Janet Greenwood

From: Lindsay Peppin <Lindsay.Peppin@hse.gov.uk> on behalf of UKREACHCA <UKREACHCA@hse.gov.uk>
Sent: 06 October 2022 09:29
To: Alison
Subject: CLP - Classification - MCL - substances on the 17th ATP - Different to EU- Helpdesk REF: 0510PXL22-0001

Dear Alison,

The relevant part of CLP is Article 4(3). For GB CLP, the text is as follows:

"If a substance is subject to mandatory classification and labelling in accordance with Title V through an entry in the GB mandatory classification and labelling list, that substance shall be classified in accordance with that entry, and a classification of that substance in accordance with Title II shall not be performed for the hazard classes or differentiations covered by that entry.

However, where the substance also falls within one or more hazard classes or differentiations not covered by an entry in the GB mandatory classification and labelling list, classification under Title II shall be carried out for those hazard classes or differentiations."

The text of EU CLP is the same, except it refers to harmonised classification and labelling, rather than mandatory classification and labelling (MCL).

Therefore, it is not true that mandatory (or harmonised) classifications should be regarded as 'minimum classifications', i.e., if a substance has an MCL of Carc 2; H351, then a supplier would be technically out of compliance if they classified and labelled as Carc. 1A/B; H350. The exception to this is where a classification is marked with an asterisk (*) on the GB MCL list (or Annex VI of EU CLP). This applies to a small number of substances, and only to certain hazard classes. Minimum classifications were created when harmonised classifications that were agreed under the Dangerous Substances Directive (DSD) were 'translated' into CLP classifications. For some hazard classes, the hazard categories didn't quite match up (this ChemicalWatch paper explains this in more detail – see Fig. 1). For such minimum classifications, when available data exists to justify a more stringent category than the given minimum, the more stringent category must be used.

An example of a substance with a minimum classification is salts of nicotine. The MCL list entry for this substance is shown below:

Index Number	Chemical Name	EC	CAS	Classification		Labelling	
614-002-00-X	salts of nicotine	—	—	Acute Tox. 2 * Acute Tox. 1 Acute Tox. 2 * Aquatic Chronic 2	H330 H310 H300 H411	GHS06 GHS09 Dgr	H330 H310 H300 H411

For this example, acute inhalation toxicity and acute oral toxicity are marked with a * and are therefore 'minimum' classifications. Suppliers must consider the data available to them and decide whether category 1 is more appropriate. For hazardous to the aquatic environment, which is not marked with a *, suppliers must apply Aquatic Chronic 2; H411 – they should not classify and label as Aquatic Chronic 1.

The ECHA guidance on labelling (section 4.5) refers to these minimum classifications, but makes it clear that it only applies to those classifications marked with a *:

"If a substance classification is harmonised and included in Part 3 of Annex VI to CLP, the corresponding hazard statement(s) relevant for this classification have to be used on the label. Note that certain harmonised classifications marked with an asterisk in Part 3 of Annex VI to CLP are minimum classifications and, based on available data, a more severe classification as well as the corresponding hazard statement may need to be assigned".

Article 4(3) of CLP also makes it clear that substances must be 'self-classified' for all hazard classes not covered by the MCL list entry. So if a substance has an MCL of Carc 2; H351 only, suppliers must apply that classification and then self-classify for physical hazards, environmental hazards and all human health hazards (other than carcinogenicity).

With these points in mind, I have provided some comments in red on your email below. For further guidance on using harmonised classifications, see Section 7 (p34) in the ECHA introductory guidance to CLP

I hope this helps,

Kind regards,

Lindsay

HSE

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From: Alison <Alison@ttenvironmental.co.uk>
Sent: 05 October 2022 17:19
To: UKREACHCA <UKREACHCA@hse.gov.uk>
Subject: Lindsay - RE: CLP - Classification - MCL - substances on the 17th ATP - Different to EU- REF: 2109MYP22-0094

Hello Max,

Many thanks for your response to the question.

The wording you used in your answer – 'GB suppliers are legally required to apply the classification and labelling in the MCL list entry', is slightly different to some of the previously understood expectations of industry. Would you be able to clarify a couple of other examples for me?

In the first example, one hazard category has been increased in the EU Annex VI Harmonised Classification List. Would a GB supplier be able to use the higher hazard category in the UK?

Substance	UK Mandatory Classification List	EU Annex VI (Post-17th ATP)

603-024-005	1,4-dioxane	204-661-8	123-91-1	Flam. Liq. 2 Carc. 2 Eye Irrit. 2 STOT SE 3	H225 H351 H319 H335	Flam. Liq. 2 Carc. 1B STOT SE 3 Eye Irrit. 2	H225 H350 H335 H319

Strictly speaking, no. The Carc 2 is not a minimum classification. The classification on the GB MCL list entry should be applied.

In the second example, a new hazard class has been added to the existing substance classification in the EU Annex VI Harmonised Classification List. Would a GB supplier be able to apply the additional hazard class in the UK?

Substance				**UK Mandatory Classification List**		**EU Annex VI**
613-102-00-0	dimethomorph (ISO); 4-(3-(4-chlorophenyl)-3-(3,4-dimethoxyphenyl)acryloyl)morpholine	404-200-2	110488-70-5	Aquatic Chronic 2	H411	Repr. 1B Aquatic Chro

At the moment, the understanding of industry is that the Mandatory Classification List works according to the same principles as the EU Annex VI classification list and therefore the following apply:

- Example 1:- The classification in the table is a minimum classification. If the manufacturer or importer has information that leads to classification in a more severe category than the category stated in the table then the more severe category should be applied. (Guidance on Labelling Section 4.5) As discussed above, the ECHA guidance only talks about those classifications marked with a *. If a manufacturer or importer has information to suggest that a more severe classification should apply, they must submit a proposal to HSE (GB CLP Agency) to amend the MCL – see Article 37A(3)(2) which states:

"A manufacturer, importer or downstream user who has new information which may lead to a change of the mandatory classification and labelling elements of a substance in the GB mandatory classification and labelling list must submit a proposal to the Agency for a revised classification."

Until the GB MCL list is amended, the classification on the list remains legally binding. The same is true in the EU.

- Example 2:- A substance listed has a harmonised/mandatory classification only for the hazard classes which are listed. The hazard classes which are not listed should be self-classified by the manufacturer, importer or downstream user based on the available data. The user can therefore add more hazard classes to a substance which is listed (if required). (ECHA FAQ 0263) Yes, this is the same in GB CLP as it is for EU CLP.

Do these principles still apply? Or must the GB supplier apply the exact classification as shown in the MCL only?

Thanks and Best Regards,
Alison

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Please consider the environment before printing this email

From: Lindsay Peppin <Lindsay.Peppin@hse.gov.uk> **On Behalf Of** UKREACHCA
Sent: 05 October 2022 11:50
To: Alison <Alison@ttenvironmental.co.uk>
Subject: CLP - Classification - MCL - substances on the 17th ATP - Different to EU- REF: 2109MYP22-0094

Dear Alison,

If a substance is listed on the MCL list, then GB suppliers are legally required to apply the classification and labelling in the MCL list entry. In our capacity as a helpdesk, we cannot advise businesses to do otherwise.

In the case of '(R)-p-mentha-1,8-diene; d-limonene', the Agency has reviewed the RAC opinion and disagrees with RACs conclusion on the environmental hazards. Both the technical report and Agency Opinion support the retention of the Aquatic Chronic 1 classification. Therefore, if the substance is being supplied in GB then this classification is required and must be represented in the labelling, regardless of the RAC opinion.

On the other hand, in the case of 'flumioxazin', the Agency technical report and Opinion support reducing the classification of the substance from Repr 1B to Repr 2 in agreement with the RAC opinion. The current classification of Repr. 1b is legally binding in GB until the GB MCL list is amended, however if a supplier chose to apply Repr. 2 prior to the list being amended, we suspect it would be of a low priority for enforcement action.

Please see here for the link to the published Technical Report & Agency Opinions.

Kind regards,

Max

Max Price
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From: Alison <Alison@ttenvironmental.co.uk>
Sent: 21 September 2022 15:51
To: UKREACHCA <UKREACHCA@hse.gov.uk>
Cc: Janet Greenwood <Janet@ttenvironmental.co.uk>
Subject: Max - JK CLP - Classification - MCL - substances on the 17th ATP - Different to EU- REF:

Dear HSE Helpdesk team,

Hope this email finds you well following the extraordinary events of the last 10 days.

We're just starting to get back to business as usual and find ourselves with a couple of follow up items following the recent meeting of the Chemical Regulation Self Help Group.

Apologies if we've asked you this before, but could you please help clarify how you anticipate companies that trade in both the UK and EU should handle the classification and labelling for these two substances which appear on both the UK Mandatory Classification List, and will now have conflicting classifications on the EU Annex VI Harmonised Classification List following the implementation of the 17th ATP:

Substance	UK Mandatory Classification List	EU Annex VI (

601-096-00-2 (Removed from 601-029-00-7)	(R)-p-mentha-1,8-diene; d-limonene	227-813-5 Substance removed from group listing in the EU 227-813-5 5989-27-5	5989-27-5 Substance [2] removed from group listing in the EU 227-813-5 5989-27-5	Flam. Liq. 3 Skin Irrit. 2 Skin Sens. 1 Aquatic Acute 1 Aquatic Chronic 1	H226 H315 H317 H400 H410	Note C	Flam. Liq. 3 Skin Irrit. 2 Skin Sens. 1B Asp. Tox. 1 Aquatic Acute Aquatic Chron
613-166-00-x	flumioxazin (ISO); 2-[7-fluoro-3-oxo-4-(prop-2-yn-1-yl)-3,4-dihydro-2H-1,4-benzoxazin-6-yl]-4,5,6,7-tetrahydro-1H-isoindole-1,3 (2H)-dione	—	103361-09-7	Repr. 1B Aquatic Acute 1 Aquatic Chronic 1	H360D H400 H410	M = 1 000 M = 1 000’	Repr. 2 Aquatic Acute Aquatic Chron

Specifically, for the highlighted hazard classes, where the EU has specified a reduced classification (and provided the relevant data via the RAC report). Is the UK supplier required to continue implementing the MCL (higher) classification or may they implement the European Annex VI classification and refer to the published data (as expert judgement)?

The primary concern of the members of the group is that for products which are sold in both jurisdictions, it is not logistically possible to amend the labelling in the middle of the distribution chain.

For substances on the 17th and 18th ATPs which are increasing classification we are assuming that companies can take a precautionary stance (apply the higher classification) without penalty from the HSE. However, for the two specific examples shown above – a lower classification we would appreciate your recommendations.

Thanks and Best Regards,
Alison

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