

Appendix H1 Relevant Skin Sensitization Test Regulations

United States

Agency/ Center or Office	Regulated Products	Legislation	Statutory Requirements
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
EPA/OPPTS	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
CPSC	Consumer Products	Federal Hazardous Substances Act (U.S.C. Title 15, Chapters 1261-1278)	16 CFR 1500.3
OSHA	Chemicals	Occupational Safety and Health Act of 1970 (U.S.C. Title 29, Chapter 15)	29 CFR 1910.1200

Europe

Agency/ Center or Office	Regulated Products	Legislation	Statutory Requirements
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	
EU	Pesticides	Directive 91/414/EEC of the European Parliament and of the Council of 15 July 1991	

International

Agency/ Center or Office	Regulated Products	Legislation	Statutory Requirements
GHS	Chemicals		GHS Part 3, Chapter 3.4