Advanced Topics in GHS: Aquatic Toxicity for Mixtures

SCHC Fall 2013 Meeting

© CGI Group Inc. CONFIDENTIAL

CGI

Experience the commitment®

Purple Book

Part 1. Introduction

Part 2. Physical Hazards

Part 3. Health

Part 4. Environmental Hazards

- Chapter 4.1 Hazardous to the Aquatic Environment
  - 4.1.1 Definitions and general considerations
  - 4.1.2 Classification criteria for substances
  - 4.1.3 Classification criteria for mixtures
    - 4.1.3.3 Classification when toxicity data are available for the complete mixture
    - 4.1.3.4 Bridging Principles
    - 4.1.3.5 Classification when toxicity data are available on ingredient(s)
  - 4.1.4 Hazard Communication
  - 4.1.5 Decision Logic

CGI

Hazardous to the Aquatic Environment

- Classification criteria developed for:
  - Three acute categories, and
  - Four chronic categories (i.e. 3 core chronic categories)
  - The acute and chronic categories are applied independently

- The basic elements used for classification are:
  - Acute aquatic toxicity
  - Chronic aquatic toxicity
  - Potential for actual bioaccumulation
  - Degradation for organic chemicals

CGI

Hazardous to the Aquatic Environment

Substance Classification Criteria:

Short-term (acute) hazard classification is based on acute aquatic toxicity data

Long-term (chronic) hazard classification is based on:

1. Chronic aquatic toxicity data

   Or in the absence of chronic aquatic toxicity data

2. Acute aquatic toxicity data + bioaccumulation and degradation data of a substance

CGI

Diagrammatically Summarized Classification Criteria for Substances

Table 4.1.2 Classification scheme for substances hazardous to the aquatic environment

Short-term (Acute) hazard (*Note 1*)	Long-term (Chronic) hazard (*Note 2*) Adequate chronic toxicity:		Data Not Available (*Note 1*)
	Data Available		
	Non-rapidly degradable substances (*Note 3*)	**Rapidly degradable substances** (*Note 3*)	
Category: Acute 1	**Category: Chronic 1**	**Category: Chronic 1**	**Category: Chronic 1**
$L(E)C_{50} \leq 1.00$	NOEC or $EC_x \leq 0.1$	NOEC or $EC_x \leq 0.01$	$L(E)C_{50} \leq 1.00$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 2	**Category: Chronic 2**	**Category: Chronic 2**	**Category: Chronic 2**
$1.00 < L(E)C_{50} \leq 10.0$	$0.1 < $ NOEC or $EC_x \leq 1$	$0.01 < $ NOEC or $EC_x \leq 0.1$	$1.00 < L(E)C_{50} \leq 10.0$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
Category: Acute 3		**Category: Chronic 3**	**Category: Chronic 3**
$10.0 < L(E)C_{50} \leq 100$		$0.1 < $ NOEC or $EC_x \leq 1$	$10.0 < L(E)C_{50} \leq 100$ and lack of rapid degradability and/or BCF $\geq$ 500 or, if absent log $K_{ow} \geq 4$
	Category: Chronic 4 (*Note 4*) Example: (*Note 5*) No acute toxicity and lack of rapid degradability and BCF $\geq$ 500 or, if absent log Kow $\geq$ 4, unless NOECs > 1 mg/l		

CGI

Tier Approach for Mixtures

- Chapter 1.3 Classification of Hazardous Substances and Mixtures
  - 1.3.2.3 Classification criteria

For most hazard classes use test data for the mixture, when available, compared to substance hazard criteria *(special consideration is given to CMRs)*
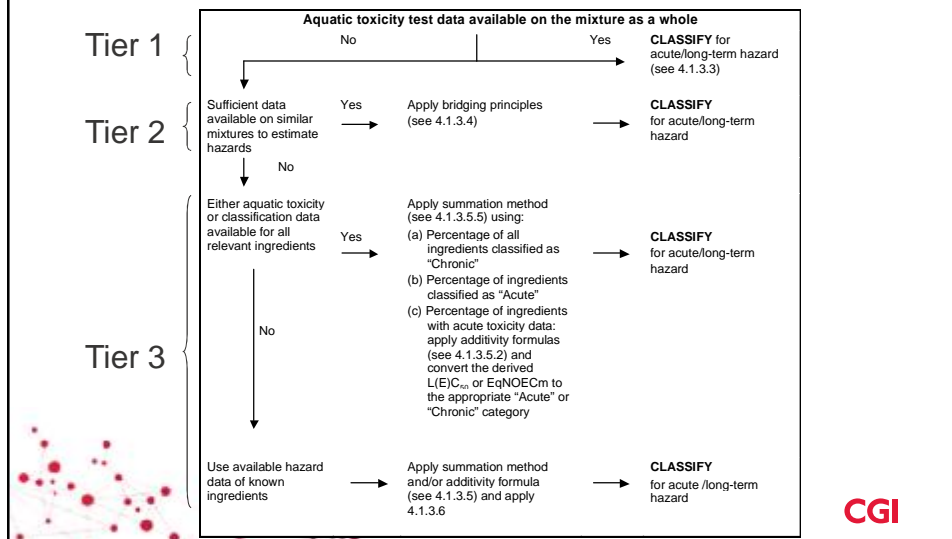
If not

Use bridging principles, if applicable

If not

Estimate hazard(s) based on the known ingredient information

CGI

Hazardous to the Aquatic Environment

Figure 4.1.2: Tiered approach to classification of mixtures for short-term (acute) and long-term (chronic) aquatic environmental hazards

Aquatic toxicity test data available on the mixture as a whole

Tier 1

No   Yes   **CLASSIFY** for acute/long-term hazard (see 4.1.3.3)

Tier 2

Sufficient data available on similar mixtures to estimate hazards   Yes   Apply bridging principles (see 4.1.3.4)   **CLASSIFY** for acute/long-term hazard

No

Tier 3

Either aquatic toxicity or classification data available for all relevant ingredients   Yes   Apply summation method (see 4.1.3.5.5) using:
(a) Percentage of all ingredients classified as "Chronic"
(b) Percentage of ingredients classified as "Acute"
(c) Percentage of ingredients with acute toxicity data: apply additivity formulas (see 4.1.3.5.2) and convert the derived L(E)C$_{50}$ or EqNOECm to the appropriate "Acute" or "Chronic" category   **CLASSIFY** for acute/long-term hazard

No

Use available hazard data of known ingredients   Apply summation method and/or additivity formula (see 4.1.3.5) and apply 4.1.3.6   **CLASSIFY** for acute /long-term hazard

CGI

Tested Mixtures Criteria (Tier 1)

Classification of mixtures when toxicity data are available for the complete mixture (GHS 4.1.3.3)

"When the mixture as a whole has been texted to determine its Acute and/or Chronic aquatic toxicity, this information can be used for classifying the mixture according to the criteria that have been agreed for substances."

- Short-term (acute) Hazard Classification:
  - Use criteria in Table 4.1.1 (a) Short-term (acute) aquatic hazard
- Long-term (chronic) Hazard Classification
  - Use criteria in Table 4.1.1. (b) Long-term (chronic) aquatic hazard/Sub-part
    - (ii) Rapidly degradable substances
      - § IF available information allows for the conclusion that all relevant ingredients are rapidly degradable, otherwise
    - (i) Non-rapidly degradable substances
  - Use criteria in Table 4.1.1 (C) "Safety net" Classification for Category Chronic 4

CGI

Tested Mixtures Classification Criteria

Short-term (Acute) hazard (*Note 1*) Data Available	Long-term (Chronic) hazard (*Note 2*)	
	Adequate chronic toxicity data available	
	Non-rapidly degradable substances (*Note 3*)	**Rapidly degradable substances** (*Note 3*)
Category: Acute 1 $L(E)C_{50} \leq 1.00$	**Category: Chronic 1** NOEC or $EC_x \leq 0.1$	**Category: Chronic 1** NOEC or $EC_x \leq 0.01$
Category: Acute 2 $1.00 < L(E)C_{50} \leq 10.0$	**Category: Chronic 2** $0.1 < $ NOEC or $EC_x \leq 1$	**Category: Chronic 2** $0.01 < $ NOEC or $EC_x \leq 0.1$
Category: Acute 3 $10.0 < L(E)C_{50} \leq 100$		**Category: Chronic 3** $0.1 < $ NOEC or $EC_x \leq 1$
	Category: Chronic 4 *(Note 4)* Example: (*Note 5*) No acute toxicity and lack of rapid degradability and BCF ≥ 500 or, if absent log Kow ≥ 4, unless NOECs > 1 mg/l	

CGI

Bridging Principles (Tier 2)

Classification of mixtures when toxicity data are not available for the complete mixture: bridging principles (GHS 4.1.3.4)

"Where the mixtures itself has not been tested to determine its aquatic environmental hazard, but there are ***sufficient data*** on **both** the ***individual ingredients*** **and** ***similar test mixtures*** to adequately characterize the hazards of the mixture, this data will be used in accordance with the following agreed bridging principles."

- Dilution
- Batching
- Concentration of mixtures which are classified with the most severe classification categories (Chronic 1 and Acute 1)
- Interpolation within one toxicity category
- Substantially similar mixtures

CGI

Un-Tested Mixtures Criteria (Tier 3)

Classification of mixtures when toxicity data are available for all ingredients or only for some ingredients of the mixture (GHS 4.1.3.5)

4.1.3.5.2 **Additivity Formulas**

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

$$\frac{\sum Ci + \sum Cj}{EqNOEC_{mix}} = \sum_{n} \frac{Ci}{NOECi} + \sum_{n} \frac{Cj}{0.1 \times NOECj}$$

4.1.3.5.5 **Summation Methods**

Sum of components classified as:	Mixture is classified as
Acute 1 x M ≥ 25%	Acute 1
(M x 10 x Acute 1) +Acute 2 ≥ 25%	Acute 2
(M x 100 x Acute 1)+ (10 x Acute 2) + Acute 3 ≥ 25%	Acute 3

Sum of components classified as:	Mixture is classified as:
Chronic 1 x M ≥ 25%	Chronic 1
(M x 10 x Chronic 1)+Chronic 2 ≥ 25%	Chronic 2
(M x 100 x Chronic 1)+(10x Chronic 2)+Chronic 3 ≥ 25%	Chronic 3
Chronic 1 + Chronic 2 + Chronic 3 +Chronic 4 ≥ 25%	Chronic 4

CGI

Additivity Formula – Acute Aquatic Toxicity

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

where:

C_I	=	concentration of ingredient i (weight percentage)
$L(E)C_{50i}$	=	LC_{50} or EC_{50} for component I, in mg/L
η	=	number of ingredients, and i is running from 1 to n;
$L(E)C_{mix}$	=	$L(E)$ C_{50} of the part of the mixture with test data

• The calculated toxicity is used to assign that portion of the mixture a short-term (acute) hazard category which is then used in applying the Acute Summation method.

CGI

Additivity Formula – Chronic Aquatic Toxicity

$$\frac{\sum Ci + \sum Cj}{EqNOECm} = \sum_{n} \frac{Ci}{NOECi} + \sum_{n} \frac{Cj}{0.1 \times NOECj}$$

where:

C_i = concentration of ingredient i (weight percentage) covering the rapidly degradable ingredients;

Cj = concentration of ingredient j (weight percentage) covering the non-rapidly degradable ingredients;

$NOEC_i$ = NOEC (or other recognized measures for chronic toxicity) for ingredient i covering the rapidly degradable ingredients, in mg/l;

$NOEC_j$ = NOEC (or other recognized measures for chronic toxicity) for ingredient j covering the non-rapidly degradable ingredients, in mg/l;

n = number of ingredients, and i and j are running from 1 to n;

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

- The calculated equivalent toxicity is used to assign that portion of the mixture a long-term (chronic) hazard category, using criteria in Table 4.1.1 (b)(ii), which is then used in applying the Chronic Summation method.

CGI

Application of the Additivity Formula

- It is preferable to calculate the toxicity (i.e. L(E)C$_{50mix}$ and/or EqNOEC$_{mix}$) using each ingredient's toxicity values that relate to the same taxonomic group (i.e. fish, crustacean or algae) and then use the highest toxicity (lowest value) obtained (i.e. use the most sensitive of the three groups).

- However, when the toxicity data for each component are not available in the same taxonomic group, select the highest toxicity (lowest value) (from the most sensitive test organism)

- The calculated acute toxicity may then be used to classify that part of the mixture which has data as Acute 1, 2 or 3 and/or Chronic 1, 2 or 3 using the same criteria described for substances

CGI

Summation Method – Acute Aquatic Toxicity

Sum of components classified as:	Mixture is classified as
Acute 1 x M $\geq$ 25%	Acute 1
(M x 10 x Acute 1) +Acute 2 $\geq$ 25%	Acute 2
(M x 100 x Acute 1)+ (10 x Acute 2) + Acute 3 $\geq$ 25%	Acute 3

L(E)C50 value	Multiplying factor (M)
$0.1 < L(E)C_{50} \leq 1$	1
$0.01 < L(E)C_{50} \leq 0.1$	10
$0.001 < L(E)C_{50} \leq 0.01$	100
$0.0001 < L(E)C_{50} \leq 0.001$	1000
(continue in factor 10 intervals)	

CGI

Summation Method – Chronic Aquatic Toxicity

Sum of components classified as:	Mixture is classified as:
Chronic 1 x M $\geq$ 25%	Chronic 1
(M x 10 x Chronic 1)+Chronic 2 $\geq$ 25%	Chronic 2
(M x 100 x Chronic 1)+(10x Chronic 2)+Chronic 3 $\geq$ 25%	Chronic 3
Chronic 1 + Chronic 2 + Chronic 3 +Chronic 4 $\geq$ 25%	Chronic 4

Chronic toxicity	M factor	
NOEC value	NRD[a] ingredients	RD[b] ingredients
$0.01 < NOEC \leq 0.1$	1	-
$0.001 < NOEC \leq 0.01$	10	1
$0.0001 < NOEC \leq 0.001$	100	10
$0.00001 < NOEC \leq 0.0001$	1000	100
$0.000001 < NOEC \leq 0.00001$	10000	1000
(continue in factor 10 intervals)		

[a] Non-rapidly degradable
[b] Rapidly degradable

CGI

Relevant Ingredients

"Relevant ingredients" of a mixture are those which are present in a concentration

≥ 0.1% (w/w) for ingredients classified as Acute and/or Chronic 1
AND

≥1% for other ingredients (Acute 2 or 3 and Chronic 2, 3 or 4),
UNLESS

there is a presumption (e.g. in the case of highly toxic ingredients) that an ingredient < 0.1% can still be relevant for the classification

CGI

Ingredients With Unknown Aquatic Toxicity

Classification of mixtures with ingredients without any useable information (GHS paragraph 4.1.3.6)

- In the event that **no usable information** on acute and/or chronic aquatic toxicity is available for one or more relevant ingredients … **classify based on the known ingredients only**…. with the additional statement.

"**X percent of the mixture consists of component(s) of unknown hazards to the aquatic environment**"

- Competent authority can decided if the statement is communicated on the label, SDS or both, or to leave the choice to the supplier.

CGI

Example To Illustrate Application Of The Un-Tested Mixture Classification Criteria

- The example mixture is blended using 2 substances and 2 mixtures
- Data used in this example is drawn from real-life Safety Data Sheets

12. Ecological Information

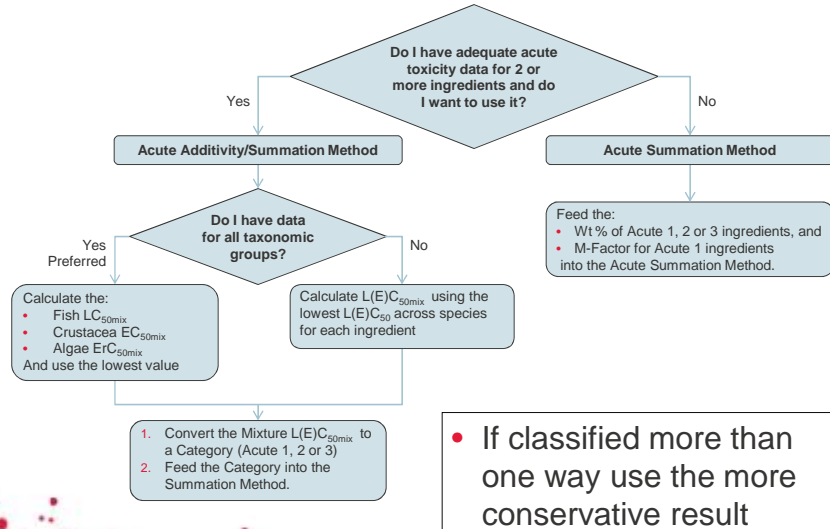| Environmental effects | This product shows a low bioaccumulation potential. | | | | |
Aquatic ecotoxicity					
Product/ingredient name		Test	Result	Species	Exposure
		-	EC50 1 mg/l	Algae	96 hours
		-	LC50 2.8 mg/l	Fish	96 hours
		-	LC50 2.3 mg/l	Fish - Rainbow Trout	96 hours
		-	Acute EC50 1.8 mg/L	Daphnia	48 hours
Conclusion/Summary	Not available.				
Biodegradability					
Conclusion/Summary	Not available.				
Partition coefficient n-octanol/water	0.75				
Bioconcentration factor	Not available.				
Other adverse effects	No known significant effects or critical hazards.				

CGI

Application Un-tested Mixture Criteria
Short-term (acute) Hazard Classification

CGI
Experience the commitment℠

Which method do I use for Short-term (acute) hazard classification?

Do I have adequate acute toxicity data for 2 or more ingredients and do I want to use it?

Yes →

Acute Additivity/Summation Method

No →

Acute Summation Method

Do I have data for all taxonomic groups?

Yes Preferred

Calculate the:
- Fish LC_{50mix}
- Crustacea EC_{50mix}
- Algae ErC_{50mix}

And use the lowest value

No →

Calculate $L(E)C_{50mix}$ using the lowest $L(E)C_{50}$ across species for each ingredient

1. Convert the Mixture $L(E)C_{50mix}$ to a Category (Acute 1, 2 or 3)
2. Feed the Category into the Summation Method.

Feed the:
- Wt % of Acute 1, 2 or 3 ingredients, and
- M-Factor for Acute 1 ingredients

into the Acute Summation Method.

- If classified more than one way use the more conservative result

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Fish	$LC_{50} = 2.6$	
		Fish (Rainbow Trout)	$LC_{50} = 2.3$	
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	~~Fish~~	~~$LC_{50} = 2.6$~~	
		Fish (Rainbow Trout)	$LC_{50} = 2.3$	
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Fish (Rainbow Trout)	$LC_{50} = 2.3$	
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	Acute 1 (M-Factor=1)

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Fish (Rainbow Trout)	$LC_{50} = 2.3$	Acute 1 (M-Factor=1)
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	
Mixture 1	25	Fish (Rainbow Trout)	$LC_{50} = 1.8$	
		Fish (Bluegill Sunfish)	$LC_{50} = 1.6$	
		Fish Fathead Minnow	$LC_{50} = 3.5$	
		Crustacean	$EC_{50} = 4.5$	
		Algae	$ErC_{50} = 29.0$	
Substance 2	12.5	Fish Fathead Minnow	$LC_{50} = 45$	
		Crustacean	$EC_{50} = 57$	
		Algae	$ErC_{50} = 64$	
Substance 3	12.5	No Data		

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Fish (Rainbow Trout)	$LC_{50} = 2.3$	Acute 1 (M-Factor=1)
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	
Mixture 1	25	Fish (Rainbow Trout)	$LC_{50} = 1.8$	
		Fish (Bluegill Sunfish)	$LC_{50} = 1.6$	
		Fish Fathead Minnow	$LC_{50} = 3.5$	
		Crustacean	$EC_{50} = 4.5$	
		Algae	$ErC_{50} = 29.0$	
~~Substance 2~~	~~12.5~~	~~Fish Fathead Minnow~~	~~$LC_{50} = 45$~~	
		~~Crustacean~~	~~$EC_{50} = 57$~~	
		~~Algae~~	~~$ErC_{50} = 64$~~	
~~Substance 3~~	~~12.5~~	~~No Data~~		

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Fish (Rainbow Trout)	$LC_{50} = 2.3$	Acute 1 (M-Factor=1)
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	
Mixture 1	**25**	~~Fish (Rainbow Trout)~~	~~$LC_{50} = 1.8$~~	
		Fish (Bluegill Sunfish)	**$LC_{50} = 1.6$**	**Acute 2**
		~~Fish Fathead Minnow~~	~~$LC_{50} = 3.5$~~	
		Crustacean	**$EC_{50} = 4.5$**	
		Algae	**$ErC_{50} = 29.0$**	

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Fish (Rainbow Trout)	$LC_{50} = 2.3$	Acute 1 (M-Factor=1)
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	
Mixture 1	25	Fish (Bluegill Sunfish)	$LC_{50} = 1.6$	Acute 2
		Crustacean	$EC_{50} = 4.5$	
		Algae	$ErC_{50} = 29.0$	
Substance 4	**30**	**No Information Available**		

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Fish (Rainbow Trout)	$LC_{50} = 2.3$	Acute 1 (M-Factor=1)
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	
Mixture 1	25	Fish (Bluegill Sunfish)	$LC_{50} = 1.6$	Acute 2
		Crustacean	$EC_{50} = 4.5$	
		Algae	$ErC_{50} = 29.0$	
Substance 4	30	No Information Available		
Mixture 2	**25**	**Product not tested. Information on components:**		
Substance 5	**12.5**	**Crustacea (Water Flea)**	$EC_{50} = 11$	
Substance 6	**12.5**	**-**	**-**	**Acute 3**

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Fish (Rainbow Trout)	$LC_{50} = 2.3$	Acute 1 (M-Factor=1)
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	
Mixture 1	25	Fish (Bluegill Sunfish)	$LC_{50} = 1.6$	Acute 2
		Crustacean	$EC_{50} = 4.5$	
		Algae	$ErC_{50} = 29.0$	
Substance 4	30	No Information Available		
~~Mixture 2~~	~~25~~	~~Product not tested. Information on components:~~		
Substance 5	**12.5**	**Crustacea (Water Flea)**	$EC_{50} = 11$	**Acute 2**
Substance 6	**12.5**	**-**	**-**	**Acute 3**

CGI

Short-term (acute) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Fish (Rainbow Trout)	$LC_{50} = 2.3$	Acute 1 (M-Factor=1)
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	
Mixture 1	25	Fish (Bluegill Sunfish)	$LC_{50} = 1.6$	Acute 2
		Crustacean	$EC_{50} = 4.5$	
		Algae	$ErC_{50} = 29.0$	
Substance 4	30	No Information Available		
Substance 5	12.5	Crustacea (Water Flea)	$EC_{50} = 11$	Acute 2
Substance 6	12.5	-	-	Acute 3

CGI

Which method do I use for Short-term (acute) hazard classification?

Do I have adequate acute toxicity data for 2 or more ingredients and do I want to use it?

Yes

Acute Additivity/Summation Method

Do I have data for all taxonomic groups?

No

Calculate $L(E)C_{50mix}$ using the lowest $L(E)C_{50}$ across species for each ingredient

1. Convert the Mixture $L(E)C_{50mix}$ to a Category (Acute 1, 2 or 3)
2. Feed the Category into the Summation Method.

CGI
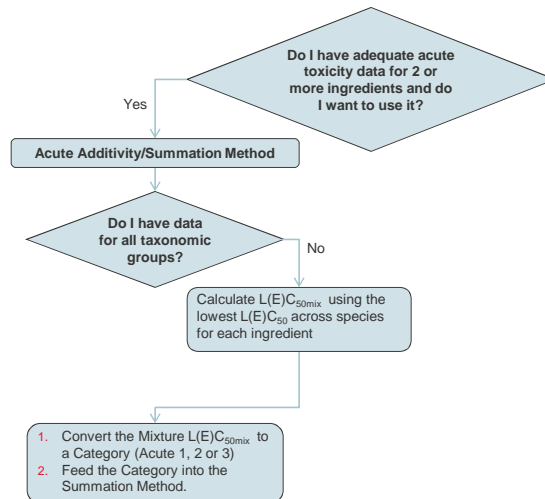
Acute Aquatic Toxicity – Additivity Formula

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

- Additivity Formula (paragraph 4.1.3.5.2)
- Test data (i.e., $L(E)C_{50}$) are available for 3 ingredients

Solve for $L(E)C_{50\,mix}$:

$$L(E)C_{50mix} = \frac{\sum C_i}{\sum_n \frac{C_i}{LC_{50i}}}$$

$$L(E)C_{50mix} = \frac{C_{Ing1} + C_{Ing2} + C_{Ing3}}{\sum_3 \frac{C_{Ing1}}{L(E)C_{50\,Ing1}} + \frac{C_{Ing2}}{L(E)C_{50\,Ing2}} + \frac{C_{Ing3}}{L(E)C_{50\,Ing3}}}$$

CGI

Acute Aquatic Toxicity – Additivity Formula

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	**20**	Fish (Rainbow Trout)	$LC_{50} = 2.3$	**Acute 1 (M-Factor=1)**
		Crustacean (Daphnia)	$EC_{50} = 1.6$	
		Algae	$ErC_{50} = 1$	
Mixture 1	**25**	**Fish (Bluegill Sunfish)**	$LC_{50} = 1.6$	**Acute 2**
		Crustacean	$EC_{50} = 4.5$	
		Algae	$ErC_{50} = 29.0$	
Substance 4	30	No Information Available		
Substance 5	12.5	**Crustacea (Water Flea)**	$EC_{50} = 11$	Acute 2
Substance 6	12.5	-	-	Acute 3

$$L(E)C_{50mix} = \frac{20 + 25 + 12.5}{\dfrac{20}{1mg/l} + \dfrac{25}{1.6mg/l} + \dfrac{12.5}{11mg/l}} = 1.56 mg/l$$

CGI

Short-term (acute) Aquatic Hazard Classification

Calculated $L(E)C_{50mix}$	Classification
1.56 mg/l	Acute 2

(a) Short-term (acute) aquatic hazard

Category: Acute 1	
96 hr LC_{50} (for fish)	≤1 mg/L and/or
48 hr EC_{50} (for crustacea)	≤1 mg/L and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	≤1 mg/L (note 3)
Category Acute 1 may be subdivided for some regulatory systems to include a lower band at $L(E)C_{50}$ ≤ 0.1 mg/L	
Category: Acute 2	
96 hr LC_{50} (for fish)	>1 - ≤10 mg/L and/or
48 hr EC_{50} (for crustacea)	>1 - ≤10 mg/L and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	>1 - ≤10 mg/L (note 3)
Category: Acute 3	
96 hr LC_{50} (for fish)	>10 - ≤100 mg/L and/or
48 hr EC_{50} (for crustacea)	>10 - ≤100 mg/L and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	>10 - ≤100 mg/L (note 3)
Some regulatory systems may extend this range beyond an $L(E)C_{50}$ of 100 mg/L through the introduction of another category.	

Therefore include 57.5% of an Acute 2 into the Summation Method as illustrated on the next slide…

CGI

Summation Method

Calculations:

Acute 1:
Acute 1 x M ≥ 25%
0%   = 0%

Sum of components classified as:	Mixture is classified as
Acute 1 x M ≥ 25%	Acute 1
(M x 10 x Acute 1) +Acute 2 ≥ 25%	Acute 2
(M x 100 x Acute 1)+ (10 x Acute 2) + Acute 3 ≥ 25%	Acute 3

	Wt%	Classification
Additivity result for that part of the mixture with toxicity data (i.e. Substance 1 & 5 and Mixture 1)	57.5%	Acute 2
Substance 4	30%	Ingredient with unknown hazards to the aquatic environment
Substance 6	12.5%	Acute 3

CGI

Summation Method

Calculations:

Acute 1:
Acute 1 x M $\geq$ 25%
   0%   = 0%

Acute 2:
(M x 10 x Acute 1) + Acute 2 $\geq$ 25%
      0%   + 62.5% = 62.5%

Label elements:

No Symbol

No Signal Word

Toxic to aquatic life

Consider:
Short-term (acute) Hazard % Unknowns: 30%

Sum of components classified as:	Mixture is classified as
Acute 1 x M $\geq$ 25%	Acute 1
(M x 10 x Acute 1) +Acute 2 $\geq$ 25%	Acute 2
(M x 100 x Acute 1)+ (10 x Acute 2) + Acute 3 $\geq$ 25%	Acute 3

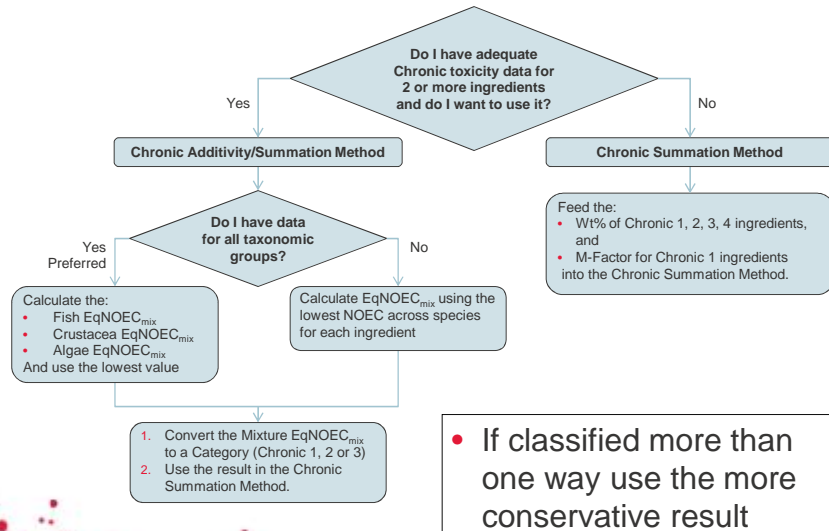|	Wt%	Classification
Additivity result for that part of the mixture with toxicity data (i.e. Substance 1 & 5 and Mixture 1)	57.5%	Acute 2
Substance 4	30%	Ingredient with unknown hazards to the aquatic environment
Substance 6	12.5%	Acute 3

CGI

Application Un-tested Mixture Criteria
Long-term (chronic) Hazard Classification

CGI
Experience the commitment

Which method do I use for Long-term (chronic) hazard classification?

Do I have adequate Chronic toxicity data for 2 or more ingredients and do I want to use it?

Yes → **Chronic Additivity/Summation Method**

No → **Chronic Summation Method**

Do I have data for all taxonomic groups?

Yes Preferred →
Calculate the:
- Fish $EqNOEC_{mix}$
- Crustacea $EqNOEC_{mix}$
- Algae $EqNOEC_{mix}$

And use the lowest value

No →
Calculate $EqNOEC_{mix}$ using the lowest NOEC across species for each ingredient

1. Convert the Mixture $EqNOEC_{mix}$ to a Category (Chronic 1, 2 or 3)
2. Use the result in the Chronic Summation Method.

Chronic Summation Method:
Feed the:
- Wt% of Chronic 1, 2, 3, 4 ingredients, and
- M-Factor for Chronic 1 ingredients
into the Chronic Summation Method.

- If classified more than one way use the more conservative result

CGI

Long-term (chronic) Hazard Information

Summary of data on the source Safety Data Sheets:
- No Chronic Toxicity data was provided
- Limited bioaccumulation data was provided
- No degradation data was provided

Therefore, all Substances in the mixture were classified using the "surrogate method" (i.e., Acute aquatic toxicity data + bioaccumulation and degradation data of a substance)
- Since no degradation data exists for any of the substances classified into an Acute category, all the substances must also be classified into the equivalent Chronic category. (See footnote 4 to Table 4.1.1.)

CGI

Chronic Classification Criteria
Table 4.1.1

(b) Long-term (chronic) aquatic hazard
(iii) Substances for which adequate chronic toxicity data are not available

<u>Category Chronic 1:</u>
96 hr LC_{50} (for fish)	≤ 1 mg/l and/or
48 hr EC_{50} (for crustacea)	≤ 1 mg/l and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	≤ 1 mg/l *(Note 3)*

and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K_{ow} ≥ 4). *(Notes 4 and 5)*

<u>Category Chronic 2:</u>
96 hr LC_{50} (for fish)	> 1 but ≤ 10 mg/l and/or
48 hr EC_{50} (for crustacea)	> 1 but ≤ 10 mg/l and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	> 1 but ≤ 10 mg/l *(Note 3)*

and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500 (or, if absent, the log K_{ow} ≥ 4). *(Notes 4 and 5)*

<u>Category Chronic 3:</u>
96 hr LC_{50} (for fish)	> 10 but ≤ 100 mg/l and/or
48 hr EC_{50} (for crustacea)	> 10 but ≤ 100 mg/l and/or
72 or 96hr ErC_{50} (for algae or other aquatic plants)	> 10 but ≤ 100 mg/l *(Note 3)*

and the substance is not rapidly degradable and/or the experimentally determined BCF is ≥ 500) (or, if absent, the log K_{ow} ≥ 4). *(Notes 4 and 5)*.

Note 4: Lack of degradability is based on either a lack of ready biodegradability or other evidence of lack rapid degradation. When no useful data on degradability are available, either experimentally determined or estimated data, the substance should be regarded as not rapidly degradable

41

CGI

Diagrammatically Summarized Classification Criteria for Substances

Table 4.1.2 Classification scheme for substances hazardous to the aquatic environment

Short-term (Acute) hazard (*Note 1*)	Long-term (Chronic) hazard (*Note 2*) Adequate chronic toxicity:		
	Data Available		Data Not Available (*Note 1*)
	Non-rapidly degradable substances (*Note 3*)	Rapidly degradable substances (*Note 3*)	
Category: Acute 1	Category: Chronic 1	Category: Chronic 1	**Category: Chronic 1**
$L(E)C_{50}$ ≤ 1.00	NOEC or EC_x ≤ 0.1	NOEC or EC_x ≤ 0.01	$L(E)C_{50}$ ≤ 1.00 and lack of rapid degradability and/or BCF ≥ 500 or, if absent log K_{ow} ≥ 4
Category: Acute 2	Category: Chronic 2	Category: Chronic 2	**Category: Chronic 2**
1.00 < $L(E)C_{50}$ ≤ 10.0	0.1 < NOEC or EC_x ≤ 1	0.01 < NOEC or EC_x ≤ 0.1	1.00 < $L(E)C_{50}$ ≤ 10.0 and lack of rapid degradability and/or BCF ≥ 500 or, if absent log K_{ow} ≥ 4
Category: Acute 3		Category: Chronic 3	**Category: Chronic 3**
10.0 < $L(E)C_{50}$ ≤ 100		0.1 < NOEC or EC_x ≤ 1	10.0 < $L(E)C_{50}$ ≤ 100 and lack of rapid degradability and/or BCF ≥ 500 or, if absent log K_{ow} ≥ 4
	Category: Chronic 4 (*Note 4*) Example: (*Note 5*) No acute toxicity and lack of rapid degradability and BCF ≥ 500 or, if absent log Kow ≥ 4, unless NOECs > 1 mg/l		

CGI

Long-term (chronic) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Algae	$ErC_{50} = 1$	**Acute 1 (M-Factor=1)** **Chronic 1 (M-Factor=1)**

CGI

Long-term (chronic) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Algae	$ErC_{50} = 1$	**Acute 1 (M-Factor=1)** **Chronic 1 (M-Factor=1)**
Mixture 1	25			
Substance 2	12.5	Fish Fathead Minnow	$LC_{50} = 45$	**Acute 2** **Chronic 2**
Substance 3	12.5	No Information Available		

CGI

Long-term (chronic) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Algae	$ErC_{50} = 1$	Acute 1 (M-Factor=1) Chronic 1 (M-Factor=1)
Mixture 1	25			
Substance 2	12.5	Fish Fathead Minnow	$LC_{50} = 45$	Acute 2 Chronic 2
Substance 3	12.5	No Information Available		
Substance 4	30	No Information Available		

CGI

Long-term (chronic) Hazard Information

Ingredient	Wt%	Species	Result (mg/l)	Classification
Substance 1	20	Algae	$ErC_{50} = 1$	Acute 1 (M-Factor=1) Chronic 1 (M-Factor=1)
Mixture 1	25			
Substance 2	12.5	Fish Fathead Minnow	$LC_{50} = 45$	Acute 2 Chronic 2
Substance 3	12.5	No Information Available		
Substance 4	30	No Information Available		
Mixture 2	25			
Substance 5	12.5	Crustacea (Water Flea)	$EC_{50} = 11$	Acute 2 Chronic 2
Substance 6	12.5	-	-	Acute 3 Chronic 3

CGI

Which method do I use for Long-term (chronic) hazard classification?

Do I have adequate Chronic toxicity data for 2 or more ingredients and do I want to use it?

No

Chronic Summation Method

Feed the:
- Wt% of Chronic 1, 2, 3, 4 ingredients, and
- M-Factor for Chronic 1 ingredients

into the Chronic Summation Method.

CGI

Chronic Aquatic Toxicity – Summation Method

Calculations:

***Chronic 1*:**
Chronic 1 x M ≥ 25%
   20%   x 1   = 20%

Sum of components classified as:	Mixture is classified as:
Chronic 1 x M ≥ 25%	Chronic 1
(M x 10 x Chronic 1)+Chronic 2 ≥ 25%	Chronic 2
(M x 100 x Chronic 1)+(10x Chronic 2)+Chronic 3 ≥ 25%	Chronic 3
Chronic 1 + Chronic 2 + Chronic 3 +Chronic 4 ≥ 25%	Chronic 4

	Wt%	Classification
Substance 1	20	Chronic 1 (MF=1)
Substance 2	12.5	Chronic 2
Substance 3	10	Unknown hazards
Substance 4	30	Unknown hazards
Substance 5	12.5	Chronic 2
Substance 6	12.5	Chronic 3

CGI

Chronic Aquatic Toxicity – Summation Method

Calculations:

Chronic 1:
Chronic 1 x M ≥ 25%
  20%   x 1   = 20%

Chronic 2:
(M x 10 x Chronic 1) + Chronic 2 ≥ 25%
(1 x 10 x 20%) + (12.5% + 12.5) = 225%

Sum of components classified as:	Mixture is classified as:
Chronic 1 x M ≥ 25%	Chronic 1
(M x 10 x Chronic 1)+Chronic 2 ≥ 25%	Chronic 2
(M x 100 x Chronic 1)+(10x Chronic 2)+Chronic 3 ≥ 25%	Chronic 3
Chronic 1 + Chronic 2 + Chronic 3 +Chronic 4 ≥ 25%	Chronic 4

	Wt%	Classification
Substance 1	20	Chronic 1 (MF=1)
Substance 2	12.5	Chronic 2
Substance 3	10	Unknown hazards
Substance 4	30	Unknown hazards
Substance 5	12.5	Chronic 2
Substance 6	12.5	Chronic 3

Label elements:

No Signal Work

Toxic to aquatic life with long lasting effects

Consider:
Long-term (chronic) Hazard % Unknowns: 40%

CGI

Hazard Communication for Example Mixture

Classification:
- Short-term (acute) Aquatic Hazard; Category 2
- Long-term (chronic) Aquatic Hazard; Category 2

Labeling:
- Applying GHS paragraph1.4.10.5.3 *Multiple hazards and precedence of hazard information …*

Toxic to aquatic life with long lasting effects

- Additionally, if required in supplemental information:

30% of the mixture consists of component(s) of unknown hazards to the aquatic environment

CGI

Questions & Feedback

Paul Brigandi
Paul.Brigandi@cgi.com
703.267.2175

CGI