

Today's newsletter is dedicated to the topic of Basic substance data, which in the meantime is significantly characterized by the impact of REACH and GHS/CLP and - especially in the current phase of the final replacement of traditional classification and labelling according to EU directives - means increased demands on hazardous substance management.

1 BASIC SUBSTANCE DATA SOURCES

For the Listed substances maintained by ProsiSoft we rely on official and semi-official sources (CLP Regulation ¹, ECHA ² website, EFFA ³). On the one hand there is now REACH registration data available and published on the ECHA website for a growing number of Basic substances, on the other hand the list of so-called harmonized classifications is continued as well in Annex VI of the CLP Regulation.

1.1 Annex VI CLP Regulation

This means for example, that even for Listed substances in the narrow sense, i.e. the substances listed in Annex VI to the CLP Regulation, suppliers may circulate different classifications and labellings.

This is also explainable, because Annex VI actually has a certain degree of liability only for the CMR hazards (carcinogenicity, mutagenicity, reproductive toxicity), and respiratory sensitization. Additionally, in the acquisition of classifications from the old Annex I of the Substances Directive the principle of the (provisional) minimum classification was applied, since often no clear reclassification was possible due to different criteria.

It also happens that in respect of certain hazards, such as acute toxicity or corrosion/irritation, no classification is given at all (this concerns mainly newer entries). Also, the lack of information on CMR properties does not mean that the substance in question has none of the corresponding hazards. Rather, manufacturer or supplier shall evaluate them on their own responsibility.

1.2 ECHA C & L Inventory

Currently, for substances placed on the market and pre-registered under REACH there is still no classification harmonized within registration consortia. The (sometimes widely different) classifications collected in the ECHA C & L Inventory are sorted after all by the number of the respective notifications. Often - but not always - a particular classification is clearly dominating. However, we have included such information only in exceptional cases in our data pool.

1.3 ECHA data on registered substances

For substances registered under REACH, ECHA publishes data taken from the submitted registration dossiers on its website. Naturally, information on areas of use and exposure scenarios may be changed or extended over time. However, even intrinsic substance data, in particular the classification and labelling data, can still have a preliminary character. We will include this information in our data pool step by step.

¹ Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (including corrections and amendments)

² European Chemicals Agency

³ European Flavour Association, formerly: European Flavour and Fragrance Association

2 NEW HSM SUBSTANCE DATA CONCEPT

In summary it can be stated that substance classifications are subject to change in increasing numbers and shorter periods - especially compared to times of the legal classifications listed in Annex I of the Substances Directive, which could be considered "set in stone". But in certain cases deviations from substance list entries were permitted even then.

Example: petroleum products, for which leaving off classification as carcinogenic with R45 or H350 was/is allowed under certain conditions (supplier information). In these cases, we recommended that you should create a copy of the relevant Listed substance and at this copy remove the cancer classification.

Now, the ability to create a copy with persisting connection to the original Listed substance - instead of an "encapsulated" copy of the Listed substance, which is no longer covered by updates through Prosisoft - would be desirable.

The upcoming new HSM data concept is aimed precisely in this direction. This concept will allow you, starting from a Listed substance at your fingertips to create a Basic substance with a reference on the Listed substance, which generates default values of the respective property values of the Basic substance. Individual property values can be modified while the connection is cancelled for that property. After deleting a modified value, the connection will be re-established, the same way you already from template substances (masters).

We will also send you information about whether there have been changes for the referenced substances from the Prosisoft original database.

3 INFORMATION ON DATA MAINTENANCE STATUS

In addition to the substance data itself we will also provide information on the maintenance status of the data delivered or deliverable by Prosisoft - i.e. metadata - in future. It will involve information on whether classification data according to the GHS resp. CLP, DSD ⁴ is present, if the substance is classified as dangerous at all, if the state of aggregation is known, if a WHC classification ⁵ is available, if there are occupational exposure limits. In the future, we could also inform about whether toxicity data are available.

Note: The metadata provided by Prosisoft in the future refer to the full Prosisoft substance data inventory, regardless of whether you have purchased the corresponding data package.

Currently, there is already a corresponding property Maintenance status ⁶, which you can use and configure yourself. It is best displayed on Advanced Substance Form (see below), so you can see all the information (instances) at a glance.

⁴ Dangerous Substances Directive (EU Substance Directive). It will expire by 1. June.2015 also for mixtures.

⁵ Since Prosisoft only delivers the Water Hazard Class classifications officially published by the UBA (German federal environmental authority), this information is especially important.

⁶ We will post the information on our substance data in a new property, so that both your own entries and the information of Prosisoft can be consulted when applying the new HSM substance data concept.

Identification	Formulations	Tech. Data	Parameter	GHS	Labeling	Ot
Maintenance status						
Description		Status				
Classification (DPD/DSD)		Not classified as hazardous				
Classification (EC-GHS)		Maintained				
Workplace exposure limits		Data available				
Water Hazard Class		Not maintained				
Acute oral toxicity		Maintained				
▶ Ecotoxicity data		Not maintained				

As always, we are grateful for your comments and suggestions. Maybe we will take them into account already in our next newsletter.



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