

Eurocolour position paper on the concepts of MOCS

The EU Commission published in November 2020 a first thought starter on the concept of More than One Constituent Substances (MOCS).¹ This paper was updated in June 2021 and the proposed application of classification rules for mixtures under CLP to substances under REACH was further extended to include not only CMR endpoints but also bioavailability.

This new approach would be a paradigm shift and in direct contradiction with the general approach of the UN GHS. Giving data on components precedence to data on the MOCS itself contradicts the legal framework and the scientific justification of classifications.

The impact on dossier evaluation would be huge according to a first evaluation of Eurocolour's member companies. At the same time, no benefit would be given as these substances are already registered under REACH, fulfilling the information requirements. Such a concept would thus only increase the bureaucratic burden and bring EU's industry at a disadvantage while the protection level of human health or the environment would simply remain the same.

Our key remarks and messages:

- No need for additional rules on MOCS
- Proposed concept on classifying MOCS contradicts GHS, CLP, and scientific basis for classification
- Benefit for human health and environmental protection highly doubtful
- Increasing information demands in evaluation process expected
- The majority of chemicals within the EU fall under the proposed MOCS definition
- Loss of essential chemical looms due to unjustified classifications

Definition of MOCS

The thought starter by the EU Commission and ECHA introduces the new term of More than One Constituent Substances (MOCS). So far, there is no equivalent definition provided by CLP or REACH Regulation. According to the paper prepared for the CARACAL Meeting in November 2020, this term shall summarize UVCB's², mono-constituent³ and multi-constituent substances⁴.

REACH defines in Article 3(1) a substance as including any additive or impurity deriving from the process used, in alignment with the GHS definition. This definition reflects the actual status of chemical products on the market. Considering that there is almost no mono-constituent substance with a purity of 100 %, the proposed definition for MOCS will affect virtually all

¹ See document CA/74/2020 prepared for CARACAL Meeting on 17th and 18th November 2020, available on [CIRCABC](#).

² UVCB = substances of Unknown or Variable composition, Complex reaction products or Biological materials.

³ Mono-constituent substances: one main constituent ≥ 80 % and impurities in concentration < 20 %.

⁴ Multi-constituent substances: a reaction mass of main constituents each between $\geq 10 - < 80$ % and impurities in concentrations < 10 %.

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chemicals falling under REACH. Therefore, the scope of the proposed action should not be underestimated.

Additionally, considering UVCBs, mono-constituent and multi-constituent substances with constituents/impurities together under a single group denomination is a step back from the aim of creating these definitions: the recognition that they are substances with important differences in their characterisations. It is, in particular, quite striking that, for UVCBs, an approach based on single components is proposed, when UVCBs are substances where single components might be even unknown.

Proposal for general approach to MOCS

The general aim is to extend the mixture classification rules from the CLP Regulation on CMR properties as well as bioaccumulation and degradation properties to MOCS. Furthermore, the paper clearly states that data on single components shall be given precedence to the data on the MOCS itself. As a result, the whole MOCS shall be classified if one of its components is classified and present in concentrations equal to or higher than the threshold for mixture classification even if data on the MOCS for the same endpoint do not support the classification.

Paradigm shift undermines GHS and contradicts the CLP Regulation as well as the scientific data basis for classifications in general

The worldwide standard for hazard communication GHS clearly states in section 1.3.2.3.1 (a) that if there is information available on a mixture, a classification decision should always be based on that data. Only if no information on the mixture is available, the bridging principle may be used, or the classification can be based on data for the individual components. EU's CLP Regulation is the implementation of UN's GHS in the EU and as such it should not contradict the worldwide standard.

The EU Commission refers in their thought starter to CLP Article 6(3) for justifying the proposed actions. However, Article 6(3) only applies to mixtures. There is no rationale, nor reasonable interpretation of the CLP Regulation that could lead to subjecting almost all substances to the rules applicable to mixtures where the CLP Regulation specifies different rules for substances and mixtures.

The different classes of substances defined in REACH encompass the actual cases of products on the market and allow to test these substances as such, i.e., already including all the known or unknown components which may have an impact on their toxicological profile. Therefore, studies performed on substances to fulfil the information demands in REACH registration consider all components. This is particularly important in cases where not all components can be identified, but their effects will be nevertheless included through the testing of the substance. As a result, the data already cover possible effects on human health or the environment by the impurities. Furthermore, possible cocktail effects of constituents/impurities are considered as the substances are tested as a whole. There is no need, nor a legal or scientific justification to

classify a substance, if there are data showing no relevant effect and therefore no hazard. A classification would be inconsistent and would only weaken hazard communication.

Loss of essential chemicals due to unjustified classification must be prevented

Even though the proposed concept only applies to specific endpoints, the consequences might be significant. Complex substances consist of several substances and elements. However, the properties of the complex substance may differ tremendously from the properties of each individual constituent. The rearrangement of the respective elements is just as important as the nominal chemical composition for the properties of a substance. This is also true for CMR, bioaccumulation and degradation properties.

Consequences for REACH Dossier and Substance Evaluation

Based on the assumption that information requirements under REACH are performed on the whole substance as it is placed on the market – including all constituents and/or impurities – it is not quite clear, how ECHA intends to transfer the proposed extension of CLP classification rules to the Dossier Evaluation. As laid down in the thought starter, the legal possibilities are currently not given.

However, the paper suggests that under Substance Evaluation, there is the possibility to ask for further studies also on individual constituents. This already indicates the intention to request for further studies from the registrants.

The increased flexibility to request studies in the biodegradation is explicitly mentioned. As PBT/vPvB assessment is so far only required for organic substances registered in a yearly tonnage above 10 t, the extension to all substances falling under the proposed MOCS definition would lead to immense efforts for the affected registrants. At the same time, there is no clear benefit shown how this approach should help to increase the protection of human health and the environment.

Conclusion

Even though there is at present only a so-called thought starter published on the MOCS concept, the proposed ideas already give reason for high concern. While there are already rules for classifying substances and mixtures within the CLP Regulation which are in line with the rules laid down in UN GHS, the proposed extension of these rules for the so-called MOCS should be seen rather critically. Data submitted under REACH registration already cover every component within the substance, also considering potential cocktail effects. Therefore, data on the whole substance should always be given precedence to data on individual components. Especially if the data on the whole substance do not support a classification, it is important to stick to this fundamental principle: a classification should wherever possible be based on the scientific data and not on theoretical considerations.

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The proposed definition would affect the majority of substances on the EU market, especially the extremely relevant group of mono constituent substances with impurities. Unjustified classification could lead to a loss of available substances. Additionally, further information demands in course of evaluation processes burdens the industry and brings it in a disadvantage. All the while, there is no benefit recognizable. The protection level of human health and the environment will not be increased as all the relevant data are also required under the current legislation.

Therefore, Eurocolour promotes

- no introduction of MOCS concept
- no undermining of GHS and CLP Regulation
 - reliable data on mixtures always takes precedence to theoretical estimations based on data on single components
 - no classification contradicting existing data
- no undermining of the scientific basis for classifications

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About Eurocolour:

Eurocolour e. V. is the umbrella association for the manufacturer of pigments, dyes, fillers, frits, ceramic and glass colours and ceramic glazes in Europe.

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