Designation: D 4236 – 94

AMERICAN SOCIETY FOR TESTING AND MATERIALS
100 Barr Harbor Dr., West Conshohocken, PA 19428

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

This standard is issued under the fixed designation D 4236; 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:*

2.1.1 *analytical laboratory*—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*—any raw or processed material, or manufactured product, marketed or represented by the producer or repackager as intended for and

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

Current edition approved March 15, 1994. Published May 1994. Originally published as D 4236 – 83. Last previous edition D 4236 – 92.

[2] ASTM Practice D 4236 has been codified into U.S. law as part of the Federal Hazardous Substances Act, 15 USC S1277. User 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.

suitable for users as defined herein.

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

2.1.4 *chronic adverse health effect(s)*—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")*—a health risk to humans, resultant from exposure to a substance that may cause a chronic adverse health effect.

2.1.6 *label*—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*—the person or entity who manufactures, processes, or imports an art material.

2.1.8 *repackager*—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*—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*—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*—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*—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 4 of 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 D 4236," 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.

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.

[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.