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August 28, 1986

Dr. Robert P. Yunick
Schenectady Chemicals, Inc.
P.O. Box 1046
Schenectady, New York 12301

Re: Isonox® 132--FDA Status for
Use in Rigid P^{VC}; Our File
No. SC0854

Dear Bob:

We have received the report you sent to Dan Dixler on August 19, 1986, presenting the results of extraction studies conducted on rigid polyvinyl chloride (PVC) containing Isonox 132. On the basis of these data, we have concluded that the antioxidant may properly be used in PVC at the levels at which it was tested in the extraction studies. In accordance with our usual practice, we have prepared two letters setting forth our conclusion, one which explains in detail the regulatory background and our analysis of the data, and one which briefly states our conclusion without discussing the data, and which, thus, may be more suitable for some marketing situations.

In your letter, you requested our advice as to how best to proceed with the process of clearing Isonox 132 for use in PVC. Firstly, with respect to the use of the product by Vista, you certainly can inform them that their use of the antioxidant would be in compliance with all Food and Drug Administration (FDA) requirements.

As far as marketing Isonox 132 for use in rigid PVC products generally, on the basis of the extraction data alone you may feel free to do so without the need for any contact with FDA, or any other preliminary action.

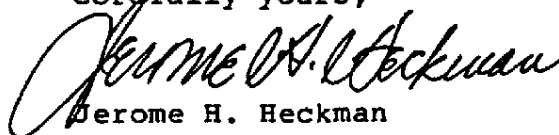
VEU-197512

Dr. Roert P. Yunick
August 28, 1986
Page 2

On the other hand, if marketing considerations demand that explicit clearance be secured for the use of the additive by way of promulgation of a Food Additive Regulation in response to a Food Additive Petition filed for this purpose, the data you have provided will provide a firm basis for such a petition. We will be happy to discuss this matter with you further and, of of course, would be pleased to work with you in the preparation and filing of a petition for Isonox 132 if this course of action is deemed necessary.

We trust you will find these letters helpful for your immediate needs. Should any questions remain, or if we may be of help in any other way at this time, please do not hesitate to let us know.

Cordially yours,


Jerome H. Heckman

Enclosures

VEV-197513