Sprixx™ Alcohol Hand Sanitizer Monogram

This information is made available to enable you, the user, to have a better understanding of our product(s) or services(s). It is complete and up-to-date to the best of our knowledge.

PART I – Company Information

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Products/Service:	Infection prevention and control products
Establishment License from Health Canada	100302-A
United States EPA	072183-CAN-001

PART II –Product Information

Product Specifications with Percentage Concentration of Actives

Parameter	Unit of Measure	Range of Variation
Assay	Ethyl Alcohol as % w/w Isopropyl Alcohol as % w/w	55.8% to 68.2% 9.0% to 11.0%
pH	$-\log_{10}{}^{[H+]}$	6.5 – 8.5
Identification	Specific gravity	0.85 – 0.88

Hospital Grade Sanitizer for Hands/Inanimate Surfaces

The chemical composition of Sprixx™ is the prescribed percentage in the specifications of the ethyl and isopropyl alcohol above and non-actives that act as skin emollients and anti-desiccating agents to leave hands moisturized without a sticky residue.

Product Recommendations for Use:

Sprixx™ is a convenient, safe, and cost-effective method for disinfecting hands and non-porous surfaces not visibly soiled. Where visible soil is present, pre-washing before disinfection is required, because alcohol is not a suitable cleaning agent to replace soap and water.

The Centre for Disease Control recommends washing with soap and water followed by disinfecting with Sprixx™.

Note:

- ***Sprixx™ contains no lanolin that may cause allergic reactions.***
- ***Sprixx™ contains no carbomers that react adversely with other chemicals such as chlorhexidene.***

Sprixx™ meets or exceeds the minimum standard for hand sanitation including the most recent CDC Guidelines For Hand Sanitizers, (Centre for Disease Control) and the World Health Organization (WHO) guidelines.

Product Approvals required for sale in Canada and the United States of America.

Hand/Inanimate Surface Sanitizers in Canada are classified as drugs and governed under Therapeutic Products Program of the Health Protection Branch. In order for these types of products to be sold in Canada, they require a Drug Identification Number (DIN), which must appear on the label of the product for sale. The drug identification number is the assurance that the product inside the package has been manufactured by a producer with an "Establishment Licence" from Health Canada, which licence requires all DIN products to be formulated, packaged, labelled and distributed in accordance with GMP (Good Manufacturing Practices).

A similar requirement exists in the United States of America where the Food and Drug Administration (FDA) regulates these products.

Sprixx™ on Toxicity

Sprixx™ is non-toxic when applied to intact skin. Sprixx™ will not harm surfaces that are proven to be unaffected by alcohol.

Sprixx™'s use should be discontinued if skin irritation or redness occurs. If irritation persists for more than 5 days, consult a physician.

Keep out of reach of children because this product is harmful if ingested or may cause eye or mucousal irritation (consult MSDS for more information).

Certified Results of Sprixx™ Effectiveness

Sprixx™ hand sanitizer was tested using the Antimicrobial Effectiveness Test – Modified USP Protocol by Gelda Scientific (accredited by Standards Council of Canada and Health Canada -Licenses# 100410A) to determine its effectiveness in killing the common pathogenic (disease causing) microorganisms.

The following common pathogenic microorganisms were used to challenge the Sprixx™ Hand Sanitizer:

Testing Organism	**Common Diseases Associated**
Staphylococcus aureus	Food borne illness
Listeria monocytogenes	Food borne illness- Listeriosis
Salmonella typhi	Food and waterborne illness- typhoid fever
Candida Albicans	Yeast Infection
E-Coli	Food Poisoning symptoms
E-coli – 0157H7	Very toxic strain of E. Coli – can be lethal
B. Capacia	Opportunistic pathogen

The results of the study carried out at Gelda Scientific showed that the Sprixx™ hand sanitizer successfully killed 99.9% of the above listed microorganisms within 15 seconds when 3 ml of product was used. Since the mid 1990's, Sprixx™ has been used effectively both in hospitals and healthcare settings, as well as consumer environments. During the SARS outbreak in Toronto in 2004, Sprixx™ was one of the products-of-choice for both healthcare providers and for consumers. Pharmax has tested and proven that the user-friendly nature of Sprixx™ **encourages** effective hand hygiene.

Alcohol – The Product of Choice

Alcohol hand antiseptics continue to be the global product of choice because of their proven overall effectiveness. Most alcohol-based hand antiseptics contain ethanol, isopropanol or n-propanol, or a combination of two of these products. Concentrations are given as either percentage of volume (= ml/100 ml), abbreviated % *V/V*; percentage of weight (= g/100 g), abbr. % *W/W*; or percentage of weight/volume

(= g/100 ml), abbr. % *W/V*. Studies of alcohols have evaluated either individual alcohols in varying concentrations (a majority of studies), combinations of two alcohols, or alcohol solutions containing small amounts of hexachlorophene, quaternary ammonium compounds, povidone-iodine, triclosan or chlorhexidine gluconate.

The antimicrobial activity of alcohols results from their ability to denature proteins. Alcohol solutions containing 60–80% alcohol are most effective, with higher concentrations being less potent. This paradox results from the fact that proteins are not denatured easily in the absence of water. The alcohol content of solutions may be expressed as a percentage by weight (*W/W*), which is not affected by temperature or other variables, or as a percentage by volume (*V/V*), which may be affected by temperature, specific gravity and reaction concentration. For example, 70% alcohol by weight is equivalent to 76.8% by volume if prepared at 15ºC, or 80.5% if prepared at 25ºC. Alcohol concentrations in antiseptic hand rubs are often expressed as a percentage by volume.

Alcohols have excellent *in vitro* germicidal activity against Gram-positive and Gram-negative vegetative bacteria (including multidrug-resistant pathogens such as MRSA and VRE), *M. tuberculosis*, and a variety of fungi. However, they have virtually no activity against bacterial spores or protozoan oocysts, and very poor activity against some non-enveloped (non-lipophilic) viruses. In tropical settings, the lack of activity against parasites is a matter of concern about the opportunity to promote the extensive use of alcohol-based hand rubs, instead of hand washing, which may at least guarantee a mechanical removal effect.

Some enveloped (lipophilic) viruses such as herpes simplex virus, human immunodeficiency virus (HIV), influenza virus, RSV and vaccinia virus are susceptible to alcohols when tested *in vitro*. Other enveloped viruses that are somewhat less susceptible, but are killed by 60–70% alcohol, include hepatitis B virus and probably hepatitis C virus.

Numerous studies have documented the *in vivo* antimicrobial activity of alcohols. Typically, log reductions of the release of test bacteria from artificially contaminated hands average 3.5 $\log_{10}$ after a 30-second application, and 4.0–5.0 $\log_{10}$ after a 1-minute application. In 1994, the FDA TFM classified ethanol 60–95% as a generally safe and effective active agent for use in antiseptic hand hygiene or HCW hand wash products. Alcohols are rapidly germicidal when applied to the skin, but have no appreciable persistent (residual) activity. However, re-growth of bacteria on the skin occurs slowly after use of alcohol-based hand antiseptics, presumably because of the sub-lethal effect alcohols have on some of the skin bacteria.

Alcohols, when used in concentrations present in alcohol-based hand rubs, also have *in vivo* activity against a number of non-enveloped viruses. A more recent study using the finger pad model test methods evaluated a commercially available product containing 60% ethanol, and found that the product reduced the infectivity titres of three non-enveloped viruses (rotavirus, adenovirus and rhinovirus) by 3 to 4 logs. Other non-enveloped viruses such as hepatitis A and enteroviruses (e.g. poliovirus) may require 70–80% alcohol to be reliably inactivated.

In general, ethanol has greater activity against viruses than isopropanol. Further *in vitro* and *in vivo* studies of both alcohol-based formulations and antimicrobial soaps are warranted to establish the minimal level of virucidal activity that is required to interrupt direct contact transmission of viruses in health-care settings.

Alcohols are not good cleansing agents, and their use is not recommended when hands are dirty or visibly contaminated with proteinaceous materials. However, when relatively small amounts of proteinaceous material (e.g. blood) are present, ethanol and isopropanol may reduce viable bacterial counts on hands, but do not obviate the need for hand washing with water and soap whenever such contamination occurs.

The efficacy of alcohol-based hand hygiene products is affected by a number of factors, including the type of alcohol used, the concentration of alcohol, the contact time, the volume of alcohol used, and whether the hands are wet when the alcohol is applied. Small volumes (0.2–0.5 ml) of alcohol applied to the hands are not more effective than washing hands with plain soap and water. Larson and colleagues documented that 1 ml of alcohol was significantly less effective than 3 ml. The ideal volume of product to apply to the hands

is not known, and may vary for different formulations. In general, however, if hands feel dry after being rubbed together for less than 10–15 seconds, it is likely that an insufficient volume of product was applied.

Frequent use of alcohol-based formulations for hand antisepsis tends to cause drying of the skin unless humectants or other skin conditioning agents are added to the formulations. Even well tolerated alcohol-based hand rubs containing humectants may cause a transient stinging sensation at the site of any broken skin (cuts, abrasions). Alcohol-based hand rub preparations with strong fragrances may be poorly tolerated by a few HCWs with respiratory allergies. Allergic contact dermatitis or contact urticaria syndrome caused by hypersensitivity to alcohol, or to various additives present in some alcohol-based hand rubs, occurs rarely.

A recent systematic review of publications between 1992 and 2002 with an adequate methodological quality on the effectiveness of alcohol-based solutions for hand hygiene showed that alcohol-based hand rubs remove organisms more effectively, require less time and irritate skin less often than hand washing with soap or other antiseptic agents and water. The availability of bedside alcohol-based solutions increased compliance with hand hygiene among HCWs. Alcohols are flammable, and HCWs handling alcohol-based preparations should respect safety standards (see Part I, Section 9.14). Because alcohols are volatile, containers should be designed so that evaporation is minimized and initial concentration is preserved.

Product Particulars: Sprixx™ Hand Sanitizer

Country of Origin	Canada
Health Canada Drug Number (DIN)	02274027
US EPA NDC Number:	060742-200
Package Formats	Hand Gel, Wipes
Shelf Life:	Five years from the date of manufacture.

Special Recommendations: Sprixx™ should not be **refilled** into an existing container or dispenser without thorough cleaning and decontamination, because some resistant microorganisms can be transferred during the refilling process. Health Canada and the EPA are considering restrictions on refilling for this reason.