

<b>Wisconsin Department of Agriculture, Trade and Consumer Protection</b> Division of Food and Recreational Safety Milk Certification Program	<b>REPORT OF CERTIFICATION</b> <i>(Fabrication of Single-Service Containers and/or Closures for Milk and/or Milk Products)</i>	FOR FDA USE ONLY				
		1	2	3	4	5

IDENTIFICATION

1. NAME OF SINGLE-SERVICE FABRICATING PLANT <b>ProAmpac</b>		2. CITY <b>Neenah</b>		3. STATE / COUNTRY <b>Wisconsin / USA</b>	
4. STREET <b>1055 Winchester Rd</b>		5. MFG. CODE NO <b>55- 4831</b>		6. CODE PRODUCT CODE      MATERIAL CODE	
7. AGENCY OR SSC, AS APPLICABLE, PROVIDING ROUTINE INSPECTION <b>N/A</b>		56 <b>4</b>	57 <b>8</b>	58 <b>3</b>	59 <b>1</b>
		60 <b>3</b>	61	62 <b>3</b>	
7.a. RATING/CERTIFICATION PERSONNEL <input type="checkbox"/> SHD <input type="checkbox"/> Other <input checked="" type="checkbox"/> SDA <input type="checkbox"/> TPC <input type="checkbox"/> SDL <input type="checkbox"/> SSC		7.b. DATE OF PLANT CERTIFICATION <b>12/17/2021</b>		7.d. EXPIRATION DATE* <b>12/16/22</b>	
7.c. SANITATION COMPLIANCE RATING <b>82</b>		MONTH      DAY      YEAR 67   68      69   70      72   72		PRODUCT CODE (60) 1. Containers 2. Closures 3. Other products 4. Containers and closures 5. Containers and other products 6. Closures and other products 7. Containers, closures and other products	
				MATERIAL CODE (62) 1. Metal 2. Paper (Includes laminates) 3. Plastic 4. Metal and paper 5. Metal and plastic 6. Paper and plastic 7. Metal, paper and plastic 8. Glass 9. Rubber 10. Paper, metal, plastic, and glass 11. Ceramic	

*EXPIRATION DATE Certification of single-service manufacturing plants may be valid for a period not to exceed one (1) or two (2) years from the earliest certification date. The expiration date is one (1) or two (2) years from the earliest certification date. <b>NOTE:</b> Certifications conducted by SSCs shall only be valid for a period not to exceed one (1) year from the earliest certification date.		8. SRO OR SSC <b>Robert Carrier</b>	
9. CERTIFICATION RECOMMENDED <input checked="" type="radio"/> YES <input type="radio"/> NO		9a. LISTING TYPE <input type="radio"/> FULL <input checked="" type="radio"/> PARTIAL	

LABORATORY CONTROL

10. NAME AND ADDRESS (OR CODE) OF APPROVED LABORATORY <b>N/A - Further Processed</b>	
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11. INSPECTION RESULTS (Place an "X" under Items debited)																										
1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c,f g,i,k	13 d,e, h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f	20 c,d,e	21	BACTI	COLI
			<b>X</b>							<b>X</b>		<b>X</b>			<b>X</b>		<b>X</b>	<b>X</b>								

12. PERMISSION TO PUBLISH	
<p>Permission is hereby granted to release and publish the above-stated certification for use by Regulatory/Rating Agencies and prospective purchasers.</p> <p>It is understood and agreed by the undersigned that the official Rating Agency or SSC, as applicable, may review and appraise the single-service fabricating plant at any time during the period of time the above certification is in effect. It is further understood that failure to maintain the above certification will subject this plant to withdrawal from the IMS Listing. We will notify the Rating Agency or SSC, as applicable, of any significant changes made in the operation of this plant. This would include, but not be limited to: changes in processing lines/equipment involved in processing IMS materials or changes to product types or materials manufactured.</p>	

12.a. NAME OF PLANT <b>ProAmpac</b>		12.b. PLANT REPRESENTATIVE AUTHORIZING RELEASE (Signature) 		12.c. TITLE <b>Greg Porter / Compliance Manager</b>	
13. SUBMISSION OF REPORT BY MILK SANITATION RATING AGENCY OR SSC, AS APPLICABLE					
13.a. DATE OF REPORT <b>12/21/2021</b>		13.b. RECOMMENDED CLASSIFICATION ACCEPTED <input checked="" type="radio"/> YES <input type="radio"/> NO		13.c. SUBMITTED BY (Signature and Title) <b>MSRO</b>	

FOR FDA USE ONLY	
13. DATE RECEIVED	15. PUBLICATION OF RATING RECOMMENDED <input type="radio"/> YES <input type="radio"/> NO      (If "NO", indicate why.)
16. DATE TRANSMITTED	17. SIGNATURE (FDA Regional Milk Specialist)

**NAME AND LOCATION OF PLANT**  
ProAmpac  
1055 Winchester Rd  
Neenah, WI 54956

<p><b>1. FLOORS</b>  Smooth; impervious; in good repair..... (a) _____  Joints between walls and floors tight; impervious..... (b) _____  Floor drains properly trapped; sloped to drain..... (c) _____</p> <p><b>2. WALLS AND CEILINGS</b>  In fabrication areas—smooth; cleanable; light-colored..... (a) _____  In fabrication and storage areas—good repair..... (b) _____  Openings in walls and ceilings effectively sealed..... (c) _____</p> <p><b>3. DOORS AND WINDOWS</b>  All outside openings protected against entrance of insects, rodents, dust, and airborne contamination..... (a) _____  Outer doors tight, self-closing..... (b) _____</p> <p><b>4. LIGHTING AND VENTILATION</b>  Adequate light in all rooms..... (a) _____  Ventilation sufficient..... (b) _____  Pressure ventilation systems properly filtered..... (c) <input checked="" type="checkbox"/></p> <p><b>5. SEPARATE ROOMS</b>  Fabrication areas separate from non-fabrication areas when required..... (a) _____  Regrinding plastic and paper trim shredding, packaging and baling conducted in separate room(s) from fabrication areas or as Appendix J permits..... (b) _____</p> <p><b>6. TOILET FACILITIES-SEWAGE DISPOSAL</b>  Disposal of sewage; other waste; in public sewage system or in compliance with Local and State Regulations..... (a) _____  All plumbing complies with Local and State plumbing Regulations..... (b) _____  Solid, tight-fitting, self-closing doors..... (c) _____  Toilet rooms and fixtures clean; in good repair..... (d) _____  Adequate light and ventilation; ducts vented to the outside..... (e) _____  Proper handwashing facilities..... (f) _____  Open windows effectively screened..... (g) _____  Employee handwashing signs posted..... (h) _____  Eating/food storage prohibited..... (i) _____</p> <p><b>7. WATER SUPPLY</b>  Safe; complies with bacteriological and construction requirements..... (a) _____  No direct or indirect connection between safe and unsafe water..... (b) _____  Sampled and examined as required..... (c) _____  Recirculated cooling water used in water baths complies with bacteriological standards, tested semi-annually..... (d) _____  Testing records maintained as required..... (e) _____</p> <p><b>8. HANDWASHING FACILITIES</b>  Hot and cold and/or warm running water, soap, individual towels or air dryers convenient to fabrication areas; covered trash containers when required; hand sanitizers used as Appendix J permits..... (a) _____  Handwashing facilities clean..... (b) _____</p> <p><b>9. PLANT CLEANLINESS</b>  Floors, walls, ceilings, overhead beams, fixtures, pipes and ducts clean in rooms as required..... (a) _____  Plant free of evidence of insects, rodents and birds..... (b) _____  Machines and appurtenances clean..... (c) _____</p>	<p><b>10. LOCKERS AND LUNCHROOMS</b>  Separate from plant operation; self-closing doors..... (a) _____  Eating/storage of food prohibited in fabrication and storage areas..... (b) _____  Locker and lunchrooms clean..... (c) _____  Cleanable trash containers provided; properly labeled, covered..... (d) _____  Handwashing facilities convenient..... (e) _____  Employee handwashing signs posted..... (f) _____</p> <p><b>11. DISPOSAL OF WASTES</b>  Stored in covered, impervious, leak-proof containers; does not apply to production scrap..... (a) <input checked="" type="checkbox"/>  Waste containers properly identified..... (b) _____  Storage of garbage/rubbish meets requirements..... (c) _____</p> <p><b>12. PERSONNEL - PRACTICES</b>  Hands washed as required..... (a) _____  Clean outer garments; hair restraints..... (b) _____  No person affected by disease in communicable form; while a carrier of such disease; or with inadequately protected wounds or lesions shall work in the fabrication areas..... (c) _____  Tobacco use in authorized areas only..... (d) _____  Unsecured jewelry not permitted in fabrication areas..... (e) _____</p> <p><b>13. PROTECTION FROM CONTAMINATION</b>  Product contact surfaces protected; all materials in process properly protected..... (a) <input checked="" type="checkbox"/>  Air under pressure directed at materials or product contact surfaces in compliance..... (b) _____  Air directed at materials or product contact surfaces by fans or blowers in compliance..... (c) _____  Pesticides approved; EPA registered..... (d) _____  Pesticides used in accordance with directions; precludes contamination of containers/closures..... (e) _____  Single-service articles in process protected from contamination..... (f) _____  Equipment cleaned after use of non-food-grade materials..... (g) _____  Cross contamination with non-food-grade material prevented..... (h) _____  No overcrowding of equipment and operations..... (i) _____  Toxic chemicals separated from raw materials and finished products..... (j) _____  Food containers manufactured by facility not used for storage of miscellaneous items or chemicals..... (k) _____</p> <p><b>14. STORAGE OF MATERIALS AND FINISHED PRODUCT</b>  Away from any wall; soiled outer turns or edges discarded..... (a) _____  Stored in clean, dry place, protected from splash, insects, and dust..... (b) _____  Containers and closures stored in original cartons and sealed until used; partially used cartons resealed during storage..... (c) _____  Containers for storage of resin, raw and reuse materials are covered, clean, impervious and properly identified..... (d) _____  In-process storage bins that touch the product contact surface constructed of cleanable, nonabsorbent material; clean..... (e) _____</p> <p><b>15. FABRICATING EQUIPMENT</b>  Contact surfaces clean; milk plant equipment utilized for preforming containers clean and sanitized prior to operation..... (a) _____</p>	<p>Makeshift devices not used; fasteners, guides, hangers, supports and baffles properly constructed; good repair..... (b) <input checked="" type="checkbox"/>  Take-off tables and other container contact surfaces properly constructed; clean; in good repair..... (c) _____  Grinders, shredders and similar equipment properly installed; protected from contamination..... (d) _____  Resin storage silos, other containers, constructed to protect resin from contamination; air vents filtered; air tubes good repair and properly protected..... (e) <input checked="" type="checkbox"/></p> <p><b>16. MATERIALS FOR CONSTRUCTION OF CONTAINERS AND/OR CLOSURES</b>  Materials from approved source..... (a) _____  Food-grade lubricants used on contact surfaces; stored to prevent cross contamination; storage clean and ventilated..... (b) <input checked="" type="checkbox"/>  Containers, closures or materials on floor not used..... (c) _____</p> <p><b>17. WAXES, ADHESIVES, SEALANTS, COATING AND INKS</b>  Handled and stored to prevent cross contamination with non-food-grade materials; storage areas clean and ventilated..... (a) <input checked="" type="checkbox"/>  Unused materials covered, labeled and properly stored..... (b) _____  Nontoxic; imparts no flavor or odor; non-contaminating; complies with 21 CFR Parts 174-178..... (c) _____  Transfer containers clean; covered, properly identified..... (d) _____  Waxing, when used, performed as required; wax kept at proper temperature..... (e) _____</p> <p><b>18. HANDLING OF CONTAINERS, CLOSURES AND EQUIPMENT</b>  Handling of container and closure surfaces minimized..... (a) _____  Hands sanitized frequently or clean, single-use gloves worn; sanitizing dispensers convenient..... (b) _____</p> <p><b>19. WRAPPING AND SHIPPING</b>  Single-service articles properly containerized prior to shipping..... (a) _____  Packaged contents protected from contamination..... (b) _____  Transportation vehicles clean; in good repair; not used for unapproved uses..... (c) _____  Paperboard containers, wrappers and dividers not reused..... (d) _____  Packaging materials in compliance..... (e) _____</p> <p><b>20. IDENTIFICATION AND RECORDS</b>  Plant identification on outer wrapping as required..... (a) _____  Glass containers properly labeled..... (b) _____  Required bacteriological tests on file; maintained as required; and in compliance..... (c) _____  Required bacteriological and chemical test records for all component parts used in final assembled product on file..... (d) _____  Information on file from suppliers of raw materials, waxes, adhesives, sealants, coatings and inks indicating compliance..... (e) _____  Information on file from suppliers of packaging materials indicating compliance..... (f) _____</p> <p><b>21. SURROUNDINGS</b>  Surroundings neat and clean and free of breeding areas, conditions attracting or harboring flies, insects or rodents..... (a) _____  Driveways graded; no standing water..... (b) _____</p>
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**REMARKS** (If additional space is required, please place information on the back of this Form or on a separate page.)  
See attached narrative report.

<b>DATE</b> 12/17/2021	<b>SANITARIAN/SRO/SSC/RMS</b> Robert Carrier
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**NOTE:** This Form has been developed for use with Appendix J of the *Grade "A" Pasteurized Milk Ordinance*.

## IMS SINGLE-SERVICE SURVEY

**PLANT NAME:** ProAmpac

**PLANT #:** 55-4831

**DATE:** December 17, 2021

A routine Interstate Milk Shippers (IMS) survey was conducted at this Single Service Manufacturing plant to determine compliance with the requirements of Appendix J of the Pasteurized Milk Ordinance (PMO). This survey was conducted by Robert Carrier, WDATCP Milk Sanitation Rating Officer. Plant personnel accompanying this survey was Compliance Manager Greg Porter.

ProAmpac is a plastic film extrusion laminating and slitting facility with a Partial plant listing for IMS related products. Processing lines included in this plant's partial listing are: Extruder1 and Winder 1.

The following violations were noted during the course of the survey.

### **A. DEBITED VIOLATIONS:**

#### **4c. Pressure ventilation systems properly filtered (2 Points)**

The two small make-up air units that bring outside air into the air handling mezzanine adjacent to the main extrusion laminating processing room of the plant are not equipped with filters. The intake of all pressure ventilation systems in fabricating areas, whether they are positive or exhaust shall be properly filtered.

#### **11a. Disposal of Wastes (2 Points)**

Several general waste containers in the plant are not covered. All refuse and garbage shall be stored in covered, impervious and leak-proof containers, except for containers designated only to the collection of production scrap. Note: Production scrap is material which remains from the manufacture of single-service containers or closures, that has been handled or treated in such a manner that it does not comply with the definition for "broke and trim" or "regrind", but may be collected for recycling. It may contain material such as containers, closures or trim that have fallen on the floor.

#### **13a. Product contact surfaces protected; all materials in process properly protected (3 Points)**

Several of the walkway cross-over platforms above the web path of Extrusion Laminator 1 have trap doors and open seams in them. The inside ledge of the trap doors and open seams in the deck plates are directly above the web path with no suitable protection in place whereby dirt and other contaminants will fall directly onto in-process materials below.

#### **15b+e. Fabricating Equipment (5 Points)**

##### **b. Makeshift devices not used; fasteners, guides, hangers, supports and baffles properly constructed; good repair**

A black fibrous friction material is wrapped around the break bars at the splicing station on the infeed to Winder 1. Visible threads are coming loose from this material. In addition, the overwrapping creates crevices that are not smooth, impervious and cleanable. All fasteners, guides, hangers, supports and baffles shall be constructed of impervious, cleanable materials and kept in good repair.

There is an unused break bar that is covered with a cork material and tape that is in, but not in contact with, the web path on the infeed to Winder 1. Cork is not an impervious, cleanable material. Tape is a non-sanitary makeshift material. Neither of which are acceptable for use on fabricating equipment.

e. Resin storage silos, other containers, constructed to protect resin from contamination; air vents filtered; air tubes good repair and properly protected

Some of the Gaylord box resin unloading hoses for Extruder 1 have duct tape wrapped around the end of the hoses near the unloading wand.

Some of the covers on in-use Gaylord boxes of resin for Extruder 1 have holes cut in them or are positioned offset from the box to accommodate the unloading hose and wand. These holes and open gaps do not provide adequate overhead protection from contamination to the resin in the boxes.

Several resin handling hoses in the Extruder 1 resin handling area were uncapped and/or stored on the floor while disconnected and not in use.

The caps used for resin lines and hoses for Extruder 1 are not tethered and many of them are stored on the floor. Air tubes used to convey resin shall have end caps, attached by a chain or cable that prevents contamination.

The resin feed hoppers for the extruders on Laminator 1 and Laminator 2 of Extruder 1 have small covers that rest on the flush openings (with no raised lip) of the top surface of the hopper and do not fit tight when closed. As such, they do not effectively prevent external contamination from migrating into the opening and falling into the resin below.

16b. Food-grade lubricants used on contact surfaces; stored to prevent cross contamination; storage clean and ventilated (3 Points)

Containers of food-grade grease are stored on an absorbent pad, which has visible oil residue on it, in the non-food-grade storage cabinet along with other non-food grade lubricants. Food-grade lubricants shall be handled and stored in a manner that shall prevent cross contamination with non-food-grade lubricants.

Pails of food-grade oils are stored directly beneath pails of non-food-grade oils on the racking in the maintenance supply area. There is visible spilled oil on external surfaces of several of these pails.

17a. Waxes, Adhesives, Sealants, Coatings and Inks (3 Points)

The cover of the primer tank for the first coater on the Extruder 1 line was left standing open and unprotected while in operation. An accumulation of dried primer and other unclean conditions exists in the vicinity of this tank. Waxes, adhesives, sealants, coatings and inks used for containers and/or closures shall be handled and stored in a manner that shall prevent cross contamination with similar non-food-grade materials.

**B. NON-DEBITED VIOLATIONS:**

9a. Plant Cleanliness

There is an accumulation of dirt, debris, and scrap material on the floor in multiple areas near and beneath Extruder 1. The floors, walls, ceilings, overhead beams, fixtures, pipes and ducts of production, storage, regrind, baling and compacting rooms shall be clean.

**C. NOTES:**

The thin gauge flexible plastic film produced under this plant's IMS listing is a 3 layer laminated structure that is used as the product contact sealant layer in the further construction/processing of end cap closures utilized on single service canister type containers. The film produced here is packaged in roll-stock form and is utilized in further manufacturing operations at another IMS listed plant.

Sani-Wipes are used as the final cleaner/sanitizer on product contact surfaces of equipment. This product is an EPA registered sanitizer and is a no-rinse sanitizer only requiring air dry before next use on product contact surfaces.

Resin for the laminating process is received in Gaylord boxes. This resin forms the product contact layer on both sides of the 3 layer laminated film structure. The manufacturer's certification letter for this Marlex 1017 LDPE resin is maintained on file at this plant and states conformity to 21 CFR 177.1520(c)2.2 when used in accordance with Table 1 of 21 CFR 176.170(c) and Table 2 of 176.170(c).

The middle PET layer of the 3 layer laminated film structure does not make contact with product or the product contact surface of the film structure. This middle layer sourced from Kolon Industries of Korea, which is not an IMS listed plant. This plant maintains certification documentation on file from the manufacturer of the film that the materials utilized in the film complies with 21 CFR 177.1630(f),(g).

Regrind is not used in the manufacture of IMS single service products at this plant.

A PEI primer A131X is used as part of the extrusion laminating process. This primer does not meet the specifications of 21 CFR 174-178. Therefore, this plant commissioned a migration study on 7/29/2015 which indicates that none of the components of the primer migrated through the 1017 LDPE layer establishing that layer as a functional barrier. The migration study tested for any detectable components of the primer on the external surface of the film and was conducted using the same film structure specifications that are utilized for the IMS listed film processed at this plant: 1 mil 1017 LDPE extruded layer, primer, 4 mil PET layer, primer, 1 mil 1017 LDPE extruded layer.

Resin silos are not utilized for the storage of resins used in the manufacture of IMS related products at this plant.

Fan blown air (<15 PSI) in contact with in-process materials takes place at the turn bars in the Extrusion Laminator 1 processing line. The air intake for this fan blown air application is equipped with an air filter manufactured by Endustria Filter Manufacturers, Inc. which is rated 98% efficient at 10 microns. PMO Appendix H requirements for fan blown air specifies, "Intake air filter efficiency shall be at least 98% SAE J726, June 1987 using Air Cleaner (AC) coarse test dust" which correlates to the modern ISO 5011 standard of 20-120 micron test particles removed at a rate of 98%.

Compressed air ( $\geq 15$  PSI) in contact with in-process materials take place at the curing sections of the Extrusion Laminator 1 processing line. A PCH High Efficiency Coalescing Filter is in place to remove moisture from the air supply piping downstream from the compressor. The final filter on the compressed air lines located near the point of application is rated to effectively remove particulates down to 0.01 of a micron. PMO Appendix H requirements for compressed air directed at in-process materials specifies, "Final filter efficiency shall be at least 99% as measured by the Dioctylphthalate Fog Method (DOP) test (with a mean particle diameter of 0.3 microns)" which correlates to the modern HEPA standard of 99% efficiency for a 0.3 micron particle size.

No processing aids are used on product or product contact surfaces of fabricating equipment in conjunction with IMS listed manufacturing operations at this plant.

Bacteriological testing of the plastic film manufactured here is not required by PMO Appendix J as this plant is not the final producer of the single service container/closure.

The stretch wrap overwrap material used over rolls of work in progress product is obtained from Berry Plastics of Evansville, IN and has a letter of guarantee that the material complies with 21 CFR 174.5,

in Green Bay, WI on an annual basis as a means to confirm compliance with PMO Appendix J, Section C bacteriological requirements. The most recent set of samples were submitted for analysis on 12/9/2020 and yielded compliant results.

The Clear Pro HL-200 Star Seal IC bags used over rolls of finished product is obtained from BMSI of Monroe, GA and has a letter of guarantee that the material complies with 21 CFR 177.1520. Documentation is on file in the form of a laboratory test report dated 10/15/2020 from Summit Laboratories of Grand Rapids, MI indicating an APC of  $<10 / 50 \text{ cm}^2$  to confirm compliance with PMO Appendix J, Section C bacteriological requirements.

Food grade lubricants, which are NSF H1 listed, are used in applications where incidental contact with product or product contact surfaces may occur on the IMS listed processing lines at this plant. These lubricants are stored in cabinets and racking in the maintenance supply storage area of the plant.

Outside make-up air for production areas of the plant is supplied via air handling equipment located on the utility mezzanine adjacent to the extrusion laminating processing room of the plant. The two smaller make-up air handling units that bring outside air into this mezzanine area (which opens directly into the processing room) are not currently equipped with intake air filters as mentioned above in this survey report.

Water for the plant is supplied by the Town of Neenah municipal water supply system.

There are no direct water bath cooling water applications utilized in conjunction with IMS listed processing operations at this plant. Recirculated cooling water is only utilized in thick walled chill rolls as part of processing operations at this plant.

There are 4 RPZ cross-connection control device(s) in place on the water distribution system in the plant that are regulated by the State's water control authority (DSPS) and were last inspected on 7/20/2021.

In general this is an under-one-roof facility with the following primary rooms: processing room including IMS extrusion laminating line and other non-IMS processing equipment, a maintenance room, a receiving dock and warehouse, and a winder/slitter processing room which also includes warehousing areas and the shipping dock. The non-production areas were found to be adequately cleaned and maintained to production room standards. Separate rooms for the office and break room facilities also exist at this plant.

Pest control services are provided by Valley Pest Control with routine service on a weekly basis. Pest control service records are maintained on file at this plant. No indications of pest activity were observed at the time of this plant survey.

There are no offsite storage facilities utilized in conjunction with products processed at this plant.

The label applied to the outer wrap and inside the core of roll stock film prior to shipment out of this plant is properly labeled including the plant name "ProAmpac", city "Neenah", and state "WI" along with other material and production information.

#### **D. REQUIRED DOCUMENTATION:**

*The following documentation is required. It is recommended that documentation supporting these items be maintained as applicable in an IMS binder to facilitate future IMS surveys.*

1. Only resin in compliance with applicable sections of 21 CFR, Parts 174 – 178 may be used to produce IMS single-service items. Component materials and component parts must be manufactured in an IMS listed facility. Documentation, in the form of letters of guarantee, must be available at the plant.

2. Line cleaning and / or sanitization procedures (written SOP) after maintenance, after cleaning with non-food grade cleaners or after producing non-IMS product.
3. Pest control records.
4. Annual Cross Connection Control Performance Tests for testable backflow protection devices.
5. Verification letters indicating that waxes, adhesives, sealants, coatings, and inks meet the applicable requirements of 21 CFR, Sections 174–178.
6. Verification that materials, which do not meet the applicable requirements of 21 CFR, Parts 174–178, are not applied to, come into contact with, or migrate to a product contact surface or incidental product contact surface of a finished product. Migration testing may be utilized to establish that a functional barrier is present or that there is no set-off of lacquer / coating components when in rollstock or nested-container form.
7. Documentation that wraps and liners meet the applicable sections of 21 CFR, Sections 174 – 178 and the bacteriological testing criteria listed in Appendix J, Section C (minimum annual test).
8. Bacteriological product testing results (refer to PMO Appendix J, Section C), performed in an IMS listed laboratory, when applicable.
9. Compressed and fan blown air filter efficiency documentation, when applicable (refer to PMO Appendix H, Section II – Air Under Pressure – Filter Performance).
10. Private well water supply and recirculated cooling water bath bacteriological test results, when applicable.
11. Documentation that glycol is food grade or USP, if used as a cooling medium in a thin-walled heat exchanger or in a recirculated water bath.
12. Air intake systems for production areas and resin silos must be filtered and inspected. If the plant has a safety policy that precludes access to these areas an alternate approach may be utilized. On the day of the survey, plant personnel may take photos of silo intake filters and final filter banks for production area HVAC units. In addition, a HVAC filter change log which identifies the specific filters, the date(s) changed and the condition of the filter(s) should be maintained.

#### **E. CONCLUSION:**

Based upon a passing score of 82 it will be recommended that this plant continue to be included on the IMS List as a certified supplier of single service product(s). The findings of this survey were discussed with plant management at the conclusion of the plant visit. If you have questions or concerns pertaining to this survey, feel free to contact me at [Robert.Carrier@Wisconsin.gov](mailto:Robert.Carrier@Wisconsin.gov) or (608)-206-9172.

U.S. Department of Health and Human Services  
 Food and Drug Administration  
**STATUS OF MANUFACTURING PLANTS**  
 (SINGLE-SERVICE CONTAINERS AND/OR CLOSURES FOR MILK AND/OR MILK PRODUCTS)

Plant ProAmpac  
 Number 55-4831  
 Date of Certification 12/17/2021

Sanitation Compliance Rating<sup>1</sup> 82

NAME OF PLANT	ITEMS OF SANITATION																				REMARKS							
	Floors	Walls and Ceilings	Doors and Windows	Lighting and Ventilation	Separate Rooms	Toilet/Facilities- Sewage Disposal	Water Supply	Handwashing Facilities	Plant Cleanliness	Lockers and Lunchrooms	Disposal of Wastes	Personnel - Practices	Protection From Contamination	Storage of Materials and Finished Product	Fabrication Equipment	Materials for Construction of Containers and/or Closures	Waxes, Adhesives, Sealants, Coating and Inks	Handling of Containers, Closures and Equipment	Wrapping and Shipping	Identification and Records		Surroundings	Bacterial Count*	Coliform Count*	Total Debits <sup>2</sup>			
ITEM	1	2	3	4	5	6	7	8	9	10	11	12	13 a,b,c, f,g,i,k	13 d,e,h,j	14	15	16 a	16 b,c	17 a,b, d,e	17 c	18	19	20 a,b,f	20 c,d,e	21			
WEIGHT	1	1	2	2	3	3	4	2	3	2	2	3	3	11	3	5	11	3	3	11	2	4	3	11	2	5	10	
ProAmpac				2							2		3		5		3	3										18
<b>TOTALS</b>				2							2		3		5		3	3										18

Footnotes:  
<sup>1</sup>Sanitation Compliance Rating = 100 – Total Debits  
<sup>2</sup>Total Debits for each manufacturing plant are the sum of the weights of the Items violated. (NOTE: Any Item or sub-item violated, indicate by placing the debit value (weight) of that Item or an "X" under that Item.)  
<sup>\*</sup>Used only when not in compliance.