

November 17, 1986

J. D. Ong

Activities Report - October, 1986
Environmental Health/Industrial Hygiene/Toxicology

1. Amvrol, a division of Wrigley's, wants to use a flexible PVC compound as a package for a thumb-shaped hard candy sucker. The sucker is to be hot molded in the PVC film at 275°F. Geon 86153, a DOP plasticized compound is being evaluated. Mr. Bachtel has expressed concerns over the possible adulteration of the candy with the phthalate plasticizer and the tin stabilizer in this compound and is working with the Geon group to find a solution.

An antifoam represented as "FDA approved" was to be used in a number of PVC resins for can coating applications. Mr. Bachtel found the clearance for this product to be very limited and not applicable to can coatings. As a result, this defoamer will be removed from the five PVC resins involved.

Alcoa uses three flexible Geon compounds for capliner applications. They require a current FDA certification letter in their files for each compound. At the request of the Geon group Mr. Bachtel prepared and sent appropriate certification letters to Alcoa for compounds PVC-A, 111-73-25-10, and 111-73-25-7.

USP Biological Tests for Plastics were performed on Geons 84702, 84756, 86153 and 87455. These tests are performed as an indication of the suitability of a plastic formulation for various medical applications. Many potential customers require the results of these tests before consideration of a product. The tests on these compounds were performed under the most severe conditions, normally not used for PVC. Three of the samples passed; only Geon 87455 failed due to a reaction to the systemic injection in mice. This compound will be retested under the normal PVC conditions.

2. The Calvert City Carbopol plant is due for FDA inspection at any time. Also, the plant now fully recognizes that all the Carbopol 900 resin series are pharmaceutical products and must be produced using Good Manufacturing Practice (GMP). Therefore, because of some concerns of D. Henneke, Mr. Bachtel performed a GMP audit of the Carbopol facilities on October 8. The plant appears to be in good shape except for some housekeeping problems due to construction. There will also need to be more detailed recordkeeping (similar to that now used for C934-P) for the other 900 series.

BFG28377

23863001

The group has now decided to proceed with the NF monographs for the 900 series since they must comply with GMP regardless of whether USP-NF monographs do or do not exist.

Mr. Bachtel has requested Cosmetic, Toiletry and Fragrance Association (CTFA) generic names for Carbopols 1706, 1724, 1731, 1754 and 940-A. The first four Carbopol resins are being used as a plasticizer or binder in toilet soap applications.

Carbopol 940-A is in actuality Carbopol 934-P produced by the new single pass technology for P&G. It will replace C-940 in Crest toothpaste until non-benzene Carbopol can be produced.

Due to labeling provisions, P&G has asked that we attempt to have CTFA assign Carbomer 940-A as a generic name for this specially produced C-934-P.

3. The OSHA Hazard Communication rule has resulted in questions and citations for violations regarding the labeling of PVC. After years of placing a cancer warning on PVC bags because of concerns about VCM, the Geon Division conducted extensive studies and assessments which showed that most of our PVC resins did not require a cancer label because residual VCM levels were sufficiently low so as to not present a hazard during use. Recently several companies have been cited for not labeling and a request for an opinion from OSHA was not favorable.

Because of this labeling problem, Dr. Hinderer and several other technical and legal representatives from other companies and the VI met with OSHA to explain our problem and present the reasons why we believe labeling is unnecessary. The delegation also noted that this cancer label has led some customers to refuse the product. OSHA appeared to understand our problem and there was some sense of agreement. However, because of the nature of the beast, it will be a while before we have convinced "the Agency."

4. BFGoodrich (Estane), Shell, and Insituform are in the final stages of data gathering for the revolutionary piping system which will enable the replacing of existing piping which often runs under cities or rivers, without digging. Our present efforts are in response to questions that EPA raised in regard to our original submission. We have now identified the materials which leach from our Estane product. Dr. Hinderer recently met with Shell and

BFG28378

23863002

Insituform to analyze the data and is now writing a risk assessment to provide to EPA. The goal for providing this second submission to EPA is November 15, 1986.

5. We received a request for help from one of our SP&C Division distributors. Union Carbide had received a shipment of our ARW and had refused to accept the material because of the absence of a cancer warning for the BNA impurity and because of questions whether use situations would be safe. We resolved the situation by notifying Union Carbide that ARW is exempt and that it does not provide a hazard under what we envision as normal use conditions.

Corporate Medical Department

6. 276 influenza vaccinations were given to employees of BFG and UGT. UGT had requested this service and was billed at cost.
7. UGT was provided medical services after its formation for several periods pending UGT's signing a service contract. The latter did not materialize and such services were discontinued. UGT has once again requested medical services for a flat monthly payment but a contract has not yet been signed.
8. The temporary quarters of the Corporate Medical Facility have proven to be quite adequate for the current medical services.

Richard A. Guyton

cc: L. Carter
L. V. Triggiani

BFG28379

23863003