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## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Centers for Disease Control and Prevention**

**[Docket Number CDC-2019-0093, NIOSH-156-E]**

### **Request for Public Comment on the Draft Immediately Dangerous to Life or Health (IDLH) Value Document for Lewisite**

**AGENCY:** Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

**ACTION:** Request for comment.

**SUMMARY:** The National Institute for Occupational Safety and Health (NIOSH) in the Centers for Disease Control and Prevention (CDC), an Operating Division of the Department of Health and Human Services (HHS), requests public comment on the draft Immediately Dangerous to Life or Health (IDLH) Value Profile document for the chemical lewisite (CAS# 541-25-3). NIOSH develops IDLH values for workplace chemical concentrations and conditions carrying immediate, unacceptable health risks. IDLH values are based on health effects considerations determined through a critical assessment of toxicology and human health effects data.

**DATES:** Electronic or written comments must be received by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**ADDRESSES:** You may submit comments, identified by docket number CDC-2019-0093 and docket number NIOSH-156-E, by either of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail*: National Institute for Occupational Safety and Health, NIOSH Docket Office, 1090 Tusculum Avenue, MS C-34, Cincinnati, Ohio 45226-1998.

*Instructions*: All information received in response to this notice must include the agency name and docket number (CDC-2019-0093; NIOSH-156-E). All relevant comments, including any personal information provided, will be posted without change to <https://www.regulations.gov>. Do not submit comments by email. CDC does not accept comments by email. For access to the docket to read background documents or comments received, go to <https://www.regulations.gov>.

**FOR FURTHER INFORMATION CONTACT:** R. Todd Niemeier, PhD, National Institute for Occupational Safety and Health, MS-C15, 1090 Tusculum Avenue, Cincinnati, OH 45226. Telephone: (513) 533-8166.

**SUPPLEMENTARY INFORMATION:** NIOSH is requesting public comment on a draft IDLH Value Profile document for the chemical lewisite. Lewisite is an oily substance that actively produces gas in room temperature air and was developed as a blister agent during World War I. NIOSH developed the draft IDLH Value Profile document to provide the scientific rationale behind the derivation of an IDLH value for lewisite. It provides a detailed summary of the health hazards of acute exposures to high airborne concentrations of lewisite and the rationale for the IDLH value. The final publication, which will address public comments, will be available on the NIOSH website and in the NIOSH docket 156-E and in Regulations.gov CDC-2019-0093.

To facilitate the review of this document, NIOSH requests comment on the following specific questions for this draft Profile document:

1. Does this document clearly outline the health hazards associated with acute (or short-term) exposures to lewisite? If not, what specific information is missing from the document?
2. Are the rationale and logic behind the derivation of an IDLH value for lewisite clearly explained? If not, what specific information is needed to clarify the basis of the IDLH value?
3. Are the conclusions supported by the data?
4. Are the tables clear and appropriate?
5. Is the document organized appropriately? If not, what improvements are needed?
6. Are you aware of any additional scientific data reported in government publications, databases, peer-reviewed journals, or other sources that should be considered in this document?

**Background:** NIOSH develops IDLH values for workplace chemical concentrations and conditions carrying immediate, unacceptable health risks. Since the establishment of the IDLH values in the 1970s, NIOSH continues to review available scientific data to improve the protocol used to derive acute exposure guidelines, in addition to the chemical-specific IDLH values. IDLH values are based on health effects considerations determined through a critical assessment of toxicology and human health effects data. This approach ensures that the IDLH values reflect an airborne concentration of a substance that represents a high-risk situation that may endanger workers' lives or health.

In 2013, NIOSH published Current Intelligence Bulletin (CIB) 66: Derivation of Immediately Dangerous to Life or Health (IDLH) Values

[<http://www.cdc.gov/niosh/docs/2014-100/pdfs/2014-100.pdf>] [NIOSH 2013]. The information presented in this CIB represents the most recent update of the scientific rationale and the methodology (hereby referred to as the IDLH methodology) used to derive IDLH values. The primary steps used to establish an IDLH value are the following:

1. Critical review of human and animal toxicity data to identify potentially relevant studies and characterize the various lines of evidence that can support the derivation of the IDLH value;
2. Determination of a chemical's mode of action or description of how a chemical exerts its toxic effects;
3. Application of duration adjustments (time scaling) to determine 30-minute-equivalent exposure concentrations and the conduct of other dosimetry adjustments, as needed;
4. Experimental or other data to establish a point of departure (POD) such as lethal concentrations (e.g., LC50), lowest observed adverse effect level (LOAEL), or no observed adverse effect level (NOAEL);
5. Selection and application of an uncertainty factor (UF) for POD or critical adverse effect concentration, identified from the available studies to account for issues associated with interspecies and intraspecies differences, severity of the observed effects, data quality, or data insufficiencies; and
6. Development of the final recommendation for the IDLH value from the various alternative lines of evidence, with use of a weight-of-evidence approach to all the data.

## **Reference**

NIOSH [2013]. Current intelligence bulletin 66: derivation of immediately dangerous to life or health (IDLH) values. Cincinnati, OH: US Department of Health and Human Services, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication 2014–100.

**John J. Howard,**

*Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.*

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