

Color-coded tools for your hygiene and safety needs

4735 W. 106th Street Zionsville, IN 46077

P: 317-876-9856 F: 800.585.8619 www.remcoproducts.com January 1, 2014

Dear Sir or Madam,

This letter will confirm that the products listed below are manufactured with materials that are known to be compliant with the relevant parts of the FDA's 21 CFR guidance. Supporting documents follow this cover letter. Please feel free to contact me with any additional questions.

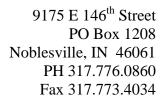
Sincerely,

Mite

**Michael Garrison** 

<u> Manufacturer – Metro Plastics</u>			
2900	Food Hoe		
2911	Floor Scraper		
6300	Mini Scoop		
6400	Small Scoop		
6400MD	Small Scoop, Metal Detectable		
6500	Large Scoop		
6500MD	Large Scoop, Metal Detectable		
6550	Mega Scoop		
6774	40" Paddle with Holes		
6775	40" Paddle without Holes		
6776	52" Paddle with Holes		
6777	52" Paddle without Holes		
6777MD	52"Paddle without Holes, Metal Detectable		
6959	Mini Bench Scraper		
6959MD	Bench Scraper, Metal Detectable		
6960	Bench Scraper		
6960MD	Bench Scraper, Metal Detectable		
6961	Small Scraper		
6961MD	Small Scraper, Metal Detectable		
6962	Large Scraper		

Metro Plastics- Continued			
6962MD	Large Scraper, Metal Detectable		
6981	Small (11" Blade) Shovel		
6981MD	Small (11" Blade) Shovel, Metal Detectable		
6982	Large (14" Blade) Shovel		
6982MD	Large (14" Blade) Shovel, Metal Detectable		
6984	Large Dual Grip Shovel		
6963	High Temp Large Scraper		
MDTK	Metal Detectable Sampler Kit		
Manufact	<u>urer - Acrofab</u>		
6901	Tub (Dump Style)		
6902	Lid		
6911	Tub (Square Style)		
6912	Lid		
6921	Aero-Tote Tub		
6922	Aero-Tote Lid		
6923	Aero-Tote Pallet		
Manufact	<u>urer – Americo</u>		
5523	Brown Pad		
5524	Blue Pad		
5525	White Pad		





Metro Plastics technologies, Inc.

May 14, 2013

Claudette Scales Remco Products 4735 W. 106<sup>th</sup> St. Zionsville, In 46077

Dear Claudette,

In reply to your request please accept the following statement to confirm that Metro Plastics uses only those materials approved by Remco for your product.

Metro Plastics affirms that all of the material used for your product meet the strict guidelines for the materials and colorants specified by Remco and that all the materials that require FDA certifications are current as of this date. Remco will be notified of changes in materials or suppliers where FDA compliance is required.

Respectfully,

Lindsey Hahn,

President, Metro Plastics



675 Wegner Drive West Chicago, IL 60185 Tel: +1 630 562 9000 Fax: +1 630 562 0700 www.clariant.masterbatches.com

#### December 28, 2009

Re: Product FDA Status for AB02760002, FDA White

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	<u>End Use Resin</u>	<b>Application</b>	<u>Use Level</u>	Restrictions *
	Nylon 6	Unknown	50:1	May be used to produce articles intended for
				uses in processing, handling, and packaging

May be used to produce articles intended for uses in processing, handling, and packaging food under Conditions of Use A - H. The colorant must be used in accordance with current good manufacturing practice, including use levels which are not in excess of those reasonably required to accomplish the intended coloring effect. There are no restrictions on use levels.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that have a suitable regulatory status for use in housewares.
- 6. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 7. Substances that are "Prior Sanctioned" for use in this application.
- 8. Substances that are the subject of applicable Food Contact Substance Notifications.
- 9. Substances supplied or specified by your company for this particular application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kent Hunny

Kurt Hsiung Quality Manager

### **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

# Table 2 -- Condition of use

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
  - Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
    - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
    - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.

Н.

J. Cooking at temperatures exceeding 250 deg.F.



1515 Miller Parkway McHenry, IL 60050 Tel: +1 815 363 0025 Fax: +1 815 363 0065 www.clariant.masterbatches.com

December 7, 2009

Re: Product FDA Status for AB33709668, Red

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	<u>End Use Resin</u>	<b>Application</b>	Use Level	Restrictions *
	Nylon	Hoes	33.00:1	Conditions of Use C-G. Not for use in articles
	-			used for packing or holding food during

cooking.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- 2. Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 6. Substances that are "Prior Sanctioned" for use in this application.
- 7. Substances that are the subject of applicable Food Contact Substance Notifications.
- 8. Substances supplied or specified by your company for this particular application.

Please note that the FDA maintains no regulations specifying the substances that may be used for packaging of wet or dry pharmaceuticals or medical devices. Testing may be necessary as appropriate for your finished product if these types of applications are your intent.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Brett Dandmen\_ Brett Garaner

Laboratory Manager

#### **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
  - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg.F.

Clariant products have not been designed for nor are they promoted or intended for use in:

- (a) medical devices catergorized by either the United States Food and Drug Administration or the International Standards Organization (ISO) as an "implant" device; or "Permanent" as defined under US Pharmacopoeia (USP) or ISO standards; or
- (b) active implantable medical devices as defined in EU Directive 90/385/EEC as amended; or
- (c) medical devices classified afor "Long Term" use as defined in EU Directive93/42/EEC as amended

Without limiting the generality of this statement, Clariant products. shall not be used in any medical device application intended for:

- (1) exposure to human tissue or body fluids for 30 days or greater;
- (2) cosmetic or reconstructive use;
- (3) reproductive implants or any birth control device; or
- (4) any critical component in a permanently (greater than 30 days) implanted medical device that supports or sustains human life.

It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, with all applicable laws and regulations.

CLARIANT MAKES NO REPRESENTATION, PROMISE, OR EXPRESS OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OR LAWFULNESS OF CLARIANT'S PRODUCTS FOR USE IN ANY MEDICAL DEVICE UNLESS EXPRESSLY STATED IN A WRITTEN AGREEMENT SIGNED BY A DULY AUTHORIZED CLARIANT REPRESENTATIVE.



1515 Miller Parkway McHenry, IL 60050 Tel: +1 815 363 0025 Fax: +1 815 363 0065 www.clariant.masterbatches.com

December 7, 2009

Re: Product FDA Status for AB63709661. Green

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	<u>End Use Resin</u>	Application	<u>Use Level</u>	Restrictions *
	Nylon	Hoes	33.00:1	Conditions of Use C-G. Not for use in articles
	•			used for packing or holding food during

cooking.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 6. Substances that are "Prior Sanctioned" for use in this application.
- 7. Substances that are the subject of applicable Food Contact Substance Notifications.
- 8. Substances supplied or specified by your company for this particular application.

Please note that the FDA maintains no regulations specifying the substances that may be used for packaging of wet or dry pharmaceuticals or medical devices. Testing may be necessary as appropriate for your finished product if these types of applications are your intent.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Brett Dardmen\_ Brett Garaner

Laboratory Manager

#### **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oll-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
  - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg.F.

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- (1) exposure to human tissue or body fluids for 30 days or greater;
- (2) cosmetic or reconstructive use;
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675 Wegner Drive West Chicago, IL 60185 Tel: +1 630 562 9000 Fax: +1 630 562 0700 www.clariant.masterbatches.com

#### December 30, 2009

Re: Product FDA Status for AB12760003, FDA Yellow

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

**Application** 

Use Parameters: End Use Resin 33% Glass-filled

33% Glass-filled Unknown Nylon 6

Use Level

Restrictions \* May be used to produce articles intended for use in processing, handling, and packaging food under Conditions of Use C - H. The finished article shall not be filled at temperatures exceeding 158°F. Use levels shall not exceed 35%.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that have a suitable regulatory status for use in housewares.
- 6. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 7. Substances that are "Prior Sanctioned" for use in this application.
- 8. Substances that are the subject of applicable Food Contact Substance Notifications.
- 9. Substances supplied or specified by your company for this particular application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kuit Hinny

Kurt Hsiung Quality Manager

#### **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
  - IX. Dry solids with the surface containing free fat or oil.

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
  - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg.F.



# Bapolene® PP5052 Polypropylene, Injection Grade

Request additional product information or price quote

#### **Key Features:**

Superior balance of stiffness and impact strength

#### Material Notes:

Polypropylene injection impact copolymer with excellent color and processability. This resin also has a superior balance of stiffness and impact strength. This product meets FDA standards for food contact applications.

Applications: Battery cases, housewares, appliances.

Bapolene® and Bapolan® are registered trademarks of Bamberger Polymers, Inc. Information provided by Bamberger Polymers

Physical Properties	Metric	English	Comments
Density	<u>0.903</u> g/cc	0.0326 lb/in <sup>3</sup>	ASTM D1505
Melt Flow	8.00 g/10 min Load 2.16 kg, Temperature 230 °C	Load 4.76 lb,	ASTM D1238
Mechanical Properties	Metric	English	Comments
Hardness, Shore D	82	82	ASTM D-2240
Tensile Strength, Yield	<b>26.9</b> MPa	<u>3900</u> psi	2 in/min (50 mm/min); ASTM D638
Elongation at Break	160 %	160 %	2 in/min (50 mm/min); ASTM D638
Elongation at Yield	14.0 %	14.0 %	2 in/min (20 mm/min); ASTM D638
Flexural Modulus	<u>1.21</u> GPa	<u>175</u> ksi	Secant @ 1% strain; ASTM D-790
Izod Impact, Notched	<u>1.17</u> J/cm	<u>2.19</u> ft-lb/in	ASTM D256
Thermal Properties	Metric	English	Comments
Deflection Temperature at 0.46 MPa (66 psi)	<u>84.0</u> °C	<u>183</u> °F	ASTM D648

**Qualitative Processing Properties** 

process

Injection Molding

Values reported are typical and should not be interpreted as specifications. Some of the values displayed above may have been converted from their original units and/or rounded in order to display the information in a consistant format. Users requiring more precise data for scientific or engineering calculations can click on the property value to see the original value as well as raw conversions to equivalent units. We advise that you only use the original value or one of its raw conversions in your calculations to minimize rounding error. We also ask that you refer to our disclaimer and terms of use regarding this information.

Data Properties Disclaimer: Bamberger Polymers shall not be responsible for the applicability or the accuracy of the information contained herein or the suitability of the products described herein for any particular purpose. It is the ultimate responsibility of the user to ensure that the product is suited and the information is applicable to the user's specific application. No warranties of any kind, either express or implied, including warranties of merchantability or fitness for a particular purpose, are made with respect to the products described herein or with respect to the use of the products described herein.

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Home

4/26/2013

Linsey Hahn – President

**Metro Plastics** 

9175 E 146<sup>th</sup> St

Noblesville, IN 46060



# **CERTENE PBM-8 – Polypropylene Impact Copolymer**

CERTENE grade PBM-8 complies with FDA regulation 21CRF 177.1520 (a)(3)(i)/(c)3.1+3.2, and most international regulations concerning the use of Polypropylene in contact with food.



675 Wegner Drive West Chicago, IL 60185 Tel: +1 630 562 9700 Fax: +1 630 562 0700 www.clariant.masterbatches.com

Metro Plastics 9175 East 146<sup>th</sup> Street Noblesville, IN 46060 Attn.: Ms. Lindsey Hahn

May 8, 2013

Rc: Product FDA Status for CPP-W1602-3, FDA White/UV

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	<u>End Use Resin</u>	<b>Application</b>	Use Level	Restrictions *
	Polypropylene	Unknown	33:1	The colorant may be used as a component of articles composed of polypropylene that complies with 21 CFR 177.1520, items 1.1,
				1.2, or 1.3, that are used in contact with all
				Food Types identified in Table 1 of 21 CFR
				176.170(c) under Conditions of Use B - G as
				described in Table 2 of 21 CFR 176.170(c).

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
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Please note that the FDA maintains no regulations specifying the substances that may be used for packaging of wet or dry pharmaceuticals or medical devices. Testing may be necessary as appropriate for your finished product if these types of applications are your intent.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kust Heining

Kurt Hsiung ISO/Product Stewardship Supervisor

# Excerpted from 21CFR176.170 (April 1, 2012)

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=176.170

# **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
  - IX. Dry solids with the surface containing free fat or oil.

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
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- E. Room temperature filled and stored (no thermal treatment in the container).
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Clariant products have not been designed for nor are they promoted or intended for use in:

- (a) medical devices catergorized by either the United States Food and Drug Administration or the International Standards Organization (ISO) as an "implant" device; or "Permanent" as defined under US Pharmacopoeia (USP) or ISO standards; or
- (b) active implantable medical devices as defined in EU Directive 90/385/EEC as amended; or
- (c) medical devices classified afor "Long Term" use as defined in EU Directive93/42/EEC as amended

Without limiting the generality of this statement, Clariant products. shall not be used in any medical device application intended for:

- (1) exposure to human tissue or body fluids for 30 days or greater;
- (2) cosmetic or reconstructive use;
- (3) reproductive implants or any birth control device; or
- (4) any critical component in a permanently (greater than 30 days) implanted medical device that supports or sustains human life.

It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, with all applicable laws and regulations.

CLARIANT MAKES NO REPRESENTATION, PROMISE, OR EXPRESS OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OR LAWFULNESS OF CLARIANT'S PRODUCTS FOR USE IN ANY MEDICAL DEVICE UNLESS EXPRESSLY STATED IN A WRITTEN AGREEMENT SIGNED BY A DULY AUTHORIZED CLARIANT REPRESENTATIVE.



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Mctro Plastics 9175 East 146<sup>th</sup> Street Noblesville, IN 46060 Attn.: Ms. Lindsey Hahn

May 8, 2013

Rc: Product FDA Status for CPP-W1602-3, FDA White/UV

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

<b>Use Parameters:</b>	<u>End Use Resin</u>	<b>Application</b>	<u>Use Level</u>	<u>Restrictions *</u>
	Polypropylene	Unknown	33:1	The colorant may be used as a component of
				articles composed of polypropylene that
				complies with 21 CFR 177.1520, items 1.1,
				1.2, or 1.3, that are used in contact with all
				Food Types identified in Table 1 of 21 CFR
				176.170(c) under Conditions of Use B - G as
				described in Table 2 of 21 CFR 176.170(c).

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 6. Substances that are "Prior Sanctioned" for use in this application.
- 7. Substances that are the subject of applicable Food Contact Substance Notifications.
- 8. Substances supplied or specified by your company for this particular application.

Please note that the FDA maintains no regulations specifying the substances that may be used for packaging of wet or dry pharmaceuticals or medical devices. Testing may be necessary as appropriate for your finished product if these types of applications are your intent.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kust Hinry

Kurt Hsiung ISO/Product Stewardship Supervisor \* Destrictions

# Excerpted from 21CFR176.170 (April 1, 2012)

#### http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=176.170

# Table 1 -- Types of Raw and Processed Foods

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
  - IX. Dry solids with the surface containing free fat or oil.

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
  - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg.F.

Clariant products have not been designed for nor are they promoted or intended for use in:

- (a) medical devices catergorized by either the United States Food and Drug Administration or the International Standards Organization (ISO) as an "implant" device; or "Permanent" as defined under US Pharmacopoeia (USP) or ISO standards; or
- (b) active implantable medical devices as defined in EU Directive 90/385/EEC as amended; or
- (c) medical devices classified afor "Long Term" use as defined in EU Directive93/42/EEC as amended

Without limiting the generality of this statement, Clariant products. shall not be used in any medical device application intended for:

- (1) exposure to human tissue or body fluids for 30 days or greater;
- (2) cosmetic or reconstructive use;
- (3) reproductive implants or any birth control device; or
- (4) any critical component in a permanently (greater than 30 days) implanted medical device that supports or sustains human life.

It is the responsibility of the medical device manufacturer and the person placing the medical device on the market to ensure compliance of the medical device, including the suitability of all raw materials and components used for its manufacture, with all applicable laws and regulations.

CLARIANT MAKES NO REPRESENTATION, PROMISE, OR EXPRESS OR IMPLIED WARRANTY CONCERNING THE SUITABILITY OR LAWFULNESS OF CLARIANT'S PRODUCTS FOR USE IN ANY MEDICAL DEVICE UNLESS EXPRESSLY STATED IN A WRITTEN AGREEMENT SIGNED BY A DULY AUTHORIZED CLARIANT REPRESENTATIVE.



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#### December 7, 2009

Re: Product FDA Status for CPP-R2614-5, FDA Red

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	End Use Resin	<b>Application</b>	Use Level	Restrictions *
	Polypropylene	Unknown	33:1	May be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or
				holding food of food types identified in Categories I through IX of Table 1, under
				Conditions of Use B through H of Table 2 in Title 21 CFR, Part 176.170(c). The colorant
				must be used in accordance with current good manufacturing practice. Use levels shall not exceed 13%.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- 2. Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that have a suitable regulatory status for use in housewares.
- 6. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 7. Substances that are "Prior Sanctioned" for use in this application.
- 8. Substances that are the subject of applicable Food Contact Substance Notifications.
- 9. Substances supplied or specified by your company for this particular application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kurt Hsiung Quality Manager

\* Restrictions: A key to the food-types and conditions of use is attached (Tables 1 and 2 from 21CFR176.170)

10.b

#### **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
    - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg.F.



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#### December 8, 2009

Re: Product FDA Status for CPP-G2372-2. Green A/S

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	End Use Resin	Application	Use Level	Restrictions *
	Polypropylene	Unknown	50:1	May be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food under Conditions of Use C - G.
				The colorant shall not be used in articles used
				for packing or holding food during cooking.
				The colorant must be used in accordance with current good manufacturing practice. Use levels shall not exceed 57%.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- 2. Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that have a suitable regulatory status for use in housewares.
- 6. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 7. Substances that are "Prior Sanctioned" for use in this application.
- 8. Substances that are the subject of applicable Food Contact Substance Notifications.
- 9. Substances supplied or specified by your company for this particular application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kowit Himmy

Kurt Hsiung Quality Manager

#### **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aquecus, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
  - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg.F.



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#### December 7, 2009

Re: Product FDA Status for CPP-BL3642-2, Blue

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	<u>End Use Resin</u>	<b>Application</b>	<u>Use Level</u>	Restrictions *
	Polypropylene	Unknown	33:1	May be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food under Conditions of Use C - G. The colorant shall not be used in articles used for packing or holding food during cooking. The colorant must be used in accordance with current good manufacturing practice, including use levels which are not in excess of those reasonably required to accomplish the intended coloring effect.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that have a suitable regulatory status for use in housewares.
- 6. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 7. Substances that are "Prior Sanctioned" for use in this application.
- 8. Substances that are the subject of applicable Food Contact Substance Notifications.
- 9. Substances supplied or specified by your company for this particular application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kurt Hsiung Quality Manager

#### Table 1 -- Types of Raw and Processed Foods

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free cil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:

VIII.

- A. Containing up to 8 percent of alcohol.
- B. Nonalcoholic.
- C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
  - Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
    - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg.F.



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#### December 8, 2009

Re: Product FDA Status for CNY-BL4470-3, Blue

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	End Use Resin	Application	Use Level	Restrictions *
	Nylon	Unknown	25:1	May be used to produce articles intended for
				uses in processing, handling, and packaging

uses in processing, handling, and packaging food under Conditions of Use A - H. The colorant must be used in accordance with current good manufacturing practice. Use levels shall not exceed 86%.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that have a suitable regulatory status for use in housewares.
- 6. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 7. Substances that are "Prior Sanctioned" for use in this application.
- 8. Substances that are the subject of applicable Food Contact Substance Notifications.
- 9. Substances supplied or specified by your company for this particular application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kink Henny

Kurt Hsiung Quality Manager

#### **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-cil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
  - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg.F.



# PBM-8 Polypropylene Impact Copolymer

PBM-8 is a **certified prime** grade **Medium-Impact** INJECTION MOLDING specially designed for applications requiring good impact resistance at low temperatures. **PBM-8** features very good processability, medium-high flow for fast mold filling, very good dimensional stability, excellent heat resistance, and optimal balance of mechanical properties. **PBM-8** typical applications include automotive parts and interior trimming, appliance parts, tackle boxes, gun and tool cases, toys, industrial components, caps, closures and housewares. Recommended processing temperature is between 210° - 220°C. **PBM-8** complies with FDA regulation 21CFR 177.1520 (a)(3)(i) / (c)3.1 + 3.2, and with most international regulations concerning the use of Polypropylene in contact with food articles.

PROPERTIES*	ASTM	UNIT	NOMINAL
	TEST	ENGLISH (METRIC)	VALUES
RESIN			
Melt Flow Rate Density Flexural Modulus <sup>1</sup> MOLDED SPECIMEN*	D 1238L D 1505 D 790	gr./10 min gr./cm <sup>3</sup> psi (MPa)	8.0 0.902 150,000 (1050)
Tensile Strength @Yield <sup>2</sup>	D 638	psi (MPa)	3500 (24)
Elongation @ Yield <sup>2</sup>	D 638	%	7
Izod Impact Notched @23°C	D 256	ft.lb/in. (J/m)	2.0 (110)
Vicat softening point	D 1525	°C.	140
HDT @ 66 psi (0.46 MPa)	D 648	°C.	85
Hardness Rockwell	D 785	R Scale	100

# Typical Properties

TYPICAL VALUE OF PROPERTIES NOT TO BE CONSTRUED AS SPECIFICATIONS.

\* - Test made on injection molded Type 1 tension test specimen according to ASTM D 2146.

1 - 1% secant @ 1.3 mm/min. speed.

2 - @ 50 mm/min.

THIS PRODUCT DATA SHEET EFFECTIVE MAY 2010 SUPERSEDES ALL DATA PREVIOUSLY PUBLISHED

The technical information, suggested uses and applications presented are made without charge and are believed to be reliable; however, the Ravago Group\* disclaims responsibility for reliance and results of use of this information. THE RAVAGO GROUP DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, CONCERNING THE PRODUCT(S) DESCRIBED HEREINABOVE, INCLUDING ANY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. The Ravago Group expressly disclaims any statements or suggestions as being inducement. All users should rely upon their own knowledge and testing in determining product suitability.

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#### December 9, 2009

Re: Product FDA Status for CPP-Y1388-3, Yellow FDA

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	<u>End Use Resin</u>	Application	<u>Use Level</u>	Restrictions *
	Polypropylene	Unknown	33:1	May be used in the manufacture of articles or components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food under Conditions of Use C - G. The finished article shall not be filled at temperatures exceeding 158°F. The colorant shall not be used in articles used for packing or holding food during cooking. The colorant must be used in accordance with current good manufacturing practice. Use levels shall not exceed 33%.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that have a suitable regulatory status for use in housewares.
- 6. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 7. Substances that are "Prior Sanctioned" for use in this application.
- 8. Substances that are the subject of applicable Food Contact Substance Notifications.
- 9. Substances supplied or specified by your company for this particular application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kint Hunny

Kurt Hsiung Quality Manager

#### **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

#### Table 2 -- Condition of use

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
  - Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
    - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
      - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.

Н.

J. Cooking at temperatures exceeding 250 deg.F.



675 Wegner Drive West Chicago, IL 60185 Tel: +1 630 562 9000 Fax: +1 630 562 0700 www.clariant.masterbatches.com

#### December 9, 2009

Re: Product FDA Status for <u>CPP-Y1388-3, Yellow FDA</u>

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	End Use Resin	<b>Application</b>	Use Level	Restrictions *
	Polypropylene	Unknown	33:1	May be used in the manufacture of articles or
				components of articles intended for use in
				producing, manufacturing, packing, processing,
				preparing, treating, packaging, transporting, or
				holding food under Conditions of Use C - G.
				The finished article shall not be filled at
				temperatures exceeding 158°F. The colorant
				shall not be used in articles used for packing or
				holding food during cooking. The colorant must
				be used in accordance with current good
				manufacturing practice. Use levels shall not
				exceed 33%.

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that have a suitable regulatory status for use in housewares.
- 6. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 7. Substances that are "Prior Sanctioned" for use in this application.
- 8. Substances that are the subject of applicable Food Contact Substance Notifications.
- 9. Substances supplied or specified by your company for this particular application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kust Many

Kurt Hsiung Quality Manager

\* Restrictions: A key to the food-types and conditions of use is attached (Tables 1 and 2 from 21CFR176.170)

10.b

#### **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:

VIII.

- A. Containing up to 8 percent of alcohol.
- B. Nonalcoholic.
- C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
  - Dry solids with the surface containing no free fat or cil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

#### Table 2 -- Condition of use

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
  - Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
    - 1. Aqueous or oil-in-water emulsion of high- or low-fat.
      - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.

Н.

J. Cooking at temperatures exceeding 250 deg.F.



June 30, 2011

Phil Vidito Metro Plastics Technologies Inc 9175 East 146<sup>th</sup> Street Noblesville, IN 46060

Dear Phil,

In response to your request, the components of A. Schulman Inc product WY\_81271-U FDA White W/UV (1031581) meet the conditions and requirements of the following sections of 21 CFR (FDA) regulations:

177.1520(c)(3.1a) 178.2010 178.3297

This product is a physical mixture of FDA approved components. Any limitations for use of these components are listed above. If this product is used as an additive or blended with other products, then the final product could have use limitations with food contact. It is the blender's responsibility to make that determination.

This declaration is based on information from our suppliers.

If you need any further regulatory, environmental, safety or health information, please feel free to contact me at 330-668-7343 or <u>Susan Fizer@us.aschulman.com</u>.

Sincerely,

Susan Fizer EHS Regulatory Manager

LOCATION: 2200 ASBURY ROAD ERIE, PENNSYLVANIA 16506 U. S. A. E-MAIL: eriez@eriez.com WEB SITE: www.eriez.com PHONE: 814/ 835-6000 FAX: 814/ 838-4960



April 26, 2013

Lindsey Hahn Metro Plastics PO Box 1208 Noblesville, IN 46061

Subject: PolyMag Stainless Powder, FDA CTS 65781

Dear Lindsey,

The PolyMag stainless powder, Eriez item number 448171, used in compounding Metro Plastics' Metal Detectable Polypropylene material, is the same alloy and composition that was originally submitted and reviewed by the FDA in August of 2006.

Please let me know if you have any additional questions.

Regards,

W. Als belles #

W. John Collins Manager – Plastics & PolyMag

CC: Bob Browning - Process Controls



April 30, 2013

Lindsey Hahn Metro Plastics Technologies Inc 9175 East 146<sup>th</sup> Street Noblesville, IN 46061

Dear Lindsey,

In response to your request, the components of A. Schulman Inc product **GY-41486-A Green** (1030603) meet the conditions and requirements of the following sections of 21 CFR (FDA) regulations:

177.1520(c)(3.1) 178.3297 184.1324

This product can be used for conditions of use C through G in 21 CFR 176.170(c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1. This product should not be used for holding or packing food while cooking.

This product is a physical mixture of FDA approved components. Any limitations for use of these components are listed above. If this product is used as an additive or blended with other products, then the final product could have use limitations with food contact. It is the blender's responsibility to make that determination.

This declaration is based on information from our suppliers.

If you need any further regulatory, environmental, safety or health information, please feel free to contact me at 330-668-7343 or <u>Susan\_Fizer@us.aschulman.com</u>.

Sincerely,

Susan Fizer EHS Regulatory Manager



April 30, 2013

Lindsey Hahn Metro Plastics Technologies Inc 9175 East 146<sup>th</sup> Street Noblesville, IN 46061

Dear Lindsey,

In response to your request, the components of A. Schulman Inc product **RY-61465 FDA Red** (1030313) meet the conditions and requirements of the following sections of 21 CFR (FDA) regulations:

177.1520(c)(3.1) 178.3297

This product can be used for conditions of use C through G in 21 CFR 176.170(c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1. This product should not be used for holding or packing food while cooking.

This product has a maximum usage level of 30% by weight.

This product is a physical mixture of FDA approved components. Any limitations for use of these components are listed above. If this product is used as an additive or blended with other products, then the final product could have use limitations with food contact. It is the blender's responsibility to make that determination.

This declaration is based on information from our suppliers.

If you need any further regulatory, environmental, safety or health information, please feel free to contact me at 330-668-7343 or <u>Susan Fizer@us.aschulman.com</u>.

Sincerely,

Susan Fizer EHS Regulatory Manager



**Public Health Service** 

Food and Drug Administration College Park, MD 20740

August 24, 2006

W. John Collins Manager, PolyMag Division Eriez P.O. Box 10608 Eire, PA 16514-0608

Dear Mr. Collins:

This correspondence is in response to your letter of July 11, 2006, in which you requested an opinion from the FDA on the regulatory status of the ingredients used to manufacture Eriez's "magnetic susceptibility" and "metal detectability" plastic additive compounds. The addition of these compounds to plastic and rubber articles may result in their incorporation into products which may see food-contact use. This letter has been logged into our tracking system as CTS 65781.

We have evaluated the compositional data presented in CTS 65781. All of the ingredients listed in CTS 65781 are either Generally Recognized as Safe as direct additives to food, prior sanctioned for the intended use, the subject of an applicable food additive regulation, or will not result in migration to food from the intended use (i.e. will not become a food additive). As such these compounds, as described, are regulated for the described use. This conclusion applies only to the formulations described in CTS 65781. If the formulations of these compounds are significantly modified, new data would need to be evaluated.

Please note that FDA does not approve or endorse products manufactured by specific companies. Rather, FDA is a regulatory agency which authorizes the use of chemicals for food-contact applications under specific conditions. If a product meets the relevant regulatory specifications, it can be marketed without any need for FDA review.

If you have any further questions regarding this matter, please do not hesitate to contact us.

Sincerely,

Paul Honigfort, Ph.D. Consumer Safety Officer Division of Food Contact Notifications, HFS-275 Office of Food Additive Safety Center for Food Safety and Applied Nutrition



April 30, 2013

Lindsey Hahn Metro Plastics Technologies Inc 9175 East 146<sup>th</sup> Street Noblesville, IN 46061

Dear Lindsey,

In response to your request, the components of A. Schulman Inc product **BY-12123 Blue** (1030257) meet the conditions and requirements of the following sections of 21 CFR (FDA) regulations:

177.1520(c)(3.1) 175.300 178.3297 181.22

This product can be used for conditions of use C through G in 21 CFR 176.170(c), Table 2 and can be used in contact with all food types as listed in 21 CFR 176.170(c), Table 1. This product should not be used for holding or packing food while cooking.

This product is a physical mixture of FDA approved components. Any limitations for use of these components are listed above. If this product is used as an additive or blended with other products, then the final product could have use limitations with food contact. It is the blender's responsibility to make that determination.

This declaration is based on information from our suppliers.

If you need any further regulatory, environmental, safety or health information, please feel free to contact me at 330-668-7343 or <u>Susan Fizer@us.aschulman.com</u>.

Sincerely,

Susan Fizer EHS Regulatory Manager



5/8/2013

LINDSEY HAHN Metro Plastics Technologies 9175 E. 146th Street Noblesville, IN 46061 USA

## FDA Status for: POA 38199

Regarding the status of your above mentioned product please be advised that this formulation conforms to one or more of the following criteria.

- 1) Substances allowed as direct food additives.
- 2) Colorants listed in the pertinent sections of 21CFR 178.3297 "Colorants for Polymers".
- 3) Polymers and/or additives listed in the pertinent 21CFR sections.
- 4) Products supplied by your company for this application.
- 5) Based upon legal opinion, supplier certification, and/or extraction results from food simulated solvents, colorants are acceptable under the FDA's conditions of use C-G, CFR 21 Part 176.170(c) Table 2 in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food regulations.

Therefore, we consider this product to meet current FDA guidelines for food packaging when used at the proper use ratio and in the agreed upon application.

We hope the above information is helpful to you. If you need additional information, or have any questions, please do not hesitate to call.

Sincerely,

Dund ANIEZ

Dan Hunter Technical Manager Badger Color Concentrates, Inc.

*Corporate Office* 1007 Fox Sttreett • Mukwonago • WI €3149 • (262)363.5710 *Site B* 705 Perkins Drive • Mukwonago • WI • 53149 *North Carolina* 116 Battleground Road • Kings Mounttain • NC •28086 • (704)937.0071



5/1/2013

Lindsey Hahn Metro Plastics Technologies 9175 E. 146th Street Noblesville, IN 46061 USA

### FDA Status for: PXC 38441

Regarding the status of your above mentioned product please be advised that this formulation conforms to one or more of the following criteria.

- 1) Substances allowed as direct food additives.
- 2) Colorants listed in the pertinent sections of 21CFR 178.3297 "Colorants for Polymers".
- 3) Polymers and/or additives listed in the pertinent 21CFR sections.
- 4) Products supplied by your company for this application.
- 5) Based upon legal opinion, supplier certification, and/or extraction results from food simulated solvents, colorants are acceptable under the FDA's conditions of use C-G, CFR 21 Part 176.170(c) Table 2 in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food regulations.

Therefore, we consider this product to meet current FDA guidelines for food packaging when used at the proper use ratio and in the agreed upon application.

We hope the above information is helpful to you. If you need additional information, or have any questions, please do not hesitate to call.

Sincerely,

Dan Hunter Technical Manager Badger Color Concentrates, Inc.

*Corporate Office* 1007 Fox Sttreett • Mukwonago • WI **5**3149 • (262)363.5710 *Site B* 705 Perkins Drive • Mukwonago • WI • 53149 *North Carolina* 116 Battleground Road • Kings Mounttain • NC •28086 • (704)937.0071



2300 Lynch Road Evansville, IN 47711 812-421-8900 812-421-8915 (Fax)

April 29, 2013

# FDA Compliance Statement

# Product: PA6 GR33 FD NA

PA6 GR33 FD NA is an FDA fashioned product manufactured by Omni Plastics, LLC. This product is made from FDA approved ingredients consistent with standards; 21CFR177.1500, 21CFR178.2010 & 21CFR177.300.

This product is not intended for use in medical applications involving implantation in the human body, hence, Omni Plastics, LLC, accepts no liability for use of its products in medical applications or product misuse.

This statement is based on our current level of knowledge and covers the above mentioned materials produced by Omni Plastics at the date of issue. Since conditions of use are outside of Omni Plastics' control, Omni Plastics makes no warranties, express or implied, and assumes no liability in connection with any use of this information.



shall not exceed 23%.

Clariant Corporation Masterbatches Division 675 Wegner Drive West Chicago, IL 60185 Tel: +1 630 562 9000 Fax: +1 630 562 0700 www.clariant.masterbatches.com

## December 7, 2009

Re: Product FDA Status for PP44760046. Purple FDA

Following is the FDA status of the above Clariant Corporation Masterbatches Division product code:

Use Parameters:	End Use Resin	Application	Use Level	Restrictions *
	Polypropylene	Unknown	33:1	May be used in the manufacture of articles or
				components of articles intended for use in
				producing, manufacturing, packing, processing,
				preparing, treating, packaging, transporting, or
				holding food under Conditions of Use C - G.
				The colorant shall not be used in articles used
				for packing or holding food during cooking.
				The colorant must be used in accordance with
				current good manufacturing practice. Use levels

The components of this product fall under one or more of the following categories for use in contact with food:

- 1. Colorants listed in 21CFR178.3297 "Colorants for Polymers."
- 2. Components that are exempt from regulation under 21CFR170.39, "Threshold of Regulation for Substances Used in Food Contact Articles."
- 3. Polymers and/or additives listed in the appropriate parts of 21CFR (174, 175, 176, 177, 178, 181, 182, 184, and 186).
- 4. Substances that, based upon legal opinion, supplier certification, and/or extraction results from food-simulating solvents, are not food additives and are acceptable for food contact applications in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food additive regulations.
- 5. Substances that have a suitable regulatory status for use in housewares.
- 6. Substances that are GRAS (Generally Recognized as Safe) for direct addition to food or for use in contact with food.
- 7. Substances that are "Prior Sanctioned" for use in this application.
- 8. Substances that are the subject of applicable Food Contact Substance Notifications.
- 9. Substances supplied or specified by your company for this particular application.

If any of the use parameters listed above are contemplated to be changed, please contact us so that we may help you to determine whether this product will still be suitable.

Sincerely,

Kuit Heining

Kurt Hsiung Quality Manager

\* Restrictions: A key to the food-types and conditions of use is attached (Tables 1 and 2 from 21CFR176.170)

# Excerpted from 21CFR176.170 (April 2006) http://www.cfsan.fda.gov/~rdb/opa-fcn3.html

## **Table 1 -- Types of Raw and Processed Foods**

- I. Nonacid, aqueous products; may contain salt or sugar or both (pH above 5.0).
- II. Acid, aqueous products; may contain salt or sugar or both, and including oil-in-water emulsions of lowor high-fat content.
- III. Aqueous, acid or nonacid products containing free oil or fat; may contain salt, and including water-in-oil emulsions of low- or high-fat content.
- IV. Dairy products and modifications:
  - A. Water-in-oil emulsions, high- or low-fat.
  - B. Oil-in-water emulsions, high- or low-fat.
- V. Low-moisture fats and oil.
- VI. Beverages:
  - A. Containing up to 8 percent of alcohol.
  - B. Nonalcoholic.
  - C. Containing more than 8 percent alcohol.
- VII. Bakery products other than those included under Types VIII or IX of this table:
  - A. Moist bakery products with surface containing free fat or oil.
  - B. Moist bakery products with surface containing no free fat or oil.
- VIII. Dry solids with the surface containing no free fat or oil (no end test required).
- IX. Dry solids with the surface containing free fat or oil.

## Table 2 -- Condition of use

- A. High temperature heat-sterilized (e.g., over 212 deg.F).
- B. Boiling water sterilized.
- C. Hot filled or pasteurized above 150 deg.F.
- D. Hot filled or pasteurized below 150 deg.F.
- E. Room temperature filled and stored (no thermal treatment in the container).
- F. Refrigerated storage (no thermal treatment in the container).
- G. Frozen storage (no thermal treatment in the container).
- H. Frozen or refrigerated storage: Ready-prepared foods intended to be reheated in container at time of use:
  - 1. Aqueous or cil-in-water emulsion of high- or low-fat.
    - 2. Aqueous, high- or low-free oil or fat.
- I. Irradiation.
- J. Cooking at temperatures exceeding 250 deg.F.

# Rainbow Colors, Inc. 935 Lee Street Elk Grove Village, IL 60007 Ph: 847-640-7700 Fax: 847-640-7707

# FDA STATUS LETTER

May 14, 2013

# To Whom It May Concern:

We certify the product PPC-BL1158-1 (FDA BLUE, Customer Part# N/A), manufactured and distributed by Rainbow Colors, Inc., has been formulated with components which may be safely used in the manufacture of articles or components of articles intended for use in contact with food; subject to the restrictions of use listed in the table below, and the provisions and definitions set forth in one or more of the following 21 CFR Sections: 178.3297, 175.300, 177.1520, 178.2010, 178.3620(a), 184: Direct Food Substances Affirmed as GRAS, or Food Contact Notifications. This product must be used in accordance with current Good Manufacturing Practice Regulations promulgated by the US Food and Drug Administration, including use levels which are not in excess of those reasonably required to accomplish the intended coloring effect:

Recommended Usage	Limitations / Restrictions of Use:		
End Use Resin: PP Application: Caps Use Level: 3 %	Use level of color concentrate shall not exceed 15% (by weight). The finished articles are to contact Aqueous, Acidic, Low Alcohol, and Fatty Foods only, under conditions of use D – G only, as described in tables 1 & 2 of 21CFR176.170(c)		

The statements above are based upon regulatory documents received from our raw material suppliers; however no testing has been performed on this product. It is the responsibility of our customers to determine that the End-Use-Resin and their use of this product are safe, lawful, and technically suitable for the intended application(s). Because of possible changes of law and regulations, as well as possible changes in our product, we cannot guarantee that the status of this product will remain unchanged. We, therefore, recommend that customers continuing to use this product verify its status periodically.

Sincerely,

Pankaj Patel Rainbow Colors, Inc.



4/26/2013

Lindsey Hahn Metro Plastics Technologies 9175 E. 146th Street Noblesville, IN 46061 USA

## FDA Status for: PRC 43067

Regarding the status of your above mentioned product please be advised that this formulation conforms to one or more of the following criteria.

- 1) Substances allowed as direct food additives.
- 2) Colorants listed in the pertinent sections of 21CFR 178.3297 "Colorants for Polymers".
- 3) Polymers and/or additives listed in the pertinent 21CFR sections.
- 4) Products supplied by your company for this application.
- 5) Based upon legal opinion, supplier certification, and/or extraction results from food simulated solvents, colorants are acceptable under the FDA's conditions of use C-G, CFR 21 Part 176.170(c) Table 2 in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food regulations.

Therefore, we consider this product to meet current FDA guidelines for food packaging when used at the proper use ratio and in the agreed upon application.

We hope the above information is helpful to you. If you need additional information, or have any questions, please do not hesitate to call.

Sincerely,

Dan Hunter Technical Manager Badger Color Concentrates, Inc.

*Corporate Office* 1007 Fox Sttreett • Mukwonago • WI €3149 • (262)363.5710 *Site B* 705 Perkins Drive • Mukwonago • WI • 53149 *North Carolina* 116 Battleground Road • Kings Mounttain • NC •28086 • (704)937.0071



4/26/2013

Lindsey Hahn Metro Plastics Technologies 9175 E. 146th Street Noblesville, IN 46061 USA

## FDA Status for: PRC 38200

Regarding the status of your above mentioned product please be advised that this formulation conforms to one or more of the following criteria.

- 1) Substances allowed as direct food additives.
- 2) Colorants listed in the pertinent sections of 21CFR 178.3297 "Colorants for Polymers".
- 3) Polymers and/or additives listed in the pertinent 21CFR sections.
- 4) Products supplied by your company for this application.
- 5) Based upon legal opinion, supplier certification, and/or extraction results from food simulated solvents, colorants are acceptable under the FDA's conditions of use C-G, CFR 21 Part 176.170(c) Table 2 in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food regulations.

Therefore, we consider this product to meet current FDA guidelines for food packaging when used at the proper use ratio and in the agreed upon application.

We hope the above information is helpful to you. If you need additional information, or have any questions, please do not hesitate to call.

Sincerely,

Jame

Dan Hunter Technical Manager Badger Color Concentrates, Inc.

Corporate Office 1007 Fox Sttreett • Mukwonago • WI **5**3149 • (262)363.5710 Site B 705 Perkins Drive • Mukwonago • WI • 53149 North Carolina 116 Battleground Road • Kings Mounttain • NC •28086 • (704)937.0071 4/26/2013

Lindsey Hahn Metro Plastics Technologies 9175 E. 146th Street Noblesville, IN 46061 USA

### FDA Status for: PYC 39906

Regarding the status of your above mentioned product please be advised that this formulation conforms to one or more of the following criteria.

) C

CENTRATES INC.

- 1) Substances allowed as direct food additives.
- 2) Colorants listed in the pertinent sections of 21CFR 178.3297 "Colorants for Polymers".
- 3) Polymers and/or additives listed in the pertinent 21CFR sections.
- 4) Products supplied by your company for this application.
- 5) Based upon legal opinion, supplier certification, and/or extraction results from food simulated solvents, colorants are acceptable under the FDA's conditions of use C-G, CFR 21 Part 176.170(c) Table 2 in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable food regulations.

Therefore, we consider this product to meet current FDA guidelines for food packaging when used at the proper use ratio and in the agreed upon application.

We hope the above information is helpful to you. If you need additional information, or have any questions, please do not hesitate to call.

Sincerely,

Dan Hunter Technical Manager Badger Color Concentrates, Inc.

Corporate Office 1007 Fox Sttreett • Mukwonago • WI **5**3149 • (262)363.5710 Site B 705 Perkins Drive • Mukwonago • WI • 53149 North Carolina 116 Battleground Road • Kings Mounttain • NC •28086 • (704)937.0071