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Global Harmonisation System for Classification and Labelling of Mixtures and Consumer Products in Malaysia

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The concept of Globally Harmonised System (GHS) was initially developed as a result of Agenda 21 in 1992 at the Rio Summit. It recommended all countries to implement GHS for the classification and labelling of chemical substances. It was adopted by the UN Economic and Social Council and endorsed by WSSD (World Summit for Sustainable Development) and targeted for implementation in 2008. UNITAR (United Nations Institute Training and Research) and the ILO (International Labour Organization) were the focal points for capacity building to assist countries implement GHS (Obadia, 2003; Silk, 2003). GHS is an internationally agreed system for classification and labelling of chemicals substances or the mixtures as physical hazard, health hazard and environmental hazard. GHS covers consumer products, workplace, pesticides and transportation. Not only GHS will protect human health and environment but also facilitate in promoting the chemical trade (Mokhtar, Ta, & Murad, 2010). In Malaysia, chemicals and chemical products were the second highest among manufactured exports, after electrical and electronic products.

There are many challenges in implementing GHS in Malaysia. This includes lack of knowledge in toxicology and expertise in classification of chemicals including mixtures. A chemical database which is important for control of industrial chemical at national level (Mokhtar, et al., 2010).

Perspectives on GHS Implementation in Malaysia

Efforts to promote GHS awareness and its implementation in Malaysia began in 2003, following the APEC Chemical Dialogue recommendation. A National Coordinating Committee on the implementation of GHS (NCCGHS) was established on August 3rd 2006 and chaired by Ministry of International Trade and Industry (MITI), members of NCCGHS included representation

from government agencies, industries, associations and civil societies. The role of the NCCGHS is to coordinate and monitor the implementation of GHS in the four sectors that is industrial workplace, transport, agriculture and consumer products. It also plays an important role to promote GHS in Malaysia, develop pool of expertise on GHS, facilitate establishment of chemical database and report GHS implementation in Malaysia to international agencies such as United Nations Institute for Training and Research (UNITAR) and Asia Pacific Economic Cooperation (APEC). A Technical working group (TWGGHS) was also established to implement the activities and programmes identified by NCCGHS.

In Malaysia GHS will be implemented at the workplace as Classification, Labelling And Safety Data Sheet, CLASS regulation 2011. The CLASS regulation will replace the existing Occupational Safety and Health (Classification, Packaging and Labelling of hazardous chemicals) regulations 1997 (CPL regulation). The CPL 1997 defines hazardous chemicals as chemicals which possess any of the properties categorised in Schedule 1 (i.e. explosive, oxidising, extremely flammable, highly flammable, flammable, very toxic, toxic, harmful, corrosive and irritant) or for which relevant information exists to indicate that the chemical is hazardous. The CLASS Regulation draft is currently available for public comments. As for the transport sector, Malaysia is already adopting UN Recommendations on the Transport of Dangerous Goods (UNRTDG). In the agriculture sector, pesticides labels have been regulated for more than 25 years by the Pesticides (Labelling) Regulations 1984. The Pesticides(Labelling) Regulations 1984 is similar to the Guidelines on Good Labelling Practice for Pesticides published by the Food and Drug Organisation of the United Nations (FAO) in 1995. Malaysia also following the FAO International Code of Conduct on the Distribution and Use of Pesticides. Pesticide Board which is the regulatory authority for pesticides in Malaysia will amend the current pesticides regulations when the international guidelines incorporate the GHS element.

The term consumer products cover almost everything that we use or consume every day. However, GHS implementation will focus only on chemical based consumer products, such as paint and cleansing agents. The government of Indonesia has already identified six chemical-based consumer products that need to comply with GHS requirements. There are paint, thinner, detergent, household pesticides and printing ink. Labelling of consumer products is still inadequate in Malaysia. The related legislation such as the Trade Description Act 1972 and Consumer Protection Act 1999 do not highlight the risk involved in using consumer products that contain hazardous substances. Consumers in general are not aware of the type of hazard in consumer product such as detergent, washing liquid, aerosol and others.

A survey conducted on college students in Taiwan showed their perception towards chemical safety is much lower compared to their perception of the traffic signs despite a high level of agreement level that chemical labelling is important (Su & Hsu, 2008). Analysis of the comprehensibility of the labels conducted by Institute for Environment and Development (LESTARI,

Malaysia) revealed that training and education are two core elements that influence the comprehension of GHS pictograms (TA, Mokhtar, & Mokhtar, 2010). However this lack of awareness also exist in other countries.

Building Block in Malaysia

Figure 1. Building Block of CLASS Regulation

	GHS Recommendation					CLASS (DOSH regulation)				
	Cat. 1	Cat. 2	Cat. 3	Cat. 4	Cat. 5	Cat. 1	Cat. 2	Cat. 3	Cat. 4	
Acute toxicity	Cat. 1	Cat. 2	Cat. 3	Cat. 4	Cat. 5	Cat. 1	Cat. 2	Cat. 3	Cat. 4	
Skin Corrosive / Irritant	Cat. 1	Cat. 2	Cat. 3			Cat. 1	Cat. 2			
Serious Eye Damage / Irritant	Cat. 1	Cat. 2A	Cat. 2B			Cat. 1	Cat. 2			
Respiratory Sensitizer	Cat. 1					Cat. 1				
Skin Sensitizer	Cat. 1					Cat. 1				
Germ Cell Mutagen	Cat. 1 A	Cat. 1B	Cat. 2			Cat. 1		Cat. 2		
Carcinogen	Cat. 1 A	Cat. 1B	Cat. 2			Cat. 1		Cat. 2		
Reproductive Toxicant	Cat. 1 A	Cat. 1B	Cat. 2	Adit. Cat.		Cat. 1		Cat. 2	Adit. Cat.	
TOST (Single exposure)	Cat. 1	Cat. 2	Cat. 3			Cat. 1	Cat. 2	Cat. 3		
TOST (Repeated exposure)	Cat. 1	Cat. 2				Cat. 1	Cat. 2			
Aspiration Hazard	Cat. 1	Cat. 2				Cat. 1				
Environmental Hazard (Acute)	Cat. 1	Cat. 2	Cat. 3			Cat. 1				
Environmental Hazard (Chronic)	Cat. 1	Cat. 2	Cat. 3	Cat. 4		Cat. 1	Cat. 2			

The GHS document allows countries to adopt the building block approach when adopting the hazard classes and hazard categories. In this approach, the division of criteria within each hazard class could be treated as building blocks (Nations, 2007). Department of Occupational Safety and Health (DOSH) of Malaysia is following building block approach. Malaysia adopted most of the hazard classes of GHS except the following: Acute Toxicity Category 5, Skin corrosion/irritation Category 3, Aspiration hazard Category 2, Aquatic environment acute hazard Categories 2 and 3 and Aquatic environment chronic hazard Categories 3 and 4. Figure 1 shows the building block for GHS in Malaysia under the CLASS regulation. Hence, other than physical hazard, there is no requirement to generate test data to determine the hazard class. The classification system itself does not include requirements for testing substances or mixtures. Hence, other than physical hazards, there is no requirement to

generate test data to determine the hazard classification. The criteria established for classifying a mixture will allow the use of available data for the mixture itself and /or similar mixtures and/or data for ingredients of the mixtures.

Methodology

GHS Toolkit

Under GHS classification of mixtures is based on available test data for the individual ingredients of the mixture using concentration limits or summation method or additivity formula. The GHS classification system for mixtures is complex(Pratt, 2002). Manual calculation using the above mention methods can be used but will be tedious and time consuming if a product contains multiple ingredients such as detergent than contains more than ten chemical substances. The GHS Toolkit was developed to facilitate the classification process of 29 hazards covering sixteen physical hazards, ten health hazards and three environmental hazards.

The toolkit has a chemical database that contains about 700 pure chemicals which were already classified according to the GHS classification. The toolkit is divided into two parts. Part one is classification of pure substances based on internationally reliable literature data. Part two consists of a programme that predicts the classification for the mixture. The Toolkit is able to predict all the classifications under the physical hazard, health hazard and environmental hazardclasses. Classes validation of the results from the toolkit was carried out by comparing the toolkits results with the manual calculation and actual experimental value of a laundry detergent manufactured in Malaysia. Figure 2 shows the front page of GHS Toolkit.

Results and Discussion

Physical Hazards

There are 16 hazard classes for physical hazard. However substance or mixture to be evaluated can be reduced depending on the state of a substance (gas, liquid or solid). When liquids or solids contain specific chemical groups in their molecules, an assessment should be conducted that takes into account the presence of those groups. Most of the physical hazards test results are not published except for flash point and explosion limit. However it is possible to classify a pure substance based on UNRTDG classifications. According to the CLASS regulation the criteria established for classifying a mixture will allow the use of available data for the mixture or similar mixtures or data for ingredients of the mixture. In the case of GHS Toolkit prediction of physical hazard for the mixtures, data for ingredients are used based on a worse case scenario for the mixtures. A locally manufactured laundry detergent was used in the case study.

All the physical hazards were not classified according to the GHS Toolkit and also CLASS regulation.

Health Hazard

A chemical is classified as a health hazard when it poses one of the following hazardous effects: acute toxicity (any route of exposure); skin corrosion or irritation; serious eye damage or eye irritation; respiratory or skin sensitization; germ cell mutagenicity; carcinogenicity; reproductive toxicity; specific target organ toxicity and aspiration hazard (Rainer, 2010). Experimental data were obtained for acute toxicity oral, skin corrosion/irritation, and eye damage. Figure 3 shows the formulation of the detergent products used in the validation study.

Table 1. *LD50 (oral) for Ingredients in the TOP Detergent*

Raw Material	Percentage	LD ₅₀ (oral)
Las-H	15.7	650
Caustic soda	4.3	CNP
MES	1.2	CNP
Soda Ash	9.4	4090
Sodium Silicate	16.4	1153
Sodium Tripolyphosphate	15	3100
Zeolite	2.2	5000
Calcium carbonate	4.6	6450
Sodium sulphate	30.6	10000
Sodium sulphite	0.17	820
Sodium percarbonate	0.38	1034

Acute Oral Toxicity for Detergent

An acute oral toxicity study was conducted on rats to determine the toxicity potential of the detergent based on a single dose test via the oral route. The acute oral toxicity class method is a stepwise procedure which uses 3 animals of a single sex per step (Schlede, Genschow, Spielmann, Stropp, & Kayser, 2005). In this study an acute oral toxicity class method (limit test 2000 mg/kg) was conducted on three female rats per treatment group at each step. The treatment group received a single dose administration of the detergent at 2000 mg/kg body weight. A control group of three female rats at each step was administered distilled water at the same dose volume as the treatment group (10 ml/kg).

Based on the acute oral toxicity LD₅₀ 5000 mg/kg body was obtained for detergent. It was not classified under the CLASS regulation and Category 5 according to GHS (3rd edition). The experimental result and the manual calculation gave the same result as the GHS Toolkit for acute toxicity (oral). The detergent powder not classified under CLASS regulation. Manual classification was also conducted using the detergent formulation shown in Table 2 to obtain Acute Toxicity Estimate (ATE mix). Table 2 was used to select the Category based on the ATE mix value.

$$\frac{100}{ATE_{mix}} = \sum_n \frac{Ci}{ATE_i}$$

ATE_{mix (Top detergent)} = 2989 mg/l, the detergent is “not classified” in CLASS regulation and has no hazard statement.

Table 2. Classification for Oral Acute Toxicity

Exposure Routes	Acute Toxicity Estimate (ATE)
Oral (mg/kg body weight)	0 < Category 1 ≤ 5 5 < Category 2 ≤ 50 50 < Category 3 ≤ 300 300 < Category 4 ≤ 2000 More than 2000 : NC (Not classified as acute toxicity)

Skin Irritation/corrosion

Skin corrosion is the production of irreversible damage to the skin; namely, visible necrosis through the epidermis and into the dermis, following the application of a test substance for up to 4 hours. Corrosive reactions are typified by ulcers, bleeding, bloody scabs, and, by the end of observation at 14 days, by discolouration due to blanching of the skin, complete areas of alpecia, and scars. *Skin Irritation* is the production of reversible damage to the skin following the application of a test substance for up to 4 hours. Skin Category 3 is not included in the Malaysian building block since GHS Toolkit is based on the local CLASS regulations, Skin Category 3 was also not included. Manual classification for the detergent powder was based on Table 3. Total percentage of constituents under Skin Category 1 was (only caustic soda) less than 5%. Therefore the detergent was classified as Category 2. The GHS Toolkit also showed the detergent was classified as Category 2.

The Irritation[®] Assay System was used to experimentally determine the potential of the detergent to cause dermal irritation. Results showed the detergent powder was an irritant above 2.5% concentration. Experimental results also showed the detergent was classified as Category 2. Hazard statement for this category was “Causes Skin Irritation”.

Serious Eye Damage/eye Irritation

Serious eye damage means the production of tissue damage in the eye, or serious physical decay of vision, following application of a test substance to the anterior surface of the eye, which is not fully reversible within 21 days of application. There are many methods to assess the eye irritation potential including Short Time Exposure (STE) test (Sakaguchi et al., 2011).

Eye irritation means the production of changes in the eye following the application of test substance to the anterior surface of the eye, which are fully reversible within 21 days of application. Manual classification for the detergent was based on Table 3. Total percentage of chemical substance with Eye Category 1 (only caustic soda) is more than 3%. Therefore it was classified as

Category 1 and GHS Toolkit also classified as Eye Category 1. Hazard Statement for this Category was “Causes Serious Eye Damage”.

Table 3. *Skin Corrosion, Eye Irritation and STOT (single exposure) Classification for Ingredients in the TOP Detergent*

Raw Material	Percentage	Skin corrosion Category	Eye irritation Category	STOT (single exposure)
Las-H	15.7	Category 2	Category 2	CNP
Caustic soda	4.3	Category 1	Category 1	1(respiratory)
MES	1.2	CNP	CNP	CNP
Soda Ash	9.4	NC	Category 2	3(respiratory)
Sodium Silicate	16.4	Category 2	Category 2	2(kidney)
Sodium	15	NC	NC	CNP
Tripolyphosphate	2.2	NC	NC	CNP
Zeolite	4.6	Category 2	Category 2	CNP
Calcium carbonate	30.6	NC	Category 2	CNP
Sodium sulphate	0.17	NC	NC	CNP
Sodium sulphite	0.38	NC	Category 2	CNP
Sodium percarbonate		CNP		CNP

Skin Sensitization and Respiratory Sensitization

Skin sensitizer means a substance that will lead to an allergic response following skin contact. Respiratory sensitizer means a substance that will lead to hypersensitivity of the airways following inhalation of the substance. There is no sufficient data for skin sensitization and respiratory sensitization for the ingredients in the TOP detergent so it is classified as “Classification Not Possible (CNP)” under the GHS for skin sensitization and respiratory sensitization.

Germ Cell Mutagenicity

A mutation means a permanent change in the amount or structure of the genetic material in a cell. A weight of evidence approach is required to assess mutagenic potential of chemicals (Morita et al., 2009). There is insufficient data for mutagenicity for the raw materials used in the detergent so it is classified as “Classification Not Possible (CNP)” according to GHS for mutagenicity.

Carcinogenicity

Carcinogenicity means a substance or a mixture of substance which induce cancer or increase its incidence. Substances which have induced benign and malignant tumours in well performed experimental studies on animals are considered also to be presumed or suspected human carcinogens. There is insufficient data for carcinogenicity for the raw materials used in the detergent so it was classified as Classification Not Possible (CNP) according to GHS for carcinogenicity.

Table 4. *LC₅₀ (fish) Values for Ingredients in the TOP Detergent*

Raw Material	Percentage (%)	LC ₅₀ (fish)
Las-H	15.7	1.9
Caustic soda	4.3	45.4
MES	1.2	CNP
Soda Ash	9.4	CNP
Sodium Silicate	16.4	478
Sodium Tripolyphosphate	15	CNP
Zeolite	2.2	1800
Calcium carbonate	4.6	CNP
Sodium sulphate	30.6	1100
Sodium sulphite	0.17	440
Sodium percarbonate	0.38	71

Reproductive Toxicity

Reproductive toxicity includes adverse effects on sexual function and fertility in adult males and females, as well as developmental toxicity in the offspring.

There is insufficient data for reproductive toxicity for the raw materials used in the detergent so it is classified as “Classification Not Possible (CNP)” according to GHS for reproductive toxicity.

Specific Target Organ Toxicity (STOT) –Single Exposure

Specific target organ toxicity (single exposure) is defined as specific, non lethal target organ toxicity arising from a single exposure to a substance or mixture.

Manual classification for the detergent based on Table 3. Total percentage of STOT category 1 was less than 10%. Detergent was classified as STOT Category 2 and hazard statement was “may cause damage to kidney and respiratory system”. GHS Toolkit also showed the same results.

Specific Target Organ Toxicity–Repeated Exposure

Target organ toxicity (repeated exposure) means specific target organ toxicity arising from a repeated exposure to a substance or mixture of the raw materials in the detergent.

Only Las-H, Soda Ash Sodium Silicate and Zeolite have data and all belong to the “not classified” category. Other raw materials have insufficient information for classification. Therefore the detergent is classified as “Classification Not Possible (CNP)” because the information available is not sufficient to it.

Aspiration Hazard

Aspiration means the entry of a product directly through the oral or nasal cavity, or indirectly from vomiting, into the trachea and lower respiratory system. Raw materials in the detergent is not classified as Aspiration hazard. GHS Toolkit too did not classify the detergent as “Aspiration hazard”.

Environmental Hazard

There are three hazard classes for environmental hazard namely:

- a) Hazardous to the aquatic environment- acute hazard
- b) Hazardous to the aquatic environment- chronic hazard and
- c) Hazardous to the ozone layer

Acute Toxicity Hazard

Acute fish toxicity test according to modified and combined methods of USEPA Method for Measuring the Acute Toxicity to Freshwater and Marine Organisms and OECD Guideline for Testing of Chemicals Method 203. The results from the experiment were $LC_{50} = 20$ mg/l. Manual classification for Top detergent using additive formula and the results were follow:

$$LC_{50\text{Top detergent}} = 11.84 \text{ (manual classification)}$$

Not classified under CLASS regulation. GHS Toolkit results also showed that the detergent was not classified for acute fish toxicity.

Chronic Hazard

Chronic hazard means the hazard of a chemical caused by its chronic toxicity following long-term exposure in the aquatic environment. TOP detergent is not classified as Chronic Hazard because the product is biodegradable and non bioaccumulative. Chronic Hazard is only for products that are biodegradable or bioaccumulative.

Hazardous to Ozone Layer

Substance hazardous to the ozone layer means a substance which, on the basis of the available evidence concerning its properties and its predicted or observed environmental fate and behaviour may present a danger to the structure of the stratospheric ozone layer. The TOP detergent is not classified as hazardous to Ozone Layer because none of the ingredients are listed in the Annexes to the Montreal Protocol.

Conclusion

GHS classification for mixtures that includes consumer products was carried out using the GHS toolkit. Comparison between experimental data or manual classification with GHS Toolkit were conducted to know the accuracy of the Toolkit. Table 5 shows that prediction using the GHS Toolkit were accurate and precise for all the health hazards and environmental hazard for TOP laundry detergent. However validations were also conducted on several mixtures that have data for skin sensitisation, germ cell mutagenicity, carcinogenicity and aspiration because valid information were not available for

ingredients in TOP detergent. TOP detergent is classified as skin corrosion Category 2, Serious Eye Damage Category 1 and Specific Target Organ Toxicity (Single Exposure) Category 2. It was not classified under physical hazard or environmental hazard.

Table 5. Comparison of the Experimental Value, Manual Classifications and Results from the Toolkit for Health Hazard and Environmental Hazard

Hazard Type	Experimental Value	Manual Classification	Results from the Toolkit
Acute Toxicity (Oral)	LD ₅₀ = 5000 mg/kg (Not classified)	Not classified	Not classified
Skin Corrosion/Irritation	Mild Irritation (Category 2)	Category 2	Category 2
Serious Eye Damage/Eye irritation	Corrosive (Category 2)	Category 1	Category 1
Respiratory or Skin Sensitization	Not available	Classification not possible	Classification not possible
Germ Cell Mutagenicity	Not available	Classification not possible	Classification not possible
Carcinogenicity	Not available	Classification not possible	Classification not possible
Reproductive Toxicity	Not available	Classification not possible	Classification not possible
Specific Target Organ Toxicity- Single exposure	Not available	Category 2	Category 2
Specific Target Organ Toxicity- Repeated exposure	Not available	Not classified	Not classified
Aspiration Hazard	Not available	Not classified	Not classified
Hazardous to the Aquatic environment (acute fish)	Not classified	Not classified	Not classified
Hazardous to the Aquatic environment (chronic)	Not classified	Not classified	Not classified
Hazardous to the ozone layer	Not Applicable	Not classified	Not classified

The toolkit was able to produce mandatory labels that were required by the local and international regulations. Manual classifications are time consuming and high tendency to make mistakes during classifications. Conventional product classifications using experimental data are expensive. Manual classifications and experiments can be replaced by the GHS Toolkit. The output of the GHS toolkit shows that the toolkit is very accurate, fast, robust, reliable in classification and labelling of products or mixtures. Consumers that have a very little knowledge on classification and labelling can use the toolkit to choose a not hazardous product. The manufacturer can also use the GHS toolkit to formulate products that does not contain any hazardous properties.

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