



Memorandum

Date Oct. 2, 1985

From Food Additive Chemistry Evaluation Branch, HFF-458

Subject FAP 5B3870 - Minnesota Mining & Manufacturing Co. (3M). Submissions dated 8-2-85 (received DCH 9-18-85) & 9-3-85. Perfluoroalkyl acrylate copolymer as an oil and water repellent for paper.

To Indirect Additives Branch, HFF-335
Attn: B. Anderson

DCH's previous memo, dated 6-28-85, requested the following additional information from 3M:

1. CAS Name and Registry No. for the polymer.
2. Average molecular weight of the polymer.
3. An infrared spectrum.
4. Technical effect data.
5. A draft of the proposed regulation.
6. A brief discussion of the chemistry of _____
7. Available data which show penetration of dye solutions into treated paper.

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The CAS Registry No. is CAS 92265-81-1. The polymer is named in terms of its four monomers. The name appears in the submitted proposed regulation. In addition to use level limitations, discussed in our 6-28-85 memo, the regulation contains a specification for fluorine. An enclosed reprint of a published article would serve as the analytical method for fluorine.

According to 3M, the molecular weight of the polymer cannot be determined because of its insolubility. The polymer will dissolve in trifluoroacetic acid, but with degradation.

An infrared spectrum is given.

Data are present which show that the intended technical effect is achieved by varying amounts of the additive.

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Finally, oil penetration data from paper with and without polymer treatment has been submitted in the form of actual paper samples. We have no further questions on this point.

DCH has no objection to a regulation for 3M's polymer.

Michael T. Flood

Michael T. Flood, Ph.D.

HFF-156; 400
HFF-458 RF/Flood
HFF-458:MTFlood:472-5680:ls1:9-27-85
RD Init: PSSchwartz

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Acting Director
Office of Compliance (HFF-300)

Amendment to §176.170 Components of paper and paperboard
in contact with aqueous and fatty foods. Food Additive
Petition No. 5B3870 - ACTION

Sanford A. Miller, Ph.D.
Director, Center for Food Safety and
Applied Nutrition (HFF-1)

OBJECTIVE

To publish the attached document (Tab A) which would amend
§176.170 of the food additive regulations.

FACTS

The attached order would amend §176.170 to permit the use
of a perfluoroalkyl copolymer as a component of paper and
paperboard in contact with non-alcoholic aqueous and fatty
foods. This order is in response to food additive petition
5B3870 submitted by Minnesota Mining and Manufacturing
Co., 3M Center, St. Paul, MN 55144. The notice of filing
(Tab B) was published in the Federal Register on December
9, 1985.

DISCUSSION

The Division of Food Chemistry and Technology concludes
that the additive is adequately identified and accomplishes
the intended technical effect. The Division further concludes
that none of the monomers used in preparation of the copolymer
will be present in the daily diet at a concentration higher
than 10 ppb.

The Division of Toxicology concludes that the additive
is safe under the prescribed conditions of use.

The Environmental Impact Section concludes that this action
will not significantly affect the quality of the human
environment and that an Environmental Impact Statement is
not necessary. The Finding of No Significant Impact (Tab
C), the Environmental Assessment (Tab D) and Supplemental
Environmental Information (Tab E) are attached.

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FILE
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OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
335	<i>Miller</i>	12/12	HFF-330	<i>Sanford A. Miller</i>	12/16/86			
HFF-335	<i>C. Miller</i>	12/17/86	HFF-301	<i>Verdeman</i>	12/23/86			
HFF-330	<i>Panzer</i>	12/16/86	HFF-300	<i>Lafer</i>	12/23/86			

The Division of Food and Color Additives concludes that Regulatory Flexibility and Impact Analyses are not necessary because this action is exempt from the Regulatory Flexibility Act and Executive Order 12291. The Division further concludes that this order may be signed by the Director or Deputy Director, Center for Food Safety and Applied Nutrition, because it does not involve novel or controversial issues.

RECOMMENDATION

We recommend that the attached order be signed and published in the Federal Register.


L. Robert Lake

Enclosures:

Tab A - Document

Tab B - Filing Notice


Tab C - Finding of No Significant Impact

Tab D - Environmental Assessment (excluding confidential information)

Tab E - Petitioner's letters of February 12, 1986 and July 16, 1986 (excluding confidential information)

DECISION

Recommended course of action:

Approved 1-20-87 Disapproved _____ Date 

Prepared by Leonard C. Gosule, HFF-335, 472-5690

GCF-1 HFC-1 HFC-222