## **Chemical Hazard Classification Process**

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## **HAZARD COMMUNICATION**

## **Hazard Classification Guidance**

for Manufacturers, Importers, and Employers





#### Occupational Safety and Health Act of 1970

"To assure safe and healthful working conditions for working men and women; by authorizing enforcement of the standards developed under the Act; by assisting and encouraging the States in their efforts to assure safe and healthful working conditions; by providing for research, information, education, and training in the field of occupational safety and health."

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This guidance document is not a standard or regulation, and it creates no new legal obligations. It contains recommendations as well as descriptions of mandatory safety and health standards. The recommendations are advisory in nature, informational in content, and are intended to assist employers in providing a safe and healthful workplace. The Occupational Safety and Health Act requires employers to comply with safety and health standards and regulations promulgated by OSHA or by a state with an OSHA-approved state plan. In addition, the Act's General Duty Clause, Section 5(a)(1), requires employers to provide their employees with a workplace free from recognized hazards likely to cause death or serious physical harm.

### **HAZARD COMMUNICATION**

# Hazard Classification Guidance for Manufacturers, Importers, and Employers

## Occupational Safety and Health Administration U.S. Department of Labor



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#### I. INTRODUCTION

OSHA's Hazard Communication Standard (HCS) is designed to protect against chemical-source injuries and illnesses by ensuring that employers and workers are provided with sufficient information to anticipate, recognize, evaluate, and control chemical hazards and take appropriate protective measures. This information is provided through safety data sheets (SDSs), labels, and employee training. In order for SDSs, labels, and training to be effective, the hazard information they convey must be complete and accurate. Thus, it is critically important to obtain comprehensive and correct information about the hazards associated with particular chemicals.

#### What is Hazard Classification?

Hazard classification is the process of evaluating the full range of available scientific evidence to determine if a chemical is hazardous, as well as to identify the level of severity of the hazardous effect. When complete, the evaluation identifies the hazard class(es) and associated hazard category of the chemical.

The HCS defines hazard class as the nature of a physical or health hazard, e.g., flammable solid, carcinogen, and acute toxicity. Hazard category means the division of criteria within each hazard class, e.g., acute toxicity and flammable liquids each include four hazard categories numbered from category 1 through category 4. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally. That is, a chemical identified as a category 2 in the acute toxicity hazard class is not necessarily less toxic than a chemical assigned a category 1 of another hazard class. The hierarchy of the categories is only specific to the hazard class. The hazard classification process provides the basis for the hazard information that is provided in SDSs, labels, and worker training.

The hazard classification process, as provided in the Hazard Communication Standard, has several steps, including:

- Identifying the chemical;
- Identifying the relevant data regarding the hazards of a chemical;
- Reviewing the relevant data to ascertain the hazards associated with the chemical;
- Determining whether the chemical will be classified as hazardous according to the definition of hazardous chemical in the standard; and
- Determining the degree of the hazard, where appropriate, by comparing the data with the criteria for health and physical hazards.

The HCS provides specific criteria for hazard classification to ensure that chemical manufacturers, importers, and other classification experts come to similar conclusions regarding the hazards of chemicals. The resulting classification is then used to determine appropriate hazard warnings. This method not only provides employers and workers with more consistent classification of hazards, but the hazard information on SDSs and labels is in a form that is more

consistent and presented in a way that facilitates the understanding of the hazards of chemicals. This hazard information can then be used when evaluating the workplace conditions to determine the hazards in the workplace, as well as to respond to exposure incidents.

The information and criteria provided in Appendix A to 29 CFR 1910.1200 are used to classify the health hazards posed by hazardous chemicals. Similarly, the information and criteria provided in Appendix B to 29 CFR 1910.1200 are used to classify the physical hazards posed by hazardous chemicals.

Hazard classification does not involve an estimation of risk. The difference between the terms hazard and risk is often poorly understood. Hazard refers to an inherent property of a substance

that is capable of causing an adverse effect. Risk, on the other hand, refers to the probability that an adverse effect will occur with specific exposure conditions. Thus, a chemical will present the same hazard in all situations due to its innate chemical or physical properties and its actions on cells and tissues. However, considerable differences may exist in the

Risk is often expressed as the simple equation:

Hazard X Exposure = Risk.

risk posed by a chemical, depending on how the chemical is contained or handled, personal protective measures used, and other conditions that result in or limit exposure. This document addresses only the hazard classification process, and will not discuss risk assessment, which is not performed under the HCS.

#### Who Must Conduct Hazard Classifications?

Only chemical manufacturers and importers are required to perform hazard classifications on the chemicals they produce or import. Under the HCS, an employer that manufactures, processes, formulates, blends, mixes, repackages, or otherwise changes the composition of a hazardous chemical is considered a "chemical manufacturer." Distributors and employers may also choose to conduct hazard classifications if they are concerned about the adequacy of the hazard information received for the chemicals they use in their business or distribute to others.

#### What Resources are Needed to Conduct a Hazard Classification?

Three primary resources are required for hazard classification. First is the complete, accurate, most up-to-date literature and data concerning the hazardous chemical in question (discussed below in Chapter V, Data Analysis). Second, is the ability to properly understand and interpret the information retrieved in order to identify and document hazards. Third, is the specific criteria for each health and physical hazard class and category defined in the Hazard Communication Standard. As mentioned above, Appendix A to 29 CFR 1910.1200 provides the classification criteria for health hazards, and Appendix B to 29 CFR 1910.1200 provides the classification criteria for physical hazards.

Manufacturers and importers of hazardous chemicals are responsible for ensuring that hazard information provided to their workers and downstream users is complete and accurate. To achieve this, the person(s) assigned to conduct hazard classifications must have the ability to

conduct complete and effective literature research and data retrieval. They should also be able to effectively interpret the literature and data in order to determine the nature and extent of physical and health hazards. A lack of qualified workers does not exempt a manufacturer or importer from compliance with the HCS.

#### How to Use This Guidance Document

The hazard classification requirements of the HCS are specification-oriented. That is, chemical manufacturers, importers, and employers evaluating chemicals are required to follow specific criteria for evaluating and classifying hazards, and they must be able to demonstrate that they have accurately reported the hazards of the chemicals produced or imported in accordance with the criteria set forth in the HCS

This document provides a detailed description of the criteria used to classify a hazardous chemical and guidance on how to apply them. In addition, a basic framework for hazard classification is provided, along with a description of the process that can be used to comply with the requirements of the HCS. An example using a mock chemical is also provided to illustrate the classification process of the given hazard.

The interpretation of information relating to the physical and health hazards associated with a chemical can be a highly technical undertaking, and should be conducted by trained staff such as toxicologists, industrial hygienists, and safety professionals. This document will not replace the need for such professional expertise. It is intended to serve only as useful guidance on the basic considerations and operational aspects involved in the conduct of hazard classifications.

Once hazard classification is complete, classifiers must select the appropriate label elements for the hazards identified. Appendix C to 29 CFR 1910.1200, Allocation of Label Elements, identifies the proper pictogram, signal word, hazard and precautionary statements for each hazard class and category in the HCS.

This document does not address detailed labeling requirements or SDSs. OSHA has developed QuickCards<sup>™</sup> and OSHA Briefs on labels, pictograms, and SDSs, as well as other guidance. These materials can be found on the HCS website at: www.osha.gov/hazcom.

#### II. THE HAZARD CLASSIFICATION PROCESS

#### Introduction

The purpose of the Hazard Communication Standard is to ensure that the hazards of all chemicals produced or imported are classified, and that the information on the hazardous chemicals is transmitted to employers and workers. The standard covers only hazardous chemicals. During the classification process, the chemical manufacturer or importer must determine if the chemical being evaluated is hazardous or not. With the alignment of the HCS to the GHS, the hazard information will be consistent in format and content, making it easier for employers and workers to understand and use. This section of the guidance clarifies what is considered a hazardous chemical.

#### What is the HCS Definition of a "Chemical"?

The definition of a chemical in the HCS is much broader than that which is commonly used in everyday speech. The HCS definition of chemical is "any substance, or mixture of substances." Thus, virtually any product is a "chemical." These various types of chemicals are defined as follows:

- **Substance** chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.
- *Element* the simplest form of matter. There are currently 118 known elements in the periodic table. Examples of elements are aluminum, carbon, chlorine, hydrogen, mercury and oxygen.
- *Chemical compound* a substance consisting of two or more elements combined or bonded together so that its constituent elements are always present in the same proportions.
- Mixture a combination or a solution composed of two or more substances in which they
  do not react

Although virtually all products are considered chemicals under this definition, the HCS identifies certain categories of chemicals that are not covered by the standard. These categories are:

- Any **hazardous waste** as defined by the *Solid Waste Disposal Act*, as amended by the *Resource Conservation and Recovery Act of 1976* (42 U.S.C. 6901 et seq.), as amended, when subject to regulations issued under that Act by the Environmental Protection Agency;
- Any hazardous substance as defined by the Comprehensive Environmental Response, Compensation and Liability Act (42 U.S.C. 9601 et seq.) when the hazardous substance is the focus of remedial or removal action being conducted under that Act in accordance with Environmental Protection Agency regulations;

- Tobacco or tobacco products;
- Wood or wood products, including lumber which will not be processed, where the chemical manufacturer or importer can establish that the only hazard they pose to employees is the potential for flammability or combustibility (wood or wood products which have been treated with a hazardous chemical covered by this standard, and wood which may be subsequently sawed or cut, generating dust, are not exempted);
- Articles, defined as a manufactured item other than a fluid or particle: (i) which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities, e.g., minute or trace amounts of a hazardous chemical, and does not pose a physical hazard or health risk to employees;
- Food or alcoholic beverages which are sold, used, or prepared in a retail establishment (such as a grocery store, restaurant, or drinking place), and foods intended for personal consumption by employees while in the workplace;
- Any drug, as that term is defined in the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), when it is in solid, final form for direct administration to the patient (e.g., tablets or pills); drugs which are packaged by the chemical manufacturer for sale to consumers in a retail establishment (e.g., over-the-counter drugs); and drugs intended for personal consumption by employees while in the workplace (e.g., first-aid supplies);
- Cosmetics which are packaged for sale to consumers in a retail establishment, and cosmetics intended for personal consumption by employees while in the workplace;
- Any consumer product or hazardous substance, as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and the Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.), respectively, where the employer can show that it is used in the workplace for the purpose intended by the chemical manufacturer or importer of the product, and the use results in a duration and frequency of exposure which is not greater than the range of exposures that could reasonably be experienced by consumers when used for the purpose intended;
- **Nuisance particulates** where the chemical manufacturer or importer can establish that they do not pose any physical or health hazard covered under this section;
- Ionizing and nonionizing radiation; and
- Biological hazards.

The HCS also does not require labeling for certain chemicals, but hazard classification is still needed for these chemicals to provide the required safety data sheet. The chemicals include:

• Any pesticide as such term is defined in the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C. 136 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;

- Any chemical substance or mixture as such terms are defined in the *Toxic Substances Control Act* (15 U.S.C. 2601 et seq.), when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Environmental Protection Agency;
- Any food, food additive, color additive, drug, cosmetic, or medical or veterinary device or product, including materials intended for use as ingredients in such products (e.g. flavors and fragrances), as such terms are defined in the *Federal Food, Drug, and Cosmetic Act* (21 U.S.C. 301 et seq.) or the *Virus-Serum-Toxin Act of 1913* (21 U.S.C. 151 et seq.), and regulations issued under those Acts, when they are subject to the labeling requirements under those Acts by either the Food and Drug Administration or the Department of Agriculture;
- Any distilled spirits (alcoholic beverages), wine, or malt beverage intended for nonindustrial use, as such terms are defined in the *Federal Alcohol Administration Act* (27 U.S.C. 201 et seq.) and regulations issued under that Act, when subject to the labeling requirements of that Act and labeling regulations issued under that Act by the Bureau of Alcohol, Tobacco, Firearms and Explosives;
- Any consumer product or hazardous substance as those terms are defined in the Consumer Product Safety Act (15 U.S.C. 2051 et seq.) and the Federal Hazardous Substances Act (15 U.S.C. 1261 et seq.) respectively, when subject to a consumer product safety standard or labeling requirement of those Acts, or regulations issued under those Acts by the Consumer Product Safety Commission; and,
- Agricultural or vegetable seed treated with pesticides and labeled in accordance with the *Federal Seed Act* (7 U.S.C. 1551 et seq.) and the labeling regulations issued under that Act by the Department of Agriculture.

#### How to Determine if a Chemical is "Hazardous"

Under the HCS, any chemical that is classified as a physical hazard, a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified is considered a hazardous chemical. The HCS definitions for physical hazard and health hazard are:

- Physical hazard means a chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, aerosols, liquids, or solids); oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water emits flammable gas. The criteria for determining whether a chemical is classified as a physical hazard are detailed in Appendix B to 29 CFR 1910.1200 Physical Hazard Criteria.
- **Health hazard** means a chemical that is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to 29 CFR 1910.1200 Health Hazard Criteria.

The definitions for each of the specific physical and health hazards identified above are the same as those found in the GHS, Rev. 3. To maintain the coverage of those hazards that were included in the 1994 Hazard Communication Standard, OSHA included hazard communication elements for the following hazards that are not found in GHS Rev. 3: combustible dusts, pyrophoric gases, and simple asphyxiants. OSHA has also created "hazards not otherwise classified", a hazard class to capture hazards for which criteria have not yet been created.

Each of these hazards are included in this guidance document. Guidance on classification of simple asphyxiants is presented in Chapter VII, Classification of Health Hazards. Guidance on classification of pyrophoric gases and combustible dusts is presented in Chapter VIII, Classification of Physical Hazards. Guidance on classification of hazards not otherwise classified is presented in Chapter IX, Classification of Hazards not Otherwise Classified.

Table II.1 lists the different health hazard classes and categories identified in the HCS. Similarly, Table II.2 lists the different physical hazard classes and categories found in the HCS. Those hazard classes listed in italicized font in these two tables are the hazard classes not identified in GHS Rev.3, but are included in the HCS to maintain workplace coverage. Explanations of the classification process for each of these hazard classes and their associated hazard categories are presented in Chapters VII and VIII of this document, respectively.

Table II.1. Health Hazard Classes and Categories.

Hazard Class	Hazard Category				
Acute Toxicity	1	2	3	4	
Skin Corrosion/Irritation	1A	1B	1C	2	
Serious Eye Damage/ Eye Irritation	1	2A	2В		
Respiratory or Skin Sensitization	1A	1B			
Germ Cell Mutagenicity	1A	1B	2		
Carcinogenicity	1A	1B	2		
Reproductive Toxicity	1A	1B	2	Lactation	
STOT – Single Exposure	1	2	3		
STOT – Repeated Exposure	1	2			
Aspiration	1				
Simple Asphyxiants	Single Category				

Table II.2. Physical Hazard Classes and Categories.

Hazard Class	Hazard Category						
Explosives	Unstable Explosives	Div 1.1	Div 1.2	Div 1.3	Div 1.4	Div 1.5	Div 1.6
Flammable Gases	1	2					
Flammable Aerosols	1	2					
Oxidizing Gases	1						
Gases under Pressure Compressed Gases Liquefied Gases Refrigerated Liquefied Gases Dissolved Gases	1						
Flammable Liquids	1	2	3	4			
Flammable Solids	1	2					
Self-Reactive Chemicals	Type A	Type B	Type C	Type D	Type E	Type F	Type G
Pyrophoric Liquids	1						
Pyrophoric Solid	1						
Pyrophoric Gases	Single category						
Self-heating Chemicals	1	2					
Chemicals, which in contact with water, emit flammable gases	1	2	3				
Oxidizing Liquids	1	2	3				
Oxidizing Solids	1	2	3				
Organic Peroxides	Type A	Type B	Type C	Type D	Type E	Type F	Type G
Corrosive to Metals	1						
Combustible Dusts	Single category						

For a hazard classification process to be complete, one must consider all possible hazards, and should document any hazards that are identified. In conducting the hazard classification, one should be cognizant of all types of physical and health hazards to properly identify the nature and severity of the chemical's hazards.

OSHA regulates a number of chemicals as toxic and hazardous substances, which are contained in Subpart Z of 29 CFR 1910. The classifier must refer to the regulations of these substances for specific hazard classification requirements. For example, the Lead standard requires that at least the hazards of reproductive/developmental toxicity, central nervous system effects, kidney effects, blood effects, and acute toxicity effects be addressed in classification (See 29 CFR 1910.1025(m)(ii)). In addition, there are certain lists that can help the classifier identify chemicals that have been deemed hazardous by nationally and internationally recognized organizations, such as the American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs), National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs), National Toxicology Program (NTP) *Report on Carcinogens* (RoC), and International Agency for Research on Cancer (IARC). Appendix C of this document contains a list of those materials regulated by OSHA as toxic and hazardous substances. Appendix D of this document contains a list of OSHA-designated carcinogens.

The classifier must evaluate all the evidence and data available for the given chemical and use the specific criteria spelled out for each health and physical hazard to classify the chemical in appropriate hazard classes and categories. In some cases, available data provides enough information to classify a chemical. In other cases, classification is determined on the basis of the total weight of evidence using expert judgment. This means that all available information bearing on the classification of the hazard must be considered together. In the case of health hazards, for example, this includes the results of valid *in vitro* tests, relevant animal data, and human experience, such as epidemiological and clinical studies, and well-documented case reports and observations.

If OSHA has designated a chemical as a carcinogen, then the chemical must be classified as a carcinogen. There are also organizations that evaluate chemicals for carcinogenicity. These organizations, such as the International Agency for Research on Cancer (IARC) and the National Toxicology Program (NTP), publish lists of hazardous chemicals that they have determined, with varying degrees of certainty, to be carcinogens. OSHA has provided a crosswalk table to aid classifiers in translating the classification from NTP or IARC into the HCS classification scheme in <a href="Chapter VII.6">Chapter VII.6</a> of this document. The discussion on carcinogens in this guidance provides more detail on the classification of carcinogens.

The definition for hazardous chemical in the standard is thus very broad. The standard does not require the testing of chemicals - only the collection and analysis of currently available data. Nevertheless, if no data is available or it is questionable, testing should be considered when hazardous properties are suspected.

## Is Hazard Classification the Same for Mixtures as for Individual Chemicals?

Generally speaking, the chemical and physical properties and hazards of pure elements and chemical compounds are precise and constant. For example, benzene has explicit boiling and flashpoints of 176 °F and 12 °F (at sea level), respectively. In contrast, the properties of the complex mixture, Stoddard Solvent, can vary considerably depending on the manufacturer and lot received, with ranges for boiling and flashpoints of 309-396 °F and 102-110 °F, respectively.

The process for evaluating mixtures may require steps in addition to those required for single chemical agents. The HCS has designated specific classification requirements for mixtures, which depend upon the availability of test data. Please see <a href="Chapter V">Chapter V</a>, Data Analysis, for a detailed discussion on classification of mixtures. In addition, the chapters for the individual hazard classes discuss the specifics necessary for classification of mixtures.

#### What is Involved in Conducting a Hazard Classification?

All possible physical or health hazards that might be associated with a chemical's use must be considered. The hazard classification process consists of four main steps:

- Selection of chemicals to evaluate;
- Collection of data;
- Analysis of the collected data using the criteria provided in the HCS; and
- Documentation of the hazard classification process and the results obtained<sup>1</sup>.

The Hazard Communication Standard provides the specific criteria upon which the hazard classification for a given chemical is based, ensuring that all those evaluating data and performing hazard classification are following the same process, resulting in similar classification conclusions. If no hazards are found, the manufacturer, importer, or employer is not required to take further action pertaining to the evaluated chemical. Documentation of the results of the analysis used in the classification process may be useful for future reference.

For many chemicals, hazard information has been compiled in readily available and reliable sources (see <a href="Appendix B">Appendix B</a> of this document). The specific classification criteria for each health or physical hazard class identified in the HCS enables manufacturers, importers, and others performing hazard classification to collect and evaluate the available data to determine if the chemical is hazardous and identify the associated level of severity.

In some cases, a chemical may present a single hazard. In other cases, several hazards may be associated with exposure to a chemical. The severity of the hazardous effect can range from mild to severe. In the HCS, for example, identified health hazards for acetic acid, as normally

12

<sup>&</sup>lt;sup>1</sup> Note that documentation of the hazard classification process and the results obtained is not required by the HCS; however OSHA recommends it. See <u>Chapter VI</u>, <u>Recording the Rationale Behind the Results Obtained</u>, of this document.

used in industry, are skin irritation/corrosion and respiratory sensitization. In contrast, exposure to lead may involve a multitude of hazards, including reproductive/developmental toxicity, central nervous system effects, kidney effects, and acute toxicity effects.

Hazard evaluation is a process that relies heavily on the professional judgment of the evaluator, particularly in the area of chronic health hazards. The specification approach of the HCS requires the chemical manufacturer, importer or employer to conduct a thorough evaluation, examining the full range of available data and producing a scientifically defensible evaluation of the chemical hazards.

#### III. IDENTIFYING HAZARDOUS CHEMICALS

The ultimate goal in the hazard classification process is to know and document the hazards of all covered chemicals you manufacture or import. In order to achieve this, you must first determine which chemicals require a hazard classification. The logical way to do this is to first prepare an inventory of all the chemicals you manufacture or import, as well as a list of the ingredients in the mixtures produced. To create the list of ingredients from the mixtures produced, consider information found in the chemical formula, on order receipts, batch sheets, and so on.

While a single SDS must be created for the mixtures produced, you may rely upon the information provided on the SDSs and labels for ingredients obtained from the chemical manufacturer or importer, unless you have reason to believe the information is incorrect. However, you may choose to conduct a hazard classification for those ingredients if there is concern about the adequacy of the hazard information received.

All employers are required to have a list of hazardous chemicals known to be present in the workplace under 29 CFR 1910.1200(e)(1)(i). If a chemical inventory is not already in place, a good start would be to review purchase orders and receipts to create an initial inventory. Next, take time to inspect the workplace to identify any additional chemicals present. It would be ideal to note the location and quantity of each chemical found. Chemical inventories are often maintained as computer files for ease and efficiency in keeping them current. With knowledge of the chemicals in your possession, you can use this information to perform hazard classifications for chemicals that you manufacture or import.

On a related safety note, the chemical inventory or survey can also be used to decide which chemicals to dispose of, as well as to identify potentially unsafe storage areas and techniques. Some chemicals should not be stored near each other due to incompatibilities and potential reactions.

#### IV. DATA COLLECTION

The second step in the hazard classification process is data collection. There are two main questions to be answered: (1) what type of data should be searched for and collected; and (2) how do I go about finding sources that might contain the desired data? You should recognize that the hazard classification process involves the identification of all of the hazards associated with a chemical, not just some of them. OSHA expects classifiers to use reasonable efforts in their search for available data for all hazard classes (see <a href="Chapter V">Chapter V</a>, Data Analysis), for a discussion on the use of available data). Specific types of data used for classification of a given hazard are discussed in the individual hazard chapters of this document. Any hazard that exists for the chemical must be identified and communicated to downstream employers and workers.

To complete the hazard identification, information is needed in three categories:

- chemical identity;
- physical and chemical properties; and
- health effects

There are numerous sources that could be searched for this information. A list of commonly used data sources is provided in <u>Appendix B</u> of this document, although other sources exist and new sources continue to appear online and in print. For new or less commonly used chemicals, there may not be much data available from any of these sources. While the HCS does not require testing, you may choose to test chemicals to determine chemical and physical properties and identify hazards.

In the sections that follow, a discussion of data needs for the three categories of information is provided. Also, a few recommended key references for the various types of data are listed. Complete and reliable data must be entered on SDSs and labels to meet the HCS requirements. Before the search for hazard data can begin, the exact chemical composition of the chemical(s) or products manufactured or imported must be identified. This chemical search includes the name of each chemical (whether it is a substance or a mixture), including active ingredients, inactive ingredients, impurities, and stabilizing additives.

#### **Chemical Identity**

The specific chemical identity of all chemicals on your chemical inventory should be carefully and completely compiled. The specific chemical identity includes:

- the chemical name along with common name and synonyms;
- the Chemical Abstracts Services (CAS) Registry Number (if available); and
- any other information that reveals the precise chemical designation and composition of the substance, such as impurities and stabilizers.

Correct identification of chemicals is critical for data retrieval. Use the precise chemical name, where available, and Chemical Abstract Service (CAS) number when searching for information. A problem with the use of common names or abbreviations is that they may be used for more than one molecular entity. To avoid confusion, literature is often indexed using the CAS number or the primary chemical name. For example, TCE is commonly used as an acronym for trichloroethylene

(CAS 79-01-6), but sometimes this same acronym is used to refer to tetrachloroethylene (CAS 127-18-4).

Additionally, the use of trade names could cause difficulty in finding information. An example of the type of chemical identification data that is needed is presented for Perclene®, a

CAS numbers are assigned by the Chemical Abstract Service of the American Chemical Society.

widely used industrial solvent. Perclene® is a trade name for perchloroethylene or Perc (common name), or more specifically tetrachloroethylene (CAS Number 127-18-4). Several databases exist that can only be searched using the CAS number or chemical name. Thus, the most effective search of computerized databases is conducted using both the precise chemical name (tetrachloroethylene) and the CAS number (CAS Number 127-18-4). Searches using the trade or common name(s) or abbreviation(s) may not return information for that chemical.

The percent composition (or exact percentage) should be available in-house for all chemicals manufactured or imported. The chemical composition information may be based on an analysis of the final or technical grade product or product formulation. A technical grade product is not usually a pure substance and often contains other chemicals such as stabilizers, solvents, carriers, "inert" ingredients, or impurities. For the purposes of hazard classification, these other chemicals must also be considered since they may have their own unique hazards and may contribute to the hazards of the chemical.

Thus, one of the initial steps is to collect as much data as possible pertaining to the physical and chemical properties and toxicity data for chemicals on your chemical inventory.

Key sources of information related to chemical identification are:

- Company records;
- SDSs and product safety bulletins from manufacturers or suppliers;
- OSHA Chemical Sampling Information pages;
- The Merck Index;
- ChemID; and
- Trade associations.

#### Physical and Chemical Properties

The physical and chemical properties of a hazardous chemical are the empirical data of the substance or mixture. That is, this data has been gathered from observation or by tests performed on the chemical. For many hazardous chemicals, this data has been compiled and is readily available.

Key sources of information related to physical and chemical properties include:

- Fire Protection Guide to Hazardous Materials;
- Department of Transportation Emergency Response Guidebook, most recent version (phmsa.dot.gov/hazmat/library/erg);
- OSHA's Occupational Chemical Database (<u>www.osha.gov/chemicaldata</u>);
- Hazardous Substances Data Bank (HSDB) (<u>toxnet.nlm.nih.gov</u>);
- Product safety bulletins from manufacturers or suppliers;
- National Institute for Occupational Safety and Health (NIOSH) documents (www.cdc.gov/niosh/topics/chemical.html);
- NIOSH Pocket Guide to Chemical Hazards (<u>www.cdc.gov/niosh/npg</u>);
- International Chemical Safety Cards (<u>www.cdc.gov/niosh/ipcs</u>);
- OECD eChemPortal (<u>www.oecd.org/env/ehs/risk-assessment/echemportalglobalportaltoinformationonchemicalsubstances.htm</u>);
- The Merck Index;
- CRC Handbook of Chemistry and Physics;
- Sax's Dangerous Properties of Industrial Materials, latest edition;
- Bretherick's Handbook of Reactive Chemicals Hazards, latest edition; and
- Trade associations.

The HCS includes classification criteria for 17 physical hazard classes (see Table II.2) and are discussed in detail in <u>Chapter VIII</u>. These physical hazard classes should not be confused with the physical and chemical properties of a chemical.

#### Health Effects

The HCS includes the classification criteria for 11 health hazard classes (see Table II.1) and are discussed in detail in <a href="Chapter VII">Chapter VII</a>. In many cases, a chemical may pose more than one type of health hazard. If your company is manufacturing a new chemical you may be required to submit pre-manufacturing health effects data to the U.S. Environmental Protection Agency (EPA) to comply with the *Toxic Substances Control Act* (TSCA). Data submitted to EPA by other companies may be available to you by contacting EPA. This data may be used to assist with hazard classification and the preparation of SDSs and labels. The company also should seek toxicity data from the literature, government, or private sources. Some recommended reference sources are listed below.

- Company-sponsored research, if available;
- SDSs and product safety bulletins from manufacturers, suppliers, or Internet sites;
- OSHA's Occupational Chemical Database (<u>www.osha.gov/chemicaldata</u>);
- Hazardous Substances Data Bank (HSDB) (toxnet.nlm.nih.gov);
- National Institute of Occupational Safety and Health (NIOSH) documents (www.cdc.gov/niosh/topics/chemical.html);
- NIOSH Pocket Guide to Chemical Hazards (<u>www.cdc.gov/niosh/npg</u>);
- Center for Disease Control's (CDC) Agency for Toxic Substances and Disease Registry (ATSDR), www.atsdr.cdc.gov/toxprofiles/index.asp
- International Chemical Safety Cards (<u>www.cdc.gov/niosh/ipcs</u>);
- NIOSH Registry of Toxic Effects of Chemical Substances (RTECS®) (www.cdc.gov/niosh/rtecs/RTECSaccess.html);
- OSHA Chemical Sampling Information pages;
- IARC Monographs on the Evaluation of Carcinogenic Risks to Humans (monographs.iarc.fr);
- NTP Annual Report on Carcinogens (<a href="https://ntp.niehs.nih.gov/pubhealth/roc">ntp.niehs.nih.gov/pubhealth/roc</a>);
- TLVs and BEIs (ACGIH) (<u>www.acgih.org/tlv-bei-guidelines/policies-procedures-presentations/overview</u>);
- OECD eChemPortal (<u>www.oecd.org/env/ehs/risk-assessment/echemportalglobalportaltoinformationonchemicalsubstances.htm</u>);
- Hawley's Condensed Chemical Dictionary, latest edition;
- Sax's Dangerous Properties of Industrial Materials, latest edition;
- Published literature; and
- Trade associations.

#### V. DATA ANALYSIS

The third step in the hazard classification process is data analysis. This step is the most demanding in terms of technical expertise. The HCS requires that chemical manufacturers and importers conduct a hazard classification to determine whether physical hazards or health hazards exist.

For both health and physical hazards, explicit classification criteria are provided in the HCS. For example, criteria are given for classifying a chemical as a flammable liquid, an organic peroxide, and for designating a chemical as acutely toxic or a carcinogen.

In some cases, the HCS establishes the criteria to be followed. For example, if a liquid has a flashpoint of less than or equal to 93°C (199.4°F), it is by definition a "flammable liquid." To determine into what category of flammable liquid the chemical is classified, you also will need to identify its initial boiling point. This involves a simple data analysis. You can rely on the flashpoint and boiling point listed in a standard reference. In the event that your company is manufacturing or importing a chemical for which there is no information on the flashpoint and boiling point, you may choose to determine the flashpoint by laboratory testing. See <u>Use of available data, test methods and test data quality</u> below for a more detailed discussion.

The following discusses the general considerations for analyzing data to complete the classification process as defined in the Hazard Communication Standard.

#### Hazard Classification

In the Hazard Communication Standard, the term "hazard classification" is used to indicate that only the intrinsic hazardous properties of chemicals are considered. Hazard classification incorporates three steps:

- a) Identification of relevant data regarding the hazards of a chemical;
- b) Subsequent review of those data to ascertain the hazards associated with the chemical;
- c) Determination of whether the chemical should be classified as hazardous and the degree of hazard, where applicable.

For many hazard classes, the criteria are semi-quantitative or qualitative and expert judgment is required to interpret the data for classification purposes.

#### Use of available data, test methods and test data quality

The criteria for determining health hazards are test-method neutral. That is, they do not specify particular test methods, as long as the methods are scientifically validated. The term "scientifically validated" refers to the process by which the reliability and the relevance of a procedure are established for a particular purpose. Any test that determines hazardous properties, which is conducted according to recognized scientific principles, can be used for purposes of a hazard determination for health hazards. Test conditions need to be standardized so that the results are reproducible for a given chemical, and the standardized test yields "valid" data for defining the hazard class of concern. OSHA allows the use of existing test data for classifying chemicals, although expert judgment also may be needed for classification purposes.

The effect of a chemical on biological systems is influenced by the physical and chemical properties of the substance and/or ingredients of the mixture and the way in which ingredient substances are biologically available. A chemical need not be classified when it can be shown by conclusive experimental data from scientifically validated test methods that the chemical is not biologically available.

For classification purposes, epidemiological data and experience on the effects of chemicals on humans (e.g., occupational data, data from accident databases) must be considered in the evaluation of the chemical's human health hazards.<sup>2</sup>

Testing is not required by the HCS. Therefore, if existing data is not available, you have the option to state this on the safety data sheet. However, if you decide to test the chemical, use the test methods specified in the appropriate health or physical hazard appendices to the HCS to gather the data (see the Classification Procedure and Guidance section for each health hazard class and for each physical hazard class of this guidance, and Appendix A and Appendix B to 29 CFR 1910.1200). Appropriate test methods for each physical hazard class are identified in the standard and discussed in each physical hazard section of this guidance.

#### Classification based on weight of evidence (WoE)

For some hazard classes, classification results directly when the data satisfy the criteria. This is the case for most physical hazard classes. For others, classification of a chemical may be determined on the basis of the total weight of evidence using expert judgment. Under the GHS, weight of evidence (WoE) means that all available information bearing on the classification of a hazard is considered together, including the results of valid *in vitro* tests, relevant animal data, and human experience, such as epidemiological and clinical studies and well-documented case reports and observations. There are several reasons to utilize a WoE approach. First, WoE makes use of all available information. This is important especially when there is conflicting information between studies. Second, less reliable studies can be pooled to draw a conclusion on the relevant endpoint. Finally, WoE allows for use of different but adequate information that is available (e.g., data on other species, or routes of exposure).

20

<sup>&</sup>lt;sup>2</sup> As human experience can also provide information on the hazards of a chemical, occupational data and data from accident databases are examples of where you can get such information.

OSHA has provided general criteria on how to perform an analysis based on weight of evidence in Appendix A.0.3 to 29 CFR 1910.1200, as well as specific criteria in the individual health chapters where weight of evidence is used (skin corrosion/irritation, serious eye damage/eye irritation, respirator or skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity - single exposure (STOT-SE), and STOT-repeated or prolonged exposure). See Appendices A.2-A.9 to 29 CFR 1910.1200.

When performing a WoE assessment to determine the classification of a chemical, the classifier must determine which data or study results have the most utility and validity to support the resulting hazard classification of the chemical. These considerations include four basic elements: data adequacy, data reliability, data relevance, and quantity of evidence. It is also necessary to understand how to apply this information to the data in order to make hazard classification decisions. Information on chemicals related to the material being classified must also be considered, as appropriate, along with site of action and mechanism or mode of action study results. In addition, both positive and negative results must be considered together in a single weight-of-evidence determination.

Most toxicity and epidemiology reports provide an analysis of the data and conclude whether the results were positive or negative, or describe the adverse effects observed at specific dose levels. Positive results mean that the exposed humans or animals were more likely to develop toxic effects than the non-exposed population.

Positive effects which are consistent with the criteria for classification, whether seen in humans or animals, normally justify classification. Where evidence is available from both humans and animals and there is a conflict between the findings, the quality and reliability of the evidence from both sources must be evaluated in order to resolve the question of classification. Reliable, good quality human data generally has precedence over other data. However, even well-designed and conducted epidemiological studies may lack a sufficient number of subjects to detect relatively rare but still significant effects, or to assess potentially confounding factors. Therefore, positive results from well-conducted animal studies are not necessarily negated by the lack of positive human experience, but require an assessment of the robustness, quality and statistical power of both the human and animal data.

Route of exposure, mechanistic information, and metabolism studies are used in determining the relevance of a health effect in humans. When such information raises doubt about relevance in humans, a lower classification may be warranted. When there is scientific evidence demonstrating that the mechanism or mode of action is not relevant to humans, the data may not justify classification.

Both positive and negative results are considered together in the weight of evidence determination. However, a single positive study performed according to established scientific principles and with statistically and biologically significant positive results may justify classification.

Statistical significance is a mathematical determination of the confidence in the outcome of a test. The usual criterion for establishing statistical significance is the p-value (probability value). A statistically significant difference in results is generally indicated by p<0.05, meaning there is less than a 5% probability that the toxic effects observed were due to chance and were not caused by the chemical. Another way of looking at it is that there is a 95% probability that the effect is real, i.e., the effect seen was the result of the chemical exposure.

The other major measure of statistical significance is the 95% confidence level for a specific data point. Most reports of toxicity testing will include some information on the confidence in the data. For example, a study with a stated confidence level of 95% and an  $LD_{50}^{3}$  with a listed value of  $9.5 \pm 1.2$  indicates that if the same study were to be repeated many times, the  $LD_{50}$  would be expected to be within the range of 8.3 - 10.7 on 95 out of every 100 times.

Hazard evaluation relies on professional judgment, particularly in the area of chronic hazards. The specific and detailed orientation of the HCS does not diminish the duty of the chemical manufacturer, importer or employer to conduct a thorough evaluation, examining all relevant data and producing a scientifically defensible classification.

#### Considerations for the classification of mixtures

Classification of mixtures is based on the following sequence for most hazard classes:

- 1. If the mixture has been tested as a whole and test data are available for the complete mixture, these results are used to classify the mixture.
- 2. If a mixture has not been tested as a whole or test data are not available for the complete mixture, the bridging principles designated in each health hazard chapter of Appendix A of the Hazard Communication Standard are used to classify the mixture.
- 3. If **test data are not available for the mixture itself, and the available information is not sufficient** to allow application of the above-mentioned bridging principles, then the method(s) described in each chapter for estimating the hazards based on the information known will be applied to classify the mixture (e.g., application of cut-off values/concentration limits).

An exception to the above order of precedence is made for Carcinogenicity, Germ Cell Mutagenicity, and Reproductive Toxicity (CMR). For these three hazard classes, mixtures are classified based upon information on the ingredient substances, unless on a case-by-case basis, justification can be provided for classifying based upon the mixture as a whole. Mixture rules for these three hazard classes are presented in Chapters VII.5, VII.6, and VII.7 of this document. See also chapters A.5, A.6, and A.7 in the Hazard Communication Standard for further information.

22

 $<sup>^3</sup>$  LD<sub>50</sub> (Lethal Dose 50) is the amount of a chemical, given all at once, which causes the death of 50% (one half) of a group of test animals.

## Bridging principles for the classification of mixtures where test data are not available for the complete mixture

Where the mixture itself has not been tested to determine its toxicity, but there are sufficient data on **both the individual ingredients and similar tested mixtures** to adequately characterize the hazards of the mixture, the following bridging principles are used, subject to any specific provisions for mixtures for each hazard class. These principles ensure that the classification process uses the available data to the greatest extent possible in characterizing the hazards of the mixture.

#### **Dilution**

For mixtures classified in accordance with all the health hazard classes of the HCS (see Appendices A.1 through A.10 to 29 CFR 1910.1200), if a tested mixture is diluted with a diluent that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then:

- (a) The new diluted mixture is classified as equivalent to the original tested mixture; or
- (b) For classification of acute toxicity, the additivity formula must be applied (see A.1.3.6 in Appendix A to 29 CFR 1910.1200).

#### **Batching**

The toxicity of a tested production batch of a mixture can be assumed to be substantially equivalent to that of another untested production batch of the same mixture, when produced by or under the control of the *same chemical manufacturer*, unless there is reason to believe there is significant variation such that the toxicity of the untested batch has changed. If the latter occurs, a new classification is necessary. The batching approach is used for mixtures classified in accordance with all the health hazard classes of the HCS (see Appendices A.1 through A.10 to 29 CFR 1910.1200).

#### **Concentration of mixtures**

The concentration of ingredients may be used to classify mixtures for the following hazard classes: acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, specific target organ toxicity - single exposure (STOT-SE), STOT-repeated or prolonged exposure, or aspiration (see Appendices A.1, A.2, A.3, A.8, A.9, or A.10 to 29 CFR 1910.1200). In these cases, if a tested mixture is classified in Category 1, and the concentration of the ingredients of the tested mixture that are in Category 1 is increased, the resulting untested mixture is classified in Category 1.

#### Interpolation within one toxicity category

For three mixtures (A, B and C) with identical ingredients, where mixtures A and B have been tested and are in the same toxicity category, and where untested mixture C has the same toxicologically active ingredients as mixtures A and B but has concentrations of toxicologically active ingredients intermediate to the concentrations in mixtures A and B, then mixture C is assumed to be in the same toxicity category as A and B. This approach to interpolating data

within one toxicity category is used for mixtures classified in accordance with the classification criteria for the following hazard classes in the HCS: acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, specific target organ toxicity - single exposure (STOT-SE), STOT-repeated or prolonged exposure, or aspiration (see Appendices A.1, A.2, A.3, A.8, A.9, or A.10 to 29 CFR 1910.1200).

#### **Substantially similar mixtures**

For mixtures classified in accordance with all health hazard categories of the HCS (see Appendices A.1 through A.10 to 29 CFR 1910.1200), given the following set of conditions:

- (a) Where there are two mixtures:
  - (i) A + B;
  - (ii) C + B;
- (b) The concentration of ingredient B is essentially the same in both mixtures;
- (c) The concentration of ingredient A in mixture (i) equals that of ingredient C in mixture (ii);
- (d) And data on toxicity for A and C are available and substantially equivalent; i.e., they are in the same hazard category and are not expected to affect the toxicity of B; then

If mixture (i) or (ii) is already classified based on test data, the other mixture can be assigned the same hazard category.

#### Aerosols

For mixtures classified in accordance with the classification criteria for acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory or skin sensitization, specific target organ toxicity - single exposure (STOT-SE), or STOT-repeated or prolonged exposure (see Appendices A.1, A.2, A.3, A.4, A.8, or A.9 to 29 CFR 1910.1200), an aerosol form of a mixture is classified in the same hazard category as the tested, non-aerosolized form of the mixture, provided the added propellant does not affect the toxicity of the mixture when spraying.

#### Use of cut-off values/concentration limits

When classifying an untested mixture based on the hazards of its ingredients, cut-off values/concentration limits<sup>4</sup> for the classified ingredients of the mixture are used for several hazard classes. While the adopted cut-off values/concentration limits adequately identify the hazard for most mixtures, there may be some that contain hazardous ingredients at lower concentrations than the specified cut-off values/concentration limits that still pose an identifiable hazard. There may also be cases where the cut-off value/concentration limit is considerably lower than the established non-hazardous level for an ingredient.

<sup>&</sup>lt;sup>4</sup> For the purposes of the HCS, the terms "cut-off values" and "concentration limits" mean the same thing.

If the chemical manufacturer, importer or other hazard classifier has information that the hazard of an ingredient will be evident (i.e., it presents a health risk) below the specified cut-off value/concentration limit, the mixture containing that ingredient must be classified accordingly.

In exceptional cases, conclusive data may demonstrate that the hazard of an ingredient will not be evident (i.e., it does not present a health risk) when present at a level above the specified cut-off value/concentration limit(s). In these cases the mixture may be classified according to those data. The data must exclude the possibility that the ingredient will behave in the mixture in a manner that would increase the hazard over that of the pure substance. Furthermore, the mixture must not contain ingredients that would affect that determination.

The HCS has established specific cut-off values for different health hazards. Table V.1 presents these cut-off values. When a substance in a specified hazard class is present in a mixture at or above the cut-off level, the mixture must be classified in that hazard class.

**Table V.1. Cut-off Values for Health Hazards** 

Hazard class	Label Cut-Off Values	SDS Cut-Off Values
Respiratory/Skin sensitization	≥ 0.1%	≥ 0.1%
Germ cell mutagenicity (Category 1)	≥ 0.1%	≥ 0.1%
Germ cell mutagenicity (Category 2)	≥ 1.0%	≥ 1.0%
Carcinogenicity	≥ 0.1%	≥ 0.1%
Reproductive toxicity	≥ 0.1%	≥ 0.1%
Specific target organ toxicity (single exposure)	≥ 1.0%	≥ 1.0%
Specific target organ toxicity (repeated exposure)	≥ 1.0%	≥ 1.0%
Specific target organ toxicity Category 3	≥20%	≥20%

#### Synergistic or antagonistic effects

When performing an assessment in accordance with the requirements of the Hazard Communication Standard, the evaluator must take into account all available information about the potential occurrence of synergistic effects among the ingredients of the mixture. Lowering the classification of a mixture to a less hazardous category on the basis of antagonistic effects may be done only if the determination is supported by sufficient data.

Synergistic effects result when the overall effect of the ingredients is greater than the sum of any of the individual effects, while antagonistic effects result from the contrasting actions or negative effect from two (or more) ingredients, so that the overall effect is less than the sum of any of the individual effects.

#### Hazard Classification of Petroleum Streams

To classify the health hazards of petroleum streams, follow the guidance presented below in conjunction with the general guidance found in Appendix A.0.1-A.0.3 to 29 CFR 1910.1200, and the classification criteria provided for the health hazards presented in Appendix A to 29 CFR 1910.1200.

- 1. For hazard classes other than carcinogenicity, germ cell mutagenicity, and reproductive toxicity ("CMR"), classify a petroleum stream as follows:
  - a) Where test data are available for the petroleum stream, the classification of the stream will always be based on those data.
  - b) Where test data are not available for the stream itself, the classification may be based on a toxicologically appropriate read across from test results of a substantially similar stream. A substantially similar stream is one that has a similar starting material, production process, and range of physico-chemical properties (e.g., boiling point and carbon number) and similar constituent compositions.
  - c) If test data are not available either for the stream itself or a substantially similar stream, then apply the method(s) described in each chapter of Appendix A to 29 CFR 1910.1200 for estimating the hazards based on the information known to classify the stream (i.e., application of cut-off values/concentration limits).

#### 2. For the CMR hazard classes:

- a) When reliable and good quality data are available to classify a petroleum stream, based on testing of the stream or the toxicologically appropriate read-across to a substantially similar stream, a weight of evidence analysis supported by that data may be relied upon for classification regardless of whether a CMR constituent is present in the stream. A substantially similar stream is one that has a similar starting material, production process, and range of physico-chemical properties (e.g., boiling point and carbon number) and similar constituent compositions.
- b) To be reliable and good quality test data, the data must be from one or more tests that reflect appropriate study design and performance. The study or studies must appropriately take into account dose and other factors such as duration, observations, and analysis (e.g., statistical analysis, test sensitivity) so as to conclusively exclude the possibility that the lack of effect(s) is due to a poor study design, e.g., insufficient dose or number of subjects. A study (or studies) is conclusive in this sense if, when viewed in conjunction with all relevant information about the chemical, its results are consistent with the relevant information and allow a strong inference that the lack of effects is not due to a poor study design.
- c) Where reliable and good quality data are not available on the stream or a substantially similar stream, then apply the method(s) described in each chapter of Appendix A of 29 CFR 1910.1200 for estimating the hazards based on the information known to classify the stream (i.e., application of cut-off values/concentration limits).

## Interface Between the HCS and U.S. Department of Transportation (DOT) labeling

As mentioned earlier, the purpose of the HCS is to ensure that the hazards of all chemicals produced or imported are classified, and that information concerning the hazards is transmitted to employers and workers. This information is transmitted by means of a comprehensive hazard communication program, which includes container labeling and other forms of warning, safety data sheets, and worker training.

With the alignment of the HCS to the GHS, one will find that there is generally a correlation between the DOT packing group and the HCS physical hazard class category. If the chemical being classified is the same chemical that has previously undergone classification to meet DOT's Hazardous Materials Regulations, you may use this data to classify the physical hazards of the chemical to meet the requirements of OSHA's Hazard Communication Standard. You may find the information contained in DOT's Hazardous Materials Regulations is another useful reference, in particular the Hazardous Materials Table, located in 49 CFR 172.101.

DOT labeling (referred to as placarding) applies to chemicals that are transported by means of rail car, aircraft, motor vehicle, and vessel. These placards must follow certain size and color requirements. The labels for the transport of dangerous goods are those prescribed by DOT's Hazardous Materials Regulations (49 CFR Parts 100-185). The classification criteria and testing procedures found in the DOT Hazardous Materials Regulations are aligned with the *UN Recommendations on the Transport of Dangerous Goods – Model Regulations*.

## VI. RECORDING THE RATIONALE BEHIND THE RESULTS OBTAINED

The fourth and final step in the hazard classification process is also important. All the other steps will be wasted if findings are not recorded carefully. If a chemical is found to be hazardous, OSHA recommends that the findings and the rationale used to arrive at these findings be documented.

The HCS no longer requires documentation of the procedures used to determine the hazards of a chemical since this is now provided through the classification procedures specified in Appendices A and B of the HCS, and all those performing hazard classification must follow the same process. However, OSHA still recommends the data, the rationale used, and other results gathered during the classification process be maintained for future reference and use.

To assist in this, OSHA recommends that a structured approach to data retrieval and compilation be adopted. This structured approach also applies to the preparation of SDSs and labels. If you decide to take such an approach, this section provides some guidelines you may wish to consider.

Compilations of three types of data are considered essential:

- Initial chemical inventory;
- Specific data retrieved for each chemical; and
- List of hazardous chemicals

#### **Chemical Inventory**

The **chemical inventory**<sup>5</sup> should consist of all chemicals that are imported or produced by the company, and those chemicals that are ingredients used in a mixture produced by the company. Classifiers may find it helpful if the chemical inventory includes the following information for future reference:

- chemical name;
- CAS Number;
- common name;
- synonyms;
- product/mixture name (if applicable); and
- percentage of ingredients in product/mixture (if applicable).

<sup>&</sup>lt;sup>5</sup> The chemical inventory is different than the list of hazardous chemicals required under paragraph (e) of the HCS (29 CFR 1910.1200). The chemicals listed on the chemical inventory would be required to appear on the list of hazardous chemicals required under paragraph (e) of the HCS if they are present in the workplace.

As discussed in Chapter III, Identifying Hazardous Chemicals, it is recommended that this chemical inventory be computerized for future sorting, additions, deletions, and status reports.

#### Specific Data Retrieved for Each Chemical

OSHA recommends that the data retrieved be organized to facilitate the preparation of SDSs and labels. Listing all the hazard classes and categories, and the relevant data obtained for each hazard will also facilitate the gathering of data to document the effectiveness and completeness of the classification process. When data are not located for a specific type of hazard or when a specific hazard would not occur due to the chemical or physical form of the chemical, this should be indicated.

The data retrieved should be listed in the basic format of the SDS to facilitate preparation of SDSs and labels, as well as to allow for future updating as the need arises. As you would expect, OSHA recommends that the data be computerized and archived in a secure location for future use. A commonly used phrase for hazard data compilations for specific chemicals is **hazards profile**. A suggested organization for the documentation is provided in Table VI.1.

## Table VI.1. LIST OF DATA RECOMMENDED FOR INCLUSION IN THE HAZARDS PROFILE FOR A CHEMICAL

(Reference source should be included for each item, where appropriate. In the event that no information on an item is known or it is not applicable, this should be so indicated.)

TYPE OF INFORMATION	DATA
Company Information	<ul> <li>Company Name, address, and telephone number</li> <li>Name of Responsible Company Official</li> <li>Date Prepared</li> </ul>
Hazards Identification	<ul> <li>Hazard classification (list appropriate health and physical hazards, including the classification rationale)</li> </ul>
Hazardous Ingredients/Identity Information	<ul> <li>Chemical Name</li> <li>Common Name and Synonyms</li> <li>CAS Number or other unique identifiers</li> <li>Impurities and stabilizing additives</li> <li>Product/Mixture Name (If Applicable)</li> <li>Percentage of Ingredients in Product/Mixture (If Applicable)</li> </ul>
Description of Controls and Protective Measures	<ul> <li>First-aid measures</li> <li>Fire-fighting measures</li> <li>Accidental release measures</li> <li>Handling and storage</li> <li>Exposures control and personal protection</li> </ul>

TYPE OF INFORMATION	DATA
Physical/Chemical Characteristics	<ul> <li>Appearance (physical state, color, etc.)</li> <li>Odor</li> <li>Odor threshold</li> <li>pH</li> <li>Melting point/freezing point</li> <li>Initial boiling point and boiling range</li> <li>Flash point</li> <li>Evaporation rate</li> <li>Flammability (solid, gas)</li> <li>Upper/lower flammability or explosive limits</li> <li>Vapor pressure</li> <li>Vapor density</li> <li>Relative density</li> <li>Solubility(ies)</li> <li>Partition coefficient: n-octanol/water</li> <li>Auto-ignition temperature</li> <li>Decomposition temperature</li> <li>Viscosity</li> </ul>
Reactivity Data	<ul> <li>Reactivity</li> <li>Chemical stability</li> <li>Possibility of hazardous reactions</li> <li>Conditions to avoid (e.g., static discharge, shock, or vibration)</li> <li>Incompatible materials</li> <li>Hazardous decomposition or byproducts</li> </ul>
Health Hazard Data	<ul> <li>Description of the various toxicological (health) effects and the available data used to identify those effects, including:         <ul> <li>Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact);</li> <li>Symptoms related to the physical, chemical and toxicological characteristics;</li> <li>Delayed and immediate effects and also chronic effects from short- and long-term exposure;</li> </ul> </li> <li>Numerical measures of toxicity (such as acute toxicity estimates); and</li> </ul>

TYPE OF INFORMATION	DATA
	<ul> <li>✓ Whether the hazardous chemical is listed as a carcinogen or potential carcinogen by</li> <li>○ National Toxicology Program (NTP) Report on Carcinogens (latest edition), or</li> <li>○ International Agency for Research on Cancer (IARC) Monographs (latest edition), or OSHA.</li> </ul>
Other Miscellaneous Information	

#### List of Hazardous Chemicals

The Hazard Communication Standard requires employers to maintain a list of hazardous chemicals present in the workplace as a part of the Written Hazard Communication Program (29 CFR 1910.1200(e)). The purpose of having a list of hazardous chemicals at your facility is to document those chemicals used or stored at the facility. Not only will the list facilitate the identification of the hazards presented by the hazardous chemicals at the facility or in a given work area, a complete list of chemicals also may help identify the information you already have on the chemicals or other ingredients used in production of the final product. Since safety data sheets are required for the chemicals you receive, this may be a good place to start the list. The hazards profile developed for each chemical (discussed above) also may be useful to determine which of the chemicals in the facility or work area are considered hazardous.

If a chemical meets the definition of hazardous chemical, as defined by the Hazard Communication Standard, and the hazardous chemical is one that requires classification, then it must be included on the hazardous chemicals list. OSHA recommends that the list be alphabetized to ease retrieval, stored so that it may be accessed easily, and archived in a secure location for future use.

## APPENDIX A. Glossary of Terms and Definitions

The following glossary presents brief explanations of acronyms and common terms used in this guidance.

**Absorbed Dose**. The amount of a substance that actually enters into the body, usually expressed as milligrams of substance per kilogram of body weight (mg/kg).

**ACGIH**. The American Conference of Governmental Industrial Hygienists is an organization of government and academic professionals engaged in occupational safety and health programs. ACGIH establishes recommended occupational exposure limits for chemical substances and physical agents known as Threshold Limit Values; see TLV.

**Acid**. A compound that undergoes dissociation in water with the formation of hydrogen ions. Acids have pH values below 7 and will neutralize bases or alkaline media. Acids will react with bases to form salts. Acids have a sour taste and with a pH in the 0 to 2 range cause severe skin and eye burns.

**Acute Dose**. The amount of a substance administered or received over a very short period of time (minutes or hours), usually within 24 hours.

**Acute Toxicity**. Those adverse effects occurring following oral or dermal administration of a single dose of a substance, or multiple doses given within 24 hours, or an inhalation exposure of 4 hours.

**Aerosol.** Any non-refillable receptacle containing a gas compressed, liquefied or dissolved under pressure, and fitted with a release device allowing the contents to be ejected as particles in suspension in a gas, or as a foam, paste, powder, liquid or gas.

**Alkali**. (Also referred to as a base). A compound that has the ability to neutralize an acid and form a salt. Alkali also forms a soluble soap with a fatty acid. Alkalis have pH values between 7 and 14. They are bitter in a water solution. Alkalis with pH values between 12 and 14 are considered to be corrosive (caustic) and will cause severe damage to the skin, eyes and mucous membranes. Common strong alkalis are the substance sodium and mixture potassium hydroxide.

**Allergic Reaction**. An abnormal immunologic response in a person who has become hypersensitive to a specific substance. Some forms of dermatitis and asthma may be caused by allergic reactions to chemicals.

**ANSI**. The American National Standards Institute is a privately funded, voluntary membership organization that identifies industrial and public needs for national consensus standards and coordinates development of such standards.

**Aspiration.** The entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system.

**ASTM**. The American Society for Testing and Materials develops voluntary consensus standards for materials, products, systems, and services. ASTM is a resource for sampling and testing methods, information on health and safety aspects of materials, safe performance guidelines, and effects of physical agents, biological agents, and chemicals.

**Autoignition Temperature**. The lowest temperature at which a flammable gas or vapor-air mixture will spontaneously ignite without spark or flame. Vapors and gases will spontaneously ignite at lower temperatures as the concentration of oxygen increases in the air. The autoignition temperature may also be influenced by the presence of catalytic substances. Materials should not be heated to greater than 80% of the autoignition temperature.

**Benign**. Not recurrent or not tending to progress; not cancerous.

**Boiling Point (BP)**. The temperature at which a liquid changes to a vapor state, at a given pressure; usually expressed in degrees of Fahrenheit or Centigrade at sea level pressure (760 mm Hg or one atmosphere). Flammable materials with low boiling points generally present special fire hazards

■ *Initial boiling point* is the temperature of a liquid at which its vapor pressure is equal to the standard pressure (101.3 kPa<sup>28</sup>; 14.7 psi), i.e., the first gas bubble appears.

**CAS Number**. A number assigned to a specific chemical by the Chemical Abstracts Service, an organization operated by the American Chemical Society. CAS Numbers are used internationally to identify specific chemicals or mixtures.

**Carcinogen.** A substance or a mixture of substances which induce cancer or increase its incidence. Substances and mixtures which have induced benign and malignant tumors in well-performed experimental studies on animals are considered also to be presumed or suspected human carcinogens unless there is strong evidence that the mechanism of tumor formation is not relevant for humans.

**cc**. Cubic centimeter is a volume measurement in the metric system that is equal in capacity to one milliliter (ml). One quart is approximately 946 cubic centimeters.

**CFR**. Code of Federal Regulations. A collection of the regulations that have been promulgated under United States law.

The letter "k" stands for "kilo": 1 kPa = 1,000 Pa.

<sup>&</sup>lt;sup>28</sup> Pascal [Pa] is the SI Unit (International System of Units) for pressure.

<sup>1</sup> Pa =  $1 \text{ N/m}^2 = 10^{-5} \text{ bar} = 0.75 \ 10^{-2} \text{ torr}$ 

**Chemical.** The name assigned to any <u>substance</u>, or mixture of <u>substances</u>.

**Chemical Name**. The name given to a chemical in the nomenclature system developed by the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS) or a name that will clearly identify the chemical for hazard classification purposes.

Chemicals which, in contact with water, emit flammable gases. Solid or liquid chemicals which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities.

Chemical which is corrosive to metals. A chemical which by chemical action will materially damage, or even destroy, metals.

**Chronic Toxicity**. Adverse effects resulting from repeated doses or exposures to a substance over a relatively prolonged period of time.

**Decomposition**. Breakdown of a material or substance into simpler substances by heat, chemical reaction, electrolysis, decay, or other processes.

**Dermal**. Relating to the skin.

**DNA**. Deoxyribonucleic acid; the molecules in the nucleus of the cell that contain genetic information.

**Dose**. The amount of a substance received at one time. Dose is usually expressed as administered or absorbed dose (e.g., milligrams material/kilogram of body weight).

**DOT**. U.S. Department of Transportation; the federal agency that regulates transportation of chemicals and other hazardous and non-hazardous substances.

**Epidemiology**. The branch of science concerned with the study of human disease in specific populations, in order to develop information about the causes of disease and identify preventive measures.

**Evaporation Rate**. The ratio of the time required to evaporate a measured volume of a liquid to the time required to evaporate the same volume of a reference liquid (butyl acetate, ethyl ether) under ideal test conditions. The higher the ratio, the slower the evaporation rate. The evaporation rate can be useful in evaluating the health and fire hazards of a material.

**Explosive Limits**. The range of concentrations of a flammable gas or vapor (percent by volume in air) in which an explosion can occur if an ignition source is present. Also see Flammable Limits, LEL, and UEL.

**Explosive chemical**. A solid or liquid chemical which is in itself capable by chemical reaction of producing gas at such a temperature and pressure and at such a speed as to cause damage to the surroundings. Pyrotechnic chemicals are included even when they do not evolve gases.

- Pyrotechnic chemical. A chemical designed to produce an effect by heat, light, sound, gas or smoke or a combination of these as the result of non-detonative self-sustaining exothermic chemical reactions.
- Explosive item. An item containing one or more explosive chemicals.
- **Pyrotechnic item**. An item containing one or more pyrotechnic chemicals.
- **Unstable explosive**. An explosive which is thermally unstable and/or too sensitive for normal handling, transport, or use.
- **Intentional explosive**. A chemical or item which is manufactured with a view to produce a practical explosive or pyrotechnic effect.

**Eye irritation**. The production of changes in the eye following the application of a test substance to the anterior surface of the eye, which are fully reversible within 21 days of application.

**Flammable**. A material which is easily ignited and burns with extreme rapidity. The two primary measures of this physical hazard are the flashpoint and the autoignition temperature.

For specific information on the definition and test methods of flammable materials, refer to 29 CFR 1910.1200. Also see: Flammable Gas, Flammable Liquid, and Flammable Solid.

**Flammable gas**. A gas having a flammable range with air at 20°C (68°F) and a standard pressure of 101.3 kPa (14.7 psi).

Flammable liquid. A liquid having a flashpoint of not more than 93°C (199.4°F).

**Flammable solid**. A solid which is a readily combustible solid, or which may cause or contribute to fire through friction.

• **Readily combustible solids**. Powdered, granular, or pasty chemicals which are dangerous if they can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly.

**Flashback**. Occurs when flame from a torch burns back into the tip, the torch, or the hose. It is often accompanied by a hissing or squealing sound with a smoky or sharp-pointed flame.

**Flashpoint**. The minimum temperature at which a liquid gives off vapor in sufficient concentration to form an ignitable mixture with air near the surface of the liquid, as determined by a method identified in Appendix B.6.3 of 29 CFR 1910.1200.

**Gases under pressure**. Gases which are contained in a receptacle at a pressure of 200 kPa (29 psi) (gauge) or more, or which are liquefied or liquefied and refrigerated. They comprise compressed gases, liquefied gases, dissolved gases and refrigerated liquefied gases.

**Genetic**. Pertaining to or carried by genes; hereditary.

**Genotoxic and genotoxicity**. These apply to agents or processes which alter the structure, information content, or segregation of DNA, including those which cause DNA damage by interfering with normal replication processes, or which in a non-physiological manner (temporarily) alter its replication. Positive genotoxicity test results are usually taken as indicators for mutagenic effects.

**Hazard**. The inherent capacity of a substance to cause an adverse effect.

**Hazard category.** The division of criteria within each hazard class, e.g., oral acute toxicity and flammable liquids include four hazard categories. These categories compare hazard severity within a hazard class and should not be taken as a comparison of hazard categories more generally.

**Hazard class.** The nature of the physical or health hazards, e.g., flammable solid, carcinogen, acute toxicity.

**Hazard not otherwise classified (HNOC).** An adverse physical or health effect identified through evaluation of scientific evidence during the classification process that does not meet the specified criteria for the physical and health hazard classes addressed in this section. This does not extend coverage to adverse physical and health effects for which there is a hazard class addressed in this section, but the effect either falls below the cut-off value/concentration limit of the hazard class or is under a GHS hazard category that has not been adopted by OSHA (e.g., acute toxicity Category 5).

**Hazardous chemical.** Any chemical which is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified.

**Health hazard.** A chemical which is classified as posing one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity (single or repeated exposure); or aspiration hazard. The criteria for determining whether a chemical is classified as a health hazard are detailed in Appendix A to 29 CFR 1910.1200 -- Health Hazard Criteria.

**IARC**. International Agency for Research on Cancer, a component of the World Health Organization, located in Lyon, France.

**Ignitable**. A solid, liquid or compressed gas which is capable of being set afire.

**Inhalation**. Breathing in of a substance in the form of a gas, vapor, fume, mist, or dust.

**In Vitro**. Outside a living organism (e.g., in a test tube).

**Latency Period**. The time that elapses between exposure and the first manifestations of disease or illness.

 $LC_{50}$  - Lethal Concentration 50, 50% Lethal Concentration. The concentration of a chemical in air or of a chemical in water which causes the death of 50% (one half) of a group of test animals. The  $LC_{50}$  can be expressed in several ways:

- as parts of material per million parts of air by volume (ppm) for gases and vapors,
- as micrograms of material per liter of air (mg/l), or
- as milligrams of material per cubic meter of air (mg/m³) for dusts and mists, as well as for gases and vapors.

 $LD_{50}$  - Lethal Dose 50. The amount of a chemical, given all at once, which causes the death of 50% (one half) of a group of test animals. The  $LD_{50}$  dose is usually expressed as milligrams or grams of material per kilogram of animal body weight (mg/kg or g/kg).

**LEL or LFL - Lower Explosive Limit or Lower Flammable Limit**. Lowest concentration of a substance in air (usually expressed in percent by volume) that will produce a flash or fire when an ignition source (heat, electric arc, or flame) is present. At concentrations lower than the LEL, propagation of a flame will not occur in the presence of an ignition source. Also see UEL.

m<sup>3</sup>. Cubic meter; a metric measure of volume, approximately 35.3 cubic feet or 1.3 cubic yards.

**Malignant Tumor**. A tumor that can invade surrounding tissues or metastasize to distant sites resulting in life-threatening consequences.

**Melting Point**. The temperature at which a solid substance changes to a liquid state.

**Metabolism (biotransformation)**. The conversion of a chemical from one form to another within the body.

**Metabolite**. A chemical produced during metabolism.

mg/kg. Milligrams of substance per kilogram of body weight, commonly used as an expression of toxicological dose (e.g., 15 mg/kg).

mg/m<sup>3</sup>. Milligrams per cubic meter; a unit for measuring concentrations of particulates or gases in the air (a weight per unit volume). For example, 20 mg/m<sup>3</sup>.

**milligram (mg)**. The most commonly used unit of measure in medicine and toxicity consisting of one thousandth of a gram  $(1x10^{-3} g)$ .

**Mixture**. a combination or a solution composed of two or more substances in which they do not react.

**ml**. Milliliter; a metric unit of volume. There are 1,000 milliliters in one liter. 1 teaspoon = 5 milliliters.

**Mutation**. A permanent change in the amount or structure of the genetic material in a cell. The term "*mutation*" applies both to heritable genetic changes that may be manifested at the phenotypic level and to the underlying DNA modifications when known (including, for example, specific base pair changes and chromosomal translocations). The terms "*mutagenic*" and "*mutagen*" are used for agents giving rise to an increased occurrence of mutations in populations of cells and/or organisms.

**NFPA**. The National Fire Protection Association is an international membership organization which promotes fire protection and prevention and establishes safeguards against loss of life and property by fire.

**NIOSH**. The National Institute for Occupational Safety and Health is a part of the Centers for Disease Control and Prevention, U.S. Public Health Service, U.S. Department of Health and Human Services.

**NTP**. The National Toxicology Program is a component of the U.S. Public Health Service. The NTP publishes the Annual Report on Carcinogens.

**Odor Threshold**. The lowest concentration of a substance in air that can be detected by smell.

**Organic peroxide**. A liquid or solid organic chemical which contains the bivalent -0-0- structure and as such is considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term organic peroxide includes mixtures containing at least one organic peroxide. Organic peroxides are thermally unstable chemicals, which may undergo exothermic self-accelerating decomposition. In addition, they may have one or more of the following properties:

- a) Be liable to explosive decomposition;
- b) Burn rapidly;
- c) Be sensitive to impact or friction;
- d) React dangerously with other substances.

**Oxidation**. A change in a chemical characterized by the loss of electrons. Oxidation is a reaction in which a substance combines with oxygen.

**Oxidizing gas.** Any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does.

• "Gases which cause or contribute to the combustion of other material more than air does" means pure gases or gas mixtures with an oxidizing power greater than 23.5% (as determined by a method specified in ISO 10156 or 10156-2; see Appendix B.4 of 29 CFR 1910.1200).

**Oxidizing liquid**. A liquid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

**Oxidizing solid**. A solid which, while in itself is not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material.

**PEL - Permissible Exposure Limit**. A legally enforceable occupational exposure limit established by OSHA, usually measured as an eight-hour time-weighted average, but also may be expressed as a ceiling concentration exposure limit.

**Physical hazard.** A chemical that is classified as posing one of the following hazardous effects: explosive; flammable (gases, aerosols, liquids, or solids); oxidizer (liquid, solid or gas); self-reactive; pyrophoric (liquid or solid); self-heating; organic peroxide; corrosive to metal; gas under pressure; or in contact with water emits flammable gas. The criteria for determining whether a chemical is classified as a physical hazard are detailed in Appendix B to 29 CFR 1910.1200 -- Physical Hazard Criteria.

**ppm**. Parts per million; the proportion (by volume) of a gas or vapor per million parts of air; also the concentration of a chemical in a liquid or solid form.

**Pyrophoric gas.** A chemical in a gaseous state that will ignite spontaneously in air at a temperature of 130°F (54.4°C) or below.

**Pyrophoric liquid**. A liquid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

**Pyrophoric solid.** A solid which, even in small quantities, is liable to ignite within five minutes after coming into contact with air.

**Reactivity**. A substance's susceptibility to undergo a chemical reaction or change that may result in dangerous side effects, such as an explosion, burning, and corrosive or toxic emissions.

**Reproductive toxicity**. This hazard includes *adverse effects on sexual function and fertility* in adult males and females, as well as *adverse effects on development of the offspring*. Some reproductive toxic effects cannot be clearly assigned to either impairment of sexual function and fertility or to developmental toxicity. Nonetheless, chemicals with these effects shall be classified as reproductive toxicants.

For classification purposes, the known induction of genetically based inheritable effects in the offspring is addressed in *Germ cell mutagenicity* (See Appendix A.5 of 29 CFR 1910.1200).

■ Adverse effects on sexual function and fertility. Any effect of chemicals that interferes with reproductive ability or sexual capacity. This includes, but is not limited to, alterations to the female and male reproductive system, adverse effects on onset of puberty, gamete production and transport, reproductive cycle normality, sexual behavior, fertility, parturition, pregnancy outcomes, premature reproductive senescence, or modifications in other functions that are dependent on the integrity of the reproductive systems.

• Adverse effects on development of the offspring. Any effect of chemicals which interferes with normal development of the conceptus either before or after birth, which is induced during pregnancy or results from parental exposure. These effects can be manifested at any point in the life span of the organism. The major manifestations of developmental toxicity include death of the developing organism, structural abnormality, altered growth and functional deficiency.

**Respiratory sensitizer**. A chemical that will lead to hypersensitivity of the airways following inhalation of the chemical.

**Risk**. The probability that an adverse effect will occur.

**Self-accelerating decomposition temperature (SADT)**. The lowest temperature at which self-accelerating decomposition may occur with a substance as packaged.

**Self-heating chemical**. A solid or liquid chemical, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat; this chemical differs from a pyrophoric liquid or solid in that it will ignite only when in large amounts (kilograms) and after long periods of time (hours or days).

Self-heating of a substance or mixture is a process where the gradual reaction of that substance or mixture with oxygen (in air) generates heat. If the rate of heat production exceeds the rate of heat loss, then the temperature of the substance or mixture will rise which, after an induction time, may lead to self-ignition and combustion.

**Self-reactive chemicals**. Thermally unstable liquid or solid chemicals liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes chemicals classified under 29 CFR 1910.1200 as explosives, organic peroxides, oxidizing liquids or oxidizing solids.

**Serious eye damage**. The production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application.

**Simple asphyxiant**. A substance or mixture that displaces oxygen in the ambient atmosphere, and can thus cause oxygen deprivation in those who are exposed, leading to unconsciousness and death.

**Skin corrosion**. The production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discoloration due to blanching of the skin, complete areas of alopecia (baldness), and scars. Histopathology should be considered to evaluate questionable lesions.

**Skin irritation**. The production of reversible damage to the skin following the application of a test substance for up to 4 hours.

**Skin sensitizer**. A chemical that will lead to an allergic response following skin contact.

**Specific target organ toxicity - single exposure (STOT-SE)**. Specific, non-lethal target organ toxicity arising from a single exposure to a chemical. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in Appendices A.1 to A.7 and A.10 of 29 CFR 1910.1200 are included.

**Specific target organ toxicity - repeated exposure (STOT-RE)**. Specific target organ toxicity arising from repeated exposure to a substance or mixture. All significant health effects that can impair function, both reversible and irreversible, immediate and/or delayed and not specifically addressed in Appendices A.1 to A.7 and A.10 of 29 CFR 1910.1200 are included.

**Solubility**. The ability of a substance to be dissolved in a solvent. Solubility is expressed according to the solvent (e.g., solubility in water, solubility in acetone, etc.).

STEL. Short-Term Exposure Limit (ACGIH terminology); see TLV.

**Substance.** Chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

**Synonym**. Another name or names by which a material is known. Methyl alcohol, for example, is also known as methanol or wood alcohol.

**Target Organ**. An organ on which a substance exerts a toxic effect.

**Teratogen**. A substance that can cause malformations or alterations in the appearance or function of a developing embryo.

**TLV - Threshold Limit Value**. The occupational exposure limit published by the American Conference of Governmental Industrial Hygienists (ACGIH). ACGIH expresses Threshold Limit Values in four ways:

- TLV-TWA: The allowable Time-Weighted Average A concentration for a normal 8-hour workday or 40-hour workweek.
- TLV-STEL: Short-Term Exposure Limit A maximum concentration for a continuous 15-minute exposure period (maximum of four such periods per day, with at least 60 minutes between exposure periods, and provided the daily TLV-TWA is not exceeded).
- TLV-C Ceiling limit A concentration that should not be exceeded even instantaneously.
- TLV-Skin The skin designation refers to the potential contribution to the overall exposure by the cutaneous route, including mucous membranes and the eye. Exposure can be either by airborne or direct contact with the substance. This designation indicates that appropriate measures should be taken to prevent skin absorption.

**Toxic Substance**. Any substance that can cause injury or illness, or which is suspected of being able to cause injury or illness under some conditions.

**Toxicity**. A relative property of a chemical agent that refers to a harmful effect on some biological mechanism and the conditions under which this effect occurs.

**Toxicology**. The study of the harmful interactions of chemicals on living organisms and biological systems.

**Trade Name**. The trademark name or commercial trade name for a material or product.

**TWA**. Time-Weighted Average; the concentration of a material to which a person is exposed, averaged over the total exposure time – generally the total workday (8 to 12 hours); also see TLV.

**UEL or UFL**. Upper explosive limit or upper flammable limit; the highest concentration of a vapor or gas (highest percentage of the substance in air) that will produce a flash of fire when an ignition source (e.g., heat, arc, or flame) is present. At higher concentrations, the mixture is too "rich" to burn. Also see LEL.

**Unstable**. Decomposing readily or another unwanted chemical change during normal handling or storage.

Vapor density. The weight of a vapor or gas compared to the weight of an equal volume of air is an expression of the density of the vapor or gas. Materials lighter than air (e.g., acetylene, methane, hydrogen) have vapor densities less than 1.0. Materials heavier than air (e.g., propane, hydrogen sulfide, and ethane) have vapor densities greater than 1.0. All vapors and gases will mix with air, but the lighter materials will tend to rise and dissipate (unless confined). Heavier vapors and gases are likely to concentrate in low places along or under floors, in sumps, sewers, manholes, trenches, and ditches, where they may create fire or health hazards.

**Vapor pressure**. Pressure exerted by a saturated vapor above its liquid in a closed container. Three facts are important to remember:

- Vapor pressure of a substance at 100° F will always be higher than the vapor pressure of the substance at 68° F (20° C),
- Vapor pressures reported on SDSs in millimeters of mercury (mmHg) are usually very low pressures; 760 mmHg is equivalent to 14.7 pounds per square inch (psi).
- The lower the boiling point of a substance, the higher its vapor pressure.

**Volatility**. The tendency or ability of a liquid or solid material to form a gas at ordinary temperatures. Liquids such as alcohol and gasoline, because of their tendency to evaporate rapidly, are called volatile liquids.