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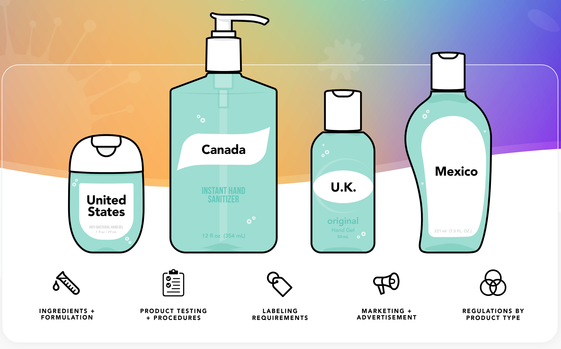
Pathway to Market
Hand Sanitizer

What you need to know about navigating regulatory guidelines and requirements to get your product to market in the United States, Canada, U.K. or Mexico.

When a company needs advice on product safety compliance measures, Shook, Hardy & Bacon can provide counsel to minimize the risk of costly government enforcement actions and litigation, while safeguarding the company's reputation. Our attorneys take a 360-degree approach to consumer product issues, protecting our clients' interests with regulators, in the media and through litigation.



INGREDIENTS + FORMULATION | PRODUCT TESTING + PROCEDURES | LABELING REQUIREMENTS | MARKETING + ADVERTISEMENT | REGULATIONS BY PRODUCT TYPE

United States

REGULATORY VARIATIONS

Due to COVID-19, the Food and Drug Administration (FDA) issued an enforcement discretion guidance that outlines that FDA will not object to a manufacturer complying with several legal requirements if a hand sanitizer is formulated, labeled and manufactured according to the guidance. It is unclear how long FDA will maintain this enforcement discretion.

TENTATIVE FINAL MONOGRAPH

A hand sanitizer may be marketed without obtaining FDA premarket approval if the product is formulated, labeled and marketed according to the Tentative Final Monograph for a hand sanitizer. An Over-the-Counter (OTC) Drug Monograph is similar to a drug recipe, which details the active ingredients, drug labeling and sometimes additional testing or manufacturing requirements. The OTC Drug Monograph regime is being reformed due to a recent change in the law, so this route will be modified in the future.

HAND SANITIZER FACTS

Active Ingredients
Benzalkonium chloride, ethyl alcohol, or isopropyl alcohol

Purpose
Regulated as a drug by the FDA, generally without premarket approval.

Use Understand the basics for marketing a hand sanitizer.

Warnings Include warning specified in the Monograph and regulations, including: • External use only • Keeping out of eyes • Poison control instructions • When to seek medical help instructions

Directions
- Formulate product based on either: •Tentative Final Monograph (TFM), approved color additive, and safe and suitable inactive ingredients •Enforcement Discretion (only can use ethyl alcohol or isopropyl alcohol and a few specified inactive ingredients, no colorants permitted)
- Develop product labeling, including: • Statement of Identity • Net Quantity • Drug Facts Panel • Name and Address of Responsible Party • Lot Code • Expiration Date* • Adverse Event Reporting Contact Information
- Implement manufacturing and testing processes and procedures according to either: • Current Good Manufacturing Practices regulations and TFM • Enforcement Discretion
- Create Adverse Event Reporting system
- Register the manufacturing facility with FDA and list the product
- Limit advertising and promotional materials, including: • No therapeutic claims beyond the FDA established use statement, which includes specific reference to any disease, infection or germ • Adequate substantiation for non-therapeutic claims

Other Information May be regulated as a dual drug and cosmetic product in certain circumstances.
**Unless exempt.*

HAND SANITIZER FACTS

Active Ingredients
Natural Health Products (e.g., Ethanol, Isopropanol); Drug Products (e.g., Benzalkonium chloride, Chlorhexidine digluconate, Chlorhexidine gluconate, Triclosan)

Purpose
Regulated as a natural health product by Natural and Non-Prescription Health Products Directorate (NNHPD), or as a drug by the Therapeutic Products Directorate (TPD).

Use Understand basics for bringing antiseptic skin products intended for domestic/personal care use to market.

Warnings Include directions for use and monograph-specific warnings regarding: • External use • Avoiding contact with eyes, discussing with physician if irritation develops • Keeping out of reach of children • Flammability notifications with alcohol-based products and contraindication warning for chlorhexidine gluconate

Directions
- Apply for product license application to obtain a Natural Product Number through NNHPD (or apply for Drug Identification Number through TPD depending on ingredients).
- **Ingredients:** Choose from NHP Ingredients Database and follow its requirements, and those from the Food and Drug Regulations (FDR) and Cosmetic Ingredient Hotlist. Consider potential ingredient-specific NNHPD monographs.
- **Specs:** NHPs must comply with NNHPD Quality of NHPs Guide; and drugs should follow the FDR requirements. Include tests and methods for characterization, identity and quantity of ingredients, purity, potency, tolerance limits, contamination, stability and quality. Follow Good Agricultural and Collection Practices and applicable Good Manufacturing Practices (GMP) standards. Interim guidance permits use of alternative GMP standards.
- **Labeling:** Must follow Monograph except with authorization by Health Canada for altered or additional claims and should be bilingual (English/French). Additional directions for use and non-therapeutic claims can be acceptable if they meet additional guidelines. Obtain site license before manufacturing, labeling, or packaging.
- **Limit Claims/Uses to:** • Antiseptic, medicated, or antibacterial (skin) cleanser • Kills harmful bacteria/germs • Effective in destroying (harmful) bacteria to provide antiseptic cleansing or • For personal hand hygiene to help prevent the spread of bacteria. To state additional claims, including regarding % reduction, persistence, time kill, antiviral efficacy, or specific organisms, must seek authorization and follow specific testing requirements.

Other Information Any antimicrobial products intended for use by health care professionals, food handlers, in commercial settings, or that make claims outside the Monograph may also require additional efficacy, safety and quality testing.

Canada

REGULATORY VARIATIONS

Hand sanitizers are regulated differently depending on use and ingredients. In Canada, "antiseptic products for human use" that are intended for personal or domestic use should follow the Antiseptic Skin Cleansers (Personal Domestic Use) Monograph (described adjacent). Any products that do not meet the Monograph criteria (e.g., additional or specific claims) or are intended for professional or commercial settings, should follow Health Canada's Human-Use Antiseptic Drug Guidance. In addition, due to COVID-19, Health Canada has permitted interim expedited licensing for alcohol-based sanitizers containing ethanol or isopropanol. But be aware that sanitizers made with industrial ethanol are being recalled.

REQUIREMENTS TO FOLLOW

The products seeking interim expedited licensing must strictly follow the requirements of the Monograph and the Natural Health Products Regulations and may only include alcohol-based sanitizers. A site license (for manufacturing, packaging, labeling, and/or import) and/or a product license (for any form of product distribution) are required, depending on the intended involvement. The interim licensing approach permits alcohol-based sanitizers for not only personal/domestic use, but also enables distribution for use in health care and commercial settings, with specific notification to Health Canada and broader GMP standards.

United Kingdom

REGULATORY VARIATIONS

Regulated as a biocide: sanitize, disinfect, kill germs or bacteria in general.

Regulated as a cosmetic: clean, moisturize, secondary antimicrobial effect.

Regulated as a medicine: treats disease, adverse conditions; stated to kill, or prevent infection with named viruses or diseases (e.g., COVID-19.)

HAND SANITIZER FACTS

Ingredients
Corrosive, toxic or flammable ingredients that require precautionary wording must be declared either with the most commonly used chemical or technical name or with a chemical nomenclature. The other ingredients must be declared by using the generic name, the chemical denomination for pre-established groups or families or the functional name of the ingredient.

Purpose
Hygiene and disinfectant; regulated as a hygiene product.

Use Understand the basics for bringing a hand sanitizer to market.

Warnings Comply with the relevant sections of NOM-189-SSA1/SCFI-2018 and NOM-030-SCFI-2006, for example. • Set out the product's name in the requisite form, trademark, country of origin and net quantity declaration • Present usage, handling, dosage and storage information on the container • Provide safety information on the container along with relevant wording which is clear, contrasting and not misleading • Include, on any part of the packaging, traceability details numerically or in plain language • If there is insufficient space on the container for instructions, these can be in a printed manual attached to the container if referenced on the container • The label must include the requisite information in Spanish—if the information is also set out in English, the Spanish characters must be the same font, size and proportion

Directions
Sanitary Registration and a Sanitary Import Permit are required; comply with the General Health Law and the Regulation on Health Products; obtain authorization from the Ministry of Health through COFEPRIS; make sure that you have complied with all Mexican Customs duties.

Other Information In the event of an adverse reaction, contact COFEPRIS.

Mexico

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Contact Us

Need a hand understanding how this applies to your business or products?

Reach out to our attorneys for experienced insight on regulatory guidance regarding hand sanitizer product safety, manufacturing and distribution.

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