Prosisoft Modules, Rule Sets and Data

Remarks on price list positions and tasks related to the system implementation

1 CONTENTS

2 PREFACE

The company name of Prosisoft GmbH is now Selerant GmbH. The name "Prosisoft" remains as the name of the product line Selerant HSM (German: Selerant GSM). In the following we use "Selerant GmbH" in connection with the activities and obligations of the company, whereas "Prosisoft" is used in connection with the product components of the HSM.

3 SOFTWARE MODULES

3.1 5101510 – HSM – Basic Module

The HSM Basic Module contains all tables, forms and functions required for the administration of master data, the region related administration of substance data (hazardous substance and dangerous goods data), and multilingual phrases (text modules).

With this module multilingual and region related Safety Data Sheets (SDS) can be generated, released and dispatched automatically based on the available data and phrases. The hierarchical region model also allows to implement an automatic redispatch of updated Safety Data Sheets for a certain region (e.g. for all EC countries) on incrementation of the corresponding version number (release number).

In the context of the automatic distribution of SDSs it will be checked whether a shipment must be accompanied with an SDS. This check includes the date of delivery of the items and SDSs and the corresponding versions in relation with the respective customers.

3.2 5101520 – HSM – Calculations

One module component calculates the classification and labelling of mixtures in accordance with the GHS and numerous further classifications and evaluations (see 4.5). The results generate data for the Sections 2,3,8,15 and 16 of the Safety Data Sheet (SDS). This makes the substance data for the issue on hazardous substance labels available too. The number of covered GHS implementations will be continuously expanded as needed.

Another component determines a proposal for dangerous goods classification for the transport modes land, sea and air. This generates the data for Section 14 of the SDS and thus the data for the generation of transport documents and for transfer to further downstream systems.

Note:

The substance classifications according to EC Directives DSD / DPD are no longer required since 1.6.2015 for the labeling and the creation of SDSs. However, currently the a. m. dangerous goods classification is still partly based on these classifications [1].

We are also currently redesigning the dangerous goods classification and transferring it to the Flow Chart Calculator FCC described below. In the foreseeable future, the separa-

[1] After importing a patch, the GHS classifications are transformed in DSD classifications („R-phrases“). Then the old classifications are really obsolete.

te dangerous goods calculations contained in this granule will therefore no longer be needed.

The FCC is tool, a function, which allows to process flow charts (decision trees), represented in configuration tables. The determined results can be stored in data containers defined for these results and put out in reports/documents.

Examples of application are the master assignment, data evaluations according to Seveso III Directive or Detergents Regulation, calculation of GHS classifications, metal contents, food allergen evaluations, display of ingredients in SDS sections 8, 11 and 12, Decopaint Directive, calculating the contents of certain substances or substance groups and much more.

After training and practise experienced users may conceive and configure their own evaluations. Since the rules are stored in tables accessible by the user, it is easy to make customer specific adaptations.

Rule sets (see 4.5) developed by Selerant GmbH are delivered in the form of Excel sheets and imported into the system by standard import tools (see 5101560 - Dynamic Migration 3.10). These rule sets are delivered by Selerant GmbH as data. They are sold as licenses and are subjected to maintenance (further development and optimisation). Since modification by the user/customer is possible, a comparison of the rule sets is necessary before updates.

This granule also comprises the Tool Settings, which are used for various customer- and process-specific system settings.

3.3 5101530 – HSM – Dangerous Goods Processing

This module generates all documents relevant for dangerous goods: transport documents in accordance with ADR (with determination of exemptions and score according to the transport category (1000-Points-Rule)), transport documents (shipper's declarations) for sea- and air transport, i.e. IMO- and IATA-Declaration.

On the next configuration level, which may be implemented **customer specificly**, further data can be determined based on the calculated dangerous goods profiles. Thus packaging provisions and -advices, packing together prohibitions per shipment in order to support the employees at the packing station. The number of packagings for the respective modes of transport depending on the ordered volumes to be delivered can be determined as well. The variety of different procedures requires a thorough analysis and description of the proceeding established at the customer, which can then be configured and implemented accordingly.

3.4 AdvF – Advanced Form

Using this advanced user interface allows the arrangement of workplace and topic related data groups and thus the efficient entering and maintenance of data. Master data as well as determined data can be displayed. The arrangement of all HSM property attributes can be configured by the user. Only the arrangement of the tabs (Classic Client) or Fast Tabs (RTC) has to be modified by Selerant GmbH.

For the use of this tool further object licenses are necessary.

3.5 FI – Formulation Integration

This function establishes an automatism, which makes recipes (development recipes or production recipes) of the ERP section of NAV available in HSM and builds the link between NAV items and HSM substances. The process rules for this interaction are configured in this module.

For the implementation there is always a detailled definition of the processes necessary. Rules and triggers must be clearly defined and agreed for an optimum in efficiency. A. o. it must be agreed which is the leading system.

In special cases the development of formulations/recipes and the management of formulation/recipe versions can be done within HSM.

Normally the recipe development and thus the product development is carried out in the ERP section.

This Prosisoft module can be adapted to the customer's needs without big programming effort, only by the setting of parameters.

Questions to be answered in context with implementation

- Is there a development of recipes?
- If yes, in which section/department is it carried out?
- Are development recipes already to be assessed with respect to their hazardous properties?
- How do development recipes become production recipes / BOMs?
- When does a product become an item?
- When should the transfer to HSM take place? When should the link between NAV item and HSM substance be established?

For the use of this function further object licenses are required.

3.6 5101540 - FCC – Flowchart Calculator

The FCC is now contained in the granule HSM – Calculations (see 3.2).

3.7 5101550 - Research Module

The research module offers the possibility to use all NAV tables, be it in HSM - be it in the ERP sector, for building evaluation macros. In order to protect sensible tables from access, the usable tables can be released for user specific access by the administrator.

For using this module knowledge of the basic data structure of the enterprise is important. The application may be simplified via creating often used evaluation macros by skilled users, which then can be run simply.

Sets of substances and items determined by a research can be stored in substance collections, which are available for further evaluations. Moreover collections can be used for downstream processing as well. Example: It is determined in which recipes / formulations substances of a certain property value are used. For the concerned mixtures (raw materials, products) a new calculation and versioning shall be carried out.

This module can be run only on a SQL database. The installation of views via execution of SQL scripts is necessary (for this a description is available). The installation of the FCC Module 5101540 is required as well.

3.8 Hazardous substances inventory

For the real-time data update of an enterprise's hazardous substances inventory (in Germany according to § 6 (10) GefStoffV (Hazardous substances ordinance)) we also offer a solution with a fixed configuration according to the customer's requirements. We configure a query on the specified tables of the NAV ERP and the desired output attributes of ERP and HSM part of your NAV system, such as CLP- and dangerous goods classification, Water Hazard Class, Seveso III category etc.

The inventory is then actualised on the push of a button. The output is usually generated as an Excel spreadsheet, which can be further processed in reports. As an option items currently not on stock can be included as well.

3.9 Determination of dangerous goods quantities for annual reports

In accordance with the local requirements, e.g. in Germany the Gefahrgutbeauftragten-Verordnung (GbV = Ordinance on dangerous goods officers), the goods processed in a selectable reporting period are grouped according to dangerous goods classes and quantity ranges in order to facilitate the preparation of the annual report by the enterprise's dangerous goods officer (tool in preparation).

3.10 5101560 – Dynamic Migration (DYM)

The HSM module is highly parameterised, has dynamic property data structures (the so-called Design), and the FCC calculations are stored in configuration tables. The exchange of such configuration data between NAV installations takes place via Excel files in RIM format.

This granule facilitates this exchange by numerous functions. Thus exports and imports can take place also batch-wise i. e. including multiple tables. Export filters can be set. Prior to the actual import of data, there are profound comparisons between the source and target data, which allow to respond to the results with specific import options. This granule is mandatory for NAV 2013 and higher.

3.11 Label Tool

In principle the label tool is a function based on the HSM standard data acquisition routines which provides the collected data as an XML file [2]. The scope of data, the file structure and the generation process have to be defined. This is basically configuration work.

A customer specific adaptation of the function is possible.

For the formatting of labels (layout) we recommend the use of a respective software, which is able to process the data from HSM as downstream function.

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[2] If only a small number of different label formats are used, an alternative is to use a function for creating RTF files, which is implemented by some GSM users.

After training with this kind of software the customer can prepare an arbitrary number of formats. The control based on agreed criteria must be implemented by Selerant GmbH in the individual case.

The calls of this function must be specified and implemented. Experience has shown that this can be done at different process positions

- On posting a production order. In this case it has to be decided whether it should be a warehouse label or a shipment label. As a consequence the scope of data will be different and must be considered.
- Release of a sales order
- Release or creation of a transfer order
- Etc.

3.12 Extended User- and Rights Administration

This function is based on the NAV role principle. In addition, it is possible to grant rights for certain properties, for certain substance types or others like that.

This tool is mostly controled by entries in tables too, so that each enterprise can create its own user- and rights concept.

Apart from the detailled description delivered by Selerant GmbH, a training is regarded useful in order to configure the rights in an efficient and low-maintenance way.

3.13 Extended manual document dispatch

The HSM Basic Module (5101510 – HSM – Basic) contains the logics for the automatic Safety Data Sheet dispatch. This dispatch function intends printing of the Safety Data Sheets to be distributed.

Already sent SDSs may be selected and sent again via a selected shipping mode to the customer.

The advanced feature adds many useful features such as

- Documents can be sent in batches.
- Documents can be compiled and sent via various order types.
- It is possible to subsequently create and send SDSs for other regions and languages.
- Already sent versions or new versions of SDSs can be sent.

3.14 Web application; Delivery on customer's request

After implementation of the Web application registered customers can log in with their password and request documents (SDSs) for specific items and regions/languages. These are then automatically generated and sent by email to the registered address.

3.15 Notifications according to Article 45 CLP Regulation

In accordance with the requirements of Article 45 CLP Regulation, for all dangerous substances/mixtures information must be forwarded to a national authority. In Germany this authority is the BfR (Bundesinstitut für Risikobewertung). In principle, a respective functionality can also be set up according to the requirements in other EU countries.

Of course, notifications according to the new Annex VIII of the CLP Regulation will also be included in our offer as soon as the reporting formalities still under discussion are specified.

3.15.1 ISi notifications

In Germany for a transitional period suppliers may send the respective SDSs to the ISi service (information system for safety data sheets) of the Institute of Occupational Safety and Health. Selerant GmbH provides such a tool.

3.15.2 BfR notifications

For the transfer of the required data in accordance with the XML scheme issued by the BfR Selerant GmbH provides the respective tool.

3.16 Batch Log – Calculation

In the standard calculation buffer results are shown after a manually triggered calculation, before data are taken over into the database. Within the scope of automatised calculations the calculation results are logged. A post-processing from the log is possible.

3.17 Laboratory test calculations

A production BOM can be calculated on a test basis without the results changing the productive HSM data.

The module supports the formulation development in the laboratory. Changes to a BOM can be checked for HSM-relevant effects. The HSM substance actually belonging to the production BOM item or a formal reference substance with the corresponding classification can be used as reference.

The production BOM is transformed virtually into an HSM formulation and is calculated using the product-related data of an HSM reference material. The result data is compared with the data of the reference substance and the comparison is displayed.

By default, the reference substance selected is the substance that is assigned to the article to which the production BOM belongs. If no substance can be determined in this way, a formal reference substance can be selected, whereby the substance list for the reference substance type stored in the setup is prefiltered.

The function is part of the basic granule, the setup and configuration, process-related, can be set up individually.

3.18 QDI – Quick-Data-Input

QDI is a configurable data entry assistant. With this wizard, the user can configure sequences of properties or property attributes (like lower value and unit) respectively - if necessary with default values - belonging to certain areas of data, so that one can scroll through this sequences and enter the corresponding data. properties or property attributes may be defined as mandatory if necessary. This can prevent that important entries are forgotten.

Any number of topic-related acquisition sequences can be configured. The user can easily do that by himself or ask Selerant GmbH.

A basic configuration with macros for the collection of important data for calculation and safety data sheet for mixtures and raw materials is included. For further configuration packages see 4.6 .

3.19 PSS Relation

By means of the function PSS Relation, relations between entities that are stored in different tables are taken into account in processes. For example, certain regions could be assigned to special SDS views so that, after request of a document for this region, the associated view is taken. Another example: For certain customers may be stored, which document types (e.g. SDS, Technical Data Sheet, Certificate of Analysis) are to be delivered to them in an automated process.

3.20 Advanced Report Generator (ARG)

This tool can be used to create custom reports with special requirements in terms of the layout, for example the presentation of data in tabular form. As a first ARG report application Selerant GmbH can deliver the workplace instruction with extended layout and also a hazardous substance label based on Office Word.

3.21 Batch generations of SDSs / Meaningful file names

Safety Data Sheets can be created batchwise for a region / language combination, also with individually configured file names in order to provide e. g. on a CD or via file transfer.

3.22 Auto completion

This feature is included in the standard and offers the opportunity to define by configuration, information filled in automatically, depending on a certain input elsewhere. Example: The input of an H-phrase in the properties GHS classification or GHS labelling effects referencing of other data such as hazard class, category, pictogram, signal word, etc. If no clear dependency exists, appropriate values are pre-filtered. This also works between different properties, e. g. classification -> labelling.

In addition to the basic configuration delivered together with this function, Selerant GmbH can give support concerning the installation of additional configurations.

3.23 PSS Import/Export

This tool can be used for the comfortable and performant import (resp. export) of data from tables of common database systems into NAV tables, where different data structures can be linked together.

3.24 Advanced Formatting

This extension allows, by means of an additional configuration table, to modify the output formatting of property attributes, e.g. numerical information, in dependence of a variety of conditions. Examples:

- Value depending: Content information can be put out e.g. in mg/kg in ppm respectively (of course including conversion), limited to a certain number of decimals or even completely suppressed.
- Region depending: Temperatures can be put out in °C or in °F (with numerical conversion) including the appropriate decimal separator.
- Substance specificly certain properties may be evaluated, e.g. in order to suppress information in certain reports.

3.25 Factbox (since NAV 2015)

With this extension certain information oft he currently focussed list entry can be displayed in a fact box, e.g. GHS classification, flash point etc. of a Listed substance. This display is configurable.

4 DATA

4.1 Design configurations

Instead of rigid data structures, for the acquisition and output of data views (e. g. EU SDS), chapters (the 16 SDS sections for example) and properties (e. g. GHS classification, flash point, etc.) are stored in configuration tables. These definitions are called design. They are supplemented by formattings which are assigned to the properties view-specific, so specific information can be output in a specific layout depending on a certain report (view).

These configurations can be customised and extended with little effort. Finished design configurations are available for the EU Safety Data Sheet (already included in HSM Basic granule), the US SDS, the workplace instruction[3], the Extended SDS incl. Exposure Scenarios, a data sheet for the internal documentation of all classifications and evaluations as well as a datasheet for the documentation of WGK classification (see 4.5.1.7) . Customomer specific reports like Conformity declarations, Certificates of analysis or technical data sheets can be configured by Selerant GmbH according to customer's specifications or by the user himself.

4.2 Substance data

Selerant GmbH delivers substance data, which are used for the calculation of classification and labelling and are printed on legally required documents like SDSs, as far as they can be obtained from officially available sources and are processed by Selerant GmbH.

Since these data are intended primarily for the HSM and the product name Prosisoft is still used for this product line, in the following we talk of the Prosisoft substance inventory etc.

On our customers‘ request further data if digitally available in the enterprise can be processed and imported, if unique assignments via key IDs are possible.

4.2.1 Basic substances and basic substance data

4.2.1.1 Basic substances

The basic substances delivered comprise:

- all substances Annex VI of Regulation (EC) No. 1272/2008 (EU-GHS, CLP) in accordance with the corresponding “ATPs” resp. Amending Regulations,
- all substances of the ECHA Candidate List in accordance with Article 59(10) of the REACH Regulation,
- further substances, which are listed in the respective national workplace exposure limits (air limit values),
- optionally: further substances contained in the Code of Practice (CoP) of EFFA (European Flavour Association)

[3] The workplace instruction is available in a simpler and in a more complex layout generated via the Advanced Report Generator (ARG).

4.2.1.2 Basic substance data

4.2.1.2.1 Substance identification numbers

This is by default (if available)

- EC number,
- Index number,
- CAS number,
- REACH Registration number, when published, without manufacturer's suffix.

If identification numbers are not unique, only one number is maintained.

Also references to the Dangerous Goods Key (see below) and Marine Pollutant entries were included.

4.2.1.2.2 Substance descriptions

Substance descriptions according to Annex VI of EU Regulation 1272/2008 (CLP) in various major languages, if available (including synonyms). The substance names of Regulation 2018/669 ("11th ATP") will be included in the database in the course of 2019, so that as of 1.12.2019 all Annex VI substances will have descriptions in (almost) all EU languages.

The EFFA substance descriptions are only available in German and English, the descriptions of EFFA natural extracts only in English.

4.2.1.2.3 Data for classification and labelling

Classification and labelling data according to Annex VI EC Regulation 1272/2008.

For substances other than those of the „Annex substances" the manufacturers' data or data published by the ECHA were taken over, for EFFA substances the data of the EFFA CoP.

If necessary the Annex VI data are replaced or completed by ECHA (European Chemicals Agency) data from the respective registration dossier.

At present, information on classification and labelling (without S-phrases) is still supplied according to the old DSD directive. This will be discontinued in the future [4].

4.2.1.2.4 Workplace exposure limits

The respective nationally defined limits for workplace air (long and/or short term) are delivered . On demand biological limits for substances or metabolites (e.g. BAT values) are quickly available too. If several limits (e.g. general or process specific) exist for a substance, the most stringent limit was taken over.

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[4] For the classification of hazardous substances, the R-phrases of the DSD were used in some cases. After importing a patch object file, this information is derived from the corresponding GHS H-statements. Above all, this patch has the positive effect of no longer having to enter any DSD data for user-created basic substances (and possibly derived from the GHS labelling beforehand).

For multiple information one substance (e.g. state of aggregation or fraction specific or general and process specific), the most stringent limit was entered for the substance. After revising the respective data port or XML port in the HF5 program version, we will be able to transfer several limit values per substance and region into your HSM installation.

It is not the lists as such, which are delivered, but the values assigned via a certain substance or substance group. It was made sure that for each group entry (e.g. “manganese compounds”) there is at least one substance contained in the substances delivered, which can be used as a template for other substances entered by the user.

For the following regions exposure limits are available or planned. The limit data are to be ordered separately for each list.

Belgium	
Denmark	
Germany	
Estonia	
Finnland	
France	
Greece	
UK	
Holland	
Ireland	
Italy	
Latvia	
Lithuania	

Norway	
Austria	
Poland	
Portugal	
Sweden	
Switzerland	
Slovakia	
Slovenia	
Czech Republic	
Spain	
Hungary	
USA	ACGIH TLV or OSHA PEL

Data on biological limit values are under preparation.

4.2.1.2.5 Substance inventories

For the following substance inventories for a substance it is marked whether it is contained in the respective inventory. Thus the data for the listing evaluations by FCC are provided (see 4.5.5.1).

Australia	AICS	
China	IECSC	
Europe	EINECS	
Europe	ELINCS	
Japan	ENCS	
Japan	ISHL	planned
Canada	DSL	
Canada	NDSL	
Korea	ECL	
New Zealand	NZIOC	
Philippines	PICCS	
USA	TSCA	

Selerant GmbH understands these list assignments as an aid without claiming to be complete. In other words, it may happen that the registration status of individual substances is not yet recorded in the Prosisoft database or that substances are registered only confidentially or based on inventory-specific IDs (in the TSCA inventory: PMN and ACC numbers, not CAS-based) [5]. The user then may have to do some research himself.

For a few inventories (TSCA and IECSC (as of 2013)) "complete" lists of all registered or non-confidential registered substances are issued - allowing a quick comparison, for other inventories a single search, e.g. be done through a website.

If a basic material is created by the user himself, the standard function "Substance Reference Check" can be used on the basis of CAS no. be checked whether this is present in one of the "complete" lists, and the assignment is entered in the material properties. The TSCA list (about 68,000 entries) is currently supplied as standard.

An adjustment of basic materials, which are entered or maintained by the customer, with substance inventories can be offered by the Selerant GmbH as a service according to effort.

[5] The descriptions for these entries like "Tetrasubstituted dioxadithiane" where not compared with the Prosisoft substance data inventory.

4.2.1.2.6 Further listings

The following assignments can be delivered or are planned. They provide data for the FCC mass based evaluations as well as for the calculations of WGK (or WHC, for region DE) and the MAL-Codes (region DK), see 4.5.1.7, 4.5.1.8, 4.5.6 and 4.5.7.

Germany	WGK	
Germany	TA-Luft class	planned
Denmark	MAL-Factor	planned [6]
IMDG	Marine Pollutant	
Switzerland	VOC Ordinance	
EU	VOC according to Decopaint Directive	
EU	VOC according to Solvent Directive	
EU	ECHA Candidate List („SVHC“)	

4.2.1.2.7 Physico-chemical data

Physico-chemical data for basic substances are currently not delivered, because they are not necessary for the classification of mixtures.

4.2.1.2.8 Toxicological data

Valid toxicological data will become available in the course of the stepwise implementation of REACH on publically accessible sources. These data will be of high importance for the classification of mixtures in accordance with GHS [7]. It is planned to make them available in the database, if there are publically available (official) sources, which can be evaluated with reasonable effort.

Data for the classification of mixtures in accordance with the criteria of the GHS hazard category 3.1 (acute toxicity) are available for a large number of important Prosisoft Listed substances and can be delivered in the future [8].

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[6] Currently the MAL-Factors for the ingredients of a mixture are derived from the Danish air limit (if available) or from the classification of the substance.

[7] For the calculation of the Acute Toxicity Estimates (ATE), the Flowchart Processor FCC has always been able to use both the values given in Table 3.1.2 of the GHS Regulation (according to the classification of the ingredients) and the actual LD_{50} and LC_{50} values, if present and not marked as "No calculation value").

[8] After toxicity data for (exactly) one substance, namely nicotine, was published for the first time with the 10th ATP amending Annex VI of the CLP Regulation, the XML port (or dataport) used to import the GHS data has been extended in this way, so that also toxicity data can be transmitted.

4.2.1.3 *Maintenance status*

The substance data also include some metadata describing whether data is available for specific substance properties at all. In particular, when new substances are added to official lists, it may happen that no classification data is currently available or that, due to the lack of knowledge of the physical state, no dangerous goods profile can be assigned.

The maintenance status currently includes the following instances:

- Physical state validated [9]
- Classification (DPD/DSD) [10]
- Classification (EC-GHS)
- Water Hazard Class
- Workplace exposure limits
- Dangerous goods assignment
- Candidate List Annex XIV

The status values of these instances are e.g. "Maintained", "Data available" etc., possibly also "Not classified as hazardous". The property "Maintenance status listed substance" [11] is displayed in the properties tree under "Regulations (Basic Substance Maintenance) / Other Regulations" and in the Fast Tab or tab "Identification" of the Advanced Form.

4.2.1.4 *Remark on completeness and correctness of substance data*

The systematics of official substance lists entails that complete records of a uniformly defined data extent are not available. Substance lists in many cases contain e.g. "minimum classifications" or "partial classifications", where the relevant data are to be completed by the distributor of the material, if necessary, or even adjusted or corrected. The scope of substances of the official substance lists is different. The use of group names generates diverse intersections, so that a specific substance may not be clearly assigned to a set of hazardous substance data.

The Prosisoft substance database is carefully maintained and constantly extended and updated; nevertheless both such a substance database as a whole and individual material records can never be defined as final, complete, or "correct".

The Prosisoft substance database provides a valuable resource in basic substance data maintenance and serves for the efficient provision of calculation input data. When used for calculation of productive mixtures the user is obliged to check completeness and adequacy of the data in each case.

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[9] At present, the state of aggregation is entered directly in the HSM substance table or card / page as solid, liquid or gaseous. The value "unknown" is not provided. These rigid entries will be converted to HSM properties in a future HSM version.

[10] Will be discontinued soon.

[11] For entering the maintenance status information with respect to activities of the user, another property "Maintenance status" is available as well.

4.3 Dangerous goods data

Dangerous goods classification profiles are taken over from the ADR, IMDG and IATA publications into tables and are available for the calculations and output on the respective documents, e.g. the IMO Declaration or Section 14 of the SDS.

Proper shipping names are currently available in German, English, French, Dutch and Italian. Extensions of the language scope can be made available as needed.

4.4 Phrases

Text modules (phrases) are delivered in an extent which

- enables the internal control of the software (internal phrases). Principally they aver delivered in German and English. Thhe user interface is also delivered in German and English by default. Further user interface languages can be provided in cooperation with the NSCs of the respective countries.
- makes text labels (captions, pre-texts) and the entire statements available in currently 30 languages. Further languages can be provided on demand.

Selerant GmbH offers the languages in packages:

- Western Europe (DE, EN, DA, ES, FI, FR, IT, NL, NO, PT, SE)
- Eastern Europe (BG, CS, HR, HU, PL, RO, SK, SL)
- Further languages (LT, LV, ET, RU, EL, TR)
- Chinese and others (CN, BS, JA, KO, SR)

Phrases for the Extended Safety Data Sheet (in accordance with the European REACH Regulation resp. with the EUPhraC phrase catalogue) are provided in German and English. Further languages can be purchased from a partner company of Selerant GmbH.

4.5 Rule sets (FCC)

The FCC- and design-configurations are delivered as RIM or DYM files. DYM is an extended RIM tool by Selerant GmbH. The installation of the Flow Chart Processor (FCC) itself is a prerequisite.

Currently the following rule sets for the FCC can be delivered:

4.5.1 Various calculations

4.5.1.1 Display of PBT- and vPvB ingredients

Basic substances can be provided with the information that the substance is a PBT or vPvB substance.

If these substances are not already considered as hazardous ingredients within the scope of the CLP calculation in Section 3 of the SDS, they shall be indicated under the label "Other hazardous ingredients" with the corresponding reasoning.

At the product, a corresponding remark is added to Section 12 of the SDS.

4.5.1.2 *Labelling acc. Biocide Products Regulation (EC)528/2012*

According to the Biocide Products Regulation (BPR), products which have been treated with biocidal products or to which biocidal products have been added must be specially labelled. The nature of the labelling depends on the nature of the biocidal product; Formal requirements are widely non-existing.

Biocidal agents, which are to be declared, are maintained at the basic substance level and, where appropriate, additional texts are assigned. The resolved formulation of a product is evaluated for biocides. If relevant ingredients are found, these are labelled "Contains a biocidal product:" and possibly additional texts in the Section 2 of the SDS.

4.5.1.3 *Chemical characterisation*

In the case of product families which are of mixtures of characteristic raw materials and are tailored to specific areas of application with defined technical properties, it is frequently possible to determine a generic chemical characterization for Section 3 of the SDS. This is intended to make a statement on component groups and non-hazardous components and not as a replacement of the information required by Annex II, Section 3.2 of Regulation (EC) 1907/2006.

Examples:

- Detergent based on: water, organic surfactant(s), perfume(s)
- Colored masterbatch based on: ethylene-propylene copolymer, pigment(s), additive
- Dispersion of: water, dye(s), resin

The text modules forming the statement, i.e. phrases for the charactering the product type and phrases for the ingredient types can be defined by the user. By default , the statement would only put out if the calculation detects ingredients with characterications (= assigned characterisation phrases).

The algorithm could also be extended that way that a certain default phrase is put out if no product characterisation is found etc.

Characterisations of ingredients are displayed in descending order by percentage without duplicates, if percentage > 10 (default) or a substance specific limit.

4.5.1.4 *Seveso III Directive (Design, Configuration, Rules)*

Based on H phrases and hazard pictograms the general hazard categories according to Directive 2012/18/EU (Seveso-III) and the corresponding volume levels are determined. The results are taken over into a respective property and are displayed in Section 15 of the SDS.

The configurations for design and FCC rules can be imported with RIM or DYM.

4.5.1.5 *Detergents Regulation (Design, Configuration, Rules)*

Within the scope of the FCC calculation declaration lists according to Regulation (EU) 648/2004 (Detergents Regulation) are generated:

- Data sheet for medical staff (ingredients according to Annex VII Section C)
- Data sheet on ingredients of detergents for the public

- Additional labelling (labelling according to Annex VII Section A)

If a product is marked as „Detergent“ (data management), the ingredients are analysed and aggregated in accordance with the detergent group assignments and identification data maintained by the user and written back into the respective properties.

The “labellings” are put out into Section 15 of the SDS. The data sheets can be generated via specific HSM report views.

The FCC- and design-configurations are delivered as RIM or DYM files and are integrated into the HSM design during installation.

In the basic package the data sheets are triggered manually. If the documents shall be generated in processes, these have to be defined anf implemented.

4.5.1.6 Master assignment (incl. 18 Masters)

Based on substance labelling a product is assigned to one of 18 categories, and a predefined model Safety Data Sheet (Master) is automatically assigned to the HSM substance.

The 18 masters, the FCC calculation- and design configurations are delivered as RIM or DYM files and are integrated into the HSM design during installation.

4.5.1.7 Water Hazard Class (WGK)

The WGK will be calculated according to the German AwSV for issue in Section 15 of the SDS for the region Germany. In addition, the self-classification documentation report will be generated for controls by the monitoring authorities.

4.5.1.8 MAL Code

The Danish MAL Code is determined on the basis of the recipe, the ingredients- and product data.

4.5.1.9 GHS Pure substance calculation

For a product containing one component at a percentage close to 100% (this criterion is set in the configuration), the properties according to the CLP Regulation stored at the corresponding raw material resp. ingredient are transferred to the product.

This option is valuable especially for products which are retailed in the supply chain without further processing (maybe apart from decanting) and where the raw material classification and -labelling can be adopted from the supplier.

4.5.1.10 Property value assignment (Autocompletion) CLP Regulation

By means of this configuration, on input of a certain value, e.g. an H-phrase, the assigned values for classification and labelling according to CLP Regulation are determined as filter set and - in case of uniqueness - automatically entered.

The property value assignment greatly facilitates manual data entry, especially for raw material and basic substance maintenance.

4.5.1.11 *Property value assignment (Autocompletion) measured value defaults*

With this configuration of defaults, after a value input (e.g. a density or fish toxicity), the standard unit, unit for reference quantities or with toxicity values, common value types and species are automatically prefilled.

The property value assignment greatly facilitates manual data entry, especially for raw material and raw material care.

4.5.1.12 *NFPA calculation and output*

The hazard rankings of the NFPA (National Fire Protection Agency) are calculated and put out on the US SDS in the form of the “NFPA Diamond”.

4.5.1.13 *HMIS calculation and output*

The hazard rankings of the HMIS (Hazardous Materials Identification System) by the American Coatings Association) are calculated and put out on the US SDS in the defined form (highlighted in colours).

4.5.1.14 *Determination of pictograms for workplace instruction*

The obligation and prohibition pictograms according to EN ISO 7010 are determined based on the hazardous substance classification and put out on the workplace instruction (internal plant instruction).

4.5.1.15 *Food allergens*

All raw materials of a product are checked whether they have been manufactured based on food allergen sources listed in the Directive 2003/89/EC resp. Directive 2006/142/EC (so-called Annex III a of Directive 2000/13/EC).

4.5.1.16 *Storage class Germany (TRGS 510) and Switzerland*

Storage classes are be determined in accordance with the flow chart in Annex 4 to the German TRGS 510. This classification is primarily based on CLP and dangerous goods classification as well as other regulations. The result of the classification is precisely one (1) storage class for one product. The storage classes form the basis for the storage compatibility concept of the TRGS 510.

This calculation also determines the storage class for Switzerland acc. to the „Leitfaden für die Praxis: Lagerung gefährlicher Stoffe“ (Practical guidance for the storage of hazardous substances of the Northwestern Swiss cantons)

In principle, calculations for other national concepts can be implemented too.

4.5.2 *Physicochemical data*

4.5.2.1 *Flash point estimation*

The calculation package allows the estimation of flash points from a recipe. The determined value is not the result of a flash point calculation as first time admitted in CLP

Regulation (EC) 1272/2008 under strict basic conditions. It should be understood as a reference point and should not be used just like that for classification purposes.

It is therefore written back into a special property. Not only is the numerical value of temperature (for the lowest flash point of the existing ingredients) considered but also the percentage of the ingredients (thus allowing to assess the relevance of the result).

4.5.2.2 Density estimation

The density of a product is calculated based on the proportions and densities of the components of the staged formulation, i.e. on the raw materials (whose density is usually communicated by the supplier via the SDS).

It is actually the arithmetic average density without consideration of thermodynamic mixing effects, which for many mixtures is a good approximation.

4.5.3 Evaluation of ingredients

4.5.3.1 (Eco-)Tox data display in SDS Section 11/12

Within the scope of FCC calculation a scan of all basic substances of the resolved formulation is performed. If for a certain ingredient there are data available on toxicity and ecotoxicity and if the ingredient exceeds a certain percentage, it will be stored as substance reference with the product data, so that these ingredient substance data can be displayed in Sections 11 and 12 of the product SDS.

FCC calculation- and HSM design configuration are delivered as RIM or DYM files and are integrated into the HSM design during installation.

4.5.3.2 DNEL/PNEC display in SDS Section 8

Within the scope of FCC calculation a scan of all basic substances of the resolved formulation is performed. If for a certain ingredient there are DNEL/PNEC data available and if the ingredient exceeds a certain percentage, it will be stored as substance reference with the product data, so that these ingredient substance data can be displayed in Section 8 of the product SDS.

FCC calculation- and HSM design configuration are delivered as RIM or DYM files and are integrated into the HSM design during installation.

4.5.4 Toxicity comments in SDS Section 11

By Regulation 830/2015/EU, the information requirements related to health hazards in Section 11 of the Safety Data Sheet have been explicitly extended. Accordingly, the hazard classes acute toxicity, skin irritation/corrosion, serious eye damage/ eye irritation, respiratory sensitisation, skin sensitisation, germ cell mutagenicity, carcinogenicity, reproductive toxicity, specific target organ toxicity after single or repeated exposure and aspiration must always be mentioned in this section.

Via the FCC the product classification regarding the a. m. hazard classes is checked. If the product is classified accordingly, for the remark attribute of the corresponding property in Section 11, the phrase "The classification criteria are met." is determined otherwise

the phrase "Based on available data, the classification criteria are not met." as specified by the regulation.

Thus, besides realizing the requirements via SDS master, there is now a function, in particular in combination with the toxicity data designation (see 4.5.3.1), powerful calculation rules are available to generate individual and sophisticated toxicity information for mixtures with a high grade of automation.

4.5.5 Evaluation of listings

4.5.5.1 Inventory status evaluation

Via the basic substances formulation of a mixture it is checked, whether each relevant ingredient is marked as assigned to a chemicals inventory. If all ingredients are listed a result phrase is generated (which can be put out on the SDS as well). Substances with no positive listing status are displayed for internal evaluations respectively reports.

By configuration it is possible to switch the evaluation from basic substance level to the raw material level.

By default the rules are defined restrictive, i.e. for a positive result the ingredient must be marked explicitly positive. This setting can easily be changed by configuration of the default rules.

The following inventory status evaluations are readily available as single packages (further evaluations may be configured on request):

4.5.5.1.1 TSCA (USA)

4.5.5.1.2 DSL/NDSL (Canada)

4.5.5.1.3 AICS (Australia)

4.5.5.1.4 PICCS (Philippines)

4.5.5.1.5 IECSC (China)

4.5.5.1.6 NZIOC (New Zealand)

4.5.5.1.7 ENCS (Japan)

4.5.5.1.8 ECL (Korea)

4.5.6 Quantity calculations (elements and other substance classes)

Selerant GmbH takes over the assignment of substances to these listings into his substance data respectively allows the users to do so. Via the FCC calculation a formulation can be checked for occurrence of these substances.

Assignments can be made in accordance with the evaluation type for basic- or listed substances but also for raw materials, if necessary with percentages.

4.5.6.1 VOC-CH / VOC-EU

VOC stands for Volatile Organic Compounds, where volatility may be defined in different ways. VOC substances or -substance groups in accordance with the Swiss incentive tax are collected in a list. VOC according to the EU Solvent Directive are defined by the vapour pressure.

It is desirable of course to communicate the result of this evaluation via the Safety Data Sheet. There is a respective information designed in Section 15.

4.5.6.2 Evaluation of contents of certain chemical components

Via the raw materials formulation of a mixture it is checked whether components contain quantities of certain chemical characterisations, which are not entered as explicit formulation components (e.g. rest monomers, solvent content etc.).

The total share of the respectively maintained components is determined and displayed for internal purposes or reports.

By configuration it is possible to switch the evaluation from raw material level to the basic substance level.

The definition of components to be considered can be easily extended.

4.5.6.3 Evaluation of contents of certain physico-chemical components

Via the raw materials formulation of a mixture it is checked whether components contain quantities of certain chemical characterisations, which are not entered as explicit formulation components (e.g. solids etc.).

The total share of the respectively maintained components is determined and displayed for internal purposes or reports.

By configuration it is possible to switch the evaluation from raw material level to the basic substance level.

The definition of components to be considered can be easily extended.

4.5.6.4 Evaluation of halogen contents

Via the raw materials formulation of a mixture it is checked whether components contain quantities of halogens or halogenated compounds not entered as explicit formulation components.

The total share of maintained halogens (e.g. “chlorine”, “halogenated organic compounds”, etc.) is determined and displayed for internal purposes or reports.

By configuration it is possible to switch the evaluation from raw material level to the basic substance level.

4.5.6.5 *Evaluation of metal- and heavy metal contents*

Via the raw materials formulation of a mixture it is checked whether components contain quantities of metals and heavy metals, which are not entered as explicit formulation components (e.g. solids content etc.).

The total share of the maintained metal- and heavy metal contents (e.g. lead, chromium, silicones, etc.) is determined and displayed for internal purposes or reports.

By configuration it is possible to switch the evaluation from raw material level to the basic substance level.

The definition of components to be considered can be easily extended.

4.5.6.6 *Evaluation of pigment contents*

Via the raw materials formulation of a mixture it is checked whether components contain quantities of metals and heavy metals, which are not entered as explicit formulation components.

The total share of the maintained pigment contents (e.g. “inorganic pigments”, “organic pigments”) is determined and displayed for internal purposes or reports.

By configuration it is possible to switch the evaluation from raw material level to the basic substance level.

4.5.7 *Evaluation of releases and certificates*

Via the raw materials formulation of a mixture it is checked whether each relevant component meets the requirements of certain certificates, e.g. with respect to heavy metal contents.If this is the case for all components then a positive result phrase is generated otherwise a negative one. Components without a positive list status are displayed for internal evaluations respectively reports.

By configuration it is possible to switch the evaluation from raw material level to the basic substance level.

By default the rules are defined non-restrictive, i.e. for a negative result the conponent must be marked explicitly negative. This setting can easily be changed by configuration of the default rules.

The following release status evaluations are readily available as single packages (further evaluations may be configured on request):

4.5.7.1 *Annex XIV- and Candidate List substances („SVHC evaluation”)*

According to Article 33 Paragraph 1 of Regulation (EC) No. 1907/2006 (REACH) the information on the occurrence of certain SVHC (Substances of Very High Concern) in a product have to be passed in the supply chain, even without request of the customer. These substances are published in the ECHA candidate list for the authorization procedure.

Candidate substances and substances of Annex XIV (basic substances!) are marked in the property "Regulative product categories". For the product (mixture), all raw materials of

the formulation according to this marking are put out in two corresponding properties in Section 3 of the SDS.

In Section 15 of the Safety Data Sheet a result phrase is put out if none of the mentioned substances is available. In the view Product Data the possibly found substances are listed.

4.5.7.2 Decopaint Directive

Based on data maintained on the level of basic substances and of the product the formulation of the product is analysed and the percentage of VOC substances in accordance with the VOC definition of Directive 2004/72/EC (Decopaint Directive) is determined. The percentages are converted by the density in g/l.

The results are written back into a property and can be put out in Section 15 of the SDS.

4.5.7.3 CONEG release

The contents of Pb, Cd, Hg, Cr (VI) in a product are summed up from the components and are compared with the requirements based on CONEG (Coalition of Northeastern Governors) respectively Directive 94/62/EEC on the content of heavy metals in packaging material.

4.5.7.4 EN 71-3 release

The contents of Pb, Cd, Hg, Cr (VI) and some other elements in a product are summed up from the components and are compared with the requirements of the EN 71-3 toy standard.

4.5.7.5 Food package printing release

It is checked whether the ingredients of a product (a printing ink) are contained in the positive lists, which are part of the various regulations on materials in contact with foodstuffs.

4.5.7.6 Phthalate release

The phthalate contents of raw materials are evaluated and put out on reports.

4.5.8 Special substance group assignments

4.5.8.1 Diaryl pigments

The substance group assignment is made for raw materials. The diaryl pigment contents according to the resolved formulation are evaluated and put out. If a certain concentration is exceeded, a hint is given in the SDS.

4.5.9 REACH calculations

4.5.9.1 REACH Compliance Check

This calculation is a compliance test, in which it is determined, whether the raw materials used in the product are suitable for the intended uses of the product.

It is checked whether the range of uses of raw materials (as reported by the supplier's use descriptors) are in line with those of the product (in accordance with the relevant information of the buyer).

4.5.9.2 REACH Content Declarations

This calculation provides the REACH relevant information of the raw material given by the supplier (e.g. the risk characterization ratio) to be displayed resp. put out by way of reference in the exposure scenario.

It can be defined in the raw material maintenance whether the raw material is relevant for REACH comparison at all respectively whether it contains ingredients relevant for output.

4.5.9.3 REACH Exposure Scenario Assignment

This calculation assigns the appropriate predefined group exposure scenarios to the product. In order to acchieve this selection, on one hand the degree of hazard of the product (as determined by the assigned master substance) is considered, on the other hand the product's ranges of use (as determined by the assigned use descriptors).

4.5.9.4 Evaluation of the REACH registration status

The lists evaluation of the REACH registration status of formulations checks the registration status of all components of a resolved formulation, i.e. based on ingredients resp. basic substances.

The list evaluation is based on the requirement that for the ingredients their registration type (Full dossier etc.) is entered together with the status (listed, not listed, unknown, irrelevant). During the calculation all ingredients are screened and it is checked whether all of them have a positive registration status. If so, this is documented with a result phrase. If an ingredient does not have this status, it is stored in a list with the respective product for further examination.

4.5.10 GHS classification and labelling

Currently, the following GHS implementations are available in HSM. Further implementations are in preparation.

4.5.10.1 EU GHS (CLP Regulation)

Based on the available product- and ingredient data there are classification proposals in accordance with GHS (CLP Regulation 1272/2008/EC respectively) determined and taken over into the respective properties of the product. For the labelling according to EU law

there is a postprocessing, which is aimed especially at the reduction of the number of P-phrases in direction of a maximum of 6, where possible.

4.5.10.2 US GHS (Hazard Communication Standard)

On the basis of well-maintained product and ingredient data, the classification and labeling of mixtures is carried out according to the GHS implementation of the USA. The US GHS does not deal with the environmental hazards, and other deviations from the EU-GHS (e.g. Category 4 Flammable liquids) are taken into account. There is no P-phrase reduction.

4.5.11 Calculations for the US SDS

Shortly mixture calculations for the new US SDS [12] will be available. These include

- Classification and labelling according to the OSHA Hazard Communication Standard (implementation of GHS in the US) published by the US Dept. of Labor. See 4.5.10.2
- Calculation of the HMIS and NFPA rankings (still used)
- Comparisons of formulation components with various lists of substances such as SARA Title III, California Proposition 65, etc.

4.6 Configuration for the Quick Data Input assistant (QDI)

Quick Data Input assistant (QDI) 3.18 further macros are available:

4.6.1 Tox- and ecotox data

In the QDI view, the QDI macro leads through the most important properties and attributes with toxicological and ecotoxicological data and facilitates the collection of these data, in particular for basic substances.

5 OTHER ACTIONS

The following actions and prerequisites have to be taken as well:

5.1 Lizences for the Tools

The Granules 5101510 to 5101560 if necessary (depending of the scope of the installation) have to licensed at Microsoft.

For the items of Selerant GmbH's offered tools the customer has to provide / communicate free object licenses, so that Selerant GmbH can convert the numbering according to these license numbers. As an alternative thee customer can order new licenses for the object numbers mentioned in the offer.

[12] The new Safety Data Sheet according to the US GHS implementation is called SDS in order to distinguish it from the old MSDS.

In principle, all modules and function blocks are only possible with objects licensed by Microsoft.

5.2 Execution of SQL Scripts

With these scripts SQL views are created, which are necessary for the functioning of the Research Module. The form the basis oft he perfomant execution of complex queries.

Option 1:

The customer adapts and runs the SQL scripts. In the scripts the placeholder „DATA-BASE“ must be replaced by the database name and “MANDANT” must be replaced by one of the companies (must be done for each company of the database).

Option 2:

Selerant GmbH adapts the SQL scripts. For this Selerant GmbH need the database name and the names of **all** companies of this SQL database. The customer executes the scripts.

Option 3:

Selerant GmbH executes the scripts.In this case Selerant GmbH needs access tot he SQL Server (SQL Server Management Studio) with the necessary rights.

5.3 PDF - Printer

For the automatical and manual dispatch of documents (Safety Data Sheets) the installation of a PDF printer on the respective client is required.

So far there is experience with:

- Acrobat Distiller
- Free PDF
- PDF-Creator
- e-Doc-Printer

Others PDF generators may be tested and adapted on request.

5.4 Label printing software

For processing label data provided by HSM as XML files into formatted label (i.e. of a certain layout) the installation of a label- or layout software is necessary. There is experience with Crystal Reports. Other software, like List & Label, EB-Soft etc. on request.

6 TERMS

HSM	Hazardous Substance Management
ERP	Enterprise Ressource Planning
FCC	Flow Chart Calculator
NSC	Navision Solution Center
GHS	Globally Harmonized System

7 MAINTENANCE / UPDATES

The maintenance costs comprise the permanent optimisation of the modules and data. Extensions are only part of the maintenance as far as they refer to existing basic functionalities and safeguard, that the user meet his legal requirements. Extensions referring to fundamentally new functions (currently e.g. the determination of hazard classes and categories of GHS) are not covered by maintenance.

7.1 Software / Objects

In the area of software, NAV standard objects and HSM objects may be affected by extensions and optimization. In this case Selerant GmbH provides the actualised objects to the IT specialists of the enterprises who can then import the objects into the database installations of their enterprise.

For this purpose the delivered objects must be merged with the respective ones installed at the customer, if necessary. In a modification documentation Selerant GmbH communicates the modifications made to the customer.

7.2 Data

Data stands for structure data (design), rule tables and substance data.

7.2.1 Design

In this context for Selerant GmbH the term „Design“ stands for the configuration of the structures of entering, maintenance and output of data. Updates for this are delivered in the form of RIM files (Excel files). Since customers may have done own design changes before the actual update a comparison of design is necessary. This can be done by the customer, Selerant GmbH offers support for this. This proceeding is recommended, since Selerant GmbH has the suitable tools for making the comparison quick and efficient.

7.2.2 Rule sets

The statements in 7.2.1 also apply to the various rule sets. In principal customers may modify and extend them. Therefore prior to the update intensive communikation between the customer and Selerant GmbH is necessary.

7.2.3 Data

The delivered data content is actualised if required. For data and phrases there exist dataports by which the data of the system may be actualized. Selerant GmbH deliveres the current data as text files.

8 MAINTENANCE

The maintenance cost is 16 % annually on the software modules and 24 % on the data. Maintenance revenue going to the Selerant GmbH in full.