



TOXICOLOGY DEPARTMENT
67317-050056-B (LHAMA)

Labeling of Hazardous Art Materials Act (LHAMA) Certification

TEST:

Evaluation of **“MasterCast 1-2-1 Clear Artwork Resin . Part B-Hardener”** for requirements of applicable sections of U.S. Federal Hazardous Substance Act (FHSA) Regulations (16 CFR 1500), ASTM Designation D 4236-94 Standard Practice for Labeling Art Materials for Chronic Health Hazards, and the Consumer Product Safety Commission Labeling Requirements for Art Materials presenting Chronic Hazards (16 CFR 1500), 67317-050056 B.

Background:

Quantitative list of the ingredients in **“MasterCast 1-2-1 Clear Artwork Resin . Part B-Hardener”** was submitted to the reviewer. 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 is determined from examination of the formulation, labeling, packaging and instructions for use supplied by the manufacturer and from examination of the art material product.

The review of the formulation of the submitted **“MasterCast 1-2-1 Clear Artwork Resin . Part B-Hardener”** sample was conducted by a board certified toxicologist, Jongsei Park, Ph.D. (Fellow, Academy of Toxicological Sciences, Diplomate, American Board of Forensic Toxicology, CLD, American Board of Bio-Analysis) according to the criteria defined in the American Society for Testing Materials (ASTM) Standard D-4236 and the U.S. Consumer Product Safety Commission (CPSC) Regulation 16 CFR 1500.14.

This review considered all the available data including the relevant data from the U.S. National Toxicology Program and the World Health Organization's International Agency for Research on Cancer and other sources of information in the U.S. National Library of Medicine's toxicology databases. All this information was used to assess the need for chronic health hazard warning including carcinogenesis, reproductive/teratogenetic hazards, neurotoxicity and other potential chronic adverse health effects. Relevant information on bioavailability and exposure were also



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considered. In the absence of specific information, reasonable judgments were made to realistically assess the potential hazards of this material.

Exposure Assessment:

In evaluating acute and chronic toxic effects of each component and of the total formulation of **"MasterCast 1-2-1 Clear Artwork Resin . Part B-Hardener"** according to the information supplied, physical and chemical form, customary or reasonably foreseeable handling and use, including possible accident or misuse, and any adverse health effects of decomposition or combustion products were taken into account. Assessment of exposure was done using the applicable sections of U.S. Federal Hazardous Substance Act (FHSA) regulations, guideline on 16 CFR 1500.135. The following exposure route(s) were considered: Inhalation, Oral ingestion and Dermal exposure.

Toxicity Assessment:

Generally accepted, well established scientific, epidemiologic and toxicological knowledge of the bioavailability, pharmacokinetics, toxic effects (acute and chronic) of each component and of the total formulation obtained as necessary through on-line access to the National Library of Medicine Toxicology Data networks, including the Hazardous Substances Data Bank, the National Institute for Occupational Safety and Health Registry of Toxic Effects of Chemical Substances, the National Cancer Institute sponsored Chemical Carcinogenesis Research Information System, the U.S. Environmental Agency sponsored Integrated Risk Information System and Genetic Toxicity file, the Oak Ridge National Laboratory Environmental Mutagen Information Database and the U.S. EPA and NIEHS sponsored Developmental and Reproductive Toxicology/Environmental Teratology Information file were taken into account.

Opinions of various regulatory agencies and scientific bodies on the potential for chronic adverse health effects of the various components of the formulation obtained from the publications of these agencies and the data sources listed above were used for evaluation. To assess product's toxicity, well established safety factors of 10 – 100X for acute effects, 100 – 1000X for chronic health effects, 10^{-6} risk at the 95 % upper bound of a multistage model for reproductive toxicants, or limits were used in determining whether or not a product would require acute or chronic health hazard labeling.



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Summary and Conclusion.

After reviews of the supplied information and risk assessment based on hazards, exposure potential, acceptable daily intake and appropriate safety factors, it was found **"MasterCast 1-2-1 Clear Artwork Resin . Part B-Hardener"** is not considered a Hazardous Substance as defined in 16 CFR 1500.3(b)(4)(A), not highly toxic, corrosive, excessively corrosive or an excessively strong sensitizer as determined in accordance with the tests prescribed, will not pose chronic adverse health effects in humans, will not constitute and may not constitute a danger to human life or health when used as intended. This product, **"MasterCast 1-2-1 Clear Artwork Resin . Part A- Resin"** contains chemicals that may cause skin irritation and/ or may cause an allergic skin reaction, may cause serious eye irritation. Label should carry signal word of "Warning" to conform with ASTM D 4236, the Labeling for Hazardous Art Materials Act, LHAMA regulations (16 CFR 1500 14(B)(8)), or the Federal Hazardous Substance Act.

Containers of materials larger than one ounce must have full precautionary labeling as determined by manufacturer. Where containers of materials which require warning labels are packed in the point of sale package which obscures the warning statement, the point of sale package must have the signal word and the following wording: "Read cautions on individual containers carefully."

Date: May 20, 2017

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