Principle

This document explains how holders of Belgian authorisations for plant protection products (PPP) have to proceed in order to comply with the rules for classification and labeling (C&L) imposed by means of Regulation (EC) N° 1272/2008 concerning on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 ("the CLP Regulation").

According to the CLP Regulation, the labeling of substances and mixtures on the market is the responsibility of the authorisation holders. On the other hand, Regulation (EC) N° 1107/2009 concerning the placing on the market of plant protection products imposes that this label has to comply with the authorisation certificate as granted by the national competent authorities.

As a way forward, the authorisation holders are required to submit a proposal for the new C&L that will be checked by the Belgian competent authorities. For each submission, a fee of 80 euro will be charged in order to cover part of the work. The proposal will finally be confirmed by means of an adapted authorisation certificate. In this way, the authorisation holders will be in the position to adapt the label of the PPP according to the CLP regulation while still complying with Regulation (EC) N° 1107/2009.

The timing for the required C&L proposal submission is as follows
(see letter FPS of june 2012):
- For new applications for PPP : to be included in the application
- For submitted but still pending applications : to be added to the application by 01/01/2013
- For already authorised PPP: by 01/01/2014.

The following possible steps may to be followed in order to generate the required C&L proposal submission:

(A) Check by means of the appropriate study result on the formulation; Completeness check for each endpoint of physico-chemistry, toxicity, and ecotoxicity which resulted in non-classification under the former directives, but could result in classification under the new regulation.

(B) In the absence of studies on the formulation, classification of the formulation occurs on the basis of calculation rules.

(C) Checklist of formulation study results to submit and/or CLP calculations to carry over substance C&L; format of the C&L proposal submission and data to be submitted.

(D) Conversion of the existing C&L (67/548/EEC and 1999/45/EC) to the CLP by means of the translation table of Annex VII of the CLP regulation; this table is given as a first indication, as normally studies on the formulation should be present (A) or a calculation can be performed (B).

Please keep in mind that the current guide is meant to draw the attention on the main differences in C&L between the DPD- and CLP-criteria, and does not replace the ECHA guidance on the CLP, which should be consulted in cases of doubt.

Explanation

(A) Check by means of the appropriate study result on the **formulation**; Completeness check for each endpoint of physico-chemistry, toxicity, and ecotoxicity which resulted in non-classification under the former directives, but could result in classification under the new regulation.

Remark: in order to obtain an indication of the new C&L, one could refer to table D.1 and D.2. These tables illustrate the concordance between existing and new hazard phrases, and are convenient only as a first approach.
However, as indicated in the table D.1, and stated under Note 1 of this table, appropriate study results take precedence over the classification obtained by conversion, which is only indicative. In the description below, the criteria of most relevant endpoints under the directives and the regulations are listed in a comparative way.

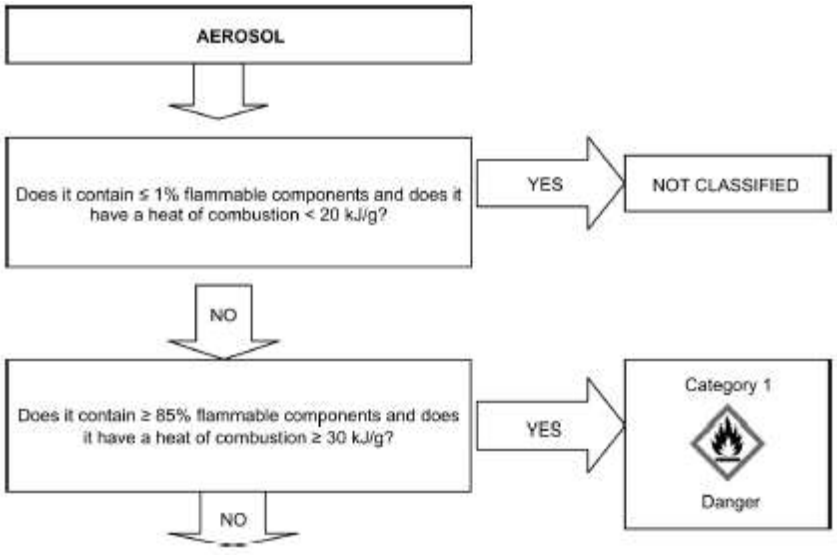
(1) Physico-chemistry

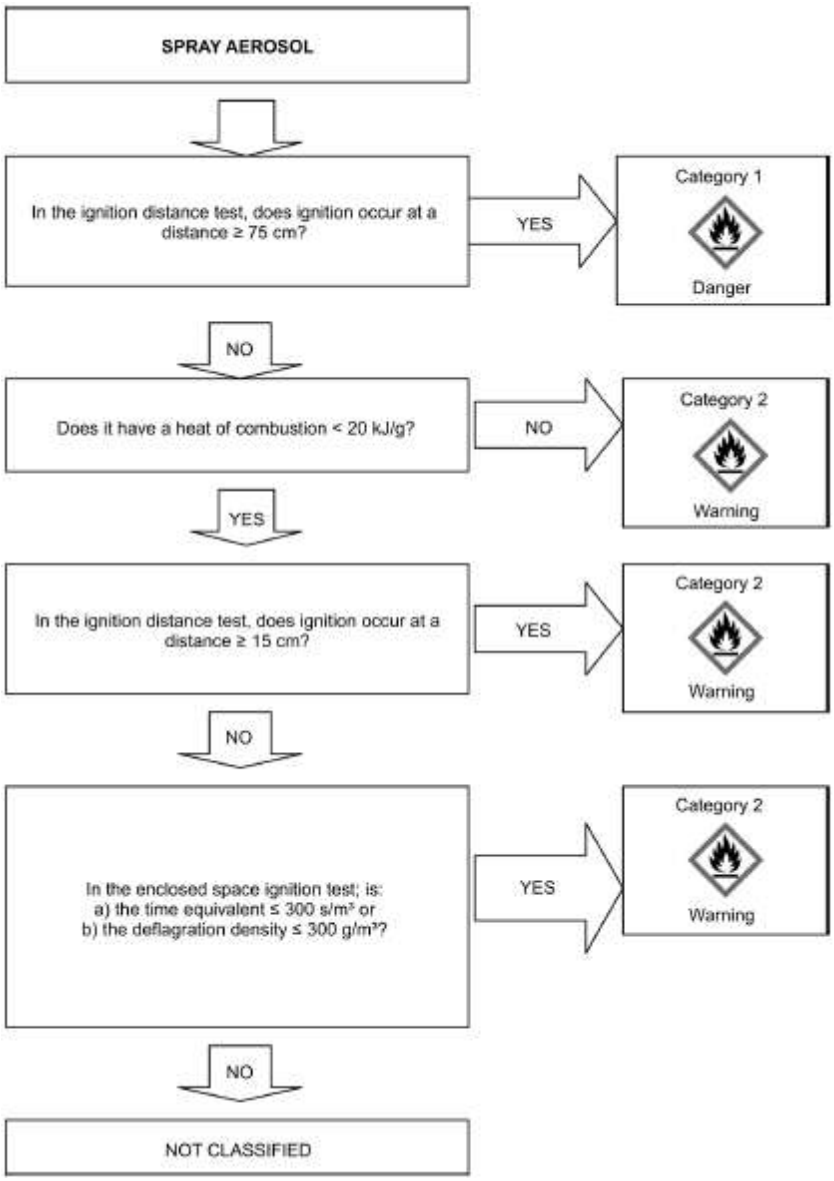
Preliminary remark:
The description and comparison of the criteria of PPP physical hazards is not exhaustive. Substance bearing characteristics such as explosivity, self-reactivity, oxidativity, pyrophoricity, self-heating or metal-corrosivity are not commonly part of PPP, or only in very exceptional cases, and are therefore not included in this chapter. The classification of gases under pressure (including their flammability) is driven by the components, and should be handled on a case by case basis.
However, most relevant and common PPP endpoints are covered below.

(a) Flammability

- Spray Aerosols (no direct corrolary in the DSD)

Table A.1: see following decision logic





Reference in ECHA-guidance: point 2.4

- Liquids

Table A.2

DSD			**CLP**		
	FP (°C)	BP (°C)	FP (°C)	BP (°C)	
F+; R12	<0	≤35	<23	≤35	Flam. Liquid 1, H224
F; R11	<21	-		>35	Flam. Liquid 2, H225
R10	≥21 and ≤55		≥21 and <23	≤35	Flam. Liquid 1, H224
				>35	Flam. Liquid 2, H225
			≥23 and ≤55	-	Flam. Liquid 3, H226
n.c.	>55 and ≤60		>55 and ≤60		

Notes:

(1) *n.c.: not classified under DSD*

(2) *FP: flash point*

(3) *BP: boiling point*

Reference in ECHA-guidance: point 2.7

- Solids

Table A.3

DSD			CLP		
				…and wetted zone stops fire for ≥4’	
F; R11	Burning time (s)	<45	<45	no	
	Or Burning rate (mm/s)	-	>2.2		Flam. Sol. 1, H228
F; R11	Burning time (s)	<45	<45	yes	
	Or Burning rate (mm/s)	-	>2.2		Flam. Sol. 2, H228
F; R11 (metal powders)	Burning time (min)	≤10	≤5		Flam. Sol. 1, H228
			>5 to ≤10		Flam. Sol. 2, H228

Reference in ECHA-guidance: point 2.8

(b) Aspiration hazard

Table A.4

DSD			CLP	
Xn; R65	Kinematic viscosity @40°C (mm²/s)	≤7	≤20.5	Asp. Tox. 1, H304
	And surface tension @25°C (mN/m)	≤33	-	

Notes:

- *Whereas hydrocarbons (chlorinated or not) and aromatic hydrocarbons present notorious aspiration hazard, other substances / mixtures may also be of concern.*
- *When a viscosity study is not present on the entire mixture, classification shall be applied if the total concentration of substances displaying aspiration hazard is ≥10%;*
- *Classification should also be based upon reliable and good quality human evidence;*
- *Normally, pressurised containers containing aspirable products but producing fine mists or aerosols will NOT be eligible for classification R65 or H304. In contrast self-pressurised containers, trigger- and pump sprayers producing coarsely pulverised sprays or stream liquids, potentially forming pools of aspirable product in the mouth should bear the classifications R65 or H304. Likewise, any product packed in a pump or trigger device where the spray device is removable, shall also be classified R65 or H304.*
- *The criteria for the aspiration hazard are currently not part of the ECHA guidance and are fully described in the Annex I part 3.10 of the CLP Regulation.*

(2) Toxicity

(a) Acute toxicity

Table B.5

		LD_{50} / LC_{50}	
Acute exposure	**DSD**	**Criteria]x-y]**	**CLP**
Oral (mg/kg bw)	T+; R28	0-5	Acute Tox. 1; H300
		5-25	Acute Tox. 2; H300
	T; R25	25-50	Acute Tox. 2; H300
		50-200	Acute Tox. 3; H301
	Xn; R22	200-300	Acute Tox. 3; H301
		300-2000	Acute Tox. 4; H302
Dermal (mg/kg bw)	T+; R27	0-50	Acute Tox. 1; H310
	T; R24	50-200	Acute Tox. 2; H310
		200-400	Acute Tox. 3; H311
	Xn; R21	400-1000	Acute Tox. 3; H311
		1000-2000	Acute Tox. 4; H312
Inhalation aerosol-mist (mg/L)			
	T+; R26	0-0.05	Acute Tox. 1; H330
		0.05-0.25	Acute Tox. 2; H330
	T; R23	0.25-0.5	
		0.5-1.0	Acute Tox. 3; H331
	Xn; R20	1.0-5.0	Acute Tox. 4; H332
Inhalation gas/vapour (mg/L)	T+; R26	0-0.5	Acute Tox. 1; H330
	T; R23	0.5-2.0	Acute Tox. 2; H330
	Xn; R20	2.0-10.0	Acute Tox. 3; H331
	n.c.	10.0-20.0	Acute Tox. 4; H332
Inhalation gas (ppm V/4h/d)	n.a.	0-100	Acute Tox. 1; H330
	n.a.	100-500	Acute Tox. 2; H330
	n.a.	500-2500	Acute Tox. 3; H331
	n.a.	2500-20000	Acute Tox. 4; H332

Reference in ECHA-guidance: point 3.1

Notes:

- *]x-y] means: exclusion of the minimum value and inclusion of the maximum value in the range;*
- *Already existent studies on identical or equivalent formulations should be submitted, along with a rationale supporting the bridging;*
- *Whereas the rat is the most common indicator species for acute studies, existing studies on other species should also be submitted, and will be evaluated and considered for classification if relevant;*
- *If a classification was allocated to any component of the formulation, based upon known effects on humans (because humans are more sensitive), further testing on laboratory animals is prohibited, and will be disregarded. In such cases, the classification should occur on the basis of the CLP calculation rules. Positive human data prevail on negative animal data;*
- *n.c.: not classified under DSD*
- *n.a.: not applied or defined under DSD*

(b) Local effects

Table B.6

	DSD			CLP		
		Exposure time]x-y]		**Exposure time]x-y] / Observation time]x-y]**		
Corrosion	**C+; R35**	0-3’		0-3’ / 0-60’		Skin Corr. 1A; H314
	C; R34	0-3’		3-60’ / 0-14d		Skin Corr. 1B; H314
				60-240’ / 0-14d		Skin Corr. 1C; H314
					Scores	
Skin irritation	**Xi, R38**	Erythema	≥2	Erythema	≥2.3, ≤4.0	Skin Irrit. 2; H315
		Edema	≥2	Edema	≥2.3, ≤4.0	
				Any irreversible effect in 2/3 animals d14		
Severe eye irritation/ damage	**Xi, R41**	Iris	=2	Iris	>1.5	Eye Dam. 1; H318
		Corn	≥3	Corn	≥3	
		Irreversible d21		Any irreversible effect in 1/3 animals d21		
Eye irritation	**Xi, R36**	Eryth	≥2.5	Eryth	≥2	Eye Irrit. 2; H319
		Chem	≥2	Chem	≥2	
		Iris[§]	≥1, <1.5	Iris	≥1	
		Corn	≥2, <3	Corn	≥1	

Reference in ECHA-guidance: point 3.2

Notes:

- *]x-y] means: exclusion of the minimum value and inclusion of the maximum value in the range*
- *24,48, 72h-average irritation scores (skin, eye):*
  - *<u>if 3</u> animals were tested one of the criteria will apply in at least 2/3 tested animals;*
    ([§] :in this case, classification trigger for iritis is ≥1, <2)
  - *<u>if 6</u> animals were tested one of the criteria will apply in all animals*
  - *<u>if 4 or 5</u> animals were tested one of the criteria will apply in at least 3/4, or 3/5 animals, respectively*
- *Corrosivity criterion: positive when observed in 1/3 animals;*
- *For eye or skin irritation, classification may be justified when a pronounced variability was observed, notwithstanding that the scores were lower than the criteria tabulated above; expert judgment will prevail.*
- *If a classification was allocated to any component of the formulation, based upon known effects on humans (because humans are more sensitive), further testing on laboratory animals is prohibited, and will be disregarded. In such cases, the classification will occur on the basis of the CLP calculation rules.*

(c) Skin sensitisation

Preliminary remarks:

- *Firstly, human evidence should also be used (either clinical or epidemiological data) to classify a formulation if such data are available. Positive human data prevail on negative animal data [high (1A) or low to moderate (1B) frequency in human].*
- *for PPP, the results of a Bühler test (any variant) on a formulation containing sensitising components will not be considered (as the GPMT or a LLNA assay have a better predictive power), and classification will happen on basis of the calculation rules. The local lymph node assay (LLNA) should be used preferably. In case the LLNA cannot be conducted a justification should be provided and the Guinea Pig Maximisation Test should be performed preferably.*
- *In the 2nd ATP of the CLP regulation, a distinction is made between 'moderate' sensitisers (cat 1B) and 'strong' sensitisers (cat 1A)*
  - *Under the DSD, the fraction of animals displaying positive effects (for GPMT and Bühler) or the average Stimulation Index (for LLNA) in treated animals (being ≥3×) is considered for classification.*
  - *Under the CLP, both the fraction of animals displaying positive effects and the induction dose of the test article are considered for classification (for GPMT and Bühler). For the LLNA assay, both the average Stimulation Index in treated animals (being ≥3×) and the EC_3 (amount of test article required to attain this positivity criterion) are considered for classification.*
  - *However, it is of note that the distinction between 'moderate' and 'strong' sensitisers is of more concern for the substances than for the formulations (only important if the formulation enters itself in another mixture).*

Table A.7

DSD			**CLP**			
	Sensitisation incidence score (%) or Stimulation Index (× fold)		**Sensitisation incidence score (%) or EC_3 [(1)] value (%)…**		**…at intradermal[(2)] or topical[(3)] induction dose (%)**	
R43	GPMT	≥30%	GPMT	≥30%	≤0.1	Skin Sens. 1A, H317
				≥60%	>0.1 and ≤1	
				≥30 to <60%	>0.1 and ≤1	Skin Sens. 1B, H317
				≥30%	>1	
	Bühler	≥15%	Bühler	≥15%	≤0.2	Skin Sens. 1A, H317
				≥60%	>0.2 and ≤20	
				15% to <60%	>0.2 and ≤20	Skin Sens. 1B, H317
				≥15%	>20	
	LLNA	≥3×	LLNA	≤2%		Skin Sens. 1A, H317
				>2%		Skin Sens. 1B, H317

Reference in ECHA-guidance: point 3.4

Notes:

- *[1]: for the LLNA test: EC_3 defined as the amount of test article (in %) required to elicit a Stimulation Index of ≥3×(= positivity criterium);*
- *[2,3]: in case of GPMT or Bühler assay, respectively*

(3) Ecotoxicity

Data on formulations which have been prepared for regulatory use in compliance with standard guidelines, such as test data on plant protection or biocidal products, are considered acceptable for classification. Where such valid test data, both acute and chronic, are available, they may be used in accordance with the general guidance below.
According Dir. 91/414/EEC and Reg (EC) No 1107/2009, all information which is necessary for the labelling of the product should be submitted for each authorisation; the other information should be submitted for each authorisation unless the authorities accept the applicant's claim that the information is already available to the authorities and can be used to the benefit of other applicants or unless he provides an acceptable justification for not supplying it.
In the tables below, an overview of the criteria according the DSD and CLP is given for formulations (Table A.8) and substances (Table A.8 and A.9); rows greyed out in the table are inappropriate for formulations, as log P_{ow}/BCF data are only attributable to substances.

Table A.8

DSD			**CLP**		
Classification	**Acute /chronic Endpoint (1)**	**Conc. (mg/L)**	**Acute /chronic Endpoint (1)**	**Conc. (mg/L)**	**Classification**
I. Acute aquatoxicity					
N; R50	$L(E)C_{50}$ (2)	≤1		≤1	**Aquatic Acute 1, H400**
II. Chronic aquatoxicity					
1 - Readily/Rapidly degradable (RD) (3)					
-	-	-	NOEC or EC_x	≤0.01	**Aquatic Chronic 1, H410**
-	-	-		>0.01 to ≤0.1	**Aquatic Chronic 2, H411**
-	-	-		>0.1 to ≤1	**Aquatic Chronic 3, H412**
2 - Not readily/ rapidly degradable (NRD) (3)					
a - Chronic studies available					
N; R50 – 53	$L(E)C_{50}$	≤1		≤1	**Aquatic Acute 1, H400**
-	-	-	NOEC or EC_x	≤0.1	**Aquatic Chronic 1, H410**
N; R51 – 53	$L(E)C_{50}$	>1 to ≤10		-	-
-	-	-	NOEC or EC_x	>0.1 to ≤1	**Aquatic Chronic 2, H411**
R52 – 53	$L(E)C_{50}$ unless NOEC	>10 to ≤100 >1	-	- -	- -
R53 (4)	$L(E)C_{50}$	>w.s.		>w.s.	**Aquatic Chronic 4, H413**
(w.s.<1 mg/L)	Log P_{ow} ≥ 3 unless BCF ≤ 100	-	Log P_{ow} ≥ 4 **or** BCF ≥ 500	- -	
	unless NOEC	>w.s.		>1 or >w.s.	

Reference in ECHA-guidance: point 4.1

Table A.9

DSD			**CLP**		
Classif.	**Acute /chronic Endpoint [1]**	**Conc. (mg/L)**	**Endpoint**	**Conc. (mg/L)**	**Classification**
2 - Not readily/ rapidly degradable (NRD) [3]					
b - Chronic studies unavailable					
N; R50 – 53	$L(E)C_{50}$ [2]	≤1		≤1	**Aquatic Acute 1, H400**
	Log P_{ow}… ≥3 …unless BCF ≤100		Log P_{ow} ≥4 **or** BCF ≥500		**Aquatic Chronic 1, H410**
N; R51 – 53	$L(E)C_{50}$	>1 to ≤10		>1 to ≤10	**Aquatic Chronic 2, H411**
	Log P_{ow}… ≥3 …unless BCF ≤100		Log P_{ow} ≥4 **or** BCF ≥500		
R52 – 53	$L(E)C_{50}$	>10 to ≤100		>10 to ≤100	**Aquatic Chronic 3, H412**
	Log P_{ow}… ≥3 …unless BCF ≤100 Unless NOEC	 >1	Log P_{ow} ≥4 **or** BCF ≥500 -		
R53 [4]	$L(E)C_{50}$	>w.s.		>w.s.	**Aquatic Chronic 4, H413**
(w.s.<1 mg/L)	Log P_{ow}… ≥3 …unless BCF ≤100 unless NOEC	 >w.s.	Log P_{ow} ≥4 **or** BCF ≥500	 >1 or >w.s.	

Notes Tables A.8-A.9:

(1) Indicator organisms: Fish, Crustacea/Chironomus; Algae/Lemna. However, if existing studies of any component on other non-target organisms (NTO) would demonstrate a higher sensitivity compared to the standard indicator organisms, then these results should be to extrapolated the mixture by means of the CLP calculation rules. Otherwise, study results of the mixture on the most sensitive NTO could be provided (only existing ones for vertebrate species or new ones in the other cases). Chronic toxicity assessment on substances should normally be present for all 3 trophic levels. If only 1 or 2 levels were assessed, then concomitant available chronic toxicity endpoints will be considered (RD or NRD), and acute toxicity endpoints will be considered for the lacking trophic level(s). Classification will happen according the most severe outcome.

(2) Based upon lowest EC_{50}-value on algae/lemna, except if the basis of EC_{50} is specified/recorded, then take E_rC_{50} (50% growth rate inhibition).

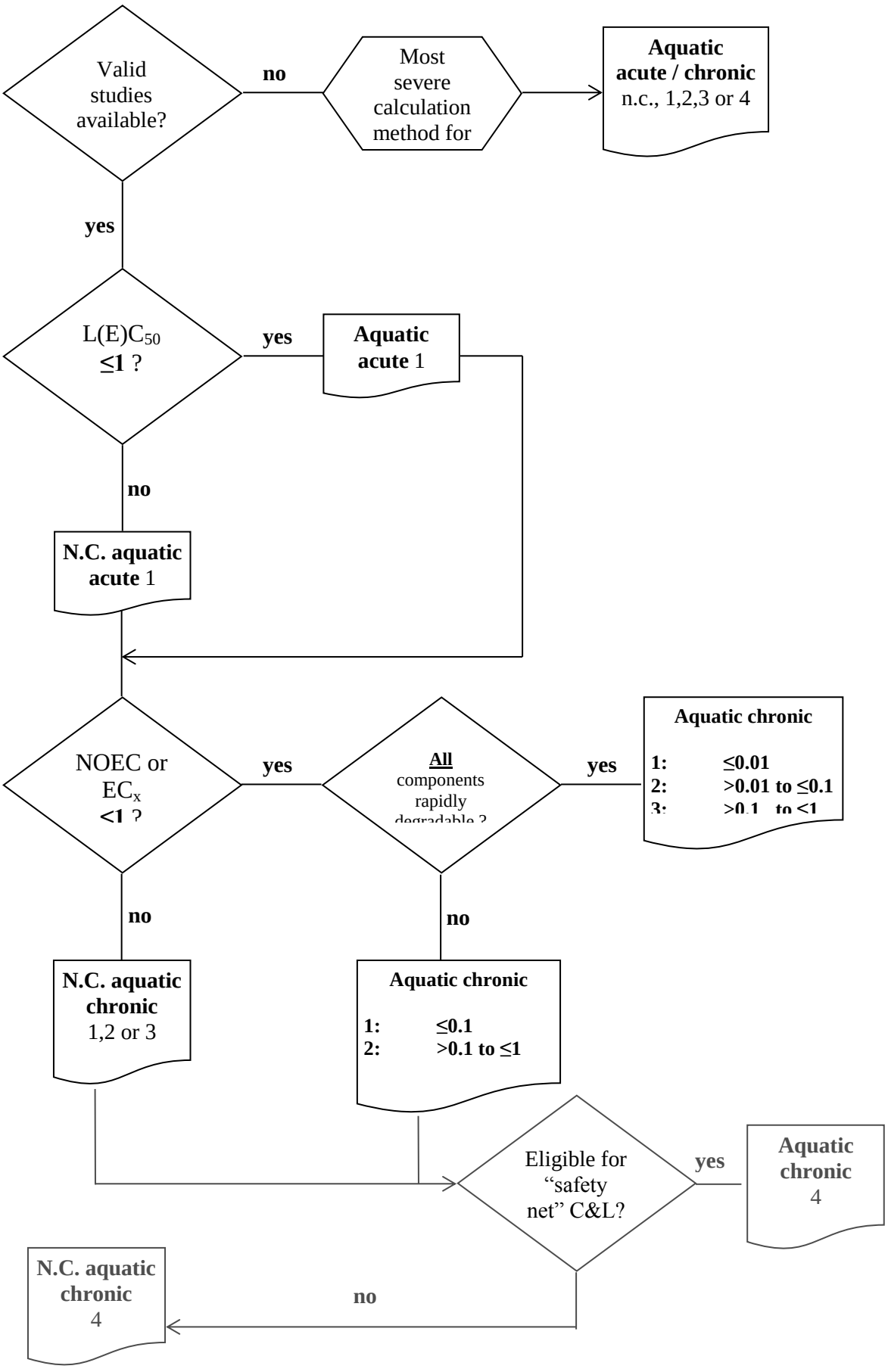
(3) In the absence of reliable degradability studies (fate) on the substance(s), the substance(s) is (are) considered not rapidly degradable; a mixture containing at least one non-rapidly degradable is considered not rapidly degradable as a whole.

(4) For poorly water soluble components or formulation (water solubility, w.s. <1 mg/L), when there is evidence that acute tests do not provide a true measure of the intrinsic toxicity.

On the next page, a simplified flowchart was proposed in order to reflect the way to classify the phytopharmaceutical products (criteria expressed in mg/L).

- In the absence of studies, the C&L will be established on the basis of the summation calculation method or the additivity method, whichever provides the most severe result (summation method is preferred);
- If chronic study results on the formulation are available however, they should be submitted;

A valid formulation study set will cover all three trophic levels, and in any case include any non-target aquatic organism (NTO) which would be the most sensitive. The tested NTO will be exposed to all toxic components of the mixture in the proportion to the composition of the formulation and levels are maintained for the duration of the test. The use of equivalent formulations in the "bridging" approach should be adequately justified.


Valid studies available?
no
Most severe calculation method for
Aquatic acute / chronic n.c., 1,2,3 or 4
yes
L(E)C50 ≤1 ?
yes
Aquatic acute 1
no
N.C. aquatic acute 1
NOEC or ECx <1 ?
yes
All components rapidly
yes
Aquatic chronic
1: ≤0.01
2: >0.01 to ≤0.1
3: >0.1 to <1
no
no
N.C. aquatic chronic 1,2 or 3
Aquatic chronic
1: ≤0.1
2: >0.1 to ≤1
Eligible for "safety net" C&L?
yes
Aquatic chronic 4
N.C. aquatic chronic 4
no

(B) In the absence of studies, classification of the formulation occurs on the basis of calculation rules.

Preliminary remarks

- *In order to ease the comparison between the calculation rules under the DPD (1999/45/EC) and the CLP-regulation, (simplified) tables with the generic concentration limits (GCL) to carry over the classification of the components to the formulation are presented;*
- *Most importantly, it should be kept in mind that the substance-specific concentration limits (SCL), established in Annex VI of the CLP regulation, take precedence over the generic ones;*
- *Calculation rules may take into account both the endpoints and/or the final concentration of the components. In these cases all elements necessary for the calculation are mentioned;*
- *For the sake of completeness, DSD and CLP classification criteria for specific target organ toxicity endpoints of components are also mentioned, as it may be necessary to revise the classification of these components.*
  In practice, this means that short-term studies or short-term intermediate phases/ sacrifices of longer-term studies need to be revisited to re-assess the need for re-classification under CLP. This is especially relevant for the revised active substances of pesticide formulations.

(1) Physico-chemistry

a) Flammability: for PPP rely only on studies of the formulation
b) Aspiration hazard: trigger value at **10%** in the formulation (both DPD and CLP)

(2) Toxicity

a) Acute toxicity

- DPD

Table B.1

Component classification				Formulation classification (%)		
	Inhalation	**Dermal**	**Oral**	**T+**	**T**	**Xn**
T+	R26	R27	R28	≥7	≥1 to <7	≥0.1 to <1
T	R23	R24	R25	-	≥25	≥3 to <25
Xn	R20	R21	R22	-	-	≥25

- CLP

Acute toxicity estimates (ATE_i) are established according to the table below and final concentrations (C_i) are determined for each component (total of n in the formulation).
The toxicity of the formulation (mixture ATE_{mix}) is estimated as follows (extended formula, normalised for the fraction of components for which acute toxicity data are known, provided the sum of all unknown is >10%) :

$$\frac{100 - (\sum C_{\text{unknown}} \text{ if } > 10\% \ )}{ATE_{mix}} = \sum_{\eta} \frac{Ci}{ATEi}$$

The point estimates of the components are derived from the $L(C)/D_{50}$ or ppm V ranges as follows:

Table B.2

	Oral		**Dermal**		**Inhalation**					
					Dust / mist		**vapours**		**gases**	
Cat.	**LD_{50} range]x-y] mg/kg bw**	**ATE ***	**LD_{50} range]x-y] mg/kg bw**	**ATE ***	**LC_{50} range]x-y] mg/L**	**ATE ***	**LC_{50} range]x-y] mg/L**	**ATE ***	**range]x-y] ppm V**	**ATE ***
1	0-5	0.5	0-50	5	0-0.05	0.005	0-0.5	0.05	0-100	10
2	5-50	5	50-200	50	0.05-0.5	0.05	0.5-2.0	0.5	100-500	100
3	50-300	100	200-1000	300	0.5-1.0	0.5	2.0-10.0	3	500-2500	700
4	300-2000	500	1000-2000	1100	1.0-5.0	1.5	10.0-20.0	11	2500-20000	4500

Notes

- *The converted acute toxicity estimates (*) are designed to be used in the calculation of the ATE for classification of a mixture based on its components and do not represent test results*
- *]x-y] means: exclusion of the minimum value and inclusion of the maximum value in the range*

General observation: substance-specific concentration limits (SCL), established in Annex VI of the CLP regulation, take precedence over the tabulated generic concentration limits (GCL).

b) Local effects

- DPD solids, liquids

Table B.3

Component classification	Formulation classification (%)				
	C+; R35	**C; R34**	**Xi; R41**	**Xi; R36-37-38***	**R66**
C+; R35	≥10	≥5 to <10	≥5	≥1 to <5	
C; R34		≥10	≥10	≥5 to <10	
Xi; R41			≥10	≥5 to <10	
Xi; R36-37-38				≥20	
R66					≥10

**apply all or some as appropriate*

- DPD gases

Table B.4

Component classification	Formulation classification (%)			
	C+; R35	**C; R34**	**Xi; R41**	**Xi; R36-37-38***
C+; R35	≥1	≥0.2 to <1	≥0.2	≥0.02 to <0.2
C; R34		≥5	≥5	≥0.5 to <5
Xi; R41			≥5	≥5 to <10
Xi; R36-37-38				≥5

**apply all or some as appropriate*

- CLP

  - **Corrosion, skin irritation**

Table B.5

Component classification	Formulation classification (%)	
	Skin Corrosive Cat. 1	**Skin irritant Cat. 2**
Skin corrosive Cat. 1A, 1B, 1C	≥5	
Skin irritant Cat. 2		≥10
(10 x Skin corrosive Cat. 1A, 1B, 1C) + Skin irritant Cat. 2		≥10
pH≤2 or ≥11.5**	≥1	
Skin corrosive Cat. 1 (no addit)*	≥1	
Skin irritant Cat. 2 (no addit)*		≥3

**to apply in case chemical classes of components are so different that additivity is inappropriate*
*** If there are indications that the substance may not be corrosive despite the low or high pH value, then further testing shall be carried out to confirm this, preferably by use of an appropriate validated in vitro test.*

Reference in ECHA-guidance: point 3.2.3.3

General observation: substance-specific concentration limits (SCL), established in Annex VI of the CLP regulation, take precedence over the tabulated generic concentration limits (GCL).

- **Eye irritation**

Table B.6

Component classification	**Formulation classification (%)**	
	Irreversible Eye Effects	**Reversible Eye Effects**
	Cat.1	**Cat.2**
Eye Effects Cat. 1 or Skin Corrosive Cat. 1	≥3	≥1 to<3
Eye Effects Cat. 2		≥10
(10 x Eye Effects Cat. 1) + Eye effects Cat. 2		≥10
Skin Corrosive Cat. 1+ Eye effects Cat. 1	≥3	≥1 to<3
10 x (Skin Corrosive Category 1+ Eye Effects Category 1) + Eye Effects Category 2		≥10
pH≤2 or ≥11.5**	≥1	
Skin corrosive Cat. 1 (no addit)*	≥1	
Skin irritant Cat. 2 (no addit)*		≥3

**to apply in case chemical classes of components are so different that additivity is inappropriate*
*** If there are indications that the substance may not be corrosive despite the low or high pH value, then further testing shall be carried out to confirm this, preferably by use of an appropriate validated in vitro test.*

Reference in ECHA-guidance: point 3.3.3.3

General observation: substance-specific concentration limits (SCL), established in Annex VI of the CLP regulation, take precedence over the tabulated generic concentration limits (GCL).

c) Sensitisation

- DPD

Table B.7

Component classification	**Formulation classification (%)**			
		Xn; R42	**R43**	***"Contains (…). May produce an allergic reaction"***
Xn; R42	Solid, liquid	≥1	-	≥0.1
	Gas	≥0.2	-	
R43	Solid, liquid	-	≥1	
	Gas	-	≥0.2	

- CLP

Table B.8

Component classification	**Formulation classification (%)**			
		Resp. Sens. 1	**Skin Sens. 1**	***"Contains (…). May produce an allergic reaction"****
Resp. Sens. 1	Solid, liquid	≥1.0	-	≥0.1
	Gas	≥0.2	-	
Resp. Sens. 1A	Solid, liquid, gas	≥0.1	-	≥0.01
Resp. Sens. 1B	Solid, liquid	≥1.0	-	≥0.1
	Gas	≥0.2	-	
Skin Sens. 1		-	≥1.0	≥0.1
Skin Sens. 1A		-	≥0.1	≥0.01
Skin Sens. 1B		-	≥1.0	≥0.1

**: for sensitising components with specific concentration limits (SCL) <0.1%, the special phrase should be mentioned when the component is present at ≥1/10th of SCL*

General observation: substance-specific concentration limits (SCL), established in Annex VI of the CLP regulation, take precedence over the tabulated generic concentration limits (GCL).

Reference in ECHA-guidance: point 3.4.3.3

d) Specific target organ toxicity – single exposure (STOT SE)

- DPD

Table B.9

Component classification				Formulation classification (%)				
	Inhalation	**Dermal**	**Oral**	**T+**	**T**	**Xn**	**Xi; R37**	**R67**
T+	R39/26	R39/27	R39/28	≥10	≥1 to <10	≥0.1 to <1		-
T	R39/23	R39/24	R39/25		≥10	≥1 to <10		-
Xn	R68/20	R68/21	R68/22			≥10		-
Xi	R37	-	-	-	-	-	≥20	-
	R67	-	-	-	-	-	-	≥15

- CLP

Table B.10

Component classification	Formulation classification (%)		
	STOT SE 1	**STOT SE 2**	**STOT SE 3**
STOT SE 1	≥10	≥1 to <10	
STOT SE 2		≥10	
STOT SE 3*			≥20

**: includes former Xi, R37(H335) and R67(H336); this GCL should be considered on a case-by-case basis, and expert judgment may be invoked to revise it up- or downwards.*

General observation: substance-specific concentration limits (SCL), established in Annex VI of the CLP regulation, take precedence over the tabulated generic concentration limits (GCL).

Reference in ECHA-guidance: point 3.8.3.3

- Comparison between DSD and CLP criteria (substance-related)

The criteria for STOT SE classification of <u>substances</u> are mentioned below:

Table B.11

		LOAEL/LOAEC	
Single exposure	**DSD**	**Criteria]x-y]**	**CLP**
Oral (mg/kg bw)	T+; R39/28	0-25	STOT SE 1, H370
	T; R39/25	25-200	
	Xn; R68/22	200-300	
		300-2000	STOT SE 2, H371
Dermal (mg/kg bw)	T+; R39/27	0-50	STOT SE 1, H370
	T; R39/24	50-400	
	Xn; R68/21	400-1000	
		1000-2000	STOT SE 2, H371
Inhalation aerosol-mist (mg/L)	T+; R39/26	0-0.25	STOT SE 1, H370
	T; R39/23	0.25-1	
	Xn; R68/20	1.0-5.0	STOT SE 2, H371
Inhalation gas/vapour (mg/L)	T+; R39/26	0-0.5	STOT SE 1, H370
	T; R39/23	0.5-2.0	
	Xn; R68/20	2.0-10.0	
	n.c.	10.0-20.0	STOT SE 2, H371
Inhalation gas (ppm V/4h/d)	n.a.	0-100	STOT SE 1, H370
	n.a.	100-500	
	n.a.	500-2500	
	n.a.	2500-20000	STOT SE 2, H371

Notes:

- *]x-y] means: exclusion of the minimum value and inclusion of the maximum value in the range*
- *n.c.: not classified under DSD*
- *n.a.: not applied or defined under DSD*

Reference in ECHA-guidance: point 3.8.2.2.1

e) Specific target organ toxicity – repeated exposure (STOT RE)

- DPD

Table B.12

Component classification				**Formulation classification (%)**		
	Inhalation	**Dermal**	**Oral**	**T**	**Xn**	**R33**
T	R48/23	R48/24	R48/25	≥10	≥1 to <10	-
Xn	R48/20	R48/21	R48/22	-	≥10	-
	R33	-	-	-	-	≥1

- CLP

Table B.13

Component classification	**Formulation classification (%)**	
	STOT RE 1	**STOT RE 2**
STOT RE 1	≥10	≥1 to <10
STOT RE 2*		≥10

**: theoretically includes former R33 (H373); however, not of application in PPP*

General observation: substance-specific concentration limits (SCL), established in Annex VI of the CLP regulation, take precedence over the tabulated generic concentration limits (GCL).

Reference in ECHA-guidance: point 3.9.3.2

- Comparison between DSD and CLP criteria (substance-related)

The criteria for STOT RE classification of substances are mentioned below:

Table B.14

		LOAEL / LOAEC	
Repeated exposure	**DSD**	**Criteria]x-y]**	**CLP**
Oral (mg/kg bw/d)	T; R48/25	0-5	STOT RE 1, H372
	Xn; R48/22	5-10	STOT RE 1, H372
		10-50	STOT RE 2, H373
	n.c.	50-100	STOT RE 2, H373
Dermal (mg/kg bw/d)	T; R48/27	0-10	STOT RE 1, H372
	Xn; R48/21	10-20	STOT RE 1, H372
		20-100	STOT RE 2, H373
	n.c.	100-200	STOT RE 2, H373
Inhalation aerosol-mist (mg/L/d)	T; R48/23	0-0.02	STOT RE 1, H372
		0.02-0.025	STOT RE 2, H373
	Xn; R48/20	0.025-0.2	STOT RE 2, H373
		0.2-0.25	n.c.
Inhalation vapour (mg/L/d)	n.a.	0-0.20	STOT RE 1, H372
	n.a.	0.02-1.0	STOT RE 2, H373
Inhalation gas (ppm V/6h/d)	n.a.	0-50	STOT RE 1, H372
	n.a.	50-250	STOT RE 2, H373

Notes:

- *]x-y] means: exclusion of the minimum value and inclusion of the maximum value in the range*
- *Criteria valid for 90d-studies; values to be multiplied by 3 when effects are observed in 28d-studies.*
- *n.c.: not classified under DSD or CLP*
- *n.a.: not applied or defined under DSD*

Reference in ECHA-guidance: point 3.9.2.2

f) C M R - endpoints

- DPD: Table B.15

Component classification	**Formulation classification (%)**							
	Carc. Cat 1 – 2 (inh – oral)	Carc. Cat 3	Muta. Cat 1 - 2	Muta. Cat 3	Repr. Cat 1 - 2		Repr. Cat 3	R64
					Gas	Non-gas		
Carc. Cat 1 – 2 (R45 or 49)	≥0.1							
Carc. Cat 3 (R40)		≥1						
Muta. Cat 1 – 2 (R46)			≥0.1					
Muta. Cat 3 (R68)				≥1				
Repr.Cat 1 – 2 (R60 or 61)					≥0.5	≥0.2		
Repr.Cat 1 – 2 (R62 or R63)							≥5	
R64								≥1

Note: the classes greyed out are mentioned only for completeness, as they are not of application in PPP, with the exception of Carbendazim (until 30.11.2014)

- CLP: Table B.16

Component classification	**Formulation classification (%)**						
	Carc. 1A – 1B (inh – oral)	Carc. 2	Muta. 1A – 1B	Muta. 2	Repr. 1A – 1B	Repr. 2	Lact.
Carc. 1A – 1B (H350)	≥0.1						
Carc. 2 (H351)		≥1					
Muta. 1A – 1B (H340)			≥0.1				
Muta. 2 (H341)				≥1			
Repr. 1A – 1B (H360 F or D)					≥0.3		
Repr. 2 (H361f or d)						≥3	
Lact.							≥0.3

Note: the classes greyed out are mentioned only for completeness, as they are not of application in PPP, with the exception of Carbendazim (until 30.11.2014). In addition substances classified Repr. 1A – 1B will be banned under regulation 1107/2009 (cut-off criteria)

General observation: substance-specific concentration limits (SCL), established in Annex VI of the CLP regulation, take precedence over the tabulated generic concentration limits (GCL).

Reference in ECHA-guidance: points 3.6.3 (C) – 3.5.3 (M) – 3.7.3 (R)

(3) Ecotoxicity

- DPD

Table B.17

Component classification	**Formulation classification (%)**		
LC_{50} or EC_{50} (mg/L)	**N, R50(-53)**	**N, R51-53**	**R52-53**
R52-53			
$10<L(E)C_{50}\leq 100$	-	-	$C_n\geq 25$
N; R51-53			
$1<L(E)C_{50}\leq 10$	-	$C_n\geq 25$	$2.5\leq C_n<25$
N; R50(-53)			
$0.1<L(E)C_{50}\leq 1$	$C_n\geq 25$	$2.5\leq C_n<25$	$0.25\leq C_n<2.5$
$0.01<L(E)C_{50}\leq 0.1$	$C_n\geq 2.5$	$0.25\leq C_n<2.5$	$0.025\leq C_n<0.25$
$0.001<L(E)C_{50}\leq 0.01$	$C_n\geq 0.25$	$0.025\leq C_n<0.25$	$0.0025\leq C_n<0.025$
$0.0001<L(E)C_{50}\leq 0.001$	$C_n\geq 0.025$	$0.0025\leq C_n<0.025$	$0.00025\leq C_n<0.0025$
$0.00001<L(E)C_{50}\leq 0.0001$	$C_n\geq 0.0025$	$0.00025\leq C_n<0.0025$	$0.000025\leq C_n<0.00025$
$L(E)C_{50}\leq 0.00001$	*	*	*

Notes:

- *For preparations containing substances with an $L(E)C_{50}$ value< 0.00001 mg/L, the corresponding GCL (*) are calculated accordingly (in factor 10 intervals).*
- *Substances classified N; R59 have GCL ≥ 0.1% in the preparations; however such cases should not occur in PPP.*

- CLP

Preliminary remarks:

- *Additionally to the acute toxicity, chronic aquatic toxicity endpoints of the components are taken on board for the calculation in the CLP. This calculation may be performed by means of the additivity method or the summation method.*
- *Shortly, the additivity method will be used if the final classification of the various components remains unknown or uncertain, and only $L(E)C_{50}$ or NOEC's are available for at least a part of the mixture. The summation method is more straightforward, and makes use of the aquatox classification of the various components. In practice, the summation method is most often used. Indeed, with the aquatic toxicity data at hand the component classification and M-factor(s) could be derived by a direct comparison with the substance criteria, which then could enter in the summation method. It will therefore usually not be necessary to use the additivity formulae. Moreover, if a reliable calculation is possible on the basis of both calculations, the most conservative figure shall be applied anyway.*

- ***Summation method****:*

For both acute and chronic effects, M-factors are defined at the substance level, reflecting the impact of the intrinsic ecotoxicity of the substance <L(E)C_{50}=1 mg/L , in steps of 10.

Table B.18

Acute toxicity	**M-factor**	**Chronic toxicity**	**M-factor**	
L(E)C_{50} (mg/L)		**NOEC (mg/L)**	**NRD**	**RD**
0.1<L(E)C_{50}≤1	1	0.01<NOEC≤0.1	1	-
0.01<L(E)C_{50}≤0.1	10	0.001<NOEC≤0.01	10	1
0.001<L(E)C_{50}≤0.01	100	0.0001<NOEC≤0.001	100	10
0.0001<L(E)C_{50}≤0.001	1000	0.00001<NOEC≤0.0001	1000	100
0.00001<L(E)C_{50}≤0.0001	10000	0.000001<NOEC≤0.00001	10000	1000
(continue in 10 × intervals)				

NRD: non-rapidly degradable or RD: rapidly degradable components

Table B.19

CLP	
∑ Components classified ≥ 25 %:	**Formulation classification**
Acute 1 × M	Acute 1; H400
Chronic 1 × M	Chronic 1; H410
(M × 10 × Chronic 1) + Chronic 2	Chronic 2; H411
(M × 100 × Chronic 1) + (10 × Chronic 2) + Chronic 3	Chronic 3; H412
Chronic 1 + Chronic 2 + Chronic 3 + Chronic 4	Chronic 4; H413

The factor of 1, 10 and 100 reflect the"weight" of classified components in the mixtures

- ***Additivity method****: the derived acute toxicity (L/EC_{50}m) and chronic toxicity (EqNOECm) endpoints are based upon the concentrations (C_i) of either rapidly (i) or non-rapidly (j) degradable components, and the concomitant endpoints of the "n" components, and is calculated as follows:*

Acute aquatic toxicity:

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

Chronic aquatic toxicity:

$$\frac{\sum Ci + \sum Cj}{EqNOECm} = \sum_{n} \frac{Ci}{NOECi} + \sum_{n} \frac{Cj}{0,1 \times NOECj}$$

(4) **Fate in the environment** (see criteria for substances and Chronic 4 criteria aquatox)

(C) Checklist of formulation study results to submit and/or CLP calculations to carry over substance C&L *(see also xls-template on fytoweb, or own template if available)*

Part 1: study results on the formulation

(1) General formulation data:

- Administrative dossier data : filenumber (N), authorisation number (/B), commercial name, company name, type (GCPF-code)
- formulation / development code of the formulation
- Classification and Labelling of the ***formulation****

= existing C&L (existing authorisation product) and proposed C&L (new authorisation product)

[see p1/8 of CLP-template]

- CLP proposal of the formulation based upon calculation and/or test results

[see p2/8 of CLP-template]

- composition of the formulation, with the labeling of each ***component*** (short notation)
  - DPD: Symbol + R-phrase(s) *and/or*:
  - CLP*: GSH pictogram + H-phrase(s)

    (to add if present in your information)

[see p3/8 of CLP-template]

***Note: the C&L elements of the formulation include:**

- DPD:
  - Symbols (e.g. Xn, N,…) and indications of danger (e.g. “flammable”, “harmful”)
  - Pictograms associated with the dangers
  - Risk phrases (R…)
  - Additional phrases issued from the DPD-legislation (other mentions)
  - Safety phrases (S…)

- CLP:
  - Classification “Category…”
  - GSH pictograms: GSH n° + pictogram
  - Signal word(s): ‘danger’ or ‘warning’
  - Hazard Statements (H…; EUH…)
  - Precautionary statements (P…)

- Further, typical PPP-phrases should be mentioned when relevant:
  - Special risk (HH, Environment) phrases (RSh…)
  - Safety precautions (SP…)

- Finally, specific labels issued from other legislations should be added where necessary (eg. Aerosol phrases,…)

Remark: CLP data of the components as mentioned in the SDS, ECHA inventory (which may include harmonised C&L of Annex VI, if any), and/or information otherwise provided by the manufacturer/importer

(2) physico-chemistry

- solids:
  - highly flammable solid ? (y/n)
  - flammability: burning time (s)
- liquids:
  - flash-point (°C)
  - boiling point (°C)
  - surface tension (N/m, 25°c)
  - kinematic viscosity (mm^2/s, 40°C)
  - dynamic viscosity (Pa.s)
  - density
- gas: flammable gas? (y/n)
- aerosol :
  - combustion heat (kJ/g)
  - ignition distance (cm)
  - Enclosed space ignition test: time equivalent (s/m^3) and deflagration density (g/m^3)

Conclusion: physical hazard C&L:

- Flammability
- Oxidising hazard
- Aspiration hazard
- Other (if relevant)

[see p4/8 of CLP-template]

(3) Toxicology

- Oral toxicity (mg/kg bw)
- Dermal toxicity (mg/kg bw)
- Inhalation toxicity (mg/L)
- Skin irritation (scores-3 or 6 animals)
- Eye irritation (scores-3 or 6 animals)
- Skin sensitisation
  - sensitisation incidence score or EC_3 value –LLNA)
  - intradermal/topical induction dose (if present)

Conclusion: human health C&L:

- Oral toxicity
- Dermal toxicity
- Inhalation toxicity
- Skin irritation
- Eye irritation
- Skin sensitisation

[see p5/8 of CLP-template]

(4) Ecotoxicology (aquatox)

- Fish
  - Exposure time (96h, 7d, 14d, 28d,…)
  - LC_{50} (mg/L)
  - NOEC (mg/L)
- Crustacea
  - Exposure time (96h, 7d, 14d, 28d,…)
  - EC_{50} (mg/L)
  - NOEC (mg/L)
- Insecta: Chironomus
  - Exposure time (96h, 7d, 14d, 28d,…)
  - EC_{50} (mg/L water or mg/kg sediment – whatever is the lowest)
  - NOEC (mg/L water or mg/kg sediment – whatever is the lowest)
- Algae
  - Exposure time (72h)
  - E_bC_{50} (mg/L)
  - E_yC_{50} (mg/L)
  - E_rC_{50} (mg/L)
  - NOEC (mg/L)
- Aquatic plants: Lemna (7d, 14d, 28d,…)
  - E_bC_{50} (mg/L)
  - E_yC_{50} (mg/L)
  - E_rC_{50} (mg/L)
  - NOEC (mg/L)
- Other Non Target Organisms (NTO)
  - Exposure time (…h, …d, …,…)
  - $L(E)C_{50}$ (mg/L)
  - NOEC (mg/L)

Conclusion: ecotoxicity C&L

- Based upon lowest value:
  - Aquatic acute
  - Aquatic chronic

[see p6/8 of CLP-template]

Part 2: calculations based upon classification of the components

Toxicology

(1) Acute toxicity and primary irritation, including sensitisation endpoints

(2) Subacute/subchronic/chronic toxicity endpoints

(a) Single exposure

(b) Repeated exposure

(3) CMR endpoints

(a) Carcinogenicity

(b) Mutagenicity

(c) Fertility / Development / Lactation

Ecotoxicology

(4) Aquatic acute endpoints

(5) Aquatic chronic endpoints

[data relevant for the calculation p2/8 and submitted classification on composition sheet p3/8 of CLP-template]

(E) Conversion of the existing C&L (67/548/EEC and 1999/45/EC) to the CLP based upon the translation table of Annex VII of the CLP regulation;

Translation between classification according the Directives and the CLP Regulation

Table A.1

Classification under Dir 67/548/EEC	Physical state	Classification under CLP		Note
		Hazard Class / Category	H- statement	
E; R2		No direct translation possible.		
E; R3		No direct translation possible.		
O; R7		Org. Perox. CD	H242	
		Org. Perox. EF	H242	
O; R8	gas	Ox. Gas 1	H270	
O; R8	liquid, solid	No direct translation possible.		
O; R9	liquid	Ox. Liq. 1	H271	
O; R9	solid	Ox. Sol. 1	H271	
R10	liquid	No direct translation possible. Correct translation of R10, liquid is: Flam. Liq. 1, H224 if flashpoint < 23 °C and initial boiling point ≤ 35°C Flam. Liq. 2, H225 if flashpoint < 23°C and initial boiling point > 35 °C Flam. Liq. 3, H226 if flashpoint ≥ 23°C		
F; R11	liquid	No direct translation possible. Correct translation of F; R11, liquid is: Flam. Liq. 1, H224 if initial boiling point ≤ 35°C Flam. Liq. 2, H225 if initial boiling point > 35°C		
F; R11	solid	No direct translation possible.		
F+; R12	gas	No direct translation possible. Correct translation of F+; R12, gaseous results either in Flam. Gas 1, H220 or Flam. Gas 2, H221.		
F+; R12	liquid	Flam. Liq. 1	H224	
F+; R12	liquid	Self-react. CD	H242	
		Self-react. EF	H242	
		Self-react. G	none	
F; R15		No translation possible.		
F; R17	liquid	Pyr. Liq. 1	H250	
F; R17	solid	Pyr. Sol. 1	H250	
Xn; R20	gas	Acute Tox. 4	H332	(1)
Xn; R20	vapours	Acute Tox. 4	H332	(1)
Xn; R20	dust/mist	Acute Tox. 4	H332	
Xn; R21		Acute Tox. 4	H312	(1)
Xn; R22		Acute Tox. 4	H302	(1)
T; R23	gas	Acute Tox. 3	H331	(1)
T; R23	vapour	Acute Tox. 2	H330	
T; R23	dust/mist	Acute Tox. 3	H331	(1)
T; R24		Acute Tox. 3	H311	(1)
T; R25		Acute Tox. 3	H301	(1)
T+; R26	gas	Acute Tox. 2	H330	(1)
T+; R26	vapour	Acute Tox. 1	H330	
T+; R26	dust/mist	Acute Tox. 2	H330	(1)

Classification under Dir 67/548/EEC	Physical state	Classification under CLP		Note
		Hazard Class / Category	H- statement	
T+; R27		Acute Tox. 1	H310	
T+; R28		Acute Tox. 2	H300	(1)
R33		STOT RE 2	H373	(3)
C; R34		Skin Corr. 1B	H314	(2)
C; R35		Skin Corr. 1A	H314	
Xi; R36		Eye Irrit. 2	H319	
Xi; R37		STOT SE 3	H335	
Xi; R38		Skin Irrit. 2	H315	
T; R39/23		STOT SE 1	H370	(3)
T; R39/24		STOT SE 1	H370	(3)
T; R39/25		STOT SE 1	H370	(3)
T+; R39/26		STOT SE 1	H370	(3)
T+; R39/27		STOT SE 1	H370	(3)
T+; R39/28		STOT SE 1	H370	(3)
Xi; R41		Eye Dam. 1	H318	
R42		Resp. Sens. 1	H334	
R43		Skin Sens. 1	H317	
Xn; R48/20		STOT RE 2	H373	(3)
Xn; R48/21		STOT RE 2	H373	(3)
Xn; R48/22		STOT RE 2	H373	(3)
T; R48/23		STOT RE 1	H372	(3)
T; R48/24		STOT RE 1	H372	(3)
T; R48/25		STOT RE 1	H372	(3)
R64		Lact.	H362	
Xn; R65		Asp. Tox. 1	H304	
R67		STOT SE 3	H336	
Xn; R68/20		STOT SE 2	H371	(3)
Xn; R68/21		STOT SE 2	H371	(3)
Xn; R68/22		STOT SE 2	H371	(3)
Carc. Cat. 1; R45		Carc. 1A	H350	
Carc. Cat. 2; R45		Carc. 1B	H350	
Carc. Cat. 1; R49		Carc. 1A	H350i	
Carc. Cat. 2; R49		Carc. 1B	H350i	
Carc. Cat. 3; R40		Carc. 2	H351	
Muta. Cat. 2; R46		Muta. 1B	H340	
Muta. Cat. 3; R68		Muta. 2	H341	
Repr. Cat. 1; R60		Repr. 1A	H360F	(4)
Repr. Cat. 2; R60		Repr. 1B	H360F	(4)
Repr. Cat. 1; R61		Repr. 1A	H360D	(4)
Repr. Cat. 2; R61		Repr. 1B	H360D	(4)
Repr. Cat. 3; R62		Repr. 2	H361f	(4)
Repr. Cat. 3; R63		Repr. 2	H361d	(4)
Repr. Cat. 1; R60 – 61		Repr. 1A	H360FD	
Repr. Cat. 1; R60 Repr. Cat. 2; R61		Repr. 1A	H360FD	
Repr. Cat. 2; R60 Repr. Cat. 1; R61		Repr. 1A	H360FD	
Repr. Cat. 2; R60 – 61		Repr. 1B	H360FD	
Repr. Cat. 3; R62 – 63		Repr. 2	H361fd	
Repr. Cat. 1; R60 Repr. Cat. 3; R63		Repr. 1A	H360Fd	

Classification under Dir 67/548/EEC	Physical state	Classification under CLP		Note
		Hazard Class / Category	H- statement	
Repr. Cat. 2; R60 Repr. Cat. 3; R63		Repr. 1B	H360Fd	
Repr. Cat. 1; R61 Repr. Cat. 3; R62		Repr. 1A	H360Df	
Repr. Cat. 2; R61 Repr. Cat. 3; R62		Repr. 1B	H360Df	
N; R50		Aquatic. Acute 1	H400	
N; R50 – 53		Aquatic Acute 1 Aquatic Chronic 1	H400 H410	
N; R51 – 53		Aquatic Chronic 2	H411	
R52 – 53		Aquatic Chronic 3	H412	
R53		Aquatic Chronic 4	H413	
N; R59		Ozone	H420	

Notes

(1) *For these classes it is possible to use the recommended minimum classification as defined in section 1.2.1.1 in Annex VI. Data or other information may be available to indicate that re classification in a more severe category is appropriate (see part B)*

(2) *It is recommended to classify in Category 1B even if it also could be possible that 1C could be applicable for certain cases. Going back to original data, may not result in a possibility to distinguish between Category 1B or 1C, since the exposure period has normally been up to 4 hours according to Regulation (EC) No 440/2008. However, for the future, when data are derived from tests following a sequential approach as foreseen in the Regulation (EC) No 440/2008, Category 1C should be considered.*

(3) *The route of exposure could be added to the hazard statement if it is conclusively proven that no other routes of exposure cause the hazard.*

(4) *Hazard statements H360 and H361 indicate a general concern for both the reproductive properties related to fertility and developmental effects; "May damage/Suspected of damaging fertility or the unborn child". According to the classification criteria (Annex I, section 3.7) the general hazard statement can be replaced by the hazard statement indicating only the property of concern, in case either fertility or developmental effects are proven to be not relevant.*

Translation between risk phrases assigned under the directives and supplementary labelling requirements under CLP (so-called '*EU left-overs*').

The table also mentions EUH phrases from Annex II of the CLP (*'special rules'* derived from the DPD)

Table D.2

Directive 67/548/EEC	**CLP Regulation**
R1	**EUH001**: Explosive when dry
R6	**EUH006**: Explosive with or without contact with air
R14	**EUH014:** Reacts violently with water
R18	**EUH018:** In use, may form flammable/explosive vapour-air mixture
R19	**EUH019:** May form explosive peroxides
R44	**EUH044:** Risk of explosion if heated under confinement
R29	**EUH029:** Contact with water liberates toxic gas
R31	**EUH031:** Contact with acids liberates toxic gas
R32	**EUH032:** Contact with acids liberates very toxic gas
R66	**EUH066:** Repeated exposure may cause skin dryness or cracking
R39-41	**EUH070:** Toxic by eye contact
-	**EUH071:** Corrosive to the respiratory tract
Directive 1999/45/EC	
DPD (id)	**EUH206:** Warning! Do not use together with other products. May release dangerous gases (chlorine)
DPD (id)	**EUH208:** Contains (name of the sensitizing substance). May produce an allergic reaction
DPD (professional user)	**EUH210:** Safety data sheet available on request
DPD, PPP	**EUH401:** To avoid risks to human health and the environment, comply with the instructions for use

Note: phrases greyed out will not be of application for PPP

Following important remarks should be considered:

C&L based upon endpoint lists under Dir 91/414/EEC (c.q. Reg (EC) no 1107/2009) or Dir 98/8/EC (c.q. regulation (EU) No 528/2012)
Relevant component endpoints, especially those of the active ingredients should be mentioned. Reliance will be given to the endpoints from the officially agreed "Listing of Endpoints", published in the Review Reports, EFSA conclusions or ECB TM biocide expert groups.

C&L proposals referred to in Dir 91/414/EEC (c.q. Reg (EC) no 1107/2009) or Dir 98/8/EC (c.q. regulation (EU) No 528/2012)
The proposed DSD classification by EFSA, or proposed by the EC DG Sanco/Env will be followed. It is of note that the existing Annex VI of Reg no 1272/2008 (i.e. converted table from Annex I of DSD 67/548/EEC) gives an indication, but proposals by expert groups having reviewed particular hazards should be considered in a first place. However, if a new official ECHA classification has been added to Annex VI, the latter will of course take precedence on the formerly proposed C&L.

Finally, the **self-classification** of substances in the ECHA Inventory database (which may include a harmonised classification if any present) will be queried and cited if published.

For more information, the reader should rely on the relevant legislations:

Regulation (EC) no 1272/2008
Regulation (EC) No 790/2009 (1st ATP, amendment of Annex VI)
Regulation (EU) No 286/2011 (2nd ATP, amendment of some criteria, a.o. for aquatoxicity)

The C&L should anyway also finally comply with the dispositions set out in:
Regulation (EU) No 547/2011 of 08/06/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products (Annex II and III).

The latest ECHA-guidance is found at:
http://echa.europa.eu/documents/10162/13562/clp_en.pdf

DISCLAIMER:
The present guide is meant to assist stakeholders in the understanding and application of the various directives and regulations concerning the classification and labeling of PPP. The authors can accept no liability for any error in this information.