



Formosa Plastics®

Formosa Plastics Corporation, U.S.A.
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Re: U.S. FDA Compliance Statement for Formolon® Suspension PVC Resins

Dear Valued Customer:

Formolon® 608, 614, 616K, 622F, 622R, 622W, 676, 676H, 680, 680H, 685, 690, 690F suspension polyvinyl chloride resins (CAS No. 9002-86-2) are common plastic materials used for various packaging applications.

The U.S. Food and Drug Administration (FDA) issues regulations covering what is suitable for food contact, medical devices and food processing. **The PVC homopolymers identified above have FDA clearance for direct food contact use according to prior sanction as “Generally Recognized As Safe” (GRAS).** The end products will also have clearance provided the end use formulation meets some minimum standards and the end products are produced using generally recognized acceptable manufacturing processes.

These PVC resins comply with Food and Drug Administration (FDA) Good Manufacturing Practices according to 21 CFR 174.5 and all sections of 21 CFR that relate to homopolymer PVC resins used in rigid applications and for flexible film. These products may also contain additives at levels that are in compliance with FDA regulations with no limitation for use in rigid polymeric products that may contact food and for flexible film with a thickness not to exceed one mil in contact with aqueous and acidic foods. They are cleared for use under FCN 688 and 21 CFR sections 178.2010. Formolon® PVC does contain a minor amount of residual vinyl chloride monomer (RVCM). Typical values are much less than 1 ppm on average.

In all food applications, we recommend that the packager or manufacturer of the final product conduct appropriate tests to evaluate the possible contribution of the container to the aroma, taste and color of the food product.

As always, *You expect more. And Formosa delivers®.* If you have questions regarding FDA compliance for any Formosa Plastics Corporation product, please contact your Sales Representative.

Kind Regards,

Fred W. Neske, CIH, CSP, CFPS
Manager – Corporate Safety & Industrial Hygiene
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