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U.S. CONSUMER PRODUCT SAFETY COMMISSION

WASHINGTON, D. C. 20207

March 1987

OFFICE OF THE
GENERAL COUNSEL

Mary Martha McNamara, Esq.
Keller and Heckman
Suite 1000
1150 17th Street, N.W.
Washington, D.C. 20036

Re: Chronic Hazard Labeling for Art Materials

Dear Ms. McNamara:

This responds to your letter of February 9, 1987, to Charles M. Jacobson concerning chronic hazard labeling of art materials under the Federal Hazardous Substances Act ("FHSA"), 15 U.S.C. §§ 1261-1276. Your letter was forwarded to the Office of the General Counsel because most of the questions you ask fall within the jurisdiction of this office. However, my response has been reviewed by the Commission's Associate Executive Director for Compliance and Administrative Litigation, Associate Executive Director for Health Sciences, and Director of the Office of Program Management and Budget, who concur with the responses to your questions.

The questions you posed, and our responses to them, are discussed separately below.

QUESTION #1: Does the definition of a toxic substance under the FHSA include substances capable of causing cancer or other chronic health hazards in human beings if exposed?

Response. Yes. The FHSA defines "toxic" as "any substance (other than a radioactive substance) which has the capacity to produce personal injury or illness to man through ingestion, inhalation, or absorption through any body surface." 15 U.S.C. § 1261(g). A product that is, or contains, a substance that is capable of inducing cancer in humans is certainly one that "has the capacity to produce . . . illness to man" if the reasonably foreseeable use or misuse of the product will result in a significant exposure of humans to the carcinogen.

ADVISORY OPINION

There is no indication in the legislative history of the FHSA that chronic hazards are not to be included within the definition of toxic. In fact, Congress, in 1981, required that where a risk of cancer, birth defects, or gene mutation would be addressed by a regulation under section 2(q)(1) of the FHSA, 15 U.S.C. § 1261(q)(l), a Chronic Hazard Advisory Panel ("CHAP") report is a prerequisite to an advance notice of proposed rulemaking. 15 U.S.C. §§ 2077, 2080(b). This would seem to be a clear indication of congressional intent that carcinogens, and substances presenting other types of chronic hazards, are included within the FHSA's definition of toxic.

Furthermore, in the judicial review of the Commission's ban of urea-formaldehyde foam insulation, which addressed a risk of cancer as well as various acute hazards, the Fifth Circuit held that the proceeding should have been conducted under the FHSA, not the CPSA. Gulf South Insulation v. CPSC, 701 F.2d 1137 (5th Cir. 1983).

Therefore, we conclude that the term "illness" in the FHSA's definition of toxic includes cancer and other diseases resulting from chronic exposure. As you note in your letter, this determination is consistent with the Commission's recent action concerning asbestos and the proposed action concerning methylene chloride, both of which were taken under the FHSA.

QUESTION #2: If [the answer to Question #1 is yes], must art materials containing substances [other than asbestos or methylene chloride] that may present a carcinogenic risk to humans during any reasonably foreseeable handling or use be labeled in accordance with Section 2(p)(l) of the FHSA?

Answer. Yes, at least where there is evidence that the substance is an actual or potential human carcinogen in accordance with sound scientific principles, where the exposure during reasonably foreseeable handling or use is such that there is a significant risk of cancer in exposed persons, and where the product is intended for use in the household. See 15 U.S.C. § 1261(f)(1), (g), and (p). The requirements of section 2(p)(l) automatically apply to hazardous substances intended for use in the household or by children. As discussed above in the answer to question # 1, we conclude that the FHSA's provisions apply fully to substances presenting chronic hazards.

Art materials, just as other chemical substances, will have to be considered individually to assess their potential for chronic hazards, in the same manner as they are reviewed for acute hazards. After such review, the labeling for the individual product should be tailored to fit within the framework provided by section 2(p)(l).

QUESTION #3: If [section 2(p)(l) labeling is required], do the labeling practices required by [ASTM labeling practice] D-4236 comply with Section 2(p)(l) of the FHSA?

Answer. Yes. We see nothing in ASTM labeling practice D-4236 that would conflict with the requirements of section 2(P)(1), and compliance with D-4236 would fulfill the requirements of section 2(p)(I). Some provisions of D-4236 may go beyond that which could be required under section 2(p)(l), such as the listing of all sensitizing components required by section 5.5 of the practice. A product's labeling would also have to address any of the other hazards specified in the FHSA, such as flammability or corrosiveness, that are presented, and the labeling should meet the placement and conspicuousness requirements specified in 16 C.F.R. § 1500.121.

QUESTION #4: If [the answer to question 3 is yes], do the labeling requirements for chronic hazards in art materials under Section 2(p)(l) of the FHSA preempt any state requirements.

Answer. Yes, at least where the state requirement is for cautionary labeling and addresses the same risk as the section 2(p) requirement. Under FHSA section 18(b)(l)(A):

> [I]f a hazardous substance or its labeling is subject to a cautionary labeling requirement under section 2(p) . . . no State or political subdivision of a State may establish or continue in effect a cautionary labeling requirement . . . designed to protect against the same risk of illness or injury unless such [state] cautionary labeling requirement is identical to the labeling requirement under section 2(p) . . .

15 U.S.C. § 1261n.

While the opinions given above are the latest interpretation of the law by this office, they could be changed subsequently by the Commission.

We hope this information is helpful to you. We greatly appreciate the voluntary efforts of the members of the Coalition in developing the ASTM labeling practice. We trust the opinions given above are consistent with our mutual desire to have a strong and effective voluntary standard for art materials.

Sincerely,

John P. Mackey

John P. Mackey
Acting General Counsel

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February 9, 1987

Mr. Charles M. Jacobson
Division of Regulatory Management
Directorate for Compliance and
Administrative Litigation
Consumer Product Safety Commission
Washington, DC 20207

Re: **Chronic Hazard Labeling for Art Materials**

Dear Mr. Jacobson:

The Consumer Product Safety Commission (Commission) recently took two actions under the Federal Hazardous Substances Act (FHSA) against chemicals that pose a chronic hazard. Specifically, the Commission proposed a rule declaring methylene chloride in household products to be a hazardous substance "due to a risk of cancer from inhalation of methylene chloride vapor." 51 FR 29778 (August 20, 1986). Then the Commission issued a Notice of Enforcement Policy declaring household products containing intentionally added asbestos to be hazardous substances requiring proper labels under the FHSA. 51 FR 33910 (September 24, 1986). Both of these actions impact, inter alia, artists' materials and raise questions among the members of the Art Supplies Labeling Coalition (Coalition), who requested that we obtain a clarification from the Commission o:n several issues affecting them.

As you know, the Coalition is composed of associations representing manufacturers, distributors, retailers, and users of art materials. It was formed to develop a voluntary standard for the labeling of chronic hazards in art supplies under the auspices of the American Society for Testing Materials (ASTM). The voluntary standard, D-4236, has been in place for several years now and manufacturers have begun to label their art material products in conformance with D-4236. At the time the standard was developed, it was thought that the automatic labeling requirements of the FHSA did not apply to chronic hazards in household products. However, these two recent actions of the Commission appear to dispel that notion.

Therefore, we would appreciate clarifications for several related issues:

(1) Does the definition of a toxic substance under the FHSA include substances capable of causing cancer or other chronic health hazards in human beings if exposed?

(2) If so, must art materials containing substances,[1] that may present a carcinogenic or other chronic hazard health risk to humans during any reasonably, foreseeable handling or use be labeled in accordance with Section 2(p)(1) of the FHSA?

(3) If so, do the labeling practice& required by D-4236 comply with Section 2(p)(1) of the FHSA?

(4) If so, do the labeling requirements for chronic hazards in art materials under Section 2(p)(1) of the FHSA preempt any state requirements?

The Coalition is anxious to preserve the voluntary standard it worked so diligently to develop, but is ever aware of its obligations under the FHSA. In this instance, we hope that the voluntary standard will emulate the FHSA. Your guidance on the Commission's present interpretation of the FHSA labeling requirements for chronic hazards in art materials will be greatly appreciated.

With best wishes,

Sincerely,

Mary Martha McNamara

Enclosure .

cc: Deborah Fanning

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[1]/We refer to substances other than asbestos and methylene chloride.

L/Attached is Appendix A.

or repackager, upon advice given by a toxicologist in accordance with Section 4 of this practice, shall adopt precautionary labeling in accordance with Section 5 of this practice and based upon generally accepted, well-established evidence that a component substance(s) is known to cause chronic adverse health effects.

3.3 To conform to this practice, labeling shall be parallel to, conform to, and minimally include any labeling practices prescribed by U.S. federal and state statutes or regulations and shall not diminish the effect of required acute toxicity warnings.

3.4 To conform to this practice, the producer or repackager shall supply a poison exposure management information source[2] the generic formulation information required for dissemination to poison control centers or provide a 24-h cost-free telephone number to poison control centers.

3.5 To conform to this practice, the producer or repackager shall have a toxicologist review as necessary, but at least every five years, art material product formulation(s) and associated label(s) based upon the then current, generally accepted, well-established scientific knowledge.

3.6 *Statement of Conformance*—"Conforms to ASTM Practice D 4236" or "Conforms to ASTM D 4236," or "Conforms to the health requirements of ASTM D 4236." This statement may be combined with other conformance statements.

4. Determination of Labeling

4.1 An art material is considered to have the potential for producing chronic adverse health effects if any customary or reasonably foreseeable use can result in a chronic hazard.

4.2 In making the determination a toxicologist(s) shall take into account the following:

4.2.1 Current chemical composition of the art material, supplied by an analytical laboratory or by an industrial chemist on behalf of a manufacturer or repackager.

4.2.2 Current generally accepted, well-established scientific knowledge of the chronic toxic potential of each component and the total formulation.

4.2.3 Specific physical and chemical form of the art material product, bioavailability, concentration, and the amount of each potentially chronic toxic component found in the formulation.

4.2.4 Reasonably foreseeable uses of the art material product as determined by consultation with users and other individuals who are experienced in use of the material(s), such as teachers, or by market studies, unless such use information has previously been determined with respect to the specific art material(s) under review.

4.2.5 Potential for known synergism and antagonism of the various components of the formulation.

4.2.6 Potentially chronic adverse health effects of decomposition or combustion products, if known, from any reasonably foreseeable use of the hazardous art material product.

4.2.7 Opinions of various regulatory agencies and scientific bodies, including the International Agency for Research on Cancer and the National Cancer Institute, on the potential for chronic adverse health effects of the various components of the formulation.

4.3 Based upon the conclusion reached in conformance with review determinations set forth herein the toxicologist(s) shall recommend precautionary labeling consistent with Section 5 of this practice.

5. Labeling Practices

5.1 *Signal Word:*

5.1.1 When a signal word for an acute hazard(s) is mandated and a chronic hazard(s) exists, the signal word shall be that for the acute hazard.

5.1.2 When only a chronic hazard(s) exists, the signal word WARNING shall be used.

5.1.3 The signal word shall be prominently visible and set in bold capitals in a size equal to or greater than the statement of potential chronic hazards.

5.2 *List of Potentially Chronic Hazards*—Potentially chronic hazards, as determined under the procedures of Section 4, shall be stated substantially in accordance with the statements listed in Annex A1 of this practice. Potentially chronic hazards noted shall be those that are clinically significant and that might be expected with any reasonably foreseeable use of the art material. The hazards should be grouped in the order of

[2] Two of the larger poison exposure management information sources are: The Rocky Mountain Poison Control Center, West 8th and Cherokee, Denver, CO 80204; and the National Poison Center Network, 125 De Soto St., Pittsburgh, PA 15213.

relative descending severity.

5.3 *Name of Chronically Hazardous Component(s)*—All components and known decomposition products of the formulation with a potential for chronic hazards, as determined under the procedures of Section 4, shall be listed prominently. Generically equivalent names may be used.

5.4 *Safe Handling Instructions*—Appropriate precautionary statements as to work practices, personal protection, and ventilation requirements shall be used substantially conforming with those listed in Annex A2 of this practice.

5.5 *List of Sensitizing Components*—To protect artists or crafts people from known sensitizers found within art materials, each label shall contain a list of those sensitizers present in sufficient amounts to contribute significantly to a known skin or respiratory sensitization.

5.6 *Combined Statements*—If an art material contains more than one component capable of causing a chronic adverse health effect, or if a single chemical can cause several different chronic adverse health effects, the potential effects may be combined into one statement.

5.7 *Information Sources*—The precautionary label shall contain a statement identifying a source for additional health information substantially in conformance with one of the phrases listed below:

5.7.1 For more health information—(24-h cost-free telephone number),

5.7.2 Contact a physician for more health information, or

5.7.3 Call your local poison control center for more health information.

5.8 *Labeling Content, Product Size*—An art material product(s) in a container larger in size than one fluid ounce (30 mL) (if the product is sold by volume) or one ounce net weight (28 g) (if the product is sold by weight) shall have full precautionary labeling, as generally described in Section 5 of this practice. An art material product(s) in a container equal to or smaller than one fluid ounce or one ounce net weight shall have a label that includes a signal word in conformance with 5.1 of this practice and a list of potentially harmful or sensitizing components in conformance with 5.3 and 5.5 of this practice.

5.9 *Supplemental Information*—Where appropriate, more detailed technical information that relates to chronic hazard(s), such as physical properties, decomposition products, detailed safety instructions, or disposal recommendations, shall be included in supplemental documents, such as Material Safety Data Sheets, technical brochures, technical data sheets and the like.

ANNEXES

(Mandatory Information)

A1. CHRONIC HAZARD STATEMENTS

MAY CAUSE STERILITY.
MAY BE HARMFUL BY BREATHING VAPORS/DUSTS.
MAY BE HARMFUL IF SWALLOWED.
MAY BE HARMFUL BY SKIN CONTACT.
MAY PRODUCE BIRTH DEFECTS IN THE DEVELOPING FETUS.
MAY BE EXCRETED IN HUMAN MILK.
MAY CAUSE HARM TO THE NURSING INFANT.
CANCER AGENT! EXPOSURE MAY PRODUCE CANCER.
CANCER AGENT BASED ON TESTS WITH LABORATORY ANIMALS.
POSSIBLE CANCER AGENT BASED ON TESTS WITH LABORATORY ANIMALS.
MAY PRODUCE ALLERGIC REACTION BY INGESTION/INHALATION/SKIN CONTACT.
MAY PRODUCE NUMBNESS OR WEAKNESS IN THE EXTREMITIES.
EXPOSURE MAY CAUSE (SPECIFY THE ORGAN(S)) DAMAGE.
HEATING/COMBUSTION MAY CAUSE HAZARDOUS DECOMPOSITION PRODUCTS.

A2. PRECAUTIONARY STATEMENTS

Keep out of reach of children.
When using do not eat, drink, or smoke.
Wash hands immediately after use.
Avoid inhalation/ingestion/skin contact.
Avoid fumes from combustion.
Keep container tightly closed when not in use.

Store in well-ventilated area.
Wear protective clothing (specify type).
Wear NIOSH[3]-certified mask for dusts/mists/fumes.
Wear NIOSH-certified respirator with an appropriate cartridge for (specify).
Wear NIOSH-certified supplied-air respirator.
Use window exhaust fan to remove vapors and assure adequate cross ventilation. (Specify explosion-proof if necessary.)
Do not heat above (specify temperature) without adequate ventilation.
Use (specify type) local exhausting hood.
Do not use/mix with (specify material).

[3] U. S. National Institute of Occupational Safety and Health.