

It is not intended to constitute an official interpretation of the complaint or proposed order, or to modify in any way the proposed order's terms.

By direction of the Commission.

Donald S. Clark,
Secretary.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[Docket No. ATSDR-2016-0001]

Availability of Draft Toxicological Profile; Glutaraldehyde

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (DHHS).

ACTION: Notice of availability and request for comment.

SUMMARY: This notice, prepared by the Agency for Toxic Substances and Disease Registry (ATSDR), announces the availability of the Toxicological Profile for Glutaraldehyde for review and comment. All toxicological profiles issued as "Drafts for Public Comment" represent ATSDR's best efforts to provide important toxicological information on priority hazardous substances. We are seeking public comments and additional information or reports on studies about the health effects of glutaraldehyde for review and potential inclusion in the profile.

Comments can include additional information or reports on studies about the health effects of glutaraldehyde. Although ATSDR will consider key studies for this substance during the profile development process, this **Federal Register** notice solicits any relevant, additional studies, particularly unpublished data. ATSDR will evaluate the quality and relevance of such data or studies for possible inclusion into the profile. ATSDR is providing a public comment period for this document as a means to best serve public health and our clients.

DATES: Written comments on this draft Toxicological Profile must be received on or before May 3, 2016.

ADDRESSES: You may submit comments, identified by docket number ATSDR-2016-0001, by any of the following methods:

- *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.

- *Mail:* Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd. NE., MS F-57, Atlanta, GA, 30329. Attn: Docket No. ATSDR-2016-0001.

Instructions: All submissions received must include the agency name and docket number for this notice. All relevant comments will be posted without change. Because all public comments regarding ATSDR Toxicological Profiles are available for public inspection, no confidential business information or other confidential information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Ms. Delores Grant, Division of Toxicology and Human Health Sciences, Agency for Toxic Substances and Disease Registry, 1600 Clifton Rd. NE., MS F-57, Atlanta, GA, 30329. Phone: (800) 232-4636 or 770-488-3351.

SUPPLEMENTARY INFORMATION: The Superfund Amendments and Reauthorization Act of 1986 (SARA) (42 U.S.C. 9601 *et seq.*) amended the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA or Superfund) (42 U.S.C. 9601 *et seq.*) by establishing certain requirements for ATSDR and the U.S. Environmental Protection Agency (U.S. EPA) regarding hazardous substances that are most commonly found at facilities on the CERCLA National Priorities List (NPL). Among these statutory requirements is a mandate for the Administrator of ATSDR to prepare toxicological profiles for each substance included on the priority list of hazardous substances [also called the Substance Priority List (SPL)]. This list identifies 275 hazardous substances that ATSDR (in cooperation with EPA) has determined pose the most significant potential threat to human health. The 2015 SPL is available online at www.atsdr.cdc.gov/spl.

In addition, ATSDR has the authority to prepare toxicological profiles for substances not found at sites on the National Priorities List, in an effort to "establish and maintain inventory of literature, research, and studies on the health effects of toxic substances" under CERCLA Section 104(i)(1)(B), to respond to requests for consultation under section 104(i)(4), and as otherwise necessary to support the site-specific response actions conducted by ATSDR.

The public comments and other data submitted in response to the **Federal Register** notices are available for public inspection at ATSDR. Comments are available for public inspection from

Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m., Eastern Time, at 4770 Buford Hwy NE., Atlanta, Georgia 30341. Please call ahead to 1-800-232-4636 and ask for a representative in the Division of Toxicology and Human Health Sciences to schedule your visit.

Availability

The Glutaraldehyde Toxicological Profile is available online at <http://www.atsdr.cdc.gov/toxprofiles/index.asp> and www.regulations.gov, Docket No. ATSDR-2016-0001.

Donna B. Knutson,

Acting Director, Office of Policy, Planning and Evaluation, National Center for Environmental Health and Agency for Toxic Substances and Disease Registry.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-4599]

List of Highest Priority Devices for Human Factors Review; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the draft guidance entitled "List of Highest Priority Devices for Human Factors Review." FDA is issuing this draft guidance document in order to inform medical device manufacturers which device types should have human factors data included in premarket submissions. FDA believes these device types have clear potential for serious harm resulting from use error and that review of human factors data in premarket submissions will help FDA evaluate the safety and effectiveness and substantial equivalence of these devices. This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by May 3, 2016.

ADDRESSES: You may submit comments as follows: