https://www.fda.gov/drugs/drug-safety-and-availability/fda-advises-consumers-not-use-hand-sanitizer-products-manufactured-eskbiochem

FDA advises consumers not to use hand sanitizer products manufactured by Eskbiochem

6/19/2020

FDA advises consumers not to use any hand sanitizer manufactured by Eskbiochem SA de CV in Mexico, due to the potential presence of methanol (wood alcohol), a substance that can be toxic when absorbed through the skin or ingested. FDA has identified the following products manufactured by Eskbiochem:

- All-Clean Hand Sanitizer (NDC: 74589-002-01)
- Esk Biochem Hand Sanitizer (NDC: 74589-007-01)
- CleanCare NoGerm Advanced Hand Sanitizer 75% Alcohol (NDC: 74589-008-04)
- Lavar 70 Gel Hand Sanitizer (NDC: 74589-006-01)
- The Good Gel Antibacterial Gel Hand Sanitizer (NDC: 74589-010-10)
- CleanCare NoGerm Advanced Hand Sanitizer 80% Alcohol (NDC: 74589-005-03)
- CleanCare NoGerm Advanced Hand Sanitizer 75% Alcohol (NDC: 74589-009-01)
- CleanCare NoGerm Advanced Hand Sanitizer 80% Alcohol (NDC: 74589-003-01)
- Saniderm Advanced Hand Sanitizer (NDC: 74589-001-01)

FDA tested samples of Lavar Gel and CleanCare No Germ. Lavar Gel contains 81 percent (v/v) methanol and no ethyl alcohol, and CleanCare No Germ contains 28 percent (v/v) methanol. Methanol is not an acceptable ingredient for hand sanitizers and should not be used due to its toxic effects.

Consumers who have been exposed to hand sanitizer containing methanol should seek immediate treatment, which is critical for potential reversal of toxic effects of methanol poisoning. Substantial methanol exposure can result in nausea, vomiting, headache, blurred vision, permanent blindness, seizures, coma, permanent damage to the nervous system or death. Although all persons using these products on their hands are at risk, young children who accidently ingest these products and adolescents and adults who drink these products as an alcohol (ethanol) substitute, are most at risk for methanol poisoning.

On June 17, 2020, FDA contacted Eskbiochem to recommend the company remove its hand sanitizer products from the market due to the risks associated with methanol poisoning. To date, the company has not taken action to remove these potentially dangerous products from the market. Therefore, FDA recommends consumers stop using these hand sanitizers and dispose of them immediately in appropriate hazardous waste containers. Do not flush or pour these products down the drain.

FDA reminds consumers to wash their hands often with soap and water for at least 20 seconds, especially after going to the bathroom; before eating; and after coughing, sneezing, or blowing one's nose. If soap and water are not readily available, the Centers for Disease Control and Prevention (CDC) recommend consumers use an alcohol-based hand sanitizer that contains at least 60 percent ethanol.

FDA remains vigilant and will continue to take action when quality issues arise with hand sanitizers. Additionally, the agency is concerned with false and misleading claims for hand sanitizers, for example that they can provide prolonged protection such as 24-hours against viruses including COVID-19, since there is no evidence to support these claims.

To date, FDA is not aware of any reports of adverse events associated with these hand sanitizer products. FDA encourages health care professionals, consumers and patients to report adverse events or quality problems experienced with the use of hand sanitizers to FDA's MedWatch Adverse Event Reporting program:

- Complete and submit the report online; or
- Download and complete the form, then submit it via fax at 1-800-FDA-0178.

https://www.fda.gov/news-events/press-announcements/fda-issues-final-rule-safety-and-effectiveness-consumer-hand-sanitizers

FDA issues final rule on safety and effectiveness of consumer hand sanitizers

Action completes a series of actions on the FDA's review of OTC antiseptic active ingredients

For Immediate Release: April 11, 2019

The U.S. Food and Drug Administration today issued a final rule designed to help ensure that hand sanitizers available over-the-counter (OTC) are safe and effective for those who rely on them. The rule establishes that certain active ingredients are not allowed to be used in OTC hand sanitizers, formally known as topical consumer antiseptic rub products, which are intended for use without water, that are marketed under the FDA's OTC Drug Review. The final rule also seeks to ensure that the agency's safety and effectiveness evaluations and determinations for consumer antiseptic rub active ingredients are consistent, up-to-date and appropriately reflect current scientific knowledge and increasing use patterns.

"Our action today aims to help provide consumers with confidence that the over-the-counter hand sanitizers they're using are safe and effective when they don't have access to water to wash with soap," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research. "In today's final regulation we finalized the FDA's previous determination that 28 active ingredients, including triclosan and benzethonium chloride, are not eligible for evaluation under the FDA's OTC Drug Review for use in consumer antiseptic rubs. We've also reaffirmed our need for more data on three other active ingredients, including ethyl alcohol, which is the most commonly used ingredient in hand sanitizers, to help the agency ensure that these products are safe and effective for regular use by consumers. We believe industry has made good progress toward providing data and we will continue to provide updates to the public about the progress of collecting this data."

Consumer antiseptic hand sanitizers provide a convenient alternative when hand washing with plain soap and water is unavailable. Millions of Americans use antiseptic rubs daily, sometimes multiple times a day, to help reduce bacteria on their hands. The Centers for Disease Control and Prevention advises that washing hands with plain soap and running water is one of the most important steps consumers can take to avoid getting sick and to prevent spreading infections to others. If soap and water are not available, the CDC recommends using an alcohol-based hand sanitizer that contains at least 60 percent alcohol.

As part of the June 30, 2016 proposed rule on consumer antiseptic rubs, the FDA requested additional scientific data to support the safety and effectiveness of active ingredients used in OTC consumer antiseptic rubs.

At this time, three active ingredients—benzalkonium chloride, ethyl alcohol, and isopropyl alcohol—are being deferred from further rulemaking to allow for the ongoing study and submission of additional safety and effectiveness data necessary to make a determination regarding whether these active ingredients are generally recognized as safe and effective for use in OTC consumer antiseptic rub products. Their status will be addressed either after completion and analysis of the studies or at another time, if these studies are not completed. At this time, the FDA does not intend to take action to remove hand sanitizers containing these three active ingredients from the market.

Less than 3% of the marketplace will be affected by the issuance of this final rule, as most OTC consumer antiseptic rubs use ethyl alcohol as the active ingredient.

The FDA is aware that retailers and pharmacies continue to market a very low number of consumer hand sanitizers containing benzethonium chloride, but that they stopped marketing hand sanitizers containing triclosan. Drug products containing any ineligible active ingredients will require approval under a new drug application or abbreviated new drug application prior to marketing.

This final rule completes a series of rulemaking actions in the FDA's ongoing review of OTC antiseptic active ingredients to determine whether these ingredients are safe and effective for their intended uses. The FDA previously issued final rules on consumer antiseptic washes (Sept. 2016) and health care antiseptics (Dec. 2017).

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