

Appendix G1

Table of Relevant Skin Sensitization Test Regulations

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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Skin Sensitization Testing: Relevant US Federal Laws, Regulations, Guidelines, and Recommendations				
Agency, Center, or Office	Regulated Products	Statutory Requirements	Regulations	Guidelines and Recommendations
FDA/CDER	Pharmaceuticals	Federal Food, Drug, and Cosmetic Act (U.S.C. Title 21, Chapter 9) Public Health Service Act (U.S.C. Title 42, Chapter 6A)	21 CFR 312 21 CFR 314	Guidance for Industry Immunotoxicology Evaluation of Investigational New Drugs (2002)
EPA/OPPTS	Chemicals as defined by Section 5 of the 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 158.50 40 CFR 158.100 40 CFR 158.340 40 CFR 700-799	OPPTS 870.2600 (2003) (see Appendix G2)
CPSC	Consumer Products	Federal Hazardous Substances Act (U.S.C. Title 15, Chapters 1261-1278)	16 CFR 1500.3	No Specific Guidelines, Guidances, or Recommendations
OSHA	Chemicals	Occupational Safety and Health Act of 1970 (U.S.C. Title 29, Chapter 15)	29 CFR 1910.1200	No Specific Guidelines, Guidances, or Recommendations

Relevant Skin Sensitization Regulations and Guidelines Europe			
Agency, Center, or Office	Regulated Products	Regulations and Directives	
EU	Dangerous Preparations (Chemicals and Chemical Mixtures)	Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 Annex V to Directive 67/548/EEC of 27 June 1967	
	Pesticides	Directive 91/414/EEC of the European Parliament and of the Council of 15 July 1991	
Relevant Skin Sensitization Regulations and Guidelines International			
Organizations	Regulated Products	Legal Instruments and Recommendations	Guidelines, Guidance, and Recommendations
GHS	Chemicals	GHS Part 3, Chapter 3.4	No Specific Guidelines, Guidances, or Recommendations
ISO	Medical Devices	NA	ISO 10993-10 (2010) (see Appendix G3)
OECD	Chemicals	NA	OECD Test Guideline 429 (2010) (see Appendix G4) OECD Test Guideline 406 (1992) (see Appendix G5)
ICH	NA	NA	No Specific Guidelines, Guidances, or Recommendations

Abbreviations: CDER = Center for Drug Evaluation and Research; CFR = Code of Federal Regulations; CPSC = U.S. Consumer Product Safety Commission; EC = European Community; EEC = European Economic Community; EPA = U.S. Environmental Protection Agency; EU = European Union; FDA = U.S. Food and Drug Administration; GHS = Globally Harmonized System of Classification and Labelling of Chemicals; ICH = International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use; ISO = International Organization for Standardization; NA = not available; OECD = Organisation for Economic Co-operation and Development; OPPTS = Office of Prevention, Pesticides and Toxic Substances; OSHA = U.S. Occupational Safety and Health Administration; US = United States; U.S.C. = United States Code.