GOJO

HAND HYGIENE TIMES

Your Canadian resource for the latest news in effective infection control program development and best practices.

Issue 2 Volume 5

Health Canada Standards and Factors Influencing the Clinical Effectiveness of ABHR

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Hand hygiene is considered the most important healthcare-associated infection (HAI) prevention intervention. The introduction of alcohol-based hand rubs (ABHRs) have increased healthcare worker (HCW) compliance with the Centers for Disease Control and Prevention, World Health Organization and Health Canada recommendations for when hand hygiene should be performed. In addition, there have been numerous peer-reviewed publications documenting that when hand hygiene compliance improves that HAIs are reduced (Ref: WHO meta-analysis).

In this paper, we will provide an overview of the recently revised Health Canada Standards for hand hygiene agents, describe the methods to evaluate ABHR efficacy and describe the factors that influence ABHR antimicrobial efficacy.

HEALTH CANADA REGULATION OF HAND ANTISEPTIC AGENTS

In Canada, Health Canada has the governmental authority to regulate hand hygiene agents. As per the Food and Drugs Act, any substance that is manufactured, sold or represented for use in the "mitigation or prevention of disease" is a drug. Section 9(1) of the Act also specifies that a drug must not be labelled "...in a manner that is false, misleading or deceptive or is likely to create an erroneous impression..." An antiseptic product is considered to be one that inactivates, reduces, prevents or arrests growth of microorganisms with the inherent intent to mitigate or prevent disease. This includes antiseptic products whether they are regulated under the Food and Drug Regulations (FDR) or the Natural Health Products Regulations (NHPR).

ANTISEPTIC SKIN CLEANSER MONOGRAPH

Since 2003, this regulation was codified in the Antiseptic Skin Cleanser Monograph (Health Canada 2003: Guidance for Industry: Product Monograph. Health Canada, October 2003).

For details on our product offering, please contact us at healthcare@GOJO.com.

Uses or purposes that fall outside the scope of this Monograph (and that require additional data and Health Canada review) include: For use on any body part other than hands (excluding minor wound cleansing products); antiseptic for use on large areas of the body (e.g. pre-operative showering or bathing); for use at the pre-injection or catheter insertion site; for use during or after skin piercing (e.g. ear piercing, tattoo); antiviral; antimycobacterial; antifungal; log or % reduction claims (e.g. Kills 99.99% of bacteria); efficacy against/highlighting of any specific organisms; persistence claims; sterile; or any claim that implies that the product provides an instantaneous/immediate effect.

GUIDANCE DOCUMENT: HUMAN-USE ANTISEPTIC DRUGS

In December 2009, Health Canada introduced the Guidance Document: Human-Use Antiseptic Drugs (http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/prodpharma/applic-demande/guide-ld/antiseptic_guide_ld-eng.pdf). The Guidance document divided hand hygiene

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THAT'S a FACT!

A study found that approximately 25% of nurses reported symptoms or signs of dermatitis on their hands, and 85% gave a history of skin problems. The variable potential of detergents to cause skin irritation can be reduced by adding emollients and humectants.

Larson, E., Girard, R., Pessoa-Silva, C. L., Boyce, J., Donaldson, L. and Pittet, D. Skin reactions related to hand hygiene and selection of hand hygiene products. Am. J. Infect. Control 34, 627-635 (2006).

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agents and their requirements into "Personal Domestic and Commercial use" and "Professional Healthcare and Food premise use". This guidance applies to antiseptic skin products for human use and is applicable to both pharmaceuticals and natural health products, falling outside the scope of the Antiseptic Skin Cleanser Monograph for personal domestic use products. Specifically, it covers professional and commercial use antiseptic skin products, as well as non-Monograph personal use products such as those making viral, specific organism, persistence and/or log reduction claims. The guidance does not provide data recommendations to support personal domestic use products (these are covered by the Monograph), except when such products make claims of efficacy against specific organisms, persistence, log reduction or % reduction and/or antiviral claims. The guidance does not apply to human-use antiseptic products for burn victims, first aid, or application to sites other than the skin (e.g., mucous membranes, catheter insertion, etc.).

COMPARISON OF THE MONOGRAPH AND GUIDANCE DOCUMENT

The requirements of the Monograph and the Guidance document differ considerably. Although the requirement for *in vivo* data is for the hand hygiene agent(s) is included in both the Monograph and Guidance document, the requirement to submit the data to Health Canada and for the data to be reviewed by Health Canada was not required by the Monograph but is required by the Guidance. The guidance outlines the categories of antiseptic products, the submission filing process, and the basic documentation required to support product efficacy. It also provides information on test organisms and detailed data requirements necessary to support specific claims and enhanced labeling. The enhance labeling can include log reduction, organism specific, antiviral or persistent activity claims.

The *in vivo* test methods (e.g., "Meets ASTM 1174, etc.") may now be reflected on the label in instances where the data requirements outlined in the guidance have been met. In addition, the Drug Product Database and the Licensed Natural Health Products Database will now reflect which products have been authorized for professional, commercial and/or personal use.

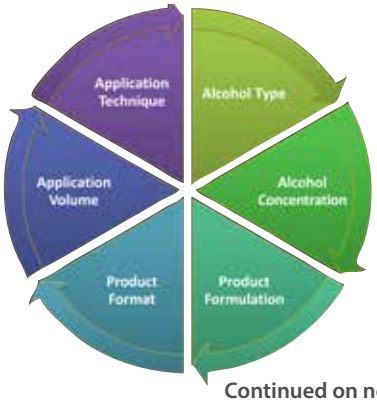
HAND HYGIENE AGENTS FOR HOSPITAL AND HEALTHCARE PROFESSIONAL USE

Currently, there are no ABHR products registered for Hospital and Healthcare Professional Use based on the new 2009 Guidance requirements. This is because in order to have such a label it requires ABHR to go through a complex registration process that requires extensive testing. Some have even questioned whether such testing may involve human safety risks and thus some specific organism testing should not be done. It should be noted that lack of approval does not mean lack of evidence. It is becoming increasingly important for those in healthcare settings who are selecting the hand hygiene agents to be used to verify the agent-related efficacy data. How can you verify the efficacy of products? This can be done by requesting third party, independent laboratory data using unmodified standard test methods. Manufacturers should have such data on file to share about their specific products. *In vitro* data (test tube) is not always predictive of *in vivo* (on hands) results and should be interpreted cautiously.

There are two ASTM International testing methods recommended for *in vivo* bactericidal testing of hand hygiene agents. The first is the ASTM E1174/ Healthcare Personnel Handwash (HCPHW). In this test, the product is evaluated at single (application 1) and multiple (application 10) uses, but no specified application volume is used. The second is the EN1500: Hygienic Hand Rub. In this test, a single (application 1) product cross-over design is used. Typically, 3 mL of product is used for 30 seconds. Until Hospital and Healthcare Professional Use Products are registered, products registered before the Guidance can be used. It should be remembered that requirements in the current Guidance do not apply to pre-Guidance monograph registrations, despite the fact that there were less standardized requirements pre-Guidance.

FORMULATION MATTERS

It should be remembered that ABHR formulations often contain alcohol, water, thickeners and moisturizers. In addition, there may be ingredients to create specific attributes, such as skin tolerance, skin moisturization, aesthetic properties (e.g., skin feel, fragrance), or enable specific delivery formats (rinse, gel, foam). Specific ingredients may improve or inhibit antimicrobial efficacy of ABHR formulations. In formulated ABHR products, alcohol concentration is not the critical determinant of efficacy: FORMULATION MATTERS (Edmonds, S.E., et al., Am J Infect Control 2012;40:521-5). This study also showed that the form (rinse, foam or gel) did not matter. ABHR efficacy increases linearly with application volume--thus it is critical that users be familiar with the amount of product that should be used (this varies by manufacturer and product) with each hand hygiene episode, the correct technique for application (http://www.youtube.com/watch?v=VQisWTZx02c), and the amount of time the product should be applied.



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View presentation of this information at:
https://www.picnet.ca/conferences-events/past-conferences-events/picnet-2014-educational-conference/abhr-presentation/

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SUMMARY

Formulation matters. Thus, hand antiseptic product efficacy should be judged on *in vivo* Health Canada performance criteria and not on just alcohol content or wet/dry time. It is critical that those making decisions on which hand antiseptic agent to use should know the *in vivo* efficacy of the products obtained from independent third party testers, scrutinize the methods, data, and dispensed vs. tested volumes. The registration of ABHRs in Canada is complex. There are multiple paths for different environments. There have been significant updates to the submission process to Health Canada in the last 6 years. Data are needed to make informed product choices. Insure you are using the best hand antiseptic agents by:

1. Getting manufacturer data on the efficacy of their products using realistic volumes;
2. Ensuing the efficacy studies are conducted by independent, third parties; and
3. Ensuring the tests of efficacy use standard, un-modified test methods as recommended by Health Canada.

About the Author

William R. Jarvis, M.D., is an acknowledged world leader in HAI control. During his 23 years with the Centers for Disease Control and Prevention (CDC), he was responsible for the supervision of epidemiological studies in healthcare settings and for the development of guidelines for the prevention of HAIs.

Dr. Jarvis is the editor for the 5th and 6th editions of the book, Hospital Infections and is a highly published expert in infectious diseases, infection control, epidemiology and public health. He has published >500 articles, book chapters and editorials on these topics. Currently, he is President of Jason and Jarvis Associates, LLC.

Product Feature

PURELL® ADVANCED HAND RUB FORMULATIONS

Unprecedented germ kill in skin friendly formulations

As a global leader in hand hygiene, GOJO understands that as science evolves and new pathogens emerge, we must improve our products to meet the changing needs of the infection prevention environment. Our next generation PURELL Advanced Hand Rub meets today's needs by delivering unprecedented germ-kill while maintaining skin health.

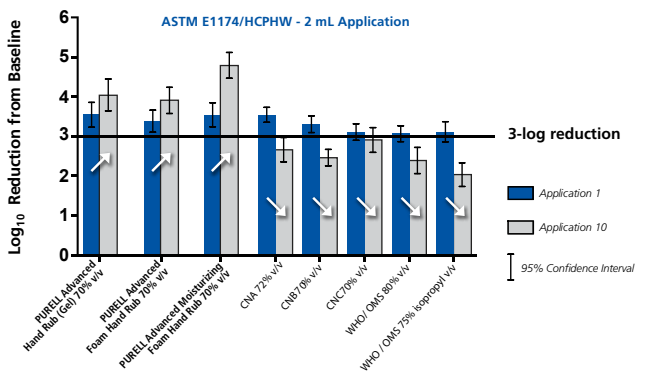
Produced with 70% ethyl alcohol, PURELL Advanced Hand Rub formulations contain a patent-pending blend of ingredients that do two things — maximize the impact of alcohol on bacteria AND maintain skin moisture and skin health. The formulations are so effective and gentle that end-users will want to use them – the ultimate path to compliance. And studies have shown that when hand hygiene compliance increases, the incidence of hospital acquired infections decreases.[1,2]

EFFICACY

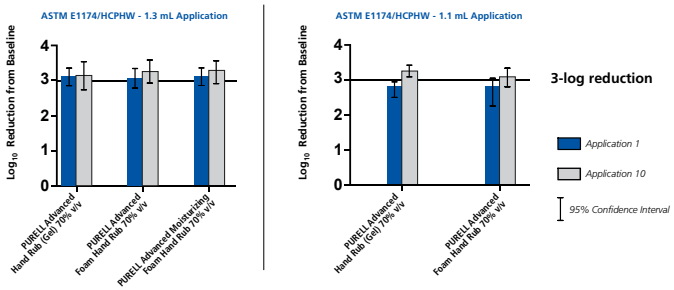
More effective than other ABHR products

Milliliter for milliliter, PURELL Advanced Hand Rub is more effective than other hand sanitizers, including products with equal and higher alcohol content. When tested on hands using the ASTM E1174/ Healthcare Personnel Hand-wash (HCPHW) test method, PURELL Advanced Hand Rub achieved a >3-log reduction at applications 1 and 10 with an application of 2.0 mL, outperformed other commercially available products and demonstrated increased efficacy with repeated use.[3-5] Other commercially available hand sanitizers and WHO-recommended formulations with 75% and 80% alcohol did not achieve a 3-log reduction at both applications 1 and 10 at the same 2.0 mL of product.[3,4]

PURELL Advanced Hand Rub Outperforms Other Leading Hand Sanitizers[1,2]



PURELL Advanced Hand Rub Provides Effective Germ Kill at Real World, In-Use Product Volumes[3,4]



Delivers the best germ kill possible with each use

With PURELL Advanced Hand Rub and GOJO® Dispensing systems, we have efficacy data to provide the confidence that you are getting the most efficacious product at each hand hygiene event. When tested at real world, in-use volumes, PURELL Advanced Hand Rub achieved a >3-log reduction on hands at applications 1 and 10 using the ASTM E1174/HCPHW test method with an application of 1.3 mL and with repeated use at application 10 with 1.1 mL.[6,7] In addition, PURELL Advanced Hand Rub keeps the hands wet at least 15 seconds as recommended by hand hygiene guidelines at dispensed amounts.[6,8] This demonstrates efficacy performance at dispensed amounts from the GOJO LTX™ and ADX™ dispenser system and 535 mL and 354 mL point-of-care bottles.

Product Feature

PURELL® ADVANCED HAND RUB FORMULATIONS

Unprecedented germ kill in skin friendly formulations (continued from page 3)

PROVEN PERFORMANCE

GOJO is the first manufacturer of ABHR to follow the process set forth for professional use products based on the 2009 Health Canada GUIDANCE DOCUMENT Human-Use Antiseptic Drugs and received approval for enhanced labeling claims.[9]

SKIN HEALTH

While killing many germs that may cause infection, PURELL Advanced Hand Rub is available in moisture-rich formulations that contain four different skin conditioners proven to maintain skin health and skin moisture while improving overall skin feel. PURELL Advanced Moisturizing Foam Hand Rub is clinically proven to lock-in moisture[10] and improve skin condition within 14 days of continued use.[10-12]

DELIVERY OPTIONS

PURELL Advanced Hand Rub is currently available in multiple foam options and gel in the GOJO® LTX™ touch free and ADX™ manual push dispenser systems along with a variety of bottle and point of care dispensing options to meet user preferences.

With PURELL Hand Sanitizer,the brand people know and trust, GOJO offers a diverse selection of effective products, state-of-the-art dispensing systems and compliance building educational and electronic monitoring solutions that put an effective hand hygiene program in the hands of your healthcare facility.

Description	TOUCH FREE			MANUAL	
	LTX-7™ 700 mL	LTX-12™ 1200 mL	TFX-12™ 1200 mL	ADX-7™ 700 mL	ADX-12™ 1200 mL
REFILLS	SKU	SKU	SKU	SKU	SKU
PURELL Advanced Hand Rub	1303-03-CAN00	1903-02-CAN00	5770-04-CAN00	8707-04-CAN00	8807-03-CAN00
PURELL Advanced Foam Hand Rub	1304-03-CAN00	1904-02-CAN00	—	8704-04-CAN00	8804-03-CAN00
PURELL Advanced Moisturizing Foam Hand Rub	1313-03-CAN00	1913-02-CAN00	5395-02-CAN00	8709-04-CAN00	8809-03-CAN00
BOTTLES	535 mL Pump Bottle	45 mL Pump Bottle	354 mL Pump Bottle	59 mL Flip Cap Bottle	
PURELL Advanced Hand Rub	—	—	3770-12-CAN00	9650-24-CAN	
PURELL Advanced Foam Hand Rub	5791-04-CAN00	5691-24-CAN00	—	—	
PURELL Advanced Moisturizing Foam Hand Rub	5795-04-CAN00	5695-24-CAN00	—	—	

GET THE DATA!

It's important to obtain scientific data supporting product efficacy to differentiate between products and make informed decisions. For efficacy questions on PURELL Advanced formulations,
email TIP@GOJO.com or call 1-800-321-9647

1 Didier Pittet, Stéphane Hugonnet, Stephan Harbarth, Philippe Mourouga, Valérie Sauvan, Sylvie Touveneau, Thomas V Perneger, and members of the Infection Control Programme. Effectiveness of a hospital-wide programme to improve compliance with hand hygiene. Lancet, 2000: 356, 1307-1312.

2 Improving hand hygiene compliance: A multidisciplinary approach. Helms et al. Association for Professionals in Infection Control and Epidemiology, Inc. Am J Infect Control, 2010: 38, 572-4.

3 Edmonds, et al. Comparative efficacy of commercially available alcohol-based hand rubs and World Health Organization-recommended hand rubs: formulation matters. Am J Infect Control. 2012 Aug;40(6):521-5. 2

4 ASTM E1174/HCPHW #100907-101, January 6, 2011, BioScience Laboratories, Bozeman, MT. ASTM E1174/HCPHW #111209-101, March 8, 2012, BioScience Laboratories, Bozeman, MT. When tested using the HCPHW test methodology against other hand sanitizers commonly used in healthcare facilities.

5 Meta-Analysis PURELL Advanced Gel, Daryl S. Paulson PhD, BioScience Laboratories, January 4, 2013. Rationale: Meta-Analysis on the data from 16 HCPHW studies. Formula: 9670-532.

6 Macinga et al. Efficacy of novel alcohol-based hand rub products at typical in-use volumes. Infect Control Hosp Epidemiol. 2013;34:299-301.

7 ASTM E1174/HCPHW #110238-101, April 25, 2011, BioScience Laboratories, Bozeman, MT. Healthcare Personnel Handwash Study #121008-101, December 27, 2012, BioScience Laboratories, Bozeman, MT.

8 Provincial Infectious Diseases Advisory Committee (PIDAC). Best Practices for Hand Hygiene in All Health Care Settings, 4th edition, April 2014.

9 PURELL Advanced Hand Rub Gel formulation. NPN 80047004. Foam in process for similar registration.

10 Acute Moisturization Analysis, Study #110212-301, April 25, 2011, BioScience Laboratories, Bozeman, MT.

11 4-Week Clinical Field Study #2011-F10232, Akron, OH, February – March, 2011.

12 4-Week Clinical Field Study #2011-F10233, Akron, OH, February – March, 2011.

A Look Ahead

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