Unique ID 1049

Topic CLP

Scope Classification

Domanda Do suppliers have to comply with the harmonised classification and labelling (C&L) of a substance in Annex VI to CLP before the application date indicated in the respective adaptation to technical progress (ATP)?

Risposta

A new or revised harmonised C&L of a substance set out in Annex VI to CLP must be applied from the date specified in the respective ATP, although suppliers may use this classification before that date.

In cases where a supplier decides not to apply the harmonised C&L of a substance before this date, the question arises whether they should nevertheless take into consideration the opinion adopted by the ECHA Risk Assessment Committee (RAC) on the harmonised C&L for that substance in the self-classification of a substance or mixture.

When suppliers consider the self-classification of their substance or mixture before placing them on the market (Article 4(1) of CLP), they must identify and examine all available information (Article 5 of CLP). The classification must reflect the latest scientific knowledge (Articles 5(1)(d) and 15 of CLP). During the transitional period for compliance with a new harmonised C&L for a substance, the RAC opinion for that substance should be considered as the latest reliable scientific evidence that should be reflected in the self-classification of the substance or mixture, unless the supplier has other scientific evidence that differs from the RAC opinion and leads to a different conclusion.

If the C&L of a substance is already harmonised in the same hazard class, compliance with the existing harmonised C&L is legally required until it is formally changed in an ATP to CLP. The new harmonised C&L may be voluntarily applied as soon as the respective ATP enters into force. At the date of applicability, as provided for in the respective ATP, the suppliers are obliged to comply with the new C&L.

FAQ Questions on REACH, CLP and BPR marked as Frequently Asked Questions (FAQ) have been agreed between ECHA, the national helpdesks and the European Commission to ensure consistency and accuracy. - FAQ

Chapter

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Unique ID 1050

Scope Labelling

Domanda If a mixture contains more than four substances contributing to the classification of the mixture, which substances should be identified on the label?

Risposta

Article 18(3) of CLP provides that the identity of all substances in a mixture that contribute to the classification of the mixture in certain hazard classes must be given on the label. A maximum of four chemical names are to be included, unless more are needed to reflect the nature and severity of the hazards.

There are no strict rules on how to decide which substances should take precedence to be named on the label, but the following may help in the selection.

For non-additive health hazards (e.g. germ cell mutagenicity, carcinogenicity, reproductive toxicity, respiratory or skin sensitisation and specific target organ toxicity categories 1 and 2), all ingredients which are present in the mixture above the generic or specific concentration limit should be considered as ”primarily responsible for the major health hazards” within the meaning of Article 18(3)(b) CLP and included on the label.

For the additive health hazards mentioned in Article 18 (3)(b) CLP (e.g. acute toxicity, skin corrosion, serious eye damage, specific target organ toxicity category 3 and aspiration hazard), all ingredients which are present in the mixture above the generic or specific concentration limits should be included on the label. However, where there are several ingredients contributing to classification for one hazard endpoint, only the ingredients primarily contributing to the classification, for example, those closest to the GCL or SCL, need to be included on the label, and thus the names of other ingredients with limited contribution to the classification are not required.

In addition, specific labelling rules apply to mixtures containing skin and respiratory sensitisers. See Annex I Table 3.4.3 and Annex II, point 2.8.

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Topic CLP

Scope Labelling

Domanda Are CLP pictograms required when outer packaging is marked with the ‘limited/excepted quantity marks’ according to the rules on the transport of dangerous goods?

Risposta

No, they are not. Article 33(1) of CLP outlines that when a package consists of an outer and an inner packaging, together with an intermediate packaging, and the outer packaging meets the labelling provisions in accordance with the rules on the transport of dangerous goods, the hazard pictograms required by CLP do not need to appear on the outer packaging.

For the purpose of CLP, transport labelling is considered to include the limited/excepted quantity marks (chapters 3.4 and 3.5 of the UN Model Regulations for the transport of dangerous goods). This is explained in the Guidance on labelling and packaging (chapter 5.4) that states that labelling in accordance with CLP is required only when neither:

'normal' transport labelling elements, nor

other transport labelling elements such as ‘limited/excepted quantity marks' are needed on the outer packaging.

This means that limited/excepted quantities are considered as transport labelling and therefore CLP pictograms are not required when those limited/excepted quantity marks are carried on the outer packaging. CLP labelling may however be used, if desired according to Article 33(1) of CLP.

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Topic CLP

Scope Scope and exemptions under CLP

Domanda What are the classification, labelling and packaging requirements for a biocidal product?

Risposta

A biocidal product has to comply with the classification, labelling and packaging requirements under the CLP Regulation and until 1 June 2015, Directive 1999/45/EC. This obligation is confirmed by Article 2(3)(e) and (m), and Article 69(1) of the Biocidal Products Regulation (EU) 528/2012 (BPR).

According to the BPR (Article 20(1)), the applicant for an authorisation of a biocidal product will have to provide a draft summary of biocidal product characteristics (SPC), taking into account the properties of the active substance(s) as well as any relevant co-formulant(s). As mandatory information, the SPC includes the hazard and precautionary statements (Article 22(2)(i) of BPR). Once authorisation is granted, the holder of the authorisation must ensure that the authorised product is classified, labelled and packaged in accordance with the approved SPC, as well as with the CLP Regulation and, until 1 June 2015, Directive 1999/45/EC (Article 69(1) of the BPR). In addition, authorised biocidal products are subject to specific label elements to ensure the effective communication of information on risks resulting from their use and risk management measures (Article 69(2)of the BPR).

When an authorisation holder wishes to change the label elements related to classification that are part of the authorisation of a product, i.e. hazard and precautionary statements, or is compelled by the CLP Regulation to do so, the change has to be notified to all the Member States in which the product is authorised or, where relevant, to ECHA (see Article 50(2) of the BPR and Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products. If the change leads to new hazard or precautionary statements, the authorisation needs to be updated to reflect this new condition.

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Topic CLP

Scope Classification

Domanda Must you re-classify and label your biocidal product when there is a change in harmonised classification?

Risposta

Yes, the classification and labelling (C&L) of biocidal products needs to be updated in line with the change in harmonised classification within the timelines specified below. If the C&L of a substance in the product is already harmonised, compliance with the existing harmonised C&L is legally required. The new harmonised C&L may be voluntarily applied as soon as the respective ATP enters into force. At the date of applicability as provided for in the respective ATP, the suppliers are obliged to comply with the new C&L.

Further to this, Article 30(3) of CLP states that the label of a biocidal product should be updated in line with the requirements of the biocidal products legislation. The Commission Implementing Regulation (EU) No 354/2013 on changes of biocidal products gives the authorisation holder 12 months after implementation of the change to notify the updated hazard and precautionary statements to all the Member States in which the product is authorised or, where relevant, ECHA (see Annex, Title 1, Section 2).

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