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September 14, 1990

TCG: ~~101~~ ERT: ~~MSH~~ 11/10 3F
XF: 283 **VISTA**

Whittaker Oil Company
Mr. John Byrne
1557 Marietta Rd., N.W.
Atlanta, GA 30377

Dear Mr. Byrne:

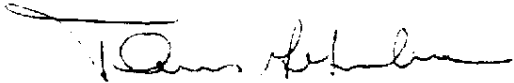
As a follow-up to my visit in July, I am providing the following information:

1. Information on DOT HM-181 proposed rules;
2. FDA citation on LPA solvents and some example pages from the FDA rules; and
3. Various VOC definitions from state regulations in your marketing area.

Please refer to the attachments for the information.

Feel free to call me at 713-588-3445 with questions on the attachments.

Sincerely,



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

dlj

cc: w/o HM-181 - P. Douvry

VVV 000013759

ATTACHMENT 1
DOT HM-181 RULEMAKING

This is an extensive rulemaking that will significantly change hazard classifications for many products, proper shipping names (specifically LPA solvents) and packaging specifications. The draft proposals are attached. It is impossible to briefly summarize, but I've attached a *Chemicalweek* article and a portion of an in-house memo on this rule to help you digest the parts pertinent to your business.

VVV 000013760

CHEMICAL SHIPPERS GET READY FOR NEW RULES

U.S. shippers of chemicals in nonbulk packaging are facing radical and, for some, costly regulatory changes. Effective Jan. 1, 1991 all international shipments must meet United Nations rules that require performance testing of nonbulk packaging. At the same time, the U.S. Department of Transportation is racing to complete HM-181, a giant set of regulations that will overhaul U.S. packaging specifications for hazardous materials, to make them more consistent with performance-based international ones.

The regulatory changes will affect a wide range of nonbulk packaging, including steel and fiber drums. But they will be toughest on small combination packages, such as those used to transport boxes of glass bottles containing specialty or laboratory chemicals. The UN rules are generally more severe than existing DOT ones for such packaging, requiring, for example, certain drop tests not currently necessary in the U.S.

Some boxes chemical shippers have used for years that "work in practice" will not pass the performance tests, says Lawrence W. Bierlein, a lawyer at Shaw, Pittman, Potts & Trowbridge (Washington) who represents clients with packaging interests. Adds Robert Temper, transportation manager at Mallinckrodt Medical (St. Louis), the UN rules could mean a significant increase in the materials and costs associated with combination packaging.

The difficulty of complying with the rules will depend on a company's busi-

ness, says Lee Martin, manager of transportation regulations at Dow Chemical (Midland, MI). "If a company has few packaging variations, it could have very few problems. But if it has a varied product line, then it may have to work quite a bit more."

At the very least, say experts, the new UN rules will mean a sharp increase in the testing burden on chemical shippers. While existing DOT rules detail the particular type of packaging necessary for a product, the international rules require a package to stand up to certain tests. For some combination packaging that means an "astronomical" number of variations to check, says Carl Banks, PPG Industries' (Pittsburgh) manager of hazardous materials and compliance. "A lot of [shippers] will be surprised by the cost and time required."

The UN committee developing the rules is trying to alleviate some of the testing burdens. One rule allows shippers to alter the contents within a box under certain conditions, without retesting the entire package. It also made provisions for a "superpackage" occasional shippers could use without testing.

DOT's sluggish pace in publishing HM-181—first proposed in 1982—has made the situation more confusing for chemical shippers. The agency intends to make its new nonbulk packaging rules "as close as possible" to those of the UN, and many shippers applaud the prospects of a uniform international regulatory system. But until DOT publishes HM-181 in final form, chemical packagers face the confusion of having to meet both U.S. and UN regulations for nonbulk packaging.

DOT says it expects to complete its rules by year-end, but few shippers are gambling on the agency meeting its schedule. Many say they have already "dual marked" nonbulk packages to meet both DOT and UN rules. "Anyone shipping internationally has to be ready to comply with both systems, until DOT's regulations are in place," acknowledges Edward Mazzullo, chief of the standards division at DOT's Office of Hazardous Materials Transportation.

DOT's failure to publish a final version of HM-181 by Jan. 1 could spell particular problems for shippers sending chemicals into the U.S. Such firms face the possibility of meeting UN rules



Bierlein: UN rules are uneven.

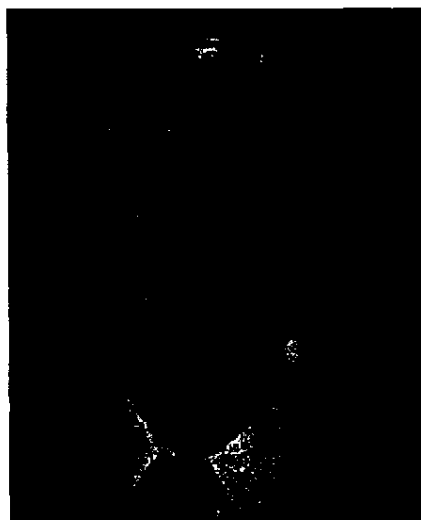
worldwide but still not being able to move nonbulk packages through the U.S. without complying with current DOT rules. Some observers, however, downplay the likelihood of such a scenario. "Theoretically it's a big problem," Bierlein concedes. "But I don't think it will really happen. DOT will be compelled to allow UN packages in," even it does not finish HM-181, he says.

Still, not everyone is happy with the goals of HM-181. Domestic shippers complain that it is expensive and unnecessary to adopt international rules for packages moving within the U.S. "If you're not shipping internationally, it doesn't make any sense," says Mallinckrodt's Temper. "It's an economic burden on the domestic shippers." He notes DOT's reason for developing HM-181 was to be consistent with the international system, not because of safety issues. "The [current DOT] system has worked, and I don't think the system to be implemented will be any better. But it will be more costly for combination packaging."

Moreover, says Temper, there still will be key differences between the UN rules and DOT's HM-181. "[DOT] wants international uniform packaging rules, but it doesn't really want to adopt the total system. Now, there are totally different packaging regulations. In the future, there may be subtly different ones."

Even some strong supporters of uniform international packaging regulations are critical of DOT's performance on HM-181. "It's certainly a step in the right direction," says Dow's Martin. "But DOT may not get the end result they're looking for" in simplifying the rules, he says.

Others are critical of the interna



Martin: 'A step in the right direction.'

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Chemical Week Business Report

August 8th

Major Company Profile

August 15th

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SPECIAL REPORT

tional performance standards in general. While the UN rules are relatively tough for combination packaging, says Bierlein, for other types of nonbulk packaging they are less stringent than those in the U.S. Drum thicknesses could probably be cut in half and still pass UN regulations, he suggests.

He also notes performance-based international standards will give shippers far more flexibility in designing packages, providing incentives to develop less-expensive packaging. While everyone is scrambling to make sure packages meet the new rules, he says, "once designers start playing around, regulatory agencies are likely to begin to get nervous." The situation could be exacerbated in the U.S., he adds, since there are fewer statistical quality-control systems in place than in Western Europe, where such systems could tend to catch packaging problems.

Despite such debates, the Jan. 1 deadline to comply with UN performance standards remains the everyday reality in the minds of many industry shipping experts. Much of Western Europe packaging already meets the UN rules, and large U.S. firms with strong

international businesses, such as Du Pont (Wilmington, DE), Dow and Eli Lilly (Indianapolis), say they have worked for several years to bring their packaging in line with both DOT and UN rules. But while some multinational shippers are already complying, "the rest of the world is stumbling," Bierlein says. "A lot of shippers that should be in compliance are still trying to figure out the system."

And, notes Stephen Nash, Eli Lilly's hazardous materials compliance representative, larger manufacturers could be vulnerable because they buy products they may have to repack to meet the new specifications. "The big crunch is going to come up and down the distribution chain," he says. "There will be folks who miss the boat. But they won't know by how much until their shipments are stopped."

As the international deadlines come closer, many firms will turn to outside laboratories to test packaging. But the number of qualified testing labs is limited, Temper points out. "It hasn't been a problem, so far. But as we get near Jan. 1, there will be a crunch."

DAVID ROTMAN

FOR COMMODITIES, APPLICATIONS STACK UP

It would be difficult to overstate the importance of the packaging market to the commodity resins business. Packaging is the largest end use for bulk plastics, accounting for 24% of total output. It is bigger than the building and transportation sectors combined—and for some resins, packaging makes up more than half the total demand.

More than 14 million pounds of commodity resins were consumed by the packaging industry in the U.S. last year, says Paul Schreiber, manager/packaging at Kline & Co. (Fairfield, NJ). More than half that amount was accounted for by just two product areas: low/linear low-density polyethylene (LDPE/LLDPE) films, and high-density polyethylene (PE) containers.

Despite environmental pressure affecting use of plastics in packaging, consumer preferences should keep the market buoyant. Most resins in packaging applications are expected to grow at about gross na-

tional product rates of 2%-3%/year, with some products doing even better.

Only the polyvinyl chloride (PVC) packaging market is expected to suffer appreciable loss, because of the environmental pressure against chlorine-containing materials, particularly in food packaging applications. But packaging is a small end-use for PVC, accounting for just under 9% of total demand. And while demand for PVC's overall share will diminish, some applications, such as PVC blister packag-

PERCENTAGE OF TOTAL PLASTICS PACKAGING

	Containers	Films	Coatings	Closures	% of packaging
HDPE	24.1	3.8	0.4	0.6	28.9%
LDPE*	2.2	24.3	5.2	0.2	31.9
PS	9.3	1.5	0	1.3	12.1
PET	7.4	0	0.1	0	7.5
PP	3.2	4.3	0.2	3.0	10.8
PVC	2.5	2.2	0.1	0.3	5.1
Other	1.0	0.8	1.8	0.1	3.7
Total	48.7	36.9	7.8	5.5	100.0%

*Includes linear low-density grades. Source: Kline & Co. (Fairfield, NJ); Modern Plastics (New York)

Reclassification of hazardous materials

Under HM-181, all hazard classes will change to the United Nations numerical system. For example, the hazard class "flammable liquid" will change to Class 3, and corrosive will change to Class 8.

There will be a "reshuffling" of some Vista products under the new regulations. As shown below, the flammable liquid hazard class will be expanded, while the combustible liquid class is reduced.

<u>FLASH POINT</u>	<u>PRESENT DOT SYSTEM</u>	<u>HM-181</u>	<u>UN SYSTEM</u>	<u>EXAMPLE</u>
Up to 100°F	Flammable Liquid	Class 3	Class 3	ALFOL 2
100°F to 141°F	Combustible Liquid	Class 3	Class 3	ALFOL 4
142°F to 200°F	Combustible Liquid	Combustible Liquid	Nonhazardous	LPA Solvent

The elimination of flash points between 142°F and 200°F for international shipments will reduce the number of UN-regulated hazardous materials, including some of the alcohols and higher flash LPA solvents. However, DOT has decided to retain the combustible liquid class, which differs from the international rule.

Other materials are reclassified entirely under the UN system. Ethylene oxide will change from "Flammable liquid" to "Poison Gas" while ethylene dichloride will be required to carry a poison label. Mixtures high in EDC content such as light and heavy ends will probably be affected as well.

Performance-oriented Packaging

This is probably the most significant revision to the regulations. By changing from "specification" to "performance" oriented packaging, DOT will eliminate over 200 pages from the regulations and cause many headaches for industry.

The present non-bulk (<118.9 gallons) packaging system is designed around specifications developed by DOT. DOT presently sets specific standards for the construction, height, thickness, diameter, etc. of packages and issues specification numbers, such as 17E. Materials which appear in the hazardous materials table are designated a fixed number of specification packagings for which it is authorized. Therefore, "off-the-shelf" packaging materials can easily be purchased.

Under the new system, all hazardous materials will be placed in one of three packing groups, each having certain packaging performance requirements. While packaging design is not specified, it must meet minimum requirements for four tests - drop, leakproofness, internal pressure, and stacking. This provides more flexibility in the type of packaging used, however it places greater responsibility on the "filler" of the package.

This requirement calls for a study of all packaging types shipped both domestically and internationally by Vista. "Standard" packaging types will have to be constructed and tested, and suppliers identified. Additionally, after January 1, 1991, if HM-181 is not passed, all packages must be dual marked with both UN and DOT approvals and meet specifications for each.

Marking/Labeling

Marking, labeling, and placarding of hazardous materials will change slightly under HM-181 due to the change in the hazard classifications. All placards and labels will be required to display the international hazard class numbers as well as the visual symbol for the hazard.

Bill of Lading Modification

Under HM-181, shipping descriptions on all Bills of Lading will have to be modified to reflect the new hazard class as well as indicate the packing group, a totally new requirement. As an example, the description for ALFOL 4 will change as follows:

From : Butyl Alcohol, Flammable Liquid, NA 1120

To : Butanols, 3, UN 1120, PG II

VVV 000013764

ATTACHMENT II
FDA STATUS OF LPA SOLVENTS

Attached is a sample memo that describes the issue of FDA status of LPA solvents. I've also attached some sample pages from the FDA regulations that are references to these uses. (Apologies for the quality of the copies but CFR's are hard to copy.)

VVV 000013765

VISTA

LPA-

Vista LPA solvents may conform to the requirements of Federal Food and Drug Administration regulations for direct and indirect food-associated applications, and may be used within the limitations of the FDA regulations where indicated. Individual uses listed below should be reviewed carefully for specific use conditions and limitations.

- A. Title 21 CFR Part 172 Subpart I and Part 173 Subpart D "Food Additives Permitted in Food for Human Consumption". In Subpart I, LPA solvents qualify as "odorless light petroleum hydrocarbons" as defined in CFR paragraph 172.884. Under this definition, LPA solvents may be used in numerous direct food contact applications as shown below.
- B. Title 21 CFR Parts 174-178 "Indirect Food Additives." In Part 178 Subpart D, LPA solvents qualify as "odorless light petroleum hydrocarbons" as defined in CFR Paragraph 178.3650. Under this definition, LPA solvents may be used in numerous food contact related applications as shown below.
- C. LPA 130 and LPA 170 solvents also qualify as technical white mineral oil in some applications as defined in CFR Paragraph 178.362(b). As such, LPA 130 and LPA 170 solvents may be used in a number of food contact applications, some of which are also covered in the preceding sections.

FDA REGULATIONFDA TITLE

CFR 172.884	Odorless Light Petroleum Hydrocarbons
CFR 173.340	Defoaming Agents Used in Processing Beet Sugar and Yeast
CFR 175.105	Adhesives
CFR 176.180	Components of Paper and Paperboard in Contact with Dry Food
CFR 176.200	Defoaming Agents Used in Coatings
CFR 176.210	Defoaming Agents Used in Manufacture of Paper and Paperboard
CFR 177.1200	Cellophane
CFR 177.1400	Hydroxyethyl Cellulose Film, Water Insoluble
CFR 177.2260	Filters, Resin Bonded
CFR 177.2600	Rubber Articles Intended for Repeat Use

VVV 000013766

Mr. Kermit Wheeler
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August 8, 1990

FDA REGULATION

FDA TITLE

CFR 177.2800	Textile and Textile Fibers
CFR 178.3120	Animal Glue
CFR 178.3570	Lubricants with Incidental Food Contact
CFR 178.3620(b)	Technical White Mineral Oil
CFR 178.3650	Odorless Light Petroleum Hydrocarbons
CFR 178.3910(b)(2)	For Drawing, Stamping, and Forming Metallic Articles

Sincerely,


J. C. Ledvina

Director, Environmental Activities

dlj

VVV 000013767

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), 376)

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.

§ 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:

List of substances	Limitations
2-Alkenyl succinic anhydrides in which the alkenyl groups are derived from olefins which contain not less than 78 and higher groups (CAS Reg. No. 70983-55-0).	
2-Alkoxy(C ₁₂ -C ₁₈) ethoxy ethoxyethylidene sodium sulfonate.	
Aluminum and calcium salts of FD & C dyes on a substrate of alumina.	
Aluminum nitrate	
Amlyose	
Barium metaborate	
2-Benzothiazolin-3-one (CAS Registry No. 2634-33-5)	
N-Bis(hydroxyethyl)ureamide	
(3-chloromethyl) sulfone C.A. Registry No. 3064-75-5	
Brax	
Caric acid	
n-Octyl alcohol	
Diethyl benzyl phthalate	
Dehilla wax	
Iron tetrachloride	
astor oil, polyoxyethylated (42 moles ethylene oxide)	
atonic soy protein hydrolyzed (hydrolyzed soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyl-trimethylammonium chloride)	
atonic soy protein (soy protein isolate modified by treatment with 3-chloro-2-hydroxypropyl-trimethylammonium chloride)	
lial hydrate	
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
	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

List of substances	
2,5-Di-tert-butyl hydroquinone	
Diphenylene glycol dibenzoate (CAS Reg. No. 120-55-8)	For use only as a
Diphenylene glycol monobutyl ether	
Diphenylene glycol monoethyl ether	
Diphenylene glycol	
N,N-Diisopropylamide of tallow fatty acids	
N-[(dimethylamino)methyl]acrylamide polymer with acrylamide and styrene	
N,N-Dioctylethylenediamine, N,N-diisooctylethylenediamine, and N-octyl-N-isooctylethylenediamine mixture produced when tall oil fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 212°-228° F, as determined by ASTM method D127-60, and an acid value of 10 maximum. ASTM Method D127-60 "Standard Method of Test for Melting Point of Petroleum and Microcrystalline Wax" (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	
Diphenylamine	
Dipropylene glycol dibenzoate (CAS Reg. No. 27138-31-4)	For use only as a
Dosodium N-octadecylsulfosuccinate	
tert-Dodecyl thioether of polyethylene glycol	
Encumide (encumylamide)	
Ethanedial, polymer with tetrahydro-4-hydroxy-5-methyl-2(1H)-pyrimidinone, propoxylated	
Ethylene oxide	Fumigant in size
Ethylene oxide adduct of mono-(2-ethylhexyl) p-phosphate	
Fatty acid (C ₁₂ -C ₁₈) diethanolamide	
Fish oil fatty acids, hydrogenated, potassium salt	
Formaldehyde	
Glycerol monocaprate	
Glycol	
Glyoxal-urea-formaldehyde condensate (CAS Reg. No. 27013-31-0) formed by reaction in the molar ratio of approximately 47:33:15, respectively. The reaction product has a number average molecular weight of 278±14 as determined by a suitable method.	For use as an
Glyoxal-urea polymer (CAS Reg. No. 53037-34-6)	For use as an
Hexamethylenetetramine	Polymerization As neutralizer and stearator
Hexylene glycol (2-methyl-2,4-pentanediol)	
Hydroxyethyl alcohol	
5-Hydroxymethoxymethyl-1-aza-3,7-dioxabicyclo[3.3.0] octane, 5-hydroxymethyl-1-aza-3,7-dioxabicyclo[3.3.0] octane, and 5-hydroxypoly[(methylenedioxy)methyl-1-aza-3,7-dioxabicyclo[3.3.0] octane mixture	For use only as
Isopropylamine hydrochloride	
Isopropyl m- and p-cresol (thymol derived)	
Itaconic acid	
Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt	Basic polymer
Meamine-formaldehyde modified with:	
Alcohols (ethyl, butyl, isobutyl, propyl, or isopropyl)	
Diethylenetriamine	
Imino-bis-butylamine	
Imino-bis-ethylenetriamine	
Imino-bis-propylamine	
Polyamines made by reacting ethylenediamine or trimethylenediamine with dichloroethane or dichloropropane	
Sulfamic 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)	For use only o

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st of
Aids

(2) Substances identified in the following list:

List of substances	Limitations
2,6-Di- <i>tert</i> -butyl hydroquinone.....	
Ethanolamine.....	
Bisphenyl glycol dibenzoate (CAS Reg. No. 120-55-8).....	For use only as a plasticizer in polymeric substances.
Bisphenyl glycol monobutyl ether.....	
Bisphenyl glycol monoethyl ether.....	
Bisphenolamine.....	
N,N-Diisopropylamide of tallow fatty acids.....	
N,N-Dimethylamino(methyl)acrylamide polymer with acrylamide and styrene.....	
N,N-Dioctylethylenediamine, N,N-diisooctylethylenediamine, and N-octylethyl-N-isooctylethylenediamine mixture produced when tall oil fatty acids are made to react with ethylenediamine such that the finished mixture has a melting point of 212°-228° F. as determined by ASTM method D127-60, and an acid value of 10 maximum. ASTM Method D127-60 "Standard Method of Test for Melting Point of Petroleum and Microcrystalline Wax" (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.	
Dihexylamine.....	For use only as plasticizer in polymeric substances.
Bisphenyl glycol dibenzoate (CAS Reg. No. 27138-31-4).....	
Sodium N-octadecylsulfosuccinamate.....	
Bis-Dodecyl ether of polyethylene glycol.....	
Acetamide (erythramide).....	
2,2,4,4-Tetrahydro-4-hydroxy-5-methyl-1H-pyrimidinone, propoxylated.....	Fumigant in sizing.
Ethylene oxide.....	
Ethylene oxide adduct of mono-(2-ethylhexyl) <i>o</i> -phosphate.....	
Fatty acid (C ₁₇ -C ₂₁) diethanolamide.....	
Refined fatty acids, hydrogenated, potassium salt.....	
Formaldehyde.....	
Glycerol monocaprate.....	
Glycerol.....	
Glycerol-urea-formaldehyde condensate (CAS Reg. No. 27013-01-0) formed by reaction in the molar ratio of approximately 47:33:15, respectively. The reaction product has a number average molecular weight of 278 ± 14 as determined by a suitable method.....	For use as an insolubilizer for starch in coatings.
Glycerol-urea polymer (CAS Reg. No. 53037-34-6).....	For use as an insolubilizer for starch.
Bisazomethylenetetramine.....	As neutralizing agent with myristic-chromic chloride and stearic-chromic chloride complex.
Hexylene glycol (2-methyl-2,4-pentanediol).....	
Hydroxyethyl alcohol.....	
5-Hydroxy-2-methyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, 5-Hydroxy-2-methyl-1-aza-3,7-dioxabicyclo[3.3.0]octane, and 5-Hydroxy-2-methyl-1-aza-3,7-dioxabicyclo[3.3.0]octane mixture.....	
Isopropylamine hydrochloride.....	
Isopropyl <i>m</i> - and <i>p</i> -cresol (thymol derived).....	
Isosorbic acid.....	
Maleic anhydride-diisobutylene copolymer, ammonium or sodium salt.....	Basic polymer.
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).....	For use only as an insolubilizer for starch

VVV 000013769

List of substances	Limitations	List of substances
Methyl methacrylate resulting from an epichlorohydrin adduct to a condensate of formaldehyde-dicyandiamide-diethylenetriamine and which product is then reacted with polyacrylamide and urea to produce a resin having a nitrogen content of 5.6 to 6.3 percent and having a minimum viscosity in 56 percent-by-weight aqueous solution of 200 centipoises at 25° C, as determined by LVT-series Brookfield viscometer using a No. 4 spindle at 60 r.p.m. (or equivalent method). Monoglycide citrate. Myristic chromic chloride complex. Naphthalene sulfonic acid-formaldehyde condensate, sodium salt. Nickel. 3-Nitrostyrene. α-[9-Octadecenyl-ω-hydroxypoly (oxyethylene); the octadecenyl group is derived from oleyl alcohol and the poly(oxyethylene) content averages not less than 20 moles. α-[p-Nonylphenyl-ω-hydroxypoly (oxyethylene) sulfate, ammonium salt; the nonyl group is a propylene trimer isomer and the poly (oxyethylene) content averages 9 or 30 moles. Oleic acid reacted with <i>N</i>-alkyl-(C₁₂-C₁₈) trimethylenediamine. Oxidized soy isolate having 50 to 70 percent of its cystine residues oxidized to cysteic acid. Petroleum alicyclic hydrocarbon resins, or the hydrogenated product thereof, complying with the identity prescribed in § 176.170(b)(2). Petroleum hydrocarbon resins (produced by the catalytic polymerization and subsequent hydrogenation of styrene, vinyltoluene, and indene types from distillates of cracked petroleum stocks). Petroleum hydrocarbons, light and odorless. Petroleum sulfonates. α-Phthalic acid modified hydrolyzed soy protein isolate. Pine oil. Poly(2-aminoethyl acrylate nitrate-co-2-hydroxyethyl acrylate) complying with the identity described in § 176.170(a). Polyamide-epichlorohydrin modified resins resulting from the reaction of the initial caprolactam-itaconic acid product with diethylenetriamine and then condensing this prepolymer with epichlorohydrin to form a cationic resin having a nitrogen content of 11-15 percent and chlorine level of 20-23 percent on a dry basis. Hydrogenated; complying with the identity prescribed § 176.3740(b) of this chapter. [2-diethylamino) ethyl methacrylate] phosphate. Polyethylene glycol (200) diacrylate. Polymers: Homopolymers and copolymers of the following monomers: Acrylamide. Acrylic acid and its methyl, ethyl, butyl, propyl, or octyl esters. Acrylonitrile. Butadiene. Crotonic acid. Cyclo acrylate. Decyl acrylate. Diethyl fumarate. Diethyl maleate. Diethyl phthalate. Diethyl fumarate. Diethyl itaconate. Diethyl maleate. Di(2-ethylhexyl) maleate. Dioctyl fumarate. Dioctyl maleate. Divinylbenzene. Ethylene. 2-Ethylhexyl acrylate. Fumaric acid. Glycidyl methacrylate. 2-Hydroxyethyl acrylate.	For use only as a dry strength and pigment retention agent employed prior to the sheetforming operation in the manufacture of paper and paperboard and used at a level not to exceed 1 percent by weight of dry fibers. Basic polymer. For use as a binder adhesive component of coatings. For use as modifiers at levels up to 30 weight-percent of the solids content of wax-polymer blend coatings. Basic polymer.	<i>N</i>-(Hydroxymethyl) acrylamide. Isobutyl acrylate. Isobutylene. Isoprene. Itaconic acid. Maleic anhydride and its methyl or butyl esters. Methacrylic acid and its methyl, ethyl, butyl, or propyl esters. Methylstyrene. Mono(2-ethylhexyl) maleate. Monomethyl maleate. 5-Norbornene-2,3-dicarboxylic acid, mono-<i>n</i>-butyl ester. Styrene. Vinyl acetate. Vinyl butyrate. Vinyl chloride. Vinyl crotonate. Vinyl hexoate. Vinylidene chloride. Vinyl pentaerythritol. Vinyl propionate. Vinyl pyrrolidone. Vinyl stearate. Vinyl sulfonic acid. Polyoxyethylene (minimum 12 moles) ester of tall oil (30% - 40% rosin acids). Polyoxypropylene-polyoxyethylene glycol (minimum molecular weight 1,900). Polyvinyl alcohol. Potassium titanate fibers produced by calcining titanium dioxide, potassium chloride, and potassium carbonate, such that the finished crystalline fibers have a nominal diameter of 0.20-0.25 micron, a length-to-diameter ratio of approximately 25:1 or greater, and consist principally of K₂Ti₂O₇ and K₂Ti₃O₈. Sodium diisobutylphenoxy diethoxyethyl sulfonate. Sodium diisobutylphenoxy monoethoxy ethylsulfonate. Sodium <i>n</i>-dodecylpolyethoxy (50 moles) sulfate. Sodium isododecylphenoxy polyethoxy (40 moles) sulfate. Sodium <i>N</i>-methyl-<i>N</i>-oleyl laurate. Sodium methyl silicate. Sodium nitrite. Sodium polyacrylate. Sodium bis-tridecylsulfosuccinate. Sodium xylene sulfonate. Stearic chromic chloride complex. Styrene-allyl alcohol copolymers. Styrene-methacrylic acid copolymer, potassium salt. Tetraethylenepentamine. α-[p-(1,1,3,3-Tetramethylbutyl)phenyl]-ω-hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium, and ammonium salts having a poly(oxyethylene) content averaging 6-8 or 40 moles. α-[p-(1,1,3,3-Tetramethylbutyl)phenyl or <i>p</i>-nonylphenyl]-ω-hydroxypoly (oxyethylene) where nonyl group is a propylene trimer isomer. Tetrasodium <i>N</i>-(1,2-dicarboxyethyl)-<i>N</i>-octadecyl sulfosuccinate. Toluene. Triethanolamine. Triethylenetetramine. Triethylenetetramine monoacetate, partially stearoylated. Urea-formaldehyde chemically modified with: Alcohol (methyl, ethyl, butyl, isobutyl, propyl, or isopropyl) acid. Diaminobutane. Diaminopropane. Diethylenetriamine. <i>N,N</i>-Dioctylethylenediamine. Diphenylamine. <i>N,N</i>-Distearylethylenediamine. Ethylenediamine.

VVV 000013770

	Limitations
Dichlorohydrin adduct cyanamide-dieth- hen reacted with resin having a nt and having a aqueous solution ed by LVT-series le at 60 r.p.m. for	For use only as a dry strength and pigment retention ad- agent employed prior to the sheetforming operation in the manufacture of paper and paperboard and used at a level not to exceed 1 percent by weight of dry fibers.
densate, sodium	
ethylene; the oc- alcohol and the than 20 moles. ethylene sulfate, propylene trimer averages 9 or 30	Basic polymer.
thylenediamine..... ent of cystine	For use as a binder adhesive component of coatings.
Limited prescribed in	For use as modifiers at levels up to 30 weight-percent of the solids content of wax-polymer blend coatings.
the catalytic po- of styrene, vinyl- of cracked petro-	
n isolate.....	
vproyl acrylate) (S.170(a).	
Suiting from the acid product with this prepolymer resin having a fine level of 20-	
he identity pre-	
sphatic.....	
r the following	Basic polymer.
Propyl, or octyl,	

List of substances	Limitations
N-(Hydroxymethyl) acrylamide.	
Isobutyl acrylate.	
Isobutylene.	
Isoprene.	
Itaconic acid.	
Maleic anhydride and its methyl or butyl esters.	
Methacrylic acid and its methyl, ethyl, butyl, or propyl esters.	
Methylstyrene.	
Mono(2-ethylhexyl) maleate.	
Monostyryl maleate.	
5-Norbornene-2,3-dicarboxylic acid, mono-n-butyl ester.	
Styrene.	
Vinyl acetate.	
Vinyl butyrate.	
Vinyl chloride.	
Vinyl crotonate.	
Vinyl hexoate.	
Vinylidene chloride.	
Vinyl pentaerythritol.	
Vinyl propionate.	
Vinyl pyridone.	
Vinyl stearate.	
Vinyl sulfonic acid.	
Polyoxyethylene (minimum 12 moles) ester of tall oil (30%-40% rosin acids).	
Polyoxypropylene-polyoxyethylene glycol (minimum molecular weight 1,800).	
Polyvinyl alcohol.	
Potassium titanate fibers produced by calcining titanium dioxide, potassium chloride, and potassium carbonate, such that the finished crystalline fibers have a nominal diameter of 0.20-0.25 micron, a length-to-diameter ratio of approximately 25:1 or greater, and consist principally of $K_2Ti_4O_{10}$ and $K_2Ti_6O_{16}$.	
Sodium disobutylphenoxypolyethoxyethyl sulfonate.	
Sodium disobutylphenoxypolyethoxyethyl sulfonate.	
Sodium n-dodecylpolyethoxy (50 moles) sulfate.	
Sodium isododecylphenoxypolyethoxy (40 moles) sulfate.	
Sodium N-methyl-N-octyl taurate.	
Sodium methyl silicate.	
Sodium nitrate.	
Sodium polycrylate.	
Sodium bis-tridecylsulfosuccinate.	
Sodium xylene sulfonate.	
Stearic chromic chloride complex.	
Styrene-allyl alcohol copolymers.	
Styrene-methacrylic acid copolymer, potassium salt.	
Tetraethylenepentamine.	Polymerization cross-linking agent.
α -[p-(1,1,3,3-Tetramethylbutyl)phenyl]- ω -hydroxypoly(oxyethylene) mixture of dihydrogen phosphate and monohydrogen phosphate esters and their sodium, potassium, and ammonium salts having a poly(oxyethylene) content averaging 6-9 or 40 moles.	
α -[p-(1,1,3,3-Tetramethylbutyl)phenyl or p-nonylphenyl]- ω -hydroxypoly(oxyethylene) where nonyl group is a propylene trimer isomer.	
Tetrasodium N-(1,2-dicarboxyethyl)-N-octadecyl sulfosuccinate.	
Toluene.	
Triethanolamine.	
Triethylenetetramine.	Polymerization cross-linking agent.
Triethylenetetramine monoacetate, partially stearoylated.	
Urea-formaldehyde chemically modified with:	
Alcohol (methyl, ethyl, butyl, propyl, or isopropyl).	
Aminomethylsulfonic acid.	
Diaminobutane.	
Diaminopropane.	
Diethylenetriamine.	
N,N-Dioctadecylthylenediamine.	
Diphenylamine.	
N,N-Distearoylthylenediamine.	
Ethylenediamine.	

VVV 000013771

List of Substances

Ureidine.
 n-bis-butylamine.
 i-bis-ethylamine.
Imino-bis-propylamine.
N-Oleoyl-*N'*-stearylethylenediamine.
Polymers made by reacting ethylenediamine or triethylenediamine with dichloroethane or dichloropropane.
Tetraethylenepentamine.
Triethylenetetramine.

Xylene.....
Xylene sulfonic acid-formaldehyde condensate, sodium salt.....
Zinc stearate.....

[42 FR 14554, Mar. 15, 1977]

EDITORIAL NOTE: For additional FEDERAL REGISTER citations affecting § 176.180, see the List of CFR Sections Affected in the Finding Aids section of this volume.

\$ 176.200 Defoaming agents used in coatings.

The defoaming agents described in this section may be safely 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.

(a) The defoaming agents are prepared as mixtures of substances described in paragraph (d) of this section.

(b) The quantity of any substance employed in the formulation of defoaming agents does not exceed the amount reasonably required to accomplish the intended physical or techni-

cal effect in the defoaming agents or any limitation further provided.

(c) Any substance employed in the production of defoaming agents and which is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter conforms with any specification in such regulation.

(d) Substances employed in the formulation of defoaming agents include:

(1) Substances generally recognized as safe in food.

(2) Substances subject to prior sanction or approval for use in defoaming agents and used in accordance with such sanction or approval.

(3) Substances identified in this paragraph (d)(3) and subject to such limitations as are provided:

List of substances	Limitations
n-Butyl alcohol.....	
tert-Butyl alcohol.....	
Butyl stearate.....	
Castor oil, sulfated, ammonium, potassium, or sodium salt.....	
Cetyl alcohol.....	
Cyclohexane.....	
Cyclohexanol.....	
Diethylene glycol monolaurate.....	
Diethylene glycol monostearate.....	
Dimers and trimers of unsaturated C_{18} fatty acids derived from:	For use only at levels not to exceed 0.1% by weight of total coating solids
Animal and vegetable fats and oils	
Tall oil	
Dimethylpolysiloxane.....	
Dipropylene glycol.....	
Ethyl alcohol.....	
Fats and oils derived from animal, manne, or vegetable sources:	
Fatty acids derived from animal, manne, or vegetable fats and oils, and salts of such acids, single or mixed, as follows:	
Aluminum.	
Ammonium.	
Calcium.	
Magnesium.	

List of substances	
Potassium.....	
Sodium.....	
Zinc.....	
Formaldehyde.....	For use as
Glyceryl mono-12-hydroxystearate.....	
Glyceryl monostearate.....	
Hexane.....	
Hexylene glycol (2-methyl-2,4-pentanediol).....	
Isobutyl alcohol.....	
Isopropyl alcohol.....	
Kerosene.....	
Lecithin hydroxylated.....	
Methyl alcohol.....	
Methylcelulose.....	
Methyl esters of fatty acids derived from animal, marine, or vegetable fats and oils.....	
Methyl oleate.....	
Methyl palmitate.....	
Mineral oil.....	
Mustardseed oil, sulfated, ammonium, potassium, or sodium salt.....	
Myristyl alcohol.....	
Naphtha.....	
β -Naphthol.....	For use as
Nonylphenol.....	As defined
Odorous light petroleum hydrocarbons.....	
Oleic acid, sulfated, ammonium, potassium, or sodium salt.....	
Parachlorometacresol.....	For use as
Peanut oil, sulfated, ammonium, potassium, or sodium salt.....	
Petrolatum.....	
Pine oil.....	
Polyacrylic acid, sodium salt.....	As a stabilizer
Polyethylene.....	
Polyethylene, oxidized.....	
Polyethylene glycol (200) disulfate.....	
Polyethylene glycol (400) dioleate.....	
Polyethylene glycol (600) dioleate.....	
Polyethylene glycol (400) esters of coconut oil fatty acids.....	
Polyethylene glycol (400) monooleate.....	
Polyethylene glycol (600) monooleate.....	
Polyethylene glycol (600) monooctadecate.....	
Polyethylene glycol (400) monostearate.....	
Polyoxybutylene-polyoxypropylene-polyoxyethylene glycol (min. mol. wt. 3,700).....	
Polyoxyethylated (min. 3 mols) cetyl alcohol.....	
Polyoxyethylated (min. 5 mols) cetyl alcohol.....	
Polyoxyethylated (min. 1.5 mols) tridecyl alcohol.....	
Polyoxyethylene (min. 15 mols) ester of rosin.....	
Polyoxyethylene (min. 8 mols) monooleate.....	
Polyoxyethylene (40) stearate.....	
Polyoxypropylated (min. 20 mols) butyl alcohol.....	
Polyoxypropylene glycol (min. mol. wt. 200).....	
Polyoxypropylene (min. 20 mols) oleate butyl ether.....	
Polyoxypropylene-polyoxyethylene glycol (min. mol. wt. 1,900).....	
Polyoxypropylene (min. 40 mols) stearate butyl ether.....	
Potassium pentachlorophenate.....	For use as
Potassium trichlorophenate.....	Co.
Propylene glycol monoester of soybean oil fatty acids.....	
Propylene glycol monoester of tallow fatty acids.....	
Ricebran oil, sulfated, ammonium, potassium, or sodium salt.....	
Rosins and rosin derivatives.....	As provided
Silica.....	
Sodium 2-mercaptobenzoate.....	For use as
Sodium pentachlorophenate.....	Co.
Sodium trichlorophenate.....	Co.
Sperm oil, sulfated, ammonium, potassium, or sodium salt.....	
Stearyl alcohol.....	
Tall oil fatty acids.....	
Tallow fatty acids, hydrogenated or sulfated.....	
Tallow, sulfated, ammonium, potassium, or sodium salt.....	
Triethanolamine.....	
Trisopropenolamine.....	

List of substances	Limitations
1. petroleum	

(e) The defoaming agents are used as follows:

(1) The quantity of defoaming agent or agents used shall not exceed the amount reasonably required to accomplish the intended effect, which is to prevent or control the formation of foam.

(2) The defoaming agents are used in the preparation and application of coatings for paper and paperboard.

§ 176.210 Defoaming agents used in the manufacture of paper and paperboard.

Defoaming agents may be safely used in the manufacture of paper and paperboard intended for use in packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) The defoaming agents are prepared from one or more of the substances named in paragraph (d) of this section, subject to any prescribed limitations.

(b) The defoaming agents are used to prevent or control the formation of foam during the manufacture of paper and paperboard prior to and during the sheet-forming process.

(c) The quantity of defoaming agent or agents during the manufacturing process shall not exceed the amount necessary to accomplish the intended technical effect.

(d) Substances permitted to be used in the formulation of defoaming agents include substances subject to prior sanctions or approval for such use and employed subject to the conditions of such sanctions or approvals, substances generally recognized as safe for use in food, substances generally recognized as safe for use in paper and paperboard, and substances listed in this paragraph, subject to the limitations, if any, prescribed.

(1) Fatty triglycerides, and the fatty acids, alcohols, and dimers derived therefrom:

Beef tallow.
Castor oil.
Coconut oil.
Corn oil.

Cottonseed oil.
Fish oil.
Lard oil.
Linseed oil.
Mustardseed oil.
Palm oil.
Peanut oil.
Rapeseed oil.
Ricebran oil.
Soybean oil.
Sperm oil.
Tall oil.

(2) Fatty triglycerides, and marine oils, and the fatty acids and alcohols derived therefrom (paragraph (d)(1) of this section) reacted with one or more of the following, with or without dehydration, to form chemicals of the category indicated in parentheses:

Aluminum hydroxide (soaps).
Ammonia (amides).
Butanol (esters).
Butoxy-polyoxypropylene, molecular weight 1,000-2,500 (esters).
Butylene glycol (esters).
Calcium hydroxide (soaps).
Diethanolamine (amides).
Diethylene glycol (esters).
Ethylene glycol (esters).
Ethylene oxide (esters and ethers).
Glycerin (mono- and diglycerides).
Hydrogen (hydrogenated compounds).
Hydrogen (amines).
Isobutanol (esters).
Isopropanol (esters).
Magnesium hydroxide (soaps).
Methanol (esters).
Morpholine (soaps).
Oxygen (air-blown oils).
Pentaerythritol (esters).
Polyoxyethylene, molecular weights 200, 300, 400, 600, 700, 1,000, 1,540, 1,580, 1,760, 4,600 (esters).
Polyoxypropylene, molecular weight 200-2,000 (esters).
Potassium hydroxide (soaps).
Propanol (esters).
Propylene glycol (esters).
Propylene oxide (esters).
Sodium hydroxide (soaps).
Sorbitol (esters).
Sulfuric acid (sulfated and sulfonated compounds).
Triethanolamine (amides and soaps).
Triisopropanolamine (amides and soaps).
Trimethylethane (esters).
Zinc hydroxide (soaps).

(3) Miscellaneous:

Food and Drug Administration, HHS

Alcohols and ketone alcohols mixture (still-bottom product from C₁₂-C₁₈ alcohol manufacturing process).

Amyl alcohol.
Butoxy polyethylene polypropylene glycol molecular weight 900-4,200.

Butoxy-polyoxypropylene molecular weight 1,000-2,500.

Butylated hydroxyanisole.

Butylated hydroxytoluene.

Calcium lignin sulfonate.

Capryl alcohol.

p-Chlorometacresol.

Cyclohexanol.

Diacetyltartaric acid ester of tallow monoglyceride.

Diethanolamine.

Diethylene triamine.

Di-(2-ethylhexyl) phthalate.

2,6-Dimethyl heptanol-4 (nonyl alcohol).

Dimethylpolysiloxane.

Di-tert-butyl hydroquinone.

Dodecylbenzene sulfonic acids.

Ethanol.

2-Ethylhexanol.

Ethylenediamine tetraacetic acid tetrasodium salt.

Formaldehyde.

Heavy oxo-fraction (a still-bottom product of iso-octyl alcohol manufacture, of approximate composition: Octyl alcohol 5 percent, nonyl alcohol 10 percent, decyl and higher alcohols 35 percent, esters 45 percent, and soaps 5 percent).

2-Heptadecenyl-4-methyl-4-hydroxymethyl-2-oxazoline.

Hexylene glycol (2-methyl-2,4-pentanediol).

12-Hydroxystearic acid.

Isobutanol.

Isopropanol.

Isopropylamine salt of dodecylbenzene sulfonic acid.

Kerosine.

Lanolin.

Methanol.

Methyl 12-hydroxystearate.

Methyl taurine-oleic acid condensate, molecular weight 486.

α,α'-(Methylenebis(4-(1,1,3,3-tetramethylbutyl)-o-phenylene))bis(omega-hydroxypoly(oxyethylene)) having 6-7.5 moles of ethylene oxide per hydroxyl group.

Mineral oil.

Mono-, di-, and triisopropanolamine.

Mono- and diisopropanolamine stearate.

Monobutyl ether of ethylene glycol.

Monoethanolamine.

Morpholine.

Myristyl alcohol.

Naphtha.

β-Naphthol.

Nonylphenol.

Odorless light petroleum hydrocarbons.

Oleyl alcohol.

Petrolatum.

o-Phenylphenol.

Pine oil.

21 CFR Ch. I (4-1-88 Edition)

Limitations

are used
ming agent
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Cottonseed oil.
Fish oil.
Lard oil.
Linseed oil.
Mustardseed oil.
Palm oil.
Peanut oil.
Rapeseed oil.
Ricebran oil.
Soybean oil.
Sperm oil.
Tall oil.

(2) Fatty triglycerides, and marine oils, and the fatty acids and alcohols derived therefrom (paragraph (d)(1) of this section) reacted with one or more of the following, with or without dehydration, to form chemicals of the category indicated in parentheses:

Aluminum hydroxide (soaps).
Ammonia (amides).
Butanol (esters).
Butoxy-polyoxypropylene, molecular weight: 1,000-2,500 (esters).
Butylene glycol (esters).
Calcium hydroxide (soaps).
Diethanolamine (amides).
Diethylene glycol (esters).
Ethylene glycol (esters).
Ethylene oxide (esters and ethers).
Glycerin (mono- and diglycerides).
Hydrogen (hydrogenated compounds).
Hydrogen (amines).
Isobutanol (esters).
Isopropanol (esters).
Magnesium hydroxide (soaps).
Methanol (esters).
Morpholine (soaps).
Oxygen (air-blown oils).
Pentaerythritol (esters).
Polyoxyethylene, molecular weights 200-300, 400, 600, 700, 1,000, 1,540, 1,580, 1,760, 4,600 (esters).
Polyoxypropylene, molecular weight 200-2,000 (esters).
Potassium hydroxide (soaps).
Propanol (esters).
Propylene glycol (esters).
Propylene oxide (esters).
Sodium hydroxide (soaps).
Sorbitol (esters).
Sulfuric acid (sulfated and sulfonated compounds).
Triethanolamine (amides and soaps).
Triisopropanolamine (amides and soaps).
Trimethylolthane (esters).
Zinc hydroxide (soaps).

(3) Miscellaneous:

Food and Drug Administration, HHS

\$ 176

Alcohols and ketone alcohols mixture (still-bottom product from C₁₂-C₁₈ alcohol manufacturing process).

Amyl alcohol.

Butoxy polyethylene polypropylene glycol molecular weight 900-4,200.

Butoxy-polyoxypropylene molecular weight 1,000-2,500.

Butylated hydroxyanisole.

Butylated hydroxytoluene.

Calcium lignin sulfonate.

Capryl alcohol.

p-Chlorometacresol.

Cyclohexanol.

Diacetyl tartaric acid ester of tallow mono-glyceride.

Diethanolamine.

Diethylene triamine.

Di-(2-ethylhexyl) phthalate.

2,6-Dimethyl heptanol-4 (nonyl alcohol).

Dimethyl polysiloxane.

Di-tert-butyl hydroquinone.

Dodecylbenzene sulfonic acids.

Ethanol.

3-Ethylhexanol.

Ethylenediamine tetraacetic acid tetrasodium salt.

Formaldehyde.

Heavy oxo-fraction (a still-bottom product of iso-octyl alcohol manufacture, of approximate composition: Octyl alcohol 5 percent, nonyl alcohol 10 percent, decyl and higher alcohols 35 percent, esters 45 percent, and soaps 5 percent).

2-Heptadecenyl-4-methyl-4-hydroxymethyl-2-oxazoline.

Hexylene glycol (2-methyl-2,4-pentanediol).

12-Hydroxystearic acid.

Isobutanol.

Isopropanol.

Isopropylamine salt of dodecylbenzene sulfonic acid.

Kerosine.

Lanolin.

Methanol.

Methyl 12-hydroxystearate.

Methyl taurine-oleic acid condensate, molecular weight 486.

α,α' -(Methylenebis(4-(1,1,3,3-tetramethylbutyl)-o-phenylene))bis[omega-hydroxypoly(oxyethylene)] having 6-7.5 moles of ethylene oxide per hydroxyl group.

Mineral oil.

Mono-, di-, and triisopropanolamine.

Mono- and diisopropanolamine stearate.

Monobutyl ether of ethylene glycol.

Monoethanolamine.

Morpholine.

Myristyl alcohol.

Naphtha.

β -Naphthol.

Nonylphenol.

Odorless light petroleum hydrocarbons.

Oleyl alcohol.

Petrolatum.

o-Phenylphenol.

Pine oil.

Polybutene, hydrogenated; complying with the identity prescribed under § 178.37 of this chapter.

Polyethylene.

Polyethylene, oxidized (air-blown).

Polymer derived from N-vinyl pyrrolidone and copolymers derived from the alkyl (C₁₂-C₁₈, C₁₀, C₁₄, C₁₆, and C₁₈) methacrylate esters, butyl methacrylate (CAS Reg. No. 97-88-1), isobutyl methacrylate (CAS Reg. No. 97-88-9) and methyl acrylate (CAS Reg. No. 80-62-6); the finished polymer contains no more than 1 percent weight of polymer units derived from N-vinyl pyrrolidone and is present at a level not to exceed 7 parts per million weight of the finished dry paper and paperboard fibers.

Polyoxyethylene (4 mols) decyl phosphate.
Polyoxyethylene (4 mols) di(2-ethylhexyl) phosphate.

Polyoxyethylene (15 mols) ester of rosin.

Polyoxyethylene (3-15 mols) tridecyl alcohol.

Polyoxypropylene, molecular weight 2,000.

Polyoxypropylene-polyoxethylene cocarbonate, minimum molecular weight 950.

Polyoxypropylene-ethylene oxide cocarbonate of ethylene diamine, molecular weight 1,700-3,800.

Polyvinyl pyrrolidone, molecular weight 40,000.

Potassium distearyl phosphate.

Potassium pentachlorophenolate.

Potassium trichlorophenolate.

Rosins and rosin derivatives identified by § 175.105(c)(5) of this chapter.

Silica.

Siloxanes and silicones, dimethyl, methyl, and hydrogen, reaction products with polyethylene-polypropylene glycol monomethyl ether (CAS Reg. No. 71965-38-3).

Sodium alkyl (C₁₂-C₁₈) benzene-sulfonate.

Sodium dioctyl sulfosuccinate.

Sodium distearyl phosphate.

Sodium lauryl sulfate.

Sodium lignin sulfonate.

Sodium 2-mercaptobenzothiazole.

Sodium naphthalenesulfonic acid (3-methyl) condensed with formaldehyde (2 moles).

Sodium orthophenylphenolate.

Sodium pentachlorophenolate.

Sodium petroleum sulfonate, molecular weight 440-450.

Sodium trichlorophenolate.

Stearyl alcohol.

α -(p-(1,1,3,3-Tetramethylbutyl)phenyl)-nonylphenyl-, or p-dodecylphenyl-(hydroxypoly(oxyethylene)) product of the condensation of 1 mole of p-phenol (alkyl group is 1,1,3,3-tetramethyl, a propylene trimer isomer, or pylene tetramer isomer) with an amount of 1.5-15 moles of ethylene oxide.

Tetrahydrofurfuryl alcohol.

Tributoxyethyl phosphate.
Tributyl phosphate.
Tridecyl alcohol.
ethanolamine.
ethylene glycol di(2-ethyl hexanoate).
Tri-(2-ethylhexyl) phosphate.
Tristearyl phosphate.
Wax, petroleum, Type I and Type II.
Wax, petroleum (oxidized).
Wax (montan).

[42 FR 14554, Mar. 15, 1977, as amended at 47 FR 17986, Apr. 27, 1982; 47 FR 46495, Oct. 19, 1982; 47 FR 56845, Dec. 21, 1982]

§ 176.230 3,5-Dimethyl-1,3,5,2H-tetrahydrothiadiazine-2-thione.

3,5-Dimethyl-1,3,5,2H-tetrahydrothiadiazine-2-thione may safely be used as a preservative in the manufacture and coating of paper and paperboard intended for use in contact with food in accordance with the following prescribed conditions:

(a) It is used as follows:

(1) In the manufacture of paper and paperboard as a preservative for substances added to the pulp suspension prior to the sheet-forming operation provided that the preservative is volatilized by heat in the drying and finishing of the paper and paperboard.

(2) As a preservative for coatings for paper and paperboard. *Provided*, That the preservative is volatilized by heat in the drying and finishing of the coated paper or paperboard.

(b) The quantity used shall not exceed the least amount reasonably required to accomplish the intended technical effect and shall not be intended to nor, in fact, accomplish any physical or technical effect in the food itself.

(c) The use of a preservative in any substance or article subject to any regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter must comply with any specifications and limitations prescribed by such regulation for the substance or article.

§ 176.250 Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane.

Poly-1,4,7,10,13-pentaaza-15-hydroxyhexadecane may be safely used as a retention aid employed prior to the sheet-forming operation in the manufacture of paper and paperboard intended for use in contact with food in an amount not to exceed that neces-

sary to accomplish the intended physical or technical effect and not to exceed 6 pounds per ton of finished paper or paperboard.

§ 176.260 Pulp from reclaimed fiber.

(a) Pulp from reclaimed fiber may be safely used as a component of articles used in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food, subject to the provisions of paragraph (b) of this section.

(b) Pulp from reclaimed fiber is prepared from the paper and paperboard products described in paragraphs (b) (1) and (2) of this section, by repulping with water to recover the fiber with the least possible amount of non-fibrous substances.

(1) Industrial waste from the manufacture of paper and paperboard products excluding that which bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the Federal Food, Drug, and Cosmetic Act.

(2) Salvage from used paper and paperboard excluding that which (i) bears or contains any poisonous or deleterious substance which is retained in the recovered pulp and that migrates to the food, except as provided in regulations promulgated under sections 406 and 409 of the act or (ii) has been used for shipping or handling any such substance.

§ 176.300 Slimicides.

(a) Slimicides may be safely used in the manufacture of paper and paperboard that contact food, in accordance with the following prescribed conditions:

(1) Slimicides are used as antimicrobial agents to control slime in the manufacture of paper and paperboard.

(2) Subject to any prescribed limitations, slimicides are prepared from one or more of the slime-control substances named in paragraph (c) of this section to which may be added optional adjuvant substances as provided for under paragraph (d) of this section.

(3) Slimicides are added to the process water used in the production of paper or paperboard, and the quantity added shall not exceed the amount necessary to accomplish the intended technical effect.

(b) To insure safe usage, the label or labeling of slimicides shall bear adequate directions for use.

List of substances

Acrolein.....	
Alkyl (C ₁₂ -C ₁₈) dimethylethyl-ammonium bromide.....	
n-Alkyl (C ₁₂ -C ₁₈) dimethyl benzyl ammonium chloride.....	At
1,2-Benzisothiazolin-3-one.....	
Bis(1,4-bromoisobutoxy)-2-butene.....	
5,5-Bis(bromoisobutoxymethyl)-m-dioxane.....	
2,6-Bis(dimethylammonomethyl) cyclohexanone.....	
1,2-Bis(monobromoisobutoxy) ethane [CA Reg. No. 3785-34-5].....	At a
Bis(trichloromethyl)sulfone.....	
4-Bromoisobutoxymethyl-m-dioxane.....	
2-Bromo-4'-hydroxyacetophenone.....	
3-Bromo-β-nitrostyrene.....	At f
Chloroethylenedithiocyanate.....	
5-Chloro-2-methyl-4-isothiazolin-3-one calcium chloride.....	At a
and 2-methyl-4-isothiazolin-3-one calcium chloride mixture at a ratio of 3 parts to 1 part.....	
Chlorinated levulinic acids.....	
Chloromethyl butanethioisulfonate.....	
Cupric nitrate.....	
n-Dialkyl (C ₁₂ -C ₁₈) benzylmethylammonium chloride.....	
1,2-Dibromo-2,4-dicyanobutane (CAS Reg. No. 35631-65-7).....	At a
2,2-Dibromo-3-nitropropionamide.....	At
2,3-Dibromoisobutyronitrile.....	
3,5-Dimethyl-1,3,5,2H-tetrahydrothiadiazine-2-thione.....	
Dipotassium and disodium ethylenebis(dithiocarbamate).....	
Disodium cyanodithiocarbamate.....	
n-Dodecylguanidine hydrochloride.....	At a
2-(p-hydroxyphenyl) glyoxyloxyhydroxymethyl chloride (CAS Registry No. 34911-46-1).....	At
2-Hydroxypropyl methanethiol sulfonate.....	
2-Mercapto-1,3,5-triazole.....	
Methylenebis(butanethioisulfonate).....	
Methylenebis(dithiocyanate).....	
2-Nitrobutyl bromoisobutyrate [CA Reg. No. 32815-95-6].....	At a
N-(α-(Nitroethyl)benzyl) ethylenediamine.....	
Potassium 2-mercaptobenzothiazole.....	
Potassium N-hydroxymethyl-N-methyldithiocarbamate.....	
Potassium N-methyldithiocarbamate.....	
Potassium pentachlorophenate.....	
Potassium trichlorophenate.....	
Silver fluoride.....	Limit
Silver nitrate.....	Ca
Sodium dimethyldithiocarbamate.....	
Sodium 2-mercaptobenzothiazole.....	
Sodium pentachlorophenate.....	
Sodium trichlorophenate.....	
3,6,8-Tetraazatricyclo[6.2.1.1 ^{2,4}] octane.....	
3,3',4,4'-Tetrachlorotetrahydrothiophene-1,1'-dioxide.....	
2-(Thiocyanomethylthio) benzothiazole.....	
vinylene bistrichloroacetate.....	

(d) Adjuvant substances permitted to be used in the preparation of slimicides include substances generally recognized as safe for use in food, substances generally recognized as safe

ATTACHMENT III
VOC DEFINITIONS AND ISSUES

I've attached several articles and trade association communications regarding the Clear Air Act Amendment impact on VOC's. Also attached are multiple state VOC definitions.

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Educating Congress on the Realities of Clean Air Attainment

Clean air legislation is the top environmental priority in 1990 for the United States Congress, the Bush Administration, and CSMA.

Bills are pending in the Senate (S. 1630) and in the House of Representatives (H.R. 3030). As Chemical Times & Trends goes to press, there is little doubt that 1990 will usher in the passage of the first major amendments to the Clean Air Act since 1977.

The Senate and House bills would extend coverage of the Clean Air Act to consumer products for the first time. Both bills originally called for a 2-year study by the Environmental Protection Agency (EPA) of the contribution of commercial and consumer products to ozone (or smog) formation in the lower atmosphere. At the conclusion of the study, EPA is required to draft regulations to reduce emissions of volatile organic compounds (VOCs) from selected categories of products and reduce ozone formation.

CSMA has been active in educating Congress on the implications of the clean air bills and is leading a consumer products coalition that seeks to amend the legislation in light of scientific and economic facts.

That lobbying has been successful, and the bills have been modified in several ways to address the concerns of industry:

First, the study time has been lengthened and both S. 1630 and H.R. 3030 now call for a three-year study.

Second, the bills require that before proposing any regulations regarding consumer products, EPA must take into account technical feasibility, cost, and competition. These are important criteria for which the industry fought hard. Thus, in drafting regulations to reduce VOC emissions, EPA must consider product efficacy.

Third, the House Energy and Commerce Committee included language in its bill that acknowledges the importance of national uniformity in regulating consumer products. It would be calamitous for manufacturers and marketers of consumer products if states impose different requirements for formulation in an effort to improve air quality. Products, after all, must move freely in interstate commerce. In an effort to achieve uniformity, H.R. 3030 includes language that requires states to consult with EPA before adopting any regulations.

The lobbying process in the 101st Congress began when the Senate Committee on Environment and Public Works held hearings on S. 1630. Dr. Ralph Engel, president of CSMA, testified on behalf of the consumer products industry, and urged that the legislation be amended to address the concerns mentioned above, and others. Dr. Engel stressed that traditionally the Clean Air Act has regulated waste and emissions. Regulation of consumer products, however, would entail not waste, but the regulation of the product

itself. Congress and EPA need to recognize this important fact and to adopt an appropriate regulatory framework.

Dr. Engel's testimony is reproduced herewith:

We welcome this opportunity to testify on legislation that would serve to amend the Clean Air Act.

The Chemical Specialties Manufacturers Association (CSMA) has a membership of more than 400 firms engaged in the manufacture, formulation, distribution, and sale of nonagricultural pesticides, including antimicrobial products, as well as automotive specialty products, detergents and cleaning compounds, personal care products, and polishes and floor maintenance products for household, institutional, and industrial use. These products are formulated and packaged in many forms and are marketed nationally.

In addition, CSMA also represents a coalition of industry associations concerned with regulations on consumer products which includes the Soap and Detergent Association (SDA) and the Cosmetics, Toiletries and Fragrance Association (CTFA), as well as a number of companies including several who produce ethical and over-the-counter pharmaceutical products.

Both of the nonattainment bills now before this committee contain provisions for the regulation of volatile organic compound

(VOC) emission from commercial and consumer products. Regardless of what has been written and said on the subject, it is impossible, at this point, to know how to approach these small sources of emissions with any certainty or knowledge of whether it is feasible to attempt to control them at all.

Commercial and consumer solvents are an entirely new and unique subject for clean air regulation. It is a category that cannot be dealt with by traditional approaches or traditional control strategies. Their contribution to ozone is not at all clear. There is, at this point, simply no reliable data base from which to determine that contribution. Neither is it clear that an attempt to control emissions from this source will either be feasible, technically or economically.

The products contemplated in proposals to regulate emissions from commercial and consumer products are not of a particular type or class, but cover a universe of commercial, household, and personal care uses—encompassing more than 700,000 products. Included are personal care products such as shaving cream, mouthwash, deodorant, perfume shampoo, and sunscreen; home care products such as window cleaner, furniture polish, floor wax, and kitchen cleaners; auto care products such as carburetor cleaners, anti-freeze, and windshield de-icer; and vital health care products such as disinfectants, sterilants, insecticides, and medicines.

It should be noted that "commercial and consumer products" could include architectural coatings, traffic coatings, and aircraft or marine products, etc. I am only addressing consumer products as outlined above.

These products cannot be viewed in the same way as traditional emission sources. The Clean Air Act, up to this point, has regulated waste emission and not

end-use consumer products created for the benefit of society. The regulation of consumer products raises many different issues. Instead of controlling valueless waste, regulation will be directed at products which themselves, because of their present composition, provide important societal and public health benefits. These benefits have to be considered as part of any regulatory decision. Obviously, it would be bad public policy to require reformulation of medicines, disinfectants, insecticides, sterilants, and a whole host of other consumer products for clear air purposes without ensuring that the products will continue to be effective.

Most consumer products are marketed nationally and rely upon the freedom of movement traditionally and constitutionally accorded to interstate commerce. If anything should move freely in the marketplace, it must be these many products that are such an important part of modern life. Any regulation of emissions from commercial and consumer products must not erect unnecessary barriers to the free flow of commerce. There must be consistency of regulation in the national marketplace. At the very least, any federal program should take particular care not to create incentives for states to adopt different or obstructive requirements for commercial and consumer products.

Both of the nonattainment bills currently before this committee move toward addressing some of these concerns. In particular, both S. 1490 and S. 1630 provide for a study of the issues prior to regulation. Both provide that, when the administrator of the Environmental Protection Agency does issue regulations, he must consider technological and economic feasibility, as well as health, environmental, and energy impacts. We believe that there are several areas of this legislation in which improvement is most necessary.

These are:

Four-Year Study Needed

Both S. 1490 and S. 1630 provide for a two-year study. During this period, EPA is directed to study and analyze the subject of emissions from consumer products. We believe this period is insufficient. The congressional Office of Technology Assessment (OTA), in its recent study, *Catching Our Breath: Next Steps for Reducing Urban Ozone*, noted that very little is known about either the ozone contribution or control technology for consumer products. For this reason, OTA excluded consumer products altogether from its emissions reduction potential and cost analyses.

CSMA believes that it is unrealistic to expect that this factual vacuum can be filled in a two-year period. A federal court in New York recently agreed. In reviewing a state implementation plan (SIP) revision regulating consumer products, the court agreed with New York State Department of Environmental Conservation's (DEC) assertion that no valid data existed to regulate these products. In fact, it further agreed that a four-year study would be required. There are no facts before this committee which suggest that the New York court was wrong in its assessment. CSMA believes that the best approach is:

First, consumer products should be defined and a complete emissions inventory of the approximately 700,000 products should be compiled.

The next step after the inventory is established is to initiate a study that would, at a minimum, identify the following:

- consumer solvent contributions to ozone formation;
- alternatives for reducing VOC emissions from products;
- economic, commercial, and technical feasibility of such methods and alternatives; and
- assess the net environmental.

health, and societal impacts and/or value of such methods and alternatives.

The study would assess and evaluate such other issues associated with volatile organic compound emissions from consumer products as are identified during the protocol development process.

The study required by the protocol would be completed no later than 36 months after the protocol has been developed.

The final report would include recommendations with respect to technically, economically, and commercially feasible methods of emissions reduction.

Following issuance of the final report, the EPA administrator would be empowered to promulgate regulations to regulate volatile organic compound emissions into the ambient air from consumer solvent products. In promulgating such regulations, the administrator would take into account the recommendations and the conclusions of the report and economic, technical, and commercial feasibility of the recommended control measures as well as their net environmental, health, and societal impacts.

EPA Discretion

At the end of such study, if the EPA administrator finds that regulation of the VOC emissions of any or all consumer products is beneficial and feasible, then such regulations can be promulgated. It must be made clear in the statute, however, that the administrator's obligation to issue regulations is discretionary and that the exercise of that discretion depends on the results of the study. Statutory language that requires regulations regardless of the outcome of the study, such as in S. 1630, prejudices the study immediately by prejudging the results before it is even conducted.

is Not Acceptable

Both bills authorize the administrator to employ a system of fees

as a method of controlling VOC emissions from consumer products. CSMA submits that any generic, unfettered provision authorizing EPA to assess fees carries too high a potential to become simply a revenue-raiser unrelated to ozone attainment, and is likely to be viewed by the courts as an unconstitutional delegation of the congressional power to tax. Economic incentives are useful for controlling emissions from stationary sources, but not for controlling emissions from consumer products. They raise the spectre of governmental regulation of the amount of products which may be sold and carry with them the potential of seriously interfering with the marketability of consumer products.

Consumer Product Norms

The interstate commerce clause of the United States Constitution prohibits barriers to the free flow of commerce among the states. CSMA believes that the goal of consistency of regulation in the national marketplace can be accommodated with need, under certain compelling and extraordinary circumstances, for states to adopt additional controls after a finding of need has been made. Current Clean Air Act provisions relating to mobile sources, motor fuels, and aircraft make such an accommodation. Moreover, during the pendency of federal regulation, the states ought to be called upon to suspend their own efforts to adopt or enforce standards relating to emissions from commercial and consumer products. S. 1490 contains such a provision respecting emissions from marine vessels. CSMA believes it is not only appropriate but a must with regard to consumer product regulation as well.

Not Stationary Sources

Both bills define "stationary source" as being "any source of an air pollutant except those emissions resulting directly from an

internal combustion engine." CSMA urges that this definition be clarified to exclude commercial and consumer products. The term "stationary source" is a term of art under the Clean Air Act. It triggers many diverse obligations. Commercial and consumer products should not be included under that definition, but should be treated separately under the specific regulatory authorities established by both bills. The addition of language which makes it clear that the term does not include commercial and consumer products is fully consistent with EPA's intent with respect to S. 1490. In its section by section analysis of the administration's draft bill, EPA described the purpose of this definition of "stationary sources" as being to "confirm that emissions from movable stationary sources such as mobile asphalt batch mixing trailers and ships at port are subject to the Act's stationary source requirements."

Unfair Penalties

Finally, CSMA is concerned about a provision in S. 1490 in which states are denied credit for emissions reductions achieved by a mandated reduction in the Reid vapor pressure of gasoline or by vehicle tailpipe or evaporative emissions measures. Artificial limits on a state's ability to claim credit for emissions reductions, without equivalent reductions in emissions inventory, unfairly inflate the emissions reduction burden to be borne by other regulated entities.

Reid vapor pressure controls are widely recognized as one of the most effective ozone control strategies, both in terms of emissions reduction and cost. Modeling shows that these controls can, by themselves, bring some areas into attainment.

S. 1490, however, requires the states to devise SIPs which project attainment without being able to count these extremely substantial reductions. For example, if, as a

result of federal controls on Reid vapor pressure, emissions go down by 50%, the state is required to plan as though emissions were not so reduced. Controls on commercial and consumer products will accordingly have to be far more draconian than the facts would actually justify. Such constraints are inconsistent with the ultimate objective of the bill, which is to achieve the national ambient air quality standard for ozone.

Summary

CSMA believes that, in the area of commercial and consumer

product regulation, both S. 1490 and S. 1630 benefit from the inquiries and analyses which have been made by both government and industry over the last two years. Both bills reflect a bit more sensitivity to the complexities involved in any regulation of emissions from this category of sources. Both reflect an awareness of the need to proceed with care and with significant improvement, in our view, along the lines discussed.

Conclusion

We appreciate this opportunity to present our views concerning

the appropriate strategy to establishing a federal scheme for addressing regulations of consumer products as part of a plan for achieving ozone attainment.

As this issue of Chemical Times & Trends goes to press, S. 1630 has passed the Senate and H.R. 3030 will be considered soon in the full House of Representatives. Members of industry are encouraged to contact the CSMA Legislative Affairs Department at (202)872-8110 for further information on this important issue.

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