

HSA ALERT: HIGH LEAD-CONTAINING "AYUKALP MAHAYOGRAJ GUGGULU" AND COUNTERFEIT "LACTOGG" CAPSULES CAUSED ADVERSE EFFECTS IN CONSUMERS; ONE CONSUMER HOSPITALISED

The Health Sciences Authority (HSA) is alerting members of the public to "ayukalp Mahayograj Guggulu", and counterfeit "LACTOGG" capsules. "ayukalp Mahayograj Guggulu" was detected with a very high level of lead, causing a consumer to experience serious adverse effects requiring hospitalisation. Separately, three members of a family took counterfeit "LACTOGG" capsules and suffered abdominal discomfort and other adverse effects. The original "LACTOGG" capsules are marketed as a probiotic supplement.

Product name	Potent ingredient/ issue	Source
"ayukalp Mahayograj	Level of lead exceeding the	Union Yoga Ayurveda
Guggulu"	permissible limit for traditional	
	medicines by 6,000 times.	
Counterfeit "LACTOGG"	Absence of the probiotic	Local e-commerce
capsules	strain Lactobacillus	platform, Shopee
	rhamnosus GG which was	
	listed on the package.	

Please refer to <u>Annex A</u> for photos of "ayukalp Mahayograj Guggulu" and <u>Annex B</u> for the characteristics and photo of counterfeit "LACTOGG" capsules tested by HSA. Counterfeit "LACTOGG" capsules may vary in composition of ingredients and could be harmful when consumed, as the production lacks quality control and safety standards.

"ayukalp Mahayograj Guggulu" caused lead poisoning in a consumer, resulting in hospitalisation

A consumer in her 30s experienced fatigue, shortness of breath during physical activity and chest discomfort. She was diagnosed with anaemia due to lead poisoning, leading to hospitalisation. She had obtained "ayukalp Mahayograj Guggulu" from Union Yoga Ayurveda after an Ayurvedic consultation and took the product for about one and a half months for back pain. HSA tested the product and detected the presence of lead, with a level exceeding 6,000 times the permissible limit for traditional medicines (10 parts per million (ppm)).

3 Lead is a toxic heavy metal and acute exposure to high levels may cause abdominal pain, nausea, vomiting, anaemia, hepatitis (inflammation of the liver) and brain injury. Long-term exposure to very high levels of lead may also cause toxic effects to the body, including the kidneys, digestive and nervous systems.

4 HSA has seized all stocks of "ayukalp Mahayograj Guggulu" from the three local branches of Union Yoga Ayurveda and the company is assisting with investigations.

Counterfeit "LACTOGG" capsules sold online caused adverse effects in consumers, including a young child

5 HSA was alerted to counterfeit "LACTOGG" capsules by a consumer in his 40s who reported adverse effects experienced by himself and his family members after taking the product. The consumer and his wife reported abdominal discomfort, vomiting and diarrhoea while their 2-year-old child developed high fever and had abnormalcoloured faeces. His other children complained that the capsules tasted different from what they were used to. The consumer suspected that the product may be counterfeit when he discovered irregularities in the printing on the product packaging and discolouration of the powdered contents in the capsules.

6 In contrast to the genuine product, HSA's analysis revealed that the tested counterfeit product did not contain the probiotic strain *Lactobacillus rhamnosus* GG,

which was listed on the packaging. Poor quality printing was also found on the product packaging.

7 The consumer had bought the counterfeit "LACTOGG" capsules from Shopee, an e-commerce platform, through a seller who sold these capsules at much lower prices compared to the genuine product sold in healthcare institutions, medical clinics, licenced retail pharmacies and established retailers. HSA has directed the platform administrator to remove the affected listings and will take enforcement actions against offenders.

Advisory to consumers

8 Consumers are advised to:

- Stop taking "ayukalp Mahayograj Guggulu" and "LACTOGG" capsules which you suspect may be counterfeits and consult a doctor if you feel unwell or are concerned about your health. These products can cause serious harm to your health.
- If you have purchased "LACTOGG" capsules from unfamiliar or online sources without an established retail presence locally or are in doubt of its authenticity, please contact ProbioCare Pte. Ltd. at e-mail: <u>info@lactogg.com</u> or Tel: 6255-5592 from 9am to 5pm (Monday to Friday). You may also contact the company to ascertain if a seller is authorised to sell the product.
- Exercise caution when buying health products from unfamiliar, dubious or online sources. They may be illegal, counterfeit or substandard, and may potentially contain potent ingredients which can harm your health. These products are often manufactured under poor conditions with no quality control, and different batches of the same product may contain variable ingredients. In addition, counterfeit health products, which may appear genuine and offered at unexpectedly low prices, may contain harmful ingredients or lack active components, which can lead to adverse health effects.
- Purchase health products only from licensed pharmacies, clinics, and reputable retailers. If buying health products online, buy them from websites with an established retail presence in Singapore.

Advisory to sellers and suppliers

9 All sellers and suppliers must stop selling "ayukalp Mahayograj Guggulu" and counterfeit "LACTOGG" capsules immediately. HSA takes a serious view against those who engage in the illegal sale and supply of these products and will take strong enforcement action against such persons. Sellers and suppliers are liable to prosecution and if convicted, may be imprisoned for up to 2 years and/or fined up to \$5,000.

10 Members of the public who have any information on the sale and supply of these illegal products may contact HSA's Enforcement Branch at Tel: 6866-3485 during office hours (Monday to Friday) or email: <u>hsa_is@hsa.gov.sg</u>.

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About the Health Sciences Authority (HSA)

The Health Sciences Authority (HSA) applies medical, pharmaceutical and scientific expertise through its three professional groups, Health Products Regulation, Blood Services and Applied Sciences, to protect and advance national health and safety. HSA is a multidisciplinary authority. It serves as the national regulator for health products, ensuring they are wisely regulated to meet standards of safety, quality and efficacy. As the national blood service, it is responsible for providing a safe and adequate blood supply. It also applies specialised scientific, forensic, investigative and analytical capabilities in serving the administration of justice. For more details, visit http://www.hsa.gov.sg/.

For more updates on public health and safety matters, follow us at <u>www.twitter.com/HSAsg</u>.

About HSA's Health Products Regulation Group

The Health Products Regulation Group (HPRG) of HSA ensures that medicines, innovative therapeutics, medical devices and health-related products are wisely regulated and meet appropriate safety, quality and efficacy standards. It contributes to the development of biomedical sciences in Singapore by administering a robust, scientific and responsive regulatory framework.

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ANNEX A

Photos of the "ayukalp Mahayograj Guggulu" tested by HSA





Characteristics and photo of counterfeit "LACTOGG" capsules tested by HSA

- Mismatched batch numbers: The counterfeit product carried the batch number 2439C6G8 on the outer packaging and 24039C6G8 on the blister pack.
- Poor quality printing: Irregular spacing of words on packaging

