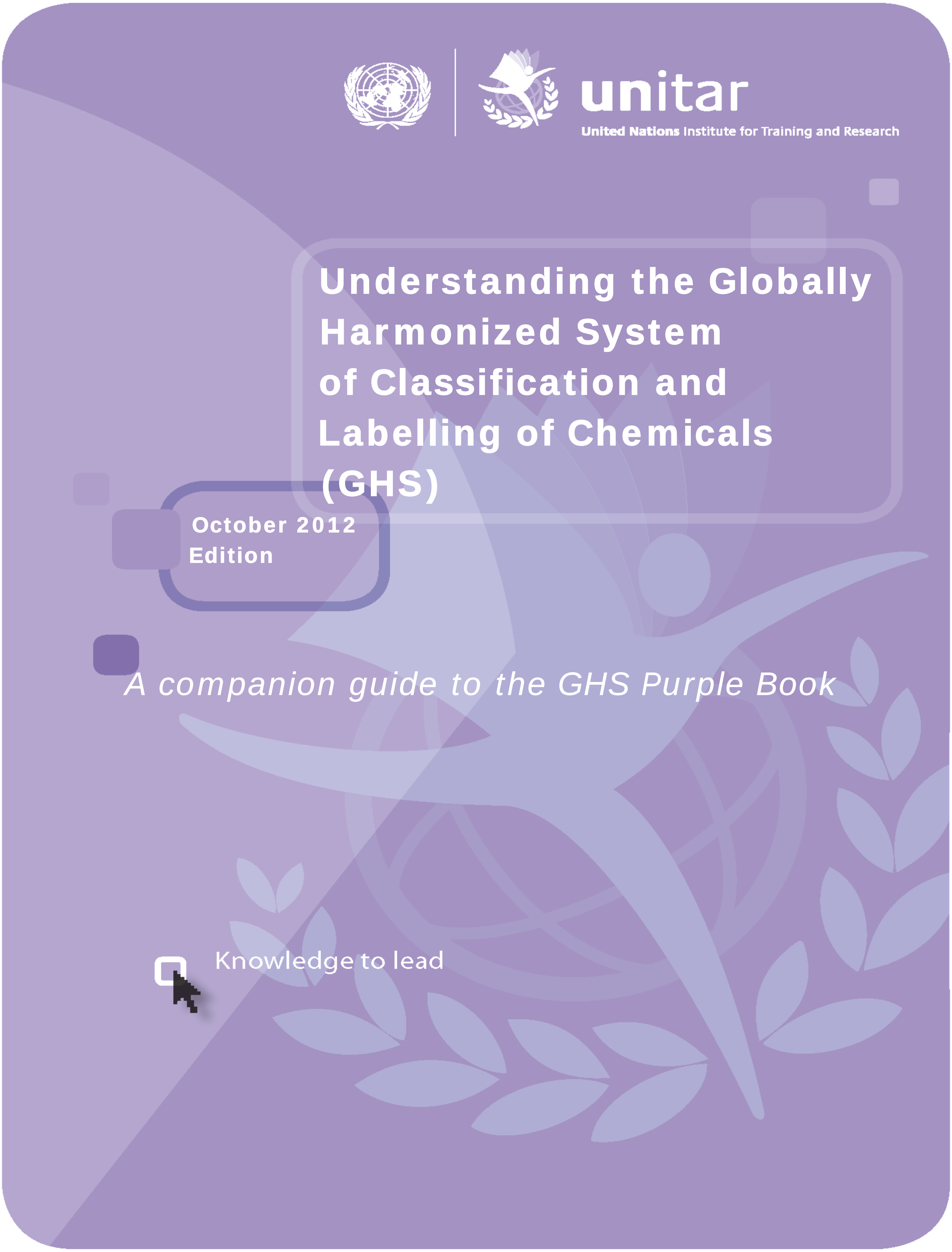

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Understanding the Globally Harmonized System of Classification and Labelling of Chemicals (GHS)

October 2012 Edition

A companion guide to the GHS Purple Book

Knowledge to lead

IOMC

INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS

A cooperative agreement among UNEP, ILO, FAO, WHO, UNIDO, UNITAR and OECD

Note on the Guide

This October 2012 guide is based on the Fourth Revision Edition (2011) of the GHS Purple Book. Unless otherwise specified, all references to the parts, chapters, sections, annexes, paragraphs, etc. refer to the Fourth Revised Edition of the GHS Purple Book. Subsequent editions of this Guide may be updated in view of ongoing revisions to the GHS Purple Book.

This document is adapted from the United States Occupational Safety and Health Administration (OSHA) “Guide to the GHS”. UNITAR gratefully acknowledges the work of OSHA in producing this document.

The views, opinions and/or interpretation of the GHS criteria contained in this guide are those of the authors and do not necessarily represent those of the Sub-Committee of Experts on the GHS (SCEGHS). For any further guidance or interpretation regarding the GHS, the reader is strongly recommended to refer directly to the “Purple Book".

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1. Background on the GHS

The purpose of this document is to describe the United Nations Globally Harmonized System of Classification and Labelling of Chemicals (GHS), why it was developed, and how it relates to the sound management of chemicals. The full official text of the system is available on the web at: http://www.unece.org/trans/danger/publi/ghs/ghs_welcome_e.html.

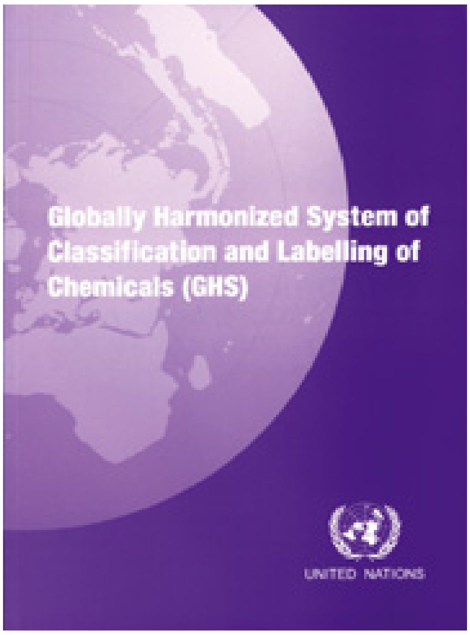
1.1 What is the GHS?

The GHS is an acronym for the *Globally Harmonized System of Classification and Labelling of Chemicals*. The GHS is a system for standardizing and harmonizing the classification and labelling of chemicals. It is a logical and comprehensive approach to:

- defining health, physical and environmental hazards of chemicals;
- creating classification processes that use available data on chemicals for comparison with the defined hazard criteria; and
- communicating hazard information, as well as protective measures, on labels and Safety Data Sheets (SDS).

When work on the GHS began, many countries already had existing regulatory systems for these types of requirements. These systems were similar in content and approach, but their differences were significant enough to require multiple classifications, labels and safety data sheets for the same product when marketed in different countries, or even in the same country when different stages of the product life cycle were covered by different regulatory authorities. This led to inconsistent protection for those potentially exposed to the chemicals, as well as creating extensive regulatory burdens on companies producing chemicals. Implementation of the GHS is harmonizing requirements in countries with existing systems, as well as establishing an internationally agreed approach that can be adopted by countries that have no such regulatory systems.

Figure 1.1
The GHS Document ("Purple Book")



The GHS itself is not a regulation or a standard. The GHS Document (referred to as "The Purple Book", shown in Figure 1.1) establishes agreed hazard classification and communication provisions with explanatory information on how to apply the system. Part 1 is an introductory section outlining the scope, definitions and hazard communication elements of the GHS. Part 2 provides information on the classification criteria for physical hazards. Part 3 provides information on classification for health hazards. Finally, Part 4 outlines classification for environmental hazards. Further information and guidance (*e.g.* for allocation of label elements and on preparation of SDS) are found in a number of annexes. The elements in the GHS supply a mechanism to meet the basic requirement of any hazard communication system, which is to decide if the chemical product produced and/or supplied is hazardous and to prepare a label and/or Safety Data Sheet as appropriate. Regulatory authorities in countries adopting the GHS will thus take the agreed criteria and provisions, and implement them through their own regulatory process and procedures rather than simply incorporating the text of the GHS into their national requirements.

The GHS document thus provides countries with the regulatory building blocks to develop or modify existing national programs that address classification of hazards and transmittal of information about those hazards and associated protective measures. This helps to ensure the safe use of chemicals as they move through the product life cycle from “cradle to grave.”

1.2 Why was the GHS developed?

The production and use of chemicals is fundamental to all economies. The global chemical business is worth approximately 3 trillion US dollars per year. Production of chemicals continues to increase globally, and much of the increase is taking place in countries that were not previously as actively involved in chemical trade. Therefore, there is a continued and demonstrated need for an internationally agreed system to ensure accurate and complete information is provided with these traded chemicals.

Chemicals directly or indirectly affect our lives and are essential to our food, our health, and our lifestyle. The widespread use of chemicals has resulted in the development of sector-specific regulations which can be different among various sectors, such as in transport, production, workplaces, agriculture, trade, and consumer products. Having readily available information on the hazardous properties of chemicals and recommended control measures allows the production, transport, use and disposal of chemicals to be managed safely. Safely managed chemicals leads to the protection of human health and the environment—a goal shared by all countries.

The sound management of chemicals needs to include systems through which chemical hazards are identified and communicated to all who are potentially exposed. These groups include workers, consumers, emergency responders and the public. It is important to know what chemicals are present and/or used, their hazards to human health and the environment, and the means to control them.

While the laws and regulations in many industrialised countries were similar before GHS implementation, they were different enough to require multiple labels for the same product, and to require multiple safety data sheets for the same product nationally and in international trade. Hazard definitions varied among countries. A product may have been considered flammable or toxic in one country, but not in another, under the existing laws when the GHS was first developed.

These differences in hazards result in differences in the labels and safety data sheets for the product. The differences impact both protection and trade. In the area of protection, users may see different label warnings or safety data sheet information for the same chemical. Implementation of GHS will standardize the information provided for key label elements and in SDSs, thus increasing comprehensibility for users of the products. This will allow the information to be used to provide appropriate protections, thus reducing adverse effects from use of the chemicals.

In the area of trade, the need to comply with multiple regulations regarding hazard classification and labeling is costly and time-consuming. Some multinational companies estimated that there were over 100 diverse hazard communication regulations for their products globally. For small and medium sized enterprises (SMEs), compliance with these varying requirements may preclude their active participation in international trade in chemicals. Thus GHS can result in these smaller companies being able to expand their international presence, in addition to reducing compliance burdens for larger companies.

1.3 What was the International Mandate?

The single most important force that drove the creation of the GHS was the international mandate (Figure 1.2) adopted at the 1992 United Nations Conference on Environment and Development (UNCED), often called the "Earth Summit". The harmonization of classification and labelling of chemicals was one of six program areas that were endorsed by the United Nations General Assembly to strengthen international efforts concerning the environmentally sound management of chemicals. It was recognized that an internationally harmonized approach to classification and labelling would provide the foundation for all countries to develop comprehensive national programs to ensure the safe use of chemicals.

Figure 1.2

International Mandate from UNCED Agenda 21, Chapter 19

"A globally harmonized hazard classification and compatible labelling system, including material safety data sheets and easily understandable symbols, should be available, if feasible, by the year 2000."

1.4 How was the GHS developed?

Figure 1.3

Existing Systems Included in the Harmonization Process

- UN Transport Recommendations
- U.S. Requirements for Workplace, Consumer and Pesticides
- European Union Dangerous Substance and Preparations Directives
- Canadian Requirements for Workplace, Consumers and Pesticides

In conjunction with its Convention and Recommendation on Safety in the Use of Chemicals at Work (C170), the International Labor Organization (ILO) studied the tasks required to achieve harmonization.

No international organization covers all aspects of chemical classification and labelling. A broad scope and extensive expertise and resources were required to develop a system. In order to proceed, several questions were considered: (a) what systems would be considered “major” and thus the basis for harmonization, and (b) how could the work be divided to get the best expertise for different aspects. Four existing systems (Figure 1.3) were deemed to be major and the primary basis for the GHS. While not considered major, requirements of other systems were examined as appropriate, and taken into account as proposals were developed.

A Coordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS) was created under the Inter-organization Programme for the Sound Management of Chemicals (IOMC) and was charged with coordinating and managing development of the system.

Figure 1.4

Key Guiding Principles of the Harmonization Process

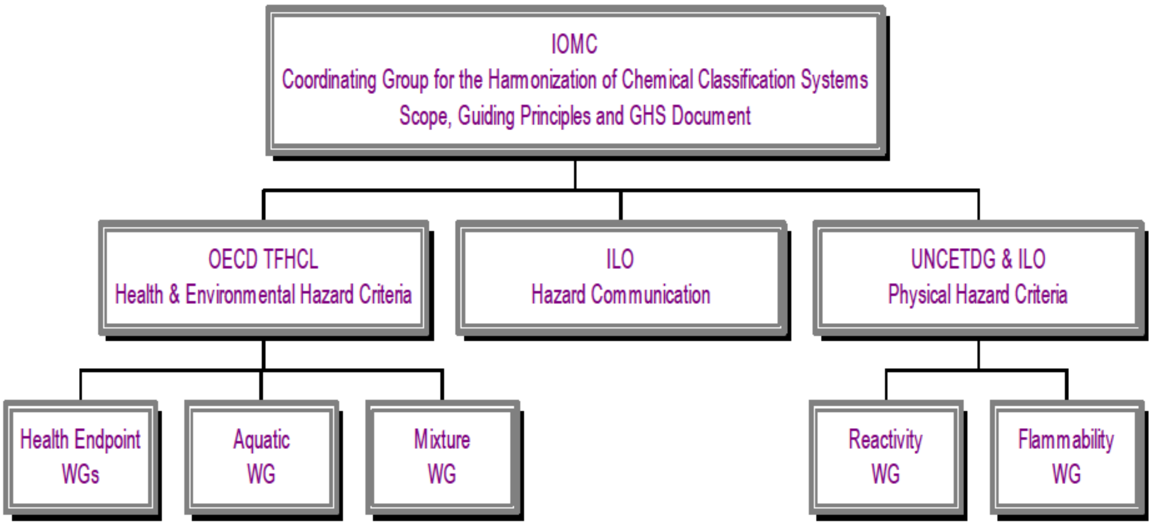
- Protection will not be reduced
- Will be based on intrinsic properties (hazards) of chemicals
- All types of chemicals will be covered
- All systems will have to be changed
- Involvement of all stakeholders should be ensured
- Comprehensibility must be addressed

The GC/HCCS worked on a consensus basis, with representatives from major stakeholders, including national governments, industry and workers. The group created a set of guiding principles (Figure 1.4). The scope and guiding principles created a common framework for the organizations that were charged with developing the different elements of the system.

In order to get the best expertise and resources, the work was divided among three technical focal points. Figure 1.5 shows how the work was assigned to the three technical focal points and the overall responsibilities of the Coordinating Group itself. The UN Committee of Experts on Transport of Dangerous

Goods was selected as the lead for work on physical hazards, in cooperation with the ILO. Based on their work in the testing guidelines and other chemical issues, the Organization for Economic Cooperation and Development (OECD) was selected for health/environmental hazards and mixtures. The ILO has a long history in SDSs and labels, and was selected to be the lead in hazard communication. The OECD and ILO groups also included representatives from governments, industry and labour.

Figure 1.5



1.5 How will the GHS be maintained and updated?

In October 1999, the United Nations Economic and Social Council decided (resolution 1999/65) to enlarge the mandate of the Committee of Experts on the Transport of Dangerous Goods by reconfiguring it into the Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals (UNCETDG/GHS). At the same time, a new Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals (GHS Sub-Committee or UNSCEGHS) was also created. It should be noted that for the transport sector, the implementation of the GHS is based on the UNRTDG.

When the IOMC completed developing the GHS, the system was presented to the UN GHS Sub-Committee, which formally adopted the system at its first session in December 2002. It was subsequently endorsed by the UNCETDG/GHS. The UN Economic and Social Council endorsed the GHS in July 2003.

The Sub-Committee of Experts on the Globally Harmonized System of Classification will:

- Act as custodian of the system, managing and giving direction to the harmonization process;
- Keep the system up-to-date, as necessary, considering the need to introduce changes or updates to ensure its continued relevance;
- Promote understanding and use of the system and encourage feedback;
- Make the system available for worldwide use;
- Make guidance available on the application of the system, and on the interpretation and use of technical criteria to support consistency of application; and
- Prepare work programs and submit recommendations to the UNCETDG/GHS.[1]

1.6 When will the GHS be implemented?

There is no international implementation schedule for the GHS. Different national systems/sectors have required different timeframes for GHS implementation. Existing systems need to consider phase-in strategies for transition from their current requirements to the new GHS requirements.

The World Summit on Sustainable Development (WSSD) and the Intergovernmental Forum for Chemical Safety (IFCS) encouraged countries to implement the new GHS as soon as possible with a view to having the system fully operational by 2008. The Ministers of the Asia-Pacific Economic Cooperation (APEC) said that as many APEC economies as possible should implement, on a voluntary basis, the GHS by 2006.

Significant progress has been made in implementing the GHS around the world. In December 2008, Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labeling and packaging of substances and mixtures was adopted. This new regulation aligned the requirements of the European Union with the GHS. In March 2012, the United States Occupational Safety and Health Administration (OSHA) aligned its Hazard Communication Standard with the requirements of the GHS. Many other countries have initiated work on adopting the GHS, and are in various stages of completion. For more information: http://www.unece.org/trans/danger/publi/ghs/implementation_e.html.

1.7 What are the benefits?

The basic goal of hazard communication is to ensure that employers, employees and the public are provided with adequate, practical, reliable and comprehensible information on the hazards of chemicals having information about the hazards, as well as precautions for safe use, allow for the sound management of the use of the chemicals by implementing

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[1] For more information: http://www.unece.org/trans/main/dgdb/dgsubc4/c4rep.html

effective preventive and protective measures for the health and safety of those exposed. Implementation of effective hazard communication thus provides benefits for **governments**, **companies**, **workers**, and **members of the public**.

The GHS has maximum value if it is accepted globally for chemical hazard communication. Consistent information will then be communicated everywhere on labels and SDSs.

It is anticipated that application of the GHS will:

- Enhance the protection of human health and the environment by providing an internationally comprehensible system;
- Provide a recognized framework to develop regulations for those countries without existing systems;
- Provide one set of criteria for classification to be used for global hazard communication facilitate international trade in chemicals whose hazards have been identified on an international basis;
- Reduce the need for testing and evaluation against multiple classification systems.

The tangible benefits to **governments** are:

- Fewer chemical accidents and incidents;
- Lower health care costs;
- Improved protection of workers and the public from chemical hazards;
- Reduced costs and eased coordination for legislation, implementation and monitoring;
- Improved inter-ministerial and inter-agency coordination and cooperation;
- Avoidance of duplication of effort in creating national systems;
- Reduction in the costs of enforcement; and
- Improved communication on chemical issues, both domestically and internationally.

Benefits to **companies** include:

- A safer work environment and transport of chemicals, and improved relations with employees;
- An increase in efficiency and reduced costs from compliance with hazard communication regulations;
- Application of expert systems resulting in maximizing expert resources and minimizing labor and costs;
- Facilitation of electronic transmission systems with international scope;
- Expanded use of training programs on health and safety;

- Reduced costs due to fewer accidents and illnesses; and
- Improved corporate image and credibility.

Benefits to **workers** and **members of the public** include:

- Improved safety for workers, consumers and others through consistent and simplified communications on chemical hazards and practices to follow for safe handling and use; and
- Greater awareness of hazards, resulting in safer use of chemicals in the workplace and in the home.

1.8 How does the GHS relate to other international chemicals management efforts?

A number of international management efforts and agreements exist that are relevant to the sound chemicals management and GHS implementation:

- The importance of implementing the GHS is recognised in the Overarching Policy Strategy (OPS) of the Strategic Approach to International Chemicals Management (SAICM), which is a policy framework for chemicals management (www.saicm.org) GHS is also included as a SAICM work area in the Global Plan of Action, including eight distinct activities.

- The Rotterdam Convention, which allows countries to monitor and control trade in certain hazardous chemicals, has close links to hazard identification and communication issues and the GHS. The Convention requires countries to ensure that chemicals used for occupational purposes have safety data sheets that follow an internationally recognised format. The international standard and format for SDS and labels can be seen as references to the GHS.

- The Stockholm Convention encourages parties to use the SDS, reports and other means of communication.

- The Basel Convention, which deals with the transboundary movement of hazardous waste, has established a correspondence working group with the UNSCEGHS in order to further promote synergies among the two bodies.

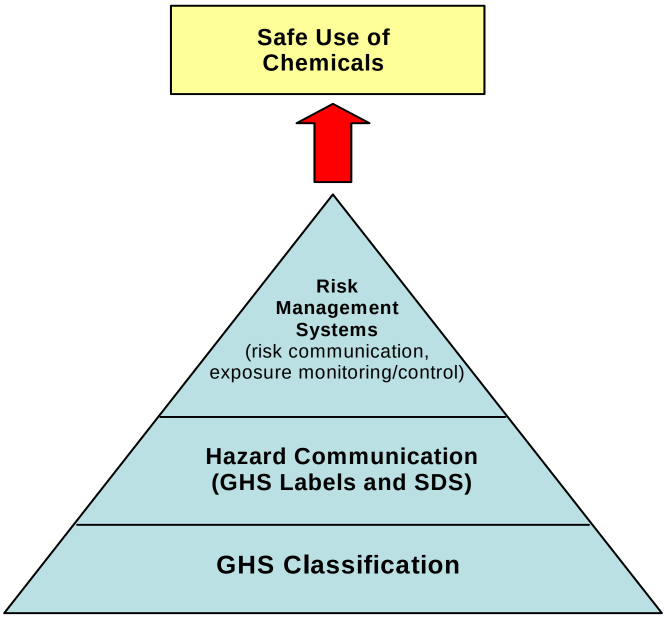
- The ILO Convention 170 also refers to the importance of evaluating chemical hazards and providing hazard information, especially in the workplace.

- The International Organisation for Standardization has developed a standard format for safety data sheets in order to establish uniformity. The ISO SDS has adopted the 16-heading SDS format of the GHS.

2. How is the GHS to be applied?

The GHS classification and communication elements are the foundation of programs to ensure the safe use of chemicals, as shown in Figure 2.1. The first two steps in any program to ensure the safe use of chemicals are to identify intrinsic hazard(s) (i.e. classification) and then to communicate that information. The design of the GHS communication elements reflects the different needs of various target audiences, such as workers and consumers. To proceed further up the pyramid, some existing national programs also include risk management systems as part of an overall program on the sound management of chemicals. The general goal of these systems is to minimize exposure, resulting in reduced risk. The systems vary in focus and include activities such as establishing exposure limits, recommending exposure monitoring methods and creating engineering controls. However, the target audiences of such systems are generally limited to workplace settings. With or without formal risk management systems, the GHS is designed to promote the safe use of chemicals.

Figure 2.1



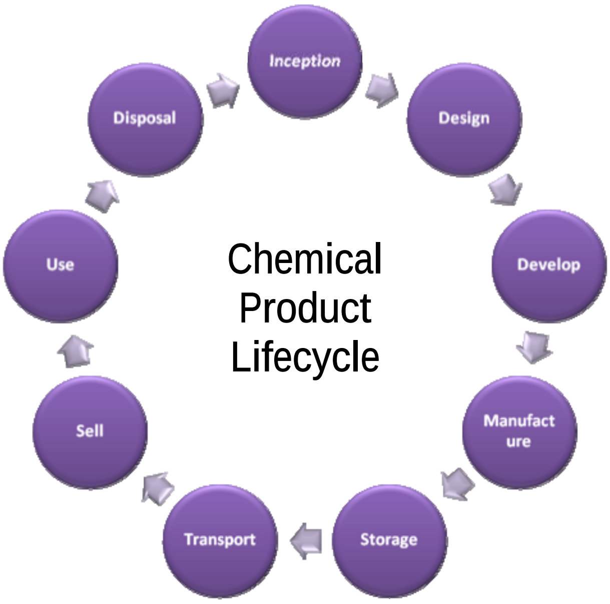
2.1 Are all chemicals covered by the GHS?

The GHS covers all hazardous chemicals. There are no complete exemptions from the scope of the GHS for a particular type of chemical or product. The term “chemical” is used broadly to include substances, products, mixtures, preparations, or any other terms that may be used by existing systems. The goal of the GHS is to identify the intrinsic hazards of chemical substances and mixtures and to convey hazard information about these hazards. The GHS is not intended to harmonize risk assessment procedures or risk management decisions, as described above. Chemical inventory (e.g. REACH, TSCA, etc.) and chemical control requirements in various countries are not harmonized by the GHS.

Classification in the GHS is criteria-based, not limiting coverage to a list that can become outdated. Several countries that have adopted the GHS have also developed lists of classifications to help chemical manufacturers comply with the GHS requirements. Existing sources, such as lists of evaluated chemicals provided by organizations that assess cancer hazards, could be used in conjunction with the GHS to promote harmonization.

2.2 Will all hazardous chemicals require a GHS label and Safety Data Sheet?

Figure 2.2



The need for GHS labels and/or Safety Data Sheets is expected to vary by product category or stage in the chemical's lifecycle from research to production to storage to end-use. The sequence of lifecycle events is shown in Figure 2.2. It is important to note that pharmaceuticals, food additives, cosmetics and pesticide residues in food will **not** be covered by the GHS at the point of consumption, but will be covered where workers may be exposed (workplaces), and in transport. Also, the medical use of human or veterinary pharmaceuticals is generally addressed in package inserts and is not part of existing hazard communication systems. Similarly, foods are generally not labelled under existing hazard communication systems. The exact requirements for labels and Safety Data Sheets will continue to be defined in national regulations. However, national requirements developed to adopt the GHS are expected to be consistent with the detailed discussion of scope provided in Chapter 1.1 of the GHS Purple Book.

2.3 How will the GHS impact existing regulations?

The GHS is a voluntary international system that imposes no binding treaty obligations on countries. To the extent that countries adopt the GHS into their systems, the regulatory changes would be binding for covered industries. For countries with existing systems, it is expected that the GHS components will be applied within the framework/infrastructure of existing hazard communication regulatory schemes. For example, exceptions and exemptions that are practical accommodations based on experience in implementing hazard communication requirements in existing regulations would not be expected to change (e.g. transportation of limited quantities).

However, the specific hazard criteria, classification processes, label elements and SDS requirements within an existing regulation will need to be modified to be consistent with the harmonized elements of the GHS. It is anticipated that **ALL** existing hazard communication systems will need to be changed in order to apply the GHS. For example, in the U.S., OSHA has changed its rules to require hazard pictograms/symbols on labels. The EU has adopted the GHS pictograms/symbols instead of those previously used in their system. Acute toxicity criteria have been changed in the EU and U.S.

Test data already generated for the classification of chemicals under existing systems should be accepted when classifying these chemicals under the GHS, thereby avoiding duplicative testing and the unnecessary use of test animals.

2.4 What is meant by GHS Building Blocks?

The GHS classification and communication requirements can be thought of as a collection of building blocks. In regulatory schemes, coverage and communication of hazards vary by the needs of target audiences and sectors. Accordingly, the GHS was designed to contain all of the hazard classes and categories, and communication tools, necessary for application to the various sectors of known regulatory schemes. The full range of harmonized elements is available to everyone, and should be used if a country or organization chooses to cover a certain effect when it adopts the GHS. However, the GHS is structured so that the appropriate elements for classification and communication, which address the specific needs of target audiences covered by a regulatory system, can be selected. Therefore, the full range of these elements does not have to be adopted for all sectors of each regulatory system.

2.5 How should the GHS Building Blocks be applied?

Appropriate implementation of the GHS means that the hazards covered by a national Competent Authority (CA) are covered consistently with the GHS criteria and requirements. The Health Canada and U.S. OSHA are examples of Competent Authorities. Competent Authorities will decide how to apply the various elements of the GHS based on the CA needs and the needs of target audiences.

When a regulatory scheme covers something that is in the GHS, and implements the GHS, that coverage should be consistent. Once a hazard class and related hazard categories are selected for inclusion in the national approach, as needed, the GHS classification criteria for the hazard class and categories within that class, assigned label elements and SDS provisions should be followed as specified in the GHS. If a regulatory system covers carcinogenicity, for example, it should follow the harmonized classification scheme, the harmonized label elements and, where appropriate, the SDS. However, the regulatory system may choose not to cover all hazard categories in a hazard class such as carcinogenicity. Further guidance on the application of the building block approach can be found in the GHS Purple Book in section 1.1.3.1.5.4.

To gain a better understanding of the building block approach, it is helpful to look at the specific sectors/target audiences. The needs and regulations of the various sectors vary depending on the type of chemical and use pattern. Different target audiences or sectors receive and use hazard information in different ways. Coverage of hazards may vary by the perceived needs of the target audience for information. The primary sectors/target audiences are transport, workplace, consumers and agriculture (pesticides). These sectors are described in more detail below.

2.5.1 Transport

For transport, it is expected that:

- GHS physical, acute and environmental hazard criteria are adopted in the transport sector;
- Packages and packaging of dangerous goods will include pictograms that address acute toxicity, physical hazards, and environmental hazards, when required; and
- GHS hazard communication elements such as signal words, hazard statements and SDS are not expected to be adopted in the transport sector.

2.5.2 Workplace

In the workplace, it is expected that most of the GHS elements will be adopted, including:

- GHS physical and health hazard criteria, as appropriate;
- Labels that have the harmonized core information under the GHS (signal words, hazard statements, and pictograms), as well as precautionary statements;
- Safety Data Sheets;
- Employee training to help ensure effective communication;
- All workplace systems may not have the jurisdiction to adopt environmental hazards.

2.5.3 Consumer

For the consumer sector, it is expected that labels will be the primary focus of GHS application. However, the appropriate GHS hazard criteria are expected to be adopted. These labels will include the core elements of the GHS (signal words, hazard statements, and pictograms), subject to some sector-specific considerations in certain systems (e.g. risk-based labeling), as well as precautionary statements.

2.5.4 Agriculture

For agricultural chemicals, it is expected that the GHS, including the appropriate GHS hazard criteria will be adopted. Pesticide labels should include the core elements of the GHS (signal words, hazard statements, and pictograms), as well as precautionary statements.

2.6 How will the GHS impact countries *without* existing regulations?

Developing and maintaining a classification and labelling system is not a simple task. The GHS can be used as a tool for developing national regulations. It is expected that countries that do not have systems will adopt the GHS as their basic scheme. The GHS provides the building blocks from which countries can construct comprehensive chemical safety and health management programs. Although the GHS will facilitate the process, many challenges exist in creating new regulations. Some important questions to consider include:

- What is the appropriate legal framework for adopting/implementing the GHS?
- What government agencies should be involved? Are there ministries/agencies ready to implement and maintain the GHS?
- How will stakeholder cooperation and support for implementing the GHS be managed?

UNITAR and ILO, working as capacity building focal points in the context of the UNSCEGHS, provide technical assistance for developing countries to implement the GHS. They have guidance materials available on developing a national GHS implementation strategy. Additionally, pilot implementation projects have been undertaken in a number of countries, and are in various stages of completion.[2] The opportunities and challenges learned from the pilot programs will be documented and are expected to facilitate future implementation.

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[2] More information on UNITAR/ILO GHS capacity building activities can be found at: http://www.unitar.org/cwm/ghs.

3. What is Classification?

Classification is the starting point for hazard communication. It involves the identification of the hazard(s) of a substance or mixture by assigning a hazard class using defined criteria. The hazard class may be further delineated into hazard categories that indicate the degree or severity of the hazard. The GHS is designed to be consistent and transparent. It draws a clear distinction between classes and categories in order to allow for **"self classification"** by the chemical producer. The GHS describes the criteria for classification and also provides a decision logic that visually describes the classification process for the hazard. The classification criteria depend on the type of test data available to characterize a hazardous effect. In some cases, these data provide numerical results that are easily translated into an appropriate classification. For other hazards, the criteria may be described as semi-quantitative or qualitative. Expert judgment may be required to interpret these data.

Figure 3.1

Hazard Classification

The term "hazard classification" is used to indicate that only the intrinsic hazardous properties of substances and mixtures are considered and involves the following 3 steps:

a) Identification of relevant data regarding the hazards of a substance or mixture;
b) Subsequent review of those data to ascertain the hazards associated with the substance or mixture; and
c) A decision on whether the substance or mixture will be classified as a hazardous substance or mixture and the degree of hazard, where appropriate, by comparison of the data with agreed hazard classification criteria.

Figure 3.1 is the Purple Book definition for hazard classification, which can be applied to all hazard classes in the GHS. The data used for classification may be obtained from tests, literature, and practical experience. The GHS health and environmental hazard criteria/definitions are test method neutral. Accordingly, tests that determine hazardous properties conducted according to internationally recognized scientific principles can be used for purposes of hazard classification.

The GHS classes that cover physical, health and environmental hazards are listed in Figures 3.2 and 3.3, respectively. As mentioned earlier, the GHS hazard definitions are criteria-based. The following information provides an overview of the GHS definitions and classification criteria, and is intended to be used as a general introduction. For applied classification and labeling purposes, consult the GHS Purple Book.

3.1 What are the GHS Physical Hazards?

The GHS physical hazards criteria, developed by the ILO and UNCETDG, were largely based on the existing criteria used by the UN Recommendations on the Transport of Dangerous Goods, Model Regulations (UNRTDG).[3] Therefore, many of the criteria are already being used on a worldwide basis. However, some additions and changes were necessary since the scope of the GHS includes all target audiences. The physical hazards classification process provides specific references to approved test methods and criteria for classification. It should be noted that GHS physical hazard criteria apply to substances and mixtures. It is assumed that mixtures will be tested for physical hazards.

In general, the GHS criteria for physical hazards are quantitative or semi-quantitative with multiple hazard categories within a hazard class.

In developing GHS criteria for physical hazards it was necessary to define physical states. In the GHS:

- A **gas** is a substance or mixture which at 50°C has a vapor pressure greater than 300 kPa (absolute); or is completely gaseous at 20°C and a standard pressure of 101.3 kPa.
- A **liquid** is a substance or mixture that is not a gas and which has a melting point or initial melting point of 20°C or less at standard pressure of 101.3 kPa.
- A **solid** is a substance or mixture that does not meet the definitions of a liquid or a gas.

The GHS physical hazards are briefly described below. For many of the physical hazards, the GHS Purple Book contains Guidance Sections with practical information to assist in applying the criteria.

Figure 3.2

Physical Hazards

- Explosives
- Flammable Gases
- Flammable Aerosols
- Oxidizing Gases
- Gases Under Pressure
- Flammable Liquids
- Flammable Solids
- Self-Reactive Substances
- Pyrophoric Liquids
- Pyrophoric Solids
- Self-Heating Substances
- Substances which, in contact with water, emit flammable gases
- Oxidizing Liquids
- Oxidizing Solids
- Organic Peroxides
- Corrosive to Metals

3.1.1 Explosives

An explosive substance (or mixture) is a solid or liquid that 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. An explosive article is an article containing one or more explosive substances or mixtures. Pyrotechnic substances are included even when they do not

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[3] http://www.unece.org/trans/danger/publi/unrec/rev13/13nature_e.html

evolve gases. A pyrotechnic substance (or mixture) is 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. A pyrotechnic article is an article containing one or more pyrotechnic substances or mixtures.

Classification as an explosive and allocation to a division is a three-step process:
- Ascertain if the material has explosive effects (Test Series 1);
- Acceptance procedure (Test Series 2 to 4);
- Assignment to one of six hazard divisions (Test Series 5 to 7).

Explosive properties are associated with certain chemical groups that can react to give very rapid increases in temperature or pressure. The GHS provides a screening procedure that is aimed at identifying the presence of such reactive groups and the potential for rapid energy release. If the screening procedure identifies the substance or mixture to be a potential explosive, the acceptance procedure has to be performed.

Table 3.1 Explosives

Division	Characteristics
--	Unstable Explosive
1.1	Mass explosion hazard
1.2	Projection hazard with no mass explosion hazard
1.3	Fire hazard, or minor projection hazard or both
1.4	Small hazard in the event of ignition or initiation
1.5	Very insensitive substances with mass explosion hazard
1.6	Extremely insensitive articles with no mass explosion hazard

Explosive substances, mixtures and articles that are not classified as unstable explosives are assigned to one of six divisions, 1.1 to 1.6, depending on the type of hazard they present. See, *UN Manual of Tests and Criteria* Part I Test Series 2 to 7.[4]

3.1.2 Flammable Gases

Flammable gas means a gas having a flammable range with air at 20°C and a standard pressure of 101.3 kPa. Substances and mixtures of this hazard class are assigned to one of two hazard categories on the basis of the outcome of the test or calculation method (ISO 10156:2010). In addition, the criteria define a chemically unstable gas as a flammable gas that is able to react explosively even in the absence of air or oxygen. Chemically unstable gases are to be classified into Category A or B depending on the available test data.

3.1.3 Flammable Aerosols

Aerosols, this means aerosol dispensers, are any non-refillable receptacles made of metal, glass or plastics and containing a gas compressed, liquefied or dissolved under pressure, with or without a liquid, paste or powder, and fitted with a release device allowing the contents to be ejected as solid or liquid

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[4] http://www.unece.org/trans/danger/publi/manual/manual_e.html

particles in suspension in a gas, as a foam, paste or powder or in a liquid state or in a gaseous state. Aerosols should be considered for classification as flammable if they contain any constituents that meet the GHS criteria for classification as a flammable liquid, gas, or solid.

An aerosol is classified in one of the three categories for this Class on the basis of its components, of its chemical heat of combustion and, if applicable, of the results of the foam test (for foam aerosols) and of the ignition distance test and enclosed space test (for spray aerosols). See decision logic in 2.3.4.1 of the Purple Book. Aerosols which do not meet the criteria for inclusion in Category 1 or Category 2 (extremely flammable or flammable aerosols) should be classified in Category 3 (non-flammable aerosols).

Aerosols are considered to be classified in Category 1, Extremely flammable, if the concentration of the flammable components >85% and the heat of combustion is ≥ 30 kJ/g to avoid excessive testing;

See the *UN Manual of Tests and Criteria* for test methods.

3.1.4 Oxidizing Gases

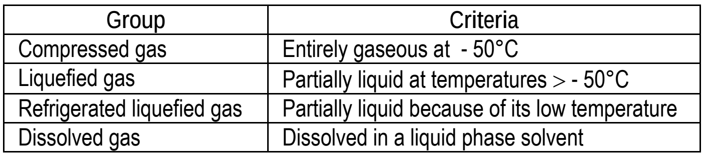
Oxidizing gas are any gas that may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does. Substances and mixtures of this hazard class are assigned to a single hazard category on the basis that, generally by providing oxygen, they cause or contribute to the combustion of other material more than air does. The test methods used for classifying oxidizing gases are: ISO 10156:. Currently, several workplace hazard communication systems cover oxidizers (solids, liquids, gases) as a class of chemicals.

3.1.5 Gases under Pressure

Gases under pressure are gases which are contained in a receptacle at a pressure of 200 kPa (gauge) or more at 20 °C, or which are liquefied or liquefied and refrigerated.

This hazard category covers four types of gases or gaseous mixtures to address the effects of sudden release of pressure or freezing which may lead to serious damage to people, property, or the environment independent of other hazards the gases may pose.

Table 3.2 Gases under Pressure



Group	Criteria
Compressed gas	Entirely gaseous at - 50°C
Liquefied gas	Partially liquid at temperatures > - 50°C
Refrigerated liquefied gas	Partially liquid because of its low temperature
Dissolved gas	Dissolved in a liquid phase solvent

For this group of gases, the following information is required:

- Vapor pressure at 50°C;

- Physical state at 20°C at standard ambient pressure;
- Critical temperature.

Criteria that use the physical state for compressed gases will be a different classification basis for some workplace systems. Data can be found in the literature, and calculated or determined by testing. Most pure gases are already classified in the UN Model Regulations. Gases are classified, according to their physical state when packaged, into one of four groups as shown in Table 3.2.

3.1.6 Flammable Liquids

Flammable liquid means a liquid having a flash point of not more than 93°C. Substances and mixtures of this hazard class are assigned to one of four hazard categories on the basis of the flash point and boiling point (See Table 3.3).

Table 3.3 Flammable Liquids

Category	Criteria
1	Flash point < 23°C (73°F) and initial boiling point ≤ 35°C (95°F)
2	Flash point < 23 °C (73°F) and initial boiling point > 35°C (95°F)
3	Flash point ≥ 23 °C (73°F) and ≤ 60 °C (140°F)
4	Flash point > 60 °C (140°F) and ≤ 93 °C (200°F)

3.1.7 Flammable Solids

Flammable solids are solids that are readily combustible, or may cause or contribute to fire through friction. Readily combustible solids are powdered, granular, or pasty substances 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.

Substances and mixtures of this hazard class are assigned to one of two hazard categories (Table 3.4) on the basis of the outcome of the UN Test N.1 (*UN Manual of Tests and Criteria*). The tests include burning time, burning rate and behavior of fire in a wetted zone of the test sample.

Table 3.4 Flammable Solids

Category	Criteria
1	Metal Powders: burning time ≤ 5 minutes Others: wetted zone does not stop fire & burning time < 45 seconds or burning > 2.2 mm/second
2	Metal Powders: burning time > 5 and ≤ 10 minutes Others: wetted zone stop fire for at least 4 minutes & burning time < 45 seconds or burning rate > 2.2 mm/second

3.1.8 Self-Reactive Substances and Mixtures

Self-reactive substances and mixtures are thermally unstable liquids or solids liable to undergo a strongly exothermic thermal decomposition even without participation of oxygen (air). This definition excludes substances and mixtures classified under the GHS as explosive, organic peroxides or as oxidizing. These substances and mixtures may have similar properties, but such hazards are addressed in their specific categories. There are exceptions to the self-reactive classification for substances and mixtures: (i) with heat of decomposition <300 J/g, or (ii) with self-accelerating decomposition temperature (SADT) > 75°C for a 50 kg package.

Substances and mixtures of this hazard class are assigned to one of the seven ‘Types’, A to G, on the basis of the outcome of the UN Test Series A to H (*UN Manual of Tests and Criteria*) (Table 3.5).

Table 3.5 Self-Reactive Substances

Type	Criteria
A	Can detonate or deflagrate rapidly, as packaged.
B	Possess explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package.
C	Possess explosive properties when the substance or mixture as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion.
D	• Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or • Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or • Does not detonate or deflagrate at all and shows a medium effect when heated under confinement.
E	Neither detonates nor deflagrates at all and shows low or no effect when heated under confinement.
F	Neither detonates in the cavitated bubble state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power.
G	Neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C to 75°C for a 50 kg package), and, for liquid mixtures, a diluent having a boiling point not less than 150°C is used for desensitization.

3.1.9 Pyrophoric Liquids

A pyrophoric liquid is a liquid, which, even in small quantities, is liable to ignite within five minutes after coming into contact with air. Substances and mixtures of this hazard class are assigned to a single hazard category on the basis of the outcome of the UN Test N.3 (*UN Manual of Tests and Criteria)*.

3.1.10 Pyrophoric Solids

A pyrophoric solid is a solid, which, even in small quantities, is liable to ignite within five minutes after coming into contact with air. Substances and mixtures of this hazard class are assigned to a single hazard category on the basis of the outcome of the UN Test N.2 (*UN Manual of Tests and Criteria)*.

3.1.11 Self-Heating Substances and Mixtures

A self-heating substance or mixture is a solid or liquid, other than a pyrophoric liquid or solid, which, by reaction with air and without energy supply, is liable to self-heat. This hazard class differs from a pyrophoric substance in that a self-heating substance or mixture will ignite only when in large amounts (kilograms) and after long periods of time (hours or days). Substances and mixtures of this hazard class are assigned to one of two hazard categories on the basis of the outcome of the UN Test N.4 (*UN Manual of Tests and Criteria)*.

3.1.12 Substances and Mixtures Which in Contact with Water, Emit Flammable Gases

Substances that, in contact with water, emit flammable gases are solids or liquids, which, by interaction with water, are liable to become spontaneously flammable or to give off flammable gases in dangerous quantities. Substances and mixtures of this hazard class are assigned to one of three hazard categories on the basis of test results (UN Test N.5 *UN Manual of Tests and Criteria*) that measure gas evolution and speed of evolution.

Table 3.6 Substances which on Contact with Water

Category	Criteria
1	≥10 L/kg/1 minute
2	≥20 L/kg/1 hour + < 10 L/kg/1 min
3	≥1 L/kg/1 hour + < 20 L/kg/1 hour
Not classified	< 1 L/kg/1 hour

3.1.13 Oxidizing Liquids

An oxidizing liquid is a liquid, which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause or contribute to the combustion of other material. Substances and mixtures of this hazard class are assigned to one of three hazard categories on the basis of test results (UN Test O.2 *UN Manual of Tests and Criteria*) which measure ignition or pressure rise time compared to defined mixtures.

3.1.14 Oxidizing Solids

An oxidizing solid is a solid, which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause or contribute to the combustion of other material. Substances and mixtures of this hazard class are assigned to one of three hazard categories on the basis of test results (UN Test O.1 *UN Manual of Tests and Criteria*) that measure mean burning time and are compared to defined mixtures. Currently, several workplace hazard communication systems cover oxidizers (solids, liquids, gases) as a class of chemicals.

3.1.15 Organic Peroxides

An organic peroxide is an organic liquid or solid which contains the bivalent -0-0- structure and may be considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term also includes organic peroxide formulations (mixtures). Such substances and mixtures may:

- Be liable to explosive decomposition;
- Burn rapidly;
- Be sensitive to impact or friction;
- React dangerously with other substances.

It should be noted that an organic peroxide is regarded as possessing explosive properties when, in laboratory testing, the formulation is liable to detonate, deflagrate rapidly, or show a violent effect when heated under confinement.

Substances and mixtures of this hazard class are assigned to one of seven 'Types', A to G, on the basis of the outcome of the UN Test Series A to H (*UN Manual of Tests and Criteria*) (Table 3.7).

Table 3.7 Organic Peroxides

Type	Criteria
A	Can detonate or deflagrate rapidly, as packaged.
B	Possess explosive properties and which, as packaged, neither detonates nor deflagrates rapidly, but is liable to undergo a thermal explosion in that package.
C	Posses explosive properties when the substance or mixture as packaged cannot detonate or deflagrate rapidly or undergo a thermal explosion.
D	• Detonates partially, does not deflagrate rapidly and shows no violent effect when heated under confinement; or • Does not detonate at all, deflagrates slowly and shows no violent effect when heated under confinement; or • Does not detonate or deflagrate at all and shows a medium effect when heated under confinement.
E	Neither detonates nor deflagrates at all and shows low or no effect when heated under confinement.
F	Neither detonates in the cavitated bubble state nor deflagrates at all and shows only a low or no effect when heated under confinement as well as low or no explosive power.
G	Neither detonates in the cavitated state nor deflagrates at all and shows no effect when heated under confinement nor any explosive power, provided that it is thermally stable (self-accelerating decomposition temperature is 60°C to 75°C for a 50 kg package), and, for liquid mixtures, a diluent having a boiling point not less than 150°C is used for desensitization.

3.1.16 Substances Corrosive to Metal

A substance or a mixture that by chemical action will materially damage, or even destroy, metals is termed 'corrosive to metal'. These substances or mixtures are classified in a single hazard category on the basis of tests. The test methods can be found in Part III, sub-section 37.4 of the *UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria.* The GHS criteria are a corrosion rate on either steel or aluminum surfaces exceeding 6.25 mm per year at a test temperature of 55°C when tested on both materials.

3.2 What are the GHS Health and Environmental Hazards?

The GHS health and environmental hazard criteria represent a harmonized approach for existing classification systems (see Figure 3.3). The work at the OECD to develop the GHS criteria included:

- A thorough analysis of existing classification systems, including the scientific basis for a system and its criteria, its rationale and an explanation of the mode of use.
- A proposal for harmonized criteria for each category. For some hazard classes the harmonized approach was easy to develop because the existing systems had similar approaches. In cases where the approach was different, a compromise consensus proposal was developed.
- Health and environmental criteria were established for substances and mixtures.

The next section briefly describes the GHS health and environmental classes. The criteria for classifying substances are presented first. Then the GHS approach to classifying mixtures is briefly discussed. The following information provides an overview of the GHS definitions and classification criteria, and is intended to be used as a general introduction. For applied classification and labeling purposes, consult the GHS Purple Book.

Figure 3.3

Health Hazards

- Acute Toxicity
- Skin Corrosion/Irritation
- Serous Eye Damage/Eye Irritation
- Respiratory or Skin Sensitization
- Germ Cell Mutagenicity
- Carcinogenicity
- Reproductive Toxicology
- Specific Target Organ Toxicity – Single Exposure
- Specific Target Organ Toxicity – Repeated Exposure
- Aspiration Toxicity

Environmental Hazards

- Hazardous to the Aquatic Environment
    - Acute aquatic toxicity
    - Chronic aquatic toxicity
        - Bioaccumulation potential
        - Rapid degradability
- Hazardous to the Ozone Layer

3.3 Health Hazards

3.3.1 AcuteToxicity

Acute toxicity refers to 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. The acute toxicity criteria differ by route of entry, and reflect variation in the rate of absorption into the body, and thus the ability to cause the adverse effect.

Table 3.8 Acute Toxicity

Acute toxicity	Cat. 1	Cat. 2	Cat. 3	Cat. 4	Category 5
Oral (mg/kg)	≤ 5	> 5 ≤ 50	> 50 ≤ 300	> 300 ≤ 2000	Criteria: • Anticipated oral LD50 between 2000 and 5000 mg/kg; • Indication of significant effect in humans;* • Any mortality at class 4;* • Significant clinical signs at class 4;* • Indications from other studies.* *If assignment to a more hazardous class is not warranted.
Dermal (mg/kg)	≤ 50	> 50 ≤ 200	> 200 ≤ 1000	> 1000 ≤ 2000	
Gases (ppm)	≤ 100	> 100 ≤ 500	> 500 ≤ 2500	> 2500 ≤ 20000	
Vapors (mg/l)	≤ 0.5	> 0.5 ≤ 2.0	> 2.0 ≤ 10	> 10 ≤ 20	
Dust & mists (mg/l)	≤ 0.05	> 0.05 ≤ 0.5	> 0.5 ≤ 1.0	> 1.0 ≤ 5	

Five GHS categories have been included in the GHS Acute Toxicity scheme from which the appropriate elements relevant to transport, consumer, worker and environmental protection can be selected. Substances are assigned to one of the five toxicity categories on the basis of LD_{50} (oral, dermal) or LC_{50} (inhalation). The LC_{50} values are based on 4-hour tests in animals. The GHS provides guidance on converting 1-hour inhalation test results to a 4-hour equivalent. The five categories are shown in the Table 3.8 Acute Toxicity.

Category 1, the most severe toxicity category, has cut-off values currently used primarily by the transport sector for classification for packing groups. Category 5 is for chemicals which are of relatively low acute toxicity but which, under certain circumstances, may pose a hazard to vulnerable populations. Criteria other than LD50/LC50 data are provided to identify substances in Category 5 unless a more hazardous class is warranted.

3.3.2 Skin Corrosion/Irritation

Skin corrosion means the production of irreversible damage to the skin following the application of a test substance for up to 4 hours. Substances and mixtures in this hazard class are assigned to a single harmonized corrosion category. See the Skin Corrosion/Irritation Table 3.9.

Several factors should be considered in determining the corrosion potential before testing is initiated:

- Human experience showing irreversible damage to the skin;
- Structure/activity or structure property relationship to a substance or mixture already classified as corrosive;

Table 3.9 Skin Corrosion/Irritation

Skin Corrosion Category 1			Skin Irritation Category 2	Mild Skin Irritation Category 3
Destruction of dermal tissue: visible necrosis in at least one animal			Reversible adverse effects in dermal tissue Draize score: ≥ 2.3 ≤ 4.0 or persistent inflammation	Reversible adverse effects in dermal tissue Draize score: ≥ 1.5 < 2.3
Subcategory 1A Exposure < 3 min. Observation < 1 hr,	Subcategory 1B Exposure < 1 hr. Observation < 14 days	Subcategory 1C Exposure < 4 hrs. Observation < 14 days		

- pH extremes of ≤ 2 and ≥ 11.5 including acid/alkali reserve capacity.

3.3.3 Skin Irritation

Skin irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours. Substances and mixtures in this hazard class are assigned to a single irritant category. For those authorities, such as pesticide regulators, wanting more than one designation for skin irritation, an additional mild irritant category is provided. See the Skin Corrosion/Irritation Table 3.9.

Several factors should be considered in determining the irritation potential before testing is initiated:

- Human experience or data showing reversible damage to the skin following exposure of up to 4 hours;
- Structure/activity or structure property relationship to a substance or mixture already classified as an irritant.

3.3.4 Eye Effects

Several factors should be considered in determining the *serious eye damage* or *eye irritation* potential before testing is initiated:

- Accumulated human and animal experience;
- Structure/activity or structure property relationship to a substance or mixture already classified;
- pH extremes like ≤ 2 and ≥ 11.5 that may produce serious eye damage.

Serious eye damage means the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the front surface of the eye, which is not fully reversible within 21 days of application. Substances and mixtures in this hazard class are assigned to a single harmonized category.

Table 3.10 Eye Effects

Category 1 Serious eye damage	Category 2 Eye Irritation	
Irreversible damage 21 days after exposure Draize score: Corneal opacity ≥ 3 Iritis > 1.5	Reversible adverse effects on cornea, iris, conjunctiva Draize score: Corneal opacity ≥ 1 Iritis ≥ 1 Redness ≥ 2 Chemosis ≥ 2	
	Irritant Subcategory 2A Reversible in 21 days	Mild Irritant Subcategory 2B Reversible in 7 days

Eye irritation means changes in the eye following the application of a test substance to the front surface of the eye, which are fully reversible within 21 days of application. Substances and mixtures in this hazard class are assigned to a single harmonized hazard category. For authorities, such as pesticide regulators, wanting more than one designation for eye irritation, one of two subcategories can be selected, depending on whether the effects are reversible in 21 or 7 days.

3.3.5 Sensitization

Respiratory sensitizer means a substance that induces hypersensitivity of the airways following inhalation of the substance. Substances and mixtures in this hazard class are assigned to one hazard category.

Skin sensitizer means a substance that will induce an allergic response following skin contact. The definition for “skin sensitizer” is equivalent to “contact sensitizer”. Substances and mixtures in this hazard class are assigned to one hazard category. Consideration should be given to classifying substances that cause immunological contact urticaria (an allergic disorder) as contact sensitizers.

3.3.6 Germ Cell Mutagenicity

Mutagen means an agent giving rise to an increased occurrence of mutations in populations of cells and/or organisms. Substances and mixtures in this hazard class are assigned to one of two hazard categories. Category 1 has two subcategories. See the Germ Cell Mutagenicity (Table 3.11) below.

Table 3.11 Germ Cell Mutagenicity

Category 1 Known / Presumed		Category 2 Suspected / Possible
Known to produce heritable mutations in human germ cells		• May induce heritable mutations in human germ cells • Positive evidence from tests in mammals and somatic cell tests • *In vivo* somatic genotoxicity supported by *in vitro* mutagenicity
Subcategory 1A Positive evidence from epidemiological studies	Subcategory 1B Positive results in: • *In vivo* heritable germ cell tests in mammals • Human germ cell tests • *In vivo* somatic mutagenicity tests, combined with some evidence of germ cell mutagenicity	

3.3.7 Carcinogenicity

Carcinogen means a substance or a mixture that induces cancer or increases its incidence. Substances and mixtures in this hazard class are assigned to one of two hazard categories. Category 1 has two subcategories. The Carcinogenicity Guidance Section in the GHS Document includes comments about IARC.

Table 3.12 Carcinogenicity

Category 1 Known or Presumed Carcinogen		Category 2 Suspected Carcinogen
Subcategory 1A Known Human Carcinogen Based on human evidence	Subcategory 1B Presumed Human Carcinogen Based on demonstrated animal carcinogenicity	Limited evidence of human or animal carcinogenicity

3.3.8 Reproductive Toxicity

Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in offspring. Substances and mixtures with reproductive and/or developmental effects are assigned to one of two hazard categories, 'known or presumed' and 'suspected'. Category 1 has two subcategories for reproductive and developmental effects. Chemicals that cause concern for the health of breastfed children have a separate category, Effects on or Via Lactation.

Table 3.13 Reproductive Toxicity

Category 1		Category 2 Suspected	Additional Category
Known or presumed to cause effects on human reproduction or on development		Human or animal evidence possibly with other information	Effects on or via lactation
Category 1A Known Based on human evidence	Category 1B Presumed Based on experimental animals		

3.3.9 Specific Target Organ Toxicity (STOT): Single Exposure & Repeated Exposure

The GHS distinguishes between single and repeated exposures for Target Organ Effects. Some existing systems distinguish between single and repeated exposures for these effects and some do not. All significant health effects, not otherwise specifically included in the GHS, that can impair function, both reversible and irreversible, immediate and/or delayed are included in the non-lethal specific target organ toxicity class (STOT). Narcotic effects and respiratory tract irritation are considered to be systemic effects following a single exposure.

Substances and mixtures of the single exposure target organ toxicity hazard class are assigned to one of three hazard categories in Table 3.14.

Table 3.14 STOT: Single Exposure

Category 1	Category 2	Category 3
Significant toxicity in humans • Reliable, good quality human case studies or epidemiological studies Presumed significant toxicity in humans • Animal studies with significant and/or severe toxic effects relevant to humans at generally low exposure (guidance)	Presumed to be harmful to human health • Animal studies with significant toxic effects relevant to humans at generally moderate exposure (guidance) • Human evidence in exceptional cases	Transient target organ effects • Narcotic effects • Respiratory tract irritation

Substances and mixtures of the repeated exposure target organ toxicity hazard class are assigned to one of two hazard categories in Table 3.15.

Table 3.15 STOT: Repeated Exposure

Category 1	Category 2
Significant toxicity in humans • Reliable, good quality human case studies or epidemiological studies Presumed significant toxicity in humans • Animal studies with significant and/or severe toxic effects relevant to humans at generally low exposure (guidance)	Presumed to be harmful to human health • Animal studies with significant toxic effects relevant to humans at generally moderate exposure (guidance) • Human evidence in exceptional cases

In order to help reach a decision about whether a substance should be classified or not, and to what degree it would be classified (Category 1 vs. Category 2), dose/concentration ‘guidance values’ are provided in the GHS. The guidance values and ranges for single and repeated doses are intended only for guidance purposes. This means that they are to be used as part of the weight of evidence approach, and to assist with decisions about classification. They are not intended as strict demarcation values. The guidance value for repeated dose effects refer to effects seen in a standard 90-day toxicity study conducted in rats. They can be used as a basis to extrapolate equivalent guidance values for toxicity studies of greater or lesser duration.

3.3.10 Aspiration Hazard

Table 3.16 Aspiration Toxicity

Category 1: Known (regarded) human	Category 2: Presumed human
• Human evidence; • Hydrocarbons with kinematic viscosity ≤ 20.5 mm^2/s at 40° C.	• Based on animal studies; • Surface tension, water solubility, boiling point; • Kinematic viscosity ≤ 14 mm2/s at 40° C & not Category 1.

Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration. Aspiration is the entry of a liquid or solid directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system. Some hydrocarbons (petroleum distillates) and certain chlorinated hydrocarbons have been shown to pose an aspiration hazard in humans. Primary alcohols, and ketones have been shown to pose an aspiration hazard only in animal studies. Substances and mixtures of this hazard class are assigned to one of two hazard categories in this hazard class on the basis of viscosity.

3.4 Environmental Hazards

3.4.1 Hazardous to the Aquatic Environment

The harmonized criteria are considered suitable for packaged goods in both supply and use in multi-modal transport schemes. Elements of it may be used for bulk land transport and bulk marine transport under MARPOL (International Convention for the Prevention of Pollution from Ships), Annex II - 73/78, insofar as this uses aquatic toxicity. Two Guidance Documents (Annexes 9 and 10 of the GHS Document) cover issues such as data interpretation and the application of the criteria to special substances. Considering the complexity of this hazard class and the breadth of the application, the Guidance Annexes are important in the application of the harmonized criteria.

3.4.1.1 Acute Aquatic Toxicity

Acute aquatic toxicity means the intrinsic property of a material to cause injury to an aquatic organism in a short-term exposure. Substances and mixtures of this hazard class are assigned to one of three toxicity categories on the basis of acute toxicity data: LC_{50} (fish) or EC_{50} (crustacea) or ErC_{50} (for algae or other aquatic plants). In some regulatory systems these acute toxicity categories may be subdivided or extended for certain sectors.

3.4.1.2 Chronic Aquatic Toxicity

Chronic aquatic toxicity means the potential or actual properties of a material to cause adverse effects to aquatic organisms during exposures that are determined in relation to the lifecycle of the organism. Substances and mixtures in this hazard class are assigned to one of four toxicity categories on the basis of acute data *and* environmental fate data: LC_{50} (fish) or EC_{50} (crustacea) or ErC_{50} (for algae or other aquatic plants) *and* degradation/ bioaccumulation.

While experimentally derived test data are preferred, where no experimental data are available, validated Quantitative Structure Activity Relationships (QSARs) for aquatic toxicity and log KOW may be used in the classification process. The log K_{OW} is a surrogate for a measured

Bioconcentration Factor (BCF), where such a measured BCF value would always take precedence.

Chronic Category IV is considered a “safety net” classification for use when the available data do not allow classification under the formal criteria, but there are some grounds for concern.

Table 3.17 Acute & Chronic Aquatic Toxicity

Acute Cat. 1 Acute toxicity ≤1.00 mg/l	Acute Cat. 2 Acute toxicity > 1.00 but ≤ 10.0 mg/l	Acute Cat. 3 Acute toxicity > 10.0 but ≤ 100 mg/l	
Chronic Cat. 1 Acute toxicity ≤ 1.00 mg/l and lack of rapid degradability and log K_{ow} ≥ 4 unless BCF < 500	Chronic Cat. 2 Acute toxicity > 1.00 but ≤ 10.0 mg/l and lack of rapid degradability and log K_{ow} ≥ 4 unless BCF < 500 and unless chronic toxicity > 1 mg/l	Chronic Cat. 3 Acute toxicity > 10.0 but ≤ 100.0 mg/l and lack of rapid degradability and log K_{ow} ≥ 4 unless BCF < 500 and unless chronic toxicity > 1 mg/l	Chronic Cat. 4 Acute toxicity > 100 mg/l and lack of rapid degradability and log K_{ow} ≥ 4 unless BCF < 500 and unless chronic toxicity > 1 mg/l

3.4.2 Hazardous to the Ozone Layer

Ozone Depleting Potential (ODP) in an integrative quantity, distinct for each halocarbon source species, that represents the extent of ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11. The Montreal Protocol is a list of substances that damage the ozone layer. The GHS require these substances to be labeled to indicate this effect. There is only one hazard category, and no criteria are provided other than reference to the list determined by countries under the Montreal Protocol.

3.5 What is the GHS approach to classifying mixtures?

For consistency and understanding the provisions for classifying mixtures, the GHS defines certain terms. These working definitions are for the purpose of evaluating or determining the hazards of a product for classification and labeling.

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

Figure 3.4

Tiered Approach to Classification of Mixtures

Generally, use test data for the mixture, if available,
Compare to substance hazard criteria
↓
Use bridging principles, if applicable
↓
Estimate hazard(s) based on the known component information

substance or changing its composition.

Mixture: Mixtures or solutions composed of two or more substances in which they do not react.

Alloy: An alloy is a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. Alloys are considered to be mixtures for the purpose of classification under the GHS.

Where impurities, additives or individual constituents of a substance or mixture have been identified and are themselves classified, they should be taken into account during classification if they exceed the cutoff value/concentration limit for a given hazard class.

As mentioned previously, the GHS physical hazard criteria apply to mixtures. It is assumed that mixtures will be tested for physical hazards. Each health and environmental class chapter in the GHS contains specific criteria for classifying mixtures as well as substances. The GHS Document or “Purple Book” should be consulted for complete information on classifying mixtures.

The process established for classifying a mixture allows the use of (a) available data for the mixture itself and/or (b) similar mixtures and/or (c) data for ingredients of the mixture. The GHS approach to the classification of mixtures for health and environmental hazards is tiered, and is dependent upon the amount of information available for the mixture itself and for its components. The process for the classification of mixtures is based on the following steps:

(1) Where test data are available for the mixture itself, the classification of the mixture will be based on that data (See exception for carcinogens, mutagens and reproductive toxins in the GHS Purple Book);
(2) Where test data are not available for the mixture itself, then the appropriate bridging principles (as described below) in the specific chapter should be used;
(3) If (i) test data are not available for the mixture itself, and (ii) the bridging principles cannot be applied, then use the calculation or cutoff values described in the specific hazard class to classify the mixture.

3.6 What are bridging principles?

Bridging principles are an important concept in the GHS for classifying untested mixtures. When a mixture has not been tested, but there are sufficient data on the components and/or similar tested mixtures, these data can be used in accordance with the following bridging principles:

- **Dilution**: If a mixture is diluted with a diluent that has an equivalent or lower toxicity, then the hazards of the new mixture are assumed to be equivalent to the original.
- **Batching**: If a batch of a complex substance is produced under a controlled process, then the hazards of the new batch are assumed to be equivalent to the previous batches.
- **Concentration of Highly Toxic Mixtures**: If a mixture is severely hazardous, then a concentrated mixture is also assumed to be severely hazardous
- **Interpolation within One Toxic Category:** Mixtures having component concentrations within a range where the hazards are known are assumed to have those known hazards.
- **Substantially Similar Mixtures**: Slight changes in the concentrations of components are not expected to change the hazards of a mixture and substitutions involving toxicologically similar components are not expected to change the hazards of a mixture
- **Aerosols**: An aerosol form of a mixture is assumed to have the same hazards as the tested, non-aerosolized form of the mixture unless the propellant affects the hazards upon spraying.

All bridging principles do not apply to every health and environmental hazard class. Consult each class to determine which bridging principles apply. When the bridging principles do not apply or cannot be used, the health and environmental hazards of mixtures are estimated based on component information.

It should be noted that toxicological predictions of effects are always of a probabilistic nature and based on extrapolation of results obtained with a limited sample of conditions, animals, and other factors. Thus, there is some remaining uncertainty and this uncertainty is increased when bridging principles are applied.

In the GHS, the methodology used to estimate these hazards varies by hazard class. The GHS Purple Book should be consulted for more complete information on classifying mixtures. Figure 3.5 summarizes the GHS mixtures approach for the various health and environmental classes.

3.7 What testing is required?

The GHS itself does not include requirements for testing substances or mixtures. Therefore, there is no requirement under the GHS to generate test data for any hazard class. Some parts of regulatory systems may require data to be generated (e.g. for pesticides), but these requirements are not related specifically to the GHS. Classification of chemicals based on the GHS is done with currently available data. The GHS criteria for determining health and environmental hazards are test method neutral, allowing different approaches as long as they are scientifically sound and validated according to international procedures and criteria already referred to in existing systems. Test data already generated for the classification of chemicals under existing systems should be accepted when classifying these chemicals under the GHS, thereby avoiding duplicative testing and the unnecessary use of test animals. The GHS physical hazard criteria are linked to specific test methods. The tests are referred to in the GHS itself, and described in the UN Manual of Tests and Criteria. It is assumed that mixtures will be tested for physical hazards.

Since the harmonized classification criteria are developed on the basis of existing data, compliance with these criteria will not require retesting chemicals for which accepted test data already exists. Therefore, using currently available information, classification is the process of identifying the hazards of a chemical and assigning a category of hazard using set criteria.

The GHS harmonizes the classification criteria – from several existing systems – for evaluating health, environmental and physical hazards of substances and mixtures. These criteria are included in the Purple Book in Part 2 (Physical Hazards), Part 3 (Health Hazards) and Part 4 (Environmental Hazards). The information for classification may be obtained from tests, practical experience, literature, or the information found in other systems, such as that provided directly by industry or found in the international rules on the transport of dangerous substances (*e.g.* the UN Recommendations on the Transport of Dangerous Goods, UNRTDG).

For example, if a substance has an initial boiling point lower than or equal to 35° C and a flashpoint lower than 23° C, then it may be classified as “highly flammable”. Experts have determined – on the basis of these criteria – that this substance is highly capable of being ignited or burning in air. Under the GHS, acceptable methods for classifying hazards have been harmonised and guidance will be provided to countries implementing the GHS on how to classify chemicals under the GHS. The list of classification categories used in the GHS is outlined in Box 2.[5]

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[5] Please refer to the GHS Purple Book for more precise definitions of these categories.

Figure 3.5 GHS Mixtures

Hazard Class	Classification Approach	Bridging Principles	Comments
Acute toxicity	Acute Toxicity Estimate (ATE): 2 formulas	All	Conversion values, relevant components usually at ≥ 1%
Serious Eye Damage & Eye Irritation	Mostly additivity approach, sometimes cutoffs	All	Relevant components usually at ≥ 1%, exceptions for certain chemical classes
Skin corrosion & Skin Irritation	Mostly additivity approach, sometimes cutoffs	All	Relevant components usually at ≥ 1%, exceptions for certain chemical classes
Skin Sensitization	Cutoffs with CA options	Dilution, Batching, Substantially similar mixtures, Aerosols	
Respiratory Sensitization	Cutoffs with CA options	Dilution, Batching, Substantially similar mixtures, Aerosols	
Germ Cell Mutagenicity	Cutoffs	Dilution, Batching, Substantially similar mixtures	Mixture test data only case-by case
Carcinogenicity	Cutoffs with CA options	Dilution, Batching, Substantially similar mixtures	Mixture test data only case-by-case

Hazard Class	Classification Approach	Bridging Principles	Comments
Reproductive Toxicity	Cutoffs with CA options	Dilution, Batching, Substantially similar mixtures	Mixture test data only case-by-case
Specific Target Organ Toxicity	Cutoffs with CA options	All	
Aspiration Toxicity	Cutoffs	Dilution, Batching, Concentration of highly toxic mixtures, Interpolation within one toxicity category, Substantially similar mixtures	
Hazardous to the Aquatic Environment	Additivity Formula (Acute only); Summation Method (Acute or Chronic); Combination of Additivity Formula & Summation Method	Dilution, Batching, Concentration of highly toxic mixtures, Interpolation within one toxicity category, Substantially similar mixtures	Relevant components usually at ≥ 1%, Mixture test data only case-by-case for chronic

4. Hazard Communication

Section 3 explained that classification is the starting point for the GHS. Once a chemical has been classified, the hazard(s) must be communicated to target audiences. The main tools of chemical hazard communication are *labels* and *safety data sheets* (SDS) that contain the hazard information in the form of hazard pictograms, signal words and other communication elements. The aim of these tools is to provide hazard information in a comprehensible form for chemicals that may pose a health, physical or environmental hazard during normal handling or use, or in emergencies. Within the GHS Purple Book a number of sections address label and safety data sheet elements. Specifically, chapter 1.4 deals with communicating hazards through labelling and chapter 1.5 addresses hazard communication through safety data sheets. A number of annexes provide further information on hazard communication. For example, Annex 1 of the Purple Book provides guidelines for the allocation of label elements and Annex 3 describes precautionary statements and precautionary pictograms.

4.1 What factors influenced development of the GHS communication tools?

Early in the process of developing the GHS communication tools, several significant issues were recognized. One of the most important was comprehensibility of the information provided. After all, the aim of the system is to present hazard information in a manner that the intended audience can easily understand and that will thus minimize the possibility of adverse effects resulting from exposure. The GHS identifies some guiding principles to assist in this process:

- Information should be conveyed in more than one way, e.g. text and symbols;
- The comprehensibility of the components of the system should take account of existing studies and literature as well as any evidence gained from testing; and
- The phrases used to indicate degree (severity) of hazard should be consistent across the health, physical and environmental hazards.

Comprehensibility is challenging for a single culture and language. Global harmonization has numerous complexities. Some factors that affected the work include:

- Different philosophies in existing systems on how and what should be communicated;
- Language differences around the world;
- Ability to translate phrases meaningfully; and
- Ability to understand and appropriately respond to symbols/pictograms.

These factors were considered in developing the GHS communication tools. The GHS Purple Book includes a comprehensibility-testing instrument in Annex 6.[6]

4.2 Labels

The GHS defines a label as follows:

- ***Label*** means an appropriate group of written, printed or graphic information elements concerning a hazardous product, selected as relevant to the target sector(s), that is affixed to, printed on, or attached to the immediate container of a hazardous product, or to the outside packaging of a hazardous product.

The label is the one hazard communication tool that is expected to be used in every sector covered by the GHS. Labels appear on containers of hazardous chemicals, and are the most immediate reminder to users of the adverse effects that may occur from exposure. As such, labels play an important role in helping to ensure that appropriate measures are in place to prevent such adverse effects.

Label elements are defined in the GHS as follows:

- ***Label element*** means one type of information that has been harmonised for use in a label, e.g., pictogram, signal word.

The GHS specifies what label elements should appear on a label by hazard class and hazard category for the harmonized information. It is these requirements that result in the same critical label information being available for a chemical regardless of which country the product originates in.

4.3 What are the harmonized GHS label elements?

In order to ensure that communication of hazard information is consistent, certain GHS label elements have been standardized or harmonized (identical with no variation) and are by hazard class and hazard category. Other label elements are harmonized with common definitions and/or principles. See Figure 4.1 for an illustration of the GHS label elements.

The standardized label elements included in the GHS are:

- **Pictograms:** A graphical composition that includes a symbol, plus a border, background pattern or colour that is intended to convey

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[6] Comprehensibility testing has also taken place in the context of the UNITAR/ILO pilot projects; see http://www2.unitar.org/cwm/ghs_partnership/CT.htm.

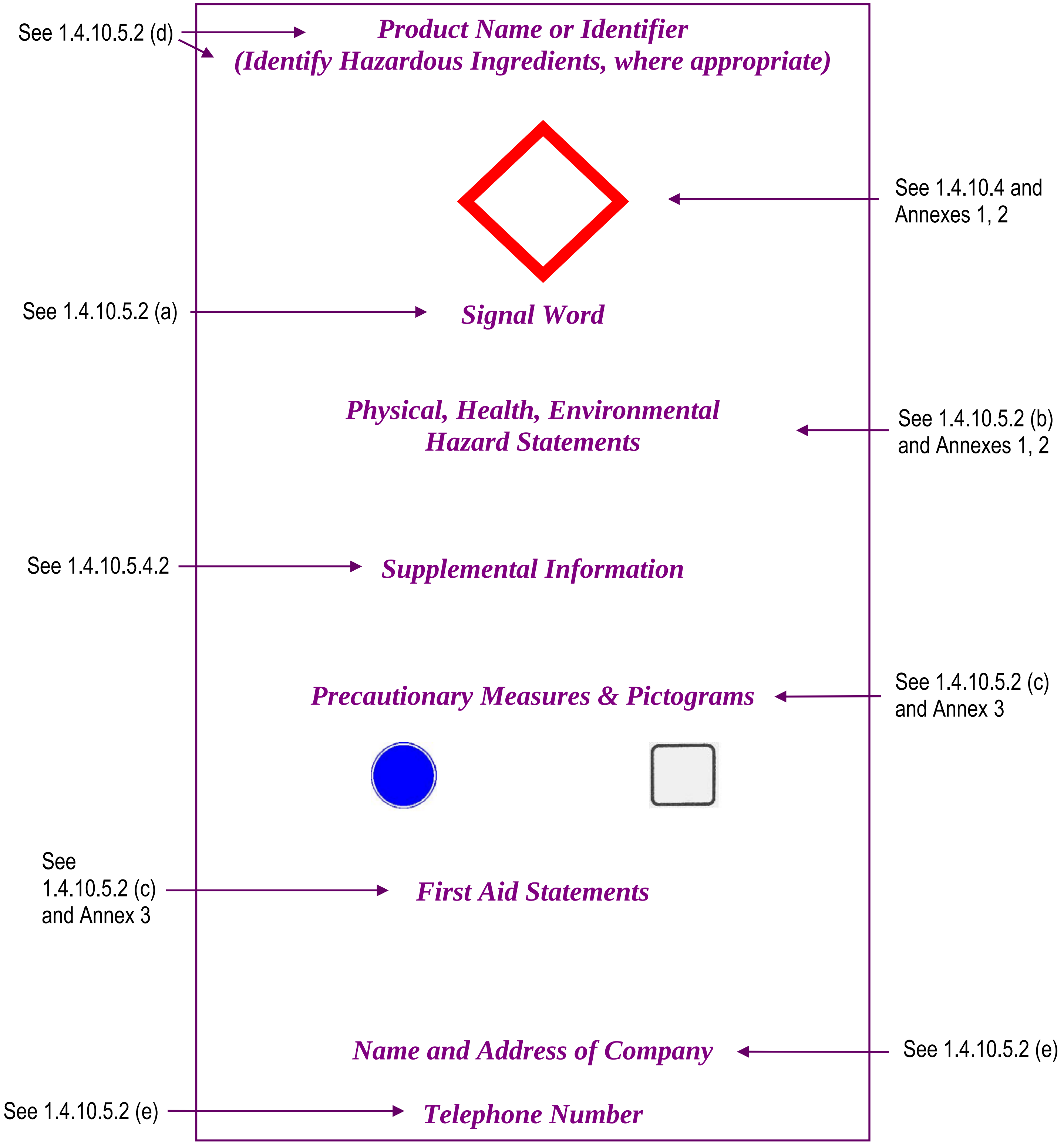
specific health, physical and environmental hazard information, assigned to a GHS hazard class and category.

- **Signal Words:** “Danger” or “Warning” are used to emphasize hazards and indicate the relative level of severity of the hazard, assigned to a GHS hazard class and category.
- **Hazard Statements:** Standard phrases assigned to a hazard class and category that describe the nature of the hazard.

The harmonized approach to these label elements makes it easier for countries to implement the system and should make it easier for companies to comply with regulations based on the GHS. The prescribed pictograms, signal words, and hazard statements can be readily selected from Annex 1 of the GHS Purple Book. These standardized elements should appear on the GHS label as indicated in the GHS for each hazard class/category in the system. The use of pictograms, signal words or hazard statements other than those that have been assigned to each of the GHS hazards would not be harmonized.

Figure 4.1

GHS Label Elements



The Section numbers refer to the sections in the GHS Purple Book.

4.3.1 Symbols/Pictograms

The GHS symbols have been incorporated into pictograms for use on the GHS label. Pictograms include the harmonized hazard symbols plus other graphic elements, such as borders, background patterns or colors intended to convey specific information. For transport, pictograms will have the background, symbol and colors currently used in the UN Recommendations on the Transport of Dangerous Goods, Model Regulations (some examples found in Figure 4.3). The transport pictograms need to have minimum dimensions as prescribed in the transport regulations. For other sectors, pictograms will have a black symbol on a white background with a red diamond frame (nine GHS pictograms found in Figure 4.2). If allowed by the competent authority, a black frame may be used for shipments within one country. The transport pictogram can be used in place of the GHS pictogram, but where a transport pictogram appears, the GHS pictogram for the same hazard should not appear. Also, GHS pictograms not required for the transport of dangerous goods should not be displayed on freight containers, road vehicles or railway wagons/tanks.

4.3.2 Signal Words

The signal word indicates the relative degree of severity of a hazard. The signal words used in the GHS are:

> **"Danger"** for the more severe hazards, and
> **"Warning"** for the less severe hazards.

Signal words are standardized and assigned to the hazard categories within hazard classes. Some lower level hazard categories do not use signal words. Only one signal word corresponding to the class of the most severe hazard should be used on a label.

4.3.3 Hazard Statements

Hazard statements are standardized and assigned phrases that describe the hazard(s) as determined by hazard classification. An appropriate statement for each GHS hazard should be included on the label for products possessing more than one hazard. The assigned label elements are provided in each hazard chapter of the GHS Purple Book as well as in Annexes 1 and 2. Figure 4.4 illustrates the assignment of standardized GHS label elements for the acute oral toxicity categories.

Figure 4.2

GHS Pictograms and Hazard Classes		
		
• Oxidizers	• Flammables • Self-reactives • Pyrophorics • Self-heating • Emits flammable gas • Organic peroxides	• Explosives • Self-reactives • Organic peroxides
		
• Acute toxicity (severe)	• Corrosive to metals • Skin corrosion • Serious eye damage	• Gases under pressure
		
• Carcinogenicity • Respiratory sensitization • Reproductive toxicity • Specific target organ toxicity (repeated) • Germ cell mutagenicity • Aspiration hazard	• Aquatic toxicity (acute) • Aquatic toxicity (chronic)	• Acute toxicity (harmful) • Skin/eye irritation • Skin sensitization • Specific target organ toxicity (single) • Hazardous to the ozone layer

Figure 4.3

(This table only provides a partial list of transport pictograms. For the transport requirements regarding marking, labelling and placarding refer to Part 5 of the UNRTDG http://www.unece.org/trans/danger/publi/unrec/rev16/16files_e.html)

Examples of Transport “Pictograms”		
 • **Flammable Gas** • **Flammable Aerosol**	 • **Flammable solids** • **Self-Reactive substances and mixtures**	 • **Pyrophoric solids** • **Phyrophoric liquids** • **Self-heating Substances and mixtures**
 • **Substances and mixtures, which in contact with water, emit flammable gases**	 • **Oxidizing gases** • **Oxidizing liquids** • **Oxidizing solids**	 • **Self reactive substances and mixtures (type B)** • **Organic peroxides**
 • **Explosives (Division 1.4)**	 • **Explosives (Division 1.5)**	 • **Explosives (Division 1.6)**
 • **Gases under pressure**	 • **Acute toxicity: Oral** • **Acute toxicity: Skin** • **Acute toxicity: Inhalation**	 • **Corrosive to metals** • **Skin corrosion/irritation**
 • **Aquatic toxicity (Acute)** • **Aquatic toxicity (Chronic)**	 • **Organic Peroxides**	

Figure 4.4

ACUTE ORAL TOXICITY – Annex 1					
	Category 1	Category 2	Category 3	Category 4	Category 5
LD$_{50}$	≤ 5 mg/kg	> 5 and ≤ 50 mg/kg	> 50 and ≤ 300 mg/kg	> 300 and ≤ 2000 mg/kg	> 2000 and ≤ 5000 mg/kg
Pictogram					No symbol
Signal word	Danger	Danger	Danger	Warning	Warning
Hazard statement	Fatal if swallowed	Fatal if swallowed	Toxic if swallowed	Harmful if swallowed	May be harmful if swallowed

Other GHS label elements include:

- **Precautionary Statements and Pictograms:** Measures to minimize or prevent adverse effects.
- **Product Identifier (ingredient disclosure):** Name or number used for a hazardous product on a label or in the SDS.
- **Supplier identification:** Name, address and telephone number.
- **Supplemental information:** non-harmonized information.

4.3.4 Precautionary Statements and Pictograms

Precautionary information supplements the hazard information by briefly providing measures to be taken to minimize or prevent adverse effects from physical, health or environmental hazards. First aid is included in precautionary information. The GHS label should include appropriate precautionary information. Annex 3 of the GHS Purple Book includes precautionary statements and pictograms that can be used on labels. These include four types of precautionary statements covering: prevention, response in cases of accidental spillage or exposure, storage, and disposal**.** The precautionary statements have been linked to each GHS hazard class and category. The goal is to promote consistent use of precautionary statements. Annex 3 is guidance and is expected to be further refined and developed over time. Some CAs have made specific precautionary statements mandatory when adopting the GHS.

4.3.5 Product Identifier (Ingredient Disclosure)

A product identifier should be used on a GHS label and it should match the product identifier used on the SDS. Where a substance or mixture is covered by the UN Model Regulations on the Transport of Dangerous Goods, the UN proper shipping name should also be used on the package.

The GHS label for a substance should include the chemical identity of the substance (name as determined by IUPAC, ISO, CAS or technical name). For mixtures/alloys, the label should include the chemical identities of all ingredients that contribute to acute toxicity, skin corrosion or serious eye damage, germ cell mutagenicity, carcinogenicity, reproductive toxicity, skin or respiratory sensitization, or Specific Target Organ Toxicity (STOT), when these hazards appear on the label. Where a product is supplied exclusively for workplace use, the Competent Authority may give suppliers discretion to include chemical identities on the SDS, in lieu of including them on labels. The Competent Authority rules for confidential business information (CBI) take priority over the rules for product identification.

4.3.6 Supplier Identification

The name, address and telephone number of the manufacturer or supplier of the product should be provided on the label.

4.3.7 Supplemental Information

Supplemental label information is non-harmonized information on the container of a hazardous product that is not required or specified under the GHS. In some cases this information may be required by a Competent Authority or it may be additional information provided at the discretion of the manufacturer/supplier. The GHS provides guidance to ensure that supplemental information does not lead to wide variation in information or undermine the GHS information. Supplemental information may be used to provide further detail that does not contradict or cast doubt on the validity of the standardized hazard information. It also may be used to provide information about hazards not yet incorporated into the GHS. The labeler should have the option of providing supplementary information related to the hazard, such as physical state or route of exposure, with the hazard statement.

4.4 How are multiple hazards handled on labels?

Where a substance or mixture presents more than one GHS hazard, there is a GHS precedence scheme for pictograms and signal words. For substances and mixtures covered by the UN Recommendations on the Transport of Dangerous Goods Model Regulations, the precedence of symbols for physical hazards should follow the rules of the UN Model Regulations.

For health hazards the following principles of precedence apply for symbols:

(a) If the skull and crossbones applies, the exclamation mark should not appear;

(b) If the corrosive symbol applies, the exclamation mark should not appear where it is used for skin or eye irritation;

(c) If the health hazard symbol appears for respiratory sensitization, the exclamation mark should not appear where it is used for skin sensitization or for skin or eye irritation.

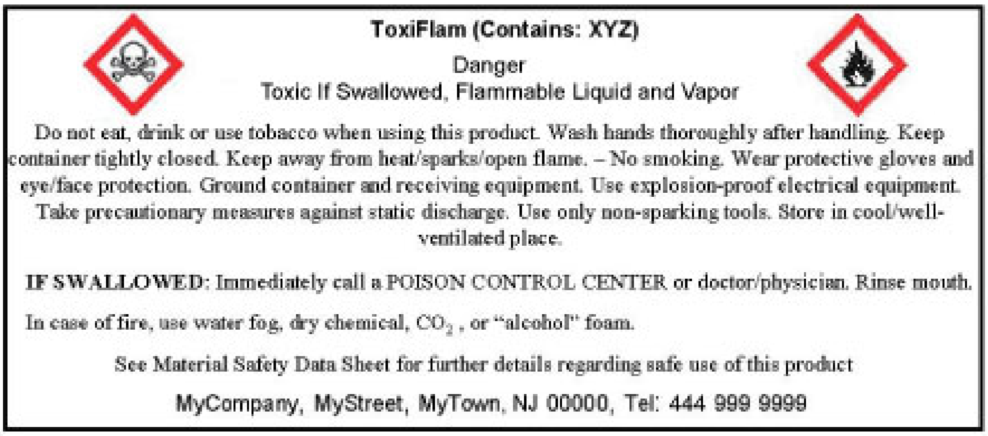
If the signal word ‘Danger’ applies, the signal word ‘Warning’ should not appear. All assigned hazard statements should appear on the label. The Competent Authority may choose to specify the order in which they appear.

4.5 Is there a specific GHS label format/layout?

The GHS hazard pictograms, signal word and hazard statements should be located together on the label. The actual label format or layout is not specified in the GHS. Competent authorities may choose to specify where information should appear on the label or allow supplier discretion.

Figure 4.5 shows an example of a GHS label for the fictional product “ToxiFlam”. The core GHS label elements are expected to replace the need for different labels.

Figure 4.5 Example of GHS Inner Container Label (e.g. bottle inside a shipping box)



ToxiFlam (Contains: XYZ)

Danger

Toxic If Swallowed, Flammable Liquid and Vapor

Do not eat, drink or use tobacco when using this product. Wash hands thoroughly after handling. Keep container tightly closed. Keep away from heat/sparks/open flame. – No smoking. Wear protective gloves and eye/face protection. Ground container and receiving equipment. Use explosion-proof electrical equipment. Take precautionary measures against static discharge. Use only non-sparking tools. Store in cool/well-ventilated place.

IF SWALLOWED: Immediately call a POISON CONTROL CENTER or doctor/physician. Rinse mouth.

In case of fire, use water fog, dry chemical, CO_2 , or “alcohol” foam.

See Material Safety Data Sheet for further details regarding safe use of this product

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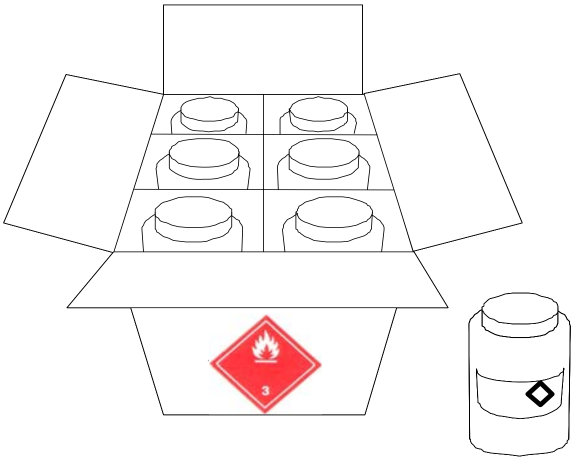
There has been discussion about the size of GHS pictograms and the idea that a GHS pictogram might be confused with a transport pictogram or “diamond”. Transport pictograms (Figure 4.3) are different in appearance than the GHS pictograms (Figure 4.2). Annex 7 of the Purple Book explains how the GHS pictograms are expected to be proportional to the size of the label text. Also, transport pictograms need to have minimum dimensions as prescribed in the applicable transport regulations.

Figure 4.13 Combination Packaging (Outer box with inner bottles)



Several arrangements for GHS labels are also provided in Annex 7 of the Purple Book. Figure 4.6 shows an arrangement for a combination packaging with an outer shipping box and inner bottles. The shipping box has a transportation pictogram. The inner bottles have a GHS label with a GHS pictogram. However, on inner packagings the GHS symbol may be replaced by the TDG symbol of the same hazard as well.

For a container such as a 55 gallon drum, the transport required markings and pictograms may be combined with the GHS label elements or presented separately. In Figure 4.7 a label arrangement for a single packaging such as a 55 gallon drum is shown. Pictograms and markings required by the transport regulations as well as GHS label and non-duplicative GHS pictogram are shown on the drum.

A label merging the transportation requirements and the GHS requirements into one label for the fictional product “ToxiFlam” is shown in Figure 4.8. This combined type label could also be used on a 55 gallon drum.

Figure 4.7 Example of Single Packaging
(55 gallon/200 liter drum)

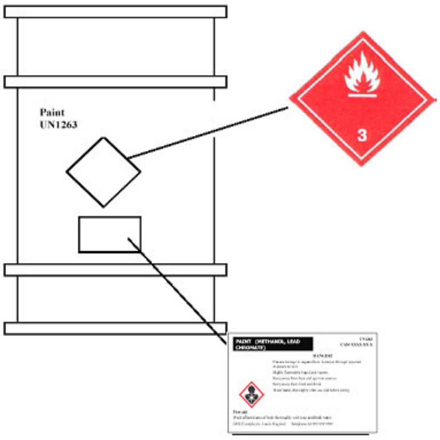
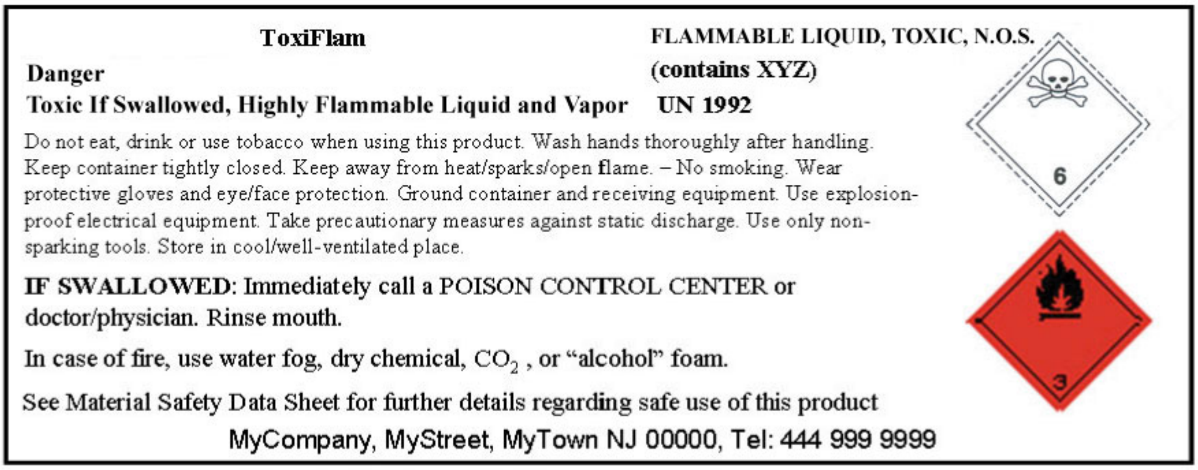


Figure 4.8 Example GHS Outer Container Label (55 gallon/200 liter drum)



ToxiFlam

Danger

Toxic If Swallowed, Highly Flammable Liquid and Vapor

FLAMMABLE LIQUID, TOXIC, N.O.S.
(contains XYZ)
UN 1992

Do not eat, drink or use tobacco when using this product. Wash hands thoroughly after handling. Keep container tightly closed. Keep away from heat/sparks/open flame. – No smoking. Wear protective gloves and eye/face protection. Ground container and receiving equipment. Use explosion-proof electrical equipment. Take precautionary measures against static discharge. Use only non-sparking tools. Store in cool/well-ventilated place.

IF SWALLOWED: Immediately call a POISON CONTROL CENTER or doctor/physician. Rinse mouth.

In case of fire, use water fog, dry chemical, CO_2 , or “alcohol” foam.

See Material Safety Data Sheet for further details regarding safe use of this product

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4.6 What about risk?

Competent Authorities may vary the application of the components of the GHS by the type of product (industrial, pesticide, consumer, etc.) or the stage in the lifecycle (workplace, farm, retail store, etc.). Once a consumer chemical is classified, the likelihood of adverse effects may be considered in deciding what informational or other steps should be taken for a given product or use setting. Annex 5 of the GHS Purple Book includes a discussion of an example of how risk-based labeling could be considered for chronic health effects of consumer products in the consumer use setting.

4.7 Are workplace containers covered in the GHS?

Products falling within the scope of the GHS will include the GHS label at the point where they are supplied to the workplace, and that label should be maintained on the supplied container in the workplace. The GHS label or label elements can also be used for workplace containers (e.g. storage tanks). However, the Competent Authority can allow employers to use alternative means of giving workers the same information in a different written or displayed format when such a format is more appropriate to the workplace and communicates the information as effectively as the GHS label. For example, label information could be displayed in the work area, rather than on the individual containers. Some examples of workplace situations where chemicals may be transferred from supplier containers include: containers for laboratory testing, storage vessels, piping or process reaction systems or temporary containers where the chemical will be used by one worker within a short timeframe.

4.8 What is the GHS Safety Data Sheet (SDS)?

The Safety Data Sheet (SDS) provides comprehensive information for use in workplace chemical management. Employers and workers use SDSs as sources of information about hazards and to obtain advice on safety precautions. The SDS is product related and, usually, is not able to provide information that is specific for any given workplace where the product may be used. However, the SDS information enables the employer to develop an active program of worker protection measures, including training, which is specific to the individual workplace and to consider any measures that may be necessary to protect the environment. Information in a SDS also provides a source of information for other target audiences such as those involved with the transport of dangerous goods, emergency responders, poison centers, and those involved with the professional use of pesticides and consumers.

The SDS should contain 16 headings (Figure 4.9). The SDS should provide a clear description of the data used to identify the hazards. Figure 4.9 and the GHS Purple Book provide the minimum information that is required in each section of the SDS. Examples of draft GHS SDSs are provided in Appendix A of this guidance document. The GHS Purple Book contains guidance on developing a GHS SDS (Annex 4).

Figure 4.9
Minimum information for an SDS

1.	**Identification of the substance or mixture and of the supplier**	(a) GHS product identifier; (b) Other means of identification; (c) Recommended use of the chemical and restrictions on use; (d) Supplier's details (including name, address, phone number, etc.); (e) Emergency phone number.
2.	**Hazards identification**	(a) GHS classification of the substance/mixture and any national or regional information; (b) GHS label elements, including precautionary statements; (Hazard symbols may be provided as a graphical reproduction of the symbols in black and white or the name of the symbol, e.g., flame, skull and crossbones.) (c) Other hazards which do not result in classification (e.g., dust explosion hazard) or are not covered by the GHS.
3.	**Composition/information on ingredients**	**<u>Substance</u>** (a) Chemical identity; (b) Common name, synonyms, etc.; (c) CAS number and other unique identifiers; (d) Impurities and stabilizing additives which are themselves classified and which contribute to the classification of the substance. **<u>Mixture</u>** The chemical identity and concentration or concentration ranges of all ingredients that are hazardous within the meaning of the GHS and are present above their cutoff levels. ***NOTE****: For information on ingredients, the competent authority rules for CBI take priority over the rules for product identification.*

4.	**First aid measures**	(a) Description of necessary measures, subdivided according to the different routes of exposure, i.e., inhalation, skin and eye contact, and ingestion; (b) Most important symptoms/effects, acute and delayed; (c) Indication of immediate medical attention and special treatment needed, if necessary.
5.	**Firefighting measures**	(a) Suitable (and unsuitable) extinguishing media; (b) Specific hazards arising from the chemical (e.g., nature of any hazardous combustion products); (c) Special protective equipment and precautions for firefighters.
6.	**Accidental release measures**	(a) Personal precautions, protective equipment and emergency procedures; (b) Environmental precautions; (c) Methods and materials for containment and cleaning up.
7.	**Handling and storage**	(a) Precautions for safe handling; (b) Conditions for safe storage, including any incompatibilities.
8.	**Exposure controls/personal protection**.	(a) Control parameters, e.g., occupational exposure limit values or biological limit values; (b) Appropriate engineering controls; (c) Individual protection measures, such as personal protective equipment.

9.	**Physical and chemical properties**	(a) Appearance (physical state, color, etc.); (b) Odor; (c) Odor threshold; (d) pH; (e) Melting point/freezing point; (f) Initial boiling point and boiling range; (g) Flash point; (h) Evaporation rate; (i) Flammability (solid, gas); (j) Upper/lower flammability or explosive limits; (k) Vapor pressure; (l) Vapor density; (m) Relative density; (n) Solubility(ies); (o) Partition coefficient: n-octanol/water; (p) Auto-ignition temperature; (q) Decomposition temperature; (r) Viscosity.
10.	**Stability and reactivity**	(a) Reactivity; (b) Chemical stability; (c) Possibility of hazardous reactions; (d) Conditions to avoid (e.g., static discharge, shock or vibration); (e) Incompatible materials; (f) Hazardous decomposition products.
11.	**Toxicological information**	Concise but complete and comprehensible description of the various toxicological (health) effects and the available data used to identify those effects, including: (a) Information on the likely routes of exposure (inhalation, ingestion, skin and eye contact); (b) Symptoms related to the physical, chemical and toxicological characteristics; (c) Delayed and immediate effects and also chronic effects from short- and long-term exposure; (d) Numerical measures of toxicity (such as acute toxicity estimates).
12.	**Ecological information**	(a) Ecotoxicity (aquatic and terrestrial, where available); (b) Persistence and degradability; (c) Bioaccumulative potential; (d) Mobility in soil; (e) Other adverse effects.

13.	**Disposal considerations**	Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.
14.	**Transport information**	(a) UN Number; (b) UN Proper shipping name; (c) Transport Hazard class(es); (d) Packing group, if applicable; (e) Environmental hazards (e.g.: Marine pollutant (Yes/No)); (f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code); (g) Special precautions that a user needs to be aware of, or needs to comply with, in connection with transport or conveyance either within or outside their premises.
15.	**Regulatory information**	Safety, health and environmental regulations specific for the product in question.
16.	**Other information including information on preparation and revision of the SDS**	

4.9 What is the difference between GHS SDSs and existing MSDS/SDSs?

Under the GHS system, Safety Data Sheets and/or Material Safety Data Sheets are simply referred to as SDS, and not MSDS. Because SDS are in use globally it is useful to have an understanding of the similarities and differences in the existing SDS content and format and the GHS SDS content and format.

4.10 When should SDSs and labels be updated?

All hazard communication systems should specify a means of responding in an appropriate and timely manner to new information and updating labels and SDS information accordingly. Updating should be carried out promptly on receipt of the information that necessitates the revision. The Competent Authority may choose to specify a time limit within which the information should be revised.

Suppliers should respond to "new and significant" information they receive about a chemical hazard by updating the label and safety data sheet for that chemical. New and significant information is any information that changes the GHS classification and leads to a change in the label information or information that may affect the SDS.

4.11 How does the GHS address Confidential Business Information (CBI)?

Confidential business information (CBI) will not be harmonized under the GHS. National authorities should establish appropriate mechanisms for CBI protection. The GHS CBI principles are that:

- CBI provisions should not compromise the health and safety of users;
- CBI claims should be limited to the names of chemicals and their concentrations in mixtures;
- Mechanisms should be established for disclosure in emergency and non-emergency situations.

4.12 Does the GHS address training?

The GHS states in Chapter 1.4, Section 1.4.9, the importance of training all target audiences to recognize and interpret label and/or SDS information, and to take appropriate action in response to chemical hazards. Training requirements should be appropriate for and commensurate with the nature of the work or exposure. Key target audiences include workers, emergency responders and also those responsible for developing labels and SDSs. To varying degrees, the training needs of additional target audiences have to be addressed. These should include training for persons involved in transport and strategies required for educating consumers in interpreting label information on products that they use.

5. References

Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (“The Purple Book”), United Nations, 2011 Fourth Revised Edition, available for purchase at: http://www.unece.org/index.php?id=24056

It may also be accessed online at: http://www.unece.org/trans/danger/publi/ghs/ghs_rev04/04files_e.html

Information about capacity building and available guidance may be accessed at the following:

http://www.unitar.org/cwm/ghs

6. Glossary

For the purposes of the GHS[7]:

ADR means the "European Agreement concerning the International Carriage of Dangerous Goods by Road", as amended;

Alloy means a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. Alloys are considered to be mixtures for the purpose of classification under the GHS;

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

ASTM means the "American Society of Testing and Materials";

BCF means "bioconcentration factor";

BOD/COD means "biochemical oxygen demand/chemical oxygen demand";

CA means "competent authority";

Carcinogen means a substance or a mixture which induce cancer or increase its incidence;

CAS means "Chemical Abstract Service";

CBI means "confidential business information";

Chemical identity means a name that will uniquely identify a chemical. This can be a name that is in accordance with the nomenclature systems of the International Union of Pure and Applied Chemistry (IUPAC) or the Chemical Abstracts Service (CAS), or a technical name;

Chemically unstable gas means a flammable gas that is able to react explosively even in the absence of air or oxygen;

Competent authority means any national body(ies) or authority(ies) designated or otherwise recognized as such in connection with the Globally Harmonized System of Classification and Labelling of Chemicals (GHS);

Compressed gas means a gas which when packaged under pressure is entirely gaseous at -50 °C; including all gases with a critical temperature $\leq$ -50 °C;

Corrosive to metal means a substance or a mixture which by chemical action will materially damage, or even destroy, metals;

Critical temperature means the temperature above which a pure gas cannot be liquefied, regardless of the degree of compression;

Dermal corrosion: see *skin corrosion*;

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[7] See chapter 1.2 of the Purple Book.

Dermal irritation: see *skin irritation*;

Dissolved gas means a gas which when packaged under pressure is dissolved in a liquid phase solvent;

Dust means solid particles of a substance or mixture suspended in a gas (usually air);

EC_{50} means the effective concentration of substance that causes 50% of the maximum response;

EC Number or (ECN) is a reference number used by the European Communities to identify dangerous substances, in particular those registered under EINECS;

ECOSOC means the Economic and Social Council of the United Nations;

ECx means the concentration associated with x% response;

EINECS means "European Inventory of Existing Commercial Chemical Substances";

ErC_{50} means EC_{50} in terms of reduction of growth rate;

EU means the "European Union";

Explosive article means an article containing one or more explosive substances;

Explosive substance means a solid or liquid substance (or mixture of substances) 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 substances are included even when they do not evolve gases;

Eye irritation means the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application;

Flammable gas means a gas having a flammable range with air at 20 °C and a standard pressure of 101.3 kPa;

Flammable liquid means a liquid having a flash point of not more than 93 °C;

Flammable solid means a solid which is readily combustible, or may cause or contribute to fire through friction;

Flash point means the lowest temperature (corrected to a standard pressure of 101.3 kPa) at which the application of an ignition source causes the vapours of a liquid to ignite under specified test conditions;

FAO means the "Food and Agriculture Organization of the United Nations";

Gas means a substance which (i) at 50 °C has a vapour pressure greater than 300 kPa (absolute); or (ii) is completely gaseous at 20 °C at a standard pressure of 101.3 kPa;

GESAMP means the "Joint Group of Experts on the Scientific Aspects of Marine Environmental Protection of IMO/FAO/UNESCO/WMO/WHO/IAEA/UN/UNEP";

GHS means the “Globally Harmonized System of Classification and Labelling of Chemicals”;

Hazard category means the division of criteria within each hazard class, e.g. oral acute toxicity includes five hazard categories and flammable liquids includes 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 means the nature of the physical, health or environmental hazard, e.g. flammable solid, carcinogen, oral acute toxicity;

Hazard statement means a statement assigned to a hazard class and category that describes the nature of the hazards of a hazardous product, including, where appropriate, the degree of hazard;

IAEA means the “International Atomic Energy Agency”;

IARC means the “International Agency for the Research on Cancer”;

ILO means the “International Labour Organization”;

IMO means the “International Maritime Organization”;

Initial boiling point means the temperature of a liquid at which its vapour pressure is equal to the standard pressure (101.3 kPa), i.e. the first gas bubble appears;

IOMC means the “Inter-organization Programme on the Sound Management of Chemicals”;

IPCS means the “International Programme on Chemical Safety”;

ISO means the “International Organization for Standardization”;

IUPAC means the “International Union of Pure and Applied Chemistry”;

Label means an appropriate group of written, printed or graphic information elements concerning a hazardous product, selected as relevant to the target sector(s), that is affixed to, printed on, or attached to the immediate container of a hazardous product, or to the outside packaging of a hazardous product;

Label element means one type of information that has been harmonized for use in a label, e.g. pictogram, signal word;

LC_{50} (50% lethal concentration) means 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;

LD_{50} means the amount of a chemical, given all at once, which causes the death of 50% (one half) of a group of test animals;

$L(E)C_{50}$ means LC_{50} or EC_{50};

Liquefied gas means a gas which when packaged under pressure, is partially liquid at temperatures above - 50 °C. A distinction is made between:

(i) High pressure liquefied gas: a gas with a critical temperature between -50 °C and +65 °C; and

(ii) Low pressure liquefied gas: a gas with a critical temperature above +65 °C;

Liquid means a substance or mixture which at 50 °C has a vapour pressure of not more than 300 kPa (3 bar), which is not completely gaseous at 20 °C and at a standard pressure of 101.3 kPa, and which has a melting point or initial melting point of 20 °C or less at a standard pressure of 101.3 kPa. A viscous substance or mixture for which a specific melting point cannot be determined shall be subjected to the ASTM D 4359-90 test; or to the test for determining fluidity (penetrometer test) prescribed in section 2.3.4 of Annex A of the European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR);

MARPOL means the "International Convention for the Prevention of Pollution from Ships";

Mist means liquid droplets of a substance or mixture suspended in a gas (usually air);

Mixture means a mixture or a solution composed of two or more substances in which they do not react;

Montreal Protocol means the Montreal Protocol on Substances that Deplete the Ozone Layer as either adjusted and/or amended by the Parties to the Protocol.

Mutagen means an agent giving rise to an increased occurrence of mutations in populations of cells and /or organisms;

Mutation means a permanent change in the amount or structure of the genetic material in a cell;

NGO means "non-governmental organization";

NOEC (no observed effect concentration) means the test concentration immediately below the lowest tested concentration with statistically significant adverse effect. The NOEC has no statistically significant adverse effect compared to the control;

OECD means the "Organization for Economic Cooperation and Development";

Organic peroxide means a liquid or solid organic substance which contains the bivalent -O-O- structure and may be considered a derivative of hydrogen peroxide, where one or both of the hydrogen atoms have been replaced by organic radicals. The term also includes organic peroxide formulations (mixtures);

Oxidizing gas means any gas which may, generally by providing oxygen, cause or contribute to the combustion of other material more than air does;

> ***NOTE:*** *"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 10156:2010.*

Oxidizing liquid means 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 means a solid which, while in itself not necessarily combustible, may, generally by yielding oxygen, cause, or contribute to, the combustion of other material;

Ozone Depleting Potential (ODP) means an integrative quantity, distinct for each halocarbon source species, that represents the extent of ozone depletion in the stratosphere expected from the halocarbon on a mass-for-mass basis relative to CFC-11. The formal definition of ODP is the ratio of integrated perturbations to total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11.

QSAR means “quantitative structure-activity relationship”;

Pictogram means a graphical composition that may include a symbol plus other graphic elements, such as a border, background pattern or colour that is intended to convey specific information;

Precautionary statement means a phrase (and/or pictogram) that describes recommended measures that should be taken to minimize or prevent adverse effects resulting from exposure to a hazardous product, or improper storage or handling of a hazardous product;

Product identifier means the name or number used for a hazardous product on a label or in the SDS. It provides a unique means by which the product user can identify the substance or mixture within the particular use setting e.g. transport, consumer or workplace;

Pyrophoric liquid means a liquid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air;

Pyrophoric solid means a solid which, even in small quantities, is liable of igniting within five minutes after coming into contact with air;

Pyrotechnic article means an article containing one or more pyrotechnic substances;

Pyrotechnic substance means a substance or mixture of substances 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;

Readily combustible solid means powdered, granular, or pasty substance or mixture which is dangerous if it can be easily ignited by brief contact with an ignition source, such as a burning match, and if the flame spreads rapidly;

Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria means the latest revised edition of the United Nations publication bearing this title, and any published amendment thereto;

Recommendations on the Transport of Dangerous Goods, Model Regulations means the latest revised edition of the United Nations publication bearing this title, and any published amendment thereto;

Refrigerated liquefied gas means a gas which when packaged is made partially liquid because of its low temperature;

Respiratory sensitizer means a substance that induces hypersensitivity of the airways following inhalation of the substance;

RID means The Regulations concerning the International Carriage of Dangerous Goods by Rail [Annex 1 to Appendix B (Uniform Rules concerning the Contract for International Carriage of Goods by Rail) (CIM) of COTIF (Convention concerning international carriage by rail)], as amended;

SAR means “Structure Activity Relationship”;

SDS means “Safety Data Sheet”;

Self-accelerating decomposition temperature (SADT) means the lowest temperature at which self-accelerating decomposition may occur with substance as packaged;

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

Self-reactive substance means a thermally unstable liquid or solid substance liable to undergo a strongly exothermic decomposition even without participation of oxygen (air). This definition excludes substances or mixtures classified under the GHS as explosive, organic peroxides or as oxidizing;

Serious eye damage means 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;

Signal word means a word used to indicate the relative level of severity of hazard and alert the reader to a potential hazard on the label. The GHS uses “Danger” and “Warning” as signal words;

Skin corrosion means the production of irreversible damage to the skin following the application of a test substance for up to 4 hours;

Skin irritation means the production of reversible damage to the skin following the application of a test substance for up to 4 hours;

Skin sensitizer means a substance that will induce an allergic response following skin contact;

Solid means a substance or mixture which does not meet the definitions of liquid or gas;

Substance means 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;

Substance which, in contact with water, emits flammable gases means a solid or liquid substance or mixture which, by interaction with water, is liable to become spontaneously flammable or to give off flammable gases in dangerous quantities;

Supplemental label element means any additional non-harmonized type of information supplied on the container of a hazardous product that is not required or specified under the GHS. In some cases this information may be required by other competent authorities or it may be additional information provided at the discretion of the manufacturer/distributor;

Symbol means a graphical element intended to succinctly convey information;

Technical name means a name that is generally used in commerce, regulations and codes to identify a substance or mixture, other than the IUPAC or CAS name, and that is recognized by the scientific community. Examples of technical names include those used for complex mixtures (e.g., petroleum fractions or natural products), pesticides (e.g., ISO or ANSI systems), dyestuffs (Colour Index system) and minerals;

UNCED means the “United Nations Conference on Environment and Development”;

UNCETDG/GHS means the “United Nations Committee of Experts on the Transport of Dangerous Goods and on the Globally Harmonized System of Classification and Labelling of Chemicals”;

UN means the “United Nations”;

UNEP means the “United Nations Environment Programme”;

UNESCO means the “United Nations Educational, Scientific and Cultural Organization”;

UNITAR means the “United Nations Institute for Training and Research”;

UNSCEGHS means the “United Nations Sub-Committee of Experts on the Globally Harmonized System of Classification and Labelling of Chemicals”;

UNSCETDG means the “United Nations Sub-Committee of Experts on the Transport of Dangerous Goods”;

Vapour means the gaseous form of a substance or mixture released from its liquid or solid state.

WHO means the “World Health Organization”;

WMO means the “World Meteorological Organization”.

Appendix A: SDS Examples (Fictional Products)

A-1: Bondit

A-2: Chemical Stuff

Appendix A-1
SDS for *BONDIT*

1. Identification

Name of the product: Bondit

Recommended use: General adhesive.

Producer: GHS Ltd., UK –
London, SE, Southwarkbridge 1

Telephone no. +44 171717 555.555 5,
Emergency no. +44 171717 333 333 3

2. Hazard(s) identification

Classification: Flammable liquid, Category 2
Eye irritation, Category 2A
Hazardous to the aquatic environment, Acute Category 3

Labelling:

Symbol: Flame, Exclamation mark
Signal word: Danger

Hazard statement:
Highly flammable liquid and vapour.
Causes severe eye irritation.
Harmful to aquatic life.

Precautionary statements:
Keep container tightly closed.
Keep away from heat/sparks/open flame. – No smoking.
Wear protective gloves and eye/face protection
Ground/Bond container and receiving equipment.
Use explosion-proof electrical/ventilating/lighting/equipment.
Take precautionary measures against static discharge.
Use only non-sparking tools.
Store in cool/well-ventilated place.
Avoid release to the environment.

3. Composition / Information on ingredients

Chemical identity: Component A 70-80%
Common name: Solvent A
Numbers of identity: CAS-Nr.:111111-11-1
Impurities: None

Chemical identity: Component C 20-25%
Common name: Not applicable
Numbers of identity: CAS-Nr.: 44444-44-4
Impurities: none

4. First-aid measures

Inhalation:
Remove person to fresh air. If respiratory irritation, dizziness, nausea, or unconsciousness occurs, seek immediate medical assistance. If breathing has stopped, give artificial respiration.

Skin contact:
Wash the contaminated area with soap and water. Remove contaminated clothing and wash before reuse. If irritation develops, get medical attention.

Eye contact:
Hold eyelids apart and flush eyes with plenty of water for at least 15 minutes. Get medical attention.

Ingestion:
If swallowed, do NOT induce vomiting. Seek immediate medical attention.

5. Firefighting measures

Suitable extinguishing media: Foam, extinguishing powder, carbon dioxide, water fog. In case of fire, cool endangered containers with water fog.

Unsuitable extinguishing media: High pressure water jet.

Specific hazards in case of fire: None are known.

Special protective equipment and precaution for fire fighters: For fires in enclosed areas, wear self-contained breathing apparatus. Do not inhale combustion gases.

6. Accidental release measures

Personal precautions:

Depending on extent of release, consider the need for fire fighters/emergency responders with adequate personal protective equipment for cleaning up.

Do not eat, drink or smoke while cleaning up. Use a self-contained respirator, a mask with filter (type A class 3) or a filtering mask (e.g., EN 405). Wear protective clothing, safety glasses and impervious gloves (e.g., neoprene gloves). Ensure adequate ventilation. Avoid all sources of ignition, hot surfaces and open flames (see also Section 7).

Environmental precautions:

Prevent spills from entering storm sewers or drains and contact with soil.

Methods and materials for containment and cleaning up:

Eliminate all ignition sources. Runoff may create fire or explosion hazard in sewer system. Absorb on fire retardant, liquid-absorbing material (treated sawdust, diatomaceous earth, sand). Shovel up and dispose of at an appropriate waste disposal facility in accordance with current applicable laws and regulations, and product characteristics at time of disposal (see also Section 13).

7. Handling and storage

Precautions for safe handling:

Avoid contact with eyes. Avoid prolonged repeated skin contact and breathing mists/vapours.
Use in well-ventilated area away from all ignition sources. Switch off all electrical devices such as parabolic heaters, hotplates, storage heaters etc. in good time for them to have cooled down before commencing work. Do not smoke; do not weld. Do not empty waste into sanitary drains. Take measures to prevent the build up of electrostatic charge.

Conditions for safe storage, including incompatibilities:

Storage containers must be grounded and bonded. Store away from all ignition sources in a cool area equipped with an automatic sprinkling system. Ensure adequate ventilation. Store at temperatures between +5 and +50°C. Store only in the original container.

8. Exposure controls / personal protection

Information on the system design:

Draw off vapours directly at the point of generation and exhaust from the work area. In the case of regular work, provide bench-mounted extraction equipment.

Exposure Limits:

Component Name (CAS-No.)	Reference	TWA		STEL	
		ppm	mg/m3	ppm	mg/m3
Component C (4444-44-4)	UK OEL	500	1200	--	--
	German MAK	200	950	--	--

Ventilation:

Use in well-ventilated area with local exhaust.

Respiratory protection:

Approved respiratory equipment must be used when airborne concentrations are unknown or exceed the exposure limits. When processing large amounts, use a light duty construction compressed air line breathing apparatus (e.g., in accordance with EN1835), a mask with filter (type A class 3, colour brown) or a filtering half mask (e.g., in accordance with EN 405) when there is inadequate ventilation.

Eye protection:

Safety glasses with side shields or chemical goggles must be worn.

Skin protection:

If prolonged or repeated skin contact is likely, neoprene gloves should be worn. Good personal hygiene practices should always be followed.

9. Physical and chemical properties

Physical state: Liquid
Colour: Colourless, transparent
Odour: Solvent, ester-like
Odour threshold: Not available
pH-value: Not applicable
Melting point: Not available
Freezing Point: Not available
Initial boiling point: 56°C
Flash point: - 22°C DIN 51755
Evaporation rate: Not available
Flammability (solid, gas): Not applicable
Explosion limits: lower limit = 1.4 Vol%; upper limit 13.0 Vol% (literature)
Vapour pressure: 240 mbar (highest partial vapour pressure) at 20°C
Vapour density: Not available
Relative density: 0.89 g/cm3 at 20°C
Solubility: Partially soluble in water at 20°C
Partition coefficient: Log Kow = 3.3

Auto-ignition temperature: Not available
Decomposition temperature: Not available

10. Stability and reactivity

Chemical stability: No decomposition, if used according to specifications.
Possibility of hazardous reactions: None are known.
Conditions to avoid: Heat, sparks, flame and build up of static electricity.
Materials to avoid: Halogens, strong acids, alkalies and ozidizers.
Hazardous decomposition products: None are known.

11. Toxicological information

Acute Toxicity:

Test	**Results**	**Basis**
Oral Toxicity (Rats)	Not Classified	Based on Ingredients
Dermal Toxicity (Rats)	Not Classified	Product Test Data
Inhalation Toxicity, Vapor (Rats)	Not Classified	Based on Testing of Similar Materials
Eye Irritation (Rabbits)	Eye Irritant Category 2A	Based on Testing of Similar Materials
Dermal Irritation (Rabbits)	Not Classified	Product Test Data

Summary Comments: May cause severe eye irritation like ocular lesions, which are reversible.

Subchronic/Chronic Toxicity:

Test	**Results**	**Comments**
Dermal Sensitization (Guinea Pig)	Not Classified: Negative response in Bueller, guinea pig test. 0% animals considered positive.	Product Test Data

Summary Comments: Component A may have a drying effect on the skin; frequent or prolonged contact may cause flaking or cracking of the skin.

12. Ecological information

Persistence and degradability: The total of the organic components contained in the product is not classified as "readily biodegradable" (OECD-301 A-F). However, this product is expected to be inherently biodegradable.

Bio-accumulative potential;
There is no evidence to suggest bioaccumulation will occur.

Mobility: Accidental spillage may lead to penetration in the soil and groundwater. However, there is no evidence that this would cause adverse ecological effects.

Aquatic Toxicity:

Test	Results	Comments
Acute Toxicity	Acute Category 3: 96 hr. LC_{50} = 65 mg/L	Product Test Data

13. Disposal considerations

Waste Disposal:
Product is suitable for burning in an enclosed, controlled burner for fuel value or disposal by supervised incineration. Such burning may be limited by local regulation. The product is suitable for processing at an appropriate government waste disposal facility. Use of these methods is subject to user compliance with applicable laws and regulations and consideration of product characteristics at time of disposal.

Recommended European waste code (EWC): 080406

14. Transport information

UN-number: 1133
UN proper shipping name: ADHESIVES
Transport hazard class: 3
Packing group: II
Marine Pollutant: No

15. Regulatory information

Inventory Status:
All components are on TSCA, AICS, and DSL.

Australian Regulations:

AS 1940 Class: PGII
Poisons Schedule: S5

U.S. Regulations:

U.S. Superfund Amendments and Reauthorization Act (SARA) Title III:

SARA (311/312) HAZARD CATEGORIES:
FIRE, ACUTE

SARA 313: This product contains the following SARA 313 Toxic Release Chemicals.

Chemical Name	CAS Number	Concentration
Component A	111111-11-1	70-80%
Component C	4444-44-4	20-25%

The following product components are cited on the lists below:

Chemical Name	CAS Number	List Citations
Component A	111111-11-1	NJ RTK, TSCA 12(b)
Component C	4444-44-4	Prop. 65, NJ RTK

16. Other information

Abbreviations and acronyms:

UK OES = United Kingdom Occupational Exposure Standards
German MAK = Germany Maximum Allowable Concentration

SDS Preparation date: July 1, 2010

The information contained herein is accurate to the best of our knowledge. My Company makes no warranty of any kind, express or implied, concerning the safe use of this material in your process or in combination with other substances.

Appendix A-2
SDS for Chemical Stuff

GHS SAFETY DATA SHEET

1. Identification

Product Name: **Chemical Stuff**
Synonyms: Methyltoxy Solution
CAS Number: 000-00-0
Product Use: Organic Synthesis
Manufacturer/Supplier: My Company
Address: My Street, Mytown, TX 00000
General Information: 713-000-0000
Transportation Emergency Number: CHEMTREC: 800-424-9300

2. Hazards Identification

GHS Classification:

Health	Environmental	Physical
Acute Toxicity – Category 2 (inhalation), Category 3 (oral/dermal) Eye Corrosion - Category 1 Skin Corrosion – Category 1 Skin Sensitization – Category 1 Mutagenicity – Category 2 Carcinogenicity – Category 1B Reproductive/Developmental – Category 2 Target Organ Toxicity (Repeated) – Category 2	Aquatic Toxicity – Acute 2	Flammable Liquid – Category 2

GHS Label:

Symbols: flame, skull and crossbones, corrosion, health hazard

Hazard Statements	Precautionary Statements
DANGER! Highly Flammable Liquid and Vapor. Fatal if inhaled. Causes severe skin burns and eye damage. May cause allergic skin reaction. Toxic if swallowed and in contact with skin May cause cancer. Suspected of damaging the unborn child. Suspected of causing genetic defects. May cause damage to cardiovascular, respiratory, nervous, and gastrointestinal systems and liver and blood through prolonged or repeated exposure. Toxic to aquatic life.	Do not eat, drink or use tobacco when using this product. Do not breathe mist/vapors. Keep container tightly closed. Keep away from heat/sparks/open flame. – No smoking. Wear respiratory protection, protective gloves and eye/face protection. Use only in a well-ventilated area. Take precautionary measures against static discharge. Use only non-sparking tools. Store container tightly closed in cool/well-ventilated place. Wash thoroughly after handling.

3. Composition / Information on Ingredients

Component	CAS Number	Weight %
Methyltoxy	000-00-0	80

(See Section 8 for Exposure Limits)

4. First Aid Measures

Eye: Eye irritation. Flush immediately with large amounts of water for at least 15 minutes. Eyelids should be held away from the eyeball to ensure thorough rinsing. Get immediate medical attention.

Skin: Itching or burning of the skin. Immediately flush the skin with plenty of water while removing contaminated clothing and shoes. Get immediate medical attention. Wash contaminated clothing before reuse.

Inhalation: Nasal irritation, headache, dizziness, nausea, vomiting, heart palpitations, breathing difficulty, cyanosis, tremors, weakness, red flushing of face, irritability. Remove exposed person from source of exposure to fresh air. If not breathing, clear airway and start cardiopulmonary resuscitation (CPR). Avoid mouth-to-mouth resuscitation.

Ingestion: Get immediate medical attention. Do not induce vomiting unless directed by medical personnel.

5. Fire Fighting Measures

Suitable Extinguishing Media: Use dry chemical, foam, or carbon dioxide to extinguish fire. Water may be ineffective but should be used to cool fire-exposed containers, structures and to protect personnel. Use water to dilute spills and to flush them away from sources of ignition.

Fire Fighting Procedures: Do not flush down sewers or other drainage systems. Exposed firefighters must wear NIOSH-approved positive pressure self-contained breathing apparatus with full-face mask and full protective clothing.

Unusual Fire and Explosion Hazards: Dangerous when exposed to heat or flame. Will form flammable or explosive mixtures with air at room temperature. Vapor or gas may spread to distant ignition sources and flash back. Vapors or gas may accumulate in low areas. Runoff to sewer may cause fire or explosion hazard. Containers may explode in heat of fire. Vapors may concentrate in confined areas. Liquid will float and may reignite on the surface of water.

Combustion Products: Irritating or toxic substances may be emitted upon thermal decomposition. Thermal decomposition products may include oxides of carbon and nitrogen.

6: Accidental Release Measures

Keep unnecessary people away; isolate hazard area and deny entry. Stay upwind; keep out of low areas. (Also see Section 8).

Vapor protective clothing should be worn for spills and leaks. Shut off ignition sources; no flares, smoking or flames in hazard area. Small spills: Take up with sand or other noncombustible absorbent material and place into containers for later disposal. Large spills: Dike far ahead of liquid spill for later disposal.

Do not flush to sewer or waterways. Prevent release to the environment if possible. Refer to Section 15 for spill/release reporting information.

7. Handling and Storage

Handling

Do not get in eyes, on skin or on clothing. Do not breathe vapors or mists. Keep container closed. Use only with adequate ventilation. Use good personal hygiene practices. Wash hands before eating, drinking, smoking. Remove contaminated clothing and clean before re-use. Destroy contaminated belts and shoes and other items that cannot be decontaminated.

Keep away from heat and flame. Keep operating temperatures below ignition temperatures at all times. Use non-sparking tools.

Storage

Store in tightly closed containers in cool, dry, well-ventilated area away from heat, sources of ignition and incompatibles. Ground lines and equipment used during transfer to reduce the possibility of static spark-initiated fire or explosion. Store at ambient or lower temperature. Store out of direct sunlight. Keep containers tightly closed and upright when not in use. Protect against physical damage.

Empty containers may contain toxic, flammable and explosive residue or vapors. Do not cut, grind, drill, or weld on or near containers unless precautions are taken against these hazards.

8. Exposure Controls / Personal Protection

Exposure Limits

Component	OSHA TWA	OSHA STEL
Methyltoxy	3 ppm (skin)	C 15 ppm (15 min.)

Engineering Controls: Local exhaust ventilation may be necessary to control air contaminants to their exposure limits. The use of local ventilation is recommended to control emissions near the source. Provide mechanical ventilation for confined spaces. Use explosion-proof ventilation equipment.

Personal Protective Equipment (PPE)

Eye Protection: Wear chemical safety goggles and face shield. Have eye-wash stations available where eye contact can occur.

Skin Protection: Avoid skin contact. Wear gloves impervious to conditions of use. Additional protection may be necessary to prevent skin contact including use of apron, face shield, boots or full body protection. A safety shower should be located in the work area. Recommended protective materials include:
Butyl rubber and for limited contact Teflon.

Respiratory Protection: If exposure limits are exceeded, NIOSH approved respiratory protection should be worn. A NIOSH approved respirator for organic vapors is generally acceptable for concentrations up to 10 times the PEL. For higher concentrations, unknown concentrations and for oxygen deficient atmospheres, use a NIOSH approved air-supplied respirator. Engineering controls are the preferred means for controlling chemical exposures. Respiratory protection may be needed for non-routine or emergency situations. Respiratory protection must be provided in accordance with OSHA 29 CFR 1910.134.

9. Physical and Chemical Properties

Flashpoint: 2°C (35°F) **Lower Flammability Limit:** >3.00%
Autoignition Temperature: 480°C (896°F) **Upper Flammability Limit:** <15.00%
Boiling Point: 77°C (170.6°F) @ 760 mm Hg **Specific Gravity:** 0.82g/ml @ 20°C
Melting Point: -82°C **% Volatile:** 100
Vapor Pressure: 100.0 mm Hg @ 23°C **Evaporation Rate (Water=1):** 5(Butyl Acetate =1)
Vapor Density(Air=1): 1.7; air = 1 **Viscosity:** 0.3 cP @ 25°C
% Solubility in Water: 10 @ 20°C **Octanol/Water Partition Coefficient:** log K_{ow}: 0.5
Pour Point: NA **pH: 7**, 8% aqueous solution
Molecular Formula: Mixture **Molecular Weight: Mixture**
Odor/Appearance: Clear, colorless liquid with mild, pungent odor.

10. Stability and Reactivity

Stability/Incompatibility: Incompatible with ammonia, amines, bromine, strong bases and strong acids.

Hazardous Reactions/Decomposition Products: Thermal decomposition products may include oxides of carbon and nitrogen.

11. Toxicological Information

Signs and Symptoms of Overexposure: Eye and nasal irritation, headache, dizziness, nausea, vomiting, heart palpitations, difficulty breathing, cyanosis, tremors, weakness, itching or burning of the skin.

Acute Effects:

Eye Contact: may cause severe conjunctival irritation and corneal damage.

Skin Contact: may cause reddening, blistering or burns with permanent damage. Harmful if absorbed through the skin. May cause allergic skin reaction.

Inhalation: may cause severe irritation with possible lung damage (pulmonary edema).

Ingestion: may cause severe gastrointestinal burns.

Target Organ Effects: May cause gastrointestinal (oral), respiratory tract, nervous system and blood effects based on experimental animal data. May cause cardiovascular system and liver effects.

Chronic Effects: based on experimental animal data, may cause changes to genetic material; adverse effects on the developing fetus or on reproduction at doses that were toxic to the mother. Methyltoxy is classified by IARC as group 2B and by NTP as reasonably anticipated to be a human carcinogen. OSHA regulates Methyltoxy as a potential carcinogen.

Medical Conditions Aggravated by Exposure: preexisting diseases of the respiratory tract, nervous system, cardiovascular system, liver or gastrointestinal tract.

Acute Toxicity Values

Oral LD_{50} (Rat) = 100 mg/kg
Dermal LD_{50} (Rabbit) = 225-300 mg/kg
Inhalation LC_{50} (Rat) = 200 ppm/4 hr., 1100 ppm vapor/1 hr

12. Ecological Information

LC_{50} (Fathead Minnows) = 9 mg/L/96 hr.
EC_{50} (Daphnia) = 8.6 mg/L/48 hr.

Bioaccumulation is not expected to be significant. This product is readily biodegradable.

13. Disposal Considerations

As sold, this product, when discarded or disposed of, is a hazardous waste according to Federal regulations (40 CFR 261). It is listed as Hazardous Waste Number Z000, listed due to its toxicity. The transportation, storage, treatment and disposal of this waste material must be conducted in compliance with 40 CFR 262, 263, 264, 268 and 270. Disposal can occur only in properly permitted facilities. Refer to state and local requirements for any additional requirements, as these may be different from Federal laws and regulations. Chemical additions, processing or otherwise altering this material may make waste management information presented in the MSDS incomplete, inaccurate or otherwise inappropriate.

14. Transport Information

U.S. Department of Transportation (DOT)

Proper Shipping Name: FLAMMABLE LIQUID, TOXIC, N.O.S (methyltoxy solution)
Hazard Class: 3, 6.1
UN/NA Number: UN1992
Packing Group: PG II
Labels Required: Flammable Liquid and Toxic

International Maritime Organization (IMDG)

Proper Shipping Name: FLAMMABLE LIQUID, TOXIC, N.O.S (methyltoxy solution)
Hazard Class: 3 Subsidiary 6.1
UN/NA Number: UN1992
Packing Group: PG II
Labels Required: Flammable Liquid and Toxic

15. Regulatory Information

U.S. Federal Regulations

Comprehensive Environmental Response and Liability Act of 1980 (CERCLA):
The reportable quantity (RQ) for this material is 1000 pounds. If appropriate, immediately report to the National Response Center (800/424-8802) as required by U.S. Federal Law. Also contact appropriate state and local regulatory agencies.

Toxic Substances Control Act (TSCA): All components of this product are included on the TSCA inventory.

Clean Water Act (CWA): Methyltoxy is a hazardous substance under the Clean Water Act. Consult Federal, State and local regulations for specific requirements.

Clean Air Act (CAA): Methyltoxy is a hazardous substance under the Clean Air Act. Consult Federal, State and local regulations for specific requirements.

Superfund Amendments and Reauthorization Act (SARA) Title III Information:

SARA Section 311/312 (40 CFR 370) Hazard Categories:
Immediate Hazard: X
Delayed Hazard: X
Fire Hazard: X
Pressure Hazard:
Reactivity Hazard:

This product contains the following toxic chemical(s) subject to reporting requirements of SARA Section 313 (40 CFR 372)

Component:	CAS Number:	Maximum %
Methyltoxy	000-00-0	80

State Regulations

California: This product contains the following chemicals(s) known to the State of California to cause cancer, birth defects or reproductive harm:

Component:	CAS Number:	%
Methyltoxy	000-00-0	80

Other Country Regulations

Canadian Environmental Protection Act: All of the components of this product are included on the Canadian Domestic Substances list (DSL).

Canadian Workplace Hazardous Materials Information System (WHMIS):

Class B-2	Flammable Liquid
Class D-1-B	Toxic
Class D-2-A	Carcinogen
Class D-2-B	Chronic Toxin
Class E	Corrosive

This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all the information required by the Controlled Products Regulations.

16. Other Information

National Fire Protection Association (NFPA) Ratings: This information is intended solely for the use of individuals trained in the NFPA system.

Health: 3 **Flammability: 3** **Reactivity: 0**
Revision Indicator: New SDS

Disclaimer: The information contained herein is accurate to the best of our knowledge. My Company makes no warranty of any kind, express or implied, concerning the safe use of this material in your process or in combination with other substances.

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