“GHS Mixture Classification and Labels/SDS Creation System (NITE-Gmiccs)”

Classification Logic

Ver.2.3

Contents

1. Introduction

The "GHS Mixture Classification and Labels Creation System" (commonly known as NITE-Gmiccs, hereinafter referred to as "this system") is a web system version of the "GHS Mixture Classification System" (hereinafter referred to as "installed version") published on the GHS website of the Ministry of Economy, Trade and Industry. Therefore, the basic logic of this system follows the installed version. This system is a specification with some logic added to the classification principle below, and this document describes the logic that this system uses.

The underlined parts of this document indicate that it is based on the own rules of this system. This system does not consider the Bridging Principle or the like, it performs classification only that can be done by calculation. If the Bridging Principle can be applied, classification should be performed using the Bridging Principle and the results should be used to create the SDS or label. For the details of GHS, please refer to United Nations GHS documents, related JIS standards (Z7252:2019, Z7253:2019), "GHS classification guidance for enterprises" (2019 Revised Edition by the Ministry of Economy, Trade and Industry).

Although this system allows GHS mixture classification to be carried out by users on their own, it is important to note that the result by this system is just an example of classification, and the user is responsible for its use. Besides, the physical hazards, except some items, are not classified by this system. The main targets of this system are health hazards and environmental hazards. Therefore, for the physical hazards that are not classified in this system, the classification results performed by business operator should be entered manually for creating the SDSs or labels.

Principle of classification

This system allows you to select classifications based on the United Nations GHS Document, 6th Revised Edition (hereinafter referred to as "UN") and based on the Japanese Industrial Standards (hereinafter referred to as "JIS").

The basis of each classification is as follows:

UN

1. The range of the basis of the GHS classification, GHS classification category, and classification logic are all based on the United Nations GHS Document, 6th Revised Edition (2015).
2. The names of the hazard classes and the hazard categories are based on "Hazard Communication of Chemicals Based on GHS—Labelling and Safety Data Sheet (SDS)" (JIS Z 7253:2019) in consideration of the use in Japan.

JIS

1. The basis of the GHS classification is based on the United Nations GHS Document, 6th Revised Edition (2015).
2. The range of GHS classification categories to use (selection based on the Building block approach) is based on the "Classification of Chemicals Based on GHS" (JIS Z 7252:2019).

3. The names of the hazard classes and the hazard categories are based on the "Hazard Communication of Chemicals Based on GHS— Labelling and Safety Data Sheet (SDS)" (JIS Z 7253:2019).
4. The classification logic of mixtures is based on the "Classification of Chemicals Based on GHS" (JIS Z 7252:2019) and the "GHS Classification Guidance for Enterprises" (revised edition in 2019, released by the Ministry of Economy, Trade and Industry).

Besides, the GHS classification category and concentration limits adopted by "UN" or "JIS" are as follows.

Table 1 GHS classification category adopted by "UN" or "JIS"

Explosives	Unstable explosives	Category 1.1	Category 1.2	Category 1.3	Category 1.4	Category 1.5	Category 1.6
Flammable gases	1A	1B	2				
Aerosols	1	2	3				
Oxidizing gases	1	2	3				
Gases under pressure	Compressed	Liquefied	Refrigerated liquefied	Dissolved			
Flammable liquids	1	2	3	4			
Flammable solids	1	2					
Self-reactive substances and mixtures	TYPE A	TYPE B	TYPE C	TYPE D	TYPE E	TYPE F	TYPE G
Pyrophoric liquids	1						
Pyrophoric solids	1						
Self-heating substances and mixtures	1	2					
Substances and mixtures which, in contact with water, emit flammable gases	1	2	3				
Oxidizing liquids	1	2	3				
Oxidizing solids	1	2	3				
Organic peroxides	TYPE A	TYPE B	TYPE C	TYPE D	TYPE E	TYPE F	TYPE G
Corrosive to metals and mixtures	1						
Desensitized explosives	1	2	3	4			
Acute toxicity	1	2	3	4	5*		
Skin corrosion/irritation	1A	1B	1C	2	3*		
Serious eye damage/eye irritation	1	2A	2B				
Respiratory sensitization or Skin sensitization	1	1A	1B				

Germ cell mutagenicity	1A	1B	2	
Carcinogenicity	1A	1B	2	
Reproductive toxicity	1A	1B	2	Effects on or via lactation
Specific target organ toxicity - Single exposure	1	2	3	
Specific target organ toxicity - Repeated exposure	1	2		
Aspiration hazard	1	2*		
Hazardous to the aquatic environment Short term (Acute)	1	2	3	
Hazardous to the aquatic environment Long term (Chronic)	1	2	3	4
Hazardous to the ozone layer	1			

＊ Classification category not adopted by "JIS"

In addition, see Table 2 for the concentration limits of the mixture whether to implement the GHS classification adopted by "UN" or "JIS".

Table 2 Concentration limits adopted by "UN" or "JIS"

	Concentration limits adopted by "JIS"	Concentration limits adopted by "UN"
Carcinogenicity Category 2	1.0%	0.1%
Reproductive toxicity Category 1A 1B	0.3%	0.1%
Reproductive toxicity Category 2	3.0%	0.1%
Specific target organ toxicity Category 1	10%	1.0%
Specific target organ toxicity Category 2	10%	1.0%

Regarding the aerosol classification.

Aerosol needs to be classified with reference to "About Aerosol Classification" as described below; however, in the specification of this system, it is classified as "Gas" for convenience.

About Aerosol Classification

"Aerosol" should be classified according to the procedure below.

(1) First, enter the 100%-converted gas component composition, select "Aerosol" as the physical state, and perform the classification.

(2) Then enter the 100%-converted non-gas component composition, select "Liquid" or "Solid" as the physical state depending on the physical state of the non-gas component, and perform the classification.

(3) In the final classification of aerosol products, use (1) for physicochemical hazards, and for the acute toxicity (Inhalation: Gas) in health hazards.
For health hazards other than acute toxicity (Inhalation: Gas) and environmental hazards, compare both (1) and (2) and use the higher in the hazard level.

* NOTE: This does not correspond to aerosol in GHS but for products (UN No. 3500) in such a combination as gas + liquid or gas + solid, classification needs to be performed twice as in the case of aerosol. However, select "Gas" as the physical state first rather than "Aerosol," and for physicochemical hazards as a product, use both the gas and non-gas components. For health hazards and environmental hazards, it would be better off comparing both and then using the higher in the hazard level.

Effects on Aquatic Environment Decision

Since it had become a necessity to consider the United Nations GHS Document for the parts with vague numbers, we implemented an original system for effects on aquatic environment.

・Multiple hazards and precedence of hazard information.

In this system, if the chemical has multiple hazards, following precedence rules were determined according to JIS Z7253:2019 and may be omitted some symbols or statements.

a)　Precedence for the allocation of symbols

Generally, following precedence rules may be applied for the health hazards.

1) If the skull and crossbones applies, the exclamation mark should not appear.

2) If the corrosive symbol applies, the exclamation mark should not appear where it is used for skin or eye irritation.

3) If the health hazard symbol appears for respiratory sensitization, the exclamation mark should not appear where it is used for skin sensitization or for skin or eye irritation.

b) Precedence for allocation of signal words

If the signal word “Danger” applies, the signal word “Warning” should not appear.

c) Precedence for allocation of hazard statements

All assigned hazard statements should appear on the label or SDS.

However, to avoid evident duplication or redundancy in the information conveyed by hazard statements, the following precedence rules may be applied.

1) If the statement H410 “Very toxic to aquatic life with long lasting effects” is assigned, the statement H400 “Very toxic to aquatic life” may be omitted.

2) If the statement H411 “Toxic to aquatic life with long lasting effects” is assigned, the statement H401 “Toxic to aquatic life” may be omitted.

3) If the statement H412 “Harmful to aquatic life with long lasting effects” is assigned, the statement H402 “Harmful to aquatic life” may be omitted.

4) If the statement H314 “Causes severe skin burns and eye damage” is assigned, the statement H318 “Causes serious eye damage” may be omitted.

2. Physical Hazards Guidance

2.3.6 Selection of assessment items according to chemical structure

Based on the physical state of the selected mixture, judge whether or not it is subject to classification by using Table 2-3-1(revised) below. Note that "Aerosol" can be selected as the physical state in this system, but both the “United Nations GHS Document 6th Revised Edition” and the "Classification of Chemicals Based on GHS" (JIS Z 7252:2019) do not include aerosol in the selection of classification items, that is, it is an original function of this system developed with reference to the two guidelines.

Table 2.3.1(revised)

Classification of Physical Hazards based on physical, chemical states and chemical structure

Section	Hazard Class	Gas	Liquids	Solid	Aerosol
2.6.1	Explosives	×	○	○	×
2.6.2	Flammable Gases	○	×	×	×
2.6.3	Aerosols	×	×	×	○
2.6.4	Oxidizing Gases	○	×	×	×
2.6.5	Gases Under Pressure	○	×	×	×
2.6.6	Flammable Liquids	×	○	×	×
2.6.7	Flammable Solid	×	×	○	×
2.6.8	Self-reactive Substances and Mixtures	×	○	○	×
2.6.9	Pyrophoric Liquids	×	○	×	×
2.6.10	Pyrophoric Solids	×	×	○	×
2.6.11	Self-heating Substances and Mixtures	×	○	○	×
2.6.12	Substances and mixtures which, in contact with water, emit flammable gases	×	○	○	×
2.6.13	Oxidizing Liquids	×	○	×	×
2.6.14	Oxidizing Solids	×	×	○	×
2.6.15	Organic Peroxides	×	○	○	×
2.6.16	Corrosive to Metals	○	○	○	×
2.6.17	Desensitized explosives	×	○	○	×

○: Subject to classification. Classification is performed by this system and the classification category is determined.

×: Not subject to classification. Classification is not performed by this system, resulting in "not classified (not applicable)".

2.4.1 Relationship between UNRTDG classification and GHS Categorization

, The cases in which the physicochemical hazards of a mixture can be classified by reference to the UNRTDG classification ("UN No," "Hazard class (here referred to as “UN class”, “subsidiary risk”)" "Packing Group") are shown according to the table below.

The shaded cells indicate items that cannot be classified by the system, the result is “Not classified”.

Table 2.4.1(revised) Comparison between GHS classification and UNRTDG classification

GHS Class	UNRTDG (Note: ( ) is a subsidiary risk)	GHS Category	Reference
1)Explosives	Transport prohibited explosives	Unstable explosives	
	1.1	Division 1.1	UN class
	1.2	Division 1.2	
	1.3	Division 1.3	
	1.4	Division 1.4	
	1.5	Division 1.5	
	1.6	Division 1.6	
2)Flammable Gases)	2.1 and 2.3(2.1)	Category1	UN class subsidiary risk
	2.2 and 2.3	Category2	
	-	Category A	
	-	Category B	
3)Aerosols	2.1 and 2.3(2.1) UN1950(aerosol)	Category1	UN class subsidiary risk
	2.1 and 2.3(2.1) UN1950(aerosol)	Category2	
	2.2 and 2.3(2.1) UN1950(aerosol)	Category3	
4)Oxidizing Gases	2.2(5.1) or 2.3(5.1)	Category1	UN class subsidiary risk
5)Gases Under Pressure	2.1 Flammable gases 2.2 Non-flammable, non-toxic gases	Compressed gas Liquefied gas Refrigerated liquefied gas Dissolved gas	
6)Flammable Liquids	3 PG I	Category1	UN class subsidiary risk
	3 PG II	Category2	
	3 PG III	Category3	
	Not dangerous goods (Flash point:60 °C or more)	Category4	
7)Flammable Solid	4.1 PG II	Category1	UN class subsidiary risk
	4.1 PGIII	Category2	

classification	UNRTDG (Note: ( ) is a subsidiary risk)	GHS Category	Reference
8)Self-reactive Substances and Mixtures	Transport prohibited substances	Type A	
	4.1、UN3221,3222,3231,3232	Type B	UN class UN number
	4.1、UN3223,3224,3233,3234	Type C	
	4.1、UN3225,3226,3235,3236	Type D	
	4.1、UN3227,3228,3237,3238	Type E	
	4.1、UN3229,3230,3239,3240	Type F	
	Not dangerous goods	Type G	
9)Pyrophoric Liquids	4.2 PG I (liquid)	Category1	Properties, UN class, Package group
10)Pyrophoric Solids	4.2 PG I (solid)	Category1	Properties, UN class, Package group
11)Self-heating Substances and Mixtures	4.2 PG II	Category1	UN class, Package group
	4.2 PG III	Category1	
12)Substances and mixtures which, in contact with water, emit flammable gases	4.3 PG I or 4.2(4.3)	Category1	UN class, Package group, subsidiary risk
	4.3 PG II	Category2	
	4.3 PG III	Category3	
13)Oxidizing Liquids	5.1 PG I (liquid)	Category1	Properties, UN class, Package group
	5.1 PG II (liquid)	Category2	
	5.1 PG III (liquid)	Category3	
14)Oxidizing Solids	5.1 PG I (solid)	Category1	Properties, UN class, Package group
	5.1 PG II (solid)	Category2	
	5.1 PG III (solid)	Category3	
15)Organic Peroxides	Transport prohibited substances	Type A	
	5.2 UN3101,3102,3111,3112	Type B	UN class UN number
	5.2 UN3103,3104,3113,3114	Type C	
	5.2 UN3105,3106,3115,3116	Type D	
	5.2 UN3107,3108,3117,3118	Type E	
	5.2 UN3109,3110,3119,3120	Type F	
	Not dangerous goods	Type G	
16)Corrosive to Metals	The UN dangerous goods transport Class 8 includes Skin Corrosion	Category1	
17) Desensitized explosives	3, UN1204,2059,3064,3343, 3357,3379(liquid)	Category1	Properties, UN class, UN number

	4.1, UN1310,1320,1321,1322, 1336,1337,1344,1347,1348, 1349,1354,1355,1356,1357, 1517,1571,2555,2556,2557, 2852,2907,3317,3319,3344, 3364,3365,3366,3367,3368, 3369,3370,3376,3380,3474 (solid)		
	-	Category2	
	-	Category3	
	-	Category4	

2.5.2 Flammable Gases

2.5.2.6 Classification method of mixtures.

Flammability/combustibility should be determined by calculation in accordance with the below method. In addition, this calculation method cannot exactly distinguish Category 1 from Category 2 but determine whether it is within the range from Category 1 to Category 2. From the standpoint of safety, Category 1 is used as the specifications of this system. Furthermore, if there is a component in the composition that cannot be classified into any of inert gas, oxidized gas, and flammable gas, it is judged that it cannot be classified because of the shortage of data.

Calculation method (1)

When consisting of flammable gases

$$\sum_{i}^{n} \frac{V_i\%}{T_{ci}}$$

Wherein,	V_i%,	each content of flammable gas;
	T_{ci},	the maximum concentration of the flammable gas in nitrogen that makes the mixture not flammable in air; Value of Tci is described in ISO10156:2010 Table 2.
	i;	the i-th gas in the mixture;
	n,	n, the number of gases in the mixture, and
	Ki,	the equivalence factor to inert gas/nitrogen. Value of Ki, is described in ISO10156:2010 Table 1.

Judge as a flammable mixed gas if Tc is 1 or more.

Calculation method (2) When including 0.5% or more of oxidizing gases (oxygen etc.) as ingredients in addition to inert gases and flammable gases:

Do the following calculation additionally.

If Tc < 1 and Tct2 ≥ 1, it may be flammable and should be checked by a test, but from the standpoint of safety, Category 1 is used as the specifications of this system.

$$\sum \frac{A_i}{0.9 \times L_i \times 100} = \text{Tct2}$$

Where:

Ai: concentrations of ingredient flammable gases;
(The molecular weight is not Considered if physical state is gas.)

Li: lower flammable limits of the gases. By referring to the ISO10156:2010.

In addition, in the absence of data on its pyrophoricity, a flammable gas mixture should be classified as a pyrophoric gas if it contains more than 1% (by volume) of pyrophoric components.

2.5.4 Oxidizing Gases

2.5.4.6 Classification method of Mixtures

1.Classification JIS and UN GHS describe that tests or calculation methods should be performed according to ISO10156: 2010. There is no equivalent classification in the Japanese Fire Service Act and HighPressure Gas Safety Act. This test method is for determining the flammable range of the three-component system of "oxidizing gas, ethylene, and nitrogen" and extremely complicated. Also, few tests have been done for mixed gases.

2. An example of pure gas classified in this class is shown in Table 2.5.27 in the Guidance.

3. classification method described in ISO10156:2010 uses the criterion that a gas mixture should be considered as more oxidizing than air if the oxidizing power of the gas mixture is higher than 0.235(23.5%) and the procedure is shown below.

The oxidizing power (OP) is calculated as follows:

$$\mathrm{OP} = \frac{\sum_{i=1}^{n} X_i C_i}{\sum_{i=1}^{n} X_i + \sum_{k=1}^{p} K_k B_k}$$

Where:

X_i : molar fraction of the i:th oxidizing gas in the mixture;

C_i : coefficient of oxygen equivalency of the i:th oxidizing gas in the mixture;

K_k : coefficient of equivalency of the inert gas k compared to nitrogen;

B_k : molar fraction of the k:th in inert gas in the mixture;

n : total number of oxidizing gases in the mixture;

p : total number of inert gases in the mixture;

2.5.6 Flammable Liquids

2.5.6.2 Classification criteria

A flammable liquid is classified in one of the four categories for this class according to the following table 2.5.31 based on the flash point and initial boiling point of the mixture itself. Besides, If the flash point is lower than 23 ° C and the information on the initial boiling point is insufficient, this system classifies as Category 1 from the viewpoint of safety.

Table 2.5.31 Criteria for flammable liquids

Category	Criteria
1	Flash point < 23° C and initial boiling point ≤ 35° C
2	Flash point < 23° C and initial boiling point > 35° C
3	Flash point ≥ 23° C and ≤ 60° C
4	Flash point > 60° C and ≤ 93° C

Notes at the classification of physical hazards

In the classification of physicochemical hazards, even if all components are "Not applicable " or " Not classified", the category may need to be considered due to interaction between components.

Therefore, if the physicochemical hazards cannot be categorized by analogy, all of them are judged "Classification not possible."

When there are results of tests as mixtures done by users and it is possible for users to enter the physical hazard classification category, it is required to enter it manually for creating labels.

3. Health Hazards Guidance (mixture)

3.5.1 Acute Toxicity

For the calculation of acute toxicity, this system is used only to calculate classification of mixtures based on their components (the additivity formulas). If there are experimental data on acute toxicity or the bridging principle can be applied, it would be better to enter the results manually.

The classification category used in this system is almost based on NITE edited version (provisional: see adopted rules), but if it is necessary in the calculation, “Not classified (Not applicable)” is selected.

About the detail of adopted data, see appendix (notes of GHS list).

3.5.1.6 (5) If data is available for all or some of the components of the mixture. (Classification by additivity formula)

If data or information on all components does not exist or not enough information is available for the assessment, it is judged "Classification not possible," and the following process is not performed.

If the toxicity and concentration of each component of the mixture are known, the ATE of the mixture is obtained from the ATE (acute toxicity estimate) of each component using the additivity formula of the following formula 1 or formula 2, as shown in Table 3.5.1 (revised). If only the acute toxicity category is available, conversion to the acute toxicity estimate (ATE) is performed according to Table 3.5.10 (revised), andcalculation is performed using this conversion value as the ATE of each ingredient. Besides, in the JIS rule, the range of "Category 5" based on the UN GHS document is included in the range of "Not classified". Therefore, if it corresponds to "Not classified" and no acute toxicity estimate (ATE) values is available, a conversion value corresponding to "category 5" is assigned and calculated.

The relevant ingredients of a mixture are those which are present in concentrations ≥ 1 % (w/w for solids, liquids, dusts, mists and vapors and v/v for gases). However, this does not apply if there is a reason to suspect that an ingredient present at a concentration <1% is still relevant for classifying the mixture for acute toxicity.

In this system, for Category 1 and Category 2, the ingredient to be considered is determined to be 0.1% or more, referring to the UN GHS document 3.1.3.3 (a).

*Category 5 is based on the GHS document.

*Acute toxicity inhalation: For a vapour which is near the gaseous phases, classification should be based on the units of ppmV (Parts per million per volume) as follows: Category 1 (100 ppmV), Category 2 (500ppmV), Category 3 (2500 ppmV), Category 4 (20000 ppmV).

*Acute toxicity inhalation: For a vapour , two calculations in ppmV and in mg/L are performed. For classification of mixtures (products), the result in ppmV is used. However, both of the results in ppmV

and in mg/L need to be presented as the calculation basis. When only a value of either ppmV or mg/L is available for ingredients in a mixture, the calculation is performed using the conversion value of the category corresponding to Table 3.5.10. (Ex: If only the toxicity value = 0.9 mg / L is available, this system uses the conversion value of Category 2 = 100 ppmV and calculates the ATEmix).

*The upper limit of a toxicity value to consider in the calculation is the estimate value in the range of Category 5. If the value is (mathematically) higher than the limit, it is considered that it does not have toxicity and included in the concentration (in the left part of the equation) but not in the acute toxicity (in the right part of the equation).

Table 3.5.1(revised): Acute toxicity hazard categories and acute toxicity estimate (ATE) values defining the respective categories

Exposure route	Category 1	Category 2	Category 3	Category 4	Category 5
Oral (mg/kg bodyweight)	ATE≦5	5＜ATE≦50	50＜ATE≦300	300＜ATE≦2000	2000＜ATE≦5000
Dermal (mg/kg bodyweight)	ATE≦50	50＜ATE≦200	200＜ATE≦1000	1000＜ATE≦2000	2000＜ATE≦5000
Inhalation:Gases (ppmV)	ATE≦100	100＜ATE≦500	500＜ATE≦2500	2500＜ATE≦20000	20000＜ATE≦50000
Inhalation:Vapours (mg/L)	ATE≦0.5	0.5＜ATE≦2.0	2.0＜ATE≦10	10＜ATE≦20	20＜ATE≦50
Inhalation:Dusts/mists (mg/L)	ATE≦0.05	0.05＜ATE≦0.5	0.5＜ATE≦1.0	1.0＜ATE≦5.0	5.0＜ATE≦12.5

Table 3.5.10(revised) Conversion value for classification from experimentally obtained acute toxicity range value (or acute toxicity category) on each exposure route.

Exposure routes	acute toxicity range estimate			Converted Acute Toxicity point estimate
Oral (mg/kg bodyweight)	0＜	Category1	≦5	0.5
	5＜	Category2	≦50	5
	50＜	Category3	≦300	100
	300＜	Category4	≦2000	500
	2000＜	Category5	≦5000	2500
	5000＜	Not classified		
Dermal (mg/kg bodyweight)	0＜	Category1	≦50	5
	50＜	Category2	≦200	50
	200＜	Category3	≦1000	300
	1000＜	Category4	≦2000	1100

	2000<	Category5	≦5000	2500
	5000<	Not classified		
Inhalation: **Gases** (ppmV)	0<	Category1	≦100	10
	100<	Category2	≦500	100
	500<	Category3	≦2500	700
	2500<	Category4	≦20000	4500
	20000※1<	Category5	≦50000*1	25000*2
	50000<	Not classified		
Inhalation: **Vapours** (mg/ l)	0<	Category1	≦0.5	0.05
	0.5<	Category2	≦2.0	0.5
	2.0<	Category3	≦10.0	3
	10.0<	Category4	≦20.0	11
	20.0※1<	Category5	≦50.0*1	25*2
	50.0<	Not classified		
Inhalation: **Dust/mist** (mg/ l)	0<	Category1	≦0.05	0.005
	0.05<	Category2	≦0.5	0.05
	0.5<	Category3	≦1.0	0.5
	1.0<	Category4	≦5.0	1.5
	5.0※1<	Category5	≦12.5*1	6.25*2
	12.5<	Not classified		

*1 This value is a system specification of this system and set to a value 2.5 times the upper limit of the estimated value in the range of Category 4 by following the upper limit of the estimated value in the range of Category 5 from the upper limit of the estimated value in the range of Category 4 of oral and dermal toxicities in the UN GHS documents.

*2 This value is a system specification of this system and set to a value of the estimated value lower limit plus the estimated value upper limit divided by 10 in the range of Category 5 by following the converted value of Category 5 of oral and dermal toxicities in the UN GHS documents

1. Data available for all ingredients

The ATE_{mix} of the mixture is determined by calculation from the ATE values for all relevant ingredients according to the following formula below for oral, dermal, or inhalation toxicity.
However, if the classification of the relevant ingredient is "Not classified (Not applicable)", it is assumed that the ATE can be neglected and the calculation of the ingredients of "Not classified (Not applicable)" is not performed.

(Formula 1) $$\frac{100}{ATE_{mix}} = \sum_{i=1}^{n} \frac{C_i}{ATE_i}$$

wherein: ATE_{mix} = ATE of the mixture
C_i = concentration of ingredient i
ATE_i = Acute Toxicity Estimate of ingredient i
n shows the number of ingredients and i is running from 1 to n.

2. When information of an ingredient or multiple ingredients of a mixture are not available, the following methods may be applied.

If the concentration of the unknown component is greater than 10%, use the Formula 2 to calculate the ATE of the mixture.

In the event that an ingredient without any useable information at all is used in a mixture at a concentration ≥ 1%, the mixture should be classified based on the known ingredients only, and additional statement "x% of the mixture consists of ingredient (s) of unknown toxicity" is described in the classification result.Furthermore, this method generally requires expert judgment.

(Formula 2)
$$\frac{100-\left(\sum C \text{ unknown if } >10\%\right)}{ATE_{\text{mix}}}=\sum_{i=1}^{n}\frac{C_{\text{i}}}{ATE_{\text{i}}}$$

wherein:

$C_{unknown}$ if > 10%: the total percentage of the unknown ingredient(s) if the concentration of the unknown ingredient (s) > 10%

ATE_{mix}: ATE of the mixture

C_i: concentration of ingredient i

ATE_i: Acute Toxicity Estimate of ingredient i

n: shows the number of ingredients and i is running from 1 to n.

- Corrective action depending on selected classification

If the classification resulted in Category 5 and the selected classification is JIS, Category 5 is not adopted, therefore, this system changes the result to "Not classified."

- Processing when a hazard category is not given

As a result of following the procedure above, if the object is classified as "Not classified", the total concentration of unknown components contained is equal to or more than the concentration to consider (0.1%), it is judged to be "classification not possible", whereas if it is lower than the concentration to consider, it is judged to be "Not classified."

- Corrective action depending on physical state of mixture

Only the physical state of mixture is "liquid" or "solid", acute toxicity (Inhalation: Gases) is classified into "Not classified (Not applicable)".

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3.5.2 Skin Corrosion/Irritation

For the calculation of skin Corrosion/Irritation, this system is used only to calculate classification of mixtures based on their ingredients (the additivity formulas). If there are experimental data on skin Corrosion/Irritation or the bridging principle can be applied, it would be better to enter the results manually.

3.5.2.7 (3) If data is available for all or some of the ingredients of the mixture. (Classification using the concentration limit)

If any ingredients with data or information for assessing Skin Corrosion/Irritation are included, the judgments below (c) is performed.

If data or information on all ingredients does not exist or not enough information is available for the assessment, it is judged "Classification not possible," and the following process is not performed.

C) Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture

The ingredient to be considered in the mixture is a component existing at a concentration of 1% or more (w/w for solids, liquids, dusts, mists, vapors, and v/v for gases). However, unless there is a possibility that it may be related to the classification of the mixture even at a concentration of less than 1% like a corrosive component, this is not the case.

In this system, it is determined with reference to the UN GHS document 3.2.3.3 that a ingredient to be considered is 0.1% or more for Category 1 and 1% or more for Category 2 and Category 3.

1. Classification of mixtures when the additivity approach applies for ingredients

If the skin corrosive component is below the concentration of Category 1 and is classified as skin irritant, 10 is used as the weighting coefficient. If the total concentration of each component exceeds the concentration limit (see Table 3.5.22 (revised)), which is the classification standard, the mixture is classified as skin corrosive / irritant.

Table 3.5.22(revised) Concentration of ingredients of a mixture when the additivity approach can apply, that would trigger classification of the mixture as hazardous to skin (skin corrosion/irritation)

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:		
	Skin corrosive	Skin irritant	
	Category 1	Category 2	Category 3
Skin Category 1	≧5 %	＜5 %、≧1 %	
Skin Category 2	－	≧10 %	＜10 %、≧1 %
Skin Category 3			≧10 %
(10 x skin Category 1) + skin Category 2	－	≧10 %	＜10 %、≧1 %
(10 × Skin Category 1) + Skin Category 2 + Skin Category 3			≧10 %

NOTE: In these cases, the sum of all ingredients of a mixture classified as skin Category 1A, 1B or 1C respectively, should each be ≥ 5% in order to classify the mixture as either skin Category 1A, 1B or 1C. In

case the sum of the skin Category 1A ingredients is < 5% but the sum of skin Category ingredients 1A+1B is ≥ 5%, the mixture should be classified as skin Category 1B. Similarly, in case the sum of skin Category 1A + 1B is < 5% but the sum of Category 1A + 1B + 1C is ≥ 5% the mixture would be classified as Category 1C.

・Corrective action depending on selected classification

If the classification resulted in Category 3 and the selected classification is JIS, Category 3 is not adopted and therefore the result is classified as "Not classified."

・Processing when a hazard category is not given As a result of following the procedure above, if the object is classified as "Not classified," the total concentration of unknown components contained is equal to or more than the minimum value of the concentration to consider (0.1%), it is judged to be "classification not possible", whereas if it is lower than the minimum value of the concentration to consider, it is judged to be "Not classified."

2. Classification of mixtures when the additivity approach can not apply for ingredients

For mixtures containing strong acids or bases, the pH should be used as classification criterion since pH will be a better indicator of skin corrosive than the concentration limits in Table 3.5.22.

A mixture containing skin corrosive or skin irritation ingredients that cannot be classified based on the additivity approach applied in Table 3.5.22 due to chemical characteristics, should be classified as Category 1 when it contains ≧1% of a skin corrosive ingredients and as Skin Category 2 when it contains ≧3% of an skin irritation ingredients. Classification of mixtures with ingredients for which the approach in Table 3.5.22 does not apply is summarized in Table 3.5.23.

Table 3.5.23 Concentration of ingredients of a mixture when the additivity approach does not apply, that would trigger classification of the mixture as hazardous to skin
(skin corrosive / skin irritation)

Ingredient	Concentration	Mixture classified as: Skin
Acid with pH≦2	≧1 %	Category1
Base with pH≧11.5	≧1 %	Category 1
Other corrosive (Category1) ingredient	≧1 %	Category 1
Other irritant (Category2) ingredient (including acids and bases)	≧3 %	Category 2

3.5.3 Serious Eye Damage/Eye Irritation

For the calculation of Serious Eye Damage/Eye Irritation, this system is used only to calculate classification of mixtures based on their components (the additivity formulas). If there are experimental data on Serious Eye Damage/Eye Irritation or the bridging principle can be applied, it would be better to enter the results manually.

3.5.3.7 (3) If data is available for all or some of the components of the mixture. (Classification using the concentration limit)

The component to be considered in the mixture is a component existing at a concentration of 1% or more (w/w for solids, liquids, dusts, mists, vapors, and v/v for gases). However, unless there is a possibility that it may be related to the classification of the mixture even at a concentration of less than 1% like a corrosive component, this is not the case.

In this system, it is determined with reference to the UN GHS document 3.3.3.3 that a ingredient to be considered is 0.1% or more for Category 1.

If any ingredients with data or information for assessing Serious Eye Damage/Eye Irritation are included, the judgments below formula 1 is performed.

If data or information on all ingredients does not exist or not enough information is available for the assessment, it is judged "Classification not possible," and the following process is not performed.

1. Classification of mixture to which addition method can be applied.

Table 3.5.32 (revised) shows the concentration limit for judging whether the mixture is classified as serious eye damage / eye irritation.

If the skin corrosive component is below the concentration of Category 1 and is classified as skin irritant, 10 is used as the weighting coefficient.

If the total concentration of each component exceeds the concentration limit (see Table 3.5.32 (revised)), which is the classification standard, the mixture is classified as serious eye damage / eye irritation.

Table 3.5.32(revised) Concentration of ingredients of a mixture when the additivity approach can apply, that would trigger classification of the mixture as hazardous to the eye

(Serious eye damage/eye irritation)

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Serious Eye Damage	Eye Irritation
	Category 1	Category 2[b]
Eye Category 1 + skin Category 1[a]	≧3 %	≧1 % but ＜3 %
10 x (skin Category 1 + eye Category 1)[a] + eye Category 2/2A/2B	—	≧10 %

a) If an ingredient is classified as both Skin Category 1 and Eye Category 1, its concentration is considered only once the calculation.

b) In JIS, it is stated that Category 2 or 2A should be determined in the classification, but in this system, it is uniformly determined as Category 2. However, since JIS states that a mixture can be classified as Category 2B when all relevant ingredients of the mixture are classified as Category 2B, a mixture containing only ingredients classified as Category 2B is judged as Category 2B also in this system.

2. Classification of mixtures to which the addition method cannot be applied

For mixtures containing strong acid or strong alkali, pH is used as classification criteria (see Table 3.5.33).

It is classified as Eye category 1 when it contains 1% or more of a corrosive or serious eye damaging ingredient, as Eye category 2 when it contains ≥ 3% of an eye irritant ingredient. Table 3.5.33 shows the concentration limit for judging whether the mixture method cannot be applied to severe eye damage / eye irritation.

Table 3.5.33 Concentration of ingredients of a mixture when the additivity approach does not apply, that would trigger classification of the mixture as hazardous to the eye

(Serious eye damage/eye irritation)

Ingredient	Concentration	Mixture classified as: Eye
Acid with pH ≤ 2	≧1 %	Category 1
Base with pH ≥ 11.5	≧1 %	Category 1
Serious Eye Damage (Category 1) ingredients	≧1 %	Category 1
Other irritant (Category 2), including acids and bases	≧3 %	Category 2

・ Processing when a hazard category is not given:

As a result of following the procedure above, if the object is classified out of category, the total concentration of unknown components contained is equal to or more than the minimum value of the

concentration to consider, it is judged to be " Classification not possible " whereas if it is lower than the minimum value of the concentration to consider, it is judged to be " Not classified."

3.5.4 Respiratory or Skin Sensitization

For the calculation of Respiratory Sensitization, this system is used only to calculate classification of mixtures based on their components. If there are experimental data on Respiratory Sensitization or the bridging principle can be applied, it would be better to enter the results manually.

If any components with data or information for assessing Respiratory Sensitization are included, perform the judgments below.
If data or information on all components does not exist or not enough information is available for the assessment, it is judged "Classification not possible," and the following process is not performed.

3.5.4.8 (3) If data is available for all or some of the components of the mixture. (Classification using the concentration limit)

When at least one component is classified as respiratory sensitizer or skin sensitizer and each of solids, liquids and gases exists at or above the respective concentration limits shown in table 3.5.46, the mixture is classified as Respiratory Sensitizing Substance Category 1 or Skin Sensitizing Substance Category 1.

In this system, if the respiratory sensitizer or skin sensitizer is below the concentration limit but is present at a concentration of 0.1% or more, that fact is described in the classification rationale.

Table 3.5.46 Concentration limits of ingredients of a mixture classified as respiratory sensitizers

Ingredient classified as:		Concentration limits triggering classification of a mixture as:		
		Respiratory sensitizer Category 1		Skin sensitizer Category 1
		Solid/Liquid	Gas*1	All physical states
Respiratory sensitizer	Category 1	≧ 1.0 %*2	≧0.2 %*2	−
	Category 1A	≧ 0.1 %	≧ 0.1 %	−
	Category 1B	≧1.0 %	≧0.2 %	−
Skin sensitizer	Category 1	−	−	≧1.0 %*2
	Category 1A	−	−	≧ 0.1 %
	Category 1B	−	−	≧1.0 %

*1: If the physical state is aerosol, it should be classified into gas and solid/liquid, their concentrations should be independently 100% converted and calculated, and then the classification category of the highest hazard among them should be used as the classification of the mixture. However, this system classifies it into gas for convenience.

*2: When the UN rule is selected in this system, the mixture is classified as category 1 when there is 0.1% or more of respiratory sensitizer or skin sensitizer corresponding to category 1.

・ Processing when a hazard category is not given:

As a result of following the procedure above, if the object is classified out of category, the total concentration of unknown ingredients contained is equal to or more than the minimum value of the

concentration to consider, it is judged to be " Classification not possible " whereas if it is lower than the minimum value of the concentration to consider, it is judged to be " Not classified."

3.5.5 Germ Cell Mutagenicity

Calculation on germ cell mutagenicity in this system is performed only for classification based on ingredient of mixture; the presence of experimental data on the mixture itself and the application of the bridging principle is not considered.

3.5.5.6 (1) If data is available for all or some of the ingredients of the mixture. (Method using the concentration limit)

Classification of a mixture for germ cell mutagenicity is basically performed by using the concentration limits of each ingredient as described below, based on the available data for each ingredient.

The mixture will be classified as a germ cell mutagen when at least one ingredient has been classified as a Category 1or Category 2 mutagen and is present at or above the concentration limit as shown in Table 3.5.51 for Category 1 and 2, respectively.

Table 3.5.51 Concentration limits of ingredients of a mixture classified as germ cell mutagens

Ingredient classified as:		Concentration limits triggering classification of a mixture as:		
		Category 1A	Category 1B	Category 2
mutagen	Category 1A	≧0.1 %	—	—
	Category 1B	—	≧0.1 %	—
	Category 2	—	—	≧1.0 %

・ Processing when a hazard category is not given:

As a result of following the procedure above, if the object is classified out of category, the total concentration of unknown components contained is equal to or more than the minimum value of the concentration to consider, it is judged to be " Classification not possible " whereas if it is lower than the minimum value of the concentration to consider, it is judged to be " Not classified."

3.5.6 Carcinogenicity

Calculation on carcinogenicity in this system is performed only for classification based on mixture components; the presence of experimental data on the mixture itself and the application of the bridging principle is not considered.

Classification of mixtures for carcinogen shall be basically performed based on the available data for each ingredient by using the concentration limits as described later.

3.5.6.6 (1) Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture. (Method using the concentration limit)

The mixture will be classified as a carcinogen when at least one ingredient has been classified as a Category 1 or 2 carcinogen and is present at or above the concentration limit as shown in Table 3.5.58 for Category 1 and 2, respectively.

* Note*

Even if an ingredient is present less than the concentration limit in the mixture, when a carcinogen classified category 2 is contained at 0.1% or more, that fact should be specified on the SDS.

Table3.5.58 Concentration limits of ingredients of a mixture classified as carcinogens

Ingredient classified as:	Concentration limits triggering classification of a mixture as:		
	Category 1 carcinogen		Category 2 carcinogen
	Category 1A	Category 1B	
Category 1A carcinogen	≧0.1 %	－	－
Category 1B carcinogen	－	≧0.1 %	－
Category 2 carcinogen	－	－	≧1.0 %*1

*1: When the UN rule is selected in this system, the mixture is classified as class2 when there is 0.1% or more of carcinogen corresponding to class 2.

・ Processing when a hazard category is not given:

As a result of following the procedure above, if the object is classified out of category, the total concentration of unknown components contained is equal to or more than the minimum value of the concentration to consider, it is judged to be " Classification not possible " whereas if it is lower than the minimum value of the concentration to consider, it is judged to be " Not classified."

3.5.7 Reproductive Toxicity

Calculation on reproductive toxicity in this system is performed only for classification based on mixture components; the presence of experimental data on the mixture itself and the application of the bridging principle is not considered.

The reproductive toxicity classification of mixtures is basically performed by using the concentration limits of each ingredient as described below, based on the available data for each ingredient.

3.5.7.6 (1) Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture. (Method using the concentration limit)

1) The mixture will be classified as a reproductive toxicant when at least one ingredient has been classified as a Category 1or 2 reproductive toxicant and is present at or above the concentration limit as shown in Table 3.5.67 for Category 1 and 2, respectively.
2) The mixture will be classified for effects on or via lactation when at least one ingredient has been classified for effects on or via lactation and is present at or above the concentration limit as shown in Table 3.5.67 for the additional category for effects on or via lactation.

* Note*

Even if an ingredient is present less than the concentration limit in the mixture, when it is contained at 0.1% or more, that fact should be specified on the SDS.

In this system, when the substances of Category 1A and Category 1B are present at concentration of 0.1% ≤ n <0.3% in the mixture, that is described in "Rationale for the classification".

Table3.5.67 Concentration limits of ingredients of a mixture classified as reproductive toxicants*

Ingredient classified as:	Concentration limits triggering classification of a mixture as:			
	Category 1 reproductive toxicant		Category 2 reproductive toxicant	Additional category for effects on or via lactation
	Category 1A	Category 1B		
Category 1A reproductive toxicant	≧0.3 %	—	—	—
Category 1B reproductive toxicant	—	≧0.3 %	—	—
Category 2 reproductive toxicant	—	—	≧3.0 %	—
Additional category for effects on or via lactation	—	—	—	≧0.3 %

* When the UN rule is selected in this system, all ingredients of o.1% or more are taken into account for reproductive toxicants and additional category in the table.

・ Processing when a hazard category is not given:

As a result of following the procedure above, if the object is classified out of category, the total concentration of unknown components contained is equal to or more than the minimum value of the concentration to consider, it is judged to be " Classification not possible " whereas if it is lower than

the minimum value of the concentration to consider, it is judged to be " Not classified."

3.5.8 Specific Target Organ Toxicity-Single Exposure

For the calculation of specific target organ toxicity-single exposure, this system is used only to calculate classification of mixtures based on their components. If there are experimental data on specific target organ toxicity-single exposure or the bridging principle can be applied, it would be better to enter the results manually.

If any components with data or information for assessing specific target organ toxicity-single exposure, are included, the judgments below is performed.
If data or information on all components does not exist or not enough information is available for the assessment, it is judged "Classification not possible," and the following process is not performed.

3.5.8.6 (3) Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture (using concentration limit)

A mixture will be classified as a specific target organ toxicant (single exposure) when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant (single exposure) and is present at or above the concentration limit as mentioned in Table 3.6.18 for Category 1 and 2 respectively.

The concentration limit is set at 10%, referring to JIS.

Table 3.5.73 Concentration limits of ingredients of a mixture as a specific target organ toxicant that would trigger classification of the mixture as Categories 1 and 2

Ingredient classified as:		Concentration limits triggering classification of a mixture as:	
		Category 1	Category 2
Specific target organ toxicant (Single exposure)	Category 1	≧10 % *1	1.0 %≦ ingredient ＜10 %
	Category 2	－	≧10 %*1

*1: When the UN rule is selected in this system, a component of 1% or more is taken into account for a specific target organ toxicant.

* Note*

- Even if an ingredient is present less than the concentration limit in the mixture, when it is contained at 1% or more, that fact should be specified on the SDS.
- Care should be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause specific target organ toxicity at <1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

(4) When extrapolating toxicity of a mixture that contains Category 3 ingredient(s)

If a mixture contains ingredients applicable to Category 3 for its respiratory tract irritation or narcotic effects, the concentrations of the ingredients shall be summed up for each effect and if the sum becomes

20% or more, the mixture is classified in Category 3 based on the effect.

・ Processing when a hazard category is not given:

As a result of following the procedure above, if the object is classified out of category, the total concentration of unknown ingredients contained is equal to or more than the minimum value of the concentration to consider, it is judged to be " Classification not possible " whereas if it is lower than the minimum value of the concentration to consider, it is judged to be " Not classified."

3.5.9 Specific Target Organ Toxicity-Repeated Exposure

For the calculation of specific target organ toxicity- repeated exposure, this system is used only to calculate classification of mixtures based on their components. If there are experimental data on specific target organ toxicity- repeated exposure or the bridging principle can be applied, it would be better to enter the results manually.

3.5.9.6 (3) Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture (using concentration limit)

The mixture will be classified as a specific target organ toxicity substance (specific organ designation) as a result of a single exposure, repeated exposure, or both when at least one ingredient has been classified as a Category 1 or Category 2 specific target organ toxicant (repeated exposure) and is present at or above the concentration limit as mentioned in Table 3.6.78 for Category 1 and 2 respectively.

The concentration limit is set at 10% referring to JIS.

Table 3.5.78 Concentration limits of ingredients of a mixture as a specific target organ toxicant that would trigger classification of the mixture

Ingredient classified as:		Concentration limits triggering classification of a mixture as:	
		Category 1	Category 2
Specific target organ toxicant (Repeated exposure)	Category 1	≧10 %*1	1.0 %≦ ingredient＜10 %
	Category 2		≧10 %*1

*1: When the UN rule is selected in this system, a component of 1% or more is taken into account for a specific target organ toxicant.

* Note*

- Even if an ingredient is present less than the concentration limit in the mixture, when it is contained at 0.1% or more, that fact should be specified on the SDS.
- Care should be exercised when toxicants affecting more than one organ system are combined that the potentiation or synergistic interactions are considered, because certain substances can cause specific target organ toxicity at <1% concentration when other ingredients in the mixture are known to potentiate its toxic effect.

- Processing when a hazard category is not given:

As a result of following the procedure above, if the object is classified out of category, the total concentration of unknown ingredients contained is equal to or more than the minimum value of the concentration to consider, it is judged to be " Classification not possible " whereas if it is lower than the minimum value of the concentration to consider, it is judged to be " Not classified."

3.5.10 Aspiration Hazard

For the calculation of aspiration hazard, this system is used only to calculate classification of mixtures based on their components. If there are experimental data on aspiration hazard or the bridging principle can be applied, it would be better to enter the results manually.

3.5.10.6 (3) Classification of mixtures when data are available for all ingredients or only for some ingredients of the mixture (using concentration limit)

In the mixture, components present at a concentration of 1% or more are considered.
The component concentration classified as Category 1 is shown in Table 3.5.82.

Table 3.5.82 Concentration of ingredient for classification of mixtures by additivity approach (Aspiration Hazard)

Ingredient	Concentration	Classification
Category 1 (kinematic viscosity ≤ 20.5 mm2/s, at 40°C.)	≧10%	Category 1
In case of a mixture which separates into two or more distinct layers, one of which contains ≥ 10% of an ingredient classified in Category 1 (kinematic viscosity ≤ 20.5 mm2/s, at 40°C.)	≧10%	Category 1

・A mixture with a kinematic viscosity higher than 20.5 mm ^{2} / s is “Not classified”.

・Corrective action depending on selected classification

If the classification resulted in Category 2 and the selected classification is JIS, Category 2 is not adopted and therefore the result needs to be classified into " Classification not possible."

・ Processing when a hazard category is not given:

As a result of following the procedure above, if the object is classified out of category, the total concentration of unknown ingredients contained is equal to or more than the minimum value of the concentration to consider, it is judged to be " Classification not possible " whereas if it is lower than the minimum value of the concentration to consider, it is judged to be " Not classified."

4. Environmental Hazards Guidance

4.4.1 Hazardous to the Aquatic Environment – Acute Hazard

For the calculation of hazardous to aquatic environment-acute hazard, this system is used only to calculate classification of mixtures based on their components. If there are experimental data on hazardous to aquatic environment-acute hazard or the bridging principle can be applied, it would be better to enter the results manually.

Classification methods of mixtures (For Hazardous to the aquatic environment Short term (Acute))

If any components with data or information for assessing hazardous to aquatic environment-acute hazard, are included, the judgments below is performed.

If data or information on all components does not exist or not enough information is available for the assessment, it is judged "Classification not possible," and the following process is not performed.

1. Not relevant ingredients

For "Not relevant ingredients " in Hazardous to the Aquatic Environmental, no numerical values are specified as the specifications of this system and all components are subject to calculation.

2. For Hazardous to the Aquatic Environmental, calculations are done by the three kinds of methods of A, B, and C below according to the GHS rules, and it is specified that the most conservative one is used from the standpoint of safety.

(2-1) Calculation method A

※ Calculation method A is carried out when there are two or more ingredients with toxicity value data of three trophic levels (fishes, crustacea, algae or other aquatic plants).

2-1-1 Determine the category for each of the three trophic levels (fishes, crustacea, algae or other aquatic plants).

2-1-1-1 Additivity formula (* Refer to Eq. 4-4-1.)

For each of the three trophic levels, determine the category from the components with toxicity values using the additivity formula.

It is allowed to assign acute toxicity category to the mixture part using this calculated toxicity value and then apply it to the summation method.

2-1-1-2 addition formula (* Refer to Eq. 4-4-1)

Toxicity value data for three trophic levels are not available, but at least one is for toxicity value data, the strongest toxicity value is adopted for each ingredient, and the classification is obtained by addition formulas.

2-1-1-3 Summation method

Following the summation method, classify from the content percentage of components without toxicity values but with categories and from the content percentage of the categories determined in 2-1-1-1 and 2-1-1-2.

2-1-2 Classification

From the results of each of the three trophic levels obtained in 2-1-1, use the category with the highest toxicity as the category of the mixture.

(2-2) Calculation method B

2-2-1 Of the three trophic levels, use the level with the highest toxicity value for each component and determine categories by the summation equation.

2-2-2 Following the summation method, determine the categories of the mixtures from the components without toxicity values but with categories and from the categories determined in 2-2-1.

(2-3) Calculation method C

Determine categories of mixtures only by the summation method without using the additivity formula.

3. Processing when a hazard category is not given.

In the case any classification not applied as a result of process described above, it is judged as "classification not possible" if mixture contains unknown component, or, it is judged as "not classified" if mixture not contains any unknown component.

formula 4-4-1 Additivity formula

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

Where:

Ci	concentration of ingredient i (weight percentage)
$L(E)C_{50i}$	LC_{50} or EC_{50} for ingredient i (mg/L)
n	number of ingredients, and i is running from 1 to n
$L(E)C_{50m}$	$L(E)C_{50}$ of the part of the mixture with test data

The calculated toxicity shall be used to assign that portion of the mixture an acute hazard category which is then subsequently used in applying the summation method;

For Category 1, determine the toxicity multiplying factor M simultaneously with reference to Table 4.5.4(Rev1) and use it later for the summation method.

Table 4.4.18 Summation method; Classification of a mixture for acute hazards based on summation of the concentrations of classified ingredients

Sum of the concentrations (in%) of ingredients classified as:	Mixture is classified as:
Acute 1 x Ma ≥ 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

Table 4.4.20(Rev1) M (toxicity multiplying factor) for ingredients with highly acute toxicity of mixtures

Calculation result	M: toxicity multiplying factor
0.1＜ Calculation result ≦1	1
0.01＜ Calculation result ≦0.1	10
0.001＜ Calculation result ≦0.01	100
0.0001＜ Calculation result ≦0.001	1000
0.00001＜ Calculation result ≦0.0001	10000

(continue in factor 10 intervals)

For the calculation of hazardous to aquatic environment-long-term hazard, this system is used only to calculate classification of mixtures based on their components. If there are experimental data on hazardous to aquatic environment-acute hazard or the bridging principle can be applied, it would be better to enter the results manually.

Classification methods of mixtures for hazardous to the aquatic environment Long term (Chronic)

1. Not relevant ingredients

For " Not relevant ingredients " in Hazardous to the Aquatic Environmental, no numerical values are specified as the specifications of this system and all components are subject to calculation.

2. For Hazardous to the Aquatic Environmental, calculations are done by the three kinds of methods of A, B, and C below according to the GHS rules, and it is specified that the most conservative one is used from the standpoint of safety.

(2-1) Calculation method A

※ Calculation method A is carried out when there are two or more ingredients with toxicity value data of three trophic levels (fishes, crustacea, algae or other aquatic plants).

2-1-1 Determine the category for each of the three trophic levels (fishes, crustacea, algae or other aquatic plants).

2-1-1-1 additivity formulas (* Refer to Eq.4-4-2.)

For each of the three trophic levels, determine the category from the components with toxicity values using the additivity formula.

It is allowed to assign acute toxicity category to the mixture part using this calculated toxicity value and then apply it to the summation method.

2-1-1-2 Additivity formula (* Refer to Eq. 4-4-2)

Toxicity value data for three trophic levels are not available, but at least one is for toxicity value data, the strongest toxicity value is adopted for each ingredient, and the classification is obtained by addition formulas.

2-1-1-3 Summation method

Following the summation method, classify from the content percentage of components without toxicity values but with categories and from the content percentage of the categories determined in 2-1-1-1 and 2-1-1-2.

2-1-2 Classification

From the results of each of the three trophic levels obtained in 2-1-1, use the category with the highest toxicity as the category of the mixture.

(2-2) Calculation method B

2-2-1 Of the three trophic levels, use the level with the highest toxicity value for each component and determine categories by the summation equation.

2-2-2 Following the summation method, determine the categories of the mixtures from the components without toxicity values but with categories and from the categories determined in 2-2-1.

(2-3) Calculation method C

Determine categories of mixtures only by the summation method without using the additivity formula.

3. Processing when a hazard category is not given:

As a result of following the procedure above, if no categories are obtained, classify it into "Classification not possible" in the case where unknown components are present or out of category in the case where unknown components are not present.

Formula 4-4-2 Additivity formula

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

where :

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

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

NOECi NOEC (or other recognized measures for chronic toxicity) for ingredient i covering the rapidly degradable ingredients, in mg/L;

NOECj 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;

EqNOECm equivalent NOEC of the part of the mixture with test data;

For Category 1, determine the toxicity multiplying factor simultaneously with reference to Table4.5.4 and use it later for the summation method.

Table 4.4.20 M (toxicity multiplying factor) for ingredients with high toxicity of mixtures

acute toxicity	M factor	Chronic toxicity	M factor	
L(E)C50 value		NOEC value	NRD[a]	RD[b]
0.1＜L(E)C50≦1	1	0.01＜NOEC≦0.1	1	－
0.01 ＜L(E)C50≦0.1	10	0.001＜NOEC≦0.01	10	1
0.001＜L(E)C50≦0.01	100	0.0001＜NOEC≦0.001	100	10
0.0001＜L(E)C50≦0.001	1000	0.00001＜NOEC≦0.0001	1000	100
0.00001＜ L(E)C50≦0.0001	10000	0.000001＜ NOEC≦0.00001	10000	1000
(continue in factor 10 intervals)		(continue in factor 10 intervals)		

[a]NRD: Non-rapidly degradable ingredients [b]RD: Rapidly degradable ingredients

Table4.4.19 (revised) Summation method; Classification of a mixture for chronic hazards based on summation of the concentrations of classified ingredients

Sum of the concentrations (in %) of ingredients 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) + (10 x Chronic 2) + Chronic 3 ≥ 25%	Chronic 3
Chronic 1 + Chronic 2 + Chronic 3 + Chronic 4 ≥ 25%	Chronic 4

* Category 4 is a safety net classification applied to the case where there is data showing the possibility of chronic toxicity and data on acute toxicity cannot be obtained and cannot be incorporated into the system. Therefore, it is not judged in this system. However, in the case where there is a basis of chronic hazards of mixtures but there is no data on acute hazards, it is allowed to enter "Long-term Category 4" manually.

4-4-2 Hazardous to the ozone layer

・Classification criteria for hazardous to ozone layer

For classification of hazards to the ozone layer in this system, the classification is performed only in the following case.

(4) Classification methods of mixtures

Any mixture containing at least one ingredient listed in the Annexes to the Montreal Protocol, at a concentration ≥ 0.1% shall be classified as Category 1.

<Update history>

Revision date	Material	Reason	Version
1, April, 2021	Whole		1.00
8, July, 2021	2.5.6 Flammable Liquids 3.5.1 Acute Toxicity	Added the details of classification logic and supplementary descriptions	1.01
31, March, 2022	3.5.1 Acute Toxicity	Partial modification of classification logic (calculation method for "Not classified" ingredient).	2.0
April, 2022	Multiple hazards and precedence of hazard information 3.5.1 Acute Toxicity 3.5.3 Serious Eye Damage/Eye Irritation Whole	Added the multiple hazards and precedence of hazard information Added the converted acute toxicity point estimate of “Not classified” without toxicity range value Added the individual classification logic in this system for serious eye damage/eye irritation Added the concentration to consider or the concentration limit value for the total concentration of unknown components	2.1
	3.5.3 Serious Eye Damage/Eye Irritation	Added the details of classification logic and supplementary descriptions	2.2
April, 2023	3.5.3 Serious Eye Damage/Eye Irritation Whole	Added revised classification logic of serious eye damage/eye irritation Corrected several errors	2.3