The Dow Chemical Company
U.S.A.

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AMBERLITE™ FPA53 Ion Exchange Resin

Food and Drug Administration (FDA)

This letter is in response to your inquiry concerning the regulatory status of **AMBERLITE™ FPA53** ion exchange resin with regards to US Regulations on food contact materials. **AMBERLITE™ FPA53 Resin** is a weak base anion resin containing tertiary amine functionality on a gel-type acrylic matrix.

Based on our review, it is our opinion that AMBERLITE™FPA53 ion exchange resin complies with the FDA regulations as found in Title 21 of the Code of Federal Regulations (CFR), Part 173 – Secondary Direct Food Additive permitted in food for human consumption, §173.25 (a)(16) with the following limitations:

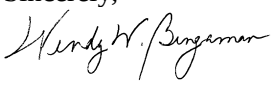
Ion exchange resins which compositionally comply with 21C.F.R.§173.25 are subject to pre-use treatment by the manufacturer and/or user in accordance with the manufacturer's directions, and meet the extractives limitations as described in paragraph (c) of 21C.F.R.§173.25.

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 provided that either: (A) food passing through the resin beds is maintained at 50ºC or less and the flow rate of the water or food passing through the beds 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 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."

For purification of water for use in the manufacture of distilled alcoholic beverages, subject to the following conditions: (I) The water is subjected to treatment through a mixed bed consisting of this resin and a strongly acidic cation exchange resin in the hydrogen form identified in 21CFR173.25, paragraphs (a)(1), (2), and (11) or (II) the treated water is subsequently subjected to treatment through a bed of activated carbon or one of the strongly acidic cation exchange resins in the hydrogen form identified in paragraphs (1), (2), and (11). (III) The temperature of the water passing through the resin beds is maintained at 30ºC or less, and the flow rate of the water passing through the beds is not less than 2 gallons per cubic foot per minute. When used under these conditions the resin is exempt from the extractive limitations as prescribed in paragraph (c)(4) of 21CFR173.25.

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

Sincerely,



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