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VISTA

November 2, 1990

Mr. T. F. Ling
Betz PaperChem
7510 Bay Meadows Way
Jacksonville, Florida 32256-7591

Dear Mr. Ling:

This letter is in response to your request for information regarding the status of Vista ALFONIC 1412-60, under 21 CFR 176.170 and 176.180.

Vista believes that this product is acceptable for use under these two sections based on the prior sanction granted this product in 21 CFR 181.30. Appropriate pages from 21 CFR 181.30, 176.170 and 176.180 are attached. The prior sanction listing applicable to ALFONIC 1412-60 is "Aliphatic Polyoxyethylene Ethers".

Sincerely,



Thomas G. Grumbles, C.I.H.
Manager Environmental Affairs

dlj

Attachment

cc: Mike Clark

VVV 000011395

use whatever limitation(s) or condition(s) may be necessary for the safety of the ingredient, or revocation to prohibit use of the ingredient, in order to prevent the adulteration of food in violation of section 402 of the Act.

(d) In proposing, after a general evaluation of use of an ingredient, regulations affirming the GRAS status of substances added directly to human food in Part 184 of this chapter or substances in food-contact surfaces in Part 186 of this chapter, or establishing a food additive regulation for substances added directly to human food in Parts 172 and 173 of this chapter or food additives in food-contact surfaces in Parts 174, 175, 176, 177, 178 and 179.45 of this chapter, the Commissioner shall, if he is aware of any prior action for use of the ingredient under conditions different from those proposed in the regulation, concurrently propose a separate regulation covering such use of the ingredient under this part. If the Commissioner is unaware of any such applicable prior sanction, the proposed regulation will so state and will require any person who intends to assert or rely on such sanction to submit proof of its existence. Any food additive or GRAS regulation promulgated after a general evaluation of use of an ingredient shall state as a determination that excluded uses would result in adulteration of the food in violation of section 402 of the Act, and the failure of any person to come forward with proof of such an applicable prior sanction in response to a proposal will constitute a waiver of the right to assert or rely on such sanction at any later time. The Commissioner will also constitute a proposal to establish a regulation under this part, incorporating the same provisions, in the event that such a regulation is determined to be appropriate as a result of submission of proof of such applicable prior sanction in response to the proposal.

Subpart B—Specific Prior-Sanctioned Food Ingredients

§ 181.22 Certain substances employed in the manufacture of food-packaging materials.

Prior to the enactment of the food additives amendment to the Federal Food, Drug, and Cosmetic Act, sanctions were granted for the usage of the substances listed in §§ 181.23, 181.24, 181.25, 181.26, 181.27, 181.28, 181.29, and 181.30 in the manufacture of packaging materials. So used, these substances are not considered "food additives" within the meaning of section 201(s) of the Act, provided that they are of good commercial grade, are suitable for association with food, and are used in accordance with good manufacturing practice. For the purpose of this subpart, good manufacturing practice for food-packaging materials includes the restriction that the quantity of any of these substances which becomes a component of food as a result of use in food-packaging materials shall not be intended to accomplish any physical or technical effect in the food itself, shall be reduced to the least amount reasonably possible, and shall not exceed any limit specified in this subpart.

[42 FR 56728, Oct. 28, 1977]

§ 181.23 Antimicrobials.

Substances classified as antimicrobials, when migrating from food-packaging material shall include:

Calcium propionate.
Methylparaben (methyl *p*-hydroxybenzoate).
Propylparaben (propyl *p*-hydroxybenzoate).
Sodium benzoate.
Sodium propionate.
Sorbic acid.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.24 Antioxidants.

Substances classified as antioxidants, when migrating from food-packaging material (limit of addition to food, 0.005 percent) shall include:

Butylated hydroxyanisole.
Butylated hydroxytoluene.
Dilauryl thiodipropionate.
Distearyl thiodipropionate.

Gum gualac.
Nordihydroguaiaretic acid.
Propyl gallate.
Thiodipropionic acid.
2,4,5-Trihydroxy butyrophenone.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.25 Driers.

Substances classified as driers, when migrating from food-packaging material shall include:

Cobalt caprylate.
Cobalt linoleate.
Cobalt naphthenate.
Cobalt tallate.
Iron caprylate.
Iron linoleate.
Iron naphthenate.
Iron tallate.
Manganese caprylate.
Manganese linoleate.
Manganese naphthenate.
Manganese tallate.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.26 Drying oils as components of finished resins.

Substances classified as drying oils, when migrating from food-packaging material (as components of finished resins) shall include:

Chinawood oil (tung oil).
Dehydrated castor oil.
Linseed oil.
Tall oil.

[42 FR 14638, Mar. 15, 1977; 42 FR 56728, Oct. 28, 1977]

§ 181.27 Plasticizers.

Substances classified as plasticizers, when migrating from food-packaging material shall include:

Acetyl tributyl citrate.
Acetyl triethyl citrate.
p-tert-Butylphenyl salicylate.
Butyl stearate.
Butylphthalyl butyl glycolate.
Dibutyl sebacate.
Di-(2-ethylhexyl) phthalate (for foods of high water content only).
Diethyl phthalate.
Diisobutyl adipate.
Diisooctyl phthalate (for foods of high water content only).
Diphenyl-2-ethylhexyl phosphate.
Epoxidized soybean oil (iodine number maximum 6; and oxirane oxygen, minimum, 6.0 percent).

Subpart A—[Reserved]

§ 176.170 Substances for Use Only as Components of Paper and Paperboard

176.110 Acrylamide-acrylic acid resins. Acrylamide-acrylic acid resins may be used as components of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

Acrylamide-acrylic acid resins are used by the polymerization of acrylamide with partial hydrolysis or by copolymerization of acrylamide and acrylic acid.

The acrylamide-acrylic acid resin must contain less than 0.2 percent residual monomer.

The resins are used as adjuvants in the manufacture of paper and paperboard in amounts not to exceed that necessary to accomplish the technical effect and not to exceed 2 percent by weight of the paper or paperboard.

§ 176.120 Alkyl ketene dimers.

Alkyl ketene dimers may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of this section.

(a) The alkyl ketene dimers are produced by the dehydrohalogenation of the acyl halides derived from fatty acids of animal or vegetable origin.

(b) The alkyl ketene dimers are used as an adjuvant in the manufacture of paper and paperboard under conditions that the alkyl ketene dimers and their hydrolysis products do not exceed 0.4 percent by weight of the paper or paperboard.

(c) The alkyl ketene dimers are used in the form of an aqueous solution in which may contain sodium sulfonate as a dispersant.

§ 176.130 Anti-offset substances.

Substances named in paragraph (b) and (c) of this section

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used to prevent the transfer of inks employed in printing and decorating paper and paperboard used for food packaging in accordance with the provisions of this section:

(a) The substances are applied to the nonfood contact, printed side of the paper or paperboard in an amount not greater than that required to accomplish the technical effect nor greater than any specific limitations, where such are provided.

(b) Anti-offset powders are prepared from substances that are generally recognized as safe in food, substances for which prior sanctions or approvals were granted and which are used in accordance with the specific provisions of such sanction or approval, and substances named in paragraph (c) of this section.

(c) The substances permitted are as follows:

Substances	Limitations
Carbon tetrachloride	Complying with § 176.3520 of this chapter.
Methyl hydrogen polysiloxanes	
Modified starch	
Silicones	
Various olefins	Complying with § 176.3520 of this chapter.
Di-2-ethyl hexanoate	

§ 176.160 Chelating agents used in the manufacture of paper and paperboard.

The substances named in paragraph (b) of this section may be safely used in the manufacture of paper and paperboard, in accordance with the conditions prescribed in paragraphs (b) and (c) of this section:

Chelating agents: 04

List of substances	Limitations
Disodium tetrachlorophosphate	Complying with § 176.3520 of this chapter.
Disodium hexachlorophosphate	
Disodium tetrachlorophosphate	
Disodium hexachlorophosphate	
Disodium tetrachlorophosphate	Complying with § 176.3520 of this chapter.
Disodium hexachlorophosphate	
Disodium tetrachlorophosphate	
Disodium hexachlorophosphate	

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(b) Any one or any combination of the substances named is used or intended for use as chelating agents.

(c) The substances are added in an amount not greater than that required to accomplish the intended technical effect nor greater than any specific limitation, where such is provided.

§ 176.160 Chromium (Cr III) complex of N-ethyl-N-heptadecylfluoro-octane sulfonyl glycine.

The chromium (Cr III) complex of N-ethyl-N-heptadecylfluoro-octane sulfonyl glycine containing up to 20 percent by weight of the chromium (Cr III) complex of heptadecylfluoro-octane sulfonic acid may be safely used as a component of paper for packaging dry food when used in accordance with the following prescribed conditions.

(a) The food additive is used as a component of paper in an amount not to exceed 0.5 percent by weight of the paper.

(b)(1) The food-contact surface of the paper is overcoated with a polymeric or resinous coating at least 1/4 mil in thickness, that meets the provision of § 176.170; or

(2) The treated paper forms one or more plies of a paper in a multiwall bag and is separated from the food by at least one ply of packaging films or grease-resistant papers which serves as a functional barrier between the food additive and the food. Such packaging films or grease-resistant papers conform with appropriate food additive regulations.

(c) The labeling of the food additive shall contain adequate directions for its use to insure compliance with the requirements of paragraphs (a) and (b) of this section.

§ 176.170 Components of paper and paperboard in contact with aqueous and fatty foods.

Substances identified in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding aqueous and fatty foods, sub-

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ject to the provisions of this section. Components of paper and paperboard in contact with dry food of the type identified under Type VIII of Table 1 in paragraph (c) of this section are subject to the provisions of § 176.180.

(a) Substances identified in paragraph (a)(1) through (5) of this section may be used as components of the food-contact surface of paper and paperboard. Paper and paperboard products shall be exempted from compliance with the extractives limitations prescribed in paragraph (c) of this section: *Provided*, That the components of the food-contact surface consist entirely of one or more of the substances identified in this paragraph: *And provided further*, That if the paper or paperboard when extracted under the conditions prescribed in paragraph (c) of this section exceeds the limitations on extractives contained in paragraph (c) of this section, information shall be

available from manufacturing records from which it is possible to determine that only substances identified in paragraph (a) are present in the contact surface of such paper or paperboard.

(1) Substances generally recognized as safe in food.

(2) Substances generally recognized as safe for their intended use in paper and paperboard products used in food packaging.

(3) Substances used in accordance with a prior sanction or approval.

(4) Substances that by regulation in Parts 170 through 189 of this chapter may be safely used without extractives limitations as components of the uncoated or coated food-contact surface of paper and paperboard in contact with aqueous or fatty food, subject to the provisions of such regulation.

(5) Substances identified in this paragraph, as follows:

List of Substances	Limitations
Acetyl peroxide	For use only as polymerization catalyst.
Acrylamide-methacrylic acid-maleic anhydride copolymers containing not more than 0.2 percent of residual acrylamide monomer and having an average nitrogen content of 14.9 percent such that a 1 percent by weight aqueous solution has a minimum viscosity of 800 centipoises at 75° F, as determined by LVG-series Brookfield viscometer (or equivalent) using a No. 2 spindle at 30 r.p.m.	For use only as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard in such an amount that the finished paper and paperboard will contain the additive at a level not in excess of 0.05 percent by weight of dry fibers in the finished paper and paperboard.
Acrylamide- <i>β</i> -methacryloyloxyethyltrimethylammonium methyl sulfate copolymer resins containing not more than 10 molar percent of <i>β</i> -methacryloyloxyethyltrimethylammonium methyl sulfate and containing less than 0.2% of residual acrylamide monomer.	For use only as a retention aid and flocculant employed prior to the sheet-forming operation in the manufacture of paper and paperboard.
Acrylonitrile polymer, reaction product with ethylenediamine sulfate having a nitrogen content of 22.5-25.0 percent (Kjeldahl dry basis) and containing no more than 0.075 percent monomer as ethylenediamine. The finished resin in a 24 percent by weight aqueous solution has a viscosity of 1,000-2,000 centipoises at 25° C as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 50 r.p.m. (or by other equivalent method).	For use only as a size promoter and retention aid at a level not to exceed 0.5 percent by weight of the dry paper and paperboard.
Acrylonitrile polymer with styrene, reaction product with ethylenediamine acetate, having a nitrogen content of 7.4-8.3 percent (Kjeldahl dry basis) and containing no more than 0.25 percent monomer as ethylenediamine.	1. For use only as a sizing material applied after the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in excess of 0.25 percent by weight of the dry paper and paperboard. 2. For use only as a sizing material applied prior to the sheet-forming operation in the manufacture of paper and paperboard in such amount that the paper and paperboard will contain the additive at a level not in excess of 1.0 percent by weight of the dry paper and paperboard.
1-Alkenyl olefins, containing not less than 72 percent of C30 and higher olefins.	For use only under the following conditions: 1. In coatings for paper and paperboard with food of Types I, II, IV-B, and VII-B described in Table 1 of paragraph (c) of this section under conditions of use E, F, and G described in Table 2 of paragraph (c) of this section. 2. In coatings for paper and paperboard with food of Type VIII described in Table 1 of paragraph (c) of this section under conditions of use A through H described in Table 2 of paragraph (c) of this section.

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List of Substances	For use or forming board or by weight
Alkylidene anhydrides mixture, in which the alkenyl groups are derived from olefins which contain not less than 72 percent of C ₃₀ -C ₄₀ groups.	For use or forming board.
Acrylamide-methacrylic acid copolymers (CAS Reg. No. 27401-00-5).	For use or forming board.
Alkyl-C ₁₂ -mercaptans	For use or forming board.
Alkyl-C ₁₂ -sulfonates	For use or forming board.
1-Methyl-1-propanol (CAS Reg. No. 124-68-5)	For use or forming board.
Bis[<i>N</i> -ethyl-2-perfluoroalkylsulfonamido ethyl] phosphates, containing not more than 15% ammonium salt, where the alkyl group is more than 95% C ₈ and the salt has a fluorine content of 50.2% to 52.8% as determined on a solids basis.	For use or forming board.
Ammonium persulfate	For use or forming board.
Ammonium thiosulfate	For use or forming board.
Ammonium zirconium carbonate (CAS Reg. No. 32535-84-5) and its tartaric acid adduct.	For use or forming board.
1,10-Antraquinone (Chemical Abstracts Service Registry No. 84-65-1) which has a purity of not less than 98 percent.	For use or forming board.
Azo-bis-isobutyronitrile	For use or forming board.
1,2-Benzothiazolin-3-one (CAS Registry No. 2634-33-5)	For use or forming board.
Benzoyl peroxide	For use or forming board.
<i>N</i> -[Bis(2-hydroxyethyl)alkyl (C ₁₂ -C ₁₈)amide	For use or forming board.
Bis(methoxymethyl)tetakis[(octadecyloxy)-methyl]melamine resins having a 5.8-6.5 percent nitrogen content.	For use or forming board.
tert-Butyl hydroperoxide	For use or forming board.
tert-Butyl peroxide	For use or forming board.
Calcium isostearate	For use or forming board.
Carrageenan and salts of carrageenan as described in §§ 172.820 and 172.826 of this chapter.	For use or forming board.
Castor oil, hydrogenated	For use or forming board.
Castor oil, sulfated, ammonium, potassium, or sodium salt	For use or forming board.
Celulose, regenerated	For use or forming board.
Chloracetamide	For use or forming board.
Cobaltous acetate	For use or forming board.

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obtain the wax-, petrolatum-, and mineral oil-corrected chloroform-soluble extractives residue (ee'). This ee' is substituted for *e* in the equations in paragraph (d)(5)(i) (a) and (b) of this section. (Note: In the case of chloroform-soluble extracts which contain high melting waxes (melting point greater than 170° F), it may be necessary to dilute the heptane solution further so that a 50-milliliter aliquot will contain only 0.1-0.2 gram of the chloroform-soluble extract residue.)

(e) Acrylonitrile copolymers identified in this section shall comply with the provisions of § 180.22 of this chapter, except where the copolymers are restricted to use in contact with food only of the type identified in paragraph (c), Table 1 under Category VIII.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 378))

(42 FR 14554, Mar. 15, 1977)

EDITORIAL NOTE: For FEDERAL REGISTER citations affecting § 176.170, see the List of CFR Sections Affected in the Finding Aids section of this volume.

List of substances	Limitations
(2-Alkenyl) succinic anhydrides in which the alkenyl groups are derived from olefins which contain not less than 78 percent C ₈ and higher groups (CAS Reg. No. 70983-55-0).	
4-[2-(2-Alkoxy(C ₈ -C ₁₈) ethoxy) ethoxy]ethyl]disodium sulfosuccinate.	
Aluminum and calcium salts of FD & C dyes on a substrate of alumina.	
Ammonium nitrate	
Amylose	
Barium metaborate	
1,2-Benzisothiazolin-3-one (CAS Registry No. 2634-33-5)	
N,N-Bis(hydroxyethyl)lauramide	
Bis(trichloromethyl) sulfone C.A. Registry No. 3064-70-8	
Borax	
Boric acid	
sec-Butyl alcohol	
Butyl benzyl phthalate	
Candelilla wax	
Carbon tetrachloride	
Castor oil, polyoxyethylated (42 moles ethylene oxide)	
Cationic soy protein hydrolyzed (hydrolyzed soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyl-trimethylammonium chloride)	
Cationic soy protein (soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyltrimethylammonium chloride)	
Chloral hydrate	
N-Cyclohexyl-p-toluene sulfonamide	
	For use as a polymerization emulsifier and latex emulsion stabilizer at levels not to exceed 5 percent by weight of total emulsion solids.
	Colorant.
	For use as preservative in coatings and sizings.
	For use only as a preservative in paper coating compositions and limited to use at a level not to exceed 0.02 mg/in ² (0.0031 mg/cm ²) of finished paper and paperboard.
	For use only as a preservative in coatings.
	For use as preservative in coatings.
	Do.
	For use only as a coating adhesive, pigment structuring agent, and fiber retention aid.
	For use only as a coating adhesive, pigment structuring agent, and fiber retention aid.
	Polymerization reaction-control agent.

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§ 176.180 Components of paper and paperboard in contact with dry food.

The substances listed in this section may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding dry food of the type identified in § 176.170(c), Table 1, under Type VIII, subject to the provisions of this section.

(a) The substances are used in amounts not to exceed that required to accomplish their intended physical or technical effect, and are so used as to accomplish no effect in food other than that ordinarily accomplished by packaging.

(b) The substances permitted to be used include the following:

(1) Substances that by § 176.170 and other applicable regulations in Parts 170 through 189 of this chapter may be safely used as components of the uncoated or coated food-contact surface of paper and paperboard, subject to the provisions of such regulation.

(2) Substances identified in the following list:

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List of substances	
tert-Butyl hydroquinone	
Butene	
Diethyl glycol dibenzoate (CAS Reg. No. 120-55-8)	For use only as
Diethyl glycol monobutyl ether	
Diethyl glycol monoethyl ether	
Octadecane	
Propionamide of tallow fatty acids	
Stylenimonomethylacrylamide polymer with acrylamide	
Styrene	
Styrylmethylenediamine, N,N-dimethylstyrylmethylenediamine, N,N-dimethylstyrylmethylenediamine mixture produced by the reaction of styrene with ethylenediamine	
Tallow fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 17-22° F, as determined by ASTM Method D127-60	
Tallow acid value of 10 maximum, ASTM Method D127-60	
Standard Method of Test for Melting Point of Petroleum Products (Revised 1960) is incorporated by reference. Copies are available from University Microfilms International, 300 N. Zeeb Rd., Ann Arbor, MI 48106, or available for inspection at the Office of the Federal Register, 1100 L St. NW., Washington, DC 20408.	
Tetramine	For use or
Tetramine glycol dibenzoate (CAS Reg. No. 27138-31-4)	
Tetramine N-octadecylsuccinamate	
Dodecyl triether of polyethylene glycol	
Urethane (erucylamide)	
Urethane, polymer with tetrahydro-4-hydroxy-5-methyl-2H-pyrimidinone, propoxylated	Fumigant
Urethane oxide adduct of mono-(2-ethylhexyl) o-phosphate	
Urethane acid (C ₁₈ -C ₂₂) diethanolamide	
Urethane of fatty acids, hydrogenated, potassium salt	
Urethane diol	
Urethane monooctadecyl	
Urethane	For use
Urethane-formaldehyde condensate (CAS Reg. No. 27013-01-0) formed by reaction in the molar ratio of approximately 47:32:15, respectively. The reaction product has a number average molecular weight of 278±14 as determined by a suitable method.	For use
Urethane-polymer (CAS Reg. No. 53037-34-6)	Polymers and
Urethane-tetramine	
Urethane glycol (2-methyl-2,4-pentanediol)	
Hydroxyethyl alcohol	For use
5-Hydroxymethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, 5-hydroxymethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, and 5-hydroxymethyl-1-aza-3,7-dioxabicyclo[3.3.0]octane mixture	
Isopropylamine hydrochloride	
Isopropyl m- and p-cresol (thymol derived)	
Isocyanic acid	
Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt	As
Melamine-formaldehyde modified with:	
Alcohols (ethyl, butyl, isobutyl, propyl, or isopropyl)	
Diethylenetriamine	
Imino-bis-butylamine	
Imino-bis-ethyleneamine	
Imino-bis-propylamine	
Polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane	
Sulfonic acid	
Tetraethylenepentamine	
Triethylenetetramine	
Methyl alcohol	
Methyl esters of mono-, di-, and tripropylene glycol	
Methyl naphthalene sulfonic acid-formaldehyde condensate, sodium salt	
Methylated poly(N-1,2-dihydroxyethylene, 1,3-imidazolidin-2-one)	

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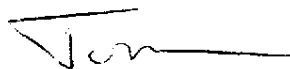
Interoffice
Communication

TO: R. D. Gamblin

FROM: T. G. Grumbles
DATE: November 2, 1990
SUBJ: PROGRESS REPORT

VISTA

1. SDA has received encouraging news from EPA regarding the SARA 313 glycol ethers definition that now includes 1,2, and 3 mole ethoxylates. EPA announced that the agency intends to initiate it's own review and modification of the definition of glycol ethers so as to exclude ethylene oxide based surfactants. This change in EPA's position was evidently prompted by a change in the EPA staffer handling this issue.
2. Beginning 1/1/91, all products identified as marine pollutants will be regulated as "Environmentally Hazardous Substances" by the IMDG Code, the hazardous material regulations for marine shipments. Containers containing these products must display a marine pollutant label as well. Our ethoxylates will be affected by this rule. MJH will be investigating whether any other products are affected.
3. MJH attended a two day HMAAC meeting on the International Marine Dangerous Goods (IMDG) Code, which regulates the transport of hazardous materials cargo by water.
4. TGG and MJH met with International Operations and the freight forwarders to review domestic and international hazardous materials transportation regulatory requirements.



T. G. Grumbles

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