

CRA SWEETENER TERMINAL AND WASH GUIDELINES

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Sweetener Terminal and Wash Guidelines

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INTRODUCTION

The CRA Sweetener Terminal and Wash Guidelines were developed by a committee of CRA members comprised of representatives from the industry.

This document has been prepared to provide general guidelines to manufactures, suppliers, and terminals of sweetener products. This manual has been prepared in order to provide best practices and minimum quality guidelines for the handling, storage, transporting, receiving, testing, and system maintenance of sweeteners. This document also is to help in achieving compliance with certain aspects of applicable regulatory standards such as Good Manufacturing Practices (GMP), customer requirements, and industry standards.

REVISIONS

This is the first draft of the CRA Sweetener Terminal and Wash Guidelines.

GENERAL INFORMATION

Section 1 Facility Requirements

1.1 General GMP

The facility shall be in compliance with Good Manufacturing Practices (GMP) given in 21 CFR 110 and customer requirements.

1.1.1. Cleaning Schedule

The facility shall have a Cleaning Schedule that is documented and complies with GMP regulations given in 21 CFR 110. An inspection of the facility shall be completed and documented. The inspection should also include a comments section for stating what corrective actions were taken. The cleaning schedule will ensure that the facility is maintained in a clean condition on a regular schedule.

1.1.2. Security

The security of the facility is of extreme importance requiring the utmost attention. Each morning an inspection of the facility should be conducted to make sure that a breech of security has not occurred. Visitors shall sign at the office before they are allowed outside the office area and shall be accompanied by an employee. All access gates, buildings, and access points shall be locked when personnel are not in the immediate area (immediate area would be defined as within eye sight of the personnel) or when the area is not in use by personnel. Every employee is a part of the security team and it is important that they understand the specific security measures. All trailers, railcars and storage tanks shall have tamper evident seals on them at all times. Exceptions include activities where: 1) vessels are within secured or supervised areas for washing, loading or heating; and 2) empty vessels that have been returned unsealed that are awaiting inspection and cleaning.

1.1.3. Product Traceability/Recall

The facility shall have product traceability and a recall program for incoming and outgoing shipments. Traceability of all products is accomplished through the vessel #, ship date, Bill of Lading (BOL) and storage tank # if applicable. The shipping records and log sheets are references that support the traceability. The recall program is to provide a prompt response and action for determining if a recall or withdrawal is necessary. The recall program is to coordinate all activities with customers, distributors, and transfer stations and for implementing the recall from start to final disposition of the product including corrective action. A mock recall exercise will be conducted yearly. The results shall be documented and filed. The facility shall have an Emergency Action Plan that includes an emergency contact list.

1.1.4. Glass and Brittle Plastic Program

The facility shall have a Glass and Brittle Plastics Program. All equipment and utensils are able to be adequately cleaned and maintained according to GMP regulations given in 21 CFR 110.The facility shall have a physical inventory of equipment. The equipment shall be monitored when operating. A preventative maintenance program shall be in place and documented for equipment.

1.1.5 Pest Control Program

There shall be a documented Pest Control program at the facility.

1.2 Building and Grounds

The sweetener facility may consist of railcar unloading and truck loading with or without a wash facility. The facility may have portable equipment or be set up with fixed pumps, lines, and storage tanks. The grounds of the facility should be in compliance with GMP regulations given in 21 CFR 110 and customer requirements. The grounds shall be maintained to prevent vermin harborage by controlling tall grass and weeds. The roads should be paved or constructed to eliminate dust and standing water.

1.3 Water

Plumbing shall be of adequate size and design to provide sufficient quantities of water as required at all use points within the terminal. The water system for the facility should have a filter capable of removing sediment from the incoming city water.

Exterior and interior drains shall provide adequate drainage to discharge water to the sewer without backup. There shall be adequate back flow prevention devices in place.

A sample of municipal water shall be taken at least annually from within the terminal. Well water, if in use, shall be tested quarterly. These samples shall be cold packed and sent overnight to a micro lab, for microbiological analysis. The micro tests shall include total plate count, coliform count and fecal coliforms. The micro results shall meet current U.S. Environmental Protection Agency regulatory standards for potable water.

1.4 Steam

Steam is used for heating the railcar to unload the product and to wash trailers. Please refer to Section 2, 2.3 Heating Instructions and Section 3,3.2 Truck Handling Washing, for guidelines for steam.

Boiler treatment chemicals shall be approved for food contact use. The certificate for FDA or USDA approval of each boiler treatment chemical shall be kept on file. Written boiler start-up and shutdown instructions shall be present and follow boiler manufacturer instructions. Boiler maintenance log sheets and service reports shall be kept on file.

1.5 Tank and Tank Accessories

A separate storage tank shall be used for each liquid sweetener. The general construction of the tank shall be stainless steel (304, 304L, or 316). The basic tank design shall meet certain requirements. Horizontal tanks shall be adequately pitched to prevent dead zones. Vertical tanks shall have a sloped bottom. If agitator is specified then it shall be vertical. Anti-swirl outlet baffles should be used especially if there are problems with mass flow measurements or entrained air. All welding shall be done by certified welders. The interior welds shall be polished with no snags or pits. All tanks and lines shall be inspected prior to placing into service. Each tank should be equipped with CIP capability. The gaskets shall be EPDM, Teflon, neoprene or other high temperature FDA or equivalent approved material for CIP. Each tank shall have the capability to recirculate within the tank.

To control condensation and microbiological growth, a steady air flow shall be maintained across the surface of the tank. The tanks should be equipped with the following accessories: HEPA system, manway, properly calibrated temperature probe, sampling port, and level indicator. If a UV system is present then it should be a properly designed and maintained system to prevent foreign material from entering the process. The air filter shall be a HEPA filter with 99% efficiency at 0.3 microns on the inlet. The air discharge vent shall be fitted with a filter. All systems shall be maintained in accordance with manufacturers' recommendations.

All actions taken on UV Lamps/Air Blower/Air Filters should be recorded on a log sheet.

Sanitary wash systems that have an air dryer shall have a 0.3-micron (maximum) air filter element. This air drying system shall be inspected at least annually to ensure proper operation.

Please see Section 2 Railcar Handling, 2.5 Air Assist Unloading for further guidelines for air.

If present, the in-swing manway or flanged manway shall be located on the tank to allow for ease of inspecting headspace and cleaning the tank.

If present, a properly calibrated temperature probe should be located near the bottom of the tank and inserted into the interior of the tank to be able to accurately read the internal temperature.

The sanitary sampling port or petcock is located near the tank discharge. The tank should be equipped with sanitary level indicators.

1.6 Pipes and Fittings

The piping materials used for sweeteners are 304, 304L or 316 stainless steel. The piping shall be heli-arc welded, purged and polished, or joined by sanitary in-line clamp gaskets. There should be separate piping with no interconnections or cross connections for each sweetener type. The piping shall allow for complete drainage of the lines. The pipes and lines shall not have any dead legs to allow for cleaning and sanitizing. There shall be a way to empty the tank to allow for cleaning and sanitation.

Piping for the tank inlet shall be large enough for desired flow rates for filling. Tank discharge piping shall be large enough for process demand and to maintain adequate flow to the pump. Other things that shall be considered in the size of the piping are temperature, viscosity, pipe length, elbows, and flow meters.

Pipes, fittings, and valves may require electric or steam heat tracing and/or insulation to prevent crystallization and to maintain temperature specification for the specific product. The outside lines should be protected with a weatherproof covering.

Acceptable gasket materials for sweeteners include Teflon, EPDM, nitrile, viton white food grade, and neoprene. The hose and tubing couplings/fittings shall be compatible material.

1.7 Pumps and Filters

Common transfer pumps may not be permissible for different sweetener types. Many trailers are equipped with their own pumps; therefore, a receiving pump may not be needed when receiving product by trailer delivery.

A positive displacement rotary with a bypass and/or an internal pressure relief valve pump should be used. The pump should have 316 stainless steel wetted parts and be of sanitary construction. A sanitary pressure gauge should be installed near the pump discharge. To protect the pump, a perforated basket style strainer should be installed on the intake side. If installed, the strainer shall be inspected and cleaned on a predetermined schedule.

The pump size is determined by the flow rate (gallons or liters per minute). Other items to consider in determining pump size are number of use points and the viscosity of the sweetener. The pump should have the capability of pumping to all use points.

All products that are transferred shall be pumped through a filter prior to going to a customer. All filters shall be inspected on a predetermined schedule. These filters can be stainless steel, y-strainers, filter bags, or filter screens.

1.8 Documentation

Procedures shall be documented and records maintained.

1.9 Sealing

The facility shall have a documented program regarding seals. The sealing program shall guarantee that the tanks, trailers, and railcars are sealed with tamper-evident cable seals when applicable.

Section 2 Railcar Handling

2.1 Equipment

Sweeteners are transported in insulated rail tank cars equipped with steam coils located in the lower half of the car between double walled carbon steel jackets. A standard six inch diameter product outlet is positioned in the bottom center of the tank car. Cars are lined with food contact approved lining.

2.2 Car Inspection

Contact the delivering railroad if the tank car exhibits evidence of damage or leakage. As a food safety measure, tamper-evident seals have been applied to all product access points at the manufacturing plant. Confirm that all product access points are cable sealed; record seal numbers and verify against rail car paperwork. The tank car dome lid can be opened once the external inspection and seal verification has been conducted. Proceed with the following steps:

- 1) Check for the presence of any off-odors, condition of inner dome and gasket, and physical condition of product surface (i.e., crystals, surface condensation, extraneous material, etc.).
- 2) Take product temperature using an unbreakable NIST thermometer or a thermometer that is crossed checked with a NIST traceable thermometer on a scheduled basis.
- 3) Sample the car from the dome using a sanitized ladle by plunging below the product surface.
- 4) If condensation is present, you may want to avoid taking a dome sample. Instead, take the sample from the bottom of the car. This is done by attaching the rail car fitting to the bottom outlet, positioning a drip bucket beneath the fitting discharge, and slowly but carefully opening the bottom discharge valve. After discharging at least half of a gallon, take the sample.
- 5) Do not attempt to take samples from a car if crystals are suspended in the product or are on the product surface, unless checking for color or non-dry solids dependent parameters. The crystals must first be dissolved; see Heating Instructions below.
- 6) Check solids using a refractometer; compare solids to product specification.

2.3 Heating Instructions

Sometimes it is necessary to heat sweetener tank cars prior to unloading (i.e., crystals present or temperature requirement). Connect steam fitting and hose to the 2" steam coil inlet and a fitting and hose to the 2" condensate discharge outlet. These connection points are clearly marked "inlet" and "outlet" and are located near the main product outlet (note: some tank cars have two sets of coils). Heating may

proceed with low pressure steam (10-20 psi; 25 psi max) until a dome temperature of 110°F for HFCS and 125°F (or higher if specified by the customer) for CS is reached or until crystals have dissolved. Steam should be shut off when HFCS reaches 110°F and when CS reaches 125°F in the dome. If crystals have not dissolved, adjust steam flow to maintain temperature until all crystals go into solution. Steam shall be shut off when a tank car is two-thirds empty. Product scorching and rail car liner damage will occur if steam is maintained on a car when steam coils are exposed.

Some type of agitation, such as filtered air agitation, has proven to be effective in reducing heating requirements. Compressed air shall be of a quality permissible to be incorporated into a food product. Dry compressed air shall be filtered through a coalescing filter to remove oil, followed by a 0.2 or less micron filter to remove microorganisms. This compressed air should be introduced in a one-half inch (1/2") line, containing a check valve (to prevent backflow), in the unloading elbow. Air pressure at 15 to 20 psi, with volume controlled by a ball valve for gentle agitation, will shorten the total heating time. Using an air lance is not recommended.

2.4 Unloading

Once the cable seals have been verified and the product is within specification, the following steps are typically performed:

- 1) Remove flange plate from main product outlet located in bottom center of rail car. Use a standard unloading adaptor with a 4" diameter cam lock fitting.
- 2) Heat high fructose corn syrup if necessary.
- 3) Attach a 4" diameter FDA approved hose to rail car adaptor.
- 4) Manually open the main product outlet valve. Start rail car unloading pump, if one is used, after confirming that all applicable valves are open.
- 5) If compressed air is used for unloading, see procedure for Air Assist Unloading of Rail Cars.

The following steps shall be undertaken after unloading a tank car of sweeteners:

- 1) Verify car is empty by opening the dome hatch.
- 2) Close, bolt down and seal the dome cover. Reattach and seal the vent cap if applicable.
- 3) Close hand valve on main outlet.
- 4) Disconnect rail car unloading hose from bottom outlet fitting.
- 5) Remove rail car fitting and reattach bottom flange plate.
- 6) Disconnect steam and condensate hoses and fittings from steam inlet and condensate outlet.
- 7) Advise the railroad when car is ready for return.

2.5 Air Assist Unloading

Rail cars can be unloaded by using filtered compressed air in the headspace above the product. Safety considerations prohibit pressures higher than

25 psi. Compressed air shall be of a quality permissible to be incorporated into a food product. This air shall be dry and clean. A coalescing filter is required to remove water after the compressor and a finite filter, 0.2-micron rated or finer, shall be used to remove solid particles and microorganisms. To extend the life of the coalescing and finite filters, a 5-micron pre-filter is recommended before the coalescing filter.

The following are safeguards when using compressed air on a rail car:

- 1) Check valves shall be in place ahead of the valve that shuts off air going into the rail car. This applies to lines for pressurizing car and for air line used to agitate syrup during heating.
- 2) The air line and fittings after the finite filter shall be constructed of stainless steel or other suitable material. Air lines and fittings shall be protected from contamination.
- 3) Air filters at rail transfer areas shall be changed on a predetermined schedule.
- 4) Inspections of in-line and air compressor particulate filters and oil/water coalescers shall be made on a predetermined schedule to assure proper operation.

Section 3 Truck Handling

3.1 Pre-Wash Inspection

A wash operator shall perform the following operations only after approving the prior commodity and inspecting the sweetener trailer for product residue and foreign materials. Trailer contents should be drained and disposed of according to applicable regulations.

3.2 Washing

The manway cover or hatch covers vent assemblies; pump, gaskets, fittings and in-line product filter shall be washed thoroughly with a dilute chlorine solution (approximately 200 ppm) or with a high-pressure wand. Disassembly of some vent housings may be necessary to properly clean the internal parts. The preferred method of cleaning would be a high-pressure wand and 180°F water. After cleaning and sanitizing, fittings and in-line product filters should be stored in a clean container (i.e., bucket) or plastic bag then placed inside a sealed cabinet (i.e., pump or fitting box) on the trailer, if applicable. If the pump is not cleaned during the normal washing procedure of the tank, a separate procedure for pump cleaning shall be applied. The hoses may be sanitized by two methods: the preferred method is by connecting them to the trailer outlet for sanitization by trailer wash water. The second method is washing with hot water to remove residual sweetener, testing for presence of glucose with glucose test strips, and then filling or soaking them in water containing approximately 200 ppm chlorine. All hose connections shall be kept off the floor at all times during and after sanitizing.

A power wash nozzle should be inserted into the trailer dome. The spinner-jet/spray nozzle shall be inspected on a predetermined schedule for proper operation.

The tanker should be flushed with warm/hot water or steam until all obvious traces of the previous contents are gone. After all flush/rinse water has drained, the wash cycle should be started by introducing water at a temperature of approximately 190°F through the wash nozzle. Timing of the wash cycle shall not begin until the discharge water from the tanker reaches 180°F. The wash must continue at 180°F for a minimum of 15 consecutive minutes. At this time, the wash water may be recycled by returning it to a hot water source (i.e., a holding tank) or it may be allowed to dump to a sanitary drain. An in-line sensor mounted in a section of piping at the trailer discharge along with a chart recorder shall be utilized to verify the temperature of the discharge water and the time of wash. The wash temperature sensor shall be cross checked with a NIST traceable thermometer weekly to ensure that the wash temperature is 180°F. The cross check temperatures shall agree within $\pm 2^\circ$ F. Recalibrate the sensor if the temperature differs more than 2° F.

Direct steam injection into the barrel of the tanker is an effective means of maintaining interior surfaces at 180°F or above for a minimum of 15 consecutive minutes. If steaming is used, a combination of steaming and power rinses shall be employed to effectively remove all traces of the prior commodity. After the wash cycle and final rinse is completed, the tanker shall be cooled with tempered water or filtered air prior to inspection of the interior.

On a predetermined schedule, test the final discharge water draining from the trailer with a glucose test strip. If it tests positive, review the wash procedures and take appropriate corrective action. If air tempering/drying is used, suitable filters shall be employed to remove dust particles, oil and odors. When the tanker is cool, it shall be inspected. If it is not adequately clean, it shall be rewashed. After the tanker has passed inspection and the gaskets are replaced, all access points shall be tightly closed and sealed prior to leaving the wash station unless being loaded immediately. Seal numbers shall be recorded on the wash ticket. Washed tankers shall be delivered to the production plant or sweetener station so that filling can be accomplished within 24 hours of washing. If 24 hours elapses prior to filling, the tanker shall be rewashed. The wash ticket shall be completed and signed by the sanitary wash operator or supervisor prior to releasing the tanker to the driver.

3.3 **Pre-Load Inspection**

The loader is responsible for verification that a vessel is suitable for loading. All trailers hauling sweetener products should be dedicated to sweeteners or products permitted on prior commodity lists. The wash ticket is required to confirm that the trailer was sanitized. All customer supplied vessels and/or customer arranged pickups should pass inspection. Vessels that do not pass an inspection shall not be loaded. Security seals shall be applied properly on all openings, cabinet doors, and hose tubes of the trailer upon arrival. The seals shall be confirmed against the wash ticket.

3.4 Loading

All products shall be loaded at their specified loading temperature or customer specification. There must be screen protection (or dome adapter with a filter vent) around the dome loading spout (or over the entire open hatch) if the trailer is bottom loaded. The temperature of the outgoing product shall be taken and recorded. The temperature probe used shall be calibrated on a predetermined schedule. Samples shall be taken during or after trailer loading. The retain sample shall be appropriately labeled to allow traceability. All access points, hose tubes and pump shall be sealed with identifiable cable seals. The seal numbers shall be recorded on the bill of lading.

Section 4 Shipping Documentation

The bill of lading shall be sent with outgoing shipments and should conform to DOT regulatory requirements and specific customer requirements. Other documents, such as the Certificate of Analysis and Wash Certificate, shall be sent if required by the customer.

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