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Standard Practice for Labeling Art Materials for Chronic Health Hazards[1]

This standard is issued under the fixed designation D4236; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

INTRODUCTION

Uninformed or careless use of some art material products can give rise to health hazards, either acute or chronic, or both. Specific and readily available warnings are needed to help protect users of any age. One way to disseminate such information is to provide appropriate precautionary labeling on art material products.

Labeling for acute health hazards, including those associated with art materials, is being addressed by such requirements as the U.S. Consumer Product Safety Act (CPSC)[2], the Federal Hazardous Substances Act, and the like. There are presently no specific national standards for labeling art materials with respect to chronic health hazards.

This practice is intended to provide a standard for developing precautionary labels concerning chronic health hazards related to the use of art materials. It is further intended to have the adaptability necessary to keep labels current with existing scientific and medical knowledge, as well as in conformity with other precautionary labeling requirements, both acute and chronic, thereby avoiding unnecessary confusion by users with respect to other precautionary labeling.

1. Scope

1.1 This practice describes a procedure for developing precautionary labels for art materials and provides hazard and precautionary statements based upon knowledge that exists in the scientific and medical communities. This practice concerns those chronic health hazards known to be associated with a product or product component(s), when the component(s) is present in a physical form, volume, or concentration that in the opinion of a toxicologist (see 2.1.11) has the potential to produce a chronic adverse health effect(s).

1.2 This practice applies exclusively to art materials packaged in sizes intended for individual users of any age or those participating in a small group.

1.3 Labeling determinations shall consider reasonable foreseeable use or misuse. The responsibility for precautionary labeling rests with the producer or repackager who markets the materials for art or craft use.

1.4 This practice does not specify test methods for determining whether a substance or product presents chronic health hazards.

1.5 This practice does not apply to products appropriately labeled for known chronic health hazards in accordance with chemical substance labeling standards and practices, such as another national consensus standard, existing labeling statutes, regulations, or guidelines.

1.6 Since knowledge about chronic health hazards is incomplete and warnings cannot cover all uses of any product, it is not possible for precautionary labeling to ensure completely safe use of an art product.

1.7 Manufacturers or repackagers may wish to determine individually or collectively precautionary labeling for art materials in accordance with this practice. Compliance may be certified by a certifying organization. Guidelines for a certifying organization are given in Appendix X1.

1.8 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Terminology

2.1 *Definitions of Terms Specific to This Standard:*

[1] This practice is under the jurisdiction of ASTM Committee D01 on Paint and Related Coatings, Materials, and Applications and is the direct responsibility of Subcommittee D01.57 on Artist Paints and Related Materials.

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[2] ASTM Practice D4236 has been codified into U.S. law as part of the Federal Hazardous Substances Act, 15 USC S1277. Users of this standard should be familiar with the law and its regulations. Under this law and its regulations (16 CRF 1500), manufacturers must submit to the CPSC (Washington DC 20207) written criteria used by the toxicologist to recommend labeling.

2.1.1 *analytical laboratory, n*—a laboratory having personnel and apparatus capable of performing quantitative or qualitative analyses of art materials, which may yield information that is used by a toxicologist for evaluation of potentially hazardous materials.

2.1.2 *art material or art material product, n*—any raw or processed material, or manufactured product, marketed or represented by the producer or repackager as intended for and suitable for users as defined herein.

2.1.3 *bioavailability, n*—the extent that a substance can be absorbed in a biologically active form.

2.1.4 *chronic adverse health effect(s), n*—a persistent toxic effect(s) that develops over time from a single, prolonged, or repeated exposure to a substance. This effect may result from exposure(s) to a substance that can, in humans, cause sterility, birth defects, harm to a developing fetus or to a nursing infant, cancer, allergenic sensitization, damage to the nervous system, or a persistent adverse effect to any other organ system.

2.1.5 *chronic health hazard(s) (hereafter referred to as "chronic hazard"), n*—a health risk to humans, resultant from exposure to a substance that may cause a chronic adverse health effect.

2.1.6 *label, n*—a display of written, printed, or graphic matter upon the immediate container of any art material product. When the product is unpackaged, or is not packaged in an immediate container intended or suitable for delivery to users, the label can be a display of such matter directly upon the article involved or upon a tag or other suitable labeling device attached to the art material.

2.1.7 *producer, n*—the person or entity who manufactures, processes, or imports an art material.

2.1.8 *repackager, n*—the person or entity who obtains materials from producers and without making changes in such materials puts them in containers intended for sale as art materials to users.

2.1.9 *sensitizer, n*—a substance known to cause, through an allergic process, a chronic adverse health effect which becomes evident in a significant number of people on re-exposure to the same substance.

2.1.10 *toxic, n*—applies to any substance that is likely to produce personal injury or illness to humans through ingestion, inhalation, or skin contact.

2.1.11 *toxicologist, n*—an individual who through education, training, and experience has expertise in the field of toxicology, as it relates to human exposure, and is either a toxicologist or physician certified by a nationally recognized certification board.

2.1.12 *users, n*—artists or crafts people of any age who create, or recreate in a limited number, largely by hand, works which may or may not have a practical use, but in which aesthetic considerations are paramount.

3. Requirements

3.1 To conform to this voluntary practice the producer or repackager of art materials shall submit art material product formulation(s) or reformulation(s) to a toxicologist for review, such review to be in accordance with Section 4of this practice. The toxicologist shall be required to keep product formulation(s) confidential.

3.1.1 Unless otherwise agreed in writing by the producer or repackager, no one other than the toxicologist shall have access to the formulation(s); except that the toxicologist shall furnish a patient's physician, on a confidential basis, the information necessary to diagnose or treat cases of exposure or accidental ingestion.

3.2 To conform to this practice, the producer 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[3] 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 5 years, art material product formulation(s) and associated label(s) based upon the then current, generally accepted, well-established scientific knowledge. If an art material producer or repackager becomes newly aware of any significant information regarding the *chronic* hazards of an art material or ways to protect against the *chronic* hazard, this new information must be incorporated into the labels of such art materials that are manufactured after 12 months from the date of discovery. If a producer or repackager reformulates an art material, the new information must be evaluated and labeled in accordance with Section 5 of this practice.

3.6 *Statement of Conformance*—"Conforms to ASTM Practice D4236," or "Conforms to ASTM D4236," or "Conforms to the health requirements of ASTM D4236." This statement may be combined with other conformance statements. The purpose of the conformance statement is to inform the purchaser, at the time of purchase, of the product's compliance with the standard. To accomplish this purpose the conformance statement should appear whenever practical on the product; however, it shall also be acceptable to place the statement on one or more of the following: (*a*) the individual product package, (*b*) a display or sign at the point of purchase, (*c*) separate explanatory literature available on request at the point of purchase, (*d*) a response to a formal request for bid or proposal.

[3] 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.

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 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 users 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*—In addition to an appropriate telephone number, 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), or

5.7.2 For further health information call a poison control center.

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. If the toxicologist determines that an art material in a container equal to or smaller than one fluid ounce (30 mL) or one ounce net weight (28 g) has the potential for producing chronic adverse health effects with customary or reasonably foreseeable use despite its small size, the toxicologist may require the product to carry all the labeling that would be required in a larger package. When the information cannot fit on the package label, the art material shall include a package insert that conveys all the required information. If the art material has a package insert, the label on the product shall include a signal word in conformance with 5.1, a list of potentially harmful or sensitizing components in conformance with 5.3 and 5.5 of this practice, and the statement "See package insert before use." For purposes of this subsection, the term "package insert" means a display of written, printed, or graphic matter upon a leaflet or suitable material accompanying the art material.[2]

5.9 The information described in Section 5 must appear (*1*) on the outside container or wrapper, if any, unless it is easily legible through the outside container or wrapper and (*2*) on all accompanying literature where there are directions for use, written or otherwise. In a case where one or more individual

product(s), which require warning labels under Sections 4 and 5, are packed within a point of sale package which obscures the warning statement(s), the point of sale package shall carry the signal word conforming to 5.1 of this practice and the following wording: "Contains: (list hazardous product(s)) that may be harmful if misused. Read cautions on individual containers carefully. Keep out of the reach of children."

5.10 Statements required under Sections 4 and 5 must be in the English language and located prominently in conspicuous and legible type in contrast by topography, layout, or color with other printed matter on the label.

5.11 *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 etc.

6. Keywords

6.1 art materials; chronic toxicity; craft materials; health labeling; precautionary statements; warning statements

ANNEXES

(Mandatory Information)

A1. CHRONIC HAZARD STATEMENTS

MAY CAUSE STERILITY.

CONTACT MAY CAUSE PERMANENT EYE DAMAGE.

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.

CANCER HAZARD BASED ON EXPERIMENTAL DATA.

CANCER HAZARD BY INHALATION BASED ON EXPERIMENTAL DATA.

POSSIBLE CANCER AGENT BASED ON TESTS WITH LABORATORY ANIMALS.

POSSIBLE CANCER HAZARD BASED ON EXPERIMENTAL DATA

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.

EXPOSURE MAY BE ESPECIALLY HARMFUL TO PEOPLE WITH () PROBLEMS.

EXPOSURE MAY CAUSE ALLERGIC REACTIONS/RESPIRATORY ALLERGIES.

EXPOSURE MAY BE HAZARDOUS TO PREGNANT WOMEN

HEATING/COMBUSTION MAY CAUSE HAZARDOUS DECOMPOSITION PRODUCTS.

MAY CAUSE (SPECIFIC EFFECT) OF (SPECIFY ORGAN).

CANCER AGENT! EXPOSURE BY (SPECIFIC ROUTE) MAY PRODUCE CANCER.

MAY CAUSE HARM TO THE DEVELOPING FETUS.

EXPOSURE MAY RESULT IN NAUSEA, HEADACHE, CONFUSION OR INSTABILITY.

MAY CAUSE DAMAGE TO RED BLOOD CELLS WITH REDUCED ABILITY TO CARRY OXYGEN.

POSSIBLE CANCER AGENT

In addition to the preceding statements, the statements listed in ANSI Z129.1 (1988), or in subsequent revisions, may also be used.

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 protective goggles/face shield.
Wear NIOSH[4]-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 ensure adequate cross ventilation. (Specify explosion-proof if necessary.)

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

Do not heat above (specify temperature) without adequate ventilation.
Use (specify type) local exhausting hood.
Do not use/mix with (specify material).
Do not dry grind.
Do not spray apply.
If pregnant or contemplating pregnancy, use only under professional supervision.
Avoid using/do not use if pregnant (or contemplating pregnancy).
Not for use by children.
Not for use in health care facilities.
Avoid breathing dust.
Use in glove box.
Shower after use.
Do not use with products containing ().

APPENDIX

(Nonmandatory Information)

X1. GUIDELINES FOR A CERTIFYING ORGANIZATION

X1.1 The term certifying organization, as used in these guidelines, refers to an organization or an institute that, after assuring that all provisions are met, certifies that an art material does conform to the labeling requirements of this practice.

X1.2 The certifying body may be funded by member manufacturers, but should include users or their representatives, as well as manufacturers' chemists, on its technical and certifying committees.

X1.3 Representative samples of art materials, labeled as conforming to this practice and bought at retail, should be analyzed at random and from time to time by an analytical laboratory to ensure they are the same as the formulation used by the toxicologist(s) for determining labeling requirements.

X1.4 The methods used by the toxicologist(s) in review and determination of the need and content of precautionary labeling for potentially chronic adverse health effects should be periodically reviewed by an advisory board composed of not less than three or more than five toxicologists, at least one of whom is certified in toxicology by a nationally recognized certification board.

X1.5 In cases where there is disagreement by participating producers or participating users, with the determination of the toxicologist(s), there should be a method whereby the toxicologist's decision can be presented to the advisory board of toxicologists for arbitration.