Designation: ~~E1302 – 13 (Reapproved 2017)~~ E1302 – 23

An American National Standard

Standard Guide for Acute Animal Toxicity Testing of Water-Miscible Metalworking Fluids[1]

This standard is issued under the fixed designation E1302; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope*

1.1 This guide defines acute animal toxicity tests and sets forth the references for procedures to assess the acute toxicity of water-miscible metalworking fluids as manufactured.

1.2 Although water-miscible metalworking fluids are typically used at high dilution, dilution rates vary widely. Additionally, there is potential for exposure to the metalworking fluid as manufactured.

1.3 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety, health, and environmental practices and determine the applicability of regulatory limitations prior to use.*

1.4 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E758 Test Method for Mammalian Acute Percutaneous Toxicity (Withdrawn 2010)[3]

E981 Test Method for Estimating Sensory Irritancy of Airborne Chemicals

E993 Test Method for Evaluation of Delayed Contact Hypersensitivity (Withdrawn 2010)[3]

E1103 Test Method for Determining Subchronic Dermal Toxicity (Withdrawn 2010)[3]

E1542 Terminology Relating to Occupational Health and Safety

E2523 Terminology for Metalworking Fluids and Operations

2.2 *CPSC Standards:*[4]

16 CFR Part 1500 ~~CFR Part 1500~~Hazardous Substances and Articles

16 CFR Part 1500.3 ~~CFR Part 1500.3~~Definitions

16 CFR Part 1500.40 ~~CFR Part 1500.40~~Method of Testing Toxic Substances

16 CFR Part 1500.41 ~~CFR Part 1500.41~~Method of Testing Primary Irritant Substances

16 CFR Part 1500.42 ~~CFR Part 1500.42~~Test for Eye Irritants

[1] This guide is under the jurisdiction of ASTM Committee E34 on Occupational Health and Safety and is the direct responsibility of Subcommittee E34.50 on Health and Safety Standards for Metal Working Fluids.

Current edition approved ~~Oct. 1, 2017~~April 1, 2023. Published ~~October 2017~~April 2023. Originally approved in 1989. Last previous edition approved in ~~2013~~2017 as ~~E1302 – 13.~~E1302 – 13 (2017). DOI: ~~10.1520/E1302-13R17.~~10.1520/E1302-23.

[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.

[3] The last approved version of this historical standard is referenced on www.astm.org.

[4] Available from Supt. of Documents, ~~U. S.~~U.S. Government Printing Office, Washington, DC 20402.

***A Summary of Changes section appears at the end of this standard**

2.3 *DOT Standards:*[4]
49 CFR Part 173, Appendix A ~~CFR Part 173, Appendix A~~
49 CFR Part 173.343a1 ~~CFR Part 173.343a1~~
49 CFR Part 173.343a2 ~~CFR Part 173.343a2~~
49 CFR Part 173.343a3 ~~CFR Part 173.343a3~~
2.4 *EPA-TSCA Standards:*[4]
40 CFR 792 ~~CFR 792~~Good Laboratory Practice
40 CFR 870.1100 ~~CFR 870.1100~~Acute Oral Toxicity
40 CFR 870.1200 ~~CFR 870.1200~~Acute Dermal Toxicity
40 CFR 870.1300 ~~CFR 870.1300~~Acute Inhalation Toxicity
40 CFR 870.2400 ~~CFR 870.2400~~Acute Eye Irritation
40 CFR 870.2500 ~~CFR 870.2500~~Acute Dermal Irritation
40 CFR 870.2600 ~~CFR 870.2600~~Skin Sensitization
2.5 *OSHA Standards:*[4]
29 CFR 1910.1200 ~~CFR 1910.1200~~Hazard Communication
29 CFR 1910.1200 Appendix A, 3(a) and 6(a) ~~CFR 1910.1200 Appendix A, 3(a) and 6(a)~~
29 CFR 1910.1200 Appendix A, 3(b) and 6(b) ~~CFR 1910.1200 Appendix A, 3(b) and 6(b)~~
29 CFR 1910.1200 Appendix A, 3(c) and 6(c) ~~CFR 1910.1200 Appendix A, 3(c) and 6(c)~~
29 CFR 1910.1200 Appendix A, 4 ~~CFR 1910.1200 Appendix A, 4~~

3. Terminology

3.1 For definitions of terms in this guide relating to toxicological testing, refer to Terminology E2523. For definitions of terms in this guide relating to occupational health and safety, refer to Terminology E1542.

3.2 *Definitions of Terms Specific to This Standard:*

3.2.1 *limit test, n*—an acute toxicity test in which, if no ill effects occur at a pre-selected maximum dose, no further testing at greater exposure levels is required. **http://sis.nlm.nih.gov/enviro/iupacglossary/glossaryl.html**

4. Significance and Use

4.1 Application of this guide will provide information on the acute toxicity of water-miscible metalworking fluids and will assist the user in evaluating the potential health hazards of the fluid and developing appropriate work practices. A water-miscible metalworking fluid is a concentrate designed to be diluted in water for use.

4.2 Water-miscible metalworking fluids are complex chemical mixtures. The United States Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (see A1.8) outlines procedures for the hazard determination of mixtures and states that if a mixture has not been tested as a whole, then the mixture shall be assumed to present the same hazards as do the components that comprise 1 % (by weight or volume) or greater of the mixture, except that the mixture shall be assumed to present a carcinogenic hazard if it contains a component in concentrations of 0.1 % or greater, which is considered to be a carcinogen (as defined in OSHA Standard 29 CFR 1910.1200). The determination of when to test a mixture as a whole and which toxicity tests are appropriate for the product must be made by a health professional qualified in evaluating toxicological data.

4.3 Acute toxicology testing of water-miscible metalworking fluids consists of several individual tests including acute oral, dermal, or inhalation toxicity, eye irritation, skin irritation or corrosion, or both, skin sensitization, and sensory irritation. Certain protocols for acute oral, dermal, and inhalation toxicity tests are limit tests; further multi-dose testing (for example, Test Method E1103) should take place if mortality is noted on any of these tests. The referenced protocols specify the species and number of animals required. Selection of tests conducted should be designed to minimize the number of animals used.

4.3.1 *Acute Oral Toxicity*—Acute oral toxicity tests (see A1.1) provide information on health hazards likely to arise from short-term exposure by the oral route. Results of this type of test are used to develop warning statements on labels as may be required by OSHA Hazard Communication Standard 29 CFR 1910.1200 (see A1.8) or Federal Hazardous Substances Act (see A1.10). These are also used to establish a dosage regimen for subchronic and other testing. Endpoint: mortality.

4.3.2 *Acute Dermal Toxicity*—Acute dermal toxicity tests (see A1.2) provide information on health hazards likely to arise from short-term exposure by the dermal route and may provide initial information on dermal absorption and the mode of toxic action of a substance. In addition, some measure of irritation caused by the fluid may be obtained by observing local tissue damage at the sight of application. Endpoint: mortality.

4.3.3 *Acute Inhalation Toxicity*—Acute inhalation toxicity tests give an indication of relative toxicity (see A1.3). The results provide an indication of the potential of the fluid to cause death and other adverse health effects when inhaled for a specified time period. Endpoint: mortality.

4.3.4 *Eye Irritation*—Eye irritation tests provide an indication of the potential of the fluid to cause eye irritation or damage upon direct contact (see A1.4). An irritant is defined as a chemical that is not corrosive, but causes a reversible inflammatory effect on living tissue by chemical action at the site of contact. Endpoint: degree of irritation.

4.3.5 *Skin Irritation or Corrosion*—Skin irritation or corrosion tests indicate the potential of the fluid to produce irritation or damage to skin (see A1.5). A corrosive chemical is one that causes visible destruction of, or irreversible alterations in, living tissue by chemical action at the site of contact. Endpoint: irritation or corrosion.

4.3.6 *Skin Sensitization*—A chemical sensitizer is a material that causes a substantial proportion of exposed people or animals to develop an allergic reaction in normal tissue after repeated exposure to the chemical. A number of methods are available for measuring skin sensitization, however, there are differences in opinion on the most appropriate method. These are due to variations in compound administration and degree of reaction to a sensitizing substance. Refer to the Code of Federal Regulations (CFR) for the various protocols (see A1.6). Additionally, toxicology testing contract labs may have standard procedures for conducting these assays. Endpoint: sensitization.

4.3.7 *Sensory Irritation*—Upon exposure to a sensory irritant, humans experience discomfort or a burning sensation of the eyes, nose, and throat, and may also cough. Test Method E981 (see A1.2.5) provides a means to evaluate the sensory irritant potential of airborne chemicals and mixtures, as well as a means to assess the comparative irritancy of compounds and formulations. However, this test method cannot be used to evaluate the relative obnoxiousness of odors. End point: upper respiratory tract irritation.

4.4 A number of federal guidelines can be used to establish general procedures for testing acute toxicity of metalworking fluids. Several references are cited in Annex A1. Regardless of the method used, Good Laboratory Practices, as outlined by the United States Environmental Protection Agency (EPA 40 CFR 792) (see A1.9) must be followed. The OSHA Hazard Communication Standard (see A1.8) outlines the responsibilities of chemical manufacturers, importers, and employers in the determination of chemical hazards and communication of information on those hazards.

4.5 The methods referenced in this guide, or appropriate alternate methods such as those suggested by the Organization for Economic Cooperation and Development (OECD), are acceptable for testing the acute toxicity of water-miscible metalworking fluids. For each test outlined in ~~Annex~~ A1.1 – A1.5, a table is included that highlights the similarities and differences between the test protocols.

5. Keywords

5.1 acute toxicity testing; dermal; eye; inhalation; metalworking fluids; oral

ANNEX

(Mandatory Information)

A1. REFERENCES FOR ACUTE ANIMAL TOXICITY TESTING

A1.1 **Acute Oral Toxicity**—See Table A1.1.

TABLE A1.2 Acute Dermal Toxicity

Protocol	Dose/Animal Toxicity Class	Number of Groups/ Dose Level	Duration of Contact	Observation Time
CPSC	LD50 <200 mg/kg Highly toxic LD50 200 to 2000 mg/kg Toxic Rabbit	ns[A]	Up to 24 h Occluded, abraded, and intact skin	14 days
DOT	LD50 <200 mg/kg Poison B Rabbit	1	24 h	48 h
EPA (TSCA)	2 g/kg-limit test Rabbit, male and female	1	24 h Occluded and abraded skin	14 days
OSHA	LD50 <200 mg/kg Highly toxic LD50 200 to 1000 mg/kg Toxic Rabbit	ns[A]	24 h	ns[A]

[A] Not specified.

TABLE A1.1 Acute Oral Toxicity

Protocol	Dose/Animal Toxicity Class	Number of Groups/Dose Level	Observation Time	Additional Endpoints
CPSC	LD50 <50 mg/kg Highly toxic LD50 50 mg to 5 g/kg Toxic Rat	ns[A]	14 days	ns[A]
DOT	LD50 <50 mg/kg Poison B Rat	1	48 h	ns[A]
EPA (TSCA)	5 g/kg-limit test Rat	1	14 days	External observations of toxicity
OSHA	LD50 <50 mg/kg Highly toxic LD50 50 to 500 mg/kg Toxic Rat	ns[A]	ns[A]	ns[A]

[A] Not specified.

TABLE A1.3 Acute Inhalation Toxicity

Protocol	Concentration/ Animal Toxicity Class	Number of groups/ Dose Levels	Exposure Duration	Observation Time	Additional Endpoints
CPSC	LC50 <2 mg/L or 200 ppm - Highly toxic LC50 2 to 20 mg/L or 200–20 000 ppm Toxic Rat	ns[A]	1 h	ns[A]	ns[A]
DOT	LC50 <2 mg/L Poison B Rat	1	1 h	48 h	ns[A]
EPA (TSCA)	5 mg/L limit test Rat; male and female	1	4 h whole body	14 days	External observation of toxicity
OSHA	LC50 <2 mg/L or 200 ppm Highly toxic LC50 2 to 20 mg/L or 200–2000 ppm Toxic Rat	ns[A]	1 h	ns[A]	ns[A]

[A] Not specified.

TABLE A1.4 Eye Irritation

NOTE 1—It may not be necessary to conduct an eye irritation test if the skin irritation/corrosion test is severely positive.

Protocol	Animals (number)	Dose	Exposure Time	Observation Time and Scoring
CPSC	Rabbit (6)	0.1 mL undiluted fluid	Unwashed	24, 48, 72 h Scoring-Draize
EPA[A] (TSCA)	Rabbit (9)	0.1 mL undiluted fluid	6-unwashed 3-washed for 1 min, 20–30 s after instillation	24, 48, 72 h, 4 and 7 days (every 3 days thereafter for 13 days if injury persists) Scoring-Draize
OSHA	Rabbit (6)	0.1 mL undiluted fluid	Unwashed	24, 48, 72 h Scoring-Draize

[A] EPA protocol gives an indication of what happens when the eye is washed following exposure. This may be useful information.

A1.1.1 Consumer Product Safety Commission (CPSC): 16 CFR part 1500.3.

A1.1.2 Department of Transportation (DOT): 49 CFR 173.343a1.