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IMPACT OF REACH AND CLP REGULATION ON THE CONTENT OF SAFETY DATA SHEET

Abstract

Safety Data Sheet (hereinafter SDS) is a document that provides a mechanism for transfer of adequate safety information on hazardous substances and mixtures. SDS allows users to undertake the necessary measures to protect human health and safety in the workplace and environment. SDS is defined by the REACH Regulation (1907/2006/EC), Annex II. By the implementation of REACH for substances and mixtures which are dangerous to human health and the environment the SDS has become an extended document that contains the Exposure scenario. It is necessary to prepare Exposure scenario for substances manufactured or imported in quantities of more than 10 t/y that have PBT and/or vPvB properties or are classified into some other class of hazard in accordance with Art. 14 of the REACH Regulation. Exposure scenario is part of the Chemical Safety Report, within the Chemical safety assessment as a part of registration dossier.

Classification, labeling and packaging of substances and mixtures is carried out in accordance with the CLP Regulation (1272/2008/EC). CLP Regulation follows the criteria for classification of chemicals given by the UN, the so-called Global Harmonized System of Classification and Labeling of Chemicals (GHS). Regulation brings new classification criteria, hazard symbols (pictograms) and warning labels and statements H and P by replacing R and S phrases.

Both of regulations have a major impact on the content of SDS, which has become larger and more complex document for its creator (manufacturer) and the end user. We believe that the industry should take some steps to create a compendious version of SDS, which will have practical application in everyday life and will be convenient to the storekeeper, carriers, end users of dangerous chemicals, i.e. for people who are in a direct contact with dangerous chemicals in order to protect themselves timely and adequately from undesirable effects.

Key words: *chemicals, safety, regulation, classification*

UTJECAJ REACH I CLP UREDBI NA SADRŽAJ SIGURNOSNO-TEHNIČKOG LISTA

Sažetak

Sigurnosno-tehnički list (u daljnjem tekstu STL) je dokument koji osigurava mehanizam prijenosa odgovarajućih sigurnosnih podataka o opasnim tvarima i smjesama. STL omogućuje korisnicima poduzimanje neophodnih mjera za zaštitu ljudskog zdravlja i sigurnosti na radnom mjestu te zaštitu okoliša. STL je definiran Uredbom REACH (1907/2006/EZ), Prilogom II. Primjenom Uredbe REACH za tvari i smjese koje su opasne za ljudsko zdravlje i okoliš STL je postao prošireni dokument koji sadrži Scenarij izloženosti. Scenarij izloženosti potrebno je izraditi za tvari koje se proizvode ili uvoze u količini većoj od 10 t/god. te koje imaju PBT i ili vPvB svojstva ili spadaju u neki drugi razred opasnosti sukladno čl. 14 Uredbe REACH. Scenarij izloženosti je sastavni dio Izvješća o kemijskoj sigurnosti koje se nalazi u Procjeni kemijske sigurnosti kao sastavni dio registracijskog dosjea. Razvrstavanje, označavanje i obilježavanje te pakiranje tvari i smjesa provodi se sukladno Uredbi CLP (1272/2008/EZ). CLP uredba preuzima kriterije za razvrstavanje kemikalija dogovorene na razini UN-a, tzv. Globalnog harmoniziranog sustava razvrstavanja i označavanja kemikalija (GHS). Uredba nosi nove kriterije razvrstavanja, simbole opasnosti (piktograme) te oznake upozorenja i obavijesti H i P koje zamjenjuju R i S oznake. Obje uredbe imaju veliki utjecaj na sadržaj STL-a koji je postao prošireniji i zahtjevniji dokument za onoga tko ga izrađuje (proizvođača) i za onoga tko ga mora znati iščitati (krajnjeg korisnika). Smatramo da bi industrija trebala poduzeti neke korake za izradom skraćene verzije STL-a koja će imati praktičnu primjenu u svakidašnjem životu prihvatljivu za skladištare, prijevoznike i krajnje korisnike opasnoh kemikalija, tj. za ljude koji su u neposrednom doticaju s opasnom kemikalijom kako bi se pravodobno i na odgovarajući način mogli zaštititi od njenih nepoželjnih utjecaja.

Ključne riječi: *kemikalije, sigurnost, regulacija, klasifikacija*

Introduction

Safety data sheets (SDS) have been generally well accepted and effective method for the provision of information to recipients of chemical substances and mixtures in the EU. They have been made an integral part of the system of Regulation (EC) No. 1907/2006 (REACH). The basic requirements of REACH for SDSs consider GHS (Globally Harmonized System) and its implementation into EU law by Regulation (EC) no.1272/2008 (CLP) and the amendment of Annex II of the REACH Regulation. REACH is the Regulation of the European Union adopted in order to improve the protection of human health and the environment from the dangers they may pose chemicals and at the same time increasing the competitiveness of the chemical industry in the European Union.

Furthermore, REACH encourages the development of other methods for risk assessment of substances, which would reduce the number of experiments on animals. Regulation is among other prescribed that all manufacturers, importers or other legal entities which trade goods in the EU have to submit so-called fixed period registration dossier for each substance. Registration dossier submitted to the European Chemicals Agency (ECHA) (http://echa.europa.eu) headquartered in Helsinki, by paying a fee that depends on the amount and properties of the produced matter. If the company does not register substances must stop production /sales/import goods throughout the EU. Registration costs for substances is 24 901 EUR per substance and 1265 EUR for intermediates. Internet site of the European Chemicals Agency is now available in the Croatian language.

After accession of Croatia to the European Union, 1st of July 2013th INA, d.d had to register all substances produced in quantities greater than 100 tons / year.

Postponement deadlines for pre-registration:
For substances that INA, d.d. not exported to the EU market the deadline for pre-registration is 31st of December 2013.

Postponement of deadlines for registration:
• for substances in quantities above 100 tones/year
• for substances classified as carcinogenic, mutagenic or toxic to reproduction (cat. 1 or 2)
• for substances classified as toxic to aquatic life , phrases R50/53 deadline for registration is 30th of June 2014
INA was pre-register and register substances under REACH before the deadlines!

CLP Regulation on classification, labeling and packaging of substances and mixtures 1272/2008/EZ entered into force on 20th Jan 2009 and after a transitional period, to replace Directive 67/548/EEC and 1999/45/EC and the current way of classification and labeling of substances and preparations (these directives have been taken in our legislation is the Regulation on classification, labeling and packaging of dangerous chemicals - Official Gazette (23/08, 64/09, 113/10, 63/12)). Before putting chemicals on the market, industry must classify, label and package substances and mixtures in accordance with the CLP Regulation.

The company may be the manufacturer of the substance or mixture, importer, manufacturer, downstream user (including formulator and re-exporters) and distributor (including retail).

Notification according to the CLP Regulation

INA has notified all substances which exported to the EU market in accordance with the CLP Regulation. For substances that are exempted from REACH (Annex IV and Annex V of REACH), notification done separately.

After joining the EU INA, d.d had to notify all substances. The deadline for notification of the substance was from 1st July to 1st August 2013. INA has notified substance before the deadline for notification of substances according to the CLP Regulation.

Labeling of substances

Labeling of the substances under this Regulation will have to be matched by 1st December 2011 for substances and mixtures for alignment is postponed until 1st June 2015.

Changes in the classification and labeling:

• symbols become pictograms
• introduces the term – signal words: "dangerous" or "harmful"
• risk phrases (R) become hazard statements (H)
• safety phrases (S) become precautionary statements (P)

SDS structure does not change significantly. However, REACH has introduced some significant changes with respect to the information required in the Safety data sheet. The information referred in the SDS must be a clear and concise. SDS provides information on occupational safety and worker safety, transport safety and environmental protection. Since the SDS in many cases does not prepare a person but more of them, it is logical to expect certain disadvantages. So it is good to give SDS made to check and adjustment before it is delivered to the user. It is best to do this one competent person

In accordance with Article 31(8) of REACH SDS must be provided free of charge on paper or electronically no later then the date on which the substance or mixture is first supplied. The supplier must submit directly to the user, and not to "submit" through its website. SDS is delivered during the first delivery of the goods.

According to Article 31(5) of REACH SDS shell be supplied in an official language of the country where the substance or mixture is placed on the market unless the country concerned provide otherwise. In Croatia is stipulated that SDS has to be written in Latin script in Croatian. In the supply chain, the provisions of REACH relating to the delivery of SDS and relate to each link in the chain. The primary responsibility for the development of SDS is on the manufacturer, importer or only representative who will consider the use of chemicals. Downstream users must also ensure SDS to take into account the needs of the end user. All participants are responsible for the content of SDS, even when they do not produce.

Substances and mixtures for which an SDS must be provide

a) without prior request

In accordance with Article 31 (1) of REACH, which is supplemented by Articles 58 (2) (a) and 59 (2) (a) of CLP, SDS has no application to be delivered to the following products:

• substances that are classified as dangerous according to Regulation (EC) no. 1272/2008 (CLP) and mixtures are classified as dangerous according to Directive 1999/45/EC (DPD)
• PBT and vPvB substances
• substances that are found on the so-called "candidate list" of authorization (list published on the ECHA website).

b) on request

According to Article 31.3 REACH as amended by Article 59 (2) (b) of the CLP, the SDS must be submitted on request for the following products that contain:

• a substance hazardous to health or the environment in an individual concentration of ≥ 1% (≥ 0.2 % by volume for gaseous mixtures)

• a PBT and vPvB substance or a substance with properties seriously hazardous to health or the environment in an individual concentration of ≥ 0.1 % for non-gaseous mixtures

• one substance for which there are Community workplace exposure limits (Directive 2004/37/EC, 2000/39/EC, 2006/15/EZ, 2009/161/EU).

SDS has 16 sections and each section is defined in Annex II. REACH, especially in parts B amendments to Regulation (EU) 453/2010:

Section 1: Identification of the substance mixture and of the company / undertaking
Section 2: Hazards identification
Section 3: Composition / information on ingredients
Section 4: First aid measures
Section 5: Firefighting measures
Section 6: Accidental release measures
Section 7: Handling and storage
Section 8: Exposure controls / personal protection
Section 9: Physical and chemical properties
Section 10: Stability and reactivity
Section 11: Toxicological information
Section 12: Ecological information
Section 13: Disposal consideration
Section 14: Transport information
Section 15: Regulatory information
Section 16: Other Information
Appendix: Exposure scenarios in accordance to Chemical safety report (CSR)
Section title certainly must include the word "The" (i.e. Section 1 title).

SDS Section 1: Identification of the substance mixture and of the company/undertaking

For substances subjected to registration under EU regulations governing the registration of product identification must match the identification specified in the registration, in addition, the state assigned a registration number. If there is no reg. number, then it must explain why this is so. The use of standard phrases:

- "No registration number is given for this substance since it is exempted from the registration requirements according to REACH Annex II and also exempted from Annex V and VI as it is a recovered substance."

- "No registration number is given yet for this pre-registered phase-in substance since the transition period for this registration has not yet expired."

The SDS must include at least the identified uses of the substance or mixture. For registered substances for which CSR is required this list of uses must be consistent with the uses identified in the CSR and Exposure scenario. The uses which the supplier advises against and why shall, where applicable, be stated. This need not be an exhaustive list. For e- mail address of the person responsible for the SDS is advisable to use the address of the company (generic e-mail address), not personal addresses. There is no special requirement that the person must be located within the territory of the EU or EEA.

SDS Section 2: Hazards Identification

This section should describe the hazards of the substance or mixture and the appropriate warning information associated with those hazards.

2.1. Classification of the substance or mixture

- for substance

When supplier has notified the information on the substance to the classification and labeling inventory (C&L inventory), the classification given in SDS must be the same as that provided in his notification. From 1st of December 2011 classification shall be made in accordance with the CLP Regulation.

- for a mixture

If the mixture is labeled according to the DPD Directive - 1999/45/EC (allowed 31st of May 2015) the classification must be indicated according to that Directive: i.e. symbol letter and R phrases, warning signs, hazard categories and phrases and for CMR effects hazard categories. If the mixture is labeled according to the CLP Regulation, then the classification is made in accordance with that Regulations: indication of hazard classes and categories and hazard statements. In the latter case, the classification according to DPD must also be indicated until 31st of May 2015. Both classification should be clearly identified.

2.2 Labeling

For substances labeling elements are those that are defined by the CLP Regulation. For mixtures label elements must be consistent with the product label: DPD Directive or the CLP Regulation 31st of May 2015 CLP Regulation or after 1st of June 2015 elements according to the CLP Regulation includes at least:

• pictogram(s), including a graphical display in color or black and white,

• the danger phrase, H and EUH, in full (or can be given entirely in section 16, if they are listed here),

• the precautionary phrase, P, fully.

Reducing the precautionary label

According to Article 28 (3) of CLP on the label should not be placed more than six precautionary statements, unless they do not arise from the nature and severity of the hazard. Determination of precautionary statements for the label should be in accordance with the CLP Regulation.

SDS Section 3: Composition / information on ingredients

In this section of the SDS states the chemical identity of the ingredient(s) of the substance or mixture, including impurities and stabilizers.

Classification for each substance (each registration number) have to be done according to Directive 67/548/EEC and CLP Regulation 1272/2008/EC. In this section should be made part of 3.1. or 3.2. depending of it if product is a substance or mixture.

3. Composition / information on ingredients						
Substance:	x		Mixture:			
Components contributing to product hazardousness:						
Substance name	Substance identification			[%]	Classification according to Directive 67/548/EEC	Classification according to regulation (EZ) No 1272/2008 (CLP/GHS)
	CAS no.	EC no.	Registration no. (REACH)			
C3-C4	68476 -40-4	270-681-9	01-2119486557-22-0009	100	F+; R12 Carc. cat. 1; R45 Muta. cat. 2; R46	Flam. Gas 1, H220 Muta. 1B, H340 Carc. 1B, H350

SDS Section 8: Exposure controls / personal protection

In this section of the Safety data sheet shall describe the applicable exposure limits in the workplace and risk management measures required.

Occupational Exposure Limit

This section must provide special monitoring parameters including exposure limit values and / or biological limit values. Here you must specify the values that have been published in the Regulation on limit values for exposure to hazardous substances at work on biological limit values. If the Regulations are not the specified value to a particular substance, and there on the European list, these data from the European list here must be entered.

8.2. Exposure controls

The information in this subsection are mandatory if the Safety data sheet is not attached exposure scenario with that information. If a substance is registered as an isolated intermediate (which remains in place or transported), the supplier shall indicate that the SDS in accordance with the specific conditions that justify this registration. Exposure controls means all safety measures and precautions to be taken while using the substance or mixture, in order to reduce to a minimum exposure of workers and the environment. Here you should list all of the information available at the workplace.

SDS section 11 toxicological information

This section is intended primarily for healthcare professionals, experts in the field of occupational safety and toxicologists.

It should provide a brief but complete and comprehensible description of the various toxicological (health) effects and the available data indicate on which these effects are identified, including, as appropriate, information on toxicokinetics, metabolism and distribution. Information in this section must match the information provided in the registration and / or report on chemical safety, if it is provided, and the classification of the substance or mixture.

Information to be provided for the following hazard classes:

(a) acute toxicity;
(b) skin corrosion / irritation;
(c) serious damage / eye irritation;
(d) respiratory or skin;
(e) mutagenicity gametes;
(f) carcinogenicity;
(g) reproductive toxicity;
(h) acute effects - single exposure;
(i) STOT (RE) - repeated exposure;
(g) risk of aspiration.

SDS section 12: Ecological information

In this section of the Safety data sheet should provide information for the purposes of assessing the impact of the substance or mixture to the environment in the event of its release to the environment. This information can be useful for dealing with the spill and in evaluating waste treatment procedures, spill control and the implementation of measures Accidental release and transport.

As needed to provide information on bioaccumulation, persistence and degradability of each relevant substance in the mixture, if they are available. Information should be provided for hazardous transformation products arising from the degradation of substances and mixtures. Assessment of PBT and vPvB substances is now mandatory (Annex XIII of REACH):

• PBT - steadily, bioaccumulative and toxic
• vPvB - very persistent and very bioaccumulative
• PNEC - concentration of the substance below which no expected adverse effects on the environment.

SDS in section 15. Regulatory information

This section of the Safety data sheet provides information on other regulations relating to the substance or mixture, that are not listed elsewhere in the Safety data sheet. Information on substances that are subject to authorization and details of any authorization granted or prohibited must be stated in subsection 15.1. It must be noted, and the use of substances that have introduced some restrictions of use in order to protect the public from the harmful effects of hazardous chemicals. Information about that the supplier conducted a chemical safety assessment for a substance should be provided in subsection 15.2. Data labeling is no longer listed in section 15 shall be given in Section 2.

SDS Section 16. Other Information

This section can be used to specify any other information that is not given in the previous sections. This section may contain an index or contents of the attached Exposure scenario. If you do it here, then you may in Section 1.2. refer on this section. This section may also include recommendations for training workers.

Exposure scenarios in accordance Chemical safety report (CSR)

In accordance with Article 31 (7) of REACH Exposure scenario in SDS must include participant in the supply chain, which is slated to produce a chemical safety report in accordance with Article 14 (registrants over 10 tons / year for classified, PBT or vPvB substances) or Article 37 Exposure scenario registrant adds SDS - in after the reporting on chemical safety as part of the registration dossier to ECHA.

Exposure scenario is a summary with instructions on how to use the chemical safely. Describes the methods and conditions of use and covers the entire cycle of chemicals, different ways of using condition and different Exposure scenarios. Exposure scenario is made only for hazardous chemicals and those PBT / vPvB manufactured or imported in quantities greater than 10 tons per year per manufacturer / importer. In the scenario of exposure necessary to compare the degree of exposure to humans and the environment and compare with numerical values (DNEL, PNEC) based on eco-toxicological and toxicological tests.

Exposure scenario:

• Always refers to one or several identified uses of the substance or mixtures indicated in Section 1.2 of the SDS
• Process conditions
• Operational conditions
• Risk management measures and waste treatment measures
• Exposure estimation and model used
• Information for DU to find out if his use is in the range of described ES

Exposure scenario should be drawn up:

• The manufacturer and importer. The task of each producer and importer of the product is the preparation of exposure scenarios as part of the chemical safety report and registration documents.

All identified uses in the life cycle of the substance, from manufacture through to waste including:

• of uses within your own company
• of uses by your customers
• of uses by companies with chemicals supplied by your customers

When you get the Exposure scenario you need to check whether your current use meets the prescribed requirements. If the conditions that apply different or your use is not covered by the Exposure scenario, you have the following options:

• contact the supplier to include your method of using the Exposure scenario
• to adapt to the conditions of use to that of Exposure scenario
• you can find the other suppliers who have made exposure scenario for your use
• about themselves prepare a Chemical safety report

• use an alternative substance, preparation or process and stop using a given substance / mixture

Impact of REACH and CLP regulation on content of SDS is huge! Content Safety Data Sheet has increased 3-4 times, and Exposure scenario as the addition of up to 10 times or more.

Benefits of REACH and CLP

- safe use of chemicals
- reduce exposure to hazardous chemicals
- avoid occupational diseases
- decreasing of eco-toxicological consequences of chemicals
- harmonized classification and labeling of chemicals
- developing RMM (Risk management measures) – reducing risks, reducing costs from health damage of workers
- developing CSR (Chemical safety report) – more efficient chemicals risk communication
- restriction of chemicals – reducing impact of dangerous chemicals on public health

Companies need to:

• Provide financial and human resources in order to successfully implement the Regulation. Each SDS and label should be changed in order to inform workers and end-users about the dangers of chemicals.

• Conduct training of workers

• Educate end-users of chemicals

• The public should be educated further through flyers

Exposure scenario includes all the uses to which a substance is produced. Reading and consideration of the Safety data sheet is very difficult for the end user. It is necessary to organize training for workers who handle chemicals and for the customers. On this way we can avoid unintended consequences of improper handling or use of that substance.

Exposure scenario for communication among downstream users is a shortened version of the Exposure scenario which is part of the Chemical Safety Report. It is one of the major shifts towards improved communication of information about the hazardous of chemicals.

ECHA has developed Chesar, a tool for Chemical Safety Assessment and Reporting. With this tool registrants will be able to generate Exposure scenarios for communication in a standardized, electronic exchange format directly from their own assessment.

ECHA also supports industry efforts to standardize the phrases used in exposure scenarios and to develop an electronic exchange standard for Exposure scenario information.

LIST OF ABBREVIATION

ABBREVIATIONS	DESCRIPTION	KRATICA	OPIS ZNAČENJA
Chesar	Chemicals Safety Assessment and Reporting tool		
C&L	Classification and Labelling		Razvrstavanje i obilježavanje
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008		Uredba o razvrstavanju, obilježavanju i pakiranju; Uredba (EC) br. 1272/2008
CMR	Carcinogen, Mutagen, or Reproductive Toxicant		Karcinogen, mutagen, reproduktivno toksičan
CSA	Chemical Safety Assessment		Procjena kemijske sigurnosti
CSR	Chemical Safety Report		Izvješće o kemijskoj sigurnosti
DNEL	Derived No Effect Level		Izvedena razina bez učinka
DPD	Dangerous Preparations Directive 1999/45/EC		Direktiva o opasnim preparatima 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC		Direktiva o opasnim tvarima 67/548/EEC
DU	Downstream User		Daljnji korisnik
ECHA	European Chemicals Agency		Europska agencija za kemikalije
ES	Exposure Scenario		Scenarij izloženosti
eSDS	Extended Safety Data Sheet (SDS with ES attached)		Prošireni Sigurnosno-tehnički list (STL s priloženim ES)
IUCLID	International Uniform ChemicaL Information Database		Međunarodna jedinstvena informacijska baza podataka o kemikalijama
SDS	Safety Data Sheet	STL	Sigurnosno-tehnički list
OC	Operational Conditions		Operativni uvjeti
OEL	Occupational Exposure Limit	GVI	Granična vrijednost izloženosti
PBT	Persistent, Bioaccumulative and Toxic substance		Uporno, bioakumulativno, toksično
PNEC(s)	Predicted No Effect Concentration(s)		Predviđene koncentracije bez učinka
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals; Regulation (EC) No 1907/2006		Registracija, evaluacija, autorizacija i ograničavanje kemikalija
RMM	Risk Management Measure		Mjere za upravljanje rizikom
SDS	Safety Data Sheet	STL	Sigurnosno tehnički list
STOT	Specific Target Organ Toxicity	TCO	Toksičnost za ciljani organ
(STOT) RE	(STOT) Repeated Exposure	TCOP	TCO ponavljano izlaganje
(STOT) SE	(STOT) Single Exposure	TCOJ	TCO jednokratno izlaganje
vPvB	Very Persistent and very Bioaccumulative		vrlo uporno i vrlo bioakumulativno

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