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

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INTRODUCTION

Uninformed or careless use of some ceramic 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. One way to disseminate such information is to provide appropriate precautionary labeling on ceramic art material products.

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

This practice is intended to provide a standard for developing precautionary labels concerning chronic adverse health hazards related to the use of ceramic 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 ceramic art materials and provides hazard and precautionary statements based upon knowledge that exists in the scientific and medical communities. This practice concerns those chronic adverse 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 has the potential to produce a chronic adverse health effect(s).

1.2 This practice is intended to apply exclusively to ceramic art materials which are packaged in sizes intended for use by artists or crafts people, either individually, or in a small group or class.

1.3 This practice applies to developing precautionary labeling for ceramic art materials intended for adult usage. Conformance to this practice does not imply that ceramic art materials will necessarily be labeled adequately or safe for use by children. Labeling determinations should consider reasonably foreseeable use or misuse by children and include as appropriate, in such instances, warnings to keep out of reach, or other specific precautionary statements. The responsibility for precautionary labeling rests with the ceramic producer or repackager who markets the material for art or craft use.

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

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

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

1.7 Manufacturers or repackagers may wish to determine individually or collectively precautionary labeling for ceramic art materials in accordance with this practice. Compliance may

[1] This practice is under the jurisdiction of ASTM Committee C21 on Ceramic Whitewares and Related Productsand is the direct responsibility of Subcommittee C21.03 on Methods for Whitewares and Environmental Concerns.

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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, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.9 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Definitions of Terms Specific to This Standard

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

2.2 *artists or crafts people*—individuals who create, or recreate in a limited number, largely by hand, works that may or may not have a practical use, but in which aesthetic considerations are paramount.

2.3 *bioavailability*—the extent to which a substance can be absorbed in a biologically active form.

2.4 *ceramic art material or ceramic art material product*—any raw or processed material, or manufactured product, marketed or represented by a ceramic producer or repackager as intended for and suitable for use in a fired product produced by artists or crafts people.

2.5 *ceramic producer*—the person or entity who manufactures, processes, or imports a ceramic art material.

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

2.7 *chronic adverse 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.

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

2.9 *repackager*—the person or entity who obtains materials from ceramic producers and, without making changes in such materials, puts them in containers intended for sale as ceramic art materials to artists or crafts people.

2.10 *sensitizer*—a substance that is 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.

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

2.12 *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.

3. Requirements

3.1 To conform to this voluntary practice, the ceramic producer or repackager of ceramic art materials shall submit ceramic 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 ceramic 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 ceramic 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 ceramic 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 number to poison control centers.

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

4. Determination of Labeling

4.1 A ceramic 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.

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