Supplementary document for the classification method for GHS classification system

Contents

1. Introduction

The GHS Classification System (hereinafter referred to as "this system") is a version with some logic added to the classification principle below for use as a tool, and this “Supplementary document for the classification method for GHS classification system” describes the logic that this system uses.

The underlined parts of this document indicates that it is based on the own rules of the 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 entered manually. For details, please refer to United Nations GHS documents, related JIS standards (Z7252:2019, Z7253:2019), classification guidance for enterprises (2019 Revised Edition by the Ministry of Economy, Trade and Industry).

Although this system allows GHS 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. Physicochemical hazards not described in this manual will not be classified automatically by the system, and therefore, the classification results should be entered manually.

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).

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.

* 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.

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 2-3-6-1 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. Need to be classified and categorized using this system.

×: Checked off. No need to be classified using this system as an exemption.

2-3-9 Relationship between UNRTDG classification and GHS Categorization

Based on the UNRTDG classification ("UN No," "Hazard class," "Packing Group") of mixtures, the corresponding GHS classification categories of physicochemical hazards of mixtures 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	
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	Compressed gas Liquefied gas Refrigerated liquefied gas Dissolved gas	
	2.2 Non-flammable, non-toxic gases		
	2.3		
6)Flammable Liquids	3 PG I	Category1	UN class subsidiary risk
	3 PG II	Category2	
	3 PG III	Category3	
	Not dangerous goods (Flash point:60degrees or more)	Category4	
7)Flammable Solid	4.1 PG II	Category1	UN class subsidiary risk
	4.1 PGIII	Category2	

(Continued on the following page.)

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	Shape, UN class, Package group
10)Pyrophoric Solids	4.2 PG I (solid)	Category1	Shape, 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	Shape, 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	Shape, 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） 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）	Category1	Shape, UN class, UN number
	-	Category2	
	-	Category3	
	-	Category4	

2.4.2 Flammable Gases

(6) Classification 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;

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 Tci is described in ISO10156:2010.

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:

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.

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

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.

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.

3. Health Hazards Guidance (mixture)

3.6.1 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.

C) If data is available for all or some of the components of the mixture.

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 addition formula of the following formula 1 or formula 2, as shown in Chart 3.5.1).

For Category 1 and Category 2 in this system, it is defined with reference to mixture classification examples of the GHS subcommittee that a component to consider needs to be 0.1% or more.

Conversion from experimentally obtained acute toxicity range values (or acute toxicity categories) to acute toxicity point estimate to be used when classifying by the addition formulas, is shown in Table 3.6.2 (revised).

This conversion value is calculated as ATE of each component.

*Category 5 is based on the GHS document.

*Acute toxicity inhalation: For steam, two calculations in ppm and in mg/L are performed. For classification of mixtures (products), the result in ppm is used. However, both of the results in ppm and in mg/L need to be presented as the calculation basis.

*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 (revised)

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
Gases (ppmV)	ATE≦100	100＜ATE≦500	500＜ATE≦2500	2500＜ATE≦20000	20000＜ATE≦50000
Vapours (mg/L)	ATE≦0.5	0.5＜ATE≦2.0	2.0＜ATE≦10	10＜ATE≦20	20＜ATE≦50
Dusts and mists	ATE≦0.05	0.05＜ATE≦0.5	0.5＜ATE≦1.0	1.0＜ATE≦5.0	5.0＜ATE≦12.5

(mg/L)					

Table 3.6.2(revised) Conversion value for classification by addition formula from experimentally obtained acute toxicity range value (or acute toxicity category) on the 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		
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		
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		
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

A) 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:

(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.

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

b) If the concentration of the unknown component is 10% or less, 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%, it shall be concluded that clear acute toxicity estimate value is not applicable to the mixture. In such cases, 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, the classification result became "Not applicable to category"

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

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 and therefore the result needs to be classified into "Not classified."

.

3.6.2 Skin Corrosion/Irritation

For the calculation of skin Corrosion/Irritation, this system is used only to calculate classification of mixtures based on their components (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.

C) If data is available for all or some of the components of the mixture.

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

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.

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

The component to be considered in the mixture is a component existing at a concentration of 1% or more (solid / liquid / dust / mist / vapor / mass / mass for gas and volume / volume for gas). 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 defined with reference to the GHS classification examples of the UN GHS subcommittee that a component to consider needs to be 0.1% or more for Category 1 and 1% or more for Category 2 and Category 3.

1.Classification of mixtures when the theory of additivity 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 3.6.4 (revised)), which is the classification standard, the mixture is classified as skin corrosive / irritant.

Table 3.6.4(revised) Concentration of ingredients of a mixture to be classified additivity approach can be applied. (skin corrosion / irritation) (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 needs to be classified into "Not classified."

・ When not classified into “Not classified”:

As a result of following the procedure above, if the object is classified not classified, 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."

3.6.3 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.

C) If data is available for all or some of the components of the mixture.

The component to be considered in the mixture is a component existing at a concentration of 1% or more (solid / liquid / dust / mist / vapor / mass / mass for gas and volume / volume for gas). 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 defined with reference to the GHS classification examples of the UN GHS subcommittee that a component to consider needs to be 0.1% or more for Category 1.

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

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

Table 3.6.7 (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 3.6.7 (revised)), which is the classification standard, the mixture is classified as serious eye damage / eye irritation.

Table 3.6.7(revised) Concentration of ingredients of a mixture to be classified (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 or skin Category 1	≧3 %	≧1 % but ＜3 %
Eye Category 2/2A	－	≧10 %
(10 x eye Category 1) + eye Category 2/2A	－	≧10%
Eye Category 1 + skin Category 1[a]	≧3 %	≧1 % but ＜3 %
10 x (skin Category 1 + eye Category 1)[a] + eye Category 2A/2B	－	≧10 %

a) If a single component is classified into both Skin Category 1 and Eye Category 1, use the concentration for calculation once.

b) It is indicated as Category 2B only when all components of the mixture are classified into Category 2B.

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

1. For mixtures containing strong or strong alkali, pH is used as classification criteria (see Table 3.6.8).

If it contains a corrosive property of 1% or more or serious damage component to the eye, severe damage to the eyes (Category 1), eye irritation (Category 2).

Table 3.6.8 shows the concentration limit for judging whether the mixture method cannot be applied to severe eye damage / eye irritation.

Table 3.6.8 Concentration of ingredients of a mixture when the additivity approach does not apply.

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

・ When not classified into not classified:

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."

3.6.4 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 (c).

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.

c) If data is available for all or some of the components of the mixture.

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 3.6.10, the mixture is classified as Respiratory Sensitizing Substance Category 1 or Skin Sensitizing Substance Category 1.

It is decided that in this system, any components less than 0.1% is not considered, as well as the cutoff value / concentration limit value.

Table 3.6.10 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	All physical states
Respiratory sensitizer	Category 1	≧ 1.0 %	≧0.2 %	–
	Category 1A	≧ 0.1 %	≧ 0.1 %	–
	Category 1B	≧1.0 %	≧0.2 %	–
Skin sensitizer	Category 1	–	–	≧1.0 %
	Category 1A	–	–	≧ 0.1 %
	Category 1B	–	–	≧1.0 %

*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.

・ When not classified into not classified:

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."

3.6.5 Germ Cell Mutagenicity

Calculation on germ cell mutagenicity 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.

A) If data is available for all or some of the components of the mixture.

If any components with data or information for assessing germ cell mutagenicity are included, perform the judgments below.

The mixture will be classified as a 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 3.6.12 for Category 1 and 2, respectively.

Table 3.6.12 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 %

* The classification results that are classified into Category 1 in the NITE Public Data without sub classification have been sub classified independently using this system

・ When not classified into not classified:

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."

3.6.6 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 of the individual ingredients of the mixture by using the concentration limits as described later in A).

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

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 3.6.14 for Category 1 and 2, respectively.

Table3.6.14 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 %

* The classification results that are classified into Category 1 in the NITE Public Data without sub classification have been sub classified independently using this system.

・ When not classified into not classified:

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."

3.6.7 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 will be based on the available test data of the individual constituents of the mixture using concentration limits for the ingredients of the mixture as described later in A).

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

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 3.6.16 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 3.6.16 for the additional category for effects on or via lactation.

Table3.6.16 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 %

* The classification results that are classified into Category 1 in the NITE Public Data without sub classification have been sub classified independently using this system.

・ When not classified into not classified:

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."

3.6.8 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, 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 (C) is not performed.

C) 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.

For the concentration limit, the UN GHS Document, 6th Revised Edition, has two numerical values and 10% is used with reference to JIS.

Table 3.6.18 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
target organ toxicant	Category 1	≧10 %	1.0 %≦ ingredient ＜10 %
	Category 2	－	≧10 %

F) 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.

・When not classified into not classified:

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."

3.6.9 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.

C) 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 3.6.20 for Category 1 and 2 respectively.

For the concentration limit, the UN GHS Document, 6th Revised Edition, has two numerical values and 10% is used with reference to JIS.

Table 3.6.20 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	Category 1	≧10 %	1.0 %≦ ingredient＜10 %
	Category 2		≧10 %

・ When not classified into not classified:

As a result of following the procedure C 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."

3.6.10 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.

C) 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 mixture classified as Category 1 is shown below.

Table 3.6.22 Component concentration for classification of mixtures by addition method (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 "Not classified."

· When not classified into not classified:

As a result of following the procedure above, any objects that cannot be classified into an existing category are all classified into "Classification not possible."

4. Environmental Hazards Guidance

4.5.1 HAZARDOUS TO THE AQUATIC ENVIRONMENT – ACUTE HAZARD (p268)

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

If any components with data or information for assessing hazardous to aquatic environment-acute hazard, 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.

(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, crustaceans, algae).

2-1-1 Determine the category for each of the three trophic levels (fish, crustaceans, algae).

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 (* Refer to Table 4.1.2.2.)

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) Process in the case classification not applied.

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 4.5.2 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 4.5.4(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

(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, crustaceans, algae).

2-1-1 Determine the category for each of the three trophic levels (fish, crustaceans, algae).

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 (* Refer to Table 4.1.2.2.)

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) When not classified into hazard categories:

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 4.5.4 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

Table4.5.3 (revised) 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.

4-3-2 Hazardous to the ozone layer (p297)

・Classification criteria for hazardous to ozone layer

For calculation of hazards to the ozone layer in this system, do only the calculation of classification based on components of mixtures.

(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.