.
- vi. Wipe down all doors, the bottom of machine, the discharge belt and the pouch magazine feeder with a damp rag.
- vii. Use compressed air to blow off the long conveyor, and then wipe down with a damp rag.
- viii. Use compressed air to blow off the taper, wipe down with a damp rag, then change tape rolls if needed.
- ix. Clean up all nonconforming pouches and dispose of salt following the guidelines listed in the *Rework and Reprocessing of Salt (R12-PR-100-007)* procedure.

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All floor space around the machine and work areas must be swept and free of Χ. debris.

b. Critical Contact Points

- Remove fill funnel and wash for 3-5 minutes with 2 ½ gallons of water with .75 mils of Dawn detergent, rinse for 2-3 minutes with hot water, and spray with Isopropyl Alcohol.
- Clean storage container with diluted Dawn detergent, rinse with water and spray ii. down with Isopropyl Alcohol.
- Put funnel into clean storage container. iii.
- viii. While Hopper #5 is drained of salt, it will be blown out and sprayed with iv.
- Isopropyl alcohol and left to air dry. V.

When cleanup is complete, the shift Production Supervisor and Operator must inspect all areas of the machine and sign Daily Clean Up for Auto #4 (R12-PR-100-F017d). The form should be filed in the Cleaning Log book. An ID sign should be posted stating the condition of the machine. RED- Not Clean, Green- Cleaned for USP, and Blue- Cleaned for tech grade.

5. Auto #5 Clean Up

a. Non-critical Contact Points

- i. Starting at the top of the machine, use compresses air to blow off all salt inside and outside of the scales.
- Empty each bucket of the scales by turning on the control panel and pressing the ii. zero buttons.
- iii. Use compressed air to blow salt off the machine from top to bottom.
- Wipe down the gripper arms, turret and suction cups with a damp rag. iv.
- Clean seal bars and change seal tape if needed. v.
- Wipe down all doors, the bottom of machine, the discharge belt and the pouch vi. magazine feeder with a damp rag.
- Use compressed air to blow off the long conveyor, and then wipe down with a vii. damp rag.
- Use compressed air to blow off the taper, wipe down with a damp rag, then viii change tape rolls if needed.
 - Clean up all nonconforming pouches and dispose of salt following the guidelines ix. listed in the *Rework and Reprocessing of Salt (R12-PR-100-007)* procedure.
 - All floor space around the machine and work areas must be swept and free of Χ. debris.

b. Critical Contact Points

Remove fill funnel and wash for 3-5 minutes with 2 ½ gallons of water with .75 mils of Dawn detergent, rinse for 2-3 minutes with hot water, and spray with Isopropyl Alcohol.



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- ii. Clean storage container with diluted Dawn detergent, rinse with water and spray down with Isopropyl Alcohol.
- iii. Put funnel into clean storage container.
- iv. viii. While Hopper #7 is drained of salt, it will be blown out and sprayed with
- v. Isopropyl alcohol and left to air dry.

When cleanup is complete, the shift Production Supervisor and Operator must inspect all areas of the machine and sign *Daily Clean Up for Auto #5 (R12-PR-100-F017e)*. The form should be filed in the Cleaning Log book. An ID sign should be posted stating the condition of the machine. RED- Not Clean, Green- Cleaned for USP, and Blue- Cleaned for tech grade.

6. Auto #6 Clean Up

a. Non-critical Contact Points

- i. Starting at the top of the machine, use compresses air to blow off all salt inside and outside of the scales.
- ii. Empty each bucket of the scales by turning on the control panel and pressing the zero buttons.
- iii. Use compressed air to blow salt off the machine from top to bottom.
- iv. Wipe down the funnel from scales, forming head, clean pull belts with a damp rag.
- v. Clean seal bars and change seal tape if needed.
- vi. Wipe down all doors, the bottom of machine, the discharge belt and the pouch magazine feeder with a damp rag.
- vii. Use compressed air to blow off the long conveyor, and then wipe down with a damp rag.
- viii. Use compressed air to blow off the combi (including machine doors), wipe down with a damp rag, then change tape rolls if needed.
- ix. Clean up all nonconforming pouches and dispose of salt following the guidelines listed in the *Rework and Reprocessing of Salt (R12-PR-100-007)* procedure.
- x. All floor space around the machine and work areas must be swept and free of debris.

b. Critical Contact Points

- i. Fill funnel and forming head need to be washed with Dawn detergent and hot water mix, rinse for 2-3 minutes with hot water, and spray with Isopropyl Alcohol
- ii. Clean storage container with diluted Dawn detergent, rinse with water and spray down with Isopropyl Alcohol.
- iii. Put funnel into clean storage container.
- iv. viii. While Hopper #7 is drained of salt, it will be blown out and sprayed with
- v. Isopropyl alcohol and left to air dry.

When cleanup is complete, the shift Production Supervisor and Operator must inspect all areas of the machine and sign *Daily Clean Up for Auto #6 (R12-PR-100-F017f)*. The form should be filed in the



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Cleaning Log book. An ID sign should be posted stating the condition of the machine. RED- Not Clean, Green- Cleaned for USP, and Blue- Cleaned for tech grade.

B. Daily Cleanup for Manual Lines

- 1. Non-critical Contact Points
 - a. Clean fill table with diluted Dawn detergent, then wipe down with a damp rag.
 - b. Open sealer by loosening the two thumb screws. Take the guide plates off each end. Using the air hose blow all salt and debris out.
 - c. Wash the sealer with diluted Dawn detergent, wipe down with damp rag and air dry.
 - d. Clean sealer conveyor belt with diluted Dawn detergent, wipe down with damp rag and air dry.
 - e. Wash packing table with Dawn detergent, wipe down with damp rag and air dry.
 - f. With a damp rag wipe taper down and change both tape rolls if needed.
 - g. All floor space around the machine and work areas must be swept and free of debris.

2. Critical Contact Points

- a. Make sure big bell is empty.
- b. Take fill funnel, small auger and collar off. Wash each for 3-5 minutes with 2 ½ gallons of water with .75 mils of Dawn detergent, rinse for 2-3 minutes with hot water, and spray with Isopropyl Alcohol.
- c. Clean storage container with diluted Dawn detergent, rinse with water and spray down with Isopropyl Alcohol.
- d. Put funnel, small auger and collar into cleaned storage container.
- e. While Hopper #1 is drained of salt, it will be blown out and sprayed with Isopropyl alcohol and left to air dry.

When cleanup is complete, the shift Production Supervisor and Operator must inspect all areas of the machine and sign *Daily Clean Up for Manual Lines (R12-PR-100-F018)*. The form should be filed in the Cleaning Log book. An ID sign should be posted stating the condition of the machine. RED- Not Clean, Green- Cleaned for USP, and Blue- Cleaned for tech grade.

C. Daily Cleanup for Carton Lines

- 1. Non-critical Contact Points
 - a. Clean out all bad cartons from the magazine area.
 - b. Spray down carton magazine, mandrels, chain conveyor and bed with water hose.
 - c. Wipe down all sheet metal with damp rags.
 - d. Use compressed air to blow off Alpha Check Weighers and then wipe down with a damp rag.
 - e. Clean up all nonconforming cartons and dispose of salt following the guidelines listed in the *Rework and Reprocessing of Salt (R12-PR-100-007)* procedure.
 - f. All floor space around the machine and work areas must be swept and free of debris.

2. Critical Contact Points

a. Make sure AMS filler is empty.



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- b. Take fill funnel, small auger, and collar off. Wash each for 3-5 minutes with 2 ½ gallons of water with .75 mils of Dawn detergent, rinse for 2-3 minutes with hot water and spray down parts with Isopropyl Alcohol.
- c. Clean storage container with diluted Dawn detergent, rinse with water and spray down with Isopropyl Alcohol.
- d. Put cleaned parts into cleaned storage container.
- e. While Hopper #2 is drained of salt, it will be blown out and sprayed with Isopropyl alcohol and left to air dry.

When clean up is complete, the shift Production Supervisor and Operator must inspect all areas of the machine and sign *Daily Clean Up for Carton Lines (R12-PR-100-F019)*. The form should be filed in the Cleaning Log book. An ID sign should be posted stating the condition of the machine. RED- Not Clean, Green- Cleaned for USP, and Blue- Cleaned for tech grade.

D. Bi-Weekly Floor Cleaning

Every other week a section of the production floor will be pressure washed as outlined on the *Bi-Weekly Floor Cleaning Form (R15-FM-100-081)*. Cleaning will be documented using this form and documentation will be maintained by the Quality Unit.

E. Semi Annual Clean Up

The following areas will be thoroughly cleaned semi-annually. Semi-Annual cleaning will be done using compressed air to remove salt and then cleaned using warm water, dawn and Isopropyl alcohol. Semi-Annual would signify once within first 6 months and another within the last 6 months of each year.

- 1. The complete ceiling and walls will be blown with compressed air to remove any salt build up. Salt hoppers need to be covered prior to blowing down the ceiling. Sealers, tapers, and production tables need to be removed from the production room prior to blowing down the ceiling.
- 2. While Hoppers #1-8 are drained of salt, they will be blown out and sprayed with Isopropyl alcohol and left to air dry.
- 3. Each production line will be thoroughly cleaned in accordance to the Daily Clean Up procedures listed above. In addition to the procedures above, the Auto Lines will be disassembled and steam cleaned.
- 4. Dock levelers will be cleaned and brushes inspected for wear and assure that they limit open space.

When clean-up is complete, the shift Production Supervisor must inspect all areas of the facility and complete the *Semi-Annual Clean Up for Repackaging (R14-PR-100-F034)*.



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F. Restroom Cleaning

The restrooms in the facility will be cleaned by Housekeeping as follows and documented on the *Repackaging Restroom Cleaning Checklist (R13-FM-100-059)*:

- Mirrors are cleaned once a day using glass cleaner and paper towels.
- Sinks are cleaned at least once a day using either a 50/50 solution of bleach/water or disinfectant.
- Toilets are cleaned at least once a day using either a 50/50 solution of bleach/water or disinfectant.
- Other washable surfaces (doorknobs, soap dispensers, etc) are cleaned using a bleach based cleaner
- Floor is swept at least once a day.
- Floor is mopped at least once a day using 50/50 solution of bleach/water.
- Trash bags are changed at least once a day.
- Paper towel dispenser and soap dispensers are checked daily and refilled as needed.

G. Warehouse Cleaning

The warehouses will be cleaned as follows:

- The floors will be swept daily.
- Trash and pallet pieces will be placed in proper receptacle.
- The trash will be collected daily and placed in the dumpster outside for collection by approved vendor.
- Trash from the RCF warehouse will be collected and taken to the Repack facility dumpster by designee.

Warehouse cleaning will be documented on either the *Repack Daily Cleaning Checklist (R13-FM-100-007)*, the *RCF Cleaning and Maintaining Checklist (R13-FM-100-084)* or the *Tannery Warehouse Cleaning and Maintaining Checklist (R16-FM-100-086)*. Documentation will be maintained by the Quality Unit.

H. Pest Control

The Repackaging facility, RCF warehouse and Tannery warehouse will be monitored and treated for rodents, birds, insects and vermin as outlined in the *Pest Control (Q12-PR-100-009)* procedure. Documentation will be maintained by the Quality Unit.



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7.0 Reference Documents

Daily Clean Up for Auto Line #1	(R12-PR-100-F017a)
Daily Clean Up for Auto Line #2	(R12-PR-100-F017b)
Daily Clean Up for Auto Line #3	(R12-PR-100-F017c)
Daily Clean Up for Auto Line #4	(R12-PR-100-F017d)
Daily Clean Up for Auto Line #5	(R12-PR-100-F017e)
Daily Clean Up for Auto Line #6	(R12-PR-100-F018f)
Daily Clean Up for Manual Lines	(R12-PR-100-F018)
Daily Clean Up for Carton Lines	(R12-PR-100-F019)
Rework and Reprocessing of Salt	(R12-PR-100-007)
Repackaging Restroom Cleaning Checklist	(R13-FM-100-059)
Repack Daily Cleaning Checklist	(R13-FM-100-007)
Semi-Annual Clean Up for Repackaging	(R14-PR-100-F034)
Bi-Weekly Floor Cleaning Form	(R15-FM-100-081)
RCF Cleaning and Maintaining Checklist	(R13-FM-100-084)
Tannery Warehouse Cleaning and Maintaining Checklist	(R16-FM-100-086)
Pest Control	(Q12-PR-100-009)

8.0 Change Information

Added Dock leveler cleaning and brush inspection.