Guideline for the development of a Material Health Statement (MHS®) – Version 2.0

Introduction

The MHS® is a voluntary statement to inform interested customers about the expected health properties of a product during its intended use phase and in a defined target scenario for productive after-use management.

The MHS® serves the customers' needs for information on a product's chemical safety. It goes beyond safety datasheets in which the specifications for composition declaration are limited to intrinsically dangerous substances with a content exceeding high thresholds (depending on properties defined for example in Art. 31 of the European Regulation 1907/2006 [1]).

The MHS® does not address physical risks like ingestion of small products or parts thereof by children. It is restricted to risks associated with chemicals that it contains, especially those that could emanate from the product during its use and after-use management and could be taken up by biological systems, including the users of the product but also the open environment.

The reporting format "MHS®" is a trademark of the EPEA Internationale Umweltforschung GmbH, which performs the assessments underpinning the statement.

The assessment of precursor products (production inputs) taking place as the background of the MHS® generation encompasses environmental benefits and detriments connected to the production stage as well as to the production of involved precursors.

Through regular updates, the MHS® offers the possibility to measure progress resulting from the evolution of recipes during its validity period.

This document sums up the applied rules and resources used for the generation of a MHS®:

- Frame conditions for the development of a MHS®
- MHS® structure, document tracking and embedding of the MHS® in the documentation of the producer
- Product Inventory: Information origin and quality
- Inventory of hazard/safety properties of chemicals
- Assessment: Information processing
- How confidentiality specifications are dealt with
- MHS® update frequency

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18. December 2006.

Frame conditions for the development of a MHS®

A product MHS® is developed together with producing companies, i.e. entities that are legally responsible for the quality of their products. The MHS® supports communication on products of companies who apply or explore application of Cradle to Cradle Design principles in their strategy for transformation to an environmentally beneficial industrial actor. A company is seen environmentally beneficial when it is using its influence in the business environment to invite and support suppliers to adopt these principles and when it invites customers to support investment for further progress by purchasing the product as it is at a point in time.

The product MHS® describes the level reached at a point in time on the way to positive material definition of the product. The positive material definition encompasses:

- Inventory: Knowledge of the product composition and knowledge of the composition of supplier products.
- Impacts: Evaluation of the product composition regarding its safety for users and in defined scenarios for productive after-use management.
- Declaration of the product composition and impact evaluations broken down to the chemical level.

With positive material definition as the goal of product optimization, the MHS® reflects work in progress along two lines of development:

- Optimization of the material definition may require intensified relationships with suppliers, who may have to overcome fears concerning unfair treatment of their know-how. Solutions being able to be offered in a positively defined way may require time.
- (Eco)toxicology is a young scientific discipline and knowledge on chemicals is also subject to progress with time.

The generation of a MHS® is a service of the independent third party EPEA aimed at producing companies and their suppliers.

MHS® structure

The MHS® is an EPEA document on a producer's product or product group. It contains the following design elements:

- The product and its manufacturer
- Date of issue and validity period
- Evaluation threshold
- After-use scenario(s) that the producer foresees
- EPEA document registration number
- A table with the following elements
    - List of chemicals identified in the product, or a placeholder mentioning whether they are undefined or defined but kept confidential. Chemicals may be grouped according to their function in the product
    - Relative amount in the product

- EPEA's assessment rating with an explanation
- A statement on the pure substance with relevance for American and European markets.

The product MHS® can be a standalone document. Alternatively, it can be integrated in the producer's documentation but still recognizable as an EPEA document. In any case, it contains a reference to the present document on the applicable assessment methodology. It may also contain a reference to external documents of the producer dealing with their concept for the use and after-use management underlying the assessment process at EPEA.

The MHS® exists in 2 forms that differ by having or not having a confidential technical annex. The confidential annex contains a recapitulation of the recipe information and of input assessments to which problematic chemical components can be traced back.

The variant with the confidential annex exists in 2 exemplars, one for the records of the producer and one for EPEA. The variant without the confidential technical annex is for release at the producer's convenience.

Product inventory: Information origin and quality

The starting point for the generation of a MHS® is the production recipe of the producer. It includes the bill of involved materials (BOM) and standard technical documentation attached to each involved supplier product (TDS), as well as product safety information the producer has a legal right to access (safety datasheets - SDS).

This information is complemented with information on the chemical composition and/or the production process that is voluntarily provided by supportive suppliers to fill inventory gaps. It may be delivered by the supplier to his customer and to EPEA, or only to EPEA. In the second case EPEA acts as a trustee.

A product MHS® development process strives for an understanding of the chemical composition that is as exact as possible, Striving for exactness is however modulated by striving also for relevance and plausibility of sufficiency (e.g. the exact chemical composition of a native wood raw material may be in most application cases irrelevant to address).

Full material definition is however not a prerequisite for developing a first product MHS®. The MHS® describes a product as it is at a point in time, including the extent to which it is still undefined.

The chemical composition of a product is qualitatively and quantitatively derived from the composition of precursor products. Chemical transformations happening during the production process as well as the contribution of precursor products to byproducts (not entering the product composition) are taken into account during their assessment. This assessment is kept outside of the scope of declaration, however.

It is the composition of the product that is declared in the MHS®. Chemicals contributing at least 100 ppm to the overall product make-up are evaluated.

The chemical composition of a product is rendered as a list of chemicals identified by their CAS number and their concentration relative to the total mass as %, ppm, ppb, etc.

The inventory quality control is based on verification of the conservation of mass after transformation of precursor products (before the process) to products and byproduct (after the process) and can also rely on laboratory analyses to verifiy the match between reality and expectations.

The inventory is done as exactly as possible as it is the basis of assessment of the product's health and safety properties during use and after-use operations.

The inventorising process can be stopped when:

- sufficient information is already available for optimization, e.g. in case of availability of environmentally better performing alternatives as low hanging fruits for optimization.
- suppliers decline to deliver information going beyond SDS and TDS.
- the necessary resources would be disproportionate to the expected result.

If recycled content is involved, it's chemical make-up is approached with information on its origin and with laboratory analyses. If a chemical is originating both from recycled and from virgin materials, contributions are summed-up in one figure per chemical.

The global contribution of the recycled content to the chemical make-up of the product is highlighted in the MHS® table.

If the chemical make-up of the recycled content cannot be approached reliably, the recycled content is listed as a component on its own.

The balance between exactness and sufficiency of inventory is determined by the assessor relying on his/her experience.

The object of a MHS® can be a single product or a group of similar products. In case of a product group MHS®, chemicals are declared and evaluated when they exceed 100 ppm in at least one product of the group.

Quantitative composition information is given as exact value or as range.

Inventory of hazard/safety properties of chemicals

Chemicals involved in the product inventory receive a statement relating to the pure substance.

The addressed chemical hazard/safety properties and applied classification rules are described in the guidance on material health assessment in the Cradle to Cradle certification standard [2].

The Cradle to Cradle methodology for assessment of chemicals does not foresee aggregation of individual intrinsic hazard/safety properties in one single statement, as yet. Currently, the following statement formats applying to the pure substance are used:

- The GreenScreen classification, with relevance on the US market and accessed via Toxnot [3]
- The occurrence in the European listing of substances in Annex XIV and XVII of the REACH regulation 1907/2006 and in the list of Substances Of Very High Concern that are candidates for inclusion Annex XIV (SVHC list) [4, 5, 6].

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[2] Cradle to Cradle Product Innovation Institute. Cradle to Cradle Certified™ Resources. Material Health Assessment Methodology.
http://www.c2ccertified.org/resources/detail/material_assessment_methodology
[3] https://toxnot.com/
[4] List of substances included in Annex XIV of REACH ("Authorisation List").
https://echa.europa.eu/en/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
[5] Substances restricted (Annex XVII of REACH). https://echa.europa.eu/en/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list
6 Candidate List of substances of very high concern for Authorisation.
https://echa.europa.eu/en/candidate-list-table

Sources used to profile chemicals for their hazard/safety properties are listed in the annex to this document.

Assessment: Information processing

The product inventory and safety information on chemicals are combined for risk assessment. The result of the risk assessment is a “Concern” statement on the chemical in the context of the product use and after-use management. The assessment results are presented as follows:

: Beneficial, no concern

: Moderate concern

: Concern due to risk of exposure of users or environmental systems to hazardous chemicals

: Unknown risk of exposure of users or environmental systems to hazardous chemicals

The chemical risk assessment depends on the possibility and intensity of exposure to hazardous chemicals emanating from the product (emission) and being taken up by biological systems, including humans during use and environmental systems after use (immission).

The risk assessment includes:

- Evaluation of qualitative exposure routes of biological systems to chemical components of products:
  - oral, dermal and inhalative exposure during use by humans
  - aquatic and terrestrial environmental routes for short and long distance exposure during and after use
- Estimation of quantitative exposure resulting from:
  - product emanations as volatile emissions or as eluates.
  - chemical dissociation and anticipated transformations of the product by disintegration, dilution or thermal treatments during and after use.
- Intrinsic exposure enhancement properties of chemicals including:
  - low vapour pressure and boiling point for volatility
  - high bioconcentration and bioaccumulation potentials resulting from their lipophilicity
  - persistence (resistance to chemical and biological degradation) in the environmental compartments that may reached in the course of use and after-use management
- Consideration of scientifically Derived No-Effect-Levels (DNEL) and levels of beneficial exposure

A comment addresses reasons for a substance to be classified in the product context with:

- high concern
- moderate or no concern when the pure substance is classified with borderline or high toxicity

Distinction between “moderate concern” and “absence of concern” is difficult. A precautionary approach is applied by labeling for “moderate concern” when the “absence of concern” is difficult to justify clearly.

How confidentiality specifications are dealt with

Confidentiality specifications of the producer or of suppliers are dealt with by replacing the chemical identity with the following placeholders and corresponding meanings:

Proprietary 1: The producer knows the component but does not want to declare it for know-how protection; EPEA is informed about the component that has been rated as the pure substance and in the product context.

Proprietary 2: The producer does not know the component but EPEA knows it because EPEA knows the composition of the supplier product it is originating from. The component has been rated as the pure substance and in the product context.

Proprietary 3: Neither the producer nor EPEA knows the identity of the chemical components but the inputs to which it can be traced back are defined. The supplier is expected to know the chemical composition of his contribution to the producer's BOM. The component has not been rated as a pure substance and is labelled as in the product context.

Undefined: Neither the producer nor EPEA is aware of the identity of the chemical component of the product but the inputs to which it can be traced back are defined. The supplier does not know as well and can not estimate reliably the chemical composition of his contribution to the producer's BOM. The undefined component is not rated as a pure substance and is labelled as in the product context. This case can apply for example for mixed recycled content.

MHS® Updates

The MHS® development process is also a process for identification of opportunities

- for optimization of the factual knowledge on the chemical make-up of a product to understand its health performance
- to increase the health performance of the product by evolution of recipes towards safer ones.

MHS® documents have a validity period of 2 years. The juxtaposition of a MHS® update with the former version allows progress measurement along these two lines of health performance development.

Resources used at EPEA *(Not exhaustive)*

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