

Review Article

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Understanding the globally harmonized system of classification and Labeling of Chemicals-The Purple Book

Subba Rao Bayya*

Associate Professor, RBVRR Women's College of Pharmacy, Barkatpura, Hyderabad, Telangana, India.

Abstract

Global Harmonized System (GHS), relating to hazard chemicals, is a process of making a regulation among countries uniform to the extent possible so as to benefit an industry to export its products to several countries with one communication system. On one side, the system is helpful to develop communication as labeling and material safety data sheets, and on the other side is helpful for the personnel in the chemical and pharmaceutical industry in using chemicals carefully, especially hazardous. Such international guidelines are believed to be the most reliable information so that the end user of hazard chemicals is confident enough in handling and using. The current article is a brief understanding of the guideline, an attempt, how the hazard chemicals are being classified, communicated as labels, symbols and material safety data sheets.

Keywords: Global Harmonized System (GHS), Chemicals, Communication, Labeling, Symbols, MSDS, Hazard.

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*Corresponding author Tel.: +91-9440763781; E-mail address: drbayyasubbarao@yahoo.com (S.R. Bayya).

1. Introduction

Earlier, country's legislations are territorial but with time, due to international agreements, there is a need that local legislation should match to the extent possible with the international legislation. Such international legislations are developed by international authority upon consensus among stake holders, national governments, industry, workers, researchers, scientists etc. Development of an international legislation is usually initiated by the industry which in turn requests the concerned local authority indicating that exporting a product is becoming cumbersome due to classification, labeling and material safety data sheets (MSDS) varies with country to country. The local authority is expected to notify the international authority and the task is taken up to develop a harmonized guideline.

Aim and Objective of GHS

Chemicals are one of the crucial commodities in business both by value and volume. Such chemicals are used either directly or indirectly as food, health or in life style and are either transported, produced, handled at work place, used in agriculture, used in trade or used as final consumer products. In order to safe guard health of personnel (or personal) and environment the guideline (1, 2) is so established by giving information in developing uniform, reliable information regarding the chemicals for careful handling, thus preventing from health and environmental issues.

Even though the guideline is not a regulation or standard, it is expected to establish hazard classification, communication and how to apply the system in a country. Hence, the guideline is not an obligatory but insists the local authority to implement without direct using of the text.

Thus the guideline is expected to develop a sound management system among workers, consumers, emergency responders and public in handling and usage of chemicals.

When and How GHS Developed?

In order to avoid differences among the national, regional and international, and wide disparity in available data among countries, United Nations had initiated to bring out a guideline as 'The Purple Book', which mentions the road map in developing classification, communications (as labeling, symbols and material safety data sheets) for the management of chemicals.

It was in 1992, United Nations Conference on Environment and Development (UNCED), often called 'The Earth Summit' as one of six programme areas; GHS was endorsed by General Assembly.

It was the International Labour Organisation (ILO) that suggested using four major existing systems to develop a harmonized system and use globally. The four suggested systems are found to be US Transport Recommendations, US Requirements for Work place, Consumer and Pesticides, EU Dangerous Substance and Preparations Directive, Canadian Requirements for Workplace, Consumers and Pesticide.

Creation of CGHCCS, Administrative Hierarchy and Work pattern of the Authority Under the Inter-Organization Program for the Sound Management of Chemicals (IOMC), a Coordinating Group for the Harmonization of Chemical Classification Systems (CG/HCCS) was established. To develop the guideline as various building blocks (classification and communication) for various end points, Figure 1 illustrates, the tasks were assigned to various organizations expertise in the field in association with the Working Groups (WG). However, in 1999, a new subcommittee of experts was created. The role of the subcommittee is as a custodian, managing and giving directions, maintain system up-to-date, promote and encourage feedback, make system for worldwide use, develop a guidance document and prepare work programs and submit recommendations to UNCETDG/GHS.

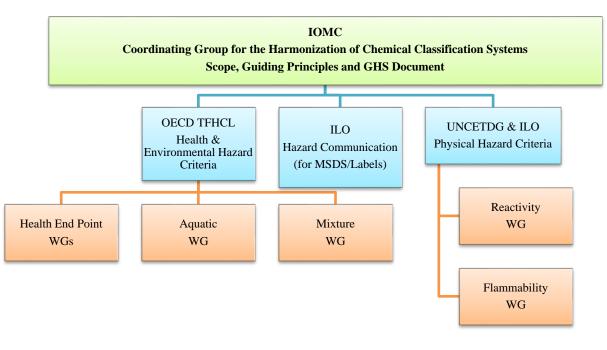


Figure 1. Administrative Hierarchy of GHS (1)

2. Implementation and Benefits of GHS

Implementation of the guideline within a country does not have either a time frame or obligation. However, countries need different time frames and phase wise transition from national to GHS. Several international bodies such as WSSD, IFCS suggested being fully operational by 2008 and APEC has suggested its economies to implement voluntarily by 2006.

Implementation of GHS ensures governments, employee, employer and the public with adequate, reliable, practical and comprehensive information on the hazards of chemicals; helps in preventive and protective precautions; provides maximum value to the adopted regulatory system; enhances protection, recognized regulations, facilitate international trade, reduces the need of testing. The system provides benefits to Government in terms of fewer chemical accidents, incidents, lower health care costs, improved protection of workers and public, avoid duplications, reduction in cost of enforcement; to companies in terms of safer work environment, improved relations, increase in efficiency, reduced costs, maximizing expert resources and minimizing labour /costs, expanding training programs on health and safety, reduced costs due to fewer accidents and illnesses, improved corporate image and credibility; to workers and public in terms of improved safety at work places with reliable information, greater awareness on hazards for safer use at work places and at home.

How GHS has to be applied?

GHS implementation is represented by a four level pyramid, Figure 2. At the base level is the GHS classification, moving top toward the hazard communication of SDS and labels, to risk management to the safe use of chemicals. This implies, every company should establish collecting data, communicating, manage and exchange information and use chemicals safely.

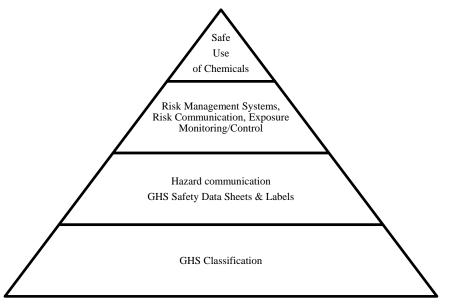


Figure 2. GHS Pyramid (3)

Criteria of Selection of Chemicals to implement or develop GHS

GHS covers all hazardous chemicals and there is no exception for a particular. GHS means a substance, product, mixture, preparation etc. as a chemical. GHS goal is to identify the intrinsic hazards (naturally existing features) of a chemical and convey to users. GHS is not intended to harmonize risk assessment procedures/risk management decisions (risk = hazard * exposure) and does not maintain international classification authority or list. GHS suggests working in conjunction with already existing lists and developing a classification/ communication, for instance, chemicals on cancer hazard. GHS classification/communication system varies with product category, stage in chemical's life cycle (Figure 3) and will not cover chemicals that are at the point of consumption for pharmaceuticals, food additives, cosmetics and pesticide residues in food. GHS covers chemicals at work place and transport. In pharmaceutical, veterinary and food use of chemicals, GHS communication system has no role but generally addressed in packaging inserts especially for the former two uses. It is necessary to understand that GHS plays role in the part of the national regulations system.

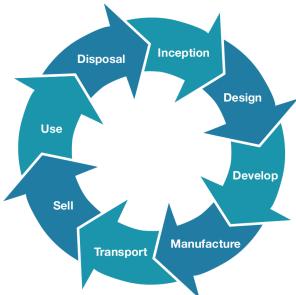


Figure 3. Product Life Cycle (1)

Development of GHS Building blocks

For various end points, taking into consideration the physical, health and environmental hazards and depending on the stage of lifecycle of the product (i.e., consumer, workplace, transport, pesticides etc.,) and depending on the sector of the industry, various hazard classessubclasses, categories-subcategories are developed, Figure 4, which finally leads to development of communication system for a particular chemical in question.

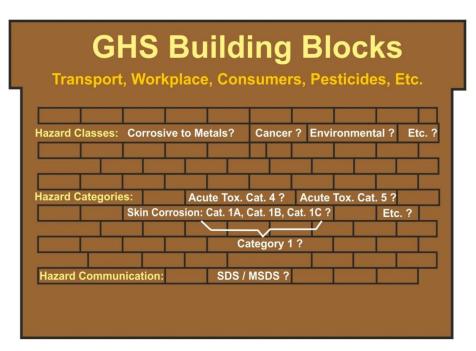


Figure 4. GHS Building Blocks (1)

3. Hazard Classification

For a chemical in question, taking into consideration for the development of GHS for the chemical depends on intrinsic hazardous properties taking into consideration the available literature, conducting tests, practical experience and after ascertaining a decision; the chemical is agreed for hazardous classification. For hazards, GHS criteria are semi-quantitative or qualitative. The hazards are classified into Physical, Health and Environmental hazards.

Physical Hazards

For developing a physical hazard, the guideline defines the three physical states for uniformity

- i. **Gas**: Is a substance or mixture which at 50°C, has a vapor pressure greater than 300 kPa; or is completely gaseous at 20 °C and a standard pressure of 101.3 kPa.
- ii. **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.
- iii. **Solid**: Is a substance or mixture that does not meet the definitions of a liquid or a gas.

GHS guidance classifies various physical hazards with appropriate definitions into explosives, flammable gases, flammable aerosols, oxidizing gases, gases under pressure, flammable liquids, flammable solids, selfreactive substances, pyrophoric liquids, pyrophoric solids, self-heating substances, substances which, in contact with water, emit flammable gases, oxidizing liquids, oxidizing solids, organic peroxides, corrosive to metals.

Explosive are sub-classified into six divisions 1.1 to 1.6 ranging from mass explosion hazard to extremely insensitive articles with no mass explosion hazard respectively.

Flammable aerosols are classified into category 1, category 2 based on components if they fall under GHS criteria for flammable gas, flammable liquid, flammable solid. Flammable aerosols are classified based on concentration of flammable components, heat of combustion, foam test, ignition distance test, enclosed space test. As a whole aerosols are classified into nonflammable (flammable component: $\leq 1\%$ and heat of combustion: < 20 kJ/g) and extremely flammable (flammable component: $\geq 85\%$ and heat of combustion: $\geq \text{kJ/g}$).

With respect to gases under pressure, they are classified into 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).

In case of flammable liquids, they are sub-categorized based on flash point. Category 1 (flash point < 23 °C and initial boiling point \leq 35 °C; Category 2 (flash point < 23 °C and initial boiling point > 35 °C), Category 3 (flash point \geq 23 °C and \leq 60 °C) and Category 4 (flash point > 60 °C and \leq 93 °C).

In case of flammable solids, based on the tests burning time, burning rate and behavior of fire in a wetted zone of the test sample, they are sub-categorized into two i.e., Category 1 (Metal Powders: burning time ≤ 5 minutes) and Category 2 (Metal Powders: burning time > 5 and \leq 10 minutes).

In case of self-reactive substances, the substance are sub-classified into Type A to G representing from 'Can detonate or deflagrate rapidly, as packaged' to '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 (selfaccelerating 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 $^{\circ}\!\mathrm{C}$ is used for desensitization.

In case of substance which on contact with water emit flammable gases and depending on the flammable gases in dangerous quantities, the substances are categorized into three categories on the basis of test results which measure gas evolution and speed of evolution i.e., Category 1 (\geq 10 L/kg/1 minute), Category 2 (\geq 20 L/kg/1 hour + < 10 L/kg/1 min), Category 3 (\geq 1 L/kg/1 hour + < 20 L/kg/1 hour) and Not Classified (< 1 L/kg/1 hour).

Similar to self-reactive substances, organic peroxides are organic liquid or solid which contains bivalent -0-0structure which are liable to explosive decomposition, burn rapidly, be sensitive to impact or friction, react dangerously with other substances and such substances are sub-categorized into seven types A-G.

In case of substances corrosive to metal, the guideline is concerned with respect to protection of metal **Table 1** Acute Toxicity – Category wise (1) equipment or installations in case of leakage and not material compatibility between the container/tank and the product.

Health Hazards

With respect to health hazards, the GHS guidance document categories the terminology limiting to acute toxicity, skin corrosion/irritation, serious eye damage/ irritation, respiratory or skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicology, target organ systemic toxicity (TOST)-single and repeated exposures, aspiration toxicity.

In case of acute toxicity, various chemicals are categorized based upon LD_{50} (oral, dermal), LC_{50} (inhalation). The LC_{50} values are based on four hour tests in animals. The GHS guidance provides converting one hour inhalation test results to a four hour equivalent. Based on the dose required for effect of LD_{50} (or LC_{50}), acute toxicity is categorized into five categories, Table 1.

Acute Toxicity	Category 1	Category 2	Category 3	Category 4	Category 5
Oral (mg/kg)	≤ 5	> 5 - ≤ 50	$> 50 - \le 300$	$> 300 - \le 2000$	Criteria
Dermal (mg/kg)	≤ 50	$>$ 50 - \leq 200	$> 200 - \le 1000$	> 1000 - ≤ 2000	- Anticipated oral LD ₅₀ between 2000 and 5000 mg/kg;
Gases (ppm)	≤ 100	$> 100 - \le 500$	> 500 - ≤ 2500	> 2500 - ≤ 5000	- Indication of significant effect in humans;
Vapors (mg/l)	≤ 0.5	$> 0.5 - \le 2.0$	> 2.0 - ≤ 10	> 10 - ≤ 20	 Any mortal at class 4; Significant clinical signs at class 4;
Dusts & Mists (mg/l)	≤ 0.05	> 0.05 - ≤ 0.5	> 0.5 - ≤ 1.0	> 1.0 - ≤ 5	 Indications from other studies; If assignment to a more hazardous class is not warranted

With respect to skin corrosion and irritation, they are demarcated by irreversible and reversible cure upon exposure to the hazard and are categorized into 1 to 3, Table 2.

Table 2 Skin Corrosion, Irritation – Category wise (1)

Skin	Corrosion Category 1	l	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	Reversible adverse effects in dermal tissue. Draize
Subcategory 1 A, Exposure < 3 min. Observation < 1 hr	Subcategory 1B, Exposure < 1 hr. Observation < 14 days	Subcategory 1C, Exposure < 4 hr. Observation < 14 days	tissue. Draize score: ≥ 2.3 to < 4.0 or persistent inflammation	score: ≥ 1.5 to < 2.3

In case of eye effects, substances are categorized into two categories i.e., Category 1 (serious eye damage) and category 2 (Eye irritation). The two categories are illustrated, Table 3, based upon irreversibility and reversibility respectively.

	Table 3	Eye effects	- Category wise	(1)
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Category 1 Serious eye damage	Category 2 Eye irritation		
Irreversible damage 21 days after exposure.	Reversible adverse effects on cornea,		
Draize score: corneal opacity \geq 3,	Iris, conjunctiva.		
iritis > 1.5	Draize score: corneal opacity ≥ 1 , iritis \geq	score: corneal opacity ≥ 1 , iritis ≥ 1 ,	
	redness ≥ 2 , chemosis ≥ 2		
	Irritant	Mild irritant	
	Subcategory 2 A	Subcategory 2B	
	Reversible in 21 days.	Reversible in 7 days	

With respect to sensitization, the chemicals are categorized into respiratory sensitizer (induces

hypersensitivity of the airways), skin sensitizer (induce allergic response following skin contact).

Under the germ cell mutagenicity, the chemicals are categorized into Category 1 (known/presumed) and **Table 4** Germ Cell Mutagenicity - Category wise (1)

Category 2 (suspected/possible), Table 4.

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

Under carcinogenicity, the chemicals are categorized into two categories, Table 5.

 Table 5 Carcinogenicity-Category wise (1)

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

With respect to reproductive toxicity, based on the chemicals into three subcategories, Table 6. intrinsic properties of chemicals, GHS defines the

 Table 6 Reproductive Toxicity – Category wise (1)

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

With respect GHS guideline, the chemicals based upon their intrinsic properties, based upon their organ impair function, both reversible or irreversible, immediate and/or delayed are included in the nonlethal target organ/systemic toxicity class (TOST). Narcotic effects and respiratory tract irritation are considered to be target **Table 7** TOST-Single Exposure (1)

the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system. With respect to organ systemic effects following a single exposure. Such chemicals are categorized into three subcategories, Table7. With respect to repeated dose effects, effects seen in a standard 90 day toxicity study conducted in rats is used for categorization, Table 8.

property, they are categorized into two, Table 9.

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

Table 8 TOST-Repeated Exposure (1)

Category 1	Category 2
Significant toxicity in humans	Presumed to be harmful to human health
- Reliable, good quality human case studies or	- Animal studies with significant toxic effects relevant to
epidemiological studies	humans at generally moderate exposure
Presumed significant toxicity in humans	- Human evidence in exceptional cases
- Animal studies with significant and/or sever toxic	
effects relevant to humans at generally low exposure	
In case of aspiration hazard, first of all aspiration	is chemical pneumonia, degree of pulmonary injury or death
defined as the entry of a liquid or solid directly throug	th following aspiration, based on the chemical intrinsic

Table 9 Aspiration Hazard – Category wise (1)

Category 1 Known (regarded) human	Category 2 Presumed human
- human evidence	- based on animal studies
	- surface tension, water solubility, boiling point
20.5 mm ² /s at 40°C.	- Kinematic viscosity $\leq 14 \text{ mm}^2/\text{s}$ at 40°C.and not Category 1.

Environmental Hazards

With respect to packaged goods supply and use, GHS considers multi-modal transport especially bulk land and marine systems under the international convention for the prevention of pollution from ships.

Hazardous to the Aquatic Environment

GHS classifies under this category the chemicals, Table 10, as hazardous to aquatic environment. A chemical which possess with an intrinsic property that upon a short term exposure causes harm to aquatic organism to be considered under the sub-category of acute aquatic toxicity. Data obtained in the form of lethal concentration-LC₅₀ (fish), effective concentration-EC₅₀ (crustacean) or ErC₅₀ (i.e., EC₅₀ in terms of reduction in **Table 10** Acute and Chronic Aquatic Toxicity (1) growth rate for algae and other aquatic plants) is used to sub-categorize.

When a chemical substance, upon exposure to aquatic organism, possess with adverse effects which in turn effects the life cycle of the organism, it is sub-categorized under chronic aquatic toxicity. Data obtained in the form of lethal concentration- LC_{50} (fish), effective concentration $-EC_{50}$ (crustacean), ErC_{50} (i.e., EC_{50} in terms of reduction in growth rate for algae and other aquatic plants) and degradation/bioaccumulation are used to sub-categorize. Where such data is not available, the guideline indicates to sub-categorize based on Quantitative Structure Activity Relationships (QSAR) and log K_{ow} - octanol/water partition coefficient (a surrogate for measured fish Bioconcentration Factor -BCF).

Acute Category IAcute CategoryAcute toxicity $\leq 1.00 \text{ mg/l}$ Acute toxicity > 1.00 but				cute Category III icity > 10.0 but < 100 mg/l
Chronic Category I	Chronic Category II	Chronic Cat	egory III	Chronic Category IV
Acute toxicity ≤ 1.00	Acute toxicity	Acute toxicity	y	Acute toxicity $> 100.0 \text{ mg/l}$
mg/l	$> 1.00 \text{ but} \le 10.0 \text{ mg/l}$	> 10.0 but ≤ 100.0 mg/l		and lack of rapid degradability
and lack of rapid	and lack of rapid			and log $K_{ow} \ge 4$ unless BCF <
degradability and log	degradability and log K_{ow} degradability and log $K_{ow} \ge$		500 and unless chronic	
$K_{ow} \ge 4$ unless BCF <	\geq 4 unless BCF < 500 and	4 unless BCF	< 500 and	toxicity > 1 mg/l
500	unless chronic toxicity > 1	ss chronic toxicity > 1 unless chronic toxicity > 1		
	mg/l	mg/l		

In general, it is necessary to emphasize that GHS indicates to avoid/minimize animal experiments and use bridging principles especially for classifying untested mixtures. The bridging principles includes for categorizing dilutions, batching, concentration of highly toxic mixtures, interpolation within one toxic category, substantially similar mixtures and aerosols. This means that based on the features of the components whose features were already known, depend upon those in categorizing the chemical substance.

Hazardous to the Ozone layer

GHS categorizes chemicals into category 1, based upon ozone depletion potential (ODP). ODP for a halocarbon is that quantity that depletes ozone layer in comparison with a standard CFC-11 (Chlorofluorocarbons). Officially, ODP is defined as the ratio of integrated perturbations to total ozone, for a differential mass emission of a particular compound relative to an equal emission of CFC-11.

Table 11 Ozone depletion (2)

Category 1Any of the controlled substances listed in
Annexes to the Montreal Protocol; or any
mixture containing at least one ingredient
listed in Annexes to the Montreal
Protocol, at a concentration ≥ 0.1 %

4. Hazard Communications

In general, a communication can be verbal or nonverbal. Such communications relating to chemicals being handled during product life cycle are emphasized and GHS emphasizes especially relating to development guideline of labels, symbols and material data safety sheets.

Labels with Symbols, Signal words and others

GHS emphasizes on labels firstly, usage of standard designated symbols (hazard pictograms) for various hazard classes such as physical, health and environmental hazard, secondly usage of either of the signal words i.e., "Danger" or "Warning" but not both and thirdly usage of hazard statements as standard phrases. GHS, in its guidance document has emphasized the usage of borders, background patterns or colors to convey specific information. For instance, for other sectors, pictograms will have a black symbol on a white background with a red diamond frame.

GHS also emphasizes to avoid confusion to the end user by avoiding multiple symbols/words where ever necessary. For instance, only one signal word corresponding to the class of the most severe hazard should be used on a label.



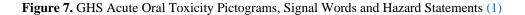
Figure 5. GHS Pictograms (1)

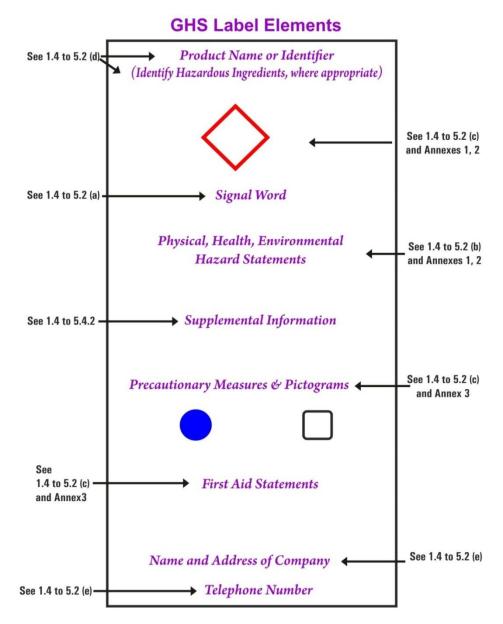
	Ex	amples of Transport "Pictog	rams"
:	Flammable Gas Flammable Aerosol	 Flammable solids Self-Reactive substances and mixtures 	 Pyrophoric solids Phyrophoric liquids Self-heating Substances and mixtures
•	Substances and mixtures, which in contact with water, emit flammable gases	 Oxidizing gases Oxidizing 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 6. GHS Transport Pictograms (1)











As a principle of precedence, where a skull and crossbones appear, symbol with exclamation should not appear; if a corrosion symbol applies, exclamation symbol should not appear where used for a chemical that possess with skin or eye irritation; if a 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.

Additionally, information relating to precautions, first-aid if any hazard occurs has to be mentioned on the labels. A label should have mention of manufacturer, contact details to seek information when ever needed. Figure 5-8, illustrates the GHS guidance symbols, label format.

Material Safety Data Sheets (MSDS)

Commonly called as SDS or MSDS, establishing it with GHS guidelines and principles is very much essential for handling of chemicals (hazard) at various stages of product life cycle. MSDS is more informative and such information is now a day required since research in pharmaceuticals and chemicals industry witnesses every day first time use of a chemical, especially in basic research. The various aspects to be established as a MSDS document with respect to a chemical are identification of the substance or mixture and of the supplier, hazards identification, composition/information on ingredients, first aid measures, firefighting measures, accidental release measures, handling and storage, exposure controls/personal protection, physical and chemical properties, stability and reactivity, toxicological information. ecological information, disposal information, considerations, transport regulatory information, other information including information on preparation and revision of the SDS.

5 Conclusion

For personnel, researcher in a work place, there is a need of reliable information so that one can safeguard his/her health while handling chemicals. In case of basic and process research in pharmaceuticals, the researchers come across with several new chemicals, which even not being used earlier. The current guideline is helping industry to develop a standardized format of communication system so that it is reliable. The guideline

also indicates that at periodical intervals, the established communications to be updated if necessary.

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Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of this article.

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