

BFGoodrich**INTER-ORGANIZATION CORRESPONDENCE**TO
C. V. PurksFIELD POINT OR DEPT. & BLDG NO
ALTC

DATE YOUR LETTER

FROM
W. C. BachtelFIELD POINT OR DEPT. & BLDG NO
D/0020, Corporate HQDATE THIS LETTER
4-2-87

SUBJECT

USE OF ACRYLIC POLYMERS IN PVC FOOD CONTACT ARTICLES

I will attempt to explain how acrylic polymers may be used in various flexible, semirigid and rigid PVC food contact articles. Part of the confusion is based on the promulgation of the original regulations and subsequent amendments.

First, in addition to the prior sanctioned uses, there are currently a number of regulations which authorize the use of PVC for food contact articles. These "end use" regulations are 175.105, 175.300, 175.320, 176.180, 177.1200 and 177.1210. So long as no chemical reaction takes place, it has always been permissible to blend polymers that are cleared under the same or applicable regulations unless specifically prohibited. Consequently, for use under the above regulations, PVC can be mixed with any of the acrylate polymers cleared under the same regulations or those cleared under 177.1010.

Otherwise, if used under the prior sanction for PVC, there are two regulations that permit the use of acrylic polymers in PVC food contact articles. They are:

177.1010 "Acrylic and Modified Acrylic Plastics, Semirigid and Rigid"

178.3790 "Polymer Modifiers in Semirigid and Rigid Vinyl Chloride Plastics"

Regulation 177.1010 when originally promulgated applied solely to final acrylic food contact articles. On July 24, 1985 it was amended to permit the listed acrylic plastics to be used as components of food contact articles in response to a petition submitted by BFG. Rather than attempting to amend each separate regulation, we had 177.1010 amended so that those acrylics cleared therein could be used under other regulations such as 175.300, 175.320, 176.180, etc.

You will note, as a result of our petition, the second sentence in the first paragraph was added. It states, "The acrylic and modified acrylic polymers or plastics described in this section also may be safely used as components of articles intended for use in contact with food." Similar references to the use of the listed acrylics are listed in paragraphs (a), (b), and (f) (see highlighted areas on enclosed copy).

The statement in paragraph (a) that at least 50 weight percent of the polymer content of the acrylic and modified acrylic materials used as components of articles shall consist of polymer units derived from one or more of the acrylic or methacrylic monomers listed in paragraph (a) (1) refers strictly to the acrylic material, not the end article when used as a component thereof. In other words, there is no limitation as to the amount of acrylate material that could be mixed with PVC,

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SBR, polyethylene, polypropylene, etc. to produce a food contact article. Obviously, if one is to call an article a "PVC food contact article" it should contain no less than 50% weight percent PVC.

Also, paragraph (4) of 177.1010 refers to the modified acrylic material, not the end food contact article. For example, 75% K-120N and 25% SAN = the modified acrylic material. Then this modified acrylic material could be used as a component, in any amount, in a PVC food contact article.

In the particular case of PVC food contact articles, any acrylic or modified acrylic material that complies with 177.1010 may be used with PVC in any amount, with any other permitted ingredients to make a finished food contact article, flexible, semirigid or rigid. For example, an acceptable flexible PVC food contact article could contain 100 parts PVC resin; 15 parts K-120N, 120 parts DOP, acceptable stabilizer, filler, colorant, etc. Then, the only restriction which would apply to the article would be due to the restrictions imposed on the DOP, stabilizer, etc., if such apply. In this example, the end food contact article would be restricted to contact with foods of high water content only because of the use of DOP.

Regulation 178.3790 "Polymer Modifiers in Semirigid and Rigid Vinyl Chloride Plastics" was promulgated in the late 60's after 177.1010 specifically for PVC modifiers. As you know, 178.3790 applied solely to semirigid and rigid PVC. It also placed limits on the amounts of modifier that could be used in PVC food contact articles.

Although originally not necessarily intended to do so, the 1975 BFG amendment of 177.1010 has changed the entire picture. 178.3790 need no longer be used as the authority for the use of acrylic based PVC modifiers.

In summary, those acrylic or modified acrylic materials acceptable for use under 21CFR 177.1010 may be used, in any amount, to fabricate flexible, semirigid or rigid PVC food contact articles. Since this fact has not been appreciated by many customers, suppliers or competitors as yet, it may be wise to "broadcast" it as little as possible.

You asked about the FDA definition of semirigid and rigid. There is currently no official FDA definition in writing. FDA does, however, use the ASTM definitions.

I hope I have cleared up some questions for you. If you have any more, please call.

- *W.C. Bachtel*

W. C. Bachtel