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

June 2024
Edition

A companion guide to the GHS Purple Book

unitar
United Nations Institute for Training and Research

Note on the Guide

This guide is based on the Tenth Revision Edition *(2023)* of the GHS Purple Book. Unless otherwise specified, all references to the parts, chapters, sections, annexes, paragraphs, etc. refer to the Tenth 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.

The first companion guide was based on the United States Occupational Safety and Health Administration *(OSHA)* “Guide to the GHS”. UNITAR gratefully acknowledges the work of OSHA in producing the guide.

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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TABLE OF CONTENTS

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

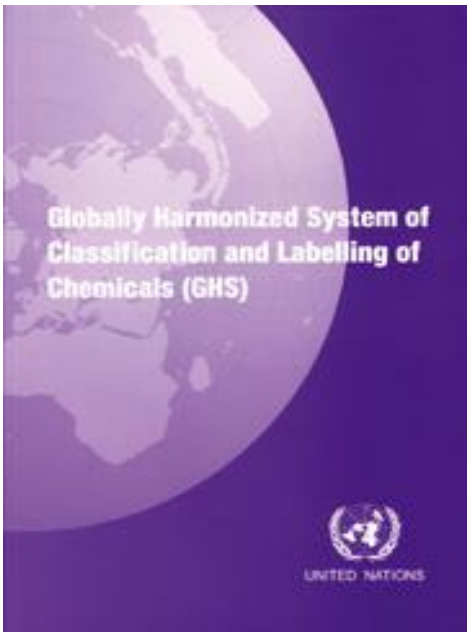
1.1 What is the GHS?

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 provides 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 SDS for the same product when marketed in different countries, or even in the same country, when different stages of the product life cycle were subject to different regulatory requirements. This contributed to potentially inconsistent protections for those exposed to chemicals, as well as regulatory and administrative burden on companies producing chemicals. Implementation of the GHS allows for harmonizing requirements in countries with existing systems, as well as establishing an internationally agreed upon approach that can be adopted by countries with regulatory systems at varying levels of maturity.

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 Figure 1.1)* establishes agreed upon 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, guidance on preparation of SDS and other hazards not resulting in classification) are found in a number of annexes. The elements in the GHS provide 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 what extent, and to prepare a label and/or Safety Data Sheet, as appropriate. Regulatory authorities in countries adopting the GHS can select criteria and provisions, as relevant, from the text of the GHS and implement them through their own regulatory process and procedures.

The GHS document thus provides countries with the regulatory building blocks to develop or modify existing national programmes that address classification of hazards and enable the transmission of globally harmonized 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”, including within a global supply chain.

1.2 Why was the GHS developed?

The production and use of chemicals is fundamental to all economies. The global chemicals industry was worth approximately 5 trillion US dollars in 2017, and is set to double by 2030 *(Global Chemicals Outlook II, UNEP, 2019).* 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 supports safer production, transport, use and disposal of chemicals. 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, particularly in an increasingly global supply chain. These groups include workers, consumers, emergency responders and the public. It is important to know what chemicals are present and/or used, the hazards they pose to human health and the environment, and the potential 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 SDS 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 the identification of hazards resulted in differences in the labels and SDS 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 has and will continue to help standardize the information provided for key label elements and in SDS, thus increasing comprehensibility for users of the products. This will allow the information to be used to provide appropriate protections, while 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. 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 help smaller companies 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?

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 single international organization covered all aspects of chemical classification and labelling. A broad scope was established and extensive expertise and resources were

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

required from a number of countries 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 the work could be divided to get the best expertise for different aspects. The existing systems that were deemed to be "major" are listed in Figure 1.3 and are 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.

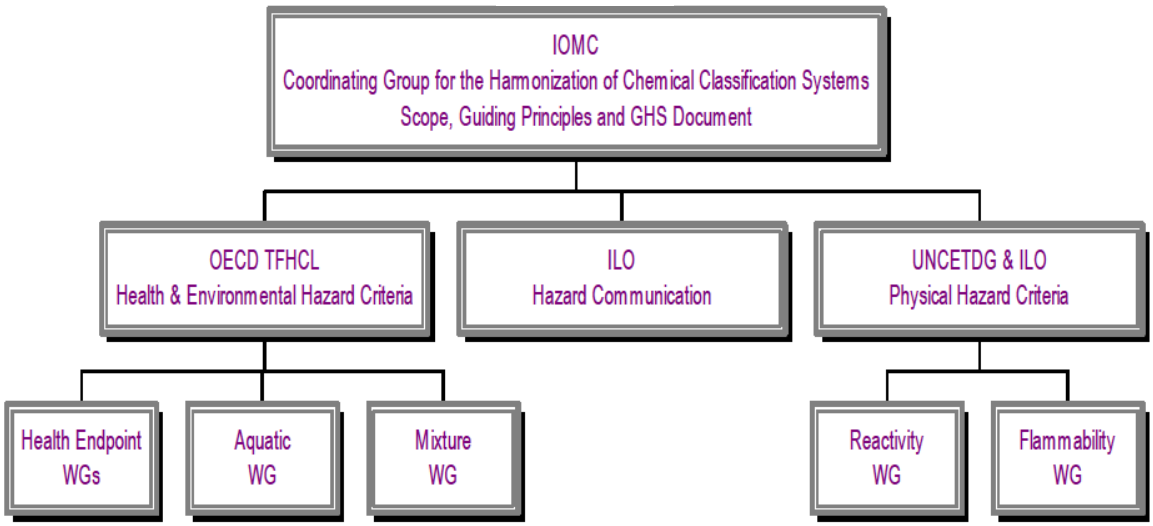
The CG/HCCS worked on a consensus basis, with representatives from major stakeholders, including national governments, industry and workers. The group created a set of guiding principles *(Figure 1.4).* The scope and guiding principles created a common framework for the organizations that were charged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

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

In order to get the best expertise and resources to advance the development of the system, the work was divided among three technical focal points. Figure 1.5 provides an overview of the governance that was set up, indicating how the work was assigned to the three technical focal points and its relation to 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 expand 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 physical hazards is based on the United Nations Recommendations on the Transport of Dangerous Goods (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 mandate is to:

- 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 and practical utility;
- Promote understanding and use of the system and encourage feedback;
- Make the system available for worldwide use and application;
- 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)* had 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.

While significant progress has been made in implementing the GHS around the world, as the GCO-II notes, it is still "not operational in more than 120 countries, mostly developing countries and economies in transition". To support the global push for implementation of the GHS, the Global Framework on Chemicals *(adopted in 2023)* agreed a new target on the GHS:

> ***Target B6*** *– By 2030, all Governments have implemented the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) in all relevant sectors as appropriate for their national circumstances.*

For more information on the global implementation status:
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, allows for the sound management of the use of the chemicals by implementing 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.

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

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 that will 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** can include:

- 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** can 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** can 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 Global Framework on Chemicals (GFC) *(https://www.chemicalsframework.org/)* has adopted a series of 28 targets, encompassing key aspects of chemicals and waste management. Within those, a target for all Governments to implement the GHS has been included.

- The importance of implementing the GHS was recognised in the Overarching Policy Strategy (OPS) of the Strategic Approach to International Chemicals Management (SAICM), which served as a policy framework for chemicals management *(www.saicm.org).* GHS was also included as a SAICM work area in the Global Plan of Action, including eight distinct activities[2].

- 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 SDS 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.

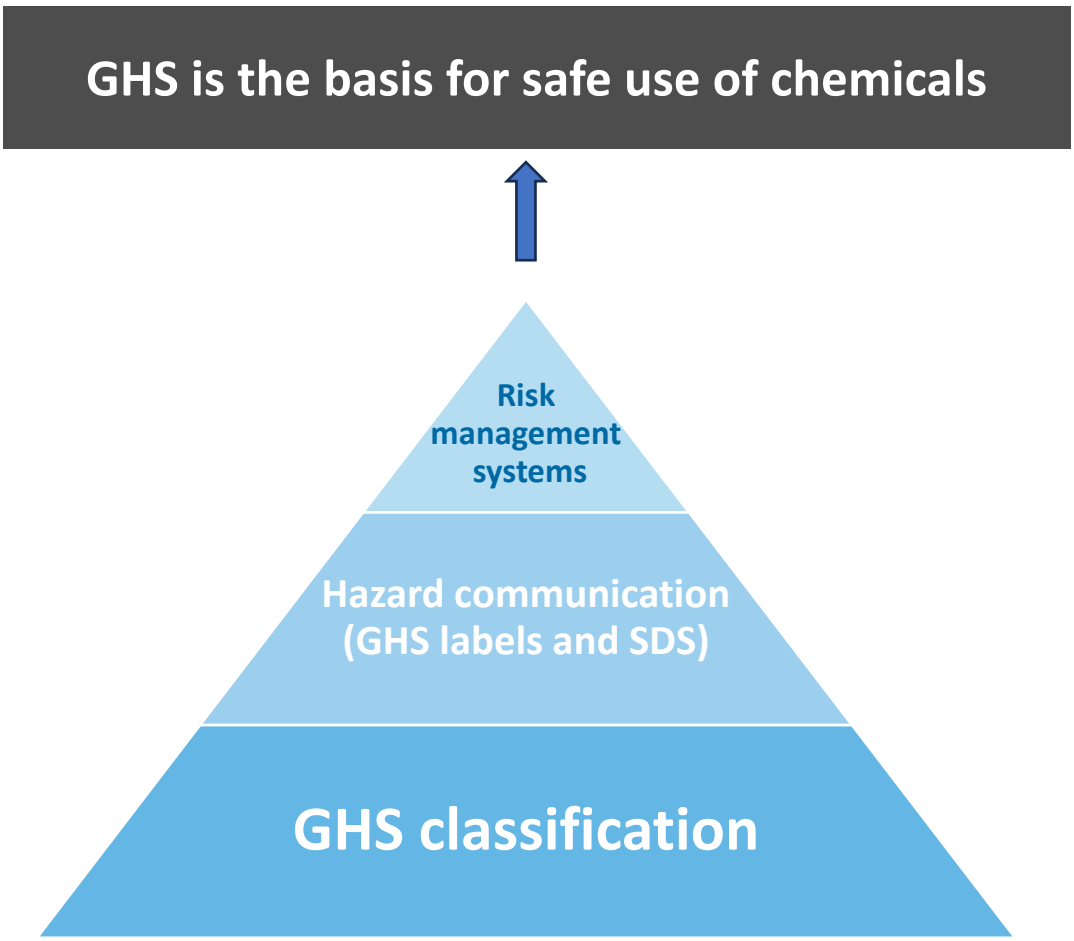
- The International Organisation for Standardization has developed a standard format for SDS in order to establish uniformity. The ISO SDS has adopted the 16-heading SDS format of the GHS.

[2] While SAICM has largely been superseded by the GFC, it remains as a useful reference for the importance 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 in Figure 2.1. The first two steps in any program to ensure the safe use of chemicals are to identify the intrinsic hazard(s) posed by the chemical of concern (i.e., hazard 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 to the instrinsic hazard and thereby reduce risk. The systems vary in focus and can 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?

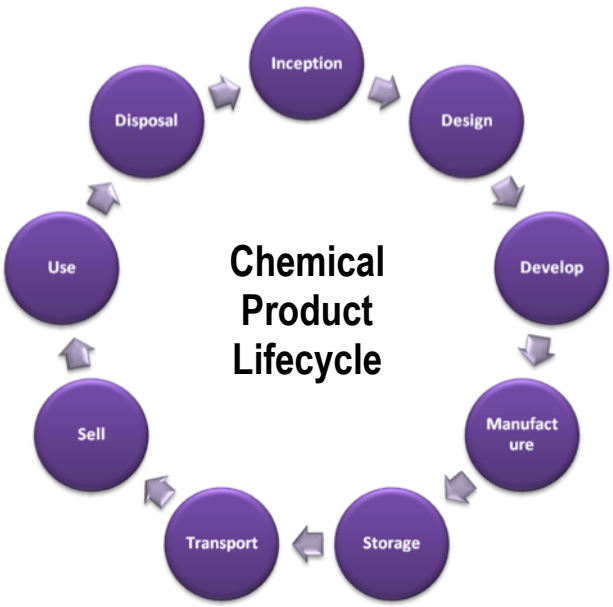
The GHS covers all hazardous chemicals. There are no complete exemptions from the scope of the GHS for a particular type of chemical or product. The term "chemical" is used broadly to include substances, products, mixtures, preparations, or any other terms that may be used by existing systems. The goal of the GHS is to identify the intrinsic hazards of chemical substances and mixtures and to convey information about these hazards. The GHS is not intended to harmonize risk assessment procedures or risk management decisions, as described above. However, information on risk management is occasionally provided in the GHS on a case-by-case basis for guidance purposes. Competent authorities are best placed to determine in regulations or standards the appropriate risk assessment procedures and risk management measures *(See GHS paragraph 1.1.2.6.1.).* 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?

The need for GHS labels and/or SDS 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

Figure 2.2



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 may be binding or voluntary in their application in the 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).* Since adoption of the GHS at the UN, countries that have aligned existing systems with the GHS have done so as expected by adopting the GHS harmonized elements while keeping in place existing frameworks/infrastructures, exceptions and exemptions.

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 relevant hazard communication systems would need to be changed in order to apply the GHS to the chosen sector and target audience. 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. 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 for the chosen sector and target audience, that coverage should be consistent. Once a hazard class and related hazard categories are selected for inclusion in the national approach, as needed for the chosen sector, 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. For example, if a regulatory system covers carcinogenicity, it should follow the harmonized classification scheme, the harmonized label elements and, if sector appropriate, the SDS. Additionally, within each hazard class, each category can be seen as a building block. Where a competent authority adopts a hazard class, it will always adopt at least the highest hazard category (e.g. Category 1), and, where more than one hazard category is adopted, these hazard categories will form an unbroken sequence. Specific 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, health hazard and environmental[3] 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;

[3] Not all workplace systems may 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[4]. 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 consistent with Annex 5 *Consumer Product Labelling Based on the Likelihood of Injury*), 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[5]. They have guidance materials available on developing a national GHS implementation strategy.

[4] Not all consumer systems may have the jurisdiction to adopt environmental hazards.
[5] More information on UNITAR/ILO GHS capacity building activities can be found at:. ***https://unitar.org/sustainable-development-goals/planet/our-portfolio/globally-harmonized-system-classification-and-labelling-chemicals***

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 divided 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).*[6] 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 generally 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 vapour 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
- Aerosols and Chemicals Under Pressure
- Oxidizing Gases
- Gases Under Pressure
- Flammable Liquids
- Flammable Solids
- Self-Reactive Substances and Mixtures
- 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
- Desensitized Explosives

3.1.1. Explosives

An *explosive substance or mixture* is a solid or liquid substance or mixture 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. An *explosive article* is an article containing one or more explosive substances or mixtures. Pyrotechnic substances or mixture are included even when they do not evolve gases. A *pyrotechnic substance or mixture* is an explosive substance or mixture that 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.

Explosive properties are associated with certain chemical groups that can react to give very rapid increases in temperature or pressure. The GHS classification of substances, mixtures and articles as explosives builds largely on the classification used for transport according to the *UN Model Regulations*. Information on their

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

transport division and, when available, some of the underlying test results according to Part I of the *Manual of Tests and Criteria*, is therefore relevant for the GHS classification. Test data is not required when classification using expert judgement is possible based on available information from previous testing and characterization. While the transport divisions are designed for the purpose of safe transport of explosives, the GHS classification draws from this classification to ensure appropriate hazard communication in other sectors, in particular supply and use. In doing this, any mitigating effects of the transport configuration on the explosive behavior, such as a particular packaging, are evaluated as they may not be present in sectors outside of transport.

Substances, mixtures, and articles are classified into one of two categories *(i.e., Category 1 and Category 2)* as follows:

- Category 1 is used for explosives in manufacturing processing, and which are not configured for transport. This category is also used for Category 2 explosives when taken out of their primary packaging for purposes other than use.
- Category 2 is used for explosives assigned a transport division and are placed into one of three sub-categories:
    - Category 2A high explosion hazard,
    - Category 2B medium explosive hazard, and
    - Category 2C low explosion hazard.

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 three hazard categories on the basis of the outcome of the test or calculation method *(ISO 10156:2017).* Additionally, *Pyrophoric gas* means a flammable gas that is liable to ignite spontaneously in air at a temperature of 54°C or below and *Chemically Unstable gas* means a flammable gas that is able to react explosively even in the absence of air or oxygen. Flammable gases that are Pyrophoric and/or Chemically Unstable Category A or B are also always classified into Category 1A.

3.1.3. Aerosols and Chemicals Under Pressure

This chapter contains the definitions, classification criteria, hazard communication elements, decision logics and guidance for Aerosols and Chemicals Under Pressure. Although they present similar hazards, Aerosols and Chemicals Under Pressure are separate hazards classes due to allowable pressure, capacity and construction of the two kinds of receptables. A substance or mixture is classified as either an Aerosol or a Chemical Under Pressure.

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 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 Table 2.3.1 Criteria for Aerosols of the Purple Book. Aerosols which do not meet the criteria for inclusion in Category 1 (*extremely flammable aerosols)* or Category 2 *(flammable aerosols)* should be classified in Category 3 *(non-flammable aerosols).*

Chemicals under pressure means liquids or solids *(e.g., pastes or powders),* pressurized with a gas at a pressure of 200 kPa *(gauge)* or more at 20 °C in pressure receptacles other than aerosol dispensers and which are not classified as gases under pressure. Chemicals Under pressure should be considered for classification as flammable if they contain any constituents that meet the GHS criteria for classification as flammable liquid, gas or solid.

Chemicals Under Pressure are classified in one of three categories of this Class on the basis of its components and heat of combustion. See Table 2.3.3 Criteria for Chemicals Under Pressure of the Purple Book. Chemicals Under Pressure which to not meet the criteria for inclusion in Category 1 *(extremely flammable chemicals under pressure)* or Category 2 *(flammable chemicals under pressure)* should be classified in Category 3 *(non-flammable chemicals under pressure).*

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 method used for classifying oxidizing gases via calculation is: ISO 10156:2017. Some Workplace hazard communication systems that have not aligned with the GHS may 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

Table 3.1 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

environment independent of other hazards the gases may pose.

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 3.1.

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 3.2).*

Table 3.2 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 3.3)* 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 3.3 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 chapters. 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 3.4).*

Table 3.4 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 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 3.5 Substances which on Contact with Water Emit Flammable Gases

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 or O.3 UN Manual of Tests and Criteria)* that measure mean burning time and are compared to defined mixtures. Some workplace hazard communication systems that have not aligned with the GHS may 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 3.6).*

Table 3.6 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	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 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 or higher for a 50 kg package), and, for liquid mixtures, a diluent having a boiling point not less than 150°C is used for desensitization.

Note: An organic peroxide shall be considered for classification based on the available oxygen content (%) according to a given formula.

3.1.16. Substances Corrosive to Metal

A *substance or a mixture which is corrosive to metals* is a substance or mixture which by chemical action will materially damage, or even destroy, metals. 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.

3.1.17. Desensitized Explosives

Desensitized explosives are solid or liquid explosive substances or mixtures which are phlegmatized to suppress their explosive properties in such a manner that they do not mass explode and do not burn too rapidly and therefore may be exempted from the hazard class "Explosives" *(Chapter 2.1; see also Note 2 of paragraph 2.1.2.2)*[7]. These substances or mixtures are classified into one of 4 hazard categories on the basis of test results that measure a corrected burning rate (A_c). The test methods can be found in Part V of the UN Recommendations on the Transport of Dangerous Goods, Manual of Tests and Criteria.

Table 3.7 Desensitized Explosives

Category	Criteria
1	Desensitized explosives with a corrected burning rate (A_C) equal to or greater than 300 kg/min but not more than 1200 kg/min
2	Desensitized explosives with a corrected burning rate (A_C) equal to or greater than 140 kg/min but less than 300 kg/min
3	Desensitized explosives with a corrected burning rate (A_C) equal to or greater than 60 kg/min but less than 140 kg/min
4	Desensitized explosives with a corrected burning rate (A_C) less than 60 kg/min

3.2 What are the GHS Health and Environmental Hazards?

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

- A thorough analysis of pre-GHS 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 pre-GHS 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.

[7] *Unstable explosives as defined in Chapter 2.1 can also be stabilized by desensitization and consequently may be classified as desensitized explosives, provided all criteria of Chapter 2.17 are met. In this case the desensitized explosive should be tested according to test series 3 (Part I of the Manual of Tests and Criteria) because information about its sensitiveness to mechanical stimuli is likely to be important for determining conditions for safe handling and use. The results should be communicated in the safety data sheet.*

Figure 3.3

Health Hazards

1. Acute Toxicity
2. Skin Corrosion/Irritation
3. Serous Eye Damage/Eye Irritation
4. Respiratory or Skin Sensitization
5. Germ Cell Mutagenicity
6. Carcinogenicity
7. Reproductive Toxicology
8. Specific Target Organ Toxicity – Single Exposure
9. Specific Target Organ Toxicity – Repeated Exposure
10. Aspiration

Environmental Hazards

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

3.3 Health Hazards

3.3.1. Acute Toxicity

Acute toxicity refers to serious adverse health effects *(i.e. lethality)* occurring after a single or short-term oral, dermal or inhalation exposure to a substance or mixture. 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

Route	Cat. 1	Cat. 2	Cat. 3	Cat. 4	Cat. 5
Oral (mg/kg)	ATE ≤ 5	5 < ATE ≤ 50	50 < ATE ≤ 300	300 < ATE ≤ 2000	2000< ATE≤ 5000 See detailed criteria in Note (g)
Dermal (mg/kg)	ATE ≤ 50	50 < ATE ≤ 200	200 < ATE ≤ 1000	1000 < ATE ≤ 2000	
Gases (ppmV)	ATE ≤ 100	100 < ATE ≤ 500	500 < ATE ≤ 2500	2500 < ATE ≤ 20000	See detailed criteria in Note (g)[8]
Vapours (mg/l)	ATE ≤ 0.5	0.5 < ATE ≤ 2.0	2.0 < ATE ≤ 10.0	10.0 < ATE ≤ 20.0	
Dusts & Mists (mg/l)	ATE ≤ 0.05	0.05 < ATE ≤ 0.5	0.5 < ATE ≤ 1.0	1.0 < ATE ≤ 5.0	

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 LD50 (oral, dermal) or LC50 (inhalation). The LC50 values are based on 4-hour tests in animals. The GHS provides guidance on the conversion of experimental values for times other a 4-hour exposure 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 in Note (g) to GHS Table 3.1.1 to identify substances in Category 5 unless a more hazardous class is warranted. Due to the high concentration required to possibly cause an adverse health effect, most countries have not adopted category 5 – if exporting this should be checked for the receiving country.
Available reliable information from experience of acute toxicity effects on humans should be taken into account using expert judgement (cf. GHS 1.3.2.4.7).

3.3.2. Skin Corrosion/Irritation

Skin corrosion refers to the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis occurring after exposure to a substance or mixture. Substances and mixtures in this hazard class are assigned to a harmonized corrosion category with the ability to place it into a sub-category when

[8] Of note, not adopted by most countries

data are sufficient and where required by a competent authority. See the Skin Corrosion/Irritation Table 3.9.

Several factors should be considered in a tiered approach to evaluating the corrosion potential:

- Human or animal data showing irreversible damage to the skin;
- *In-vitro/ex vivo* data;
- *Other existing animal skin data;*
- pH extremes of ≤ 2 and ≥ 11.5 including acid/alkali reserve.
- Non-test methods, such as structure/activity or structure property relationship to a substance or mixture already classified as corrosive;
- An overall weight of evidence assessment when a conclusive classification is not possible in the tiers listed above.

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 Mean score: ≥ 2.3 ≤ 4.0 or persistent inflammation	Reversible adverse effects in dermal tissue Mean 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		

3.3.3. Skin Irritation

Skin irritation refers to the production of reversible damage to the skin occurring after exposure to a substance or mixture. Substances and mixtures can be assigned into one of two irritant categories. For those authorities, such as pesticide regulators, wanting a designation for mild irritation, Skin Irritation Category 3 is provided as a building block option. See the Skin Corrosion/Irritation Table 3.9.

Several factors should be considered in a tiered approach to evaluating the irritation potential:

- Human or animal data showing reversible damage to the skin following a 4-hour exposure;
- *In-vitro/ex vivo* data;
- *Other existing animal skin data;*
- Non-test methods, such as structure/activity or structure property relationship to a substance or mixture already classified as an irritant;
- An overall weight of evidence assessment when a conclusive classification is not possible in the tiers listed above.

3.3.4. Eye Effects

Several factors should be considered in a tiered approach for evaluating *serious eye damage* or *eye irritation* potential:

- Human and animal data;
- Defined approaches or in-vitro/ex vivo data;
- Human, standard animal or in-vitro/ex vivo data for skin corrosion;
- Other existing animal data;
- pH extremes of ≤ 2 and ≥ 11.5 including acid/alkali reserve capacity that may produce serious eye damage;
- Non-test methods, such as structure/activity or structure property relationship to a substance or mixture already classified;
- An overall weight of evidence assessment when a conclusive classification is not possible in the tiers listed above.

Table 3.10 Eye Effects

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

Serious eye damage refers to the production of tissue damage in the eye, or serious physical decay of vision, which is not fully reversible, occurring after exposure of the eye to a substance or mixture.

Eye irritation refers to the production of changes in the eye, which are normally fully reversible within 21 days, occurring after the exposure of the eye to a substance or mixture. Substances and mixtures in this hazard class are assigned to a single harmonized hazard category 2/2A. For those authorities wanting a designation for mild eye irritation, Eye Irritation Category 2B is provided as a building block option, depending on whether the effects are reversible within 7 days.

3.3.5. Sensitization

Respiratory sensitizer refers to hypersensitivity of the airways occurring after inhalation of a substance or a mixture. Substances and mixtures in this hazard class are assigned to Category 1, where sub-categorization is not required by a competent authority or where data are not sufficient for sub-categorization.
Skin sensitizer refers to an allergic response occurring after skin contact with a substance or a mixture.
Substances and mixtures in this hazard class are assigned to Category 1, where sub-categorization is not required by a competent authority or where data are not sufficient for sub-categorization using a tiered evaluation approach. **All available and relevant information of sufficient quality is considered with respect to the classification:**

- Human and animal data;
- Standard animal data;
- Defined approach data;

- Stand-alone *in chemico/in vitro* data;
- Non stand-alone *in chemico/in vitro* data
- Non-test method data;
- An overall weight of evidence assessment when a conclusive classification is not possible in the tiers listed above.

Consideration should be given to classifying substances that cause immunological contact urticaria *(an allergic disorder)* as skin sensitizers.

Table 3.11 Respiratory Sensitization

CATEGORY 1:	Respiratory sensitizer
	A substance is classified as a respiratory sensitizer if there is: (a) Evidence in humans that the substance can lead to specific respiratory hypersensitivity and/or (b) Positive results from an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency of occurrence in humans; or a probability of occurrence of a high sensitization rate in humans based on animal or other tests. Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans; or a probability of occurrence of a low to moderate sensitization rate in humans based on animal or other tests. Severity of reaction may also be considered.

Table 3.12 Skin Sensitization

CATEGORY 1:	Skin sensitizer
	A substance is classified as a skin sensitizer if there is: (a) Evidence in humans that the substance can lead to sensitization in a substantial number of persons, or (b) Positive results from an appropriate animal test.
Sub-category 1A:	Substances showing a high frequency of occurrence in humans and/or a high potency in animals. Severity of reaction may also be considered.
Sub-category 1B:	Substances showing a low to moderate frequency of occurrence in humans and/or a low to moderate potency in animals. Severity of reaction may also be considered.

3.3.6. Germ Cell Mutagenicity

Germ cell mutagenicity refers to heritable gene mutations, including heritable structural and numerical chromosome aberrations in germ cells occurring after exposure to a substance or mixture. 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 3.13) below.

Table 3.13 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

Carcinogenicity refers to the induction of cancer or an increase in the incidence of cancer occurring after exposure to a substance or mixture. 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 3.14 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 refers to adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring, occurring after exposure to a substance or mixture.

Table 3.15 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		

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.

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

The GHS distinguishes between single and repeated exposures for Target Organ Effects:

- *Specific target organ toxicity – single exposure* refers to specific, non-lethal toxic effects on target organs occurring after a single exposure to a substance or mixture.
- *Specific target organ toxicity-repeated exposure* refers to specific toxic effects on target organs occurring after repeated exposure to a substance or mixture.

Some previous systems distinguished between single and repeated exposures for these effects and some did 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 specific target organ toxicity classes *(STOT).* Transient 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 3.16.

Table 3.16 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 3.17.

Table 3.17 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

Aspiration means the entry of a liquid or solid chemical directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system. Aspiration toxicity includes severe acute effects such as chemical pneumonia, varying degrees of pulmonary injury or death following aspiration. Some hydrocarbons (petroleum distillates) and certain chlorinated hydrocarbons have been shown to pose an aspiration hazard in humans and are classified into Category 1. Primary alcohols, and ketones have been shown to pose an aspiration hazard only in animal studies and are classified into Category 2. Substances and mixtures of this hazard class are assigned to one of two hazard categories in this hazard class on the basis of chemical identity and viscosity.

Table 3.18 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 40º C & not Category 1.

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, 1973, as modified by the Protocol of 1978 relating thereto, as amended), 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 substance to be injurious to an organism in a short-term aquatic exposure to that substance. 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 intrinsic property of a substance to cause adverse effects to aquatic organisms during aquatic exposures which 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 long-term chronic toxicity data: NOEC *(fish)* or NOEC *(crustacea)* or NOEC *(for algae or other aquatic plants).* In the absence of adequate chronic toxicity data the long-term *(chronic)* hazard classification can be based on acute aquatic toxicity in combination with information on rapid degradability and/or bioaccumulation data.

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 4 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 3.19 Acute & Chronic Aquatic Toxicity

Classification categories			
Short-term (acute) hazard	**Long-term (chronic) hazard**		
	Adequate chronic toxicity data available		**Adequate chronic toxicity data not available**
	Non-rapidly degradable substances	**Rapidly degradable substances**	
Category: Acute 1 $L(E)C_{50} \leq 1.00$	**Category: Chronic 1** NOEC or $EC_x \leq 0.1$	**Category: Chronic 1** NOEC or $EC_x \leq 0.01$	**Category: Chronic 1** $L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 2 $1.00 < L(E)C_{50} \leq 10.0$	**Category: Chronic 2** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 2** $0.01 <$ NOEC or $EC_x \leq 0.1$	**Category: Chronic 2** $1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 3 $10.0 < L(E)C_{50} \leq 100$		**Category: Chronic 3** $0.1 <$ NOEC or $EC_x \leq 1$	**Category: Chronic 3** $10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or BCF ≥ 500 or, if absent log $K_{ow} \geq 4$
	Category: Chronic 4 Example: (*Note 5*) No acute toxicity and lack of rapid degradability and BCF ≥ 500 or, if absent log Kow ≥ 4, unless NOECs > 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 requires 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 substance or changing its composition.

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

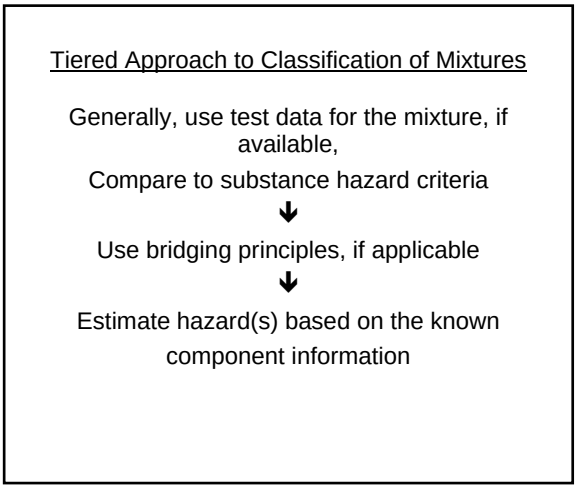
Alloy: An alloy is a metallic material, homogeneous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means. Alloys are considered to be mixtures for the purpose of classification under the GHS.

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 generally 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:

Figure 3.4



(1) Where test data are available for the mixture itself, the classification of the mixture will be based on that data *(See exception for e.g. 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. 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 generally 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 harmonized the classification criteria – from several pre-GHS 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.[9]

[9] 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	All	
Respiratory Sensitization	Cutoffs with CA options	All	
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
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	

Hazard Class	Classification Approach	Bridging Principles	Comments
Aspiration Toxicity	Additivity in conjunction with viscosity data	Dilution, Batching, Concentration of highly toxic mixtures, Interpolation within one toxicity category, substantially similar mixtures	
Hazardous to the Aquatic Environment	Additivity Formula; 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 SDS. A number of annexes provide further information on hazard communication. For example, Annex 1 of the Purple Book provides classification and labelling summary tables 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.[10]

[10] Comprehensibility testing also took place as part of a series of UNITAR/ILO pilot projects; see http://www2.unitar.org/cwm/ghs_partnership/CT.htm.

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 **Error! Reference source not found.** for a n illustration of the GHS label elements.

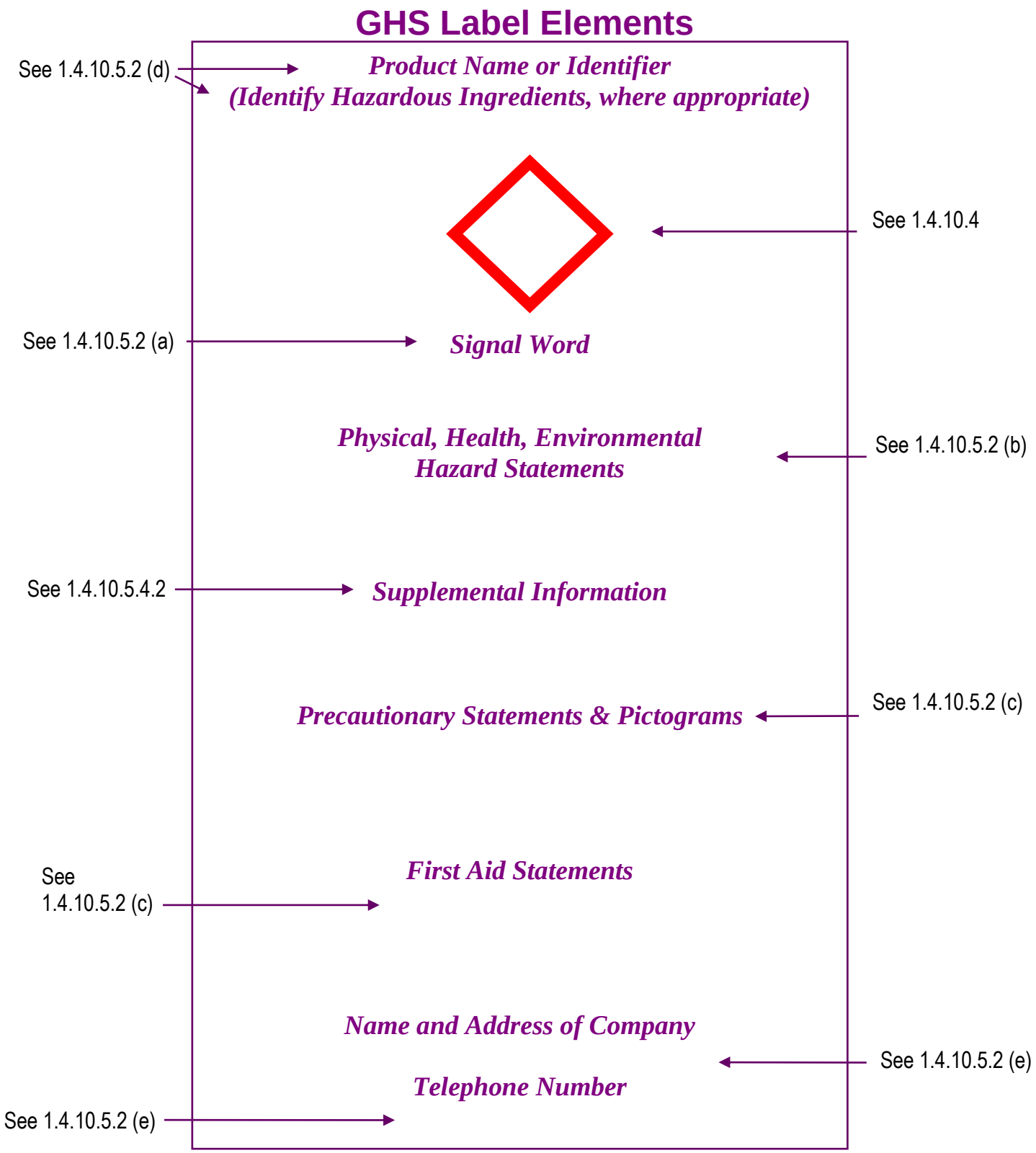
The standardized label elements included in the GHS are:

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



The Section numbers refer to the sections in the GHS

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. Figure 4.4 illustrates the assignment of standardized GHS label elements for the acute oral toxicity categories.

Figure 4.2

GHS Pictograms and Symbol Name		
		
Flame Over Circle	Flame	Exploding Bomb
		
Skull And Crossbones	Corrosion	Gas Cylinder
		
Health Hazard	Environment	Exclamation Mark

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 https://unece.org/transport/dangerous-goods/un-model-regulations-rev-22)

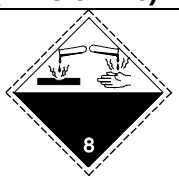
Examples of Transport "Pictograms"		
 • Flammable Gas • Flammable Aerosol	 • Flammable solids • Self-Reactive substances and mixtures	 • Pyrophoric solids • Phyrophoric liquids • Self-heating Substances and mixtures
 • Substances and mixtures, which in contact with water, emit flammable gases	 • Oxidizing 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 assignment of standardized GHS label elements for the acute oral toxicity categories

ACUTE ORAL TOXICITY – Annex 1					
	Category 1	Category 2	Category 3	Category 4	Category 5
LD_{50}	ATE ≤ 5 mg/kg	5< ATE ≤ 50 mg/kg	50 < ATE ≤ 300 mg/kg	300 < ATE ≤ 2000 mg/kg	2000 < ATE ≤ 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 are linked to specific GHS hazard class and category combinations. 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 apply, 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.

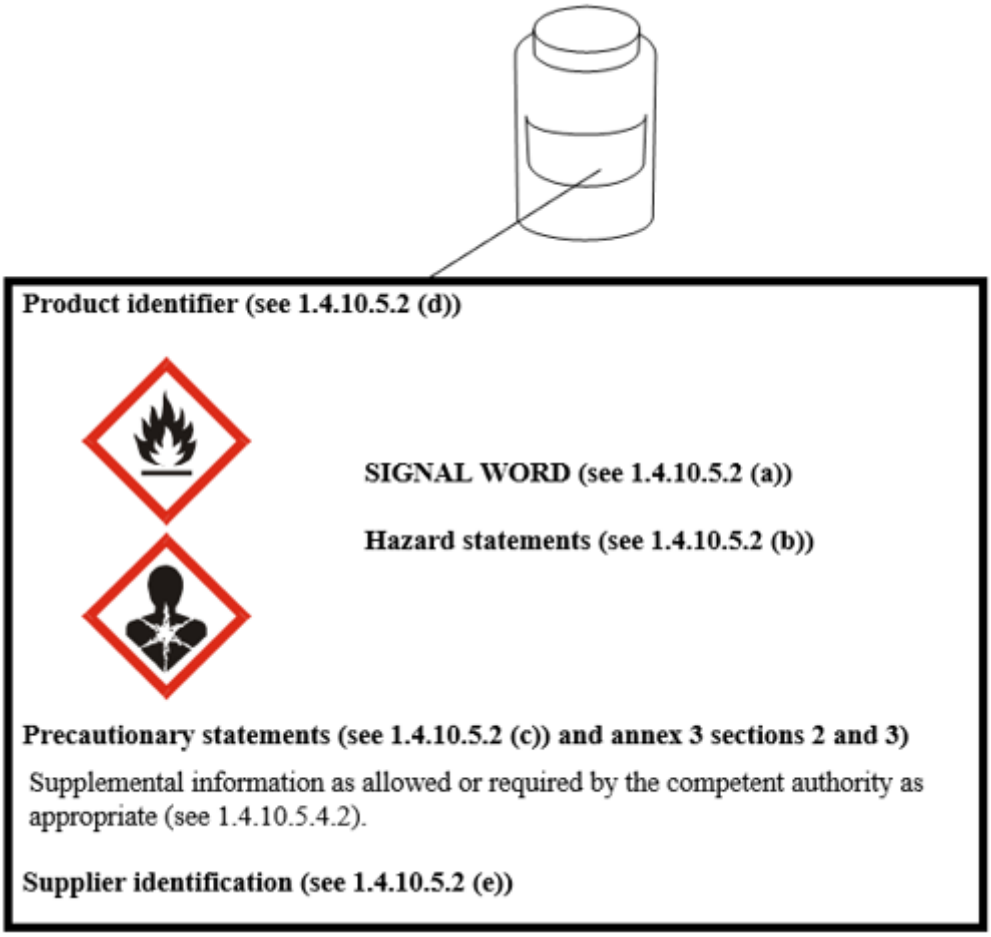
If the signal word **'Danger'** applies, the signal word **'Warning'** should not appear. All assigned hazard statements should appear on the label. The Competent Authority may choose to specify the order in which they appear.

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 on inner packaging

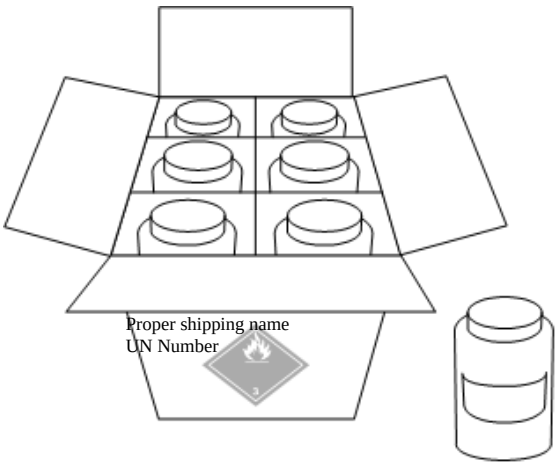
Figure 4.5 Example of GHS Label on inner packaging (e.g. a plastic bottle inside a box)



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 () are different in appearance to the GHS pictograms (). 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.

Several arrangements for GHS labels are also provided in Annex 7 of the Purple Book[11]. 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.

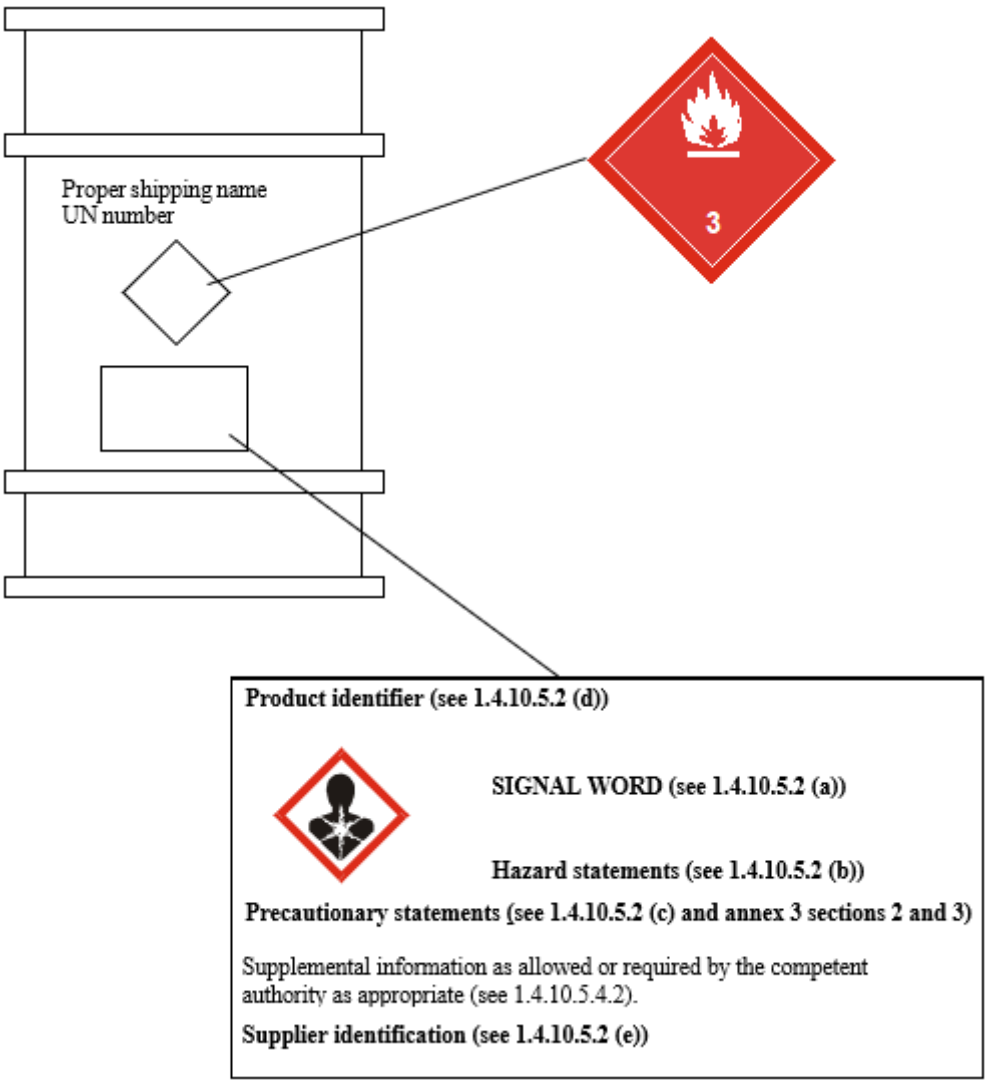
Figure 4.6 Combination Packaging (Outer box with inner bottles)



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.

[11] Figures 4.5, 4.6 and 4.7 are expected to come from the GHS 11th revision, as per proceedings of the 44th session of the Sub-committee of experts on the GHS

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



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?

The 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 4.8).* The SDS should provide a clear description of the data used to identify the hazards. Figure 4.8, Figure 4, Chapter 1.5 and Table 1.5.2 of and the GHS Purple Book provide the minimum information that is required in each section of the SDS. The GHS Purple Book contains guidance on developing a GHS SDS *(Annex 4).*

Figure 4.8 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 <u>may</u> 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**	Physical state; Colour; Odour; Melting point/freezing point; Boiling point or initial boiling point and boiling range; Flammability; Lower and upper explosion limit/flammability limit; Flash point; Auto-ignition temperature; Decomposition temperature; pH; Kinematic viscosity; Solubility; Partition coefficient: n-octanol/water (log value); Vapour pressure; Density and/or relative density; Relative vapour density; Particle characteristic.
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. (May refer to any national or regional regulations).
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 IMO instruments; (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 When should SDSs and labels be updated, reviewed or revised?

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 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.

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

CBI will not be harmonized under the GHS. National authorities should establish appropriate mechanisms for CBI protection. The relevant 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.

4.11 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, 2023 Tenth Revised Edition, can be accessed online at:
https://unece.org/transport/dangerous-goods/ghs-rev10-2023

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

https://unitar.org/sustainable-development-goals/planet/our-portfolio/globally-harmonized-system-classification-and-labelling-chemicals

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