Mr. D. C. Kay
Bakelite Company
9 East 41st Street
New York

May 8, 1956

Mr. A. J. Dragonette
Mr. H. F. Robertson

Colorant - Rigid Vinyl Sheeting

Dear Mr. Kay:

In regard to the colorant External D & C Yellow No. 3, which was included in the formulation you submitted to me, I had an opportunity to discuss this yesterday with Dr. A. J. Lehman, Chief Pharmacologist of the Food and Drug Administration. He informed me that he did not think this colorant would be acceptable. It is an external colorant certified for "externally applied drugs and cosmetics," which means drugs and cosmetics that are applied only to external parts of the body and not to the lips or any body surface covered by mucous membrane.

Colorants used in food packaging materials should be ones acceptable for internal consumption unless it can be adequately demonstrated that none of the colorant would migrate from the material in extraction studies. Because of the solubility of the yellow referred to above, it is expected that it would be extracted from the vinyl sheeting.

An endeavor should be made to secure a pigment for which the manufacturer can supply information as to its acceptability as a colorant in food packaging materials such as vinyls. It may be quite difficult to find an acceptable yellow.

Very truly yours,

MEDICAL DIRECTOR

Thomas W. Hale, M. D.
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FOR INTERNAL CORRESPONDENCE

BAKELITE COMPANY

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30 EAST 42nd STREET, NEW YORK 17, NEW YORK

To (Name) Dr. T. W. Nale
Company Industrial Medical & Toxicology Dept.
Location 300 Madison Avenue
New York 17, New York

Date April 24, 1956
Originating Dept. New Product Engineering
Answering letter date
Subject Mrs Lawrence Held for letter from Kohnstam Co. Re Colorant

Copy to Mr. A. J. Dragonette
Mr. H. F. Robertson

Information recently given to us by Mr. F. W. Rose, the attorney for International Latex Company, makes it imperative that we get additional and more specific approvals on our food packaging grade rigid vinyl sheet and cast vinyl film. This additional approval is necessary to our continued progress with Latex in their program of packaging cut and dressed poultry. A copy of my letter to Mr. A. J. Dragonette is attached for your reference which explains Mr. Rose's directions to us and views regarding the necessary approvals.

To assist you in preparing your request for the specific approvals which appear necessary to satisfy the request of International Latex, there are attached proposed drafts of letters to the three government agencies involved giving complete formulation data and compound designation.

Mr. Rose particularly requested that we include the colorant in the formulation since in his opinion it can be just as important as the stabilizer.

The letter to Mr. Mehurin will be for general use in our promotion of the packaging grade cast film, as you have already requested his approval of our rigid calendered sheeting VCAA 3400 in your letter of April 16 to Mr. Mehurin.

D. C. Kay
D. C. Kay

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INDUSTRIAL MEDICAL & TOXICOLOGY DEPARTMENT

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Mr. A. J. Dragonette
Bakelite Company
New York 17, New York

April 11, 1956

New Product Engineering

Mr. H. F. Robertson

Government Approvals on
Packaging Grade Vinyl

A visit to International Latex on Friday, April 6 by Bill Corbet and me pointed up the need for additional approvals from government agencies if our packaging grade rigid vinyl and cast film is to be considered by International Latex for packaging chickens.

Mr. F. W. Rose, attorney for Latex, has quite thoroughly investigated the approvals needed in putting packaged chicken on the market in a container such as Latex contemplates using. His investigation included a talk with one of the five assistant commissioners of the F.D.A.

Mr. Rose found that the final approval in poultry packaging must come from Dr. Roy E. Willis, Chief of Poultry Inspection Branch, Poultry Division, Agricultural Marketing Service, Department of Agriculture, Beltsville, Maryland. Dr. Herman S. Miller is Director of the Poultry Division. Dr. Frank Renne can act for Dr. Willis in Dr. Willis's absence. Mr. Rose stated that approval by the Meat Inspection Branch is not even relevant when it comes to packaging poultry.

Before International Latex can proceed in developing a suitable poultry package, Mr. Rose insists on being able to write directly to the Poultry Inspection Branch to secure approval on a definite compound designation, such as VCAA 3400 Yellow 523. After such an approval is received from Dr. Willis, Latex can proceed on their own in getting the necessary approval on the particular physical form of the proposed package. This latter approval will involve a test shipment of chickens in the proposed package under the careful scrutiny of the Poultry Inspection Branch. Then, and only then, will International Latex be free to sell their package.

To enable International Latex to get an approval on the compound from Dr. Willis of the Poultry Inspection Branch, we should write to at least Dr. Lehman of the F.D.A. and Dr. Willis of the Poultry Inspection Branch giving them the formulation on VCAA 3400 Yellow 523 and VCAA 3400 Yellow 524.

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For completeness, we should also give this information to Mr. Mehurin f the Meat Inspection Branch. Then when International Latex -- or any other prospect -- writes to Dr. Willie the compound designation will serve as a reference number by which approval can be given by Dr. Willie to an inquirer without revealing the formulation.

The above approach would, of course, include our cast film VBAB 9023 Natural which we are suggesting as a suitable cover for the chicken package.

For example: - Mr. F. W. Rose of Latex proposed to write to Dr. Willie with a request such as: "Will Bakelite rigid vinyl compound VCAA 3400 Yellow 523 and "Krene" cast film VBAB 9023 Natural be suitable compounds from which to form a package for shipping cut and dressed poultry?" If Dr. Willie has on file a letter from us tying in these compounds with their ingredients, he may be able to answer immediately: "Bakelite rigid vinyl compound VCAA 3400 Yellow 523 and "Krene" cast film VBAB 9023 Natural are acceptable for use in federally inspected poultry packaging houses provided the physical form of the package is suitable." If Dr. Willie is not familiar with the ingredients of the compounds, he can readily contact Dr. Lehman who would also have a letter in his files tying in formulation with compound number.

I feel that Mr. F. W. Rose's request is reasonable and will involve little effort on our part now that we have already presented the information on the magnesium epoxystearate stabilizer to both Lehman and Mehurin. Photostats of letters from the F.D.A., Meat Inspection Branch, and the Poultry Inspection Branch which O.K.'d our compounds by designation, rather than by naming the ingredients would be very helpful in talking with prospects. All we have now are letters from Dr. Lehman and Dr. Mehurin which name the stabilizer as being acceptable. We do not wish to tell prospects what stabilizer we are using and the prospect would undoubtedly feel more secure if he could write directly to the government agencies involved and get a letter of approval for his own protection.

D. C. Kay

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Dr. A. J. Lehman
Chief, Division of Pharmacology
Food and Drug Administration
Department of Health, Education
and Welfare
Washington, D. C.

Dear Dr. Lehman:

Bakelite Company plans to promote the use of a Bakelite rigid vinyl sheet, VCAA 3400 Yellow 523 and Yellow 524, and a "Krene" cast vinyl film, VBAB 9023 Natural, for packaging as wide a range of food products as possible. The formulations of these compounds are:

VCAA 3400 Yellow 523
VCAA 3400 Yellow 524

Ingredient	Percentage
VYNS vinyl resin (90/10 vinyl chloride/ vinyl acetate ratio)	97.3 (minus colorant)
Magnesium epoxystearate (prepared from G-60)	2.0 - 3.0
Zinc stearate	.2
External D & C Yellow No. 3 Lake (K7150) (H. Kohnstamm Co. N.Y.C.)	.50- 1.00
Titanium dioxide	.25 - .50

VBAB 9023 Natural

VYNW vinyl resin (95/5 vinyl chloride/ vinyl acetate ratio)	73.5
DOP	24.0
G-60 (Rohm & Haas)	2.0
Acrawax C	.17
Durocer wax	.33
	100.00 %

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For previous correspondence on this subject refer to my letters of _____ and your answering letters _____.

If you have no objection to the use of these formulations in packaging the various food products under your control, would you please send us a letter giving your opinion and mentioning the compounds by product designation only rather than by formulation.

Very truly yours,

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Mr. R. M. Mehurin
Chief, Laboratory Section
Meat Inspection Branch
Agricultural Research Service
U. S. Department of Agriculture
Washington 25, D. C.

Dear Mr. Mehurin:

Bakelite Company plans to promote the use of "Krene" cast vinyl film, VBAB 9023 Natural, for packaging red meat and meat products. The formulation is:

VBAB 9023 Natural

Ingredient	Percentage
VYNW vinyl resin (95/5 vinyl chloride/ vinyl acetate ratio)	73.5
DOP	24.0
G-60 (Rohm & Haas)	2.0
Acrawax C	.17
Durocer wax	.33
	100.00 %

If you have no objection to the use of this formulation in packaging red meat and other food products under your supervision, would you please send us a letter giving your opinion and mentioning the product by compound designation rather than by formulation.

Letters similar to this are also being written to Dr. A. J. Lehman of the F.D.A. and Dr. Roy E. Willie of the Poultry Inspection Branch for their opinions on their respective products.

Very truly yours,

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Dr. Roy E. Willie
Chief, Poultry Inspection Branch
Poultry Division
Agricultural Marketing Service
Department of Agriculture
Beltsville, Maryland

Dear Dr. Willie:

Bakelite Company plans to promote the use of a Bakelite rigid vinyl sheet, VCAA 3400 Yellow 523 and Yellow 524, and a "Krene" cast vinyl film, VBAB 9023 Natural, for packaging poultry. The formulations are:

VCAA 3400 Yellow 523
VCAA 3400 Yellow 524

Ingredient	Percentage
VYNS vinyl resin (90/10 vinyl chloride/ vinyl acetate ratio)	97.3 (minus colorant)
Magnesium epoxystearate (prepared from G-60)	2.0 - 3.0
Zinc stearate	.2
External D & C Yellow No. 3 Lake (K7150) (H. Kohnstamm Co. N.Y.C.)	.50 - 1.00
Titanium dioxide	.25 - .50

Barkley 7-9760

VBAB 9023 Natural

VYNW vinyl resin (95/5 vinyl chloride/ vinyl acetate ratio)	73.5
DOP	24.0
G-60 (Rohm & Haas)	2.0
Acrawax C	.17
Durocer wax	.33
	100.00 %

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If you have no objection to the use of these formulations in packaging poultry and other food products under your supervision, would you please send us a letter giving your opinion and mentioning the compounds by product designation rather than by formulation.

Letters similar to this are also being written to Dr. A. J. Lehman of the F.D.A. and Mr. R. M. Mehurin of the Meat Inspection Branch for their opinion on their respective products.

Very truly yours,

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