September 2, 1988

H. W. Dietz

ACTIVITIES REPORT FOR AUGUST, 1988

1. No Foul

The Organotin Antifouling Paint Control Act of 1988 (OAPCA) was enacted 6-16-88. This act establishes a certifying program under which only antifouling paints that do not exceed the release rate of 4 micrograms of organotin per square centimeter per day may be sold and used. Antifouling paint is defined as a coating, paint or treatment applied to a vessel to control fouling organisms. This definition could be interpreted to include No Foul rubber.

EPA is reviewing all release data submitted to the Agency before enactment of OAPCA. We have received notice from EPA that companies which have not submitted data previously have 30 days to do so or lose FIFRA registration. BFG has not submitted release data for No Foul.

I have discussed the new requirements with the No Foul personnel. The required release rate analysis method is not usable with No Foul. However, by calculation, assuming complete release of TBTO over the service life, we can estimate that the average release rate would fall below the limit.

I have discussed this information with EPA asking for a testing exemption based on these calculations. I expect a reply within the week.

2. Hycar Elastomers

I have submitted five Hycar VT elastomer compositions to our European consultant, RCC Consulting and Registration. They will be reviewed for clearance under the German BGA regulations. BFG clearance is essential to sales of these elastomers in Europe for a variety of applications.

3. Hydrophilics

A Drug Master File (DMF #7618) has been established with the FDA for Carbopol 976. The nonproprietary drug name for C-976 is polycarbophil. There has been a growing interest in the use of polycarbophil as a bioadhesive and for opthalmic applications.

We recieved USDA acceptance for the use of Goodrite K-796 and KXP-123 as ingredients in boiler water treatment compounds, steam lines and/or cooling system formulations in federally inspected meat and poultry establishments.

EPA has expressed concern about applicator exposure to residual benzene and acrylic monomer from the use of Carbopol 1342 as an inert pesticide ingredient. I have supplied information to EPA that the formulated products sold to applicators with C-1342 would likely contain less than 8 ppm benzene and 20 ppm acrylic acid. Since little vaporization of either residual is likely from the formulated product, applicator exposure would be essentially dermal and dermal contact protection used for the active pesticide ingredient would provide protection from benzene and acrylic acid exposure. EPA will consider this new information at their next product committee meeting.

4. SPI

I attended an initial meeting of an ad hoc SPI-National Food Processors Association (NFPA) meeting being formed to address FDA's microwave susceptor food packaging concerns. The susceptor packages contain a metallized film to concentrate heat from the microwaves to cook food. FDA is concerned because temperatures as high as 600°F in the susceptor area have been reached. Food packaging materials have been tested at maximum temperatures of 275°F. FDA will hold a public meeting Sept. 20 to address their concerns. "Fall out" from this issue could result in increased requirements to obtain FDA clearance for all packaging components in the future.

The new SPI-NFPA has requested a $2,000 contribution to support the analytical work needed to define the issues. A poll of our Chemical divisions and Corporate Research resulted in a belief that BFG should not financially support this effort.

5. Estanes

An inquiry was received from SPI counsel, Keller & Heckman, about the interest in forming a joint effort with other polyurethane manufacturers to obtain FDA clearance for polyether polyurethanes. I informed J. Heckman that a joint effort was already under way with expectations of filing a petition in September. BASF instigated the original request. I have been contacted regarding the BFG, Dow, DuPont petition by BASF.

The FDA has asked for additional information on Estane 586311 in regard to its use in Wisconsin Pharmacal's

female condom. ALTC is developing the information to be submitted for inclusion in DMF #5361 as soon as possible.

Kimberly Clark is planning on using Estane X4270 or its successor in a leg band application for disposable diapers. They were concerned about the potential for free MDI which might come into contact with infant skin during use of the diaper. At the request of D. Hall, ALTC, I discussed their concern with Dr. W. Landin (Kimberly Clark). Since the Estane polyurethanes are stoichiometrically reacted, there is little chance of free MDI remaining. Furthermore, in past extraction studies related to medical applications, no MDA was detected in extracts from this class of polyurethanes at a detection level of 5 ppb except under extremely high temperatures. (MDA is a hydrolysis product of MDI.) Under the test conditions any free MDI extracted would have been detected as MDA.

6. Goodrite 3110X123

We had obtained a PMN exemption for the production of 100,000 lbs of 3110X123, an alkylated diphenylamine. One of our customers indicated that this amount was insufficient and requested that we file a PMN with EPA. There have been no toxicity studies done to date on 3110X123. At the request of the product group, I prepared a statement for the PMN discussing the probably toxicological similarity between 3110X123 and four structurally related alkylated diphenylamines. This class of substances displays minimal acute toxic, irritative and mutagenic potential.

7. Reactive Liquid Polymers

Conrail employees and other neighbors have complained about the obnoxious odors given off at Akron Chemical during RLP production. Akron Chemical has attributed these odors to dimers of butadiene and acrylonitrile-butadiene (4-vinyl-1-cyclohexene and 1-cyclohexene-3-carbonitrile). I provided a summary of available toxicity data for both compounds in preparation for a meeting of Akron Chemical personnel with Conrail employees. Based on the data available, air concentrations of both compounds would have to be extremely high to cause adverse effects.

8. Geons

A customer, Electromedics, Inc., uses four Geon compounds to injection mold some medical device fittings. We were requested to supply the company with compositional information to be transmitted to the Swedish, Italian and French authorities to obtain approval for their products.

This was an urgent request. After I finally obtained the required information on the Geon compounds involved, I developed a compositional disclosure letter using generic identification with approximate quantities. The draft response was reviewed by Legal. Legal felt Electromedics' request letter, as stated, constituted a tighter secrecy agreement than our usual document. However, the product group felt my letter still gave away too much information. They requested the company to send forms from the various countries which we were to fill out and submit directly. Although this was originally an urgent request as attested to by the dozen or so phone calls between Electromedics and myself, we have yet to receive any governmental forms to complete since my last communication August 8.

R. Krock requested a review of two rigid PVC compounds promoted as "food grade" to determine their FDA status. On review, I found that Geon 87403 trans 002 was not acceptable for food contact applications due to inclusion of one ingredient without regard to its limitations. I provided information to the technical group regarding limitations on the offending ingredient.

The Geon group is interested in producing some vinyl copolymers. I prepared a summary of the FDA status and limitations and/or specifications for ethylene-vinyl acetate, ethylene-vinyl chloride and vinyl chloride-vinyl acetate copolymers for the product group.

W. C. Bachtel

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