FDA’s final rule on antibacterial soaps bans 19 ingredients

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Nineteen ingredients commonly used in antibacterial soaps and washes, including two suspected endocrine disruptors linked to reproductive and developmental harm, are being phased out with the publication of a new federal rule.

In announcing the rule, the Food and Drug Administration reassured consumers that there are still effective measures to prevent the spread of germs, including foodborne pathogens.

“Washing with plain soap and running water remains one of the most important steps consumers can take to avoid getting sick and to prevent spreading germs to others,” FDA reports.

Companies have a year to get the 19 ingredients out of over-the-counter antiseptic wash products, according to the rule. The agency has been mulling the mandate for decades, having issued a Tentative Final Monograph in June 1994.

The most commonly used of the 19 ingredients — triclosan and triclocarban — are of such concern to some that they were at the heart of a 2010 civil suit filed by the Natural Resources Defense Council. At that time, the organization asked the U.S. District Court for the Southern District of New York to order FDA to issue a final rule regulating the two chemicals.

“Companies will no longer be able to market antibacterial washes with these ingredients because manufacturers did not demonstrate that the ingredients are both safe for long-term daily use and more effective than plain soap and water in preventing illness and the spread of certain infections,” according to a news release from FDA.

About 40 percent of the soap products currently available have one or more of the banned ingredients, according to an FDA spokeswoman who participated in a conference call with media representatives.

The rule does not apply to hand sanitizers or wipes that don’t require the use of water or to antibacterial products
used in health care settings. It does apply to liquid soaps, bar soaps and body washes that are intended to be used with water and require rinsing, are marketed for antibacterial properties, and include any of the 19 ingredients specified in the rule.

“Consumers may think antibacterial washes are more effective at preventing the spread of germs, but we have no scientific evidence that they are any better than plain soap and water,” said Janet Woodcock, director of FDA’s Center for Drug Evaluation and Research, in the news release. “In fact, some data suggests that antibacterial ingredients may do more harm than good over the long-term.”

The agency issued a proposed rule in 2013 after some data suggested that long-term exposure to certain active ingredients used in antibacterial products could pose health risks, such as bacterial resistance or hormonal effects.

The 19 banned ingredients are:

- Cloflucarban;
- Fluorosalan;
- Hexachlorophene;
- Hexylresorcinol;
- Iodophors, which are iodine-containing ingredients;
- Iodine complex, which is ammonium ether sulfate and polyoxyethylene sorbitan monolaurate;
- Iodine complex of phosphate ester of alkylaryloxy polyethylene glycol;
- Nonylphenoxypoly, or ethyleneoxy, ethanoliodine;
- Poloxamer, an iodine complex of Povidone-iodine 5 percent to 10 percent;
- Undecoylium chloride iodine complex;
- Methylbenzethonium chloride;
- Phenol greater than 1.5 percent;
- Phenol less than 1.5 percent;
- Secondary amyltricresols;
- Sodium oxychlorosene;
- Tribromsalan;
- Triclocarban;
- Triclosan, and
- Triple dye.

FDA’s 2013 proposed rule also required manufacturers to provide data on the safety and effectiveness of certain ingredients if they wanted to continue using the substances.

“This included data from clinical studies demonstrating that these products were superior to non-antibacterial washes in preventing human illness or reducing infection,” according to FDA.

“Antibacterial hand and body wash manufacturers did not provide the necessary data to establish safety and effectiveness for the 19 active ingredients addressed in this final rulemaking. For these ingredients, either no additional data were submitted or the data and information that were submitted were not sufficient for the agency to find that these ingredients are Generally Recognized as Safe and Effective (GRAS/GRAE).”

Federal officials are holding off on a final decision about three other ingredients at the request of industry. Those
ingredients — benzalkonium chloride, benzethonium chloride and chloroxylenol (PCMX) — can be used for the coming year while industry develops and submits new safety and effectiveness data to FDA.

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