

SINGAPORE, 27 DECEMBER 2013

HSA UPDATES

"HSA UPDATES" addresses topics of current public interest, and is subject to change as more information becomes available. HSA UPDATES NO 3/2013

HSA UPDATES ON REVIEW OF ANTIBACTERIAL SOAPS AND BODY WASHES

The Health Sciences Authority (HSA) is updating members of the public on its review of antibacterial soaps and body washes. A variety of antibacterial agents is used in the manufacture of antiseptic hand soaps and body washes, of which triclosan is commonly used.

2 Triclosan is an ingredient added to many consumer products to reduce or prevent bacterial contamination. It may be added to antibacterial soaps and body washes, toothpastes, some cosmetics and topical antiseptics, and can be found in products such as clothing, kitchenware, furniture, and toys.

3 Triclosan is not currently known to be harmful in humans. Recent laboratory data involving animals have suggested that long-term and daily exposure to certain active ingredients used in antibacterial soaps such as triclosan could pose certain health risks. However, this finding has not been observed in humans and data showing effects in animals does not always predict effects in humans. More research is needed to review the effectiveness and long term safety of antiseptic active ingredients such as triclosan.

Background Information

4 The Food and Drug Administration in the United States of America (US FDA) is currently reviewing the safety and efficacy of antibacterial agents as some new data suggests that long-term and daily exposure to certain active ingredients used in antibacterial soaps could pose certain health risks. Much of the information available, based on the US domestic sampling and studies, relates to triclosan. Information on and evaluation of other antiseptic active ingredients is much more limited. Animal studies have shown that triclosan may alter the way hormones work in the body and laboratory studies have raised the possibility that triclosan contributes to making bacteria resistant to antibiotics. Hence, US FDA is initiating further scientific and regulatory review of triclosan and its impact on human use.

HSA's Review

5 In Singapore, triclosan can be used as an antiseptic in topical antiseptic preparations and cosmetic preparations for the treatment of acne, as well as a preservative in cosmetic products, such as hand soaps, body washes and toothpaste.

6 HSA had previously conducted a risk assessment when triclosan is used as a topical antiseptic at a concentration of 1% and had assessed that it is within acceptable safety limits.

7 As a preservative in cosmetic products to slow or stop the growth of bacteria, fungi, and mildew, triclosan is allowed to be used up to a maximum of 0.3%. This limit is also adopted in the European Union and under the ASEAN Cosmetic Directive. As these are rinse-off products, there is minimal contact time between the products and the body surface, resulting in minimal exposure of the user to triclosan.

8 Although the new animal study data suggests that long-term and daily exposure to certain active ingredients used in antibacterial soaps and body washes could pose certain health risks, this finding has not been observed in humans. More data is therefore needed to review the effectiveness and long term safety of these active ingredients and triclosan. HSA will be conducting further benefit-risk analysis as new data surfaces.

Consumer Advisory

9 Triclosan is not currently known to be harmful in humans. At this point in time, based on available data, there is insufficient evidence to recommend changing consumer use of anti-bacterial products, including those containing triclosan. Consumers should continue to wash their hands as an effective way of protecting themselves against germs, together with proper handwashing techniques. Consumers concerned about using antibacterial hand soaps or body washes containing triclosan can consider just washing with regular soap and water. Information on appropriate hand disinfection can be obtained from http://www.hpb.gov.sg/HOPPortal/health-article/5652.

10 HSA is closely monitoring the international developments concerning the review of active ingredients found in antibacterial products such as triclosan and will initiate appropriate regulatory actions based on the outcome of the review.

HEALTH SCIENCES AUTHORITY SINGAPORE 27 DECEMBER 2013

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 on Twitter at <u>www.twitter.com/HSAsg</u>.