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AMBERLITE™ FPC12 H Ion Exchange Resin

Food and Drug Administration (FDA)

This letter provides the regulatory status of AMBERLITE™ FPC12 H ion exchange resin with regard to the US food contact regulations.

AMBERLITE™ FPC12 H ion exchange resin can be described as a sulfonated copolymer of styrene and divinylbenzene.

Based on our review, we conclude that AMBERLITE™ FPC12 H 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)(1). AMBERLITE™ FPC12 H ion exchange resin may be safely used in the purification of food including potable water. Please note, that ion exchange resins which compositionally comply with 21 CFR §173.25 are subject to pre-use treatment by the manufacturer and/or user in accordance with the manufacturer’s directions to meet the extractives limitations as described in paragraph (c) of 21 CFR §173.25.

The above information relates specifically to AMBERLITE™ FPC12 H resin. We recommend that customers use this information to determine the suitability of the resin for their intended use(s). We recommend that you contact us on a periodic basis to confirm the regulatory status of this product.

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

Sincerely,

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