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HAZARDOUS SUBSTANCES – WHAT'S NEW IN EUROPE?

Dr Wolfgang Schäfer assesses the most important terms and the resulting consequences

The CLP Regulation – or the GHS – was developed by the United Nations and has already been implemented in European law. It includes a completely new system of classification and labelling of hazardous substances. This presents new challenges for ink manufacturers like Marabu.

In the modern world chemicals are part of our occupational and private environment. The benefit from the use of those products is accompanied by the awareness and experience that certain substances and mixtures may have dangerous properties for humans and environment. At the same time, as a part of globalisation, there is a strong expansion from international trading with chemicals. As a result the development of regulations for different areas like classification and labelling of chemicals or transportation has started. Due to the non-harmonised approach the regulations worldwide are very inconsistent.

This results in totally different classification and labelling for substances and mixtures. In the EU, for example, a substance with an acute oral toxicity of LD50 = 257 mg/kg is classified as harmful; however, in the USA, the same substance is toxic and on the opposite in India this product is non-toxic. The varying hazard assessments are problematic in themselves and hinder the international exchange of goods.

CLASSIFICATION AND LABELLING OF CHEMICALS WITH GHS

In 1992 the United Nations Conference on Environment and Development (UNCED) made a commitment to harmonise the classification and labelling of chemicals worldwide. The international community of states gave the UN the mandate to develop the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). In 2003 the first version of the GHS was published as the so-called 'purple book' which, since then, is subject to a continuous improvement process.

The following goals from GHS have been expected:

- Worldwide harmonized system for classification and labelling of chemicals
- To provide a recognised framework for those countries without existing system
- Better protection of human health and environment by providing enhanced and consistent information on chemical hazards
- Worldwide harmonised system, which helps to minimise exposure and risk

- during transportation of chemicals
- Improvement of occupational safety
- Facilitation of the worldwide trade in chemicals, of which hazards have been properly assessed
- To reduce the need for testing and evaluation of chemicals

STRUCTURE OF THE GHS

One of the objectives of the work on GHS has been the development of a harmonised hazard communication system through labelling and safety data sheets (SDS) based on the worldwide harmonised classification criteria for substances and mixtures.

Basically the GHS distinguishes between three different types of hazards:

- Physical Hazards
- Health Hazards
- Environmental hazards

GHS uses pictograms for the hazard communication through labelling (see pictograms). A pictogram means a graphical composition that includes a symbol plus other graphic elements, such as a border, background pattern or colour that is intended

to convey specific information.

In total the GHS comprises of 16 classes for physical hazards, ten classes for health hazards and one class for environmental hazards. For each hazard class the classification criteria are specified in the GHS.

Additionally, signal words are used to indicate the relative level of severity of hazard and to alert the user to a potential hazard on the label. The signal word 'Danger' is used for more severe hazard categories, whereas less severe hazards make use of the signal word 'Warning'.

As well as the pictograms and signal words, the GHS uses hazard statements (H phrases) and precautionary statements (P phrases). The H phrases are used for describing the hazardous property more precisely, whereas the P phrases are used to indicate important risk management measures for handling of the product to minimise or prevent adverse effects.

Together with the corresponding safety data sheet, ink manufacturers like Marabu are able to advise humans, who are working with hazardous chemicals, about the hazard properties and provide information about precautions, which are necessary to ensure safe handling,



Explosive



Flammable



Oxidising



Compressed gas



Corrosives



Toxic cat 1-3

Warning
Lower systemic health hazards

Systemic health hazards



Environment

storage and disposal of those products.

- Referring to safety data sheets the GHS contains guidelines
- for establishing a safety data sheet
- requirements for the structure of the safety data sheet including the arrangement of the chapters and the corresponding 16 headings
- guidance for preparation the safety data sheet

REGULATION ON CLASSIFICATION, LABELLING AND PACKAGING OF SUBSTANCES AND MIXTURES (EC) NO 1272/2008

The UN GHS forms the basis for the worldwide harmonisation of regulations for the classification and labelling of hazardous substances and mixtures as well as for the harmonisation of the national and regional systems for classification and labelling. The UN GHS is a recommendation which must be implemented by the individual countries with binding force. In the EU, the GHS has been implemented and brought into force by the European Regulation (EC) No. 1272/2008 on Classification, Labelling and Packaging of substances and mixtures better known as 'CLP Regulation' and was immediately valid in all member states of the EU.

The CLP regulation complements the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation (EC) No. 1907/2006, which mainly deals with substances and forces manufacturers/importers of chemicals, depending on a tonnage band, to provide a basic set of health and safety data to close knowledge gaps.

The CLP regulation incorporates most of the classification criteria and labelling rules agreed in the UN GHS, namely new classification criteria, hazard symbols (pictograms), signal words, and Hazard (H phrases) and Precautionary (P phrases) statements, while taking account of some elements which are part of the current EU legislation. Therefore, the CLP will be similar but may not be identical to the way GHS is introduced into the legal framework of countries outside the EU.

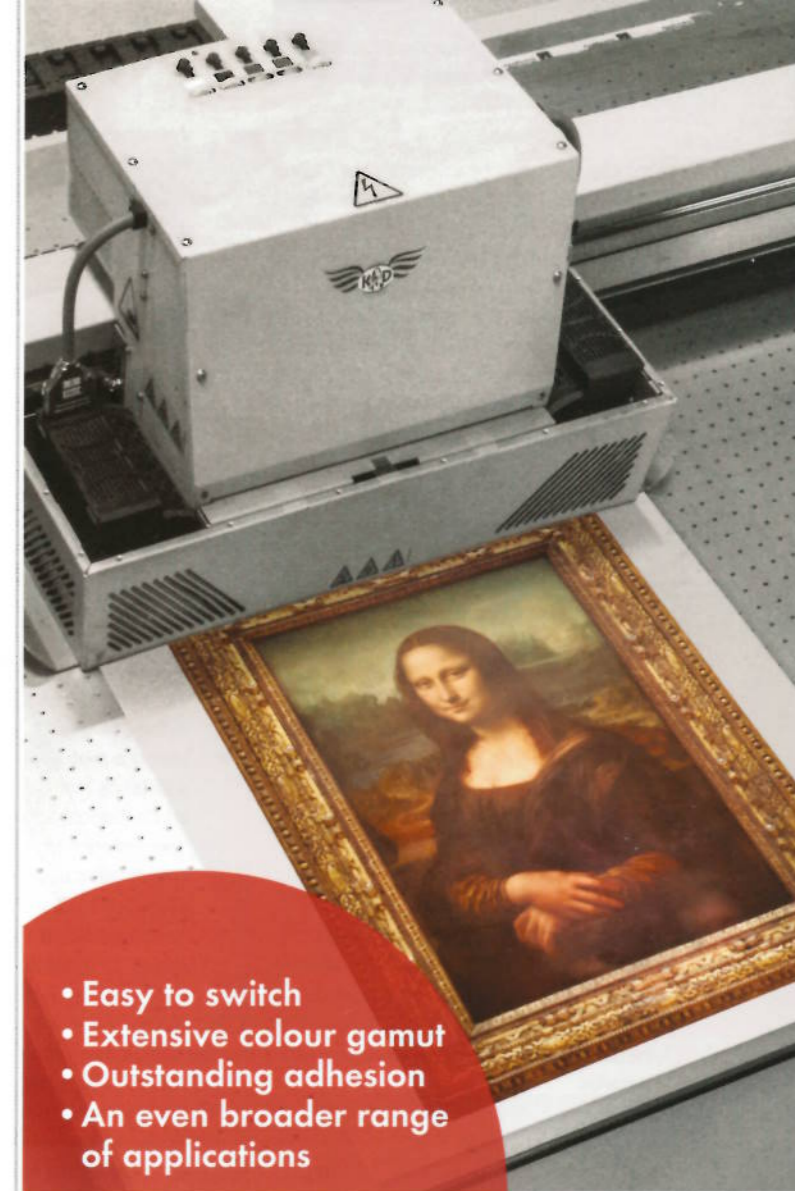
The CLP regulation is legally binding across the EU member states and requires industry to appropriately classify, label and package their substances and mixtures before placing them on the market. It will replace the current system contained in the Dangerous Substance Directive (67/548/EEC) and the Dangerous Preparations Directive (1999/45/EC) by 1 June 2015.

The CLP regulation entered into force on 20 January 2009. However, not all provisions of the CLP regulation will be obligatory immediately. In article 61, transition periods were defined which resulted in two target dates, namely 1 December 2010 and 1 June 2015 (see figure 2).

Since 1 December 2010 the following rules apply:

- Substances must be classified in accordance with both DSD and CLP
- Substances must be labelled and packaged in accordance with CLP only, but substances already classified, labelled and packaged according to DSD and placed on the market before 1 December 2012 only had to be re-labelled and re-packaged by 1 December 2012
- Mixtures must continue to be classified, labelled and packaged until 1 June 2015 in accordance with the DPD. Prior to this date mixtures could be classified, labelled and packaged according to CLP, but then the labelling and packaging provisions of DPD shall no longer apply to the mixture and labelling and packaging must respect the provisions of CLP.
- Classification of a substance according to DSD must be provided in the safety data sheet until 1 June 2015, in addition to the CLP classification. This is valid for the safety data sheet for substances as such and for safety data sheets for mixtures containing these substances.
- The classification of a mixture according to DPD must be provided in the safety data sheet until 1 June 2015.
- Until 1 June 2015, if a mixture is classified, labelled and packaged according to CLP, the CLP classification must appear on the safety data sheet along with the classification based on DPD. However, a

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supplier may choose to identify the CLP classification of a mixture in advance of applying CLP to it in full.

From 1 June 2015 the following rules apply:

- Substances must be classified in accordance with CLP only
- Mixtures must be classified, labelled and packaged in accordance with CLP only, but mixtures already classified, labelled and packaged according to DPD and placed on the market (ie 'on the shelves') before 1 June 2015 will only have to be re-labelled and re-packaged by 1 June 2017
- Only CLP classifications of substances and mixtures must be provided in the safety data sheet

COMPARISON OF CLP WITH DSD/DPD

The Dangerous Substances Directive 67/548/EEC (DSD), the Dangerous Preparations Directive 1999/45/EC (DPD) and CLP are conceptually similar as all of them deal with the classification, hazard communication through labelling and packaging.

The most obvious differences are:

- The previous term 'dangerous' will be replaced by the term 'hazardous', which is defined as any substance or a mixture fulfilling the criteria relating to the physical hazards, health hazards or environmental hazards
- The previous orange coloured 'danger symbols' will be replaced by the 'nine pictograms'. New symbols in comparison to the old system are the GHS04 (compressed gas), the GHS07 (lower systemic health hazards) and the GHS08 (systemic health hazards)
- The number of hazard classes has increased, in particular for the physical hazards (from five to 16). This leads to a more explicit differentiation of physical properties
- CLP introduces the two UN GHS signal words 'Danger' and 'Warning' to indicate the severity of a hazard
- The previous risk phrases (R-phrases) will be replaced by the hazard statement (H-phrases), which describe the nature of the hazards of a substance or mixture, including, where appropriate, the degree of hazard
- The previous safety phrase (S phrase) will be replaced by the precautionary statement (P phrases), which is a description of the measure or measures recommended to minimise or prevent adverse effects resulting from exposure to a hazardous substance or mixture due to its use
- The term 'supplier' is not used in DSD or DPD. Under CLP it means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a mixture

- Due to lower threshold values in the CLP system, the same formulation will lead to more hazardous classifications in comparison to the old system

CLASSIFICATION AND LABELLING UNDER THE CLP REGULATION

Suppliers have to notify a substance to the Classification & Labelling (C&L) inventory established at ECHA in cases where they are placing the substance on the market and they either:

- Manufacture a substance subject to registration under the REACH regulation; or
- Import a substance subject to registration under the REACH regulation; or
- Manufacture or import a substance on its own classified as hazardous, irrespective of the quantity; or
- Import a mixture which contains a substance that is classified as hazardous and is present above the relevant concentration limit, which results in the classification of the mixture as hazardous according to CLP regulation; or
- Import an article containing a substance subject to registration under article 7 of the REACH regulation

Manufacturers or Only Representatives (OR) may submit the information needed for the notification to the inventory as a part of a REACH registration dossier. If a separate notification to the C&L inventory is necessary, the EU importer, for example the ink manufacturer, would normally have to submit the notification. This Task may be delegated to companies providing this service like TÜV SÜD etc.

The substances must be notified at ECHA within one month from being placed on the market. In C&L inventory these notifications are made anonymous and will be accessible to the public.

STATUS GHS IMPLEMENTATION WORLDWIDE

The adoption of the GHS is expected to facilitate international trading by increasing consistency between the laws in different countries that currently have different hazard communication requirements. There is no set international implementation schedule for GHS. Different countries will require different time frames to update current regulation or implement new ones.

Information regarding the actual status of the national implementation of GHS for several countries is provided in figure 3.

More details about the status of the implementation of the GHS can be found under the link from the United Nations Economic Commission for Europe (UNECE): http://www.unece.org/trans/danger/publi/ghs/implementation_e.html

The information on this page is compiled

country by country. Since the implementation is a dynamic process, this information will be regularly reviewed and updated.

TASK MANAGEMENT FOR THE IMPLEMENTATION OF THE CLP REGULATION

The efforts for the implementation of the requirements of the CLP regulation should not be underestimated. For ink manufacturers like Marabu, as shown previously, a simple change over from the existing classification and labelling system to CLP is not possible due to the new elements from the new regulation. The most important measures are collected in the following list:

- Training of the responsible persons in the product safety department
- Actualisation of existing software or implementation of new software able to calculate classification of mixtures according to CLP
- Evaluation of the calculated classification
- Generation of the SDS containing the classification information according to CLP in all EU languages
- Adaptation of the labelling process to the CLP requirements, installation of an interface between the classification module and the labelling software. Labelling information must be available in all EU languages
- Definition of the labels' layout
- Adaptation to the correct packaging in the shipment department
- Training of internal workers and sales forces
- Generation of information documents for customers
- Adaptation of operation instructions
- Adaptation of the labelling of in-house tanks, containers and cans in the production site as well as in the laboratory
- Adaptation of the working directory and catalogue of hazardous materials
- Check and adaptation of the risk assessment documents as well as the explosion protection documents

Marabu already delivers products to China classified and labelled in accordance with the China GHS. For the rest of the world, Marabu is well prepared for the substantial impact of the requirements in 2015 and will start to use CLP classification and labelling in the first quarter of 2015 to match the EU and others deadline of 1 June 2015. Marabu has been certified to ISO 9001 since 1995 and to ISO 14001 since 2003. ■

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