
**COMMITTEE OF EXPERTS ON THE TRANSPORT OF
DANGEROUS GOODS AND ON THE GLOBALLY
HARMONIZED SYSTEM OF CLASSIFICATION
AND LABELLING OF CHEMICALS**

Sub-Committee of Experts on the Globally
Harmonized System of Classification
and Labelling of Chemicals

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IMPLEMENTATION OF THE GHS

Reports from Governments or organizations

Results of a European Union (EU)/United States of America (USA) project
assessing two chemicals according to principles of the GHS

Transmitted by the experts from the United States of America and Germany

Background

A pilot project between occupational safety and health authorities in the EU and USA was conducted in 2005. The pilot was recommended at a 2003 joint conference on occupational safety and health where implementation of the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) was discussed. The objective of this pilot project was to better understand the application of the GHS. Two pilot chemicals were selected—methyl tert-butyl ether (MTBE) and glutaraldehyde. The EU took the lead on gathering information needed for the pilot on MTBE, and the USA on glutaraldehyde. Stakeholder representatives were also included in the work. The countries exchanged information regarding the key studies available to assess the hazards of these chemicals; classified them according to GHS criteria; prepared safety data sheets (SDS) according to GHS guidance; and examined possible control banding approaches. The results were then reviewed to determine whether there were suggestions or proposals that could be made to improve implementation of the GHS. Germany and the USA would like to describe the pilot in more detail, and share the results with members of the Subcommittee. The Subcommittee may wish to consider whether extension of this pilot to all members might be useful to help further identify what guidance or assistance will be needed to ensure consistent application of the GHS to chemicals around the world.

Project report

1. Data collection and exchange on the two chemicals, identification of key studies

The lead country for each chemical identified existing information that was available to complete a hazard assessment for purposes of classification and labeling and preparation of a safety data sheet. This information was exchanged with the other country. The key studies for discussion of the hazards were identified by the lead country to facilitate the process.

2. Preparation of proposals for GHS classification, labels and safety data sheets

Each country evaluated the data on both chemicals, and proposed a GHS classification and label based on their evaluation. For glutaraldehyde, classifications and labels were prepared for the substance and in addition for the generally marketed mixture (i.e. 2%). The classification proposals were exchanged and discussed. Safety data sheets were then prepared according to GHS guidance.

3. Control banding

While application of the GHS criteria was the primary issue of concern, using this information to determine the appropriate workplace controls is also a concern. Therefore, the EU and the USA expanded the pilot to examine possible control banding solutions to control exposures to the chemicals involved.

There were also discussions regarding the possibility of considering inclusion of control banding recommendations on safety data sheets.

4. Project results and recommendations

The pilot project exploring the application of GHS classification criteria, label and safety data sheet guidance, and control banding principles for selected chemicals proved to be effective for identifying potential differences in interpretation. The exercise helped to demonstrate that multiple factors can impact the outcome of hazard classifications, particularly the availability of complete and accessible data for all evaluators. Germany and the USA believe the results of this exercise clearly indicate the need for development of appropriate guidance and tools to ensure consistent results with the application of the GHS, especially for use in Small to Medium Enterprises (SMEs).

First, it may be useful to document the classification and labelling proposal for each chemical. It may help to develop a structured, standardized template which could be made available to everybody applying the GHS (e.g. on the UN GHS homepage).

Secondly, preparation of the safety data sheet proved to be challenging. A similar approach may facilitate this as well, i.e., the availability of a structured, standardized template would be very helpful to develop commonly accepted safety data sheets. This too could be made available on the UN web page to assist in assuring that safety data sheets are developed in a consistent manner around the world.

Given identical data sets, the independent classification of single chemicals was found to result in general agreement. While there were some differences initially, these were generally resolved following discussions between the experts from each country. There were issues regarding the availability of data in some situations where the studies were considered to be proprietary. This is an issue that will impact consistent application of the GHS.

While the pilot was initially designed to address single substances, the use of glutaraldehyde in solution extended the pilot to some consideration of mixtures. It was in this area that there were potentially significant differences in the approaches to classification and labeling. The GHS offers two approaches to evaluate mixtures: if a substance is diluted with a substance that has an equivalent or lower toxicity classification than the least toxic original ingredient, and which is not expected to affect the toxicity of other ingredients, then the new mixture may be classified as equivalent to the original mixture. On the other hand, GHS allows as well that if a mixture is diluted with water or other totally non-toxic material, that the toxicity of the mixture can be calculated from test data on the undiluted mixture. These two approaches were found to possibly lead to deviating classifications for the same mixture.

Thus, Germany and the USA believe there is a further need to explore application of the GHS to mixtures, reflecting the reality that packaged chemical products as well as workplace exposures rarely are limited to a single chemical. Our countries intend to continue this work to further determine what the differences are, and what guidance may help to address those differences.

However, it appears that this pilot project approach may be useful to conduct on a broader scale, including as many member countries as possible from the Subcommittee, as well as representatives from stakeholders. This would give a more complete picture of the issues likely to be raised, particularly when dealing with mixtures. The Subcommittee could then use the results of the project to identify what technical assistance will be required to ensure consistent application of the GHS around the world. The experts from Germany and the USA invite experts from other member countries to consider whether a Subcommittee pilot project could be conducted that is similar to that which we have completed, and to use the results to identify further guidance needed to improve application of the GHS globally. The Subcommittee could then consider how such guidance will be developed and made available.
