

TO: Dave Penney-Austin

TGG: JCL: ERT: MJH: AJO: RF
XF: _____

FROM: T. G. Grumbles

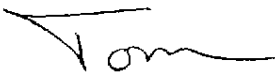
DATE: April 13, 1990

Interoffice
Communication

SUBJ: TOXICOLOGY TESTING FOR ALFONIC NOVEL 10-44 ETHOXYLATE AND
10-44 ETHER SULFATE

VISTA

Testing for both of the subject products was done in 1988, a full panel, except for inhalation, of acute tests were run. Copies are attached.



T. G. Grumbles

dlj

Attachment

cc: VPSAG LIST (without attachment)

A. M. Nielsen, J. R. Roheim, Diana Fenton, Lee Matheson, Curt Elsik-Austin

W. L. McClain

VVV 000012886

TGG: JCL: ERT: MJH: AIC

TO: Dave Penney-Austin

XF: _____

FROM: T. G. Grumbles

DATE: April 13, 1990

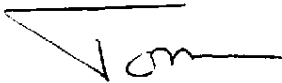
Interoffice
Communication

SUBJ: FDA STATUS OF VISTA ALUMINA

VISTA

Attached are documents regarding our research on the FDA status of Vista's Alumina.

Let me know if you have further questions.



T. G. Grumbles

dlj

Attachment

cc: VPSAG LIST

A. M. Nielsen, J. R. Roheim, Diana Fenton, Lee Matheson, Curt Elsik-Austin

W. L. McClain

VVV 000012887

Vista Chemical Company

900 Threadneedle
Houston, Texas 77079
(713) 588-3000

P.O. Box 19029
Houston, Texas 77224
Fax (713) 588-3236

November 8, 1989

TGG: JCL: ~~EST~~: MJH: AJO: RF

XF: FDA/Alumina ~~3735~~

XXF: Customer Exp. 283.1

VISTA

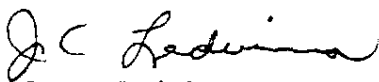
Mr. Dave Capella
Michelman, Inc.
9089 Shell Rd.
Cincinnati, OH 45226

RE: FDA STATUS OF VISTA DISPAL ALUMINA

Dear Mr. Capella:

You called today asking whether Vista DISPAL Alumina can be considered FDA allowed according to 21 CFR 176.170. This section deals with components of paper and paperboard in contact with aqueous and fatty foods. We believe DISPAL Alumina is generally recognized as safe (GRAS) per 21 CFR 182.90. As a result, DISPAL Alumina satisfies the language at 21 CFR 176.170(a)(2) and is considered FDA allowed as a component on paper and paperboard in contact with aqueous and fatty foods.

Sincerely,



J. C. Ledvina
Director, Environmental Activities

dlj

cc: R. J. Tuttle, D. L. Cohen

VVV 000012888

*file: 9001
FDA-Dispord.*
QCL

RECEIVED

JUL 07 89

DAVID L COHEN

To: D. L. Cohen

From: R. J. Tuttle
Date: June 30, 1989

Interoffice
Communication

Subject: DISPAL Alumina - FDA Status for Anti-skid Application

VISTA

Thanks for finalizing this issue with Keller and Heckman. Based on their research, our anti-skid customers can use DISPAL alumina in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable FDA regulations. I suggest we use the following paragraph to confirm Vista's understanding of this issue in response to customer inquiry:

Based on extensive research by our outside counsel, Vista believes that DISPAL alumina can be used as an anti-skid agent for paper and paperboard products employed in food-contact applications. We believe such use would be in full compliance with the Federal Food, Drug and Cosmetic Act and all applicable FDA regulations. Additional information regarding this opinion will be provided upon request.

I suggest marketing use the above paragraph to provide written confirmation of our verbal description. This will provide the customer with a clearly defined representation of our understanding, while maintaining adequate product liability protection. As we discussed, the additional information is contained in the two attached documents:

- 1.) 1-Page summary from Peter de la Cruz - This letter can be submitted to the customer upon request.
- 2.) 5-Page detailed opinion, also from de la Cruz - This information should not be released to the customer without contacting Vista's legal department for approval.

Marketing personnel should contact either you or Joe Ledvina with questions regarding this issue.

R. J. Tuttle

R. J. Tuttle

cc: SLB LBD PSD JTF GSH JAH JLN CFP LBP JLP GDS JFN-VCE HO-VCFE

VVV 000012889

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CABLE ADDRESS "KELMAN"

WRITER'S DIRECT DIAL NUMBER
(202) 956-5641

June 23, 1989

VIA TELECOPY

Mr. David Cohen
Vista Chemical Company
15990 N. Barker's Landing Road
Post Office Box 19029
Houston, Texas 77224

RE: FDA Status of Dispal 180

Dear Mr. Cohen:

You have provided information regarding the identity of Dispal 180 which is intended for use as an antiskid agent for use in paper and paperboard employed in food-contact applications. You requested that we review the information and provide our opinion regarding the Food and Drug Administration (FDA) status of Dispal 180 for this intended use. We have completed our review of the information before us and are happy to provide our opinion that Dispal 180 can be used in full compliance with the Federal Food, Drug, and Cosmetic Act and all applicable FDA regulations.

We trust that we have been responsive to your request for our opinion. If you should have any questions, or if we can be of further assistance, please do not hesitate to let us know.

Cordially yours,

Peter L. de la Cruz
Peter L. de la Cruz

VVV 000012890

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June 23, 1989

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VIA TELECOPY

Mr. David Cohen
Vista Chemical Company
15990 N. Barker's Landing Road
Post Office Box 19029
Houston, Texas 77224

RE: FDA Status of Aluminum Oxide Monohydrate

Dear David:

In several telephone conversations, Jeff Fenton and you provided information regarding the identity and intended use of Vista's aluminum oxide monohydrate product known as Dispal 180. This substance is applied as an antiskid agent to paper and paperboard. Antiskid properties are important for paper boxes which will be stacked during shipping to minimize the amount of shifting. This effect is also important for paper which will be made into large rolls to minimize "telescoping" of the rolled paper during handling. You requested that we provide our opinion regarding the Food and Drug Administration (FDA) status of aluminum oxide monohydrate for use as an antiskid agent on paper and paperboard food-contact articles.

We have completed our review of the information before us, and, as discussed more fully below, are happy to provide our opinion that the aluminum oxide monohydrate can be used, as intended, as an antiskid agent in paper and paperboard food-contact products in full compliance with the Federal Food, Drug, and Cosmetic Act and the applicable Food Additive Regulations.

VVV 000012891

A. Regulatory Framework

Before discussing the FDA status of aluminum oxide monohydrate, it may be helpful to review the applicable regulatory background surrounding the use of food-contact substances. Section 201(s) of the Act defines a food additive, in relevant part, as:

[a]ny substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component . . . of any food . . . if such substance is not generally recognized . . . to be safe under the conditions of its intended use; except that such term does not include--

* * *

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act.

This definition is repeated in section 170.3(e) of the Food Additive Regulations which adds, again in relevant part, the following explanatory information:

A material used in the production of containers and packages is subject to the definition if it may reasonably be expected to become a component . . . directly or indirectly of food packed in the container If there is no migration of a packaging component from the package to the food, it does not become a component of the food and thus is not a food additive.

Section 409 of the Act requires, in relevant part, that a food additive as defined above be used in conformity with an applicable Food Additive Regulation. Thus, a component of a food contact surface that may reasonably be expected to become a component of food must be (a) the subject of an applicable Food Additive Regulation, (b) the subject of a prior sanction, or (c) deemed generally recognized as safe (GRAS). However, if the substance is not reasonably expected to become a component of food, it is not a food additive and may be used as intended without the need for prior consultation with or action by FDA.

B. FDA Status of Aluminum Oxide Monohydrate

We understand that Vista's aluminum oxide monohydrate is crystallized with the aid of nitric acid and that the resulting nitrate ion content of the products ranges from 0.2 to 1.1 weight percent. Aluminum oxide monohydrate is completely insoluble in water but is applied to paper and paperboard in the form of a water dispersion of very small particles to impart antiskid properties to these materials. The application rate is approximately 1 lb/5,000 ft².

Aluminum oxide monohydrate is not cleared by a specific FDA regulation for use in food-contact applications. However, most of the applications for aluminum monohydrate oxide as an antiskid agent do not involve direct food contact with the substance. For example, and as mentioned earlier, the outside surfaces of cartons are sprayed so that when stacked will not shift during shipment. No food contact occurs in this application. Another application for aluminum oxide monohydrate involves spraying paper before it is configured into large rolls to reduce the tendency of the rolls to "telescope" during handling. Although paper from these rolls could conceivably contact food directly, very little, if any, uncoated paper is used in direct contact with aqueous or fatty food since the paper has no structural integrity if used uncoated in contact with such foods. The paper could, however, contact dry foods without undue deterioration.

Most food contact papers are either latex coated or polymer coated prior to use in contact with aqueous or fatty food. Both of these types of coatings would separate the aluminum oxide monohydrate from direct food contact and essentially eliminate the possibility of the aluminum oxide particles from becoming components of food. In essence, these coatings would serve as a functional barrier to the physical transfer of aluminum oxide monohydrate from the paper to the food. As mentioned earlier, since aluminum oxide monohydrate is completely insoluble in water and fat, it would not be expected to be extracted by aqueous or fatty foods.

In sum, there is no realistic expectation that aluminum oxide monohydrate will transfer, either physically or by means of solubility, from treated paper and paperboard into food. Since aluminum oxide monohydrate is not reasonably expected to become a component of food under its intended conditions of use, it is not a "food additive," and can be used, as intended, in full compliance with the Federal Food, Drug, and Cosmetic Act and the applicable Food Additive Regulations.

Mr. David Cohen
June 23, 1989
Page 4

KELLER AND HECKMAN

As an added measure of comfort in our opinion, we note that aluminum oxide with no water of hydration (alumina) is cleared for limited food-contact use under 21 C.F.R. § 176.180 (components of paper and paperboard in contact with dry food). Also, aluminum oxide trihydrate (aluminum hydroxide) is GRAS under § 182.90 (substances migrating to food from paper and paperboard products). It is reasonable to assume that the toxicology of aluminum oxide will not vary due to the amount of water of hydration. In other words, if aluminum oxide trihydrate is GRAS, it follows that aluminum oxide monohydrate is GRAS as well. Furthermore, ingestion of any of the aluminum oxide compounds would give rise to the same aluminum salt in the stomach (aluminum chloride). Therefore, we conclude that even were minuscule amounts of the aluminum oxide monohydrate to become a component of food, such minuscule levels would be generally recognized as safe.

Finally, it should be noted that the small amount of nitrate ion in the aluminum oxide monohydrate raises no health or safety concerns whatsoever. With the exception of the adhesives regulation (§ 175.105), nitric acid, the source of the nitrate ion, is not cleared for use in food or food-contact articles. However, sodium nitrate, another source of the nitrate ion which can be converted to nitric acid in the stomach, is very broadly cleared as a direct food additive. For example, it is prior sanctioned by the United States Department of Agriculture (USDA) in the production of cured red meat and poultry products (§ 181.33). It is also cleared as a preservative and color fixative under § 172.170 at levels up to 200 parts per million (ppm) in the finished meat product.

Even if all of the nitrate ion were to migrate from aluminum oxide monohydrate treated paper into 10 g food/in² of food contact surface, the concentration of nitrate ion in the food would not exceed 0.7 ppm. In actual use, however, and as discussed above, little if any of the antiskid agent is expected to migrate to food. Therefore, the level of nitrate ion in the food resulting from the use of aluminum oxide monohydrate would be far less than 0.7 ppm. Clearly, such minuscule levels, if any, would be readily considered GRAS.

We trust we have been responsive regarding your request concerning the FDA status of aluminum oxide monohydrate as an antiskid agent on paper and paperboard. If you should have any

VVV 000012894

Mr. David Cohen
June 23, 1989
Page 5

KELLER AND HECKMAN

questions regarding this matter, or if there is any other way in which we can be of assistance, please do not hesitate to let us know.

Cordially yours,


Peter L. de la Cruz

VVV 000012895

To: G. S. Hoenes - VCC Houston
cc: J. T. Fenton - VCC Ponca City
From: H. Ogino - VCFE Tokyo
Date: June 12, 1989 / Ref. No. 891420
Subject: F.D.A. Status of Alumina

Interoffice
Communication

RECE
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While you were here, you explained Hakuto that alumina is G.R.A.S. (Generally Recognized As Safe) at F.D.A.

Tomisaki-san, Hakuto Chem., wants to confirm of followings:

1. CATAPAL is G.R.A.S. Or all aluminas are G.R.A.S. and CATAPAL /or DISPAL is one of them.
2. What does G.R.A.S. mean? If material is G.R.A.S., can it be used in foods or related products (materials) without any regulations?
3. If above answer is "No", what restrictions are there on CATAPAL /or DISPAL when these are used as coating and anti-skid agent on carton boxes for foods?

Please advise at your earliest convenience.

Best Regards,


H. Ogino

HO/mj

VVV 000012896