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Supersedes: March 5, 2012

## **AMBERLITE™ FPA55 Ion Exchange Resin**

### **Food and Drug Administration (FDA)**

This letter is in response to your inquiry concerning the regulatory status of AMBERLITE™ FPA55 Resin with regard to the US food contact regulations. AMBERLITE™ FPA55 Resin is a weak base anion exchange resin with tertiary amine functionality.

Based on our review, it is our opinion that AMBERLITE™ FPA55 Resin complies with the FDA regulations found in 21 C.F.R. §173.25 for use in the purification of foods and potable water. Please note, Ion Exchange Resins that compositionally comply with 21 C.F.R. §173.25 are subject to pre-use treatment by the manufacturer and/or user in accordance with the manufacturer's directions, and should meet the extractives limitations as described in paragraph (c) of 21 C.F.R. §173.25.

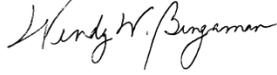
AMBERLITE™ FPA55 Resin has also been the subject of a Food Contact Notification submitted by Rohm and Haas. FDA clearance was obtained (on August 31, 2002) under Food Contact Notification #254. This information is publicly available and can be found on the US Food and Drug Administration Website  
<http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=fcsListing&id=254>

This resin can be used to treat water and aqueous food only of the types identified in Categories I, II, and VI-B in Table 1 of 21CFR176.170 (c) provided that either: (A) the temperature of the water or food passing through the resin bed is maintained at 50°C or less and the flow rate of the water or food passing through the bed is not less than 0.5 gallon per cubic foot per minute; or (B) extracts of the resin will be found to contain no more than 1 milligram/kilogram (ppm) dimethylaminopropylamine in each of the food simulants, distilled water and 10 percent ethanol, when the resin is subjected to the following test under conditions simulating the actual temperature and flow rate of use: "The Determination of 3-Dimethylaminopropylamine in Food Simulating Extracts of Ion Exchange Resins."

The above information relates specifically to the product reviewed. We recommend that customers make their own determination on the suitability of this product for their particular application. We believe this information to be reliable as of the date of this letter. Please feel free to contact us should you have further questions.

If you have any additional questions, please feel free to contact us.

Sincerely,



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