

ch 1, 1988

H. W. Dietz

ACTIVITIES REPORT FOR FEBRUARY, 1988

1. Hydrophilics

The Cosmetic, Toiletry and Fragrance Association (CTFA) recently amended the carbomer nomenclature. All numeric designations are being omitted from the carbomer name. Previously each Carbopol resin had a carbomer name (i.e. Carbopol 934 = carbomer 934, Carbopol 940 = carbomer 940, etc.) With this change, all listed Carbopol resins will be generically named as carbomer in the CTFA dictionary. The trade name-number will be listed under the Carbomer designation. Sixteen Carbopol products are affected by this nomenclature change. Eleven will be listed under carbomer. The others will not without further disclosure of cross-linking agents.

For one of these Carbopol 1342, CTFA has withdrawn the name carbomer 1342. This will seriously affect our customers' mandatory cosmetic labeling requirements. Before assigning a generic name for C-1342, CTFA wants the specific name of the comonomer we have described as a "long chain alkyl methacrylate" which we consider proprietary. C-1342 is the first of a series of hydrophilic copolymer for which CTFA generic names will be essential for cosmetic labeling purposes. After conversations with CTFA and the product group, I have drafted a letter requesting a generic name for such copolymers listing the possible comonomer (acrylate or methacrylate) within a stated C chain length designation.

Acceptance of this proposal along with the generic carbomer name change would simplify addition or deletion of products from the CTFA dictionary.

We have been negotiating with EPA to obtain clearance for the use of Carbopol 1342 as a drift control agent in Monsanto's herbicide product "No Mix." We also indicated to EPA that, as a longer term goal, we wanted to obtain clearance for C-1342 as an inert ingredient in various pesticide formulations for agricultural use. Our EPA contact has verbally indicated that we would most likely get the desired clearances with minimal additional product information and without further toxicity data.

We are collecting the requested data and should be able to submit it within the next two months. This could be a considerable market for this product.

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Interest continues in the use of polycarbophil and calcium polycarbophil in wide variety of drug and cosmetic products. Many of these applications are not covered by the FDA OTC Drug Panel evaluation as an antidiarrheal. I have outlined what additional toxicology data will be needed depending on the intended end use for the product group.

I have also established contact with Insite Vision and Dr. Robinson regarding changes needed in the USP monograph for calcium polycarbophil.

I am continuing to work with our European consultant to obtain clearance for calcium polycarbophil in Europe. Recent developments indicate much less data and expense will be required to obtain clearance than originally thought.

2. No Foul

I have returned the necessary forms to EPA to register the Jacksonville, Florida facility as a pesticide establishment. Finally, No Foul production should be in compliance with FIFRA requirements.

3. Polyurethanes

Wisconsin Pharmacal Company, Jackson, Wisconsin has developed a new unique product, a so-called "female condom" utilizing Estane 58630. I have supplied Wisconsin Pharmacal with USP tests performed on the base resin Estane 5714 used in Estane 58630. I also entered the composition of Estane 58030 into our FDA masterfile and authorized FDA to review the masterfile in the evaluation of Wisconsin Pharmacal's use.

Femshield, Wisconsin's name for the "female condom" has a lot of publicity. Ms. Conrady, V.P. Lab Services, informed me that a press conference was held February 24 to introduce the product. She has promised to send me the press release packet for Femshield in the event BFG is contacted.

4. Geons

Northwest Container uses Geon 87453 to produce food packaging sold to several USDA inspected meat and poultry processing establishments. Recently USDA inspectors in a couple of Northwestern's customers' plants asked for an FDA certification letter from the packaging material supplier. Northwestern sent a copy of our certification letter for Geon 87453 to their customers. The USDA

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inspectors would not accept this letter since it did not identify the packaging. The packing plants were threatened with a shutdown. I discussed the USDA requirements with K. Holt, Northwestern, and faxed him an example of a certification letter he could adopt to his product and supply his customers.

5. Geltrol

One of our European customers wants to obtain German approval for the use of Geltrol in food contact articles. I have supplied preliminary information to our European consultant so that he can determine what other information is needed, timing and expense of obtaining BGA clearance.

6. FDA Clearances

Direct terminal access to the Geon, SP&C and E&L recipes and raw materials catalog continues to save considerable time and effort in evaluating the FDA status or other uses of BFG products. In many instances, I have been able to give an inquirer the FDA status of a compound within 1½ hours as compared to the days or weeks previously required to obtain compositional information, evaluate and report.

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cc: R. K. Hinderer

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