Technical Guide for Art & Craft Products

TRA, LHAMA, CPSR, REACH, PROP 65, SDS, USP 51/61/62

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Toxicological Risk Assessments (TRA)

What is TRA?

Toxicological risk assessments (TRA) is a hazardous substance control that identifies dangerous chemical substances in consumer products, which is of great concern to consumers, retailers, and law makers. In addition to posing serious health risks to the general public these chemicals are toxic to the environment.

The principle of toxicological risk assessment is based on evaluating the hazard or inherent toxicity of the individual chemical ingredient, such as acute toxicity, repeat dose toxicity, skin sensitivity, skin/eye irritation, aspiration hazard, reproductive toxicity, or carcinogenicity, in relation to the potential consumer exposure to the chemical.

Standards that Requires TRA by Countries

United States

- Federal Hazardous Substances Act (FHSA)
- 16 CFR 1500 Hazardous Substances and Articles

Canada

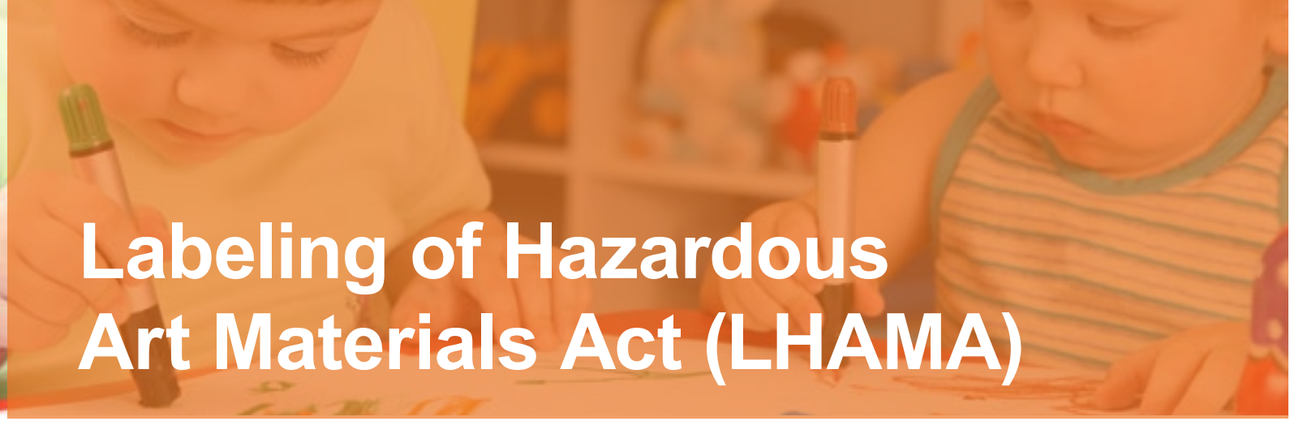
- Hazardous Product Act RSC 1985
- Consumer Chemical Container Regulations 2001
- Toy Regulations (SOR 2011-17)
- Canada Consumer Product Safety Act SC 2011

United Kingdom

- European Union (Withdrawal) Act 2018

European Union

- Directive 1994/45/EC
- Directive 67/548/EEC:“DSD”
- Directive 2006/121/EC
- EN 71/9 Directive 1999/45/EC: Dangerous Preparation Directive. “Toy”
- Regulation (EC) No 1907/2006: REACH
- Regulation (EC) No 1272/2008 on classification, labeling, and packaging (CLP) of substances and mixtures



Labeling of Hazardous Art Materials Act (LHAMA)

What is LHAMA?

The labeling of Hazardous Art Materials Act (LHAMA), enacted on November 18, 1990, regulates art materials that are distributed in the US. The law requires that any art material intended for use in households, schools, or by children, be reviewed by a Board-Certified Toxicologist to determine if it has the potential to produce chronic, long-term health hazards.

The purpose of LHAMA is to minimize the potential risks associated with the use of the art materials that present chronic health hazards and appropriate warnings as defined in the Federal regulations and as noted in ASTM F963 section 5.13 are required.

LHAMA is currently within the standards below:

- Federal Hazardous Substances Act (P.L. 86-613)
- 16 CFR Part 1500 – Hazardous Substances and Articles
- Labeling of Hazardous Act Materials Act (15 U.S.C. 1277)
- ASTM D-4236-94. (2011 Updated)

LHAMA Scope

The U.S. Consumer Product Safety Commission (CPSC) will enforce against materials sold as part of an art, craft, model or hobby kit, including but not limited to:

- Colored Pencils
- Adhesives
- Crayons
- Glues
- Paints
- Putties

*If adhesives, glues, putties are sold separately (not part of a kit), intended for general repair or construction uses are not subject to LHAMA; however, if they are intended for arts and craft uses, they would fall under the LHAMA requirement.

LHAMA Warning Statements

Precautionary Statements	Precautionary Statements
Keep Out of Reach of Children	May Cause Sterility
When Using Do Not Eat, Drink or Smoke	Contact May Cause Permanent Eye Damage
Wash Hands Immediately After Use	May Be Harmful By Breathing Vapors/Dusts
Avoid Inhalation/Ingestion/Skin Contact	May Be Harmful By Skin Contact
Avoid Fumes From Combustion	May Produce Birth Defects In The Developing Fetus
Keep Container Tightly Closed When Not In Use	May Be Excreted In Human Milk
Store In Well-Ventilated Area	May Cause Harm To The Nursing Infant
Wear Protective Clothing (Specify Type)	Cancer Agent! Exposure May Produce Cancer
Wear Protective Goggles/Face Shield	Cancer Agent! Based on Tests With Laboratory Animals
Wear NIOSH-Certified Mask for Dust/Mist/Fumes	Possible Cancer Agent Based On Tests With Laboratory Animals
Wear NIOSH-Certified Respirator With An Appropriate Cartridge For (Specify)	May Produce Allergic Reaction By Ingestion/ Inhalation Skin Contact
Wear NIOSH-Certified Supplied Air Respirator	May Produce Numbness or Weakness In The Extremities
Use Window Exhaust Fan To Remove Vapors And Ensure Adequate Cross Ventilation. (Specify Explosion-Proof If Necessary)	Exposure May Cause (Specify The Organ) Damage
Do Not Heat Above (Specify Temperature) Without Adequate Ventilation	
Use (Specify Type) Local Exhausting Hood	
Do Not Use/Mix With (Specify Material)	

16 CFR 1500.14 - Products Requiring Special Labeling Under Section 3(B) of The Art

If the art material is not chronically hazardous, a conformance statement to inform the purchaser of the product's compliance should be affixed on the product package.

The followings are three valid examples:

- "Conforms to ASTM Practice D-4236."
- "Conforms to ASTM D-4236."
- "Conforms to the health requirements of ASTM D-4236."

Determination of Hazardous Substance Content - US

Hazardous Substance Regulation	(Title 16 CFR)
Toxic Substance	1500.3(b)5, 1500.3(c)2, and 1500.40
Corrosive Substance	1500.3(b)7, 1500.3(c)3, and 1500.41
Irritant Substance	1500.3(b)8, 1500.3(c)4, 1500.41 and 1500.42
Strong Sensitizer	1500.3(b)9, 1500.3(c)5, and 1500.13
Pressure-Generating Substance	1500.3(c)7
Radioactive Substance	1500.3(b)11, and 1500.3(c)8
Flammability	1500.3(b)10, 1500.3(c)6, 1500.43 and 1610

Cosmetic Product Safety Report (CPSR)

What is CPSR?

More and more art and craft products have fallen into the cosmetic category; hence, complying with the Cosmetic Products Regulation becomes inevitable. Preparing the Cosmetic Product Safety Report (CPSR) is mandatory for manufacturers, importers and retailers in cosmetic industry. All cosmetic products that wish to be sold in the European Union countries will be obligated to comply with **Cosmetic Products Regulation EC 1223/2009**, a national law within the EU since 2013. In order to comply with Regulation (EC) No 1223/2009, a Product Information File (PIF) must be completed for all Cosmetics intended to be marketed within the EU.

The CPSR is comprised of two parts:

Part A: Cosmetic Product Safety Information

Part A of the CPSR is intended to collect the necessary data to justify the safety of the cosmetic product. It is required to contain the following information:

- Quantitative and qualitative composition of the cosmetic product
- Physic-chemical characteristics, microbiological and toxicological specifications of the raw materials
- Impurities, traces, information about the packaging material
- Normal and reasonably foreseeable use of the cosmetic product
- Exposure to the cosmetic product and substances
- Undesirable effects of the products

Part B: Cosmetic Product Safety Assessment

Part B of the CPSR is the actual evaluation of the safety of the cosmetic product and contains the following:

- Explanation of the scientific reasoning leading to the assessment conclusion
- Statement on the safety of the cosmetic product
- Warning labels and instruction for use
- Assessor's credentials and approval

EU REACH

What is REACH?

REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) is an EU regulation that enforces to all chemicals used in consumer products and for industrial purposes. The objective of REACH is to safely manage the risk of chemicals that may be dangerous to the consumers and the environment. REACH requires manufacturers and importers of consumer goods to identify and report the use of chemical substances throughout the supply chain and in their product to European regulatory authorities, and to provide end users with the appropriate safety information.

Summary of Obligations

Requirement to inform customers and consumers under REACH

- EU or EEA suppliers of articles containing Candidate List substances at concentrations greater than 0.1% w/w must provide their customers with sufficient information to allow safe use of the article.
- Upon request from a consumer, EU or EEA suppliers of articles containing Candidate List substances at concentrations greater than 0.1% w/w must provide sufficient information to allow safe use of the article. This information must be provided within 45 days of receipt of the request.

Requirement to notify ECHA under REACH

- EU and EEA manufacturers or importers of articles must notify ECHA if their article contains a Candidate List substance. This obligation applies if the substance is present in those articles in quantities totaling more than one metric ton per manufacturer or importer per year and if the substance is present in those articles at a concentration greater than 0.1% w/w. The notifications must be submitted no later than 6 months after inclusion in the Candidate List.

Requirement to notify ECHA under the Waste Framework Directive (SCIP Database)

- EU suppliers of articles containing substances on the Candidate List in concentrations greater than 0.1% w/w when placing them on the EU market must submit information on these articles to ECHA. This information is published in the SCIP database established under the Waste Framework Directive (WFD). This ensures that information on articles containing Candidate List substances is available to waste operators and consumers.

California Proposition 65 (CA-PROP 65)

What is CA-PROP 65?

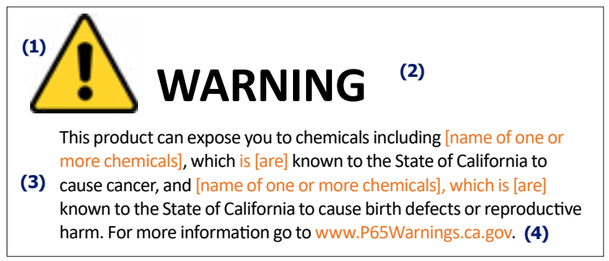
California Proposition 65 (formally titled “The Safe Drinking Water and Toxic Enforcement Act of 1986”) requires the State to publish a list of chemicals known to cause cancer or birth defects or other reproductive harm. This list, which must be updated at least once a year, has grown to include approximately 988 chemicals since it was first published in 1987. The objectives of CA-Prop 65 is to protect California’s drinking water sources from chemical contamination and to enable Californians to make informed decisions about their exposures to harmful chemicals before product purchase.

Summary of Obligations

If the product(s) sold in California expose one or more chemicals listed under Proposition 65 that exceeds the “Safe Harbor” limits, the manufacturer, producer, packager, importer, supplier, or distributor of the product should comply with the Proposition 65 by providing a Warning Label on the product in the correct form.

General Requirements of Warning Label

- The warning has to feature the full name of a listed chemical a minimum of one time. Chemicals cannot be abbreviated. For example; DEHP should be written Di(2-ethylhexyl) phthalate.
- Warning labels must be visible to consumers. Letters have to be rendered in a minimum 6-point type.
- If the consumer information of a product is in another language other than English, the warning label must also provide in that language + English.



(1) Symbol: Black exclamation point in a yellow equilateral triangle with bold black outline.

(2) “WARNING” should be all capital letters and in bold print.

(3) Disclose the associated dangers of the chemical with either “Cancer”, “Reproductive Harm”, or both.

(4) URL of the Proposition 65 warnings website address (www.P65Warnings.ca.gov)

(5) If the warning is included on a product, a short-form warning is allowed and does not need to feature the name of the listed chemical, however, the other requirements must be met.

Safety Data Sheet (SDS)

What is SDS?

The Safety Data Sheet (SDS) is a detailed information bulletin prepared by the manufacturer or importer of a chemical that describes the physical and chemical properties, physical and health hazards, routes of exposure, precautions for safe handling and use, emergency and first-aid procedures, and control measures. Information on a SDS aids in the selection of safe products and helps prepare employers and employees to respond effectively to daily exposure situations as well as to emergency situations.

Information Required for SDS - (16 Parts Per GHS and US Compliance)

1) Identification
2) Hazard(s) identification
3) Composition / information on ingredients
4) First-aid measures
5) Fire-fighting measures
6) Accidental release measures
7) Handling and storage
8) Exposure controls / personal protection
9) Physical and chemical properties
2) Stability and reactivity
3) Toxicological information
4) Ecological information
5) Disposal considerations
6) Transport information
7) Regulatory information
8) Other information, including date of preparation or last revision

When is SDS Required?

Upon request, where preparation is not classified as dangerous according to Directive 1999/45/EC, but contains:

- >1% (>0.2% for gas) of a substance posing human health or environmental hazards
- >0.1% PBT or vPvB substance
- Substance with Community workplace exposure limits

From June 1, 2015

- Upon request, where mixture is not classified as hazardous according to Regulation (EC) No 1272/2008, but contains: >0.1% of a substance that is carcinogenic category 2; toxic for reproduction category 1A, 1B, and 2; skin sensitizer category 1; respiratory sensitizer category 1; or has effects on or via lactation.

Micro-Biological Testing

What is Micro-Biological Testing?

Micro-biological testing checks for the presence of microorganisms in a particular sample. Such testing is essential for consumer product safety, to look for signs of contamination in products that will be distributed to the public. Consumer products such as food items, cosmetics, toys and juvenile products are common for microbiological testing.

Applicable Testing Requirements for Art Materials in Toys in Liquid/Semi-liquid/Powder Form

- **Anaerobic / aerobic total microbial counts**

  To indicate the level of microorganisms in a product and determine if a product is currently contaminated with bacteria or fungi, and presence or absence of potential pathogens.

  - EU : BP/EP - Microbiological Contamination
  - US : USP 61/62 - Cleanliness of Materials

- **Microbiological effectiveness of preservatives**

  To assure the preservative in a product, or the antimicrobial action created by the properties of a product, is sufficient to combat the introduction of microorganisms.

  - EU : BP/EP- Efficacy of antimicrobial preservation
  - US : USP 51 -Preservative Effectiveness

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