

## **Environmental Hazard Classification and Labelling under the ‘CLP Regulation’**

This ‘Note’ provides brief guidance on CLP environmental hazard classification and labelling for active substances and ‘mixtures’ (i.e. formulated products) - which relate to the hazard to aquatic life and also the ozone layer. The document was originally written for internal use by CRD Ecotoxicology Branch as an aid to the classification and labelling of pesticides and biocides, but is now also being made available on CRD’s website. The guidance is not intended to be definitive and more comprehensive guidance is included on ECHA’s website at <http://echa.europa.eu/regulations/clp/classification> .

Criteria for CLP environmental hazard classification were amended under Reg. (EU) No 286/2011 (Second ‘Adaptation to Technical Progress’) and therefore it is important to use the most up-to-date guidance. ECHA’s ‘Guidance on the application of the CLP criteria’ (dated November 2012) provides the most relevant detailed guidance – with Section 4 dealing with hazards to the aquatic environment and Section 5.1 hazards to the ozone layer. This ‘Note’ briefly summarizes this guidance.

### **1 Background**

The ‘CLP Regulation’ (Reg. (EC) No 1272/2008, with amendments under Reg. (EU) No 286/2011), includes requirements in relation to the classification, labelling and packaging of (active) ‘substances’ and ‘mixtures’ (i.e. formulated products). The methodology used is based on the UN ‘Global Harmonised System of Classification and Labelling of Chemicals’ (GHS). It applies to plant protection products, biocides, and to other chemicals covered by Regulation (EC) No 1907/2006 (i.e. ‘REACH’).

Requirements under the ‘CLP Regulation’ progressively replace those under the Dangerous Substance Directive 67/548/EEC (‘DSD’) and the Dangerous Preparations Directive 1999/45/EC (‘DPD’) – which are implemented in the UK under the Chemicals (Hazard Information and Packaging for Supply) Regulations 2009 (known as ‘CHIP 4’).

Substances are required to be classified and labelled in accordance with the (amended) CLP Regulation from 1 December 2012 and ‘mixtures’ from 1 June 2015. A 2 year derogation to these CLP implementation dates is permitted for substances and ‘mixtures’ already in the supply chain - provided they are labelled in accordance with DSD or DSD requirements.

It is CRD policy to make a full assessment of the classification and labelling of a plant protection product when it is relevant to product authorisation (i.e. for a new product, major formulation change, or re-registration /renewal). Currently this can relate to either ‘CHIP4’ or CLP classification but it is CRD’s future intention to set a deadline by which all product applications will be required to be classified under ‘CLP’ – so to comply with the CLP product implementation deadline of 1 June 2015 (for more details please see CRD’s ‘Regulatory Updated 03/2013 dated 21<sup>st</sup> January 2013).

### **2 Aquatic Life Hazard Classification and Labelling for ‘substances’**

There is one aquatic life acute hazard category and four chronic (long-term) categories. Supporting data to determine these classifications should be from scientific valid studies conducted to standard (e.g. OECD) test guidelines. Hazard classification categories, criteria and associated labelling requirements are summarised in Table 1.

Table 1 CLP Aquatic Hazard Classification - categories, criteria and associated labelling for 'substances' and also 'mixtures' with formulation toxicity data

Aquatic hazard classification	Criteria for hazard classification for 'substances' and 'mixtures'	GHS09 Pictogram	Signal word	Hazard statement ###	Precautionary statements ***
'Acute category 1' #	Fish 96h LC50, crustacean 48h EC50, algae 72 / 96h ErC50, or higher aquatic plant 7-14 day ErC50: $\leq 1$ mg /L		'Warning'	H400 'Very toxic to aquatic life'	P273, P391 & P501.
'Chronic category 1' #	<p>i) <u>Chronic toxicity data available for substance /mixture and not 'rapidly degradable'</u>###: Chronic NOEC** for fish, crustacea, algae or other aquatic plants <math>\leq 0.1</math> mg /L</p> <p>ii) <u>Chronic toxicity data available for substance /mixture and 'rapidly degradable'</u>###: Chronic NOEC** for fish, crustacea, algae or other aquatic plants <math>\leq 0.01</math> mg /L</p> <p>iii) <u>Chronic toxicity data not available for substance and not 'rapidly degradable' and/or fish BCF &gt; 500 (or in absence of data log Kow &gt; 4):</u> Criteria as for 'Acute category 1'</p>		'Warning'	H410 'Very toxic to aquatic life with long lasting effects'	P273, P391 & P501.
'Chronic category 2'	<p>i) <u>Chronic toxicity data available for substance /mixture and not 'rapidly degradable'</u>###: Chronic NOEC** for fish, crustacea, algae or other aquatic plants <math>&gt; 0.1</math> to <math>\leq 1</math> mg /L</p> <p>ii) <u>Chronic toxicity data available for substance /mixture and 'rapidly degradable'</u>###: Chronic NOEC** for fish, crustacea, algae or other aquatic plants <math>&gt; 0.01</math> to <math>\leq 0.1</math> mg /L</p> <p>iii) <u>Chronic toxicity data not available for substance and not 'rapidly degradable' and/or fish BCF &gt; 500 (or in absence of data log Kow &gt; 4):</u> Fish 96h LC50, crustacean 48h EC50, algae 72 / 96h ErC50, or higher aquatic plant 7 day ErC50: <math>&gt; 1</math> mg /L to <math>\leq 10</math> mg /L</p>		No 'signal word' required	H411 'Toxic to aquatic life with long lasting effects'	P273, P391 & P501.
'Chronic category 3'	<p>i) <u>Chronic toxicity data available for substance /mixture and 'rapidly degradable'</u>###: Chronic NOEC** for fish, crustacea, algae or other aquatic plants <math>&gt; 0.1</math> to <math>\leq 1</math> mg /L</p> <p>ii) <u>Chronic toxicity data not available for substance and not 'rapidly degradable' and/or fish BCF &gt; 500 (or in absence of data log Kow &gt; 4):</u> Fish 96h LC50, crustacean 48h EC50, algae 72 / 96h ErC50, or higher aquatic plant 7 day ErC50: <math>&gt; 10</math> mg /L to <math>\leq 100</math> mg /L</p>	Not required	No 'signal word' required	H412 'Harmful to aquatic life with long lasting effects'	P273 & P501.
'Chronic category 4' ('Safety net' classification)	Applies when data does not allow classification under above criteria but where there are 'some grounds for concern'. Includes for example poorly water soluble compounds ( $< 1$ mg/L) for which effects are less than 50% at up to limit of solubility but which are: not 'rapidly degraded' and which have a fish BCF $\geq 500$ (or in absence of data log Kow $\geq 4$ ); unless 'other scientific evidence' shows 'classification to be unnecessary' e.g. chronic NOECs $>$ water solubility or $> 1$ mg/L or where other evidence of 'rapid degradation' exists (i.e. using methods not included in the standard definition)	Not required	No 'signal word' required	H413 'May cause long lasting harmful effects to aquatic life'	P273 & P501.

\* Toxicity endpoints should relate to the most sensitive tested species in each aquatic group. In relation to determining 'Acute category 1', for algae and aquatic plants where an ErC50 is not determined, the lowest EC50 value should be used. Where four or more valid acute toxicity endpoints for the most sensitive test species are available, a calculated geometric mean value may be used in the hazard evaluation.

\*\* Or 'equivalent ECx (e.g. EC10)' from chronic toxicity study.

\*\*\* P273 'Avoid release to the environment (only applies if this is not the intended use);

\*\*\* P391 'Collect spillage';

\*\*\* EU 'P501' wording 'Dispose of contents/ container to ...' (in accordance with local/ regional/ national/ international regulation - to be specified).

\*\*\* UK agreed P501 wording for Professional pesticide /biocide products: 'Dispose of contents/container to a licensed hazardous-waste disposal contractor or collection site except for empty clean containers which can be disposed of as non-hazardous waste.'

\*\*\* UK agreed P501 wording for Amateur concentrate pesticide /biocide products: 'Dispose of contents/container to a household waste recycling centre as hazardous waste except for empty containers which can be disposed of in the dustbin. Contact your local council for details.'

\*\*\* UK agreed P501 wording for Amateur RTU pesticide /biocide products: 'Dispose of contents/container to a household waste recycling centre as hazardous waste except for empty containers which can be disposed of by recycling . Contact your local council for details.'

# When classifying a substance as 'Acute category 1' and/or as 'Chronic category 1', the appropriate M-factor should also be indicated (for possible later use in classifying 'mixtures' using the 'Summation method') – see further guidance below.

## Mixtures are considered to be 'rapidly degradable' where all of their 'relevant components' are classed as such, otherwise a 'non-rapidly degradable' classification applies.

### In line with Article 27 of CLP, to avoid unnecessary duplication of hazard statements, for labelling purposes where the criteria indicates H400 applies in addition to H410, H411, H412 or H413, the appropriate 'hazard statement' for inclusion on the label is 'H410' - together with its associated pictogram and 'signal word'.

For substances (and also mixtures), where there are data gaps, a 'weight of evidence' approach may be appropriate to determine the appropriate hazard classification.

#### Criteria defining 'rapid degradation' of substances (for classification purposes)

Degradation in this context refers to full mineralisation of an organic test compound (i.e. conversion of organic carbon content to carbon dioxide) and is not applicable to inorganic compounds and metals. Substances may be considered to have 'rapid degradation' in the following circumstances:

- i) If in a 28 day 'ready biodegradability' study (OECD 310) the following levels of degradation are achieved within 10 days of the 'start of degradation' (taken to be when 10% has degraded): at least 70% degradation in tests based on dissolved organic carbon removal or at least 60% of theoretical maximum in tests based on oxygen depletion or carbon dioxide generation.
- ii) Where only BOD (Biochemical Oxygen Demand) and COD (Chemical Oxygen Demand) data are available: Section 4.1.2.9.5 of Annex I of Regulation (EU) No.286/2011 states that a 5 day BOD: COD ratio of  $\geq 0.5$  indicates 'rapid degradation'. However, Section 2.2 of Annex II of ECHA (2009) guidance states that this method should only be used 'when no other measured degradability data are available' and advises that 'for substances where the chemical structure is known, the theoretical oxygen demand (ThOD) can be calculated and this value should be used instead of the chemical oxygen demand (COD)'.
- iii) 'If other convincing scientific evidence is available to demonstrate that the substance can be degraded (biotically and /or abiotically) in the aquatic environment to a level >70% within a 28 day period.'

When no useful data on degradability are available (either experimentally determined or estimated), the substance should be regarded as not rapidly degradable. Where multiple or conflicting datasets exist for a single chemical, a 'weight of evidence' approach should be followed taking account of the quality of the data.

### **3 Aquatic Life Hazard Classification and Labelling for 'mixtures'**

The aquatic environmental hazard classification system for 'mixtures' (i.e. formulated products) is similar to that for substances. A tiered approach is taken to determine a mixture's classification. Available toxicity data on the 'mixture' is first evaluated and if sufficient and acceptable, the 'mixture' is classified on this basis (Table 1). However, it should be noted that 'mixture' toxicity testing should not be conducted solely for the purposes of classification and labelling. Alternatively, it may be possible to extrapolate toxicity data from similar mixtures - taking account of 'bridging principles' (Section 3.2). In the absence of 'mixture' toxicity data, hazard classification data for each of the mixture's 'relevant components' may be considered using the 'Summation method' or 'Additivity formulae' (Sections 3.3). Labelling requirements for 'mixtures' are determined by their hazard classification in the same way as for 'substances', with identical labelling required (Table 1).

Where there is a lack of adequate mixture toxicity data and insufficient data covering 'relevant components', in line with Section 4.1.3.6 of Reg. EC No. 286/2011, the mixture should be classified based on the hazard posed from its known 'relevant components', with the following additional statement included on the label and Safety Data Sheet 'Contains x % of components with unknown hazards to the aquatic environment.' However, this incomplete classification would not usually be an acceptable option for Plant Protection Products intended for outside use.

#### **3.1 Use of formulation toxicity data on the 'mixture' to determine its aquatic hazard classification**

Where formulation toxicity data are available on the 'mixture', its aquatic hazard classification may be determined in the same way as 'substances' (see Table 1).

With respect to determining the long-term hazard classification (which requires information on toxicity and substance degradability), where all of the 'relevant components' (Section 3.3.1) of a mixture are rapidly degradable, the 'mixture' should also be regarded as 'rapidly degradable'. In all other cases, the mixture should be regarded as 'not rapidly degradable'.

#### **3.2 Use of formulation toxicity data on a similar 'mixture' to determine the aquatic hazard classification**

Where the mixture itself has not been tested to determine its aquatic hazard classification but there is information on individual components and similar mixtures to adequately characterise the hazards of a mixture, these data may be used in accordance with 'Bridging principles' set out in Sections 1.1.3 and 4.1.3.4 of Annex I of Reg. (EC) No. 1272/2008 and amended under A(2), A(3) and D(4.1.3.4) of Annex I of Reg. (EC) No. 286/2011. These (amended) 'Bridging principles' are summarised below:

- i) If a mixture is formed by diluting another tested mixture or a substance classified for its aquatic environmental hazard with a diluent which has an equivalent or lower aquatic hazard than the least toxic original component and which is not expected to affect the aquatic hazards of other components, then the resultant mixture may be classified as equivalent to the original tested

- mixture or substance. Alternatively, the 'Summation method' may be used [details below].
- ii) If a mixture is formed by diluting another classified mixture or substance with water or other totally non-toxic material, the toxicity of the mixture can be calculated from the original mixture or substance [i.e. toxicity is reduced in proportion to the extent of dilution].
  - iii) The hazard classification of a tested production batch can be assumed to be substantially equivalent to that of another production batch of the same commercial product when produced by or under the control of the same supplier, unless there is reason to believe there is significant variation such that the hazard classification of the batch has changed – in which case a new evaluation is necessary.
  - iv) If a mixture is classified in the highest hazard category or sub-category (i.e. 'Acute Category 1' and 'Chronic category 1' for aquatic hazards) and the concentrations of the ingredients of the mixture that are in that category or sub-category is increased, the resultant untested mixture shall be classified in that category or sub-category without additional testing.
  - v) For three mixtures (A, B and C) with identical components, where mixture A and B have been tested and are in the same hazard category, and where untested mixture C has the same hazardous components as mixture A and B but at concentrations intermediate to that in A and B, 'mixture C' is assumed to be in the same hazard category as A and B.
  - vi) Comparison of 'substantially similar mixtures': where two mixtures (1 and 2) each contain 'component B' at the same concentration plus 'component A' in 'mixture 1' and 'component C' in 'mixture 2', with the same mixture concentration and hazard classification for components A and C, if 'mixture 1' or 'mixture 2' is already classified based on test data, then the other mixture shall be assigned the same hazard category.
  - vii) The following maximum variations (plus or minus) in the initial concentration range of constituents are permitted without the need to review the mixture classification: 30% variation when present at  $\leq 2.5$  w/w; 20% variation when present at  $> 2.5$ -10% w/w, 10% variation when present at  $> 10$ %-25% w/w, 5% variation when present at  $> 25$ %-100% (e.g. constituent present at 15% w/w, maximum permitted variation without classification review = 13.5-16.5% w/w)

### **3.3 Use of data on a mixture's relevant components to determination its hazard classification**

In order to determine the CLP hazard classification of a mixture in the absence of valid mixture toxicity data, it is first necessary to identify its 'relevant components' (Section 3.3.1). 'Additive toxicity formulae' (Section 3.3.2) and /or the 'Summation method' (Section 3.3.3) may then be used to determine the mixture's hazard classification – with usually it only being necessary to use the 'Summation method'. Fuller details are included in Sections D.4.1.3 of Annex 1 of Reg. EC No. 286/2011.

#### **3.3.1 Identification of 'relevant components' in a mixture**

'Relevant components' are those that qualify for environmental hazard classification as individual substances and that are present in the mixture at or above a determined relevant concentration. For components classified as 'Chronic 2', 'Chronic 3' or 'Chronic 4', the relevant concentration is 1% w/w or greater. For 'highly toxic' components classified as 'Acute 1' and /or 'Chronic 1' the relevant % w/w

concentration is 0.1 divided by the 'Multiplying factor'. The 'Multiplication factor' is determined by the level of acute or chronic toxicity of the component – as set out in Table 2.

Table 2 'Multiplying factors' for highly toxic components (i.e. 'Acute 1' or 'Chronic 1')

Acute toxicity L(E)C50 (mg /litre)	M-factor	Chronic toxicity NOEC (mg/litre)	M-factor	
			Non-rapidly degradable components	Rapidly degradable components
>0.1 to ≤ 1.0	1	>0.01 to ≤ 0.1	1	N/A <sup>#</sup>
>0.01 to ≤ 0.1	10	>0.001 to ≤ 0.01	10	1
>0.001 to ≤ 0.01	100	>0.0001 to ≤ 0.001	100	10
>0.0001 to ≤ 0.001	1000	>0.00001 to ≤ 0.0001	1000	100
>0.00001 to ≤ 0.0001	10000	>0.000001 to ≤ 0.00001	10000	1000
(Continuing in factor 10 intervals)		(Continuing in factor 10 intervals)		

# M-factor not applicable as not classified as 'chronic category 1'

Therefore, a 'highly toxic' component in a mixture with an acute EC50 of 0.06 mg /litre would be 'relevant' for classification purposes when present at 0.1 /10 = 0.01% w/w or above and a 'highly toxic' non-rapidly degradable component with a chronic NOEC of 0.0005 mg /litre would be 'relevant' for classification purposes when present at 0.1 /100 = 0.001% w/w or above.

### 3.3.2 Use of additivity formulae

Section D.4.1.3.5.2 of Annex 1 of Reg. EC No. 286/2011 includes mention of use of 'additivity formulae' to assess combined toxicity in situations where mixtures consists of a combination of components that are already classified (as Acute 1 and/or Chronic 1-4) and others that have not previously been considered for classification but for which adequate toxicity data are available.

Section 4.4.1.4.5 of ECHA's revised 'Guidance on the Application of the CLP Criteria' (draft on ECHA website dated April 2011) notes that 'With the aquatic toxicity data at hand the ingredient substance classification could easily be gained by direct comparison with the substance criteria, which then could be fed straight into the summation method. It will therefore usually not be necessary to use the additivity formulae.' However, given their inclusion in the CLP regulation, details in relation to use of these formulae are summarised below.

a) Based on acute aquatic toxicity:

$$\frac{\sum C_i}{L(E)C_{50m}} = \sum_{\eta} \frac{C_i}{L(E)C_{50i}}$$

Where:

- C<sub>i</sub>= concentration of each component (% w/w)
- L(E)C<sub>50i</sub> Aquatic life acute toxicity endpoint for each component (mg/l)
- η Number of components
- L(E)C<sub>50m</sub> Combined acute toxicity endpoint for component mixture

The calculated acute toxicity may then be used to assign the portion of the mixture considered an acute hazard category, which is then subsequently used in applying the 'summation method'.

b) Based on chronic aquatic toxicity:

$$\frac{\sum C_i + \sum C_j}{EqNOEC_m} = \sum_n \frac{C_i}{NOEC_i} + \sum_n \frac{C_j}{0,1 \times NOEC_j}$$

Where:

$C_i$  = concentration of each rapidly degradable component (% w/w)

$C_j$  = concentration of each non-rapidly degradable component (% w/w)

$NOEC_i$  = NOEC (or 'other recognised measures for chronic toxicity') of each rapidly degradable component in mg/l

$NOEC_j$  = NOEC (or 'other recognised measures for chronic toxicity') of each non-rapidly degradable component in mg/l

$\eta$  = Number of 'rapidly degradable' or 'non-rapidly degradable' components from 1 to n

$EqNOEC_m$  = Equivalent NOEC for part of the mixture with test data

The above 'equivalent toxicity' thus reflects the fact that non-rapidly degradable substances are classified one hazard category level more 'severe' (equivalent to an order of magnitude increase in toxicity) than rapidly degrading substances. It is given in terms of the equivalent toxicity of a rapidly degradable substance and as such may be used to assign that portion of the mixture a long-term hazard category based on the criteria in Table 1 for rapidly degradable substances.

When applying additivity formulae, component endpoints should preferably (where sufficient valid data are available) relate to effects in the same taxonomic group (fish, crustacean, algae or higher aquatic plants), with results from the most sensitive test species and group being used. Where, for the different components, toxicity data are not available from the same taxonomic group, Section D.4.1.3.5.3 of Annex I of Reg. EC No. 286/2011 states that toxicity values from the most sensitive test group for each component should be used. If using the formulae a mixture is classified in more than one way, the method yielding the more conservative result should be used.

### 3.3.3 Use of the 'Summation method'

Using this method, the classification of a mixture is based on the summation of the classification of its 'relevant components', taking into account their relative toxicities (including 'multiplication factors' for 'highly toxic' components) and concentrations. Each classification category is considered in turn as detailed in Table 3. The highest applicable chronic category is allocated to the mixture, together with 'Acute category 1' if also required.

Table 3 Classification of mixtures for acute and chronic (long-term) hazards based on the summation of classified relevant components

Sum of components contributing to mixture hazard classification:	Mixture classified as:
%w/w of 'Acute category 1' x M-factor = >25%	Acute category 1
%w/w of 'Chronic category 1' x M-factor = >25%	Chronic category 1
(%w/w of 'Chronic category 1' x M-factor x 10) + (%w/w of 'Chronic category 2') = >25%	Chronic category 2
(%w/w of 'Chronic category 1' x M-factor x 100) + (%w/w of 'Chronic category 2' x 10) + (%w/w of 'Chronic category 3') = >25%	Chronic category 3
(%w/w of 'Chronic category 1') + (%w/w of 'Chronic category 2') + (%w/w of 'Chronic category 3') + (%w/w of 'Chronic category 4') = >25%	Chronic category 4

#### 4 Hazard classification and labelling in relation to danger to the ozone layer

Details in relation to the hazard to the ozone layer are included in Part E.5 of Annex I of Reg. (EU) No. 286/2011. A substance should be classed as 'Hazardous to the Ozone layer' (Category 1) if the available evidence indicates that it may present a danger to the structure and /or functioning of the stratospheric ozone layer. This includes substances that deplete the ozone layer listed in Annex I to Regulation (EC) No 1005/2009 of the European Parliament and of the Council of 16 September 2009. Any substances having an Ozone Depleting Potential (ODP) greater or equal to the lowest ODP (i.e. 0.005) of the substances currently listed in this Annex should be classified as 'Hazardous to the ozone layer (category 1)'.

A mixture containing a substance/s classified as 'Hazardous to the Ozone layer (Category 1)' at a total concentration  $\geq 0.1\%$  must also be similarly classified. 'Labelling elements' for substances or mixtures classed as 'Hazardous to the Ozone layer' (Category 1) are detailed in Table 4.

Table 4 Labelling elements for substances or mixtures classified as 'Hazardous to the Ozone layer (Category 1)'

Symbol /pictogram	
Signal word	Warning
Hazard statement	H420: Harms public health and the environment by destroying ozone in the upper atmosphere
Precautionary statement	P502: Refer to manufacturer/supplier for information on recovery/recycling

**References** (mostly present on CRD's Wisdom file plan at: Pesticide Legislation and Policy /European Legislation /Classification and Labelling).

- ECHA (2009) 'Introductory Guidance on the CLP Regulation', CRD ref. w.001420125
- ECHA (2012) 'Guidance on the application of the CLP criteria: Guidance to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP) of substances and mixtures' (on ECHA website).
- European Union (2009) 'Commission Regulation (EC) No 1272/2008 of 16 December 2008', Official J of EU, L353, 31/12/2008, CRD ref. w.001420122
- European Union (2011) 'Commission Regulation (EU) No 286/2011 of 10 March 2011', Official J of EU, L83, 30/3/2011, CRD ref. w.001420121

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## Appendix I 'Mixture' classification – worked examples:

1. Aquatic toxicity data for a professional outside used pesticide 'mixture' (i.e. product) indicates fish to be the most acutely sensitive group - with a fish acute 96 hour LC50 = 0.05 mg mixture /L. Based on its acute toxicity to aquatic life, does the 'mixture' qualify for acute hazard classification and what are its associated labelling requirements?

Answer: Using Table 1, the mixture is classified as 'Acute category 1' based on its acute LC50 being below the trigger value of  $\leq 1$  mg/L. The GHS09 pictogram is required, together with the signal word 'Warning', the Hazard statement H400 'Very toxic to aquatic life' and precautionary statements P391 and P501.

2. In the absence of aquatic chronic toxicity data on the above mixture (formulation), it is proposed to determine its chronic aquatic hazard classification based on the chronic toxicity of its two 'classified' non-readily degradable components ('Component A' and 'Component B') - which are present at 0.05% w/w and 10% w/w respectively (see Table 1 for classification criteria).

'Component A' is classified as 'Chronic category 1' - based on it being 'non-rapidly degradable' and a fish chronic NOEC of 0.0003 mg/L.

'Component B' is classified as 'Chronic category 2' - based on it being non-rapidly degradable and a fish chronic NOEC of 0.5 mg/L

- a) To determine the mixture's chronic hazard classification, multiplication (M) factors are required to be allocated to 'Chronic category 1' components. Using Table 2, what is the M-factor for component A?

Answer: For 'Component A', based on its chronic toxicity, M-factor = 100.

- b) What are the 'relevant components' trigger concentrations for each and are they 'relevant components' (for classification purposes) in the mixture?

Answer:

For 'Component A', as a 'Chronic category 1' substance, its 'relevant component' trigger concentration = 0.1 divided by its M-factor of 100 = 0.001% w/w. It is present at 0.05% (i.e.  $>0.001\%$ ) and is therefore a 'relevant component'.

For 'Component B', as a 'Chronic category 2' substance, its 'relevant component' trigger concentration = 1% w/w. It is present at 10% (i.e.  $>1\%$ ) and is therefore a 'relevant component'.

- c) Using the 'Summation method' (Table 3), based on the concentrations, chronic aquatic hazard classifications and M-factors of its 'relevant components', what is the chronic hazard classification of the mixture?

Answer:

Consider if mixture is chronic category 1: %w/w of 'chronic category 1' (0.05) x M-factor (100) = 5% w/w, which is  $<25\%$  - therefore mixture is not 'chronic category 1'

Consider if mixture is chronic category 2: [%w/w of 'chronic category 1' (0.05) x M-factor (100) x 10] + [%w/w of 'chronic category 2' (10%)] = 50 + 10 = 60% w/w, which is  $>25\%$  - therefore mixture is classified as 'chronic category 2'

- d) From Table 1, what are the mixture's CLP labelling requirements?

Answer:

The GHS09 pictogram is required, together with the signal word 'Warning', the Hazard statement H411 'Toxic to aquatic life with long-lasting effects' and precautionary statements P391 and P501.