



# SCIENCE REGULATORY SERVICES INTERNATIONAL

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Original Follows by Mail

December 8, 1993

Mr. Frank Van Haste  
General Manager  
NOVACHEM  
955 Connecticut Avenue  
Bridgeport, CT 06607-1222

Subject: SuperNova™ Chemical Purging Compounds –  
Evaluation and Certified Opinion on suitability of Components  
for use in Manufacture of Plastics for Food Contact Uses

Dear Mr. Van Haste:

We have, at NOVACHEM's request, reviewed the FDA approval status of the various ingredients used in the formulation of NOVACHEM's purge products. The purpose of this review was to establish whether these ingredients are suitable and safe for use in the manufacture of plastics intended for food contact uses. As a result of this review and evaluation we can report to you that all of the ingredients in the formulary listing which you provided are suitable and safe for use in the manufacture of plastics intended for food contact uses.

By way of background, the type of use involved here puts the ingredients into the category of substances which may have indirect food contact. As such, FDA approval for use would generally fall under the regulations at 21 CFR 174 – 178 and 186. The general policy of FDA with regard to such indirect food additive materials is stated at 21 CFR 174. In summary, this policy is:

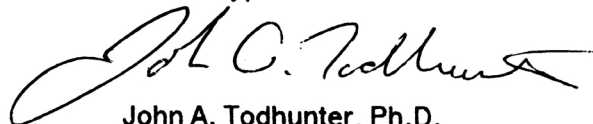
- (a) The amount of the substance used in an indirect food contact use shall be only that which is reasonably necessary to achieve the intended physical or technical effect;
- (b) The substance shall be of a purity suitable for its intended purpose;
- (c) Any specific approval for indirect food additive use does not relieve the need for compliance with other applicable provisions of the Food, Drug, and Cosmetic Act or grant approval for a direct food additive use;
- (d) Any GRAS or Prior Sanctioned substance may be used as an indirect food additive; and,
- (e) Any substance permitted by regulation under 21 CFR 175, 176, 177, 178, and 179.45 or permitted as a direct food additive under 21 CFR 172 or 173 may, subject to any limitations imposed by the specific approval regulation, be used as an indirect food additive.

The various ingredients in the purge product can be grouped into two broad classes: (A) polymeric materials; and, (B) miscellaneous adjuvants. The 21 CFR food contact approval status for these various ingredients is summarized in the Confidential Attachment to this report letter (the confidentiality of the attachment is so as to preclude inadvertant disclosure of NOVACHEM's proprietary formulation should you desire to share the letter report itself with any parties outside of NOVACHEM).

Based on our review of the FDA status of the ingredients in NOVACHEM's purge product and of the known health and safety characteristics of these ingredients, it is our opinion that:

- (a) The components in NOVACHEM's purge product are safe for the intended purpose of use as ingredients of the purge product.
- (b) These components, when used as ingredients of a purge product in the manufacture of plastics, are not anticipated to become incorporated as components of finished food contact articles and are not indirect food additives subject to 21 CFR approval.
- (c) All of these components are approved for various broad or limited indirect food additive uses under 21 CFR.

Sincerely,



John A. Todhunter, Ph.D.  
Fellow, American Institute of Chemists  
Diplomate, American Board of Toxicology  
Certified Regulatory Affairs Professional

***Note from NOVACHEM:***

***We have scanned and re-presented the text of this letter for readability.  
An actual photocopy of the original can be provided on request.***