
HAZCOM AND REGULATORY CHALLENGES FOR COSMETICS, PERSONAL CARE, AND CONSUMER PRODUCTS

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Goals of the Presentation

Labeling Requirements for Consumer Products and Cosmetics.

Differences between FHSA/CPSC and OSHA Hazard Communication Labeling

Regulatory Challenges





Definition of a “Consumer Product” in the US

- “any article, or component part thereof, produced or distributed (i) for sale to a consumer for use in or around a permanent or temporary household or residence, a school, in recreation, or otherwise, or (ii) for the personal use, consumption or enjoyment of a consumer in or around a permanent or temporary household or residence, a school, in recreation or otherwise ...”
- a product must be “customarily produced or distributed for sale to, or use or consumption by, or enjoyment of, a consumer”

(15 U.S.C. § 2052(a)(5))





Canadian Consumer Product Definition

Canada defines a consumer product as “a product, including its components, parts or accessories, that may reasonably be expected to be obtained by an individual to be used for non-commercial purposes, including for domestic, recreational and sports purposes, and includes its packaging.”

[H129-149-2023-eng.pdf](#)





— EU Consumer Product Definition

There are several differences between EU States on the definition of a consumer, but the majority define a consumer as a “natural person who is acting for the purposes which are outside his trade, business and profession.”

Consumer protection in the EU



OSHA SDS Requirements

29 CFR 1910.1200(b)(6) fully exempts [and does not require labels or SDSs for]:

- Consumer products or hazardous substances regulated under the Consumer Product Safety Act (CPSA) or Federal Hazardous Substances Act (FHSA) “where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended”



How is a hazard communicated if OSHA SDS nor Labels are required?

- Hazards are communicated for consumer use of a product through the *consumer product label*.
- In the US, hazardous consumer chemicals must be labeled according to the FHSA as administered by the Consumer Product Safety Commission (CPSC) and the CPSC implementing regulations.

Global Requirements for Consumer Product Labelling

- In Canada, hazardous consumer products must comply with the Consumer Chemicals and Containers Regulations (CCCR).
- The hazard information must be in French and English and the CCCR uses unique symbols, signal words, and hazard phrases that may not align with the Globally Harmonized System (GHS).

Global Requirements for Consumer Product Labelling Cont.

In the EU, the “regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures” (CLP) is applied to hazardous consumer products.

- There are specific additional precautionary phrases and a Tactile Warning of Danger (TWD) for certain hazard categories for consumer products.

Extra-Strength Hard-Surface Cleaner

Ingredient	CASRN	% weight in product	LD50-Oral	LD50-Dermal	LC50-Inhalation	Eye/Skin Corrosion
Water	7732-18-5	90.4	>10000 mg/kg	>2000 mg/kg	>10000 ppm	No
Lauramine Oxide	1643-20-5	6.0	1,064 mg/kg	> 2000 mg/kg	No data	Yes Eye-1, Skin-2
Alcohols, C12-14, ethoxylated	68439-50-9	1.5	> 2,000 mg/kg	> 2,000 mg/kg	No data	No
Butoxyethanol	111-76-2	1.1	880 mg/kg	1,060 mg/kg	450 ppm	No
Sodium Citrate	64-04-2	0.3	5400 mg/kg	2680 mg/kg	No data	No
Fragrance- "Squeaky Clean"	Mixture	0.3	> 5,000 mg/kg	> 2,000 mg/kg	No data	No
Sodium EDTA	64-02-8	0.2	1780 mg/kg	No data	No data	No
Preservative (MCI/MI Blend)	55965-84-9	0.1	457 mg/kg	660 mg/kg	1.23 mg/m ³	Yes, Eye, Skin-2
Dye	N/A	0.1	Non-hazardous.			



Acute Toxicity Calculations

The acute toxicity estimates based on the ATE_{mix} are noted below.

End-Point	Calculated Value
Oral ATE_{mix}	13,158 mg/kg
Dermal ATE_{mix}	25,974 mg/kg

Note: To simplify the calculation, ingredients present at less than 1% are not considered for the US or Canada. Classification in the EU is subject to CLP.

GHS Classification of Extra-Strength Hard-Surface Cleaner

- Lauramine Oxide is present at 6.0% wt. in the final formulation.
 - Category 1- Serious Eye Damage
 - Category 2- Skin Irritation
- Classification of Extra-Strength Hard Surface Cleaner
 - Category 1- Serious Eye Damage

Based on this classification, the mixture will need to be labeled in accordance with the Federal Hazardous Substances Act, Consumer Chemicals and Containers Regulations, Global Harmonized System, and Classification, Labelling and Packaging.



GHS Label for Extra-Strength Hard-Surface Cleaner

Signal Word: Danger

Pictogram:



Statement of Principal Hazard:

Causes serious eye damage.

Prevention:

Wear splash-resistant goggles.

Response:

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor.

Storage/Disposal:

Not required.



CPSC has not adopted GHS.

OSHA has adopted GHS and incorporated it into the Hazard Communication Standard.

FHSA does not have the same definition as GHS for a hazardous chemical!

The SDS authored for industrial/commercial use most likely (unless non-hazardous) will not match the hazards of the consumer label.

What do you label when you have a multi-use product?

- FHSA text must be kept together and separate from the GHS text.
- Cautionary language will need to be based on FHSA definitions of hazards.
- GHS and FHSA requirements may be placed on the same label as long as GHS text **does not** contradict the FHSA label.



Consumer Product Labeling in the US

1. “A product must be toxic, **corrosive**, flammable or combustible, an irritant, or a strong sensitizer, or which generate pressure through decomposition, heat or other means, as defined in the act and regulations;
2. Have the potential to cause substantial personal injury or **substantial illness during or as a result of any customary or reasonably foreseeable handling or use**, including reasonably foreseeable ingestion by children;
...”
...

eCFR :: 16 CFR Part 1500 -- Hazardous Substances and Articles:
Administration and Enforcement Regulations



Consumer Product Classifications for Example Product

USA: DANGER
Corrosive to eyes.

Canada: DANGER
CORROSIVE

EU:



Danger: Causes serious eye damage.



US Labeling Requirements for Example Product under FHSA

Primary display panel:

DANGER: Corrosive to eyes.
Read other warnings on back label.

*This is an example of a product specific warning applied to the consumer label due to a known hazard during consumer use.

On Back Panel:

Wear eye protection. Contains Lauramine Oxide. **DO NOT MIX WITH OTHER HOUSEHOLD CLEANERS, INCLUDING BLEACH, AS TOXIC FUMES MAY RESULT.** KEEP OUT OF REACH OF CHILDREN. FIRST AID: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor. IF SWALLOWED, DO NOT induce vomiting, drink a glass of water. Call POISON CENTER or doctor immediately. **Contains:** Water, Lauramine oxide, Alcohols, C12-14, ethoxylated, Butoxyethanol, Sodium Citrate, Fragrance, Sodium EDTA, Methylchloroisothiazolinone and methylisothiazolinone (3:1), Dye, Contains fragrance allergens. For more ingredient information, please visit <https://www.letthechemicalsdothework.com> or call 1 (800) 555-5555.



Regulatory Challenges with Consumer Product Labeling in the US

- California Proposition 65 Warning Requirements
- California Cleaning Product Right to Know Act
- Volatile Organic Compound (VOC) Emission Standards
 - Promulgates national VOC emission standards for certain categories of consumer and commercial products pursuant to section 183(e) of the Clean Air Act. Cleaning products are covered under 40 CFR 59 Subpart C.
- Do Not Flush
 - Several states have laws requiring manufacturers of wipe products to label their packaging with the “Do Not Flush” and include the “Do Not Flush” symbol.
- Product Specific Labeling Requirements
- Emerging Labeling Regulations



Labeling Requirements for Example Product under CCCR

Main Display Panel:

Signal Word: DANGER

Symbol:



Primary Hazard Statement

CORROSIVE

All hazard warnings must be in Canadian French and English. Products classified as Corrosive require a child-resistant closure and instructions for opening/closing the container may also need to be included on the label.

Labeling Requirements for Example Product under CCCR

The Specific Hazard Statement

CAUSES BURNS

DANGEROUS FUMES FORM
WHEN MIXED WITH OTHER
PRODUCTS

Negative Instructions

Do not mix with other
household cleaners, including
bleach.

Do not get in eyes.

Do not swallow.

Do not get on skin or clothing.

Do not breathe fumes.

Positive Instructions

Handle with care.

Keep out of reach of children.

Wear safety glasses and gloves.

Use only in a well-ventilated area.

First Aid Statement

FIRST AID TREATMENT

Contains Lauramine oxide.

If swallowed, contact a Poison Control Centre or doctor immediately. Do NOT induce vomiting. If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor. If on skin, rinse well with water. If on clothes, remove clothes. If breathed in, move person to fresh air.



Labeling Requirements for Example Product under EU CLP

Signal Word: Danger

Pictogram:



Statement of Principal Hazard:

Causes serious eye damage

Ingredient Disclosure:

Contains 5-15% Amphoteric Surfactants, Butoxyethanol, Sodium Citrate, Fragrance (Limonene, Hexyl Cinnamal), Sodium EDTA, Methylisothiazolinone (MIT) 0.07% w/w and Chloromethylisothiazolinone (CMIT) 0.03% w/w

Precautionary statements (CLP):

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Wear eye protection.

IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a doctor, a POISON CENTER.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a doctor, a POISON CENTER.





Personal Care Product

- The grouping of products as a “personal care product” is actually misleading.
- FDA regulates products grouped under “personal care” under cosmetics, drugs, medical devices, dietary supplements, and even consumer products (under FHSA/CPSC).
- These products usually fit under the Canadian Cosmetic Definition of “any substance or mixture of substances, manufactured, sold or represented for use in cleansing, improving or altering the complexion, skin, hair or teeth and includes deodorants and perfumes”

Cosmetics Safety Q&A: Personal Care Products | FDA

Regulatory information for cosmetics - Canada.ca

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United States Cosmetic Definition

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body ... for cleansing, beautifying, promoting attractiveness, or altering the appearance"

(FD&C Act, sec. 201(i))





EU Cosmetic Definition

“Any substance or mixture intended to be placed in contact with the external parts of the human body (epidermis, hair system, nails, lips and external genital organs) or with the teeth and the mucous membranes of the oral cavity with a view exclusively or mainly to cleaning them, perfuming them, changing their appearance, protecting them, keeping them in good condition or correcting body odours”

Regulation - 1223/2009 - EN - Cosmetic Products
Regulation - EUR-Lex



Regulations Impacting a Cosmetic Label in the United States

- **Federal Food, Drug, and Cosmetic Act**
 - A cosmetic may be considered misbranding if labeling is false or misleading, label is missing manufacturer/distributor, or net quantity of ingredients.
 - Additionally, all required information should be stated prominently in language easily read and understood by consumers under customary conditions of purchase and use.

US Cosmetic Label Requirements

Principal Display Panel:

- Name of Product
- Identity
- 740.10 Warning (if applicable)
- Net Quantity of Contents

Information Panels:

- Directions for safe use
- Warnings
- Name and place of business
- Ingredient declaration
- Any other required information

Modernization of Cosmetic Regulation Act (MoCRA) Labeling Updates

- Contact Information- Cosmetic product labels must include the contact information of the Responsible Person to allow consumers to report adverse events or ask questions.
- Fragrance Allergen Disclosure- FDA has announced that fragrance allergens will need to be disclosed on the cosmetic label. However, these guidelines have not yet been published.
- California Safe Cosmetics Act of 2005 and California Cosmetics Fragrance & Flavor Ingredient Right to Know Act of 2020 – Both require companies to report products containing specific hazardous ingredients to the California Department of Public Health (CDPH).



Canadian Cosmetic Labelling

In Canada, cosmetic labeling is regulated in the following areas by The Food and Drugs Act (FDA) and the Cosmetic Regulations (CR):

- Product identity on label
- Contact information for consumer questions on the product
- Listing of ingredients on the label
- Avoidable hazards from the cosmetic

Canadian Cosmetic Labelling

The Consumer Packaging and Labeling Act (CPLA) and Regulations requires:

- Product's identification in English and Canadian French
- Net quantity in metric units in English and Canadian French
- Identity and address of business for the dealer

These regulations only apply to cosmetics sold to consumers. Use by cosmeticians, hairdressers, etc. to be applied to their clients is not regulated through this standard.



EU Cosmetic Labeling Requirements

The European Union regulates Cosmetic Labeling according to Article 19 of Regulation (EC) No 1223/2009 of the European Parliament and of the Council.

Required label elements:

- Name and address of the responsible person.
- Country of Origin (if imported)
- Net weight (Nominal content)
- Date of minimal durability
- Warnings/Precautions for Use
- Batch Number of manufacture or reference to identify cosmetic product
- Function of cosmetic product
- List of Ingredients
- Symbols:
 - Reference to enclosed or attached information
 - Period-after-opening
 - Date of minimum durability



Regulatory Challenges with Cosmetics

- Everchanging regulatory landscape with cosmetics.
- Increasing requirements for disclosure of ingredient information and fragrance allergens.
- Region specific disclosure and labeling requirements.

Recap

- Hazards are communicated through labeling rather than safety data sheets for the majority of applicable products.
- Consumer/Cosmetic label should be primary method of communication for hazards. However, if an SDS is provided it is recommended to include a note that the SDS is for industrial users and not consumers.

Example Statement: “This SDS is not applicable for consumer use of our products. For consumer use, all precautionary and first aid language is provided on the product label in accordance with the applicable government regulations.”



Questions?

Thank you!



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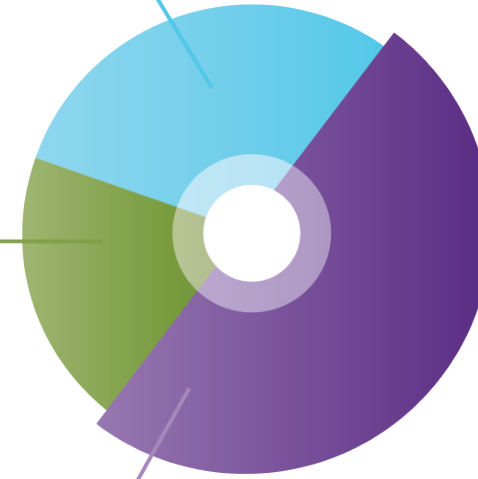
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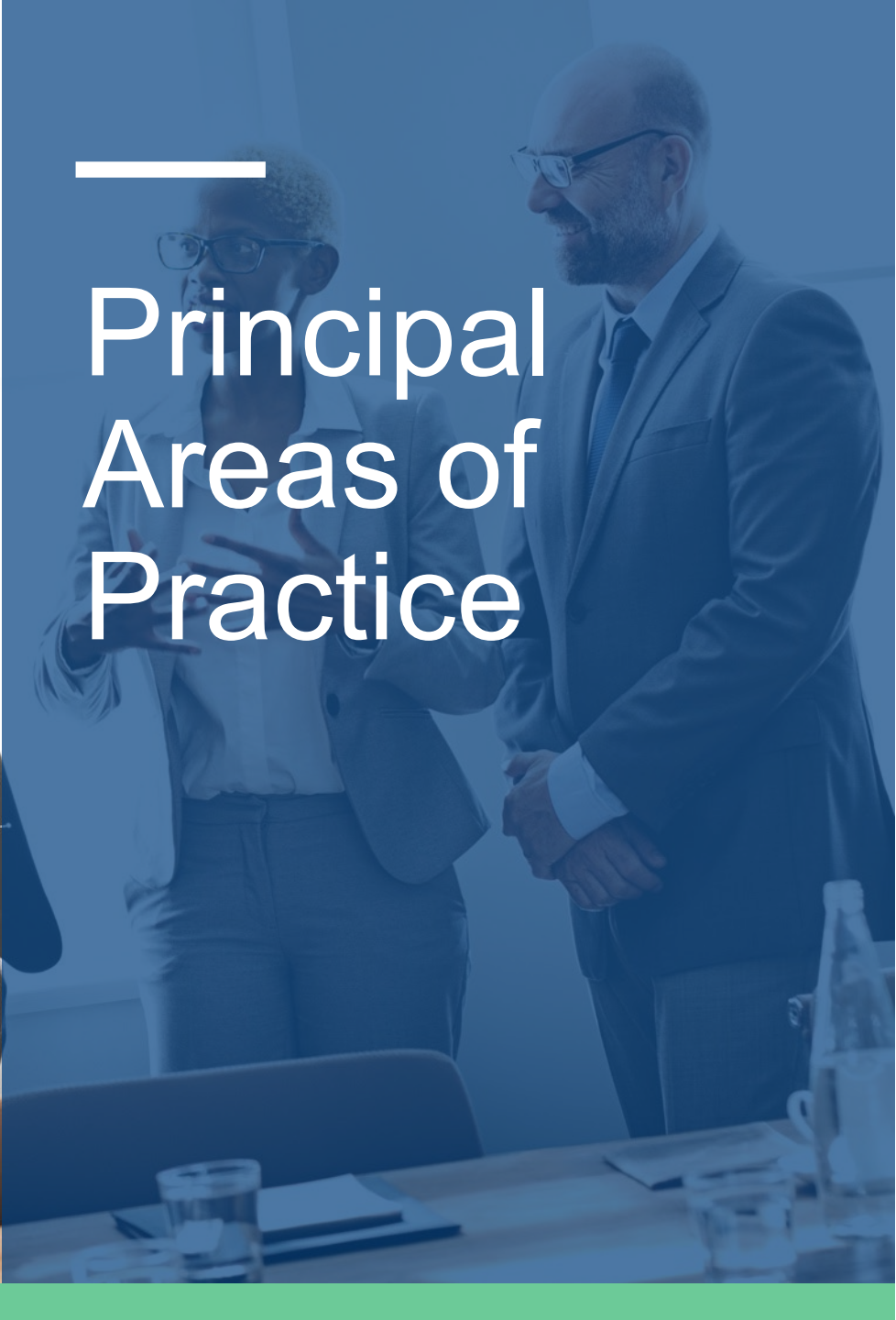
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