

How are cosmetics regulated in the USA and in Canada?

LOBBYING FOR COSMETIC COMPANIES

- ANSM
- European Commission
- ISO, CEN , AFNOR
- Foreign countries authorities

SHARED SERVICES


- Regulatory watch
- Free Sale Certificates : <https://www.cosmedcvl.fr/>
- Training
- Purchasing group
- Events, Congress

WORLDWIDE REGULATORY WATCH – ACCESS TO THE DATABASE

YOUR **WORLDWIDE** REGULATORY **MONITORING**

 **120** Countries monitored (Europe & international).
On-line available databases 24 hours, 7 days

 **1500** Updated factsheets and summary tables

 **48h** Deadline answer to your regulatory requests
from a specialized team

 **7 days a week** Email alerts at each
regulatory amendment



Updated database - Experts assistance



CHOOSE your tailored solution

1 database France / Europe OR International

2 databases France / Europe AND International

EUROPEAN DATABASE

- . French and E.U regulations
- . Specificities of E.U
- . Summary Tables of regulated ingredients
- . Product Information File
- . Assessment of ingredients
- . Notification of cosmetic product
- . Labelling, Claims
- . Cosmetovigilance
- . PAO tool
- . REACH, CLP
- . Actors' Obligations ...

INTERNATIONAL DATABASE

- . Classification of products: cosmetics, quasi-drugs, OTC, Natural Products
- . Fact sheets on regulations
- . Summary tables of regulated substances
- . Labelling, Claims
- . Registration / Notification of products ...
- . Comparative substances tables (UV filters ...)



NEW COSMED REGULATORY monitoring in english
A real asset for foreign subsidiaries and / or distributors

Cosmetic regulation in USA

Regulatory framework



- Food, Drug & Cosmetic Act (FD&C act)
 - Cosmetics: Chapter 21
- Fair Packaging and Labeling Act (FPLA)



Very different regulations and philosophy from Europe



Definitions and classification





■ Cosmetics

Articles intended to be **poured, sprinkled, sprayed, introduced, massaged**, or otherwise **applied** to the **human body...** to **cleanse, beautify, make more attractive, or alter appearance.**

■ Drug

Articles intended to **diagnose, cure, treat or prevent the onset of disease**

Articles (non-food) intended to **modify the structure or any function of the** body of humans or other animals

■ Classification criteria

The classification of the products is done according to :

- **Claims used** (any claim involving modification of skin structure or function will result in classification of the product as an OTC)
- **Consumer perception**
- **Ingredients used** (any ingredient with a therapeutic function will result in the product being classified as OTC).





■ Cosmetics

- Moisturizing skin creams
- Fragrances
- Eye and face make-up
- Nail products
- Hair products (Shampoos, hair dyes, etc.)
- Deodorants
- Oral care products (cleaning)
- Etc...

Any substance intended to be used as a component of a cosmetic product.

■ OTC drug

- Sun protection product
- Anti-dandruff shampoos
- Acne products
- Anti-cavity toothpastes
- Antiperspirant
- Skin protection product, especially lip stick, diaper rash etc...

- Antibacterial hand cleansing gel

■ Case of soap

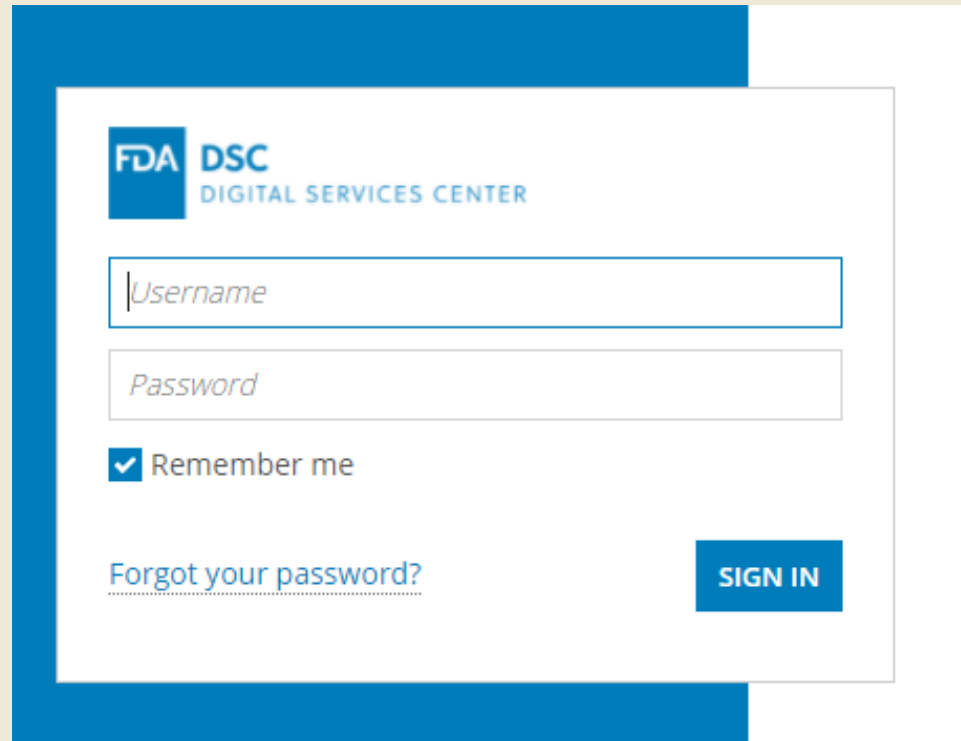


- **Ingredients:** "alkaline salts of fatty acids", resulting from the reaction between fatty acids and a strong base.
- **Ingredient responsible for the detergent action:** only alkaline salts of fatty acids should be used for cleaning.
- **Deemed use:** to be considered a soap, the product can only be sold for that function.
 - No regulated substances
 - No registration
 - No CPSC pre-approval
 - No test required

Registration



- VCRP Program
- Voluntary registration of establishments and products
- No pre-approval from authorities
- Local (before or after marketing) and foreign (after marketing) plants
- Form FDA 2511 / online portal



The image shows a screenshot of the FDA DSC Digital Services Center login portal. The page features the FDA DSC logo at the top left, followed by two input fields for 'Username' and 'Password'. Below these fields is a checked checkbox labeled 'Remember me'. At the bottom left, there is a link for 'Forgot your password?' and a blue 'SIGN IN' button on the right.



■ Establishments

- Only for manufacturing and/or packaging companies
- Does not apply to distribution companies
- **Information needed:**
 - Type of establishment (manufacturing, packaging etc...)
 - Name of the establishment
 - Name of parent company, if any
 - Address
 - Function of the declarant (owner or operator)
 - Subsidiaries, if any

Cosm Cosmetic products

- Form FDA 2512/ notification portal
- **Information needed:**
 - Type of company indicated on the label (manufacturer, packager, distributor)
 - Address of this company
 - Information on the manufacturer or (subcontractor)
 - Company name provided via form 2511
 - Conditioner information
 - Product distribution in the USA (> 1000\$/year)
 - Product Information
 - Brand/product name
 - Product website, if applicable
 - Product image
 - Formula (in descending order of preference)
 - Identity of the declarant (manufacturer, packer, distributor etc.)

Controlled substances





Cosmetics

- Around 10 restricted/banned substances:
 - Solar filters
 - ESB
 - Mercury derivatives
 - Etc...
- Positive list of dyes
- Security criteria +++.

Color Additives That Are Exempt from Certification and Permitted for Use in Cosmetics (21 CFR Part 73 Subpart C—Cosmetics)

Color Additive	Eye Area	Generally (Includes Lipsticks)	External Use	Specific Limitations and Comments
Aluminum powder	Yes	No	Yes	
Annatto	Yes	Yes	Yes	
Bismuth citrate	No	No	Subject to limitations	Hair on the scalp
Bismuth oxychloride	Yes	Yes	Yes	
Bronze powder	Yes	Yes	Yes	
Caramel	Yes	Yes	Yes	
Carmine	Yes	Yes	Yes	
β-Carotene	Yes	Yes	Yes	
Chromium hydroxide green	Yes	No	Yes	
Chromium oxide greens	Yes	No	Yes	
Copper powder	Yes	Yes	Yes	
Dihydroxyacetone	No	No	Subject to limitations	For use in tanning preparations

Color Additives That Are Subject to Certification and Permitted for Use in Cosmetics*

Includes Straight Colors and Lakes

(21 CFR Part 74 Subpart C—Cosmetics and 21 CFR Part 82 Subparts B, C, and D)

Color Additive	Eye Area**	Generally (Includes Lipsticks)	External Use	Specific Limitations and Comments	21 CFR Section
D&C Black No. 2	Subject to Limitations	Subject to Limitations	Subject to Limitations	Eyeliner, brush-on-brow, eye shadow, mascara, lipstick, blushers & rouge, makeup & foundation, nail enamel	74.2052
D&C Black No. 3	Subject to Limitations	No	Subject to Limitations	Eyeliner, eye shadow, mascara, face powder	74.2053
FD&C Blue No. 1	Yes, also Al lake	Yes	Yes		74.2101
D&C Blue No. 4	No	No	Yes		74.2104
D&C Brown No. 1	No	No	Yes		74.2151
FD&C Green No. 3	No	Yes	Yes		74.2203
D&C Green No. 5	Yes	Yes	Yes		74.2205
D&C Green No. 6	No	No	Yes		74.2206

Local specificities

California & Maryland

- In 2020 and 2021, ban of about 20 substances by 01/01/25:
 - Dibutyl phthalate (CAS No. 84-74-2)
 - Diethylhexyl phthalate (CAS No. 117-81-7)
 - Formaldehyde (CAS No. 50-00-0)
 - Paraformaldehyde (CAS No. 30525-89-4)
 - Methylene glycol (CAS no. 463-57-0)
 - Quaternium-15 (CAS No. 51229-78-8)
 - Mercury (CAS No. 7439-97-6)
 - Isobutylparaben (CAS No. 4247-02-3)
 - Isopropylparaben (CAS No. 4191-73-5)
 - m-Phenylenediamine and its salts (CAS no. 108-45-2)
 - o-Phenylenediamine and its salts (CAS No. 95-54-5)
 - Per- and polyfluoroalkyl substances (PFAS) and their salts

■ Volatile organic compounds (VOC)

- VOCs regulated at the federal and state level (California, NY, Rhode Island etc...)
- Different limits and product categories for different states:
 - Hair products (Sprays, Mousses, Hairspray, Styling products, Styling gels)
 - Nail polish remover
 - Scented products
 - Shaving product (cream, gel)
 - Antiperspirant
 - Deodorants
 - Temporary colouring product (aerosol)
 - Dry shampoos

	USA (EPA)	Ohio	Maryland	California				Utah	New Hampshire	Delaware
				Actual	effective date 01/01/2023	effective date 01/01/2029	effective date 01/01/2031			
Sprays pour cheveux (Hair finishing spray)	80	55	55	55	50	50	50	6	55	55
Mousses pour cheveux	16	6	6	6	6	6	6	6	6	6
Laque (Hair shine)	55	55	55	55	55	50	50	55	55	55
Produit coiffant (Hair styling) : aérosol et pompe	6	6	6	6	6	6	6	6	6	6
Produit coiffant (Hair styling) : autres formes	2	2	2	2	2	2	2	2	2	2
Gels coiffants	6	6	/	6	6	6	6	6	6	6
Dissolvants pour les ongles	85	75	1	1	1	1	1	1	1	1
Produits parfumés contenant ≤ 20% de concentré	/	/	/	75	Cette catégorie a été remplacée par les catégories "aérosols" et "non aérosol", Voir ci-dessous			/	/	/
Produits parfumés > 20% de concentré	/	/	/	65	Cette catégorie a été remplacée par les catégories "aérosols" et "non aérosol", Voir ci-dessous			/	/	/
Produits parfumés aérosol	/	/	/	/	70	70	50	/	/	/
Produits parfumés non aérosol	/	/	/	/	≤ 7% fragrance 70	≤ 7% fragrance 70	≤ 10% fragrance 50	/	/	/
Produits parfumés non aérosol > 7%	/	/	/	/	> 7% fragrance 75	> 7% fragrance 75	> 10% fragrance 75	/	/	/
Crème de rasage	5	5	5	5	5	5	5	/	5	5
Gel de rasage	/	7	4	4	4	4	4	/	4	4

Labelling





Principal Display Panel (PDP):

- Declaration of identity
- Net amount of content

Information Panels :

- Company name and address
- Distributor's declaration
- Material facts
- Warnings and precautions
- Ingredients (INCI)

Information
Panel

INGREDIENTS: SESAMUM
INDICUM (SESAME SEED) OIL,
PRUNUS AMYGDALUS DULCIS
(SWEET ALMOND) OIL, SIMMONDIA
CHENSIS (JOJOBA)
OIL, LINNANTHUS ALBA
(MEADOWFOAM SEED) OIL,
ELITYROSPERMUM PARKEI
(SHEA BUTTER), TOCOPHERYL
ACETATE, TOCOPHEROL
(VITAMIN E), BISABOLOL,
FRAGRANCE

Paraben-Free
Colorant-Free
Non-Comedogenic
No Animal Testing



HDPE



Made in U.S.A



HEALTHY SKIN CARE
FOR ACTIVE PEOPLE

RELAXING
BODY OIL

WITH
ORGANIC PLANT OILS
VITAMIN E & BISABOLOL

NET WT. 3.6 FL. OZ. (100 ML)

LIGHT NATURAL OIL
FORMULA THAT DEEPLY
MOISTURIZES SOOTHES
AND NOURISHES THE
SKIN. GLIDES ON EASILY
AND VANISHES INTO
SKIN LEAVING THE SKIN
SOFT, SUPPLE AND WITH
A HEALTHY GLOW.
99.5% ORGANIC OILS.
DIRECTIONS: SMOOTH
LIBERALLY OVER ENTIRE
BODY IDEALLY ON
SLIGHTLY DAMP SKIN
AFTER BATHING.

SHENUI Inc.
SEATTLE, WA 98104

WWW.SHENUI.COM
1-877-743-6840

Principal
Display
Panel

Claims



- No regulatory framework
- Paying attention to definitions
- May cause the product to be classified as OTC/drug/medical device





- FDA Warning Letters
- Official message from the US FDA to a manufacturer who broke the rules
- Used to understand the philosophy of the FDA
- As a "case law"

- Beware of consumer groups
- Claims, effectiveness of products +++

Unaccepted Claims

A healthy skin barrier will help reduce the severity of skin conditions that are common with diabetes

A natural antiseptic and antibacterial

A neuropeptide that gives Botox-like results, it works synergistically with X and increases the benefits... caused by the muscle contractions of facial expressions

A powerful whitener and collagen protector

A pure plant extract, which acts to help microcirculation, and assists GABA in communicating its muscle relaxation message

A reduction in cellulite in just two weeks

A skin respiratory factor that helps skin cells to promote the healing process through the uptake of oxygen

A super anti-oxidant... eliminates age spots, contains protection from ultraviolet A and B and boosts collagen synthesis

Abolishing wrinkles has never been so easy

Accelerates cell renewal

Activates epidermal regeneration and targets damage done by free radical agents

Acts as a topical Botox

Add [x] Intensive Nourishing Cream with Anti-Inflammatory, Keratolytic & Barrier Repair technology to your regimen.

Adds UV protective qualities as well as essential fatty acids

Advanced collagen boosters and botox alternatives that actually work

Age-repairing antioxidant that encourages collagen production

Aid in reducing skin inflammation

Allow blood vessels to relax and improve circulation

Allowing foam for new cell growth.

Allowing the stem cells to increase their potency and promote cell regeneration, tissue is reconstructed to a denser quality and more elastic skin

Amazing product for a vast variety of skin ailments

An age-repairing antioxidant that promotes the regeneration of damaged skin

Security and PIF



Product information file

- Obligation to place safe products on the market
- If claim: substantiation of claim
- No requirement for a PIF or security assessment
 - But can help to demonstrate the security of product
- No concept of a responsible person



Safety responsibility = marketer

■ Product information file

Authorized

- USA

Prohibitions

- California
- Virginie
- Nevada
- Illinois
- Hawaï
- Maine
- Maryland

■ Good manufacturing process

- US cosmetic GMP (draft)
- ISO 22716



■ Cosmetovigilance

- No obligation to report AEs or SAEs but strongly recommended
- Security obligation +++.
- Via the MedWatch system

Report a Problem

How to Report a Problem

You can report a problem with a cosmetic to FDA in either of these ways:

- 1. Contact MedWatch**, FDA's Safety Information and Adverse Event Reporting Program:
 - By Phone: **1-800-FDA-1088**
 - Online: File a voluntary report at <http://www.fda.gov/medwatch>
- 2. Contact a Consumer Complaint Coordinator** in your area. Locate one here: <http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators>

Who Should Report a Problem

A consumer, a healthcare provider, or a salon professional can report a problem.

What Information to Provide in Your Report

When you contact FDA, you are asked to include the following information in your report, if known:

- **About the Person Affected**
 - Name and contact information (address, phone, and e-mail address)
 - Age, gender, and ethnicity
- **About the Product**
 - Name of the product and the manufacturer
 - Product codes or identifying marks on the label or container *[Note: do not discard the product packaging and labeling. They provide information that will help FDA investigate the problem]*
 - When and where the product was purchased
- **About the Problem**
 - Description of the reaction or problem
 - Description of medical treatment provided, if any



Cosmetic regulation in Canada

- Regulatory framework



Santé
Canada

Health
Canada

- Food and Drugs Act (FDA)
- Canada Consumer Product Safety Act
- Consumer Packaging and Labelling Act
- **Cosmetic Regulations**



Regulations straddling the US and Europe



Definitions and classification



Cosmetics

Substances or mixtures of substances manufactured, sold or represented for use in **cleansing, improving or altering the complexion, skin, hair or teeth**, including deodorants and perfumes

Drug

- Drugs include substances or mixtures of substances manufactured, sold or represented for use in :
 - a) the **diagnosis, treatment, mitigation or prevention of a disease**, disorder or abnormal physical state, or its symptoms, in humans or animals;
 - b) the **restoration, correction or modification of organic functions** in humans or animals;
 - c) **disinfection of premises** where food is kept.

Natural Health Products

A substance set out in Schedule 1, a combination of substances in which all the medicinal ingredients are substances set out in Schedule 1, a homeopathic medicine or a traditional medicine that is manufactured, sold or represented for use in :

- **(a) the diagnosis, treatment, mitigation or prevention of a disease**, disorder or abnormal physical state, or its symptoms, in human beings
- **(b) the restoration or correction of organic functions** in humans;
- **(c) the modification of organic functions in humans**, such as the modification of those functions so as to maintain or promote health.

Classification

Cosmetics

- Moisturizing skin creams
- Fragrances
- Eye and face make-up
- Nail products
- Cleansing shampoos
- Products for indefinite periods,
- Hair dyes
- Deodorants
- Oral care products (cleaning)
- Anti-aging products
- Anti-stain products
- Soap
- Etc...

OTC / PSN

- Sun protection product
- Anti-dandruff shampoos
- Acne products
- Anti-cavity toothpastes
- Antiperspirant
- Aromatherapy
- Skin antiseptic products
- Medicated skin care products



■ Classification criteria

The classification of products is done according to :

- From the **presentation**
 - **Consumer perception**
- About the **composition**
- The level of **action**
- Additional criteria:
 - Benefit/risk balance
 - Previous decisions
 - **International classification**

Registration



- Mandatory online declaration within 10 days of placing products on the market
- No pre-approval from authorities

- **Section 1: Type of Report**

- **Section 2: Product**

- Name of the product (brand, common name etc...)
- Identity of the declarant
- Date of sale of the product
- Other name of the product (variant, colors, fragrances etc...)
- Product description
- Application area
- Product function
- Product shape

- **Section 3: Declarant**

- Company name and address
- Website
- Contact person
- Email address
- Phone

- **Section 4: Manufacturing and Distribution**

- Type of contact person (distributor - manufacturer - importer)
- Company name
- Name of contact person

- **Section 5: Ingredients**

- Name of the ingredient
- Concentration range
- Condition of use

- **Section 6: Documents and Images**

- Product label(s) if specific warning

Controlled substances



- Hot List
 - List of prohibited substances
 - Restricted Substances List

No positive list (dye - preservative)



Liste des ingrédients dont l'usage est interdit dans les cosmétiques

A B C D E F G H I J L M N O P S T U V W X Y Z

Substance chimique	No CAS (incluant mais sans s'y limiter) ¹	Synonymes et composés apparentés (incluant, sans s'y limiter) ²
1- et 2-Naphtylamines et leurs sels	134-32-7; 91-59-8	
1-(4-Méthoxyphényl)-1-pentène-3-one	104-27-8	α -methylanisalacetone
1,2-Époxybutane	106-88-7	
1,3-Diméthylpentylamine et ses sels	105-41-9	
11- α -Hydroxyprégn-4-ène-3,20-dione et ses esters	80-75-1	
1-Butyl-3-(N-crotonoylsulfanilyl) urée	52964-42-8	2-Butenamide, N-[4- [[[(butylamino)carbonyl]amino]sulfonyl]phenyl]-; Crotonoylcarbutamide
1-Méthoxy-2,4-diaminobenzène et ses sels	615-05-4	2,4-diaminoanisole; CI 76050
1-Méthoxy-2,5-diaminobenzène et ses sels	5307-02-8	2,5-diaminoanisole

Liste des ingrédients dont l'utilisation est restreinte dans les cosmétiques

Les ingrédients suivants sont seulement permis dans les produits cosmétiques selon les conditions spécifiées ci-dessous :

Les mises en garde et précautions nécessaires doivent être présentes sur l'étiquette en anglais et en français.

A B C D E F G H I K M P S T U Z

Information sur l'ingrédient			Restrictions		
Substance chimique	Numéro de registre CAS (incluant mais sans s'y limiter) ¹	Synonymes et composés apparentés (incluant, sans s'y limiter) ²	Conditions d'utilisation selon le type de produit ³	Concentration maximale permise ⁴	Mises en garde et précautions nécessaires (énoncé qui précise ce qui suit) ⁵
1-Naphthol, et ses sels	90-15-3		a) Dans les teintures pour les cheveux lorsqu'utilisé comme agent oxydant seulement	a) 2 %	
			b) En combinaison avec du peroxyde d'hydrogène	b) 1 %	
2-Bromo-2-nitropropane-1,3-diol	52-51-7		a) Interdit dans les cosmétiques contenant des amines ou des amides.		

Mentions	Language	Product with an inner and external label		Product with an external label only	Comments
		Inner label	External label		
Identity of the product (function of the product)	English + French	X	X	X	Mandatory mention except when the function is obvious
Net quantity	English + French or bilingual unit of measurement	X		X	In bold letters
Name and address of the manufacturer	English or French or English + French	X	X	X	Or the one of the distributors for imported product
Precautions of use, caution and instructions	English + French	See the specific requirements for each category of product or sort of packaging			
Ingredients list	INCI	X		X	For small containers or decorative containers: card attached

Claims



Guidelines for the Nonprescription and Cosmetic Industry Regarding Non-therapeutic Advertising and Labelling Claims

Skin Care/Makeup



NON-THERAPEUTIC CLAIMS

- Heals dry skin
- Repairs dry skin
- Replenish/Protect the skin's moisture barrier
- Protects/Relieves/Soothes dry skin
- Cools/Soothes skin after shaving/epilation
- Cleans/Cleanses skin
- Prevents/Protects against nicks/cuts/irritation during shaving
- Hydrates/Lubricates/Moisturizes
- Reinforces/Strengthens skin (via moisturization)
- Improves the look of acne scars
- Relieves redness/itching due to dryness
- Reduces the look of age spots

THERAPEUTIC/HEALTH CLAIMS

- Heals (unqualified)
- Repairs (damaged) skin
- Repairs the skin's moisture barrier
- Calms/Protects/Relieves/Soothes abrasions/bites/insect bites/ cuts/nicks/irritated skin/ inflamed skin/rashes/ sunburns*
- Numbs
- Treats burns/infections
- Any impression or reference to pain or irritation
- Removes/Reduces scars
- Reduces redness due to rosacea (or other circulatory-related causes)
- Reduces redness (due to sunburns)
- Any reference to rosacea
- Eliminates age spots
- Prevents new spots from appearing**
- Prevents the onset/emergence of age spots**
- Any impression or reference to skin de-pigmentation

Security and PIF



Product information file

- Obligation to place safe products on the market
- If claim: substantiation of claim
- No requirement for a PIF or security assessment
 - But can help to demonstrate the security of product
- No concept of a responsible person

Animal testing

- Not ban



Safety responsibility = marketer

■ Good manufacturing process

- ISO 22716



■ Cosmetovigilance

Under the **Canada Consumer Product Safety Act**, industry must report any health or safety incident related to a consumer product.

Industry should provide the following detailed information:

•Product Information

- Product name and brand
- Product description
- Where the product was obtained (store or other)
- Recommended age on packaging
- Numbers on the product or on the packaging
 - Serial number
 - Model number

• Universal Product Code (UPC)

- Date of manufacture or import
- Date of purchase of the product
- Place of manufacture or origin of the product (address)

•Incident Information

- Injured persons
- Type of injury
- Date of incident
- Description of the incident
- Type of medical care received



Thank you for your attention