

IS D-GERM SAFE TO USE AS A HAND SANITISER?

- D-Germ contains 70% v/v Propyl Alcohol, 0.5 % Chlorhexidine Gluconate and an emollient.
- Propyl (n-Propanol) Alcohol is safe to use in hand disinfectant because:
 - It has been used safely in hand disinfectants since 1965 – Periodic Safety Update Review Data available;
 - It is accepted as an active ingredient in the formulation of hand sanitisers world-wide (Reference 1, 2, 3);
 - World Health Organization (WHO) listed Propyl Alcohol as an active ingredient for hand disinfectants in the 2009 Hand Hygiene Guidelines in Health Care (Ref 4; page 29);
 - Propyl Alcohol is used as the reference alcohol in the EN (European Norms) 12791 for surgical hand preparation (Ref 5, Table I.10.1; Page 29);
 - It is listed as one of the three alcohols suitable for use in alcohol based hand sanitisers in South Africa by the SANS490:2020 (Ref 7);
 - There is no available data or literature that Propyl Alcohol is absorbed through the skin even with frequent use such as by healthcare workers in a healthcare setting (Ref 2);
 - The risk of ingestion is low, because Propyl alcohol has a very unpleasant taste which is worse than ethanol. This reduces the risk of intentional or accidental ingestion significantly.
- D-Germ has been used in hospitals and retail sector in South Africa since 2002 with no reported negative health issues:
 - D-Germ is registered as a S0 drug with the South African Health Products Regulatory Authority (SAHPRA);
 - SAHPRA guidelines and GMP requirements are adhere to, ensuring quality, efficacy and safety;
 - It is compliant to the SANS490:2020. This standard specifies the requirements for Alcohol-Based Hand Rubs in South Africa;
 - All alcohols purchased from Sasol (Base Chemicals) and used in our hand sanitisers have undergone rigorous purification processes and is suitable for direct contact with human skin (Ref 6);
 - It has passed the following EN tests (these are listed as criteria when selecting a hand hygiene disinfectant in the WHO Guidelines on Hand Hygiene in Health Care (Ref 4; page 30):
 - EN1500 Hygiene Hand Rub

Board of Directors:

Dr. Meinrad Lugan* (Chairman), Jens Papperitz* (Managing Director), Scott Farrell (Chief Financial Officer)

* German

- EN12791 Surgical Hand Rub
 - EN14476 Virucidal Efficacy
 - EN13624 Yeasticidal Efficacy
 - EN13727 Bactericidal Efficacy
- The labelling of D-Germ adheres to the SANS490:2020 specifically regarding safety measures:
 - keep out of reach of children,
 - not to be taken orally,
 - keep away from open flame.
 - It contains an emollient which reduces the risk of skin irritation.

For supporting documents, please contact us on info.za@bbraun.com

REFERENCES:

1. Schülke & Mayr (Asia) Pte. Ltd, 2021. Available at: <https://www.schuelke.com/sg-en/knowledge/article/1-propanol.php> (Accessed on: September 2021).
2. Bessonneau, V., Clément, M., & Thomas, O. (2010). Can intensive use of alcohol-based hand rubs lead to passive alcoholization?. *International journal of environmental research and public health*, 7(8), 3038–3050. <https://doi.org/10.3390/ijerph7083038>.
3. Berardi, A., Perinelli, D. R., Merchant, H. A., Bisharat, L., Basheti, I. A., Bonacucina, G., Cespi, M., & Palmieri, G. F. (2020). Hand sanitisers amid CoViD-19: A critical review of alcohol-based products on the market and formulation approaches to respond to increasing demand. *International journal of pharmaceutics*, 584, 119431. <https://doi.org/10.1016/j.ijpharm.2020.119431>.
4. WHO. 2009. Patient Safety, WHO Guidelines on Hand Hygiene in Health Care: A summary
5. WHO. 2009. Patient Safety, WHO Guidelines on Hand Hygiene in Health Care Available at: <https://www.who.int/publications/i/item/9789241597906> (Accessed on: August 2021).
6. Sasol (Base Chemicals) Statement: Suitable Base Chemicals Products for Hand Sanitizer and Surface Sanitizer Applications dated 30 September 2021
7. Amendment to SANS 490 defining alcohol-based hand rubs and sanitisers to contain minimum alcohol content; SABS Media Release dated 24 February 2021.