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PART I

(Part II begins on page 25897)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 191]

BANNED HAZARDOUS SUBSTANCES

Proposed Exemption of Certain Lead-Containing Paints and Other Similar Surface-Coating Materials

The Commissioner of Food and Drugs has received a petition from the National Paint and Coating Association, 1500 Rhode Island Avenue NW., Washington, DC 20005, submitted pursuant to section 702(a) (1) (B) of the Federal Food, Drug, and Cosmetic Act, proposing an amendment to a regulation (21 CFR 191.8(a) (2) (3)) promulgated under section 3(e) (1) (B) of the Federal Hazardous Substances Act. The proposed amendment would exempt certain lead-containing coatings from classification as banned hazardous substances.

The petition states that the submission is on behalf of its members which manufacture and market certain specialty paints in which lead is a necessary component.

Section 191.8(a)(2) was promulgated in the Federal Register of March 11, 1972 (37 F.R. 5229), and its effective date was confirmed in part in the Federal Register of August 18, 1972 (37 F.R. 16878).

The proposed amendment prepared by the petitioner reads as follows: ..

§ 191.8 Banned hazardous substances.

(a) • • •

(2) (i) • • •

(ii) The provisions of this subdivision (i) do not apply to:

(f) Automotive, agricultural, and industrial equipment finish coatings;

(g) Industrial (and commercial building) maintenance coatings, including traffic and safety marking coatings;

(h) Graphic art coatings (products marketed solely for application on billboards, road signs, and similar uses and for identification marking in industrial buildings);

(i) Finishes (coatings for automobiles, agricultural and industrial equipment, lawn and garden equipment, boats, outboard motors, motorized recreational vehicles, and appliances);

(j) Exterior marine coatings for small craft applications;

(k) Exterior rubber-based roof coatings; and

(l) Exterior primer coatings for wood siding containing extractives (products marketed solely for application on redwood and cedar);

Provided, That these products bear on the main panel of their label, in addition to any labeling that may be required under the act or regulations promulgated pursuant thereto, the signal word "WARNING" and the following statement: "CONTAINS LEAD. DRIED FILM OF THIS PAINT MAY BE HARMFUL IF EATEN OR CHEWED. See other cautions on (side or back) panel." These products shall also bear on their label the following additional statement or its practical equivalent:

Do not apply on toys and other children's articles, furniture, or interior surfaces of any dwelling or facility which may be occupied or used by children.

Do not apply on those exterior surfaces of dwelling units such as window sills, porches, steps, or railings, to which children may be commonly exposed.

Keep out of reach of children.

The placement, conspicuousness, and content of the above labeling shall be in accordance with the requirements of § 191.101.

• • • • •

The following is the statement of grounds given in the petition in support of the proposed amendment:

On March 11, 1972, the Food and Drug Administration published an order in the Federal Register (37 F.R. 5231) under section 2(q) (1) (B) of the Federal Hazardous Substances Act which, in part, declared any paints or other similar surface-coating materials intended, or packaged in a form suitable, for use in or around the household, to be banned hazardous substances if: (1) Shipped in interstate commerce between December 31, 1972, and December 31, 1973, and (2) containing lead compounds of which the lead content is in excess of 0.5 percent of the total weight of the contained solids or dried paint film. On August 18, 1972, this portion of the order was confirmed as effective; that portion of the order pertaining to a 1.0% percentage level remained under consideration by the Agency.

The Federal Hazardous Substances Act applies to paint products which are found to be toxic, which are intended or packaged in a form suitable for use in or around a household, and which may cause substantial personal injury or illness as a result of "reasonably foreseeable ingestion by children" (15 U.S.C. 1261(f)(1)(A)). Most paints in liquid form are not considered toxic under this act because the viscosity of the paint product renders the ingestion hazard extremely remote. Only after the paint product has been applied to a surface accessible to children, and then usually only after the film has flaked or chipped, does a hazard arise that children may ingest the lead content.

Thus, this petition is not necessary because of the requirements of the act since the specialty paints, which are the subject of this petition, are neither intended nor likely to be used on surfaces which are reasonably available to children or on surfaces which will enable flaking and chipping of the paint. This petition is required only because the language of § 191.8(a)(6)(i) appears to be broader in scope than the language in the statute and broader in scope than is necessary to protect against the lead hazard from the dried paint film. The pertinent portion of the regulation reads as follows: "Any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around the household". If this operative language had been limited to surface-coating materials which after application would pose a lead hazard because of reasonably foreseeable ingestion by children, it is clear that the regulation would not apply to these specialty products. This petition for an amendment is submitted, therefore, only to clarify the scope of § 191.8(a)(6)(i) of the regulations.

The Definitions and Procedural and Interpretative Regulations, under FHSA (21 CFR Part 191.1), specify that the act covers those products that under customary or reasonably foreseeable conditions of storage or use may be brought into or around a home, apartment, or other place people dwell, including a garage, carport, barn, or storage shed. The same regulations expressly state that the act does not cover industrial supplies that might be taken into a home by a serviceman. The interpretations specifically provide that a product intended or used exclusively for industrial use does not become subject to the act simply because an industrial worker could possibly misappropriate a supply for his own use.

Thus, the interpretative regulation leaves no doubt that industrial coatings, such as original finish coatings for automobiles, industrial equipment, and farm and garden equipment are outside the scope of the act and therefore remain unaffected by the proposed tolerances. The specialized coating products which are the subject of the petition are similar to the industrial or factory-applied coatings in many respects. They are intended primarily for application to nonhousehold surfaces, usually by professional painters, and they are not intended or suitable for use on surfaces accessible to children which would create a hazard. The March 11 regulation appears to cover these specialized paints solely because they may at times be found in or around the household in packaged form and not because of any finding that they pose a lead hazard to children.

Congress, in enacting the Federal Hazardous Substances Act, contemplated the dangers offered by a product or article in its liquid state and in its packaged form and thus designed the act to regulate all products "intended or packaged in a form suitable for use in or around the household." Implicit in the quoted language is the assumption that the particular hazard from a product is posed simply because that product is present in the household in packaged form. While this is true of a substance which presents a hazard in its liquid state as, for example, the flammability hazard of certain liquid paints, this is not true of the lead ingestion hazard from paints. The particular hazard posed by lead content in paint does not occur from the liquid paint in the package but, instead, the hazard occurs solely from the dried paint film if ingested by children.

The best information available indicates that children who are disposed to chew paint chips confine their activity primarily to interior surfaces in the home and, perhaps, infrequently to an accessible exterior surface. Children usually are attracted by flakes from old, chipped paint film rather than newly-applied surfaces, and by toys or other articles which they may place in their mouths. This is due in large part to the limited physical abilities of the young children suffering from "pica," the habit of ingesting nonfood items.

As pointed out in comments to the subject regulation, submitted by Dr. Barry King and Dr. Julian Chisholm (noted authorities on lead poisoning), the most critical age for exposure of a child through ingestion of paint, putty, and other lead-containing nonfood materials is usually 1 to 3 years of age. In view of both the restricted mobility and physical limitations of children in this age bracket, they neither have access to, nor are capable of chewing or ingesting, paint chips from surfaces to which the products for which exemptions are herein requested are applied. In fact, we are not aware of any documented case where a child has attempted to ingest the paint film on automobiles, farm and garden implements, etc.

The American Academy of Pediatrics, in its November 30, 1971 memorandum to the Food and Drug Administration, appears to confirm this: "The American Academy of Pediatrics endorses the principle contained in the petition filed with the Commissioner that paints containing more than minute traces of lead be designed as banned hazardous substances, if intended for use on children's products or interior surfaces (emphasis supplied)." Further, the Senate Committee Report on the Lead-Based Paint Poisoning Prevention Act Amendments of 1971 refers specifically to coatings "intended for interior residential surfaces" (S. Rept. No. 92-462, 92d Cong., 2d Sess. (1972)).

Similarly, under the Lead-Based Paint Poisoning Prevention Act (Public Law 91-695) the Secretary of Housing and Urban Development, in consultation with the Secretary of Health, Education, and Welfare, was instructed to develop and carry out a demonstration and research program "to determine the nature and extent of the problem of lead-based paint poisoning in the United States, particularly in urban areas, and the methods by which lead-based paint can most effectively be removed from interior surfaces, porches, and exterior surfaces to which children may be commonly exposed, of residential housing."

Acting under this authority, the Secretary of HUD has determined that the existing conditions that pose a lead paint hazard to children are those surfaces reasonably available to children that present peeling or flaking paint. This has been recently confirmed by the agency by a publication in the October 31, 1972, issue of the Federal Register (at page 23782) entitled "Prohibition of Use of Lead-Based Paint and Elimination of Lead-Based Paint Hazard." This revises pertinent parts of the Code of Federal Regulations already promulgated under authority of the Lead-Based Paint Poisoning Prevention Act. In this revision, with respect to the use of and elimination of existing hazards caused by lead-based paint, the Secretary of HUD defines "applicable surfaces" as all interior surfaces and those exterior surfaces, such as stairs, decks, porches, railings, windows, and doors, which are readily accessible to children under 7 years of age." Further, "Health Hazard," with respect to lead-based paint, is defined to mean "swallowing (ing), gnawing, peeling, and loose lead-based paint on applicable surfaces."

Since the prohibition against use of lead-based paint under this revision extends only to use on "applicable surfaces of any residential structure," clearly then these are the only surfaces found by this agency to pose a lead hazard to children. There is no indication by HUD that the surfaces to which the products under consideration are applied present either an existing or future lead poisoning hazard to children.

It is clear from the foregoing that the hazard sought to be prevented by lead tolerances established in § 191.8(a)(6)(i) is lead ingestion by children who tend to chew dried paint film on interior and exterior household surfaces accessible to these children, and on toys or other articles intended for use by these children. The regulation is not intended to nor should it reasonably apply to the specialized paints under consideration since, through customary or reasonably foreseeable conditions of use, they will not cause a lead hazard for plus children, even though they are packaged in a form suitable for use in or around the household, and thus, incidentally may meet

the definitional test of §1501.1(a), namely, that "under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling." Thus, petitioners believe these products should not be subject to the provisions of the regulation.

Unlike interior household paints or even exterior paints for household application which could conceivably be substituted for interior use or applied on an exterior surface accessible to children, these specialized products are never marketed for such application. They are neither intended, designed, nor suitable for use in areas accessible to children. These products are limited in purpose and, since they are not general household products, are thus purchased infrequently and never stored around the household in any significant quantity. Furthermore, most of these products are intended for the professional consumer.

The precautionary label proposed in this petition adds an extra measure of protection against any conceivable risk from its lead content due to misuse. The possibility of misusing these products, even without the precautionary label is, however, very remote. The quick odor and rough texture of an industrial maintenance coating, such as a red-lead primer in which lead is an important protective material, make it exceedingly unlikely that anyone would use it on interior household surfaces or other surfaces accessible to children. Other specialty products, such as automobile refinishes, are generally too expensive to be feasible for use on such surfaces. Others, such as hobby coatings in aerosol containers, are packaged in quantities too small for practical use on household surfaces. Additional significant factors militating against misuse of these products are explained in the following discussions of the individual products along with an explanation of why lead is a necessary component in these coatings.

DISCUSSION OF SPECIAL PURPOSE COATINGS

1. *Automotive, agricultural, and industrial equipment refinish coatings.* Automotive, agricultural, and industrial equipment refinish coatings are designed for use by automobile repair shops or agricultural or industrial equipment dealers for the refinish of automobiles, trucks, agricultural, and industrial machinery. These refinish coatings are marketed through automotive warehouse distributors to automotive parts jobbers, and then to automotive body shops. Agricultural and industrial equipment coatings are sold by equipment manufacturers and subsidiaries to equipment dealers.

Although these refinish coatings are intended for use by automotive body shops or farm and industrial equipment dealers and are not marketed primarily for retail customers, some of these companies have a secondary retail trade. Such retail customers use these coatings to refinish automobiles, agricultural equipment, and industrial machinery. This refinishing may occur in or shops a garage, barn, or shed.

These coatings are usually high-gloss and are customarily applied by spray equipment. Lead is an essential ingredient in many of these coatings for three reasons. First, it is a catalytic drier, necessary to speed the oxidation process and, thereby, prevent dirt or dust from becoming embedded in the film. Second, lead-containing pigments are necessary to match original equipment colors and to prevent a displeasing patchwork effect in coloring which otherwise would appear after a short time due to color chalking and fading. Finally, lead provides the essential resistance to weathering, heat, and other environmental conditions in which automobiles, agricultural, and industrial equipment are peculiarly exposed.

When used for the intended purpose, there exists no health hazard to children. Indeed, the only difference between the original factory-applied finish (which is not regulated by the act unless applied to any toy or other article intended for use by children) and the refinish product is that a can of the latter may find its way into or near the home. The hazard exists, however, not from the liquid in the container but only from the dried film and then only if the film can be ingested by children. It is not reasonably foreseeable that a child would chew on the paint because of the hard substrate to which the paint is applied.

Because of the nature of these refinishing products and their labeling, it is not reasonably foreseeable that they would be used for other than their intended purpose. There are many reasons for this:

a. Spray application, usually with high-pressure sprayers, is recommended for all of these products, and satisfactory results are not obtained with a brush or roller;

b. The high gloss colors found in most of these coatings are not suitable for surfaces in the home;

c. At the retail level, automotive refinishes are roughly twice as expensive as household enamels and paints, and thus it is exceedingly unlikely that consumers would purchase automotive refinish coatings for use on either an interior or exterior household surface since cheaper, better-suited products are more readily available. Further, each color preclude purchasing more than is actually needed to refinish an automobile;

d. These refinishes, in contrast to general purpose household enamels and paints, often require careful preparation of the metal surface, including grinding, sanding, and priming in order to obtain proper adhesion; and

e. The proposed warning label would provide additional protection by indicating to the purchaser that such coatings should not be applied on any surface accessible to children.

2. *Industrial (and commercial building) maintenance coatings, including traffic and safety marking coatings.* This category includes a variety of coatings sold for maintenance of plant and equipment, commercial buildings, structural steel (such as bridges), or for safety markings or pavement markings in streets or parking lots. Lead, obtained such as in the commonly used red-lead primer, is an important ingredient in these coatings, principally because it resists corrosion. Lead pigments also achieve the brilliant opaque and durable colors required for safety markings on pavements and industrial areas. There are no substitutes for the lead colors that will adequately perform the same purpose. Organic compounds are weaker in tinting strength, are less durable to weathering, and have a tendency to bleed when overpainted.

These products are intended for uses which pose no health hazard of children. Industrial plants, commercial office buildings, metal equipment, structural steel bridges, and the like are not accessible to children. Additionally, the Congress, after hearings, has recognized that such uses are not hazardous. In amending the Lead-Based Paint Poisoning Prevention Act of 1971 (Public Law 91-695), Congress eliminated the language "any building or structure," and substituted "interior surfaces, porches, and exterior surfaces to which children may be commonly exposed" in order to exclude industrial and commercial building maintenance use (S. Rep. No. [illegible], [illegible] Cong., [illegible]).

Again it is not reasonably foreseeable that industrial maintenance coatings would be misused and applied to a household surface accessible to children. Large volume users purchase these products directly from manufacturers, and these products are generally unavailable for use around the household. Some retail outlets may stock and sell certain lines of these coatings in limited volumes to smaller industrial accounts. Such industrial maintenance coatings normally are labeled "Intended for professional use only and not for retail sale." In addition, they will bear the lead warning label required by the proposed amendment. Thus, the possibility of household use is virtually eliminated.

3. *Graphic art coatings* (products marketed solely for application on billboards, road signs, and similar uses, and for identification marking of industrial buildings). These paints or coatings, applied freehand or by hand using a stencil or similar technique, are used to present a graphic image or convey a message. On the basis of intended use and because of a general lack of access by household consumers and children to either the coating or coated surface, graphic arts coatings should be excluded from the regulation.

While these coatings may be obtained by some dealers, they are intended principally for use by professional sign painters for the application of colors to billboards, billboard structures, road signs, and similar items and for identification markings of industrial buildings and the equipment installed therein. Most of these coatings are used only under

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specific shop conditions for application to plastic and metal surfaces, such as illuminated signs advertising particular businesses (e.g., service stations), or for road-directional markers.

The need for such contrasting colors is mandatory for these types of identification. Existing technology provides no substitute materials for lead which will provide the brilliance, color permanence, and film durability necessary for extended periods of service, particularly under the temperature, sunlight, and humidity conditions of outdoor exposure. Furthermore, for many of these uses, such as application to road signs, these coatings are baked on. No acceptable unlead colorants, which can withstand such baking, are presently available.

4. *Touchup coatings for automobiles, agricultural and industrial equipment, lawn and garden equipment, boats, outboard motors, motorized recreational vehicles, and appliances.* These coatings are packaged in small containers or in aerosol containers for use by the consumer in making minor surface repairs to his automobile, household appliance, or other mechanical equipment which may be found in the vicinity of his home. While intended primarily for use in and around the household, they are neither intended nor suitable for application to large surface areas accessible to children. The hard metal surface of the vehicles, appliances, or other equipment on which these coatings are applied do not lend themselves to chewing by children. The very thin, hard coating film on such surfaces cannot be removed and ingested by chewing.

These coatings are packaged and marketed in small quantities, discouraging their use on anything except an extremely small area. As with automotive refinish coatings, they generally are not suited for use other than as intended. Furthermore, to insure against any misuse of this product, each container will carry the required labeling, warning of the lead content and restricting the use of the product.

5. *Exterior marine coatings for small craft application.* The bulk of marine coatings are marketed for industrial use only, are sold in containers not suitable for use in and around the household, and, therefore, are outside the coverage of the act. Yet, marine coatings also are sold in significant volumes at retail for use by consumers in coating small craft, and these coatings could be found in or around the household.

Lead is an essential ingredient for these coatings, primarily for the same reasons it is needed in industrial maintenance. Lead is a necessary component for corrosion control; there are no satisfactory substitutes. As with automotive refinish coatings, lead is needed in marine coatings to provide resistance to weathering and other environmental conditions.

When used for their intended purpose, marine coatings do not pose a lead hazard to children since the coated surfaces are not accessible to them. Furthermore, it is not reasonably foreseeable that such coatings would be misused for other purposes in or around a household because other, better suited, less costly coatings are more readily available. Finally, the proposed warning label would clearly indicate to the consumer that the coating should not be applied on any areas accessible to children.

6. *Exterior rubber-based roof coatings.* These coatings are unique in that they are rubber-based as opposed to the types of materials used in other coatings. Lead oxides are the only known materials available for curing the liquid coatings when applied to surfaces such as roofs where waterproofing is essential. Oxides of no other metals exert any influence on the cure of these rubberized coatings. In addition, lead oxides are required for improved water resistance. These surfaces are obviously not accessible to children and, thus, the intended or reasonably foreseeable use will not create a health hazard for children.

7. *Exterior wood primer coatings for wood siding containing extractives (products marketed solely for use on redwood or cedar).* Lumber used for fabrication of siding materials may at times be cedar or redwood, each of which contains water-soluble materials which can be leached by moisture and deposited at or near the paint surface. These staining chemicals can have increased solubility in the high pH of emulsion paints and can accelerate the development of unsightly stains on the paint film. A lead compound primer is used when the bare substrate is cedar or redwood, in order to insolubilize the stains before they reach the topcoat. Continued manufacture and sale of exterior staining wood primers of this type, which contains lead, is necessary for this limited purpose.

We do not believe that the use of this product poses a reasonably foreseeable lead hazard to children for each of the following reasons:

a. A lead-containing primer need only be used once, and thus, there is no buildup of layers of lead-containing paint, which is recognized as a primary cause of lead poisoning;

b. Exterior house siding is not readily accessible to children in the areas that porch railings and ornamental surfaces are accessible;

c. Staining, as distinguished from penetrating, woods are not widely used for siding; and

d. Some of the primer penetrates the wood substrate and thus, should the coating peel little, if any, of the primer pools with it.

Summary

While a number of these special purpose coatings may be found in or near the household in packaged form, no lead hazard to children arises either before or after they are applied to the surfaces for which they are intended. Only "household" paints that are intended to be applied to surfaces accessible to children can pose the lead hazard sought to be prevented by the regulation in question.

We are not aware of any data, including reports in medical literature or human experience, which indicate that children have ingested dried paint films from the types of surfaces on which the products described herein are applied, nor is it reasonably foreseeable that such ingestion would occur. Additionally, considering the inaccessibility of the surfaces to which these paint films are applied and/or the hardness of the film or substrate to which they are applied, ingestion of these products after application is not reasonably foreseeable. Finally, and as previously pointed out, the likelihood of misuse of these products is exceedingly remote.

Accordingly, this petition is submitted in the interest of establishing, for both the consumer and the industry, clarity and certainty with respect to the scope of the subject regulation. This would also avoid the possibility of unwarranted regulatory action resulting from a lack of such clarity and certainty and provide a sound enforcement basis for labeling these classes of products.

Procedure

Since this petition is filed prior to the implementation date (December 31, 1972) of the lead order, it is requested that the publication of this petition have the effect of suspending the effective date of the order, pending review of comments and promulgation of a final order in this matter, only as it applies to those paints and similar surface coating materials which petitioners submit should not be subject to the order. Without such a suspension, the manufacture and distribution of the products would be totally disrupted. Manufacturers have not known and still do not know whether to continue or discontinue the marketing of these specialized coatings since there is a substantial unresolved question of their status under the lead order. Additionally, until this question is finally resolved by a final order, customers of these manufacturers, such as distributors or users having a mandatory recall basis, cannot with confidence continue to purchase such products. This is because it may be necessary for them to introduce the products into interstate commerce subsequent to the December 31, 1972, implementation date. This petition is not intended to affect the implementation date of the lead standards as they apply to other paints and surface-coating materials.

An additional factor for consideration relates to the labeling required by the proposed amendment. Until the Commissioner determines by regulation the acceptable or desirable label statements for the special-purpose coatings under consideration, manufacturers cannot with confidence label or relabel new products. It will be necessary, therefore, to consider lead time for an implementation date for such labeling as may be required.

Since this petition was received prior to the implementation date (December 31, 1972) of § 191.8(a)(3)(i)(b), the publication of this proposed amendment shall have the effect of suspending said implementation date, only as it applies

to those paints and similar surface-coating materials as described in this proposal, pending survey of comments and promulgation of an order in this matter. This proposal will in no way affect the implementation date of § 191.-.(a)(6)(i)(b) as it applies to other paints and similar surface-coating materials.

This proposal is being issued pursuant to provisions of the Federal Hazardous Substances Act (sec. 2(q)(1)(B), (2), 74 Stat. 372, as amended by 80 Stat. 1304; 15 U.S.C. 1261 (q)(1)(B), (2)) and the Federal Food, Drug, and Cosmetic Act (sec. 701(e), 52 Stat. 1055, as amended; (21 U.S.C. 371(e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120). Interested persons may, within 60 days after publication hereof in the Federal Register, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 20, 1972.

Sam D. Fine,
Associate Commissioner for Compliance.

[FR Doc.72-20737 Filed 12-4-72;8:45 am]

(a) Amounts deposited pursuant to subdivisions (ii), (iii), and (iii) of this subparagraph (including any voluntary deposits made pursuant to paragraph (b) (2) of this section), and

(b) Amounts paid pursuant to paragraph (a) (1) of § 1.1461-3, for such calendar year,

the withholding agent shall deposit the balance of tax due for such year with a Federal Reserve bank or authorized commercial bank on or before the 15th day of the third month following the close of the calendar year.

(v) *Transitional rules.* Notwithstanding the provisions of paragraph (a) (2) of § 1.1461-3 and of subdivisions (i) and (ii) of this subparagraph, the aggregate amount of tax required to be withheld under chapter 3 of the Code by any withholding agent after December 31, 1966, and before June 1, 1967, shall be deposited with a Federal Reserve bank on or before June 22, 1967. For the purpose of paragraph (b) (2) of this section any amount deposited in accordance with the requirement of this subparagraph shall be considered as if it were deposited with respect to amounts withheld during the calendar quarter beginning April 1, 1967.

(3) *Cross reference.* For rules relating to the adjustment of deposits, see § 1.1461-4(b) and § 1.6416-1. For rules requiring payment of any undeposited tax, see § 1.1461-3.

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[FR Doc.72-20913 Filed 12-4-72;8:45 am]

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

[7 CFR Part 905]

ORANGES, GRAPEFRUIT, TANGERINES, AND TANGELOS GROWN IN FLORIDA

Proposed Handling Limitations

Consideration is being given to the following proposal submitted by the committee, established under the marketing agreement, as amended, and Order No. 905, as amended (7 CFR Part 905), regulating the handling of oranges, grapefruit, tangerines, and tangelos grown in Florida, effective under the applicable provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674). The proposal would extend current grade and size limitations, for the period January 1, 1973, through September 30, 1973, applicable to oranges, including Navel, Temple, and Murcott Honey oranges (but not including Valencia, Lue Gim Gong, and similar late maturing oranges of the Valencia type), handled between the production area and any point outside thereof in the continental United States, Canada, or Mexico.

The proposed extension of the period of regulation of certain varieties of oranges is designed to continue in effect the current quality and size requirements for such fruits consistent with (1) the available supply and the demand for such fruits; and (2) improving returns to producers pursuant to the declared policy of the act.

The proposal is as follows:

Order. In § 905.545 (Orange Regulation 71; 37 F.R. 23788, 24432, 25496) the provisions of paragraph (a) preceding subparagraph (1) thereof are amended to read as follows:

§ 905.545 Orange Regulation 71.

(a) During the period January 1, 1973, through September 30, 1973, no handler shall ship between the production area and any point outside thereof in the continental United States, Canada, or Mexico.

* * * * *

All persons who desire to submit written data, views, or arguments in connection with the aforesaid proposal shall file the same, in quadruplicate, with the Hearing Clerk, U.S. Department of Agriculture, Room 112, Administration Building, Washington, D.C. 20250, not later than the 10th day after publication of the notice in the FEDERAL REGISTER. All written submissions made pursuant to this notice will be made available for public inspection at the office of the Hearing Clerk during regular business hours (7 CFR 1.27(b)).

Dated: November 30, 1972.

PAUL A. NICHOLSON,
Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc.72-20915 Filed 12-4-72;8:46 am]

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 191]

BANNED HAZARDOUS SUBSTANCES

Proposed Exemption of Certain Lead-Containing Paints and Other Similar Surface-Coating Materials

The Commissioner of Food and Drugs has received a petition from the National Paint and Coating Association, 1500 Rhode Island Avenue NW., Washington, D.C. 20005, submitted pursuant to section 702(e)(1)(B) of the Federal Food, Drug, and Cosmetic Act, proposing an amendment to a regulation (21 CFR 191.9(a)(5)(i)) promulgated under section 2(q)(1)(B) of the Federal Hazardous Substances Act. The proposed amendment would exempt certain lead-containing coatings from classification as banned hazardous substances.

The petition states that the submission is on behalf of its members which manufacture and market certain specialty paints in which lead is a necessary component.

Section 191.9(a)(5) was promulgated in the FEDERAL REGISTER of March 11, 1972 (37 F.R. 5228), and its effective date was confirmed in part in the FEDERAL REGISTER of August 10, 1972 (37 F.R. 16078).

The proposed amendment prepared by the petitioner reads as follows:

§ 191.9 Banned hazardous substances.

(a) * * *

(5)(i) * * *

(c) The provisions of this subdivision (i) do not apply to:

(1) Automotive, agricultural, and industrial equipment refinish coatings;

(2) Industrial (and commercial building) maintenance coatings, including traffic and safety marking coatings;

(3) Graphic art coatings (products marketed solely for application on billboards, road signs, and similar uses and for identification marking on industrial buildings);

(4) Touchup coatings for automobiles, agricultural and industrial equipment, lawn and garden equipment, boats, outboard motors, motorized recreational vehicles, and appliances;

(5) Exterior marine coatings for small craft application;

(6) Exterior rubber-based roof coatings; and

(7) Exterior primer coatings for wood siding containing extractives (products marketed solely for application on redwood and cedar):

Provided, That these products bear on the main panel of their label, in addition to any labeling that may be required under the act or regulations promulgated pursuant thereto, the signal word "WARNING" and the following statement: "CONTAINS LEAD. DRIED FILM OF THIS PAINT MAY BE HARMFUL IF EATEN OR CHEWED. See other cautions on (side or back) panel." These products shall also bear on their label the following additional statement or its practical equivalent:

Do not apply on toys and other children's articles, furniture, or interior surfaces of any dwelling or facility which may be occupied or used by children.

Do not apply on those interior surfaces of dwelling units, such as window sills, porches, stairs, or railings, to which children may be commonly exposed.

Keep out of reach of children.

The placement, conspicuousness, and contrast of the above labeling shall be in accordance with the requirements of § 191.103.

* * * * *

The following is the statement of grounds given in the petition in support of the proposed amendment:

On March 11, 1972, the Food and Drug Administration published an order in the FEDERAL REGISTER (37 F.R. 5229) under section 2(q)(1)(B) of the Federal Hazardous Substances Act which, in part, declared any paints or other similar surface-coating materials intended, or packaged in a form suitable for use in or around the household, to be banned hazardous substances if: (1) Shipped in interstate commerce between December 31, 1972, and December 31, 1973, and (2) containing lead compounds of which the lead content is in excess of 0.5 percent of the total weight of the contained solids or dried paint film. On August 10, 1972, this portion of the order was confirmed as effective; that portion of the order pertaining to a 0.06 percent lead level remained under consideration by the Agency.

The Federal Hazardous Substances Act applies to paint products which are found to be toxic, which are intended or packaged in a form suitable for use in or around a household, and which may cause substantial personal injury or illness as a result of "reasonably foreseeable ingestion by children" (15 U.S.C. 1261(f)(1)(A)). Most paints in liquid form are not considered toxic under the act because the viscosity of the paint would tend to reduce the ingestion hazard either [illegible] Only after the paint [illegible] been applied to a surface across [illegible] and then usually [illegible] film has flaked or chipped, does a hazard arise that children may ingest the dried content.

[illegible] petition is not necessary because [illegible] the requirements of the act since the specialty paints, which are the subject of this petition, are neither intended nor likely to be used on surfaces which are reasonably available to children or on surfaces which will enable flaking and chipping of the paint. The petition is required only because the language of § 191.9(a)(1)(i) appears to be broader in scope than the language in the statute and broader in scope than is necessary to protect against the lead hazard from the dried paint film. The pertinent portion of the regulation reads as follows: "Any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around the household". If this operative language had been limited to surface-coating materials which after application would pose a lead hazard because of reasonably foreseeable ingestion by children, it is clear that the regulation would not apply to these specialty products. This petition for an amendment is submitted, therefore, only to clarify the scope of § 191.9(a)(1)(i) of the regulations.

The Definitions and Procedural and Interpretative Regulations, under FHSA (21 CFR Part 191.1), specify that the act covers those products that under customary or reasonably foreseeable conditions of storage or use may be brought into or around a house, apartment, or other place people dwell, including a garage, carport, barn, or storage shed. The same regulations expressly state that the act does not cover industrial supplies that might be taken into a home by a serviceman. The interpretations specifically provide that a product labeled as and marketed solely for industrial use does not become subject to the act simply because an industrial worker could possibly misapply or operate a supply for his own use.

Thus, this interpretative regulation leaves no doubt that industrial coatings, such as original finish coatings for automobiles, industrial equipment, and farm and garden equipment are outside the scope of the act and therefore remain unaffected by the proposed tolerances. The specialized coating products which are the subject of this petition are similar to the industrial or factory-applied coatings in many respects. They are intended primarily for application to non-household surfaces, usually by professional painters, and they are not intended or suitable for use on surfaces accessible to children which would create a hazard. The March 11 regulation appears to cover these specialized paints solely because they may at times be found in or around the household in packaged form and not because of any finding that they pose a lead hazard to children.

Concern in enacting the Federal Hazardous Substances Act, contemplated the dangers offered by a product or part in its liquid state and in its packaged form and thus designed the act to regulate all products "intended or packaged in a form suitable for use in or around the household." Implicit in the quoted language is the assumption that the particular hazard from a product is posed simply because that product is present in the household in packaged form. While this is true of a substance which presents a hazard in its liquid state as, for example, the flammability hazard of certain liquid paints, this is not true of the lead ingestion hazard from paints. The particular hazard posed by lead content in paint does not occur from the liquid paint in the package but, instead, the hazard occurs solely from the dried paint film if ingested by children.

The best information available indicates that children who are diagnosed to chew paint chips confine their activity primarily to interior surfaces in the house and, perhaps, infrequently to an accessible exterior surface. Children usually are attracted by flakes from old, chipped paint film rather than newly-coated surfaces, and by toys or other articles which they may place in their mouths. This is due in large part to the limited physical abilities of the young children suffering from "pica," the habit of ingesting nonfood items.

As pointed out in comments to the subject regulation, submitted by Dr. Barry Kaeg and Dr. Julian Chisholm (noted authorities on lead poisoning), the most critical are for exposure of a child through ingestion of paint, putty, and other lead-containing nonfood materials is usually 1 to 3 years of age. In view of both the restricted mobility and physical limitations of children in this age bracket, they neither have access to, nor are capable of chewing or ingesting, paint chips from surfaces to which the products for which exemptions are herein requested are applied. In fact, we are not aware of any documented case where a child has attempted to ingest the paint film on automobiles, farm and garden implements, etc.

The American Academy of Pediatrics, in its November 30, 1971 memorandum to the Food and Drug Administration, appears to confirm this: "The American Academy of Pediatrics endorses the principle contained in the petition filed with the Commissioner that paints containing more than minute traces of lead be declared as banned hazardous substances, if intended for use on children's products or interior surfaces (emphasis supplied)." Further, the Senate Committee Report on the Lead-Based Paint Poisoning Prevention Act Amendments of 1972 refers specifically to coatings "intended for interior residential surfaces" (S. Rep. No. [illegible], 92d Cong., 2d Sess. [illegible]).

[illegible] for the Lead-Based Paint [illegible] Prevention Act [illegible] Secretary of Housing and [illegible] [illegible] authorized to determine [illegible] [illegible] [illegible] [illegible] of the problem of lead-based paint poisoning in the United States, [illegible] urban areas, and the [illegible] lead-based paint can be [illegible] from interior surfaces [illegible] children may be commonly exposed to the chemical lowering."

Acting under this authority, the Secretary of HUD has determined that the existing conditions that pose a lead paint hazard to children are those surfaces reasonably available to children that present peeling or flaking paint. The has been recently confirmed by the Secretary by a publication in the October 21, 1972, issue of the Federal Register (at page 22732) entitled "Prohibition of Use of Lead-Based Paint and Elimination of Lead-Based Paint Hazard." This revises pertinent parts of the Code of Federal Regulations already promulgated under authority of the Lead-Based Paint Poisoning Prevention Act. In this revision, with respect to the use of and elimination of existing hazards caused by lead-based paint, the Secretary of HUD defines "applicable surfaces" as all interior surfaces and those exterior surfaces such as stairs, decks, porches, railings, windows, and doors, which are readily accessible to children under 7 years of age." Further, "Health Hazard," with respect to lead-based paint, is defined to mean "cracking (and scaling, peeling, and loose lead-based paint on applicable surfaces."

Since the prohibition against use of lead-based paint under this revision extends only to use on "applicable surfaces of any residential structure," clearly then these are the only surfaces found by this agency to pose a lead hazard to children. There is no indication by HUD that the surfaces to which the products under consideration are applied present either an existing or future lead poisoning hazard to children.

It is clear from the foregoing that the harm sought to be prevented by lead poisoning or exhibited here in § 191.9(a)(1)(i) is lead ingestion by children who tend to chew dried paint film on interior and exterior household surfaces accessible to these children, and not type or other articles intended for use by these children. The regulation is not intended to nor should it reasonably apply to the specialized paints under consideration since, through customary or reasonably foreseeable conditions of use, they will not present a lead hazard for nice children, even when they are packaged in a form suitable for use in or around the household, and thus incidentally may meet

the definitional test of § 191.1(c), namely, that "under any reasonably foreseeable conditions of purchase, storage, or use the article may be found in or around a dwelling." Thus, petitioners believe these products should not be subject to the provisions of the regulation.

Unlike interior household paints or even exterior paints for household application which could conceivably be consumed for interior use or applied on an exterior surface accessible to children, these specialized products are never marketed for such application. They are neither intended, designed, nor suitable for use in areas accessible to children. These products are limited in purpose and, since they are not general household products, are used purchased infrequently and never stored around the household in any significant quantity. Furthermore, most of these products are intended for the professional consumer.

The precautionary label proposed in this petition adds an extra measure of protection against any conceivable risk from its lead content due to misuse. The possibility of misusing these products, even without the precautionary label is, however, very remote. The garish color and rough texture of an industrial maintenance coating, such as a red-lead primer in which lead is an important protection material, makes it exceedingly unlikely that anyone would use it on interior household surfaces or other surfaces accessible to children. Other specialty products, such as automobile refinishes, are generally too expensive to be feasible for use on such surfaces. Others, such as touchup coatings in aerosol containers, are packaged in quantities too small for practical use on household surfaces. Additional significant factors militating against misuse of these products are explained in the following discussion of the individual products along with an explanation of why lead is a necessary component in these coatings.

DESCRIPTION OF SPECIAL PURPOSE COATINGS

1. *Automotive, agricultural, and industrial equipment refinish coatings.* Automotive, agricultural, and industrial equipment refinish coatings are designed for use by automobile repair shops or agricultural or industrial equipment dealers for the refinish of automobiles, trucks, agricultural, and industrial machinery. These refinish coatings are marketed through automotive warehouse distributors to automotive parts jobbers, and then to automotive body shops. Agricultural and industrial equipment coatings are sold by equipment manufacturers and subsidiaries to equipment dealers.

Although these refinish coatings are intended for use by automotive body shops or farm and industrial equipment dealers and are not marketed primarily for retail customers, some of these companies have a secondary retail trade. Such retail customers use these coatings to refinish automobiles, agricultural equipment, and industrial machinery. This refinishing may occur in or about a garage, barn, or shed.

These coatings are usually high-gloss and are customarily applied by spray equipment. Lead is an essential ingredient in many of these coatings for three reasons. First, it is a catalytic drier necessary to speed the oxidation process and, thereby, prevent dirt or dust from becoming embedded in the film. Second, lead-containing pigments are necessary to match original equipment colors and to prevent a displeasing patchwork effect in coloring which otherwise would appear after a short time due to color chalking and fading. Finally, lead provides the essential resistance to weathering, heat, and other environmental conditions to which automobiles, agricultural and industrial equipment are peculiarly exposed.

When used for the intended purpose, there exists no health hazard to children. Indeed, the only difference between the original factory-applied finish (which is not regulated by the act unless applied to any toy or other articles intended for use by children) and the refinish product is that a can of the latter may find its way into or near the home. The hazard exists, however, not from the liquid in the container but only from the dried film and then only if the film can be ingested by children. It is not reasonably foreseeable that a child would chew on the paint because of the hard substrate to which the paint is applied.

Because of the nature of these refinishing products and their labeling, it is not reasonably foreseeable that they would be used for other than their intended purpose. There are many reasons for this:

a. Spray application, usually with high-pressure sprayers, is recommended for all of these products, and satisfactory results are not obtained with a brush or roller;

b. The high gloss colors found in most of these coatings are not suitable for surfaces in the home;

c. At the retail level, automotive refinishes are roughly twice as expensive as household enamels and paints, and thus it is exceedingly unlikely that consumers would purchase automotive refinish coatings for use on either an interior or exterior household surface since cheaper, better-suited products are more readily available. Further, such uses preclude purchasing more than is normally needed to refinish an automobile;

d. These refinishes, in contrast to general purpose household enamels and paints, often require careful preparation of the metal surface, including grinding, sanding, and priming in order to obtain proper adhesion; and

e. The proposed warning label would provide additional protection by indicating to the purchaser that such coatings should not be applied on any surface accessible to children.

2. *Industrial (and commercial building) maintenance coatings, including traffic and safety markings coatings.* This category includes a variety of coatings sold for maintenance of plant and equipment, commercial buildings, structural steel (such as bridges), or for safety markings or pavement markings in streets or parking lots. Lead pigment, such as in the commonly used red-lead primer, is an important ingredient in these coatings principally because it resists corrosion. Lead pigments also achieve the brilliant opaque and durable colors required for safety markings on pavements and industrial areas. There are no substitutes for the lead colors that will adequately perform the same purposes. Organic compounds are weaker in tinting strength, are less durable to weathering, and have a tendency to bleed when overpainted.

These products are intended for use which pose no health hazard of children. Industrial plants, commercial office buildings, metal equipment, structural steel, bridges, and the like are not accessible to children. Additionally, the Congress, after hearings, has recognized that such uses are not hazardous in enacting the Lead-Based Paint Poisoning Prevention Act of 1971 (Public Law 91-695). Congress eliminated the language "any building or structure," and substituted "interior surfaces, porches, and exterior surfaces to which children may be commonly exposed" in order to exclude industrial and commercial building maintenance use (H. Rep. No. 91-1432, 91st Cong., second session 4-6 (1970)).

Again it is not reasonably foreseeable that industrial maintenance coatings would be misused and applied to a household surface accessible to children. Large volume users purchase these products directly from manufacturers, and these products are generally unavailable for use around the household. Some retail outlets may stock and sell certain lines of these coatings in limited volume to smaller industrial accounts. Such industrial maintenance coatings normally are labeled "Intended for professional use only and not for retail sale." In addition, they will bear the lead warning label required by the proposed amendment. Thus, the possibility of household use is virtually eliminated.

3. *Graphic art coatings (products marketed solely for application on billboards, road signs, and similar uses, and for identification marking of industrial buildings).* These paints or coatings, applied freehand or by hand using a stencil or similar technique, are used to present a graphic image or convey a message. On the basis of intended use and because of a general lack of access by household consumers and children to either the coating or coated surface, graphic arts coatings should be excluded from the regulation.

While these coatings may be stocked by some dealers, they are intended principally for use by professional sign painters for the application of colors to billboards, billboard structures, road signs, and similar items and for identification markings of industrial buildings and the equipment installed therein. Most of these coatings are used only under

specific shop conditions for application to plastic and metal surfaces, such as illuminated signs advertising particular businesses (e.g., service stations), or for road-directional markers.

The need for such contrasting colors is mandatory for these types of identification. Existing technology provides no substitute materials for lead which will provide the brilliance, color permanence, and film durability necessary for extended periods of service, particularly under the temperature, sunlight, and humidity conditions of outdoor exposure. Furthermore, for many of these uses, such as application to road signs, these coatings are baked on. No acceptable substitute enamels, which can withstand such baking, are presently available.

4. *Touchup coatings for automobiles, agricultural and industrial equipment, lawn and garden equipment, boats, outboard motors, motorized recreational vehicles, and appliances.* These coatings are packaged in small containers or in aerosol containers for use by the consumer in making minor surface repairs to his automobile, household appliance, or other mechanical equipment which may be found in the vicinity of his home. While intended primarily for use in and around the household, they are neither intended nor suitable for application to large surface areas accessible to children. The hard metal surface of the vehicles, appliances, or other equipment on which these coatings are applied do not lend themselves to chewing by children. The very thin, hard coating film on such surfaces cannot be removed and ingested by chewing.

These coatings are packaged and marketed in small quantities, discouraging their use on anything except an extremely small area. As with automotive refinish coatings, they generally are not suited for use other than as intended. Furthermore, to insure against any misuse of this product, each container will carry the required labeling, warning of the lead content and restricting the use of this product.

5. *Exterior marine coatings for small craft application.* The bulk of marine coatings are marketed for industrial use only, are sold in containers not suitable for use in and around the household, and, therefore, are outside the coverage of the act. Yet, marine coatings also are sold in significant volume at retail for use by consumers in coating small craft, and these coatings could be found in or around the household.

Lead is an essential ingredient for these coatings, primarily for the same reasons it is needed in industrial maintenance. Lead is a necessary component for corrosion control; there are no satisfactory substitutes. As with automotive refinish coatings, lead is needed in marine coatings to provide resistance to weathering and other environmental conditions.

When used for their intended purpose, marine coatings do not pose a lead hazard to children since the coated surfaces are not accessible to them. Furthermore, it is not reasonably foreseeable that such coatings would be misused for other purposes in or around a household because other, better suited, less costly coatings are more readily available. Finally, the proposed warning label would clearly indicate to the consumer that the coating should not be applied on any areas accessible to children.

6. *Exterior rubber-based roof coatings.* These coatings are unique in that they are rubber-based as opposed to the types of materials used in other coatings. Lead oxides are the only known materials available for curing the liquid coatings when applied to surfaces such as roofs where waterproofing is essential. Oxides of no other metals exert any influence on the cure of these rubberized coatings. In addition, lead oxides are required for improved water resistance. These surfaces are obviously not accessible to children and, thus, the intended or reasonably foreseeable use will not create a health hazard for children.

7. *Exterior wood primer coatings for wood siding containing extractives (products marketed solely for use on redwood or cedar).* Lumber used for fabrication of siding materials may at times be cedar or redwood, each of which contains water-soluble materials which can be leached by moisture and deposited at or near the paint surface. These staining chemicals can have increased solubility in the high pH of emulsion paints and can accentuate the development of unsightly stains on the paint film. A lead compound primer is used when the bare substrate is cedar or redwood, in order to insolubilize the stains before they reach the topcoat. Continued manufacture and sale of exterior staining wood primers of this type, which contains lead, is necessary for this limited purpose.

We do not believe that the use of this product poses a reasonably foreseeable lead hazard to children for each of the following reasons:

a. A lead-containing primer need only be used once, and thus, there is no buildup of layers of lead-containing paint, which is recognized as a primary cause of lead poisoning;

b. Exterior house siding is not readily accessible to children in the sense that porch railings and ornamental surfaces are accessible;

c. Staining, as distinguished from nonstaining, woods are not widely used for siding; and

d. Some of the primer penetrates the wood substrate and thus, should the coating peel, little, if any, of the primer peels with it.

Summary

While a number of these special purpose coatings may be found in or near the household in packaged form, no lead hazard to children arises either before or after they are applied to the surfaces for which they are intended. Only "household" paints that are intended to be applied to surfaces accessible to children can pose the lead hazard sought to be prevented by the regulation in question.

We are not aware of any data, including reports in medical literature or human experience, which indicate that children have ingested dried paint films from the types of surfaces on which the products described herein are applied, nor is it reasonably foreseeable that such ingestion would occur. Additionally, considering the insensibility of the surfaces to which these paint films are applied and or the hardness of the film or substrate to which they are applied, ingestion of these products after application is not reasonably foreseeable. Finally, and as previously pointed out, the likelihood of misuse of these products is exceedingly remote.

Accordingly, this petition is submitted in the interest of establishing, for both the consumer and the industry, clarity and certainty with respect to the scope of the subject regulation. This would also avoid the possibility of unwarranted regulatory action resulting from a lack of such clarity and certainty and provide a sound enforcement basis for labeling these classes of products.

Procedure

Since this petition is filed prior to the implementation date (December 31, 1972) of the lead order, it is requested that the publication of this petition have the effect of suspending the effective date of the order, pending review of comments and promulgation of a final order in this matter, only as it applies to those paints and similar surface coating materials which petitioners submit should not be subject to the order. Without such a suspension, the manufacture and distribution of the products would be totally disrupted. Manufacturers have not known and still do not know whether to continue or discontinue the marketing of these specialized coatings since there is a substantial unresolved question of their status under the lead order. Additionally, until this question is finally resolved by a final order, customers of these manufacturers, such as distributors or users having a secondary retail trade, cannot with confidence continue to purchase such products. This is because it may be necessary for them to introduce the products into interstate commerce subsequent to the December 31, 1972, implementation date. This petition is not intended to affect the implementation date of the lead standards as they apply to other paints and surface-coating materials.

An additional factor for consideration relates to the labeling required by the proposed amendment. Until the Commissioner determines by regulation the acceptable or desirable [sic] statements for the special-purpose coatings under consideration, manufacturers cannot with confidence label or relabel new production. It will be necessary, therefore, to consider lead time for an implementation date for such labeling as may be required.

Since this petition was received prior to the implementation date (December [illegible], 1972) of § 191.9[illegible], the publication of this proposed amendment shall have the effect of suspending said implementation date, only as it applies

to those paints and similar surface-coating materials as described in this proposal, pending review of comments and promulgation of an order in this matter. This proposal will in no way affect the implementation date of § 191.-[illegible](b) as it applies to other paint or similar surface-coating materials.

This proposal is being issued pursuant to provisions of the Federal Hazardous Substances Act (sec. 2(q)(1)(B), 74 Stat. 372, as amended by 80 Stat. 1304; 15 U.S.C. 1261(q)(1)(B), (2)) and the Federal Food, Drug, and Cosmetic Act (sec. [illegible] 52 Stat. 1055, as amended; (21 U.S.C. 371(e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 2.120). Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 28, 1972.

SAM D FINE,
Associate Commissioner for Compliance.

[FR Doc 72-20783 Filed 12-4-72; 8:45 am]

Social and Rehabilitation Service

[45 CFR Parts 201, 206]

PUBLIC ASSISTANCE PROGRAMS

Payments for Ineligible Cases and Overpayments for Eligible Cases; Exclusion of Expenditures

Notice is hereby given that the regulations set forth in tentative form below are proposed by the Administrator, Social and Rehabilitation Service, with the approval of the Secretary of Health Education, and Welfare. The proposed regulations relate to the programs of financial and medical assistance, authorized under title I, IV-A, X, XIV, XVI, and XIX of the Social Security Act.

The proposed regulations would exclude from Federal financial participation, all expenditures for payments for ineligible cases and overpayments for eligible cases.

Prior to the adoption of the proposed regulations, consideration will be given to any comments, suggestions, or objections thereto which are submitted in writing to the Administrator, Social and Rehabilitation Service, Department of Health, Education, and Welfare, 330 Independence Avenue SW., Washington, DC 20201, within a period of 30 days from the date of publication of this notice in the FEDERAL REGISTER. It is the policy of the Department that 30 days' notice will be given for proposed rule making in the formulation of rules and regulations governing the Department's grant programs. Compliance with such procedures, however, would involve delay in implementing urgently needed measures found to be necessary for the proper and efficient administration of the assistance programs, which are to become effective January 1, 1973. Such delay would be contrary to the public interest. Accordingly, we find that there is good cause to reduce the usual period of notice. Comments received will be available for public inspection in room 3121 of the Department's offices at: 301 C Street SW., Washington, D.C. on Monday through Friday of each week from 8:30 a.m. to 5 p.m. (area code 202—962-7381).

The proposed regulations are to be issued under section 1102, 49 Stat. [illegible] 42 U.S.C. 1302.

Dated: November 29, 1972.

JOHN D. TWINAME,
Administrator Social and Rehabilitation Service.

Approved: November 29, 1972.

ELLIOT L. RICHARDSON,
Secretary.

1. Section 201.5 of Part 201, of Chapter II, Title 45 of the Code of Federal Regulations is revised to read as set forth below:

§ 201.5 Grants.

To States with approved plans, grants are made, prior to the commencement of each quarter, for estimated expenditures under the plan for assistance, services, training, and administration. The amount of the quarterly grant award is based upon estimates submitted by the State, containing information required by the Administrator, and such other information available to the Department as may be necessary to estimate expenditures properly subject to Federal financial participation:

(a) *Form and manner of submittal.* (1) Time and place: The estimates for public assistance grants for each quarterly period must be forwarded to the Department of Health, Education and Welfare, Social and Rehabilitation Service, Washington, D.C. 20201, Attention: Office of Financial Management with copy to the regional office 45 days prior to the period of the estimate. They include a certification of State funds available and a justification statement in support of the estimates. A statement of quarterly expenditures and any necessary supporting schedules must be forwarded to the same addressee not later than 30 days after the end of the quarter. An annual supplement to the statement of expenditures, for accounting for social service expenditures in accordance with the limitations of section 1130 of the Social Security Act, must also be forwarded to the same addressee not later than 90 days after the end of the Federal fiscal year.

(2) Description of forms: "State Agency Expenditure Projection—Quarterly Projection by Program" represents the State agency's estimate of the total amount and the Federal share of expenditures for assistance, services, training and administration to be made during the quarter for each of the public assistance programs under the Act. From these estimates the State and Federal shares of the total expenditures are computed. The State's computed share of total estimated expenditures is the amount of State and local funds necessary for the quarter. The Federal share is the basis for the funds to be advanced for the quarter. The State agency must also certify, on this form or otherwise, the amount of State funds receivable of any kind or nature or derived from the Federal Government actually on hand and available for expenditure. This certification must be signed by the executive officer of the State agency, whether he be salaried or a person officially designated for this, or by a fiscal officer of the agency if required by State law or regulation. (A form "Certificate of Availability of State Funds for Assistance and Administration during Quarter" is available for submitting this information, but its use is optional.) If the amount of State funds for State and local funds is insufficient to participate in the program, when so available for expenditures is not sufficient to cover the State's proportionate share of the amount estimated to be expended, the certification must contain a statement showing the source from which the amount of the deficiency is expected to be derived and the time when this amount is expected to be made available.

(3) The State agency must also submit a quarterly statement of expenditures for each of the public assistance programs under the Act. This is an accounting statement of the disposition of the Federal funds granted for past periods and provides the basis for making the adjustments necessary when the estimate for any State for any prior quarter was greater or less than the amount the State actually expended in the quarter. The statement of expenditures also shows the share of the Federal Government in any recoupment, from whatever source, of expenditures claimed in any prior period, and also in expenditures not properly subject to Federal financial participation which are administratively by the State agency or have been revealed in the course of an audit.

(4) Effective for quarters beginning with the quarter commencing January 1, 1973, all expenditures for payments of financial and medical assistance for ineligible individuals or families and overpayments for eligible cases shall be excluded from State estimates and expenditure reports.

(b) *Review.* The State's estimate are examined by the regional office staff and are forwarded with recommendations as required to the central office. In comparing the grant, the central office reviews the State's estimate other relevant information, and any adjustments to be made for prior periods. Relevant information as to payments for ineligible individuals or families and overpayments includes the most recent data available from reports (as required under § 205.40 of this chapter) on quality control reviews of State samples or the national

federal register

TUESDAY, DECEMBER 5, 1972

WASHINGTON, D.C.

Volume 37 ■ Number 234

Pages 25809–25906

PART I

(Part II begins on page 25897)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 191]

BANNED HAZARDOUS SUBSTANCES

Proposed Exemption of Certain Lead-Containing Paints and Other Similar Surface-Coating Materials

The Commissioner of Food and Drugs has received a petition from the National Paint and Coating Association, 1500 Rhode Island Avenue NW., Washington, DC 20005, submitted pursuant to section 701(e)(2)(B) of the Federal Food, Drug, and Cosmetic Act, proposing an amendment to a regulation (21 CFR 191.8(a)(6)(i)) promulgated under section 2(q)(1)(B) of the Federal Hazardous Substances Act. The proposed amendment would exempt certain lead-containing coatings from classification as banned hazardous substances.

The petition states that the submission is on behalf of its members which manufacture and market certain specialty paints in which lead is a necessary component.

Section 191.8(a)(6) was promulgated in the FEDERAL REGISTER of March 11, 1972 (37 F.R. 5229), and its effective date was confirmed in part in the FEDERAL REGISTER of August 10, 1972 (37 F.R. 16078).

The proposed amendment prepared by the petitioner reads as follows: ..

§ 191.8 Banned hazardous substances.

(a) • • •

(6) (i) • • •

(c) The provisions of this subdivision (i) do not apply to:

(1) Automotive, agricultural, and industrial equipment refinish coatings;

(2) Industrial (and commercial building) maintenance coatings, including traffic and safety marking coatings;

(3) Graphic art coatings (products marketed solely for application on billboards, road signs, and similar uses and for identification marking in industrial buildings);

(4) Touchup coatings for automotive, agricultural and industrial equipment, lawn and garden equipment, boats, outboard motors, motorized recreational vehicles, and appliances;

(5) Exterior marine coatings for small craft application;

(6) Exterior rubber-based roof coatings; and

(7) Exterior primer coatings for wood siding containing extractives (products marketed solely for application on redwood and cedar):

Provided, That these products bear on the main panel of their label, in addition to any labeling that may be required under the act or regulations promulgated pursuant thereto, the signal word "WARNING" and the following statement: "CONTAINS LEAD. DRIED FILM OF THIS PAINT MAY BE HARMFUL IF EATEN OR CHEWED. See other cautions on (side or back) panel." These products shall also bear on their label the following additional statement or its practical equivalent:

Do not apply on toys and other children's articles, furniture, or interior surfaces of any dwelling or facility which may be occupied or used by children.

Do not apply on those exterior surfaces of dwelling units such as window sills, porches, stairs, or railings to which children may be commonly exposed.

Keep out of reach of children.

The placement, conspicuousness, and contrast of the above labeling shall be in accordance with the requirements of § 191.101.

• • • • •

The following is the statement of grounds given in the petition in support of the proposed amendment:

On March 11, 1972, the Food and Drug Administration published an order in the FEDERAL REGISTER (37 F.R. 5229) under section 2(q)(1)(B) of the Federal Hazardous Substances Act which, in part, declared any paints or other similar surface-coating materials intended, or packaged in a form suitable for use in or around the household, to be banned hazardous substances if: (1) Shipped in interstate commerce between December 31, 1972, and December 31, 1973, and (2) containing lead compounds of which the lead content is in excess of 0.5 percent of the total weight of the contained solids or dried paint film. On August 10, 1972, this portion of the order was confirmed as effective; that portion of the order pertaining to a 0.06 percent lead level remained under consideration by the Agency.

The Federal Hazardous Substances Act applies to paint products which are found to be toxic, which are intended or packaged in a form suitable for use in or around a household and which may cause substantial personal injury or illness as a result of "reasonably foreseeable ingestion by children" (15 U.S.C. 1261(f)(1)(A).) Most paints in liquid form are not considered toxic under this act because the viscosity of the paint product renders the ingestion hazard extremely remote. Only after the paint product has been applied to a surface accessible to children, and then usually only after the film has flaked or chipped, does a hazard arise that children may ingest the lead content.

Thus, this petition is not necessary because of the requirements of the act since the specialty paints, which are the subject of this petition, are neither intended nor likely to be used on surfaces which are reasonably available to children or on surfaces which will enable flaking and chipping of the paint. This petition is required only because the language of § 191.8(a)(8)(i) appears to be broader in scope than the language in the statute and broader in scope than is necessary to protect against the lead hazard from the dried paint film. The pertinent portion of the regulation reads as follows: "Any paint or other similar surface-coating material intended, or packaged in a form suitable, for use in or around the household". If this operative language had been limited to surface-coating materials which after application would pose a lead hazard because of reasonably foreseeable ingestion by children, it is clear that the regulation would not apply to these specialty products. This petition for an amendment is submitted, therefore, only to clarify the scope of § 191.8(a)(8)(i) of the regulations.

The Definitions and Procedural and Interpretative Regulations, under FHSA (21 CFR Part 191.1), specify that the act covers those products that under customary or reasonably foreseeable conditions of storage or use may be brought into or around a house, apartment, or other place people dwell, including a garage, carport, barn, or storage shed. The same regulations expressly state that the act does not cover industrial supplies that might be taken into a home by a serviceman. The interpretations specifically provide that a product labeled as and marketed solely for industrial use does not become subject to the act simply because an industrial worker could possibly misappropriate a supply for his own use.

Thus, this interpretative regulation leaves no doubt that industrial coatings, such as original finish coatings for automobiles, industrial equipment, and farm and garden equipment are outside the scope of the act and therefore remain unaffected by the proposed tolerances. The specialized coating products which are the subject of this petition are similar to the industrial or factory-applied coatings in many respects. They are intended primarily for application to nonhousehold surfaces, usually by professional painters, and they are not intended or suitable for use on surfaces accessible to children which would create a hazard. The March 11 regulation appears to cover these specialized paints solely because they may at times be found in or around the household in packaged form and not because of any finding that they pose a lead hazard to children.

Congress, in enacting the Federal Hazardous Substances Act, contemplated the dangers offered by a product or article in its liquid state and in its packaged form and thus designed the act to regulate all products "intended or packaged in a form suitable for use in or around the household." Implicit in the quoted language is the assumption that the particular hazard from a product is present simply because that product is present in the household in packaged form. While this is true of a substance which presents a hazard in its liquid state as, for example, the flammability hazard of certain liquid paints, this is not true of the lead ingestion hazard from paints. The particular hazard posed by lead content in paint does not occur from the liquid paint in the package but, instead, the hazard occurs solely from the dried paint film if ingested by children.

The best information available indicates that children who are disposed to chew paint chips confine their activity primarily to interior surfaces in the house and, perhaps, infrequently to an accessible exterior surface. Children usually are attracted by flakes from old, chipped paint film rather than newly-coated surfaces, and by toys or other articles which they may place in their mouths. This is due in large part to the limited physical abilities of the young children suffering from "pica," the habit of ingesting nonfood items.

As pointed out in comments to the subject regulation, submitted by Dr. Barry Zing and Dr. Julian Chisholm (noted authorities on lead poisoning), the most critical age for exposure of a child through ingestion of paint, putty, and other lead-containing nonfood materials is usually 1 to 3 years of age. In view of both the restricted mobility and physical limitations of children in this age bracket, they neither have access to, nor are capable of chewing or ingesting, paint chips from surfaces to which the products for which exemptions are herein requested are applied. In fact, we are not aware of any documented case where a child has attempted to ingest the paint film on automobiles, farm and garden implements, etc.

The American Academy of Pediatrics, in its November 30, 1971 memorandum to the Food and Drug Administration, appears to confirm this: "The American Academy of Pediatrics endorses the principle contained in the petition filed with the Commissioner that paints containing more than minute traces of lead be declared as banned hazardous substances, if intended for use on children's products or interior surfaces (emphasis supplied)." Further, the Senate Committee Report on the Lead-Based Paint Poisoning Prevention Act Amendments of 1972 refers specifically to coatings "intended for interior residential surfaces" (S. Rep. No. 92-883, 92d Cong., 2d Sess. (1972)).

Similarly, under the Lead-Based Paint Poisoning Prevention Act (Public Law 91-695) the Secretary of Housing and Urban Development, in consultation with the Secretary of Health, Education, and Welfare, was instructed to develop and carry out a demonstration and research program "to determine the nature and extent of the problem of lead-based paint poisoning in the United States, particularly in urban areas, and the methods by which lead-based paint can most effectively be removed from interior surfaces, porches, and exterior surfaces to which children may be commonly exposed, of residential housing."

Acting under this authority, the Secretary of HUD has determined that the existing conditions that pose a lead paint hazard to children are those surfaces reasonably available to children that present peeling or flaking paint. This has been recently confirmed by the agency by a publication in the October 31, 1972, issue of the FEDERAL REGISTER (at page 23732) entitled "Prohibition of Use of Lead-Based Paint and Elimination of Lead-Based Paint Hazard." This revises pertinent parts of the Code of Federal Regulations already promulgated under authority of the Lead-Based Paint Poisoning Prevention Act. In this revision, with respect to the use of and elimination of existing hazards caused by lead-based paint, the Secretary of HUD defines "applicable surfaces" as all interior surfaces and those exterior surfaces, such as stairs, decks, porches, railings, windows, and doors, which are readily accessible to children under 7 years of age." Further, "Health Hazard," with respect to lead-based paint, is defined to mean "cracking (and), scaling, peeling, and loose lead-based paint on applicable surfaces."

Since the prohibition against use of lead-based paint under this revision extends only to use on "applicable surfaces of any residential structure," clearly then these are the only surfaces found by this agency to pose a lead hazard to children. There is no indication by HUD that the surfaces to which the products under consideration are applied present either an existing or future lead poisoning hazard to children.

It is clear from the foregoing that the hazard sought to be prevented by lead tolerances established in § 191.8(a)(8) is lead ingestion by children who tend to chew dried paint film on interior and exterior household surfaces accessible to these children, and on toys or other articles intended for use by these children. The regulation is not intended to nor should it reasonably apply to the specialized paints under consideration since, through customary or reasonably foreseeable conditions of use, they will not cause a lead hazard for plan children, even though they are packaged in a form suitable for use in or around the household, and thus, incidentally may meet

the additional test of § 1500.(a), namely, that "under any reasonably foreseeable condition of purchase, storage, or use the article may be found in or around a dwelling." Thus, petitioners believe these products should not be subject to the provisions of the regulation.

Unlike interior household paints or even exterior paints for household application which could conceivably be substituted for interior use or applied on an exterior surface accessible to children, these specialized products are never marketed for such application. They are neither intended, designed, nor suitable for use in areas accessible to children. These products are limited in purpose and, since they are not general household products, are thus purchased infrequently and never stored around the household in any significant quantity. Furthermore, most of these products are intended for the professional consumer.

The precautionary label proposed in this petition adds an extra measure of protection against any conceivable risk from its lead content due to misuse. The possibility of misusing these products, even without the precautionary label is, however, very remote. The garish color and rough texture of an industrial maintenance coating, such as a red-lead primer in which lead is an important protection material, makes it exceedingly unlikely that anyone would use it on interior household surfaces or other surfaces accessible to children. Other specialty products, such as automobile refinishes, are generally too expensive to be feasible for use on such surfaces. Others, such as touchup coatings in aerosol containers, are packaged in quantities too small for practical use on household surfaces. Additional significant factors militating against misuse of these products are explained in the following discussion of the individual products along with an explanation of why lead is a necessary component in these coatings.

DISCUSSION OF SPECIAL PURPOSE COATINGS

1. *Automotive, agricultural, and industrial equipment refinish coatings.* Automotive, agricultural, and industrial equipment refinish coatings are designed for use by automobile repair shops or agricultural or industrial equipment dealers for the refinish of automobiles, trucks, agricultural, and industrial machinery. These refinish coatings are marketed through automotive warehouse distributors to automotive parts jobbers, and then to automotive body shops. Agricultural and industrial equipment coatings are sold by equipment manufacturers and subsidiaries to equipment dealers.

Although these refinish coatings are intended for use by automotive body shops or farm and industrial equipment dealers and are not marketed primarily for retail customers, some of these companies have a relatively small trade. Such retail customers use these coatings to refinish automobiles, agricultural equipment, and industrial machinery. This refinishing may occur in, or about a garage, barn, or shed.

These coatings are usually high-gloss and are customarily applied by spray equipment. Lead is an essential ingredient in many of these coatings for three reasons. First, it is a catalytic drier, necessary to speed the oxidation process and, thereby, prevent dirt or dust from becoming embedded in the film. Second, lead-containing pigments are necessary to match original equipment colors and to prevent a displeasing patchwork effect in coloring which otherwise would appear after a short time due to color chalking and fading. Finally, lead provides the essential resistance to weathering, heat, and other environmental conditions to which automobiles, agricultural, and industrial equipment are peculiarly exposed.

When used for the intended purpose, there exists no health hazard to children. Indeed, the only difference between the original factory-applied finish (which is not regulated by the act unless applied to any toy or other article intended for use by children) and the refinish product is that a can of the latter may find its way into or near the home. The hazard exists, however, not from the liquid in the container but only from the dried film and then only if the film can be ingested by children. It is not reasonably foreseeable that a child would chew on the paint because of the hard substrate to which the paint is applied.

Because of the nature of these refinishing products and their labeling, it is not reasonably foreseeable that they would be used for other than their intended purpose. There are many reasons for this:

a. Spray application, usually with high-pressure sprayers, is recommended for all of these products, and satisfactory results are not obtained with a brush or roller;

b. The high gloss colors found in most of these coatings are not suitable for surfaces in the home;

c. At the retail level, automotive refinishes are roughly twice as expensive as household enamels and paints, and thus it is exceedingly unlikely that consumers would purchase automotive refinish coatings for use on either an interior or exterior household surface since cheaper, better-suited products are more readily available. Further, such costs preclude purchasing more than is actually needed to refinish an automobile;

d. These refinishes, in contrast to general purpose household enamels and paints, often require careful preparation of the metal surface, including grinding, etching, and priming in order to obtain proper adhesion; and

e. The proposed warning label would provide additional protection by indicating to the purchaser that such coatings should not be applied on any surface accessible to children.

2. *Industrial (and commercial building) maintenance coatings, including traffic and safety markings coatings.* This category includes a variety of coatings sold for maintenance of plant and equipment, commercial buildings, structural steel (such as bridges), or for safety markings or pavement markings in streets or parking lots. Lead pigments, such as in the commonly used red-lead primer, is an important ingredient in these coatings, principally because it resists corrosion. Lead pigments also achieve the brilliant opaque and durable colors required for safety markings on pavements and industrial areas. There are no substitutes for the lead colors that will adequately perform the same purposes. Organic compounds are weaker in hiding strength, are less durable to weathering, and have a tendency to bleed when overpainted.

These products are intended for uses which pose no health hazard to children. Industrial plants, commercial office buildings, metal equipment, structural steel, bridges, and the like are not accessible to children. Additionally, the Congress after hearings, has recognized that such uses are not hazardous in enacting the Lead-Based Paint Poisoning Prevention Act of 1971 (Public Law 91-695), Congress eliminated the language "any building or structure," and substituted "interior surfaces, porches, and exterior surfaces to which children may be commonly exposed" in order to exclude industrial and commercial building maintenance use (H. Rep. No. 91-1432, 91st Cong., second session 4-5(1970)).

Again it is not reasonably foreseeable that industrial maintenance coatings would be misused and applied to a household surface accessible to children. Large volume users purchase these products directly from manufacturers, and these products are generally unavailable for use around the household. Some retail outlets may stock and sell certain lines of these coatings in limited volume to small industrial accounts. Such industrial maintenance coatings normally are labeled "Intended for professional use only and not for retail sale." In addition, they will bear the lead warning label required by the proposed amendment. Thus, the possibility of household use is virtually eliminated.

3. *Graphic art coatings* (products marketed solely for application on billboards, road signs, and similar uses, and for identification marking of industrial buildings). These paints or coatings, applied freehand or by hand using a stencil or similar technique, are used to present a graphic image or convey a message. On the basis of intended use and because of a general lack of access by household consumers and children to either the coating or coated surface, graphic arts coatings should be excluded from the regulation.

While these coatings may be stocked by some dealers, they are intended principally for use by professional sign painters for the application of colors to billboards, billboard structures, road signs, and similar items and for identification markings of industrial buildings and the equipment installed therein. Most of these coatings are used only under

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specific shop conditions for application to plants and metal surfaces, such as illuminated signs advertising particular businesses (e.g., service stations), or for road-directional markers.

The need for such contrasting colors is mandatory for these types of identification. Existing technology provides no substitute materials for lead which will provide the brilliance, color permanence, and film durability necessary for extended periods of service, particularly under the temperature, sunlight, and humidity conditions of outdoor exposure. Furthermore, for many of these uses, such as application to road signs, these coatings are baked on. No acceptable nonlead alternate, which can withstand such baking, are presently available.

4. *Traffic coatings for automobiles, agricultural and industrial equipment, lawn and garden equipment, boats, outboard motors, motorized recreational vehicles, and appliances.* These coatings are packaged in small containers or in aerosol containers for use by the consumer in making minor surface repairs to his automobile, household appliance, or other mechanical equipment which may be found in the vicinity of his home. While intended primarily for use in and around the household, they are neither intended nor suitable for application to large surface areas accessible to children. The hard metal surface of the vehicles, appliances, or other equipment on which these coatings are applied do not lend themselves to chewing by children. The very thin, hard coating film on such surfaces cannot be removed and ingested by chewing.

These coatings are packaged and marketed in small quantities, discouraging their use on anything except an extremely small area. As with automotive refinish coatings, they generally are not suited for use other than as intended. Furthermore, to insure against any misuse of this product, each container will carry the required labeling, warning of the lead content and restricting the use of the product.

5. *Exterior marine coatings for small craft application.* The bulk of marine coatings are marketed for industrial use only, are sold in containers not suitable for use in and around the household, and, therefore, are outside the coverage of the act. Yet, marine coatings also are sold in significant volume at retail for use by consumers in coating small craft, and these coatings could be found in or around the household.

Lead is an essential ingredient for these coatings, primarily for the same reasons it is needed in industrial maintenance. Lead is a necessary component for corrosion control; there are no satisfactory substitutes. As with automotive refinish coatings, lead is needed in marine coatings to provide resistance to weathering and other environmental conditions.

When used for their intended purpose, marine coatings do not pose a lead hazard to children since the coated surfaces are not accessible to them. Furthermore, it is not reasonably foreseeable that such coatings would be misused for other purposes in or around a household because other, better suited, less costly coatings are more readily available. Finally, the proposed warning label would clearly indicate to the consumer that the coating should not be applied on any areas accessible to children.

6. *Exterior rubber-based roof coatings.* These coatings are unique in that they are rubber-based as opposed to the types of materials used in other coatings. Lead oxides are the only known materials available for curing the liquid coatings when applied to surfaces such as roofs where waterproofing is essential. Oxides of no other metals exert any influence on the cure of these rubberized coatings. In addition, lead oxides are required for improved water resistance. These surfaces are obviously not accessible to children and, thus, the intended or reasonably foreseeable use will not create a health hazard for children.

7. *Exterior wood primer coatings for wood siding containing extractives (products marketed solely for use on redwood or cedar).* Lumber used for fabrication of siding materials may at times be cedar or redwood, each of which contains water-soluble materials which can be leached by moisture and deposited at or near the paint surface. These staining chemicals can have increased solubility in the high pH of emulsion paints and can accentuate the development of unsightly stains on the paint film. A lead compound primer is used when the bare substrate is cedar or redwood, in order to insolubilize the stains before they reach the topcoat. Continued manufacture and sale of exterior staining wood primers of this type, which contains lead, is necessary for this limited purpose.

We do not believe that the use of this product poses a reasonably foreseeable lead hazard to children for each of the following reasons:

a. A lead-containing primer need only be used once, and thus, there is no buildup of layers of lead-containing paint, which is recognized as a primary cause of lead poisoning;

b. Exterior house siding is not readily accessible to children in the sense that porch railings and ornamental surfaces are accessible;

c. Staining, as distinguished from nonstaining, woods are not widely used for siding; and

d. Some of the primer penetrates the wood substrate and thus, should the coating peel, little, if any, of the primer peels with it.

Summary

While a number of these special purpose coatings may be found in or near the household in packaged form, no lead hazard to children arises either before or after they are applied to the surfaces for which they are intended. Only "household" paints that are intended to be applied to surfaces accessible to children can pose the lead hazard sought to be prevented by the regulation in question.

We are not aware of any data, including reports in medical literature or human experience, which indicate that children have ingested dried paint films from the types of surfaces on which the products described herein are applied, nor is it reasonably foreseeable that such ingestion would occur. Additionally, considering the inaccessibility of the surfaces to which these paint films are applied and/or the hardness of the film or substrate to which they are applied, ingestion of these products after application is not reasonably foreseeable. Finally, and as previously pointed out, the likelihood of misuse of these products is exceedingly remote.

Accordingly, this petition is submitted in the interest of establishing, for both the consumer and the industry, clarity and certainty with respect to the scope of the subject regulation. This would also avoid the possibility of unwarranted regulatory action resulting from a lack of such clarity and certainty and provide a sound enforcement basis for labeling these classes of products.

Procedure

Since this petition is filed prior to the implementation date (December 31, 1972) of the lead order, it is requested that the publication of this petition have the effect of suspending the effective date of the order, pending review of comments and promulgation of a final order in this matter, only as it applies to those paints and similar surface coating materials which petitioners submit should not be subject to the order. Without such a suspension, the manufacture and distribution of the products would be totally disrupted. Manufacturers have not known and still do not know whether to continue or discontinue the marketing of these specialized coatings since there is a substantial unresolved question of their status under the lead order. Additionally, until this question is finally resolved by a final order, customers of these manufacturers, such as distributors or users having a secondary resale trade, cannot with confidence continue to purchase such products. This is because it may be necessary for them to introduce the products into interstate commerce subsequent to the December 31, 1972, implementation date. This petition is not intended to affect the implementation date of the lead standards as they apply to other paints and surface-coating materials.

An additional factor for consideration relates to the labeling required by the proposed amendment. Until the Commissioner determines by regulation the acceptable or desirable label statements for the special-purpose coatings under consideration, manufacturers cannot with confidence label or relabel new production. It will be necessary, therefore, to consider lead time for an implementation date for such labeling as may be required.

Since this petition was received prior to the implementation date (December 31, 1972) of § 191.9(a)(2)(i)(b), the publication of this proposed amendment shall have the effect of suspending said implementation date, only as it applies

[illegible]

to those paints and similar surface-coating materials as described in this proposal pending review of comments and promulgation of an order in this matter. This proposal will in no way affect the implementation date of § 191.-[illegible] (b) (1) (b) as it applies to other paint and similar surface-coating materials.

This proposal is being issued pursuant to provisions of the Federal Hazardous Substances Act (sec. 3(e)(1)(B), (2), 74 Stat. 372, as amended by 80 Stat. 1304; 15 U.S.C. 1261 (q)(1)(B), (2)) and the Federal Food, Drug, and Cosmetic Act (sec. 701(e), 52 Stat. 1055, as amended; (21 U.S.C. 371(e)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 1.120). Interested persons may, within 60 days after publication hereof in the FEDERAL REGISTER, file with the Hearing Clerk, Department of Health, Education, and Welfare, Room 6-88, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate) regarding this proposal. Comments may be accompanied by a memorandum or brief in support thereof. Received comments may be seen in the above office during working hours, Monday through Friday.

Dated: November 20, 1972.

Sam D. Fine,
Associate Commissioner for Compliance.

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