

VISTA ABERDEEN
GOOD MANUFACTURING PRACTICES MANUAL
FOR RESIN
FEBRUARY 10, 1993

TABLE OF CONTENTS

	<u>Page Numbers</u>
Administrative	1
Incoming Raw Materials	2
Manufacturing/Reaction	3
Post-Reaction	4
Storage/Packaging	6
Shipping	8

The Vista Aberdeen Resin Good Manufacturing Practices Manual is a guide that outlines the commitment by Vista and the Aberdeen Plant to produce a resin for use in indirect food contact applications, hereafter referred to as Indirect Food Contact or IFC resins. The following pages will focus on the methods and procedures used by our Vinyl Department to consistently produce this resin.

A

VISTA ABERDEEN RESIN
GOOD MANUFACTURING PRACTICES MANUAL

Administrative

Vinyl plant personnel are taught the basic need of producing IFC (Indirect Food Contact) resins. All resins in specification will be IFC resins. Specialized training is also given to individuals by job requirement. Training and testing assures that each individual understands the special attention required to produce IFC resin.

The Vinyl Operations Superintendent or designee and the Chief Plant Chemist or designee will coordinate the Vinyl Department's GMP effort. They ensure that new raw materials or raw material suppliers are checked for Indirect Food Contact acceptability and make process and procedural changes to prevent adulteration of IFC resins.

Each shift is responsible for recording the reactor number, batch number, time, and product of each batch produced. The resin formula selected by the operator will automatically feed the ingredients in the predetermined amounts. Each shift must maintain the quality of the resin and will segregate non-IFC resin from IFC resin.

Resin production is continuously monitored for abnormal conditions. Data is collected throughout the manufacturing process. This data serves as an audit trail and production history report for future troubleshooting. The data collected includes the following:

Reactor No.	Batch No.	Recipe Charge Quantities
Run Temperatures/pressures	Run time	Blend No.
Blend tank No.	Dryer No.	Silo No.
Dates of Operation	Railcar No.	

All recipe changes are reviewed by the Shift Supervisor to assure that only technically necessary amounts of raw materials are used.

All product changes are reviewed by the Vinyl Operations Superintendent or designee.

Periodic audits of the plant's IFC resin program will be completed by the environmental and legal departments. These audits will check the effectiveness of our good manufacturing practices.

A

VISTA ABERDEEN RESIN
GOOD MANUFACTURING PRACTICES MANUAL

Incoming Raw Materials

We rely on our suppliers to provide consistent quality raw materials. The lab reviews the raw material quality specifications using written specifications, quality spot checks, or suppliers' certificates of analysis. Our suppliers' certificates of analysis are filed by the plant chemist.

Only approved suppliers and raw materials are used in our products. New suppliers and raw materials are verified as FDA acceptable prior to use in the plant by vendor guarantee (e.g., our initiator supplier guarantees a FDA acceptable raw material) or testing (e.g., suspending agent concentrations are tested prior to use in IFC resins.) Whenever required for testing the resin made with the raw material will be segregated and held separately until IFC status is determined.

We require that all raw materials be clearly labeled prior to acceptance or use. It is the supplier's responsibility to label all material in a clear and appropriate manner as required by Federal law. Those materials unmarked or believed to be adulterated will be tested for identification and disposed of if identification is not possible. If a raw material is erroneously used, the process will be tested to review FDA status concerns. Products made outside normal recipe concentration ranges are reviewed by the shift supervisor, operations engineer, or the operations superintendent and laboratory personnel to decide the product disposition. Any non-IFC resin will be segregated.

A

VISTA ABERDEEN RESIN
GOOD MANUFACTURING PRACTICES MANUAL

Manufacturing/Reaction

To insure that we produce the IFC resin we intend to produce in our reactors, Vista:

1. Uses specific formulas for each product.
2. Tests the process continuously.
3. Reviews formula changes outside normal ranges.
4. Documents run conditions and audits trial runs.

Reactor charging is performed automatically by the supervisory control system using recipe information stored on a data base contained in the computer. Operators are responsible for monitoring to ensure the charge recipe is accurately followed by checking that the correct amounts are charged. Operators also record the charged amounts. Dual meters are used to measure the charge quantities to ensure accuracy.

Finished resin is sampled and tested at several points in the process: this includes reactor slurries, hourly dryer samples, and railcar samples. If the tested material is out of specification, it is segregated and an investigation is initiated to correct the problem. Resin that is not IFC resin is sold to non-IFC customers.

Some means of detecting charge errors are:

1. Charge tank level
2. Reactor pressure
3. Finished product testing
4. Statistical Process Control charts
5. Other measures

Other measures include:

1. Cooling water leaks to the reactor can be detected by level changes, pressure differences, coarse resin production, and occasionally reactor foaming. Resin that may be adulterated is tested and determined to be IFC resin or not.
2. Reactor cleaning agent leaks can be detected by resin specifications, VCM readings, and the system alarms. Resin testing will determine the status of the resin.
3. Steam problems are typically noted through unusual reactor temperatures. Steam also affects resin properties and testing will reveal steam difficulties.

A

VISTA ABERDEEN RESIN
GOOD MANUFACTURING PRACTICES MANUAL

Post Reaction

Final RVCM values for shipped products are accomplished through four steps:

1. Reactor stripping
2. Blend tank aeration
3. Resin drying (rates and temperature)
4. Silo aeration for particular resins

The reactor stripping procedure requires a reactor to be stripped to a specific temperature and held at that temperature for a set time to meet governmental standards. The stripping data is recorded on charts and reactor sheets. During the dump of each batch, residual VCM samples are caught and analyzed. If residual VCM values become abnormally high, the reactor process is investigated and changed accordingly.

Residual VCM is reduced further to levels suitable for an IFC customer through blend tank and silo aeration and drying. In the slurry blend tanks the solids are purged with air which also reduces residual VCM levels. Residual VCM is greatly reduced in the dryers. The combination of air and heat drives much of the VCM from the resin. Residual VCM testing on the dryers is performed on a regular basis. All railcars, trucks, and bag lots are tested prior to leaving the plant. High residual VCM product is sold as non-IFC resin.

To ensure unadulterated or noncontaminated resin, dryer samples are caught every hour to two hours. Two stage inlet air filters have been installed on the dryers to catch possible contaminants in the air and prevent adulterating the resin. The dryer, normally cleaned on a regular basis, will be shut down and cleaned if high contamination occurs. If contamination is still a problem, slurry samples are caught and tested. A contaminated blend tank will be dried out and washed. The contaminated resin will be dried as non-IFC resin.

As coordinators, the Vinyl Superintendent or his designee and the Chief Plant Chemist or his designee must check all post-reaction additives for FDA status. The additives must not result in non-IFC resin. Lab tests will verify all resin product specifications.

Calibrated meters, double metering systems, and level gages provide methods to assure the correct amounts are added to the resin.

Kill agents are measured in a funnel or metering system. The kill amounts are recorded on the batch sheets.

A

VISTA ABERDEEN RESIN
GOOD MANUFACTURING PRACTICES MANUAL

Post Reaction(continued)

Hydroquinone in excess quantities will be detected by process testing. Any material with more than the technically required amount of hydroquinone will be sold as non-IFC resin.

Lead is not in contact with IFC resin. The Vinyl Department has no lead in the area.

A

VISTA ABERDEEN RESIN
GOOD MANUFACTURING PRACTICES MANUAL

Storage/Packaging

Truck and railcar heels are vacuumed and/or washed and the compartments visually inspected prior to loading. Pond resin, debox, dryblend, and compound railcars are appropriately cleaned before being used in prime resin service. Prime resin is loaded in dedicated railcars. Particular cars are designated as IFC resin cars. If a car contains an unusually large heel, the heel material is identified so IFC resin will not be shipped in a non-IFC railcar.

The silos are clearly identified and the fill transfer lines appropriately marked to reduce the potential for mixing of non-IFC resin and IFC resin. When transfer lines are switched the panel operator informs the "A" Operator of the switch and the "A" Operator verifies the dryer, silo, and product numbers. If mixing of non-IFC and IFC resin does occur the resin will be sold as non-IFC resin.

Each operator logs the correct product, time, and reactor for correct lab analysis. The operator initials those samples he has logged in. Any material found to be off-specification is resampled and retested to verify the results. The lab double checks residual VCM log-ins for any clerical errors.

The Yard Operators are responsible for loading the correct product in railcars and trucks. The Yard Operators check the daily report prior to loading to verify the product type in each silo. Products are loaded out of clearly identified silos and the load time, product, amount, and silo are recorded on a load sheet.

Non-IFC resin is segregated as one of the following:

1. Debox material
2. Pond resin
3. Sifter overflow
4. Culls
5. Start-up material
6. Laboratory sample remnants

Material that has been tested as non-prime becomes Debox material. Debox material is sent to a silo designated for non-IFC customers. Once a product has been tested and retested as off specification, the Panel Operator and "A" Operator switch transfer and possibly slurry lines so Debox (non-IFC) material will not contaminate IFC resin. A variety of process changes are made to get back to IFC resin, such as dryer cleaning, reactor hydroblasting and drilling, and blend tank cleaning. The process is continuously sampled and when material is back into specification, the switch back to IFC resin specified silos is made.

A

VISTA ABERDEEN RESIN
GOOD MANUFACTURING PRACTICES MANUAL

Storage/Packaging (continued)

Pond resin is resin that settles out in our resin settling basins. This contaminated resin is dried in a completely separate system and building than IFC resin. There is a specific blend tank, dryer, transfer system, and silo for pond resin so this material will not adulterate IFC resin.

Sifter overflow is typically oversized particles or statically charged material from the dryer outlet. Sifter overflow is either boxed in gaylords with large labels identifying it as sifter overflow or it is reworked into non-IFC Debox material.

Culls material is large chunks of resin removed by the reactor dump screener. This material is sold as non-IFC resin. The culls are stored in super sacks and a dumpster and never come in contact with IFC resin.

Start-up material is resin dried as a dryer is started up. The resin is segregated and sold as non-IFC resin.

Laboratory sample remnants are mixed and sold to non-IFC customers as Debox material.

The only resin packaging operation in the compound area is the bagging operation. Resin is occasionally bagged in 50-pound bags. The entire system is separate from the compound system. The operation is a closed system and there is no contact with possible compound additives.

All railcars and bulk trucks for resin shipment are loaded in a different area than compound railcars and trucks. The railcars, trucks, and silos are clearly labeled and load sheets are filled out on each shipment.

All non-IFC products are clearly labeled. Debox material is shipped as Debox and not an IFC resin. Pond resin is shipped as pond resin and not as IFC resin. Sifter overflow that is boxed in gaylords is labelled with stickers on all four sides indicating "Sifter Overflow". Culls are stored in supersacks and a dumpster. These supersacks are the only type in the plant and the sack and PVC label identify the culls.

VISTA ABERDEEN RESIN
GOOD MANUFACTURING PRACTICES MANUAL

Shipping

IFC resin is shipped in the following containers:

1. Bags
2. Trucks
3. Railcars

All bags used for resin are previously unused plastic lined bags. These bags are labeled clearly as resin. The Shift Supervisor or Chief Lead Operator is responsible for checking the bagging procedure on his shift to ensure the right product is being bagged and clearly labelled.

All railcar heels are vacuumed and some washed prior to a visual inspection. All trucks are visually inspected prior to loading. The yard operators are responsible for railcar and truck inspection. If the railcar or truck is not clean it will be washed out and air dried before loading.

All non-IFC resin is segregated prior to loading or bagging. All railcars, trucks, and bagged skids are tested prior to shipment. If the material is non-IFC, it is offloaded from the railcar or truck and sold as Debox or downgraded. Any bagged material that is tested as non-IFC is processed through the Debox system as is any broken bag material.

All railcar, truck, and bag shipments are visually inspected prior to shipment. Railcars and trucks are sealed with Vista seals that must be cut to remove. All bag shipments are stacked according to skid stacking procedures or customer preference.