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PLASTIC PRODUCTS AND RESINS DEPARTMENT

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July 30, 1976

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In our meeting on June 11 we agreed that I would conduct Section 121.2555 specification tests on sintered TPE made from high solids dispersion and on finished FEP made with C-8 dispersing agent.

We have completed these tests as well as all other tests specified in 121.2555 and find that both the TPE and the FEP are well within the limits specified. I know of no technical reason why finished products made from these resins would not conform with 121.2555.

The level of extractables on sintered TPE made from high solids TD-37X was as follows:

<u>Solvent</u> (1)	<u>Total</u> (2) <u>Extractables, mg/in²</u>	<u>Extracted</u> (3) <u>Fluoride, mg/in²</u>
Heptane	0.072	-- --
Ethyl Acetate	0.105	-- --
50% Ethanol	0.039	0.00019
Water	0.12	0.00012

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(1) All solvents were distilled.

(2) Corrected for solvent blank. FDA maximum allowable extractables is 0.2.

(3) FDA maximum allowable fluoride is 0.03.

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The thermal instability index for TD-37X high solids sintered product as determined by ASTM D1457-56T was 20.4, well below the maximum specified value of 50.

The FEP cubes produced from the added C-8 recipe had the following level of extractables (duplicate determinations):

<u>Solvent</u> ⁽¹⁾	<u>Total</u> ⁽²⁾ <u>Extractables, mg/in²</u>	<u>Extracted</u> ⁽³⁾ <u>Fluoride, mg/in²</u>
Heptane	0.054/0.031	--
Ethyl Acetate	0.018/0.026	--
50% Ethanol	0.059/0.11	0.00055/0.001
Water	0.064/0.059	0.00062/0.00064

(1) All solvents were distilled.

(2) Corrected for solvent blank. FDA maximum allowable extractables is 0.2.

(3) FDA maximum allowable fluoride is 0.03.

The melt viscosity of the FEP changed from 8.77 after five minutes holdup to 7.77 after 30 minutes holdup at 372°C. This is a 12% change. The FDA maximum allowable change is 50%. The infrared index requirement is also satisfied.

These data confirm that the minor changes being made in our processes have no effect upon the ability of these products to be converted into finished products which meet all the requirements of FDA regulation 121.2555.

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