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Vista Chemical Company

900 Threadneedle
Houston, Texas 77079
(713) 588-3000

P.O. Box 19029
Houston, Texas 77224
Fax (713) 588-3236

February 23, 1990

VISTA

Food and Drug Administration
Center for Drugs and Biologics
Central Document Room
12420 Parklawn Drive
Room 2-14
Rockville, MD 20852
Attention: Allen Beadle

RE: DMF 6151

Dear Mr. Beadle:

Attached is a modified Drug Master File (DMF6151) for Vista Chemical Company polyvinyl chloride (PVC) resins. This modification adds another resin type to Vista's slate of PVC products. It also establishes lower limits for several ingredients at 0.0%. The home office address and reference authorization list has also been updated.

Should any questions arise in connection with this matter, please contact me directly. My phone number is (713)588-3446.

Sincerely,

J. C. Ledvina

J. C. Ledvina
Director, Environmental Activities

dlj

Attachments

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VISTA CHEMICAL COMPANY

DRUG MASTER FILE

FOR

POLYVINYL CHLORIDE PRODUCTS

DMF 6151

January 31, 1990

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ADDRESS LIST

1. Manufacturing Facility Addresses:

   Vista Chemical Company
   Oklahoma City, Oklahoma

   Vista Chemical Company
   Aberdeen, Mississippi

2. Address Correspondence To:

   Joseph C. Ledvina
   Vista Chemical Company
   900 Threadneedle
   Houston, Texas 77079

3. Home Address:

   Vista Chemical Company
   900 Threadneedle
   Houston, Texas 77079

4. Name and Title of Individual Addresses:

   Joseph C. Ledvina
   Director of Environmental Activities

5. Holder of Drug Master File:

   Vista Chemical Company

REFERENCE AUTHORIZATION

The following persons are authorized by Vista Chemical Company to refer the Food and Drug Administration to this Drug Master File in conjunction with the review of new drug applications or other FDA drug approval processes.

1. American Mirrex
2. Klockner-Pentaplast of America, Inc.
3. Nibco

Joseph C. Ledvina
Director of Environmental Activities

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VISTA PVC 5265 RESIN

Confidential Product Formulation

1.	Polyvinyl chloride homopolymer	99.84 to 99.97%
2.	Glycerol Monostearate (21 C.F.R. 182.1324)	0.00 to 0.1%
	OR	
	Calcium Stearate (21 C.F.R. 184.1229)	0.0 to 0.5%
3.	Butylated hydroxytoluene (21 C.F.R. 181.24)	0.0 to 0.15%
	OR	
	ISONOX 132	0.0 to 0.18%

at least:
95% 2,6,-di-tert-butyl 4-secondary butyl phenol
1-2% 2,4,6,tri-tertbutyl phenol
1-2% 2,4, di-tert butyl 6-secondary butyl phenol
1-2% di-butyl phenol
[See attached reference 1]

Description

Vista 5265 PVC resin is a general purpose, low molecular weight PVC homopolymer for use primarily in injection molding processes where low melt viscosity and good physical properties are required.

Applications

Vista 5265 PVC resin is designed to provide an optimum balance between ease of processing and excellent physical properties. It can be used to replace general purpose PVC resin of higher molecular weight to increase productivity and gain processing latitude with minimal reduction of physical properties.

The low melt viscosity of Vista 5265 PVC resin makes it ideally suited for injection molding applications. The molecular weight is such that it can be used to formulate Type I and Type II rigid injection molding compounds. Eliminating the costly pelletizing step and the associated heat history results in a less expensive, more consistent product.

The excellent heat stability and low melt viscosity of Vista 5265 PVC resin has resulted in wide acceptance for rigid and cellular profile extrusion and vacuum formable sheeting.

Properties	Typical
ASTM D 1755 Classification	GP-1-16000
Specific Viscosity (0.4 g in 100 ml Nitrobenzene at 25° C)	0.26
Inherent Viscosity ASTM D 1234-66T (Method A)	0.68
Bulk Density	
(g/cc)	0.55
(lb/cu ft)	34.3
Volatiles, %	0.3
Particle Size	
% on 40 Mesh	nil
% through 200 Mesh	<5

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VISTA PVC 5305 RESIN

Confidential Product Formulation

1.	Polyvinyl chloride homopolymer	99.84	to 99.979%
2.	Glycerol Monostearate (21 C.F.R. 182.132)	0.00	to 0.1%
	OR		
	Calcium Stearate (21 C.F.R. 184.1229)	0.0	to 0.05%
3.	Butylated hydroxytoluene (21 C.F.R. 181.24)	0.0	to 0.15%
	OR		
	ISONOX 132	0.01	to 0.18%

at least:
95% 2,6,-di-tert-butyl 4-secondary butyl phenol
1-2% 2,4,6,tri-tertbutyl phenol
1-2% 2,4, di-tert butyl 6-secondary butyl phenol
1-2% di-butyl phenol
[See attached reference 1]

Description

Vista 5305 PVC resin is a general purpose, low molecular weight PVC homopolymer for use in calendering, extrusion and injection molding processes where low melt viscosity and good physical properties are required.

Applications

Vista 5305 PVC resin is designed to provide an optimum balance between ease of processing and excellent physical properties. It can be used to replace general purpose PVC resin of higher molecular weight to increase productivity and gain processing latitude with minimal reduction of physical properties.

The low melt viscosity of Vista 5305 PVC resin makes it ideally suited for injection molding applications. The molecular weight is such that it can be used to formulate Type I and Type II rigid injection molding compounds with minimum quantities of expensive processing aids and impact modifiers. This eliminates the dusting problems traditionally associated with these micro ingredients, thereby allowing the use of dryblends. Eliminating the costly pelletizing step and the associated heat history results in a less expensive, more consistent product.

The excellent heat stability and low melt viscosity of Vista 5305 PVC resin has resulted in wide acceptance for rigid and cellular profile extrusion. In some instances, it can be compounded into an acceptable replacement for more expensive copolymer formulations.

Properties	Typical
ASTM D 1755 Classification	GP-2-16000
Specific Viscosity (0.4 g in 100 ml Nitrobenzene at 25° C)	0.30
Inherent Viscosity ASTM D 1243-66T (Method A)	0.74
Bulk Density	
(g/cc)	0.535
(lb/cu ft)	36
Volatiles, %	0.3
Particle Size	
% on 40 Mesh	nil
% through 200 Mesh	<5

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VISTA PVC 5385 RESIN

Confidential Product Formulation

1.	Polyvinyl chloride homopolymer	99.835 to 99.989%
2.	Calcium Stearate (21 C.F.R. 184.1229)	0.0 to 0.5%
3.	Butylated hydroxytoluene (21 C.F.R. 181.24)	0.0 to 0.15%

OR

ISONOX 132 — 0.0 to 0.18%
at least:
95% 2,6,-di-tert-butyl 4-secondary butyl phenol
1-2% 2,4,6,tri-tertbutyl phenol
1-2% 2,4, di-tert butyl 6-secondary butyl phenol
1-2% di-butyl phenol
[See attached reference 1]

Description

Vista 5385 PVC resin can be used in either extrusion, calendering or injection molding processes for rigid and flexible products.

Applications

Vista 5385 PVC resin is a versatile resin that can be used for many diverse rigid and flexible applications.

Its excellent heat stability, consistency and processing characteristics are ideal for rigid applications such as PVC pipe, siding and other profiles. These properties allow the production of high quality end products at high production rates.

The low gel content, uniform absorption of plasticizer, and high clarity make Vista 5385 resin an ideal choice for flexible applications involving calendering, extrusion or injection molding.

5385

Properties	Typical
ASTM D 1755 Classification	GP-4-16000
Specific Viscosity (0.4 g in 100 ml Nitrobenzene at 25° C)	0.37
Inherent Viscosity ASTM D 1243-58T (Method A	0.92
Bulk Density g/cc	0.545
(lb/cu ft)	34
Volatiles, %	0.3
Particle Size	
% on 40 Mesh	nil
% through 200 Mesh	<5.0

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VISTA PVC 5395 RESIN

Confidential Product Formulation

1.	Polyvinyl chloride homopolymer	99.835 to 99.989%
2.	Calcium Stearate (21 C.F.R. 184.1229)	0.0 to 0.5%
3.	Butylated hydroxytoluene (21 C.F.R. 181.24)	0.0 to 0.15%

OR

ISONOX 132 — 0.0 to 0.18%
at least:
95% 2,6,-di-tert-butyl 4-secondary butyl phenol
1-2% 2,4,6,tri-tertbutyl phenol
1-2% 2,4, di-tert butyl 6-secondary butyl phenol
1-2% di-butyl phenol
[See attached reference 1]

Description

Vista 5395 PVC resin can be used in either extrusion, calendering or injection molding processes for flexible film and the medical market for flexible products.

Applications

Vista 5395 PVC resin is a versatile resin that can be used for many diverse rigid and flexible applications.

Its excellent heat stability, consistency and processing characteristics allow the production of high quality end products at high production rates.

The low gel content, uniform absorption of plasticizer, and high clarity make Vista 5395 resin an ideal choice for flexible applications involving calendering, extrusion, or injection molding or blown flexible film.

Properties	Typical
ASTM D 1755 Classification	GP-4-16000
Specific Viscosity (0.4 g in 100 ml Nitrobenzene at 25° C)	0.37
Inherent Viscosity ASTM D 1243-58T (Method A)	0.92
Bulk Density	
(g/cc)	0.56
(lb/cu ft)	33.5
Volatiles, %	0.3
Particle Size	
% on 40 Mesh	nil
% through 200 Mesh	<5.0

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VISTA PVC 5415 RESIN

Confidential Product Formulation

1.	Polyvinyl chloride homopolymer	99.82 to 99.989%
2.	Calcium Stearate (21 C.F.R. 184.1229)	0.0 to 0.5%
3.	Butylated hydroxytoluene (21 C.F.R. 181.24)	0.0 to 0.15%

Description

Vista 5415 PVC resin is a general purpose PVC homopolymer which can be used in either extrusion, calendering or injection molding processes for rigid and flexible products.

Applications

The uniform absorption of high levels of plasticizer, low gel content, high clarity and excellent heat stability of formulations based on Vista 5415 resin allow it to be used in many diverse applications.

The relatively high molecular weight of Vista 5415 PVC resin makes it particularly suitable for flexible applications requiring good physical properties and their retention on aging.

The combination of optimum physical properties and processing allows the use of plasticized dryblend formulation in most applications.

Properties	Typical
ASTM D 1755 Classification	GP-5-15300
Specific Viscosity (0.4 g in 100 ml Nitrobenzene at 25° C)	0.42
Inherent Viscosity ASTM D 1243-66T (Method A)	1.02
Bulk Density	
(g/cc)	0.50
(lb/cu ft)	32
Volatiles, %	0.3
Particle Size	
% on 40 Mesh	nil
% through 200 Mesh	<5.0

VISTA PVC 5465 RESIN

Confidential Product Formulation

1.	Polyvinyl chloride homopolymer	99.82	to	99.989%
2.	Calcium Stearate (21 C.F.R. 184.1229)	0.0	to	0.5%
3.	Butylated hydroxytoluene (21 C.F.R. 181.24)	0.0	to	0.15%

Description

Vista 5465 PVC resin is a general purpose high molecular weight homopolymer for calendering, extrusion and injection molding where the development of maximum physical properties is desired. The production of Vista 5465 is uniquely designed to produce a PVC resin having a correct balance of properties. Its molecular weight is sufficiently high to give the quality of "toughness" to the finished article while the melt viscosity is sufficiently low to allow for ease of manufacture.

Applications

Vista 5465 PVC resin is particularly suitable for use in flexible applications where the development and retention of maximum physical properties are desired.

The uniform absorption of high levels of plasticizer, low gel content, high clarity, excellent heat stability and high molecular weight of Vista 5465 allow it to be used in many diverse and demanding applications. They include calendering, injection molding (60A durometer), extrusion of sheeting, wire and cable, and flexible profile formulations.