

MAY 14 1970

LAW OFFICES

KELLER AND HECKMAN

1712 N STREET, N W

WASHINGTON, D. C. 20036

JOSEPH E. KELLER
JEROME H. HECKMAN
CHARLES M. MEHRAN
WILLIAM H. BORGHESE, JR.
ROBERT E. TIERNAN
WAYNE V. BLACK
THOMAS J. HUGHES, JR.
DAVID L. HILL
MARTIN W. BERCOVICI

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

May 11, 1970

Mr. Robert M. Miller
Hercules, Inc.
Delaware Trust Building
Wilmington, Delaware 19899

Dear Bob:

Following up once again on our recent correspondence concerning the FDA "Statement of Policy" published on April 9, 1970, we thought it might be worthwhile to bring to your attention, and that of all of the other members of the Food, Drug and Cosmetic Packaging Materials Committee, the following two bits of information:

(1) We have been advised by our good friend Einar Wulfsberg that he has seen recent letters sent by the Food and Drug Administration in response to miscellaneous inquiries, which letters apparently are setting forth the following "stock paragraph" on the practical import of the Statement:

"Substances which have been regarded by the Food and Drug Administration in the past as generally recognized as safe (GRAS) or prior sanctioned (PS) or not food additives under conditions of intended use are now being reexamined in the light of current scientific information and principles for evaluating safety. We anticipate that this review may require a lengthy period of time. In the meantime, we do not propose to initiate regulatory action adverse to their continued use without prior notification."

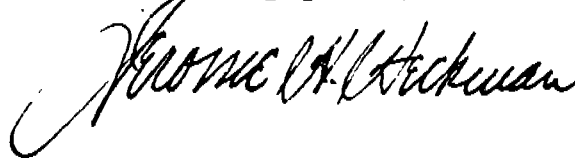
ASI-PR 0000877

Mr. Robert M. Miller
May 11, 1970
Page 2

(2) In addition, the May 4, 1970, issue of Chemical Engineering reflects contacts by this publication with FDA during which the Staff has apparently advised the press that its Statement of Policy "doesn't revoke permission to use the [GRAS or Prior Sanctioned] additives." A copy of a sheet from the May 4 issue of Chemical Engineering is enclosed so that you can see all of its coverage of this matter.

As far as we are concerned, we are delighted to say that most of what is being said now serves to substantiate the opinions and advice we have been giving the Committee since the Statement of Policy was issued.

Cordially yours,



Enclosure

cc: SPI Food, Drug and Cosmetic
Packaging Materials Committee

MAY 1970

LAW OFFICES
KELLER AND HECKMAN

1212 N STREET, N. W.
WASHINGTON, D. C. 20036

JOSEPH E KELLER
JEROME H HECKMAN
CHARLES M MEEHAN
WILLIAM H. BORGHESE, JR
ROBERT R TIERNAN
WAYNE V. BLACK
THOMAS J. HUGHES, JR
DAVID L. HILL
MARTIN W. BERCOVICI

TELEPHONE
202 296-2700
CABLE ADDRESS "KELMAN"

May 5, 1970

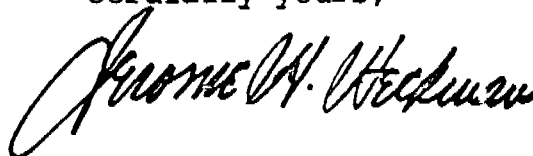
Mr. Robert M. Miller
Hercules, Inc.
Delaware Trust Building
Wilmington, Delaware 19899

Dear Bob:

I thought you and the other members of the Food, Drug and Cosmetic Packaging Materials Committee might well be interested in the enclosed letter and accompanying memorandum sent to me recently by Bill Larkin of M & T Chemicals, Inc.

Suffice it to say that we believe M & T is taking a very responsible position on the recent FDA "Statement of Policy" and its implications for PVC materials.

Cordially yours,



Enclosures

cc: SPI Food, Drug and Cosmetic
Packaging Materials Committee

ASI-PR 0000880

M&T Chemicals Inc.

SUBSIDIARY OF AMERICAN CAN COMPANY



RESEARCH LABORATORY,

P.O. BOX 1104, RAHWAY, NEW JERSEY 07065

April 24, 1970

Mr. Jerome H. Heckman
Keller & Heckman
1712 N. Street, N.W.
Washington, D. C. 20036

Re: SPI, Food Drug and Cosmetic Packaging
Materials Committee

Dear Jerry,

Enclosed is a copy of a letter sent out today to all of our salesmen, sales correspondants, Technical Service and Marketing personnel. I hope that it will help to prevent the spread of misinformation. Feel free to advise members of the SPI Packaging Materials Committee of our action in this matter if it will be generally helpful.

Very truly yours,

M&T CHEMICALS INC.

W. A. Larkin
Market Manager

WAL/krf

cc: J. Kaplan
A. Sheldon
R. Zedler

ASI-PR 0000881

M&T Chemicals Inc.

SUBSIDIARY OF AMERICAN CAN COMPANY

Inter-Office Correspondence

TO: Distribution

FROM: W. A. Larkin
Rahway Lab

FILE:

DATE: April 24, 1970

Referring to yours of:

Referring to ours of:

Subject:

Non Tin Food Grade PVC Stabilizers

On April 9th, the FDA issued an announcement in the Federal Register which, in essence, stated that anyone holding a letter of opinion from the FDA relative to the use of "generally recognized as safe" (GRAS) materials for any application would be required to forward copies of these letters to the FDA for what we believe to be essentially review. It happens that a number of data sheets covering "non tin" food grade PVC stabilizers, including some of the "calcium" zinc systems refer to the compounds being sold as "generally recognized as safe". Several of our salesmen have already been asked, "Does this mean that only the octyltin stabilizers are approved for use since the non tin systems which were promoted as 'generally recognized as safe' must now clear a second review?" This is not the case. It must be remembered that even PVC polymer, itself, is the subject of prior sanctions and would fall in the same category as certain of the "non tin" stabilizer systems. Our position is as follows.

We believe that the recent FDA request involves only review of existing letters and that essentially nothing will change relative to the status of any "non tin" system currently in use. Further, having reviewed those "non tin" systems being used as food grade PVC stabilizers we find that a great many are regulated by specific regulations and are not even the subject of the recent FDA request.

There is a definite place for both "non tin" systems (calcium zinc) and for octyltin stabilized PVC. As representatives of M&T, contacting customers, you are instructed not to imply in any manner that there is any question relative to the safety of currently used "non tin" systems. This approach is not to be used as any kind of a selling point for the octyltin materials. The octyltins offer specific advantages which, of course, you should continue to promote.

ASI-PR 0000882

The better processability of PVC compounds stabilized with octyltins, the greater output rates which can be achieved with octyltin systems, the exceptional clarity and the water blush resistance, as well as the superior physical property characteristics of the finished plastics containing octyltins are some of our major selling points.

I know that I can depend on your cooperation in this matter. If you have any questions, or your customers have any questions, please refer them to me.

Wm G. Zedler

CC; R. Zedler
J. Kaplan
P. Chapin