

## **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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**Programme of work for the biennium 2013–2014**

### **Addressing complex substances and substances of unknown or variable composition, complex reaction products and biological materials (UVCBs) in the GHS**

**Transmitted by the expert from the International Petroleum Industry  
Environmental Conservation Association (IPIECA)**

#### **I. Introduction**

1. There are a variety of terms that are being used to describe mixtures that are not simple, intentionally formulated mixtures (i.e., the combination of 2 or more substances in which they do not react). Those terms include complex mixtures, complex substances, multi-component substances, and UVCBs.
2. The concepts of complex substance and UVCB are well established and accepted by many competent authorities. However, the GHS does not define the terms “Substances of Unknown or Variable composition, Complex reaction products and Biological materials (UVCBs)” or “complex substances.”
3. This paper proposes a new work stream in the 2013-2014 biennium of the Sub-Committee to add definitions for “Substances of Unknown or Variable composition, Complex reaction products and Biological materials (UVCBs)” and “complex substances” to the GHS.
4. Because these terms can be confused with intentionally formulated mixtures, the proposed work stream could attempt to incorporate into the GHS consistent terminology to support the hazard classification process for these substances. These added definitions will:
  - (a) promote global consistency in classifying materials that are complex mixtures or multi-component substances or complex substances or UVCBs; and
  - (b) result in more consistent hazard communication of these types of substances by industry.

## II. Background

### GHS definitions

5. On the issue of substance identification, the GHS Chapter 1.2 *Definitions and Abbreviations* includes definitions for “Substance,” “Mixture,” and “Technical name.” These definitions follow:

“**Substance** means chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the product and any impurities deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;”

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

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

6. The GHS has further discussion in paragraph 1.3.3 *Specific considerations for the classification of mixtures* that states “to ensure a full understanding of the provisions for classifying mixtures, definitions of certain terms are required.” The intent of these definitions is to ensure that all products within the scope of the GHS are evaluated to determine their hazards, and are subsequently classified according to the GHS criteria as appropriate; and that the evaluation is based on the actual product involved. Paragraph 1.3.3.1.3 states “These definitions should be used to maintain consistency when classifying substances and mixtures in the GHS.”

7. GHS Chapter 4.1 *Hazardous to the Aquatic Environment* defines related terms. Specifically, paragraph 4.1.1.1 *Definitions* equates “complex mixtures” to “multi-component substances” to “complex substances”:

“**Complex mixtures** or multi-component substances or complex substances means mixtures comprising a complex mix of individual substances with different solubilities and physico-chemical properties. In most cases, they can be characterized as a homologous series of substances with a certain range of carbon chain length/number of degree of substitution.”

8. In implementing the GHS, it seems that additional guidance is needed in order to assure that these definitions are applied in a consistent manner globally. More specifically, in IPIECA’s view, definitions are needed for “Substances of Unknown or Variable composition, Complex reaction products and Biological materials (UVCBs)” and “complex substances.”

### Chemical abstracts service

9. The Chemical Abstract Services (CAS) Registry is the main system used by government and industry worldwide to uniquely define chemicals, and the assignment of names and numbers for UVCBs began decades ago in the process of implementing the CAS Registry.

10. As discussed in the *Chemical Abstracts Index Guide 2007*,<sup>1</sup> the chemical nomenclature used by CAS has developed in parallel and generally in accordance with the nomenclature rules published by the International Union of Pure and Applied Chemistry (IUPAC).

11. CAS utilizes its nomenclature rules and policies in developing a formal chemical description or designation, known as a Chemical Abstracts (CA) Index Name, and assigning the associated CAS Registry Number (CASRN), when adding a unique chemical substance to the CAS Registry. Each CASRN is a unique 10-digit numeric identifier that designates only one substance. CASRNs and their associated definitions provide a reliable common link among the various nomenclature terms used to describe chemical substances and are the international standard for chemical substance identifiers used by scientists, industry, and regulatory bodies worldwide.

12. The CAS Registry includes: elements; isotopes; organic compounds; inorganic compounds; and UVCBs.<sup>2</sup> Approximately 70 million substances have CAS numbers and many are UVCBs. As an example, of the almost 67,000 chemical substances on the public U.S. Toxic Substances Control Act (TSCA) Inventory, over 16,000 (approximately a quarter of the total) are UVCBs. UVCB substances comprise a variety of types of chemicals, including some natural fats and oils, forest product chemicals, polymers, by-products with commercial purposes, complex inorganics, biologics, petroleum process streams, and others.

13. Because UVCBs are assigned a unique name and number in accordance with the nomenclature rules of CAS, they are considered substances and not mixtures. CAS assigns CA Index names and CASRNs only to chemical substances. CAS does not assign CA Index names and CASRNs to intentional mixtures. Rather, CAS assigns CA Index Names and CASRNs to the individual components of the mixture.<sup>3</sup>

### III. Issue/Discussion

14. The consistent classification and labelling of complex substances and UVCBs is not straightforward due to the complicated nature and chemistry of these substances. While the GHS provides a well-structured approach that is readily applicable to most substances and mixtures, for complex substances and UVCBs, application of GHS principles may be subject to interpretation and therefore not be consistent. For example, GHS establishes the principle that when components of mixtures are classified for CMR endpoints, those components should be considered prior to consideration of data on the whole mixture. It is known that UVCB substances can have individual components which can drive toxicity, but the GHS guidance is silent on how to handle UVCBs or complex substances.

15. Variations in classification results can follow from the application and definition of terms such as complex mixtures or multi-component substances or complex substances or UVCBs. Regardless of the term used and definition, how complex substances/UVCBs are treated concerning classification, SDS ingredient disclosure, and labelling varies from system to system. For example, in Canada WHMIS uses the term complex mixture but

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<sup>1</sup> American Chemical Society, Chemical Abstracts Service, "Naming and Indexing of Chemical Substances for Chemical Abstracts, 2007 Edition" (*Chemical Abstracts Index Guide 2007*), available online at <http://www.cas.org>.

<sup>2</sup> American Chemical Society, Chemical Abstracts Service, "CAS Registry and CAS Registry Numbers," available online at <http://www.cas.org>.

<sup>3</sup> American Chemical Society, Chemical Abstracts Service, "CAS (Chemical Abstracts Service) Registration Criteria-Overview," available online at <http://www.cas.org>.

allows the generic name of a complex mixture to be disclosed in place of the ingredients of the complex mixture, and the concentration cut-off values do not apply to complex mixtures or a component that was a complex mixture. Also, per Canada WHMIS, under *Substance Specific Issues* the classification of coal would be based on the properties of the complex mixture and not on its individual components. However, in the EU UVCBs are addressed as substances under the European Commission Regulation (1272/2008) on Classification, Labelling and Packaging of Substances and Mixtures.

16. Characterizing complex mixtures, multi-component substances, complex substances, and UVCB substances differently under the various GHS implementation schemes globally results in the loss of consistency (and cost efficiency) that is the fundamental GHS goal of harmonization, and barriers to global trade. Furthermore, the terminology around these types of substances needs to be clarified to promote better understanding of what is meant by these terms.

## IV. Proposal

17. This paper proposes **a new work stream in the 2013-2014 biennium** of the Sub-Committee to add definitions for “Substances of Unknown or Variable composition, Complex reaction products and Biological materials (UVCBs)” and “complex substances” to the GHS. Next steps could include:

- (a) Survey and analysis of competent authority definitions for UVCBs and complex substances;
  - (b) Discussion of proposed definitions for UVCBs and complex substances for the GHS; and
  - (c) Review of GHS text to assess any needed changes (e.g., amendments to Chapter 4.1 *Hazardous to the Aquatic Environment* and Annex 9).
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