

An Update: Revision 8 the Globally Harmonized System (GHS)

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AISE



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(Label from the Association for Soaps, Detergents and Maintenance Products (AISE) and from the Japan Soap and Detergent Association (JSDA)-The New Precaution Pictograms for keeping out of Reach of Children).

The Globally Harmonized System (GHS) stands for Classification and Labeling of Chemicals. This system defines and classifies the hazards of chemicals or the products containing chemicals, hazardous materials or substances based on the well known of the US Occupational Safety and Health Administration (OSHA)'s "Right-to-Know law or Standard", thereby, communicating health and safety information on Labels and Safety Data Sheets (SDSs) of chemicals and products in question in the global supply chains..

Hazard communication (HAZCOM) of the US OSHA is the basic concept of the GHS and is developed by the internationally known team of subject matter experts related to HAZCOM standard.

Main Elements in the GHS

The two important elements of GHS are:

1. Classification of the hazards of chemicals according to the GHS of the European Union (EU)'s Directives (67/548/EEC & 1999/45/EC with amendment. GHS provides guidance on classifying pure chemicals and mixtures according to its criteria or rules.
2. Communication of the hazards and precautionary information using **SDSs and Labels:**

The Labels - With the GHS, certain information will appear on the label. For example, the chemical identity may be required. Standardized hazard statements, signal words and symbols will appear on the label according to the classification of that chemical or mixture. Precautionary statements may also be required, if adopted by the country's

regulatory agencies with authorization at all levels of the governments and compliance requirements.

The Safety Data Sheets (SDS) - The GHS SDS has 16 sections in a set order, and minimum information is prescribed.

Europe

The GHS is a 'non-binding' system of hazard communication (HAZCOM), first adopted in Europe into the new European Union (EU) Classification, Labeling and Packaging (CLP) regulations (in force as of January 20, 2009). These regulations were used for new products and mixtures in December 2010 and 2015 respectively. A two-year transition period was given for existing products labeled and packaged according to the EU Directives 67/548/EEC and 1999/45/EC including amendments.

United States

In the United States, the final rule became effective on May 26, 2012 with amendment under the hazard communication standard (HAZCOM) that was finalized in 2012.

- December 1, 2013 - Train employees on the new label elements and SDS format.
- June 1, 2015 - Comply with all modified provisions of the final rule, except December 1, 2015 - Distributors may ship products labeled by manufacturers under the old system until December 1, 2015.
- June 1, 2016 - Update alternative workplace labeling and hazard communication program as necessary, and provide additional employee training for newly identified physical or health hazards.
- Transition Period - Comply with either 29 CFR 1910.1200, or the current standard, or both.

Canada

The Hazardous Products Regulations were published in Canada Gazette, Part II on February 11, 2015. Both the amended Hazardous Products Act and new regulations are currently in force. It means that suppliers may begin to use and follow the new requirements for **Labels and SDSs** for hazardous products sold, distributed, or imported into Canada. The Canadian WHMIS regulations were also required to be updated at the provincial, federal, and territorial occupational health and safety. A multi-year transition plan has been announced. From now until May 31, 2017 suppliers (manufacturers and importers) can use WHMIS 1988 or WHMIS 2015 to classify and communicate the hazards of their products (suppliers must use one system or the

other). Beginning June 1, 2017 to May 31, 2018, distributors and suppliers importing for their own use can continue to use WHMIS 1988 or WHMIS 2015.

The GHS in Different Countries

Currently many different countries have different systems for classification and labeling of chemical products. In addition, several different systems can exist even within the same country. This situation has been expensive for governments to regulate and enforce, costly for companies who have to comply with many different systems, and confusing for workers who need to understand the hazards of a chemical in order to work safely. Some of the known benefits of the GHS are: Promoting regulatory efficiency, facilitating trade, easing compliance, reducing costs, providing improved consistent hazard information, encouraging the safe transport, handling and use of chemicals, promoting better emergency response to chemical incidents, and reducing the need for animal testing.

Scope of GHS

GHS covers all hazardous chemicals, materials, and substances. Once approved and may be adopted to cover all hazardous chemicals, materials and substances in the workplace, transport, consumer products, pesticides and pharmaceuticals. The target audiences for GHS include workers, transport workers, emergency responders and consumers.

GHS hazard groups

There are three major hazard groups: (1) Physical hazards (2) Health hazards (3) Environmental hazards. Within each of these hazard groups there are classes and categories. Each of these parts is called a building block. Each country can determine which building blocks of the GHS it will use in their different sectors such as workplaces, transportation, and consumers. Once the building blocks are chosen, the corresponding GHS rules for classification and labels must be used.

Classes within the Health hazard group

Criteria for classifying chemicals have been developed for the following health hazard classes:

Acute toxicity, skin corrosion/irritation, serious eye damage/eye irritation, respiratory or skin sensitization, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity - single exposure, specific target organ toxicity, repeated exposure, and aspiration hazard.

Classes within the Physical hazard group

Criteria for classifying chemicals have been developed for the following physical hazard classes:

Explosives; Flammable gases; Aerosols; Oxidizing gases; Gases under pressure; Flammable liquids; Flammable solids; Self-reactive substances and mixtures; Pyrophoric liquids; Pyrophoric solids; Self-heating substances and mixtures; Substances and mixtures which, in contact with water, emit flammable gases; Oxidizing liquids; Oxidizing solids; Organic peroxides; Corrosive to metals.

Classes within the Environmental hazard group

Criteria for classifying chemicals have been developed for the following environmental hazard classes:

Hazardous to the aquatic environment (acute and chronic) and hazardous to the ozone layer.

The GHS Revision # 8 of 2019-The current Information on the GHS criteria for the different hazard classes

The most current information on GHS classification, labels and SDS as well as other criteria is available in the 8th revised edition of the GHS of Classification and labeling of Chemicals) from the United Nations Economic Commission for Europe (UNECE). The 8th revision of the GHS has been published in a printed form by the United Nations Economic Commission for Europe (UNECE) and was initially introduced in 2005, this revision of the GHS is now available at web page:

<https://www.foodpackagingforum.org/news/8th-revision-of-ghs-published>. The **GHS Rev.8 of 2019** includes, *inter alia*, new classification criteria, hazard communication elements, decision logics and guidance for chemicals under pressure; new provisions for the use of in vitro/ex vivo data and non-test methods to assess skin corrosion and skin irritation; miscellaneous amendments to clarify the classification criteria for Specific Target Organ Toxicity; revised and further rationalized precautionary statements and an editorial revision of Sections 2 and 3 of Annex 3; new examples of precautionary pictograms to convey the precautionary statement “Keep out reach of children”; a new example in Annex 7 addressing labeling of sets or kits; guidance on the identification of dust explosion hazards and the need for risk assessment, prevention, mitigation, and hazard communication. GHS is a dynamic system. The international GHS committee meets twice a year to work on developing potential new hazard classes as well as resolving specific issues, and updating the latest GHS publication.

Implementation of GHS

Countries and sectors such as consumer, environmental, workplace, transportation within a country will implement GHS at varying times depending on their local needed circumstances. Almost 72 countries have implanted this system with some variations as needed within the specific circumstances. Countries that have adopted or implemented and to find out more about the status of GHS implementation, please see the web page at: http://www.unece.org/trans/danger/publi/ghs/implementation_e.html. **Notification of substances in articles is important and the producers and importers have to notify to European Chemical Agency (ECHA) about the substances listed on the Candidate list which are present in their articles if the substance is present in their relevant articles above a concentration of 0.1% weight by weight.**

Major changes

A-Classification Criteria for Aerosols now under three categories based on

- Flammable properties
- Heat of combustion; and
- Test results from ignition distance test and other tests performed in accordance with UN TDG Manual of Tests and Criteria

B-New Chemicals under Pressure Hazard Category

- Defined as liquids or solids 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.
- New guidance for Skin Corrosion/Irritation classification using in vitro/ex vivo test data
- The use of new Precautionary Pictograms for "Keep out of Reach of Children"

The below examples are included in the Annex and come from the Association for Soaps, Detergents and Maintenance Products (AISE) and from the Japan Soap and Detergent Association (JSDA).



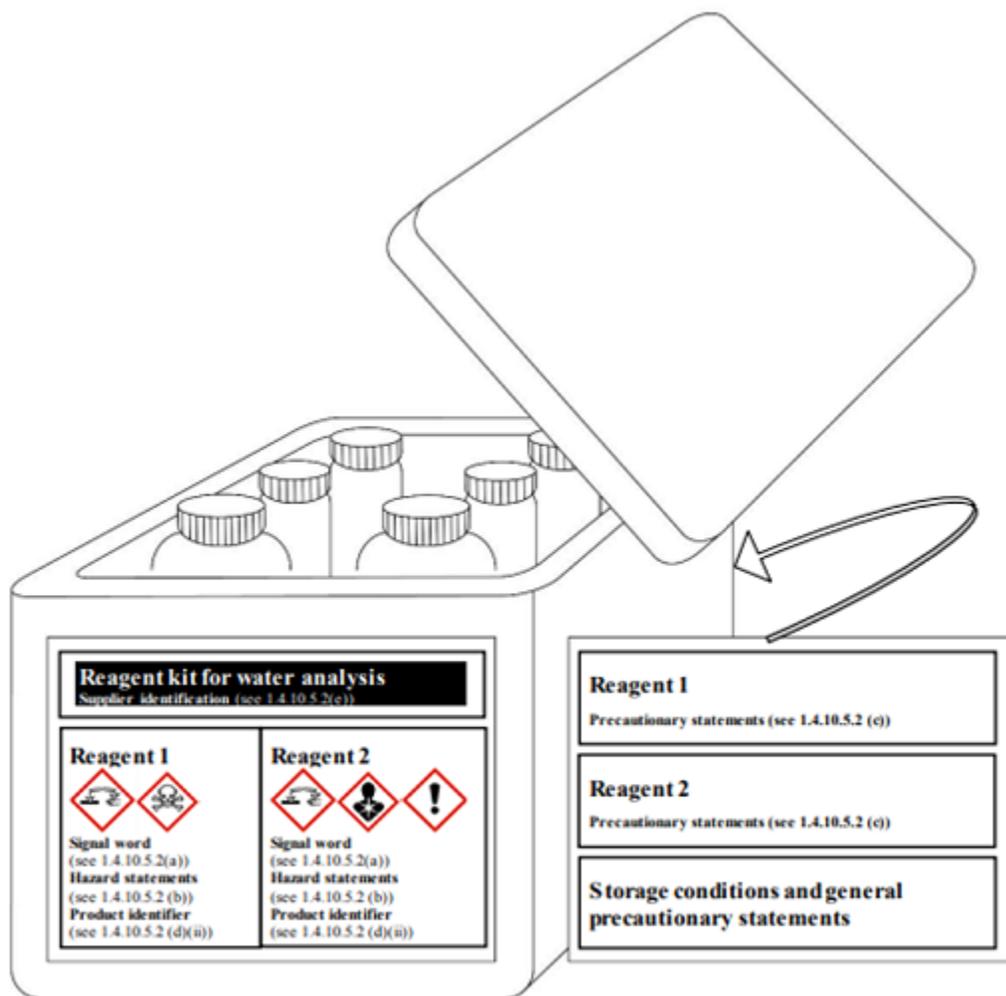
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New Labeling Example for Sets or Kits

A new labeling example for sets or kits will be added. Generally a set or kit contains two or more small removable inner containers. Each inner container contains different products which can be hazardous or not hazardous substances or mixtures. This new example illustrates ways to label sets or kits where the manufacturer/supplier or competent authority has determined there is insufficient space to place together on each inner container within the kit.



For more information, visit the web page at:

<http://www.unece.org/fileadmin/DAM/trans/doc/2018/dgac10c4/ST-SG-AC.10-C.4-2018-10e.pdf>.

- New Annex 11 on Dust Explosion - providing guidance on this particular hazard and ways to mitigate and communicate.
- Notification of substances in articles

- Producers and importers have to notify to ECHA the substances listed on the Candidate list which are present in their articles, if both the following conditions are met:
- The substance is present in their relevant articles above a concentration of 0.1% weight by weight.
- The substance is present in these relevant articles in quantities totaling over one tone per year.
- Companies have to notify no later than six months after the inclusion of the substance in the Candidate List.
- Exemptions
- There are two cases when a notification will not need to be required.
- The producer or importer of an article can exclude the exposure of humans and the environment to the substance during normal or reasonably foreseeable conditions of use of the article, including its disposal. In these cases, the producers and importers will give appropriate instructions to the recipient of the article.
- The substance has already been registered by a manufacturer or importer in the EU for that use.
- Legal reference of regulatory affairs.

Substances of Very High Concern (SVHCs) in articles

EU's ECHA has systems for substance tracking and the ECHA database for substances of very high concern (SVHCs) in articles.

ECHA still working on several steps to be taken before going through the implementation of submitting notifications to the agency, and the strong role that member states have to play in this respect. There is also need look at the involvement of national authorities and how they will interpret this legal text, which they will need to translate into their national law, as well as how it could be process in harmonizing across the EU.

References:

- Introduction to Information on Candidate List substances in articles, web page at: <https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles>
- Candidate List of substances of very high concern for Authorization, web page at: <https://echa.europa.eu/candidate-list-table>

- GHS implementation, webpage at:
https://www.unece.org/trans/danger/publi/ghs/implementation_e.html.
- Introduction to Information on Candidate List substances in articles, web page at:
<https://echa.europa.eu/information-on-chemicals/candidate-list-substances-in-articles>
- Guidance on requirements for substances in articles, web page at:
https://echa.europa.eu/documents/10162/23036412/articles_en.pdf/cc2e3f93-8391-4944-88e4-efed5fb5112c
- Guidance on requirements for substances in articles, web page at:
https://echa.europa.eu/documents/10162/23036412/nutshell_guidance_articles2_en.pdf/1e13dcce-b46b-43cb-904e-6c4675613e9d.
- The 8th Edition revision of GHS, web page at:
<https://www.foodpackagingforum.org/news/8th-revision-of-ghs-published>.

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August 15, 2019