SUMMARY OF THE CALIFORNIA
CLEANING PRODUCT RIGHT TO KNOW ACT OF 2017

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I INTRODUCTION

On October 15, 2017, Governor Brown signed into law the California Cleaning Product Right to Know Act of 2017 ("Act"). This law requires manufacturers of cleaning products to disclose ingredient information on both the product's label and on the company's Web site.

This summary is prepared specifically for the members of ISSA, and provides an overview of the following:

- Scope of products subject to the ingredient disclosure requirements
- Entities responsible for disclosing ingredient information
- Ingredient and other information that must be disclosed via the Web and product label

This summary provides a general overview of the Act. However, members are encouraged to review the complete text of the Act in conjunction with this summary to fully assess their obligations.

II SCOPE OF COVERAGE

This section will: define the scope of cleaning products subject to the ingredient disclosure requirements of the Act; describe those product categories exempt from the disclosure requirements; and discuss the entities that are responsible for such disclosure.

A. Products Subject to Disclosure under the Program. A critical first step in your compliance journey is defining the cleaning products that are subject to the ingredient disclosure requirements of the Act.

The Act's ingredient disclosure requirements apply to **"designated products"** that in turn is defined as: "a finished product that is an air care product, automotive product, general cleaning product, or a polish or floor maintenance product used primarily for janitorial, domestic or institutional cleaning purposes."

> **1. Air Care Products:** products intended to enhance or condition the indoor environment by eliminating unpleasant odors or freshening the air.
>
> **2. Automotive Products:** products intended to maintain the appearance of a motor vehicle including products for washing, waxing, polishing, cleaning, or treating the

exterior or interior surfaces of motor vehicles. Does not include automotive paint or paint repair products.

3. General Cleaning Products: this category includes soaps, detergents or other products the purpose of which is to clean, disinfect, or otherwise care for: fabric, dishes, or other wares; surfaces including but not limited to floors, furniture, countertops, showers, and baths; or other hard surfaces, such as stove tops, microwaves, and other appliances. Examples of covered products under this category include:

- General purpose cleaners
- Glass cleaners
- Disinfectants (Web site only; exempt from labeling provisions)
- Floor cleaners
- Laundry and dish detergents
- Bathroom and tile cleaners
- Carpet cleaners

4. Polish or Floor Maintenance Products: this category includes products such as polishes, waxes, or restorers, labeled to indicate that the purpose of the product is to polish, protect, buff, condition, temporarily seal, or maintain furniture, floors, metal, leather, or other surfaces.

B. Household and Institutional Products. The Act's definition of "designated products" includes the aforementioned cleaning products that are intended for either household, institutional, or janitorial cleaning purposes.

C. Sold in the State. In order to be subject to the ingredient disclosure requirements of the Act, the designated product must be sold in the state of California in addition to meeting the definitions set forth above.

D. Products That are Exempt from the Disclosure Requirements of the Act.

1. Foods, drugs, and cosmetics, including personal care items such as

- Toothpaste
- Shampoo
- Hand soap
- Hand sanitizers (rubs and washes)

2. Industrial products specifically manufactured for, and exclusively used in, the following:

- Oil and gas production.
- Steel production.
- Heavy industry manufacturing.
- Industrial water treatment.
- Industrial textile maintenance and processing other than industrial laundering.
- Food and beverage processing and packaging.

- Other industrial manufacturing processes.

3. A trial sample of a designated product that is not packaged for individual sale, resale, or retail and includes a statement indicating that the product is not for sale or resale.

E. Who Must Disclose. Under the Program the **manufacturer** has primary responsibility for disclosing ingredients in covered products. Please note, however, that the Act defines "manufacturer" in such a manner as to also include **private label distributors** in addition to "traditional" manufacturers.

Specifically, "manufacturer" is defined by the Act as:

1. A person or entity who manufactures the designated product and whose name appears on the product label; or

2. A person or entity who the product is manufactured for or distributed by, as identified on the product label pursuant to the federal Fair Packaging and Labeling Act.

From California's perspective, if there is reason to question a product's compliance with the disclosure requirements, the official inquiry will typically start with the entity whose name appears on the label (i.e., private label distributor, manufacturer).

E. Method of Disclosure. The Act requires ingredient information to be disclosed on <u>both</u> the product label and the manufacturer's Web site.

III PRODUCT LABEL INGREDIENT DISCLOSURE (Section 108954)

A manufacturer of a designated product sold in California must disclose ingredient information on the product label according to one of the following options provided under the Act, and described below. Effective date for label disclosure is January 1, 2021. Products manufactured prior to that date are not subject to the disclosure requirements provided they display a date of manufacture (or code indicating such).

A. Option No. 1: Label Disclosure. Under this option, the product label must set forth the following ingredient information:

1. Intentionally Added Ingredients. A list of each "intentionally added ingredient" contained in the product that is included on a "designated list" (See Section VIII for definitions).

2. Fragrance Allergen. A list of each fragrance allergen included on Annex III of the EU Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004 on January 1, 2018, when present in the product at a concentration at or above 0.01 percent (100 ppm). The manufacturer shall determine the total concentration of each fragrance allergen by adding contributions of the fragrance

allergen from all fragrance ingredients and other ingredients in the designated product, including its presence in essential oils.

3. Prop 65 Ingredients. Notwithstanding No. 1 above, an intentionally added ingredient listed under California Proposition 65 is not required to be disclosed on the product label until January 1, 2023.

B. Option No. 2: Label Disclosure. Under this option, the product label must set forth the following ingredient information:

1. Intentionally Added Ingredients. A list of all intentionally added ingredients contained in the designated product unless it is confidential business information. (See discussion at §VI below on Confidential Business Information.)

Note: fragrance ingredients or colorants may be listed on the product label as "fragrances" or "colorants," respectively.

2. Fragrance Allergen. A statement that reads "Contains fragrance allergen(s)" shall be included on the product label when a fragrance allergen included on Annex III of the EU Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004, or subsequent updates to those regulations, is present in the product at a concentration at or above 0.01 percent (100 ppm). The manufacturer shall determine the total concentration of each fragrance allergen by adding contributions of the fragrance allergen from all fragrance ingredients and other ingredients in the designated product, including its presence in essential oils.

3. Prop 65 Ingredients. Notwithstanding No. 1 above, an intentionally added ingredient that is on the California Proposition 65 list is not be required to be listed on the product label until January 1, 2023.

C. Web Site and Toll-Free Number. In addition, under either option above, the manufacturer must list on the product label the manufacturer's toll-free telephone number and Web site address.

Furthermore, if a designated product label does not include a full list of intentionally added ingredients, it shall include the following information:

1. A statement that reads: "For more ingredient information visit _____"

2. A Web site address that provides all of the information required by Section 108954.5 of the Act (see discussion below on Web site disclosure in Section IV).

3. A toll-free phone number.

D. Disinfectants. Disinfectant products are not subject to the above product label ingredient disclosure requirements, but are subject to the Web site disclosure requirements discussed in Section IV below.

IV WEB SITE INGREDIENT DISCLOSURE (Section 108954.5)

Manufacturers must post ingredient and other information discussed below in this section for each designated product on their Web sites in an "electronically readable format" (see §VIII for definition). Effective date for Web site disclosure is January 1, 2020. Products manufactured prior to that date are not subject to the disclosure requirements provided they display a date of manufacture (or code indicating such).

A. Intentionally Added Ingredients. A list of all intentionally added ingredients contained in the product except for the following:

1. Fragrance ingredients that are subject to disclosure under Section B below

2. Intenti**o**nally added ingredients that are considered confidential business information

Prop 65 substances are not required to be listed until January 1, 2023.

Intentionally added ingredients shall be 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.

B. Nonfunctional Constituents. A list of all "nonfunctional constituents" (as defined in §VIII below) present in the designated product at a concentration at or above 100 ppm.

1. Prop 65 Substance. A nonfunctional constituent that is also a Prop 65 substance shall also be included on the list of nonfunctional constituents.

2. 1, 4 dioxane. Notwithstanding the above, 1,4 dioxane must be listed if it is present in the finished product at a concentration at or above 10 ppm.

C. CAS Numbers. For each intentionally added ingredient or nonfunctional constituent, the Chemical Abstract Service (CAS) number shall be listed along with the name of the ingredient. If a CAS number is not available or if the ingredient is considered confidential business information, the phrase "not available" or "withheld" respectively.

D. Functional Purpose. Include the functional purpose served by each intentionally added ingredient. For fragrance ingredients or colorants, the manufacturer may list the function as a "fragrance ingredient" or "colorant."

E. Links to Designated Lists. Electronic links for designated lists shall be grouped together in a single location for any intentionally added ingredient or nonfunctional constituent that is included on a designated list and any fragrance allergen included on Annex III of the EU

Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004, or subsequent updates to those regulations.

F. Safety Data Sheets. A link must be provided to the Safety Data Sheet required by OSHA.

G. Accessibility. If a product is required to include a Web site address pursuant to paragraph (1) of subdivision (b) of Section 108954 (see discussion at Section III(C) above), the information required to be provided by this Section IV shall be posted no more than five clicks from the Uniform Resource Locator (URL) printed on the designated product label and no more than four clicks from a product-specific Web site. If a URL is not required to be included on the designated product label (i.e., all intentionally added ingredients are listed on label), the information required by this Section IV shall be posted no more than five clicks from the manufacturer's Web site and no more than four clicks from a product-specific Web site.

H. Additional Information. In addition to the information required above, the manufacturer of a designated product shall post on its Web site, in an electronically readable format, all of the following information related to **fragrance ingredients or allergens** contained in the designated product:

1. A list of all fragrance ingredients that are included on a designated list.

2. A list of all fragrance allergens included on Annex III of the EU Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004, or subsequent updates to those regulations, when present in the product at a concentration at or above 0.01 percent (100 ppm). The manufacturer shall determine the total concentration of each fragrance allergen by adding contributions of the fragrance allergen from all fragrance ingredients and other ingredients in the designated product, including its presence in essential oils.

3. Notwithstanding paragraph No. 1 above, a fragrance ingredient that is listed on California's Prop 65 list shall not be required to be listed until January 1, 2023.

4. A list of all fragrance ingredients, other than those described in paragraphs No. 1 to 3, inclusive, that are present in the designated product at a concentration at or above 0.01 percent (100 ppm), unless it is confidential business information.

I. OSHA Hazard Communication Standard. Manufacturers of designated products regulated under the OSHA Hazard Communication Standard shall make the information set forth in this Section IV available in an "easily printable format." A manufacturer may satisfy this requirement by including this information on the product's SDS or in a separate printable list.

J. Percentages, Quantity of Ingredient Present. Manufacturers are <u>NOT</u> required to disclose the weight or amount of an intentionally added ingredient, including a fragrance ingredient, or nonfunctional constituent, present in a designated product.

V NOMENCLATURE

An intentionally added ingredient, fragrance ingredient, or nonfunctional constituent required to be disclosed (and not protected as CBI) shall be listed or posted pursuant to the following nomenclature systems, in the order in which they are listed. If a name is available in either of the first listed systems, that name shall be used. If a name is not available in those systems, then a name from the next listed system shall be used, and so forth.

A. Household and Commercial Products Association Consumer Product Ingredients Dictionary (HCPA Dictionary) or International Nomenclature of Cosmetic Ingredients (INCI).

B. International Union of Pure and Applied Chemistry nomenclature (IUPAC).

C. Chemical Abstracts Index name.

D. Common Chemical Name.

VI CONFIDENTIAL BUSINESS INFORMATION (Section 108955)

A. General. In order to protect confidential business information, the Act does NOT require manufacturers to:

1. Disclose the weight or amount of an intentionally added ingredient, including a fragrance ingredient, or nonfunctional constituent, present in a designated product,

2. Disclose how a product is manufactured,

3. List intentionally added ingredients or nonfunctional constituents present in a designated product at a concentration below one percent (1%) in any particular order.

B. Confidential Business Information. A manufacturer may protect and is not required to disclose any intentionally added ingredient, including any fragrance ingredient, or combination of intentionally added ingredients that meet the definition of confidential business information as defined in the Act, and reproduced below.

"Confidential business information" means any intentionally added ingredient or combination of ingredients for which a claim has been approved by the federal Environmental Protection Agency for inclusion on the Toxic Substances Control Act (TSCA) Confidential Inventory, OR for which the manufacturer or its supplier claim protection under the California Uniform Trade Secrets Act as required by Section 108955 of the Act. Confidential business information shall NOT include any of the following:

1. An intentionally added ingredient or combination of ingredients that is on a designated list, as defined in the Act (See § VIII Definitions below).

2. A nonfunctional constituent, as defined in the Act and §VIII Definitions below.

3. A fragrance allergen included on Annex III of the EU Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004, or subsequent updates to those regulations, when present in the product at a concentration at or above 0.01 percent (100 ppm).

A "trade secret" is defined by the California Uniform Trade Secrets Act as information, including a formula, pattern, compilation, program, device, method, technique, or process, that:

- Derives independent economic value, actual or potential, from not being generally known to the public or to other persons who can obtain economic value from its disclosure or use; and
- Is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

C. What to Disclose when Claiming Confidential Business Information (CBI). When a manufacturer is protecting certain ingredient information as CBI, it must still disclose some general identify information about the ingredient as set forth below.

1. A manufacturer that protects an intentionally added ingredient, including a fragrance ingredient, or combination of intentionally added ingredients as CBI by declining to disclose the specific name of the chemical or chemicals being protected shall use the **generic name** for the intentionally added ingredient or combination of intentionally added ingredients as provided in the federal Toxic Substances Control Act (TSCA) Confidential Inventory.

2. If the intentionally added ingredient or combination of intentionally added ingredients is not included in the TSCA Confidential Inventory, but the manufacturer claims protection for those ingredients or combination of ingredients as CBI under the California Uniform Trade Secrets Act, the manufacturer shall use a name for the intentionally added ingredient or combination of intentionally added ingredients that is only as generic as necessary to protect the confidential identity of the intentionally added ingredient or combination of intentionally added ingredients.

In developing the generic name, the manufacturer shall use the generic name framework provided by the federal Environmental Protection Agency guidance for the TSCA Confidential Inventory, the European Chemicals Agency guidance for alternative chemical names, the New Jersey Trade Secret Registry Number system, or the Canadian Hazardous Materials Information Review Act Registry Number system, if applicable.

D. Justification for CBI. A manufacturer that protects an intentionally added ingredient, including a fragrance ingredient, or combination of intentionally added ingredients pursuant to the California Uniform Trade Secrets Act shall maintain justification for protecting CBI consistent with the requirements of the Act and provide that justification on request for audit by the Attorney General.

E. Supplier and CBI. A supplier to a manufacturer that protects an intentionally added ingredient, including a fragrance ingredient, or combination of intentionally added ingredients as CBI shall follow the guidelines specified in paragraphs B, C, and D above; and the manufacturer shall use the generic name provided by the supplier to identify the ingredient.

VII EFFECTIVE DATES AND UPDATES

A. The online ingredient disclosure requirements apply to a designated product sold in the state on or after January 1, 2020.

B. The product label disclosure requirements apply to a designated product sold in the state on or after January 1, 2021.

C. A manufacturer may label a designated product manufactured before January 1, 2021, in accordance with the Act.

D. A designated product manufactured prior to the effective dates specified above does not need to comply with the ingredient disclosure provisions of the Act if the designated product displays either of the following on the designated product:

1. The day, month, and year of manufacture of the product, or

2. A code indicating the date described in paragraph 1 above.

E. Updates to Online Disclosures. A manufacturer that is required to make a revision to information disclosed **online** pursuant to due to a change in a designated trait list or in Annex III of the EU Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004 shall make the revision no later than **six months** after the adoption of the revised list by its authoritative body, unless a later effective date for changes is imposed pursuant to California Proposition 65 or Annex III of the EU Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004.

F. Update to Product Label Disclosures. A manufacturer that is required to make a revision to information disclosed on a product label pursuant due to a change in a designated trait list or in Annex III of the EU Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004 shall make the revision no later than **18 months** after the adoption of the revised list by its authoritative body, unless a later effective date for changes is imposed pursuant to California Proposition 65 or Annex III of the EU Cosmetics Regulation No. 1223/2009 as required to be labeled by the EU Detergents Regulation No. 648/2004.

G. Updates Due to Changes in Chemical Naming Protocols. A manufacturer shall make any revision required because of a change in the chemical naming protocols (set forth in § V above) when it revises its label pursuant to paragraph F above in this section.

H. A designated product manufactured prior to the expiration of the time periods described in paragraph E or F above in this section shall be deemed in compliance with this chapter if the designated product displays either of the following on the designated product:

1. The day, month, and year of manufacture of the product, or

2. A code indicating the date described in paragraph 1.

I. Date Code. If a manufacturer uses a code to indicate the date on the product, the manufacturer shall provide a statement on the manufacturer's Web site that indicates that the information on the date of manufacture of a designated product may be obtained by calling a toll-free phone number and shall provide the toll-free phone number, or post on the manufacturer's Web site how to determine the date from the code on the designated product.

VIII DEFINITIONS

The following is a partial reproduction of the pertinent definitions that are set forth in the Act. Definitions not included below are set forth in the body of the document in relevant sections.

A. Designated List: means any of the following, including subsequent revisions when adopted by the authoritative body:

1. Chemicals known to the State of California to cause cancer or reproductive toxicity that are listed pursuant to the Safe Drinking Water and Toxic Enforcement Act of 1986 (Chapter 6.6 (commencing with Section 25249.5) of Division 20) (i.e., Prop 65 List).

2. Chemicals classified by the European Union as carcinogens, mutagens, or reproductive toxicants pursuant to Category 1A or 1B in Annex VI to Regulation (EC) 1272/2008.

3. Chemicals included in the European Union Candidate List of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006 on the basis of Article 57(f) for endocrine disrupting properties.

4. Chemicals for which a reference dose or reference concentration has been developed based on neurotoxicity in the federal Environmental Protection Agency's Integrated Risk Information System.

5. Chemicals that are identified as carcinogenic to humans, likely to be carcinogenic to humans, or as Group A, B1, or B2 carcinogens in the federal Environmental Protection Agency's Integrated Risk Information System.

6. Chemicals included in the European Chemicals Agency Candidate List of Substances of Very High Concern in accordance with Article 59 of Regulation (EC) 1907/2006 on the basis of Article 57(d), Article 57(e), or Article 57(f) of Regulation (EC) 1907/2006

for persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative properties.
7. Chemicals that are identified as persistent, bioaccumulative, and inherently toxic to the environment by the Canadian Environmental Protection Act Environmental Registry Domestic Substances List.

8. Chemicals classified by the European Union in Annex VI to Regulation (EC) 1272/2008 as respiratory sensitizer category 1.

9. Group 1, 2A, or 2B carcinogens identified by the International Agency for Research on Cancer.

10. Neurotoxicants that are identified in the federal Agency for Toxic Substances and Disease Registry's Toxic Substances Portal, Health Effects of Exposure to Substances and Carcinogens, Nervous System.

11. Persistent bioaccumulative and toxic priority chemicals that are identified by the federal Environmental Protection Agency National Waste Minimization Program.

12. Reproductive or developmental toxicants identified in Monographs on the Potential Human Reproductive and Developmental Effects published by the federal National Toxicology Program, Office of Health Assessment and Translation.

13. Chemicals identified by the federal Environmental Protection Agency's Toxics Release Inventory as Persistent, Bioaccumulative and Toxic Chemicals that are subject to reporting under Section 313 of the Emergency Planning and Community Right-to-Know Act of 1986 (42 U.S.C. Sec. 11001, et seq.).

14. The Washington Department of Ecology's Persistent, Bioaccumulative, Toxic (PBT) Chemicals identified in Chapter 173-333 of Title 173 of the Washington Administrative Code.

15. Chemicals that are identified as known to be, or reasonably anticipated to be, human carcinogens by the 13th Report on Carcinogens prepared by the federal National Toxicology Program. Subsequent revisions to this list shall not be incorporated.

16. Chemicals for which notification levels, as defined in Section 116455, have been established by the State Department of Public Health or the State Water Resources Control Board.

17. Chemicals for which primary maximum contaminant levels have been established and adopted under Section 64431 or 64444 of Title 22 of the California Code of Regulations.

18. Chemicals identified as toxic air contaminants under Section 93000 or 93001 of Title 17 of the California Code of Regulations.

19. Chemicals that are identified as priority pollutants in the California water quality control plans pursuant to subdivision (c) of Section 303 of the federal Clean Water Act and in Section 131.38 of Title 40 of the Code of Federal Regulations, or identified as pollutants by the state or the federal Environmental Protection Agency for one or more water bodies in the state under subdivision (d) of Section 303 of the federal Clean Water Act and Section 130.7 of Title 40 of the Code of Federal Regulations.

20. Chemicals that are identified with noncancer endpoints and listed with an inhalation or oral reference exposure level by the Office of Environmental Health Hazard Assessment pursuant to paragraph (2) of subdivision (b) of Section 44360.

21. Chemicals identified as priority chemicals by the California Environmental Contaminant Biomonitoring Program pursuant to Section 105449.

22. Chemicals that are identified on Part A of the list of Chemicals for Priority Action prepared by the Oslo and Paris Conventions for the Protection of the Marine Environment of the North-East Atlantic.

B. Electronically Readable Format: means that the information provided is all of the following:

1. Machine readable by automated systems, including, but not limited to, Web browsers, accessibility software to aid the disabled, automated scripts, and other software programs or applications.

2. Not restricted from access by search engines.

3. Not restricted from access by a requirement for registration, the provision of personally identifiable information, or the use of CAPTCHA or similar challenge response test technologies, whether visual, auditory, or otherwise.

4. Conforms to the most current version of the Web Content Accessibility Guidelines (WCAG) adopted by the Web Content Accessibility Guidelines Working Group of the World Wide Web Consortium.

C. Fragrance Ingredient: means any intentionally added substance or complex mixture of aroma chemicals, natural essential oils, and other functional ingredient or ingredients for which the sole purpose is to impart an odor or scent, or to counteract an odor.

D. Intentionally Added Ingredient: means a chemical that a manufacturer has intentionally added to a designated product and that has a functional or technical effect in the designated product, including, but not limited to, the components of intentionally added fragrance ingredients and colorants and intentional breakdown products of an added chemical that also have a functional or technical effect in the designated product.

E. Nonfunctional Constituent: means one of the following substances, that is an incidental component of an intentionally added ingredient, a breakdown product of an intentionally added ingredient, or a byproduct of the manufacturing process that has no functional or technical effect on the designated product:

1. 1,4-Dioxane.
2. 1,1-Dichloroethane.
3. Acrylic acid.
4. Benzene.
5. Benzidine.
6. 1,3-Butadiene.
7. Carbon tetrachloride.
8. Chloroform.
9. Ethylene oxide.
10. Nitrilotriacetic acid.
11. Butyl benzyl phthalate.
12. Butyl decyl phthalate.
13. Di(2-ethylhexyl) phthalate.
14. Diethyl phthalate.
15. Diisobutyl phthalate.
16. Di(n-octyl) phthalate.
17. Diisononyl phthalate.
18. Dioctyl phthalate.
19. Butylparaben.
20. Ethylparaben.
21. Isobutylparaben.
22. Methylparaben.
23. Propylparaben.
24. Formaldehyde.
25. 1-(3-chloroallyl)-3,5,7-triaza-1-azoniaadamantane chloride.
26. DMDM hydantoin.
27. Diazolidinyl urea.
28. Glyoxal.
29. Imidazolidinyl urea.
30. Polyoxymethylene urea.
31. Sodium hydroxymethylglycinate.
32. 2-Bromo-2-nitropropane-1,3-diol.
33. N-Nitrosodimethylamine.
34. N-Nitrosodiethylamine.

F. Product Label: means a display of written, printed, or graphic material that is affixed to a product or its immediate container or wrapper.