

CONSUMER CHEMICAL PRODUCT LABELING – LESS HARMONIZED THAN GHS!

SCHC POSTER – NOVEMBER 9, 2020



CONSUMER PRODUCT LABELING IN THE US, CANADA AND THE EU



The requirements for consumer product labeling differ significantly between the US, Canada and the EU.

In the US, hazardous consumer chemicals must be labeled according to Federal Hazardous Substances Act (FHSA). Challenges include the California Proposition 65 updated warning requirements and the California Cleaning Product Right to Know Act which requires manufacturers of cleaning products, household and industrial, to disclose information related to known hazardous chemicals on the label and website.

Hazardous consumer chemicals, in Canada, must comply with the Consumer Chemicals and Containers Regulations (CCCR). The CCCR requires the use of unique symbols, prescribed hazard phrases, and the hazard information must be in French and English. The required CCCR phrases and signal words are not always aligned with those in the UN GHS.

The EU applies “Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures” (CLP) to hazardous consumer products, with the requirement of additional precautionary phrases, and a Tactile Warning of Danger (TWD) for certain hazard categories.

This poster will demonstrate the differences between jurisdictions and challenges that companies face with labeling hazardous consumer chemical products and why a single label is often not feasible.

THE PRODUCT FORMULATION FOR FABULOUS HOUSEHOLD CLEANER (FHC)



For the purposes of this poster, the following fictional (though plausible) formulation was used for our Fabulous Household Cleaner (FHC):

Ingredients	CASRN	% weight in product	LD50 - Oral	LD50 - Dermal	LC50 - Inhalation	Eye/Skin Corrosion
water	7732-18-5	85.00	90000 mg/kg	>2000 mg/kg	>10000 ppm	No
sodium hydroxide	1310-73-2	6.00	340 mg/kg	1350 mg/kg	no data	yes
2-butoxyethanol	111-76-2	6.00	1746 mg/kg	99 mg/kg	450 ppm	No
Yellow #5	1934-21-0	2.50	>2000	>2000	>10000 ppm	Not hazardous
Citrus Fragrance	Mixture	0.50				Less than 1%

NOTE: None of the other acute hazard categories of concern were triggered by ingredients of the formulation



ACUTE TOXICITY CALCULATIONS FOR FHC

The acute toxicity estimates based on the ATE_{mix} formula are below. Note that ingredients present at less than 1% are not considered for either the US or Canada. The classification rules in the EU are subject to the CLP.

End-Point	Calculated Value
Acute Oral Toxicity	4295.91 mg/kg
Acute Dermal Toxicity	2823.53 mg/kg
Acute Inhalation Toxicity	919.11 ppm (or mL/m ³)



CONSUMER PRODUCT CLASSIFICATIONS FOR FHC

Based on the known information and calculated toxicity values, the product classification for each jurisdiction would be as follows:

USA

- Corrosive
- Toxic (oral, dermal and inhalation)

Canada

- Corrosive
- Toxic (dermal)
- Harmful (inhalation)

EU

- Skin corrosion/irritation, Category 1, Sub-Category 1A



CONSUMER PRODUCT CLASSIFICATIONS FOR FHC – KEY DIFFERENCES

As noted in the previous slide, the classification of the same formulation under the rules in the US, Canada and the EU are significantly different.

These classification variations will result in considerably different label information required between the three jurisdictions.

LABELLING OF FHC IN THE US





US LABELING REQUIREMENTS FOR FHC UNDER THE FHSA

The classification of the Fabulous Household Cleaner is:

USA

- Corrosive
- Toxic (oral, dermal and inhalation)

Based on this classification, the product would need to be labelled in accordance with the Federal Hazardous Substances Act.



US LABELING REQUIREMENTS FOR FHC UNDER THE FHSA

– LABEL ELEMENTS

Signal Word:

- WARNING or CAUTION

Statement(s) of Principal Hazard:

- Corrosive to skin and eyes.
- Harmful if ingested, inhaled or in contact with skin.

Cautionary Statements:

- Keep out of reach of children
- Do not ingest.
- Do not get in eyes or on skin.
- Wear gloves and a mask.
- Use in well-ventilated areas.

First Aid Statement:

- Contains 2-butoxyethanol and sodium hydroxide
- If swallowed, contact a Poison Control Centre or doctor immediately.
- If in eyes or on skin, rinse well with water.
- If in eyes rinse with water for 15 minutes.
- If on clothes, remove clothes
- If breathed in, remove person to fresh air.



US LABELING REQUIREMENTS FOR FHC UNDER THE FHSA – OTHER CONSIDERATIONS

All cautionary labeling may appear on the principal display panel on the immediate container and, if appropriate, on any other container or wrapper or instructional material provided with the product.

Where all of the required information does not fit, the signal word, the statement of principal hazard(s), and a statement “to read carefully any cautionary material on the back/side” must appear on the principal display panel.

- All cautionary statements placed on the principal display panel (or other display surface) shall be separated on all sides from other printed or graphic matter.



FHSA LABEL INFORMATION FOR FABULOUS HOUSEHOLD CLEANER

On principal display panel:

CAUTION or WARNING

Corrosive to skin and eyes. Harmful if ingested, inhaled or in contact with skin. Read carefully other cautions on the [back/side] panel,

On the back or side panel:

Keep out of reach of children. Do not ingest. Do not get in eyes or on skin. Wear gloves and a mask. Use in well-ventilated areas. Contains 2-butoxyethanol and sodium hydroxide. If swallowed, contact a Poison Control Centre or doctor immediately. If in eyes or on skin, rinse well with water. If in eyes rinse with water for 15 minutes. If on clothes, remove clothes. If breathed in, remove person to fresh air.

ADDITIONAL LABELING REQUIREMENTS IN THE US FOR CLEANING PRODUCTS

California and New York State



US PRODUCT LABELLING – PROP 65

- Proposition 65 has been in effect for many years in the State of California.
- It imposes a “Duty to Warn” of the presence of carcinogens and reproductive toxins in products available to the residents of the state.
- The duty to warn can be satisfied by
 - A statement in Section 15 of an SDS for products intended for occupational/professional use; or
 - A statement on the product label for consumer use
 - A statement on the label of a product for occupational/professional use is also acceptable.





PROP 65 – REVISED CLEAR AND REASONABLE WARNING

On August 31, 2016 OEHHA adopted amendments to Article 6, Clear and Reasonable Warnings for Prop65.

Latest amendments has two parts:

- Subarticle 1 - that is mandatory part of regulation and addresses responsibility in supply chain
- Subarticle 2 - that is “voluntary” and establishes specific guidance on methods and content for safe harbor warnings.
- New amendments took effect August 30, 2018.
- If you had product on the market prior to that date, then it’s not applicable.



PROP 65 – PRODUCT EXPOSURE WARNING WORDING

Content

- The warning symbol, which consists of a black exclamation point in a white or yellow equilateral triangle. The symbol shall be placed to the left of the text of the warning, in a size no smaller than the height of the word “WARNING”.
- The word “WARNING” in all capital letters and bold print, and
- One of the following warnings:
 - a) For exposures to listed carcinogens, the words, “This product can expose you to chemicals including [**name of one or more chemicals**], which is [are] known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.”



STATES LAWS



California Cleaning Product Right to Know Act of 2017 S.B. 258

New York Household Cleansing Product Information Disclosure Program beginning implementation

Phased in requirements for manufacturers of cleaning products:

- including household cleaners, and clothes and dish detergents;
- ingredient disclosures on product labels and manufacturer websites;
- complex questions regarding which ingredients must be disclosed;
- whether certain chemical identities may be withheld to protect confidential business information (CBI)





CA CLEANING PRODUCT DISCLOSURE LAWS

SB 258, Cleaning Product Right to Know Act of 2017

Requires manufacturers of certain cleaning products sold in California to disclose on the product label and on the product's Internet web site certain information related to known hazardous chemicals contained in the product.

- Manufacturers must meet the phased in approach:
 - Implemented January 1, 2020 to comply with the online disclosure requirements;
 - Until January 1, 2021 to comply with the product label disclosure requirements; and
 - Until January 1, 2023 to list any intentionally added ingredient that is regulated by California's Safe Drinking Water and Toxic Enforcement Act (commonly known as Proposition 65).

There is no federal equivalent.



CALIFORNIA CLEANING PRODUCT DISCLOSURE LAWS



Certain Clean Products - “designated products”:

- General cleaning products
 - Soaps and detergents for fabric, dishes, counters, and appliances.
- Air care product
 - Indoor air fresheners.
- Automotive product
 - Cleaning, polishing, or waxing products for the exterior or interior.
- Polish or floor maintenance product
 - used primarily for janitorial, domestic or institutional cleaning purposes.

It does not apply to foods, drugs and cosmetics (including personal care items such as shampoo, hand soap, and toothpaste), trial samples, or industrial products specifically manufactured for certain industrial manufacturing processes.

CALIFORNIA CLEANING PRODUCT DISCLOSURE LAWS



The product label will be required to disclose:

- Each intentionally added ingredient listed in descending order of predominance by weight*, that is
 - Included on any of 22 specified designated chemical lists – including chemicals listed pursuant to Proposition 65.
- If the CAS number is not available or an ingredient is confidential business information, the CAS number must be cited as “not available” or “withheld”
- To protect confidential business information (CBI), manufacturer is not required to disclose how a product is manufactured or the weight or amount of an intentionally added ingredient, including a fragrance ingredient, or a nonfunctional constituent, only if it is not on a list**.
- Alternatively, the manufacturers may list all intentionally added ingredients unless it is confidential business information

* Not required to list ingredients or nonfunctional constituents in order if they are present in a designated product at a concentration of less than one percent

** An ingredient may be protected as CBI if the claim is approved by the US EPA under TSCA or if claim protection under the Uniform Trade Secrets Act

CALIFORNIA CLEANING PRODUCT DISCLOSURE LAWS - CONTINUED



- Requires the disclosure of fragrance allergens greater than 0.01 percent (100 ppm).
- Additional requirements include the manufacturer's toll-free telephone number and Internet web site address on the product label



CALIFORNIA CLEANING PRODUCT DISCLOSURE LAWS

If a product does not comply, it cannot be sold in California:

- Under the state's Unfair Competition Law, lawsuits could be filed seeking civil penalties of up to \$2,500 per violation.

If a designated list changes:

- A company will have 6 months to update its online information and 18 months to update its product labels.

All products manufactured before the deadline but sold after...

- Must prominently display the date of manufacture (day, month and year), or a code indicating the date of manufacture.

NEW YORK HOUSEHOLD CLEANING PRODUCT LAWS



The initial New York Department of Environmental Conservation Household Cleansing Product Information Disclosure Program was ruled “Null and Void”

- August 27, 2019 – the State of New York Supreme Court invalidated the New York Department of Environmental Conservation (NYDEC) Household Cleansing Product Information Disclosure Program (Disclosure Program).

The constitutional issues surrounding this legislation have since been resolved and the New York Department of Environment Conservation has begun implementing the new household cleaning product laws according to the legislative procedure.

- The Act includes some, but not all, of the same lists as California but has additional requirements.



<http://www.nycourts.gov/>



SIMILAR LEGISLATION IN OTHER STATES

- Legislation pertaining to cleaning products is pending in other States including:
 - Maryland;
 - Minnesota; and
 - Oregon.

INFORMATION NEEDED FOR THE WEBSITE OF FABULOUS HOUSEHOLD CLEANER (FHC)



Is FHC regulated under the SB 258? It appears yes: “Designated product” means a finished product that is ... general cleaning product, ... the label will need to be compliant as of January 1, 2021 (will not be discussed here)

The website needs to be compliant now with the following:

- Intentionally Added Ingredients. A list of all intentionally added ingredients listed in descending order of predominance by weight in the product, except that ingredients present at a weight below one percent (1%) may be listed following the other ingredients without respect to the order of predominance by weight.
- Nonfunctional Constituents. A list of all “nonfunctional constituents” present in the designated product at a concentration at or above 100 ppm.



INFORMATION NEEDED FOR THE WEBSITE OF FABULOUS HOUSEHOLD CLEANER (FHC)

The website needs to be compliant now with the following:

- **Fragrance allergen** included on Annex III of the EU Cosmetics Regulation No. 1223/2009 present in the product at a concentration at or above 0.01 percent (100 ppm) aggregated.
- **CASRN, Functional Purpose, Links to Designated List, Links to SDS, Accessibility** (not more than 5 clicks), **Fragrance ingredients** if listed on a designated list such and the EU Cosmetic Regulations, **OSHA communication standards**

SDS may have such wording as

STATES RIGHT TO KNOW: California, New Jersey, Pennsylvania, Minnesota, Massachusetts, and Wisconsin. Complies with listed States Right to Know Acts.

The following statement is made in order to comply with the California State Drinking Water Act. California

Proposition 65: This product does not contain any chemicals known to the State of California to cause cancer and/or to cause birth defects and other reproductive harm.



FORMULA FOR FABULOUS HOUSEHOLD CLEANER (FHC)

- Water CAS#7735-18-5 85%
- Sodium Hydroxide CAS#1310-73-2 6%
- Yellow #5 CAS#1934-21-0 2.5%
- Citrus Fragrance Mix 0.5%
- 2 butoxyethanol CAS#111-76-2 6%

Even though **Citrus Fragrance** is added at 0.5%, it needs to be broken down and determined if any of the substance are in any of the 22 designated lists.

- Benzyl salicylate (CAS #118-58-1) 1.712% EC# 204-262-9
- Citronellol (CAS#106-22-9) 2.5350% EC# 203-375-0
- Geraniol (CAS# 106-24-1) 2.7249% EC#203-377-1
- AMYL CINNAMAL; 2-benzylideneheptanal (CAS#122-40-7) 3.1147% EC#204-541-5
- Linalool (CAS#78-70-6) 4.7007% EC# 201-134-4

MOCK WEB SITE –FHC – EXAMPLE ONLY



Water	Dilutant: CAS#7735-18-5
Sodium Hydroxide	Disinfectant: CAS#1310-73-2
2 butoxyethanol	Solvent: CAS#111-76-2 *
Yellow #5	Colorant: CAS#1934-21-0
AMYL CINNAMAL; 2-benzylideneheptanal	Fragrance: CAS#122-40-7**

*see: https://echa.europa.eu/documents/10162/13562/cmr_report_en.pdf for more information

**see:

https://ec.europa.eu/health/sites/health/files/endocrine_disruptors/docs/cosmetic_1223_2009_regulation_en.pdf for more information

Click here for SDS

All intentionally added ingredients, listed from highest to lowest concentration, CASRN, functional purpose, link to the designated list (not actually on the list), link to SDS, big font, for fragrance since it is on the EU Cosmetics Regulation No. 1223/2009 of allergens and present at 156ppm which is above 100ppm it needs to be listed

STATE WARNING CHALLENGES

- No always having 100% formulation;
- In some cases, the entire formulation may be proprietary;
- Not necessarily being able to comply with multiple State's website and label requirements in one website (may need a dedicated State page) and one label; and
- Fitting all information on one label.

Additional challenges may arise during implementation.



LABELLING REQUIREMENTS OF FHC UNDER THE CCCR



CANADIAN LABELING REQUIREMENTS FOR FHC UNDER THE CCCR



The Canadian classification of the Fabulous Household Cleaner is:

Canada

- Corrosive
- Toxic (dermal)
- Harmful (inhalation)

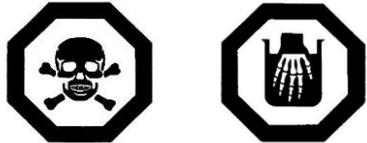
Based on this classification, the product would need to be labelled in accordance with the Consumer Chemicals and Containers Regulations.

CANADIAN LABELING REQUIREMENTS FOR FHC UNDER THE CCCR – LABEL ELEMENTS

Signal Word:

- DANGER

Symbols:



Primary Hazard Statement(s):

- CORROSIVE
- POISON

Specific Hazard Statements:

- CAUSES BURNS
- CONTENTS HARMFUL
- FUMES MAY BE HARMFUL

Negative Instructions:

- Do not get in eyes.
- Do not get in eyes or on skin or clothing.
- Do not breathe fumes.

Positive Instructions:

- Handle with care.
- Keep out of reach of children.
- Use only in a well-ventilated area.
- Wear gloves, safety glasses and a mask.



CANADIAN LABELING REQUIREMENTS FOR FHC UNDER THE CCCR – LABEL ELEMENTS

First Aid Statement:

- **FIRST AID TREATMENT**
- Contains 2-butoxyethanol and sodium hydroxide
- If swallowed, contact a Poison Control Centre or doctor immediately.
- Do not induce vomiting.
- If in eyes or on skin, rinse well with water.
- If in eyes rinse with water for 15 minutes.
- If on clothes, remove clothes
- If breathed in, remove person to fresh air.

CANADIAN LABELING REQUIREMENTS FOR FHC UNDER THE CCCR – OTHER CONSIDERATIONS



The signal word, symbol(s) and primary hazard statement(s) must be on the main display panel.

All other hazard warnings must be elsewhere on the package (except the bottom) and must be clearly separated from all other text on the product label.

All hazard warnings must be in French and English

Products classified as Toxic or Corrosive require a child-resistant closure.

- Instructions for opening/closing the container may also have to be on the product label.

CCCR LABEL INFORMATION FOR FABULOUS HOUSEHOLD CLEANER



On Main Display Panel:



DANGER
CORROSIVE/CORROSIF
POISON

On the English secondary panel:

CAUSES BURNS. CONTENTS HARMFUL. FUMES MAY BE HARMFUL. Do not get in eyes. Do not get in eyes or on skin or clothing. Do not breathe fumes. Handle with care. Keep out of reach of children. Use only in a well-ventilated area. Wear gloves, safety glasses and a mask. **FIRST AID TREATMENT:** Contains 2-butoxyethanol and sodium hydroxide. If swallowed, contact a Poison Control Centre or doctor immediately. Do not induce vomiting. If in eyes or on skin, rinse well with water. If in eyes rinse with water for 15 minutes. If on clothes, remove clothes. If breathed in, remove person to fresh air.

CCCR LABEL INFORMATION FOR FABULOUS HOUSEHOLD CLEANER - CONTINUED



On the French secondary panel:

PROVOQUE DES BRÛLURES. CONTENU NOCIF. LES ÊMANATIONS PEUVENT ÊTRE NOCIF. Éviter tout contact avec les yeux. Éviter tout contact avec les yeux, la peau et les vêtements . Ne pas respire les émanations. Manipuler avec soin. Tenir hors de la portée des enfants. N'utiliser que dans un endroit bien aéré. Portez des gants, des lunettes de sécurité et un masque. **PREMIERS SOINS:** Contient 2-butoxyéthanol et hydroxyde de sodium. En cas d'ingestion, appeler immédiatement un centre antipoison ou un médecin. Ne pas provoquer le vomissement. En case de contact avec les yeux ou la peau, bien rincer avec de l'eau. Enc as de contact avec les yeux, rincer avec de l'eau pendant 15 minutes. Enc as de contact avec les vêtements, enlever ceux-ci. En cas d'inhalation, transporter à l'air frais la personne exposée.

LABELLING OF FHC UNDER THE CLP





EU LABELING REQUIREMENTS FOR FHC UNDER THE CLP

The EU classification of the Fabulous Household Cleaner is:

EU

- Skin corrosion/irritation, Category 1, Sub-Category 1A

Based on this classification, the product would need to be labelled in accordance with the CLP.

EU LABELING REQUIREMENTS FOR FHC UNDER THE CLP – LABEL ELEMENTS



Signal Word:

- Danger

Pictogram:



Ingredient Disclosure:

- Contains: Sodium hydroxide

Hazard statements (CLP):

- H314 - Causes severe skin burns and eye damage.

Precautionary statements (CLP):

- P101 - If medical advice is needed, have product container or label at hand.
- P102 - Keep out of reach of children.
- P280 - Wear eye protection, protective gloves.
- P301+P330+P331+P310 - IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a doctor, a POISON CENTER.
- P303+P361+P353+P310 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.. Immediately call a doctor, a POISON CENTER.
- P305+P351+P338+P310 - 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.



EU LABELING REQUIREMENTS FOR FHC UNDER THE CLP – OTHER CONSIDERATIONS

Location of information on the CLP label:

- The hazard pictograms, signal word, hazard statements and precautionary statements must be kept together on the label;
- Hazard statements must be grouped together on the label;
- Precautionary statements must be grouped together on the label; and
- In the case where more than one language is used on the label, the hazard and precautionary statements of the same language must be grouped together on the label.

Any obligatory supplemental information must be included in the section for supplemental labelling and placed alongside the required label elements.

The P-codes do not need to appear on the product label

Label information must be in the language of the member state where it is being placed on the market.

- Multiple languages are acceptable

EU LABELING REQUIREMENTS FOR FHC UNDER THE CLP – UPCOMING REQUIREMENTS



A Unique Formula Identifier (UFI) code will be required January 1, 2021

- A new label element will be required on certain product labels from 2021 – a 16-character code called the unique formula identifier (UFI). By 2025, the UFI will be mandatory on the label of all products classified for health or physical hazards.

CLP LABEL INFORMATION FOR FABULOUS HOUSEHOLD CLEANER



Danger

Causes severe skin burns and eye damage.

Contains: Sodium hydroxide

If medical advice is needed, have product container or label at hand. Keep out of reach of children. Wear eye protection, protective gloves. IF SWALLOWED: rinse mouth. Do NOT induce vomiting. Immediately call a doctor, a POISON CENTER. IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water. Immediately call a doctor, a POISON CENTER. 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.

DISCUSSION OF DIFFERENCES BETWEEN JURISDICTIONS





DIFFERENCES BETWEEN JURISDICTIONS

Product Classification:

As noted on Slide #5, the product classification differs significantly between all 3 jurisdictions.

- This is due to the different classification criteria between the FHSA, CCCR and CLP.

Signal Word:

In Canada and the EU, the required signal word is DANGER (can be title-case for the EU). In the US it is either WARNING or CAUTION.

- In the US, the signal word DANGER is only allowed to be present when a product is classified as Highly Toxic and must be accompanied by the word POISON.

Pictograms/Symbols:

There is no requirement in the US to have pictograms or symbols except when a product is classified as Highly Toxic. The CCCR symbols are unique to Canada and are very different from those required under the CLP.

- Size of the pictogram or symbol is relative to the main display area of the container



DIFFERENCES BETWEEN JURISDICTIONS

Required Hazard Phrases:

In both the EU and Canada the required phrases are prescribed by the regulations. The FHSA in the US does not specify what phrases need to be used to communicate the precautionary information.

- Generally the CLP and/or CCCR phrases will be acceptable in the US.

Text Sizing:

The CCCR and the FHSA prescribe how big the warning information must be, relative to the size of the main display area of the label. The CLP only regulates pictogram size.

Bilingual Label Information:

Canada requires all CCCR warning information be present in both official languages (English and French)

- This presents a challenge to many manufacturers of hazardous consumer chemicals since it is often difficult to fit all the required information along with other desired information, such as directions for use, on the product label.

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