

Appendix F1

Table of Relevant U.S. Federal and International Ocular Testing Regulations for Hazard Classification and Labeling

Note to the Reader:

Regulations may be updated in the future. It is recommended that users review the most current version of all regulations identified.

Electronic versions of United States Code (U.S.C.) can be obtained at:
<http://www.gpoaccess.gov/uscode/index.html>

Electronic versions of the Code of Federal Regulations (CFR) can be obtained at:
<http://www.gpoaccess.gov/cfr/index.html>

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Eye Irritation/Corrosion Testing:				
Relevant U.S. Federal Laws, Regulations, Guidelines, and Recommendations				
Agency, Center, or Office	Regulated Products	Statutory Requirements	Regulations (Applications)	Guidelines and Recommendations
CPSC	Consumer Products	Federal Hazardous Substances Act (U.S.C. Title 15, Chapter 47)	16 CFR 1500.3 (Definitions) 16 CFR 1500.42 (Test for Eye Irritants) 16 CFR 1500.121 (Labeling)	Animal Testing Policy (1984)
EPA/OPPTS	Chemicals as defined by the Toxic Substances Control Act Pesticides	Toxic Substances Control Act (U.S.C. Title 15, Chapter 53) Federal Insecticide, Fungicide, and Rodenticide Act (U.S.C. Title 7, Chapter 6)	40 CFR 716 (Safety Data) 40 CFR 717 (Adverse Reactions) 40 CFR 720 (Premanufacture Notification) 40 CFR 156 (Labeling) 40 CFR 158 (Pesticide Data)	OPPTS 870.2400 (1998) ¹ Label Review Manual (2003) ²

¹ See **Appendix F2**.

² Available at: <http://www.epa.gov/oppfead1/labeling/lrm/>.

Eye Irritation/Corrosion Testing:

Relevant U.S. Federal Laws, Regulations, Guidelines, and Recommendations

Agency, Center, or Office	Regulated Products	Statutory Requirements	Regulations (Applications)	Guidelines and Recommendation s
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Eye Irritation/Corrosion Testing:				
Relevant U.S. Federal Laws, Regulations, Guidelines, and Recommendations (continued)				
Agency, Center, or Office	Regulated Products	Statutory Requirements	Regulations (Applications)	Guidelines and Recommendations
FDA/CFSAN	Cosmetics ³	Federal Food, Drug, and Cosmetic Act (U.S.C. Title 21, Chapter 9)	21 CFR 70 (Color additives in food, medical devices, and cosmetics) 21 CFR 312 (IND Application) 21 CFR 314 (IND Approval)	No Specific Guidelines or Recommendations on Eye Irritation/Corrosion Testing Are Provided.
FDA/CDER	Pharmaceuticals	Public Health Service Act (U.S.C. Title 42, Chapter 6A)	21 CFR 701 (Cosmetic Labeling) 21 CFR 740 (Cosmetic Warning Statement)	
OSHA	Chemicals	Occupational Safety and Health Act of 1970 (U.S.C. Title 29, Chapter 15)	29 CFR 1910.1200 (Hazard Communication Standard)	No Specific Guidelines or Recommendations on Eye Irritation/Corrosion Testing Are

³ FDA does not have authority for pre-market approval of cosmetics or cosmetic ingredients with the exception of color additives. However, the FDA may enforce action against products or ingredients that are in violation of Federal labeling laws, including provision of adequate safety information.

Eye Irritation/Corrosion Testing:				
Relevant U.S. Federal Laws, Regulations, Guidelines, and Recommendations (continued)				
Agency, Center, or Office	Regulated Products	Statutory Requirements	Regulations (Applications)	Guidelines and Recommendations
			16 CFR 1500.42 (Test for Eye Irritants)	Provided.

Relevant Ocular Testing Regulations for Hazard Classification and Labeling: European Union	
Regulated Products	Regulations and Directives
Substances and Mixtures	<p>Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 (CLP, Classification Labelling and Packaging), amending and repealing Directives 67/548/EEC (DSD, Dangerous Substances Directive) and 1999/45/EC (DPD, Dangerous Preparations Directive), and amending Regulation (EC) No 1907/2006.</p> <p>Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 (REACH, Registration, Evaluation, Authorisation and Restriction of Chemicals)</p>
Plant Protection Products	Council Directive 91/414/EEC of 15 July 1991 as amended
Cosmetics	Council Directive 76/768/EEC of 27 July 1976 as amended
Biocidal Products	Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 as amended

Relevant Ocular Testing Regulations for Hazard Classification and Labeling: United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

Scope	Legal Instruments and Recommendations
Chemicals (Substances and Mixtures)	Globally Harmonized System of Classification and Labelling of Chemicals (UN 2007), Part 3, Chapter 3.2.4 (Serious eye damage/eye irritation)