



TOXICOLOGY DEPARTMENT  
67318-090133 (LHAMA)

## Labeling of Hazardous Art Materials Act (LHAMA) Certification

### TEST:

Evaluation of **“Eli-Chem Resins Ltd., Ultra-Cast Resin, Ultra-Cast 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), 67318-090133.

### Product Information:

According to the submitted ingredient list, **“Eli-Chem Resins Ltd., Ultra-Cast Resin, Ultra-Cast Hardener”** contains (insert ingredients), as a starting raw material.

### Background:

Quantitative list of the ingredients in **“Eli-Chem Resins Ltd., Ultra-Cast Resin, Ultra-Cast 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 **“Eli-Chem Resins Ltd., Ultra-Cast Resin, Ultra-Cast 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 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 “**Eli-Chem Resins Ltd., Ultra-Cast Resin, Ultra-Cast 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.

### Summary and Conclusion:

After reviews of the supplied information and risk assessment based on hazards, exposure potential, acceptable daily intake and appropriate safety factors, I found "**Eli-Chem Resins Ltd., Ultra-Cast Resin, Ultra-Cast Hardener**" contains a chemical (CAS #25068-38-6) that is an eye irritant, skin irritant, skin sensitizer and shows carcinogenicity. It also contains a chemical (CAS #135108-88-2) that



is an eye irritant, skin irritant and skin sensitizer. It should carry pictograms of and signal word of "Danger" with Hazard Statements of H315 (Causes Skin Irritation), H319 (Causes Serious Eye Irritation), H317 (May Cause an Allergic Skin Reaction), and H350 (May Cause Cancer).

Date: *Sep. 27. 2018*

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