



Clariant Corporation  
Masterbatches Division

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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:

<u>Use Parameters:</u>	<u>End Use Resin</u>	<u>Application</u>	<u>Use Level</u>	<u>Restrictions *</u>
	33% Glass-filled Nylon 6	Unknown	20:1	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."
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,

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Kurt Hsiung  
Quality Manager

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



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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.