

Implementing REACH and GHS

Brief information

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The 1st of Dezember 2010 poses an important landmark for the implementation of REACH and GHS. This day the new provisions for classification and labelling of substances and new requirements for the Safety Data Sheet become mandatory. It is also the deadline of the first transition period for REACH registration.

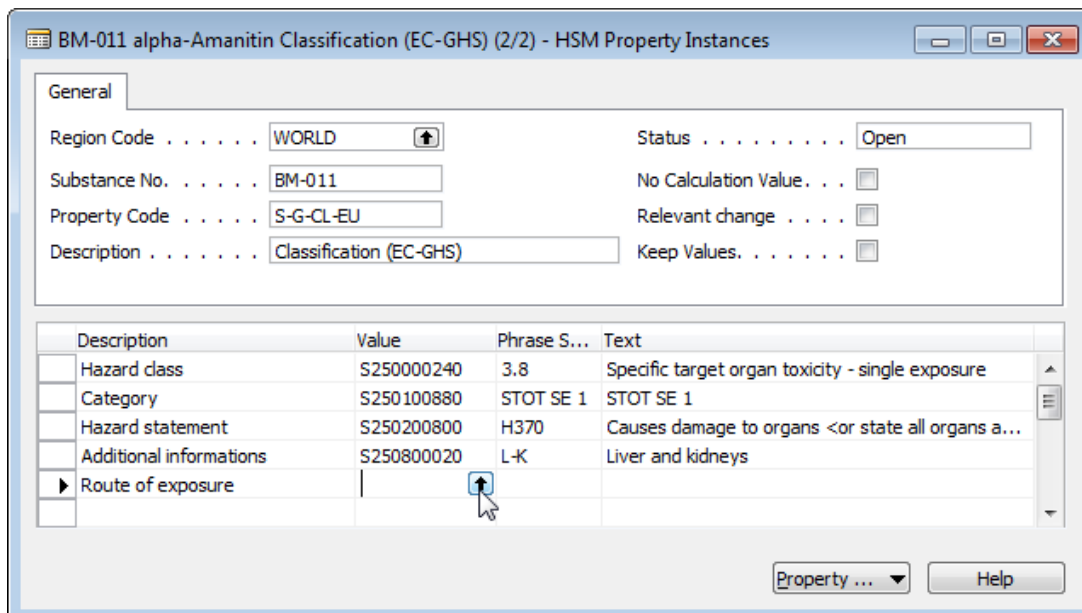
Especially the new SDS provisions make an update of the HSM module necessary.

1 Classification and Labelling

1.1 Substances

From 01.12.2010 substances must be classified and labelled in accordance with the CLP¹ Regulation (EC GHS Regulation). For substances marketed already before 01.12.2010 this gets mandatory only on 01.12.2012.

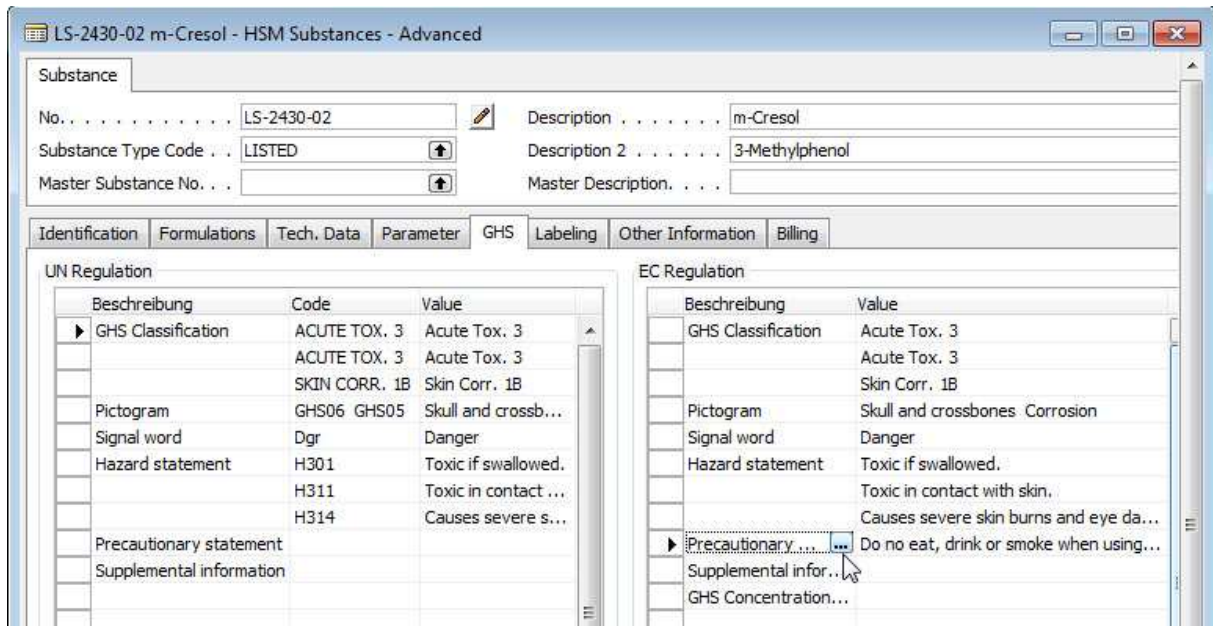
The still current HSM version already allows entering of the new classifications and labelling elements (hazard pictograms, signal words, hazard²- and precautionary statements³) according to the installed set of languages. The substance data of Annex VI of the CLP Regulation (Harmonised classification and labeling) are available too.



¹ Classification, Labelling and Packaging of Substances and Mixtures

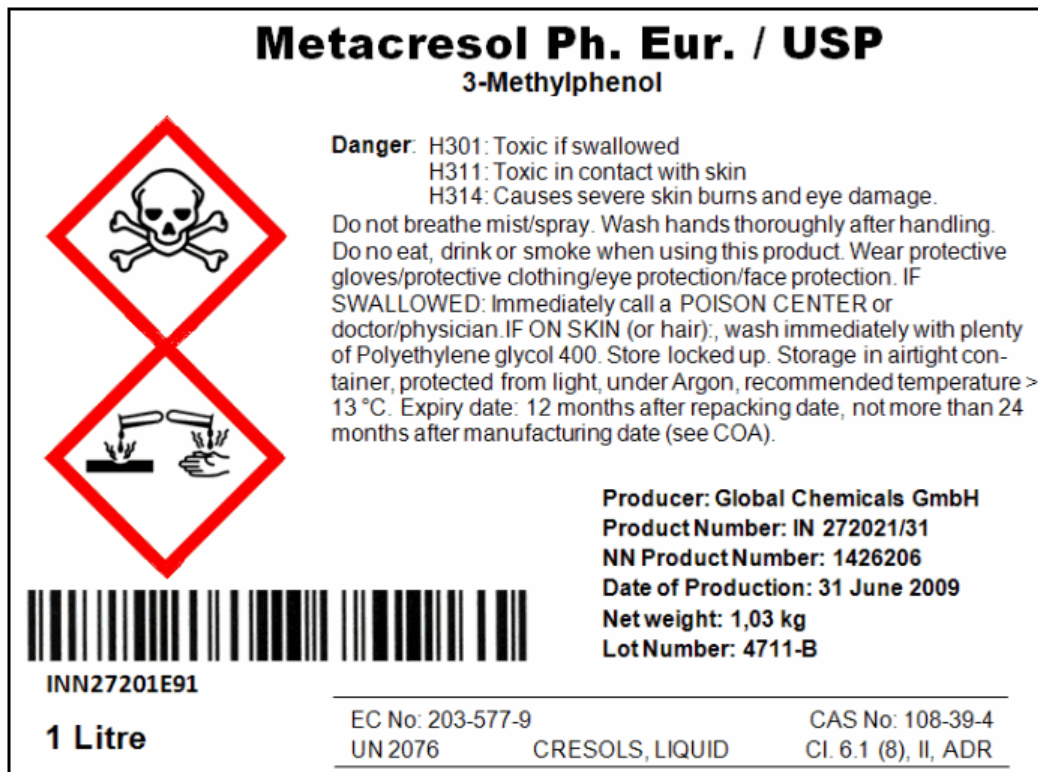
² H-phrases

³ P-phrases



The HSM label printing module is already prepared for the generation of CLP-compliant labels, which poses higher layout requirements. For example, it is not possible any longer to print black pictograms on a orange coloured surface, and the new pictogram shape needs more space.

Also the precautionary statements cause problems. According to the labelling tables for some substances there can be 50 or more, whereas the regulation regards 6 P-phrases sufficient in general. An ECHA working party with representatives of authorities, industry and the Commission shall make practical recommendations for this issue.



In order to enable manufacturers of mixtures to furthermore classify their products according to the old substance legislation, substance manufacturers have to give information in accordance with old and new law in their Safety Data Sheets. But on the substance label, from 01.12.2010 for newly packed substances only CLP classification is allowed.

1.2 Mixtures

With respect to classification and labelling, manufacturers of mixtures may proceed as usual until mid 2015.

Nevertheless, from 01.12.2010 Safety Data Sheets must be generated in accordance with the current version of the REACH Regulation (s. b.), also if classification is made according to the old law. For existing SDSs there is a two years transition period.

Prosisoft plans to provide the calculations for mixtures according to CLP early 2011, so that the users may become familiar with the new classifications and labelling elements. In practice, most manufacturers will not yet apply these in the coming year. It is recommendable to wait with application, especially because valid toxicity data of substances are not available in most cases. Toxicity data are necessary for suitable classification results with respect to acute toxicity. This situation will become gradually better during the REACH implementation process.

In HSM the labelling calculations according to CLP will not be carried out in an external module (DLL) but directly in NAV. A prerequisite for that is the installation of the FCC (Flow Chart Calculator) Prosisoft tool.

With this tool all kinds of decision trees can be represented in NAV, simply by adding entries to the relevant FCC rule tables. This way not only GHS classifications can be calculated but also VOC contents according to the EC Decopaint Directive, evaluations according to the EC Detergents Regulation, TSCA listing, check for SVHC substances⁴ etc.

2 Safety Data Sheet

2.1 New Layout

From 01.12.2010 the provisions of the REGULATION (EU) No 453/2010 for amending the REACH Regulation with respect to Annex II (Safety Data Sheet), published 31.05.2010, will become mandatory. These provisions apply to substances and mixtures. If they have been put on the market before 01.12.2010, there is a transition period until 01.12.2012.

The regulation contains two annexes, which differ mainly by the fact, that in the final Annex II the references to classification and labelling according to the old EU law are omitted.

Annex I will replace Annex II of the REACH Regulation by 01.12.2010 and will be replaced in turn by the Annex II of Regulation 453/2010 on 01.06.2015. For mixtures put on the market before 01.06.2015 there is a transition period until 01.06.2017.

The general structure with 16 sections will stay. Important changes among others are:

⁴ Substances of Very High Concern (ECHA Candidate List for the authorization process)

- (Sub-)section headings according to Part B must be displayed / printed in any case, i.e. even there are no corresponding data available.
- In Chapter 2 besides the classification also the labelling including the S- and/or P-phrases must be displayed. Hazard symbols, hazard pictogram respectively must be displayed as graphics mandatorily.
- In Chapter 15 only the information not yet mentioned in the previous chapters must be displayed. E.g. the a.m. information of Chapter 2 does not to be displayed again here.
- For Chapter 16 there are more detailed specifications.

Prosisoft will provide an update for the new requirements.

2.2 Extended Safety Data Sheet

On 01.12.2010 the first registration deadline for substances ≥ 1000 t p.a, CMR substances ≥ 1 t p.a. and R50/53 substances ≥ 1 t00 p.a. will expire. From this time the manufacturers of mixtures, as Downstream Users (DU), will more often receive so-called Extended Safety Data Sheets (eSDS) with attached Exposure Scenarios (ES) from their raw material suppliers. The safe uses described there must make sure that expositions and emissions of all ingredients of the product are below the DNEL⁵ und PNEC⁶ limit values derived from (eco-)toxicological data.

The DU is obliged to forward the information contained in the ES in the supply chain in appropriate time, i.e. generate eSDSs for his own products. How this is to be done, is not regulated in detail by the lawmaker. It is e.g. possible to

- copy or scan the ES and attach them to the own SDS. This way it not possible to focus on specific conditions of use of the customer, and the ES is not transferred into the corresponding SDS language.
- enter the standardized phrases ((e.g. according to the descriptor system of the ECHA) of the supplier's ES into the hazardous substance management system, if necessary omit descriptors not relevant for the customer's uses, and generate the ES in the desired language.
- apply the DPD+ Method developed by CEFIC⁷. Based on the resolved formulation a lead substance is defined for each path or exposure (or emission). For this purpose for all substances and hazards a LSI⁸ is determined, which calculated by concentration, limit according to DPD⁹ and volatility, if necessary. The OCS¹⁰ und RMMs¹¹ of the lead substance should also cover all other ingredients with respect to this path of emission.
- use so-called Generic Exposure Scenarios (GESs) for groups of substances and mixtures.

Prosisoft will provide descriptors for Sectors of Use (SU), Product Categories (PC), Process Categories (PROC) etc. as phrases and design configurations. In this field of processes the FCC (s.a.) could be

⁵ Derived No Effect Level (human beings)

⁶ Predicted No Effect Concentration (environment)

⁷ European chemical manufacturers association

⁸ Lead Substance Indicator

⁹ Dangerous Preparations Directive 1999/45/EC

¹⁰ Operation Conditions

¹¹ Risk Management Measures

helpful as well and e.g. be used for the determination of the lead substances of a mixture, if the DPD+ Method is applied.