Appendix 1

Basic Manual for Calculation of the Estimated Human Exposure Used in the Risk Assessment of Consumer Products

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I Purpose of This Document

This Appendix describes the algorithms (calculations) needed to estimate the amount of human exposure for each possible route of exposure (inhalation, dermal, or oral) shown in Figure 1[fn] for use in the risk assessment of consumer products.

The amount of general exposure may represent “Intake amount” of chemical substances from mediums such as the air, or “Uptake amount” of it into a human body. In exposure assessments, it is important to clarify whether the target amount is either the aforementioned “Intake” or “Uptake”. “Intake” is generally estimated using measured or estimated values of the concentration in the medium, frequency and duration of application. With respect to an estimate of transition from the “Intake” amount to the “Uptake” amount, there is little necessary information with a few exceptions. Therefore, in this Appendix, firstly the “Intake” amount should be calculated using the algorithms corresponding to the scenario set for each exposure route, and then the “Uptake” amount should be estimated by multiplying the value obtained by the uptake fraction (a). The “Uptake” value obtained is the Estimated Human Exposure (EHE). Without the case that the uptake fraction of the humans or animals used in the hazard assessment of chemical substances, has been identified, a = 1 (100 %) for the uptake fraction (a) should always be used as the uptake fraction, in every exposure route.

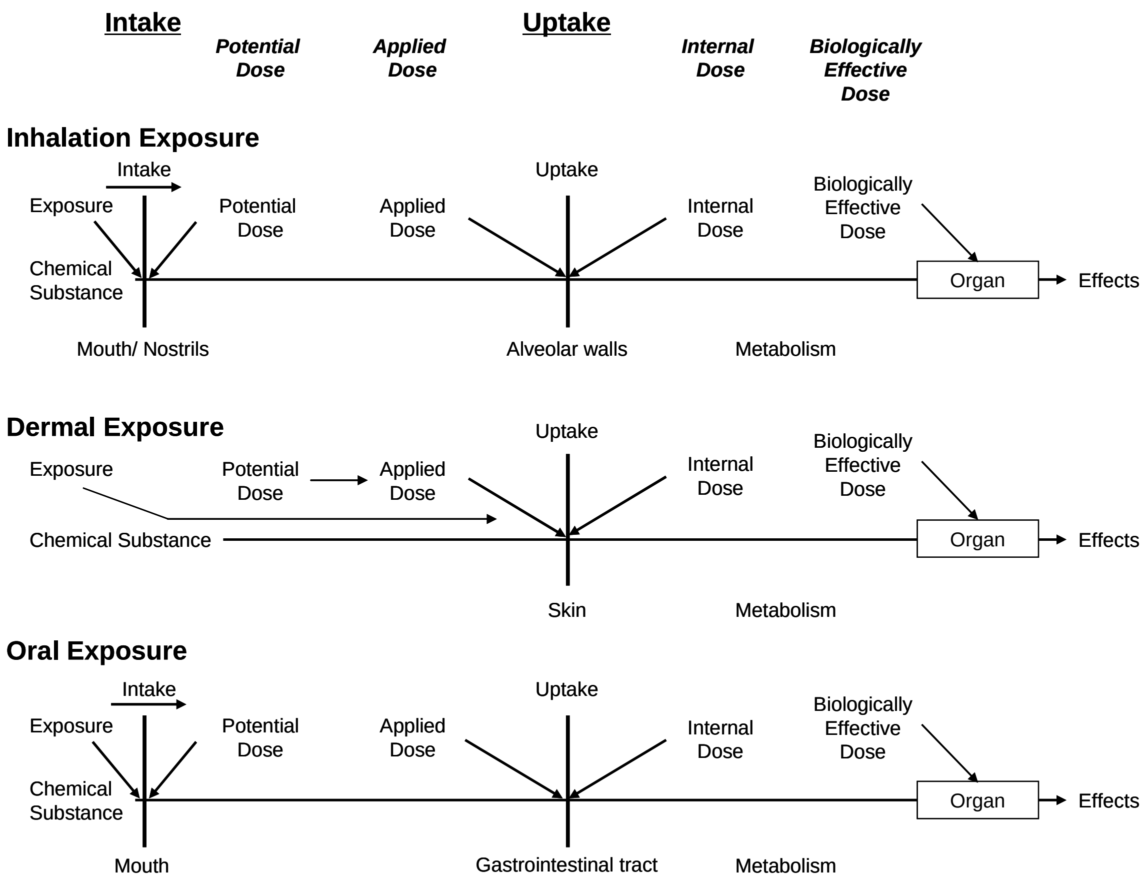


Figure I Schematic of Dose and Exposure

Although this Appendix describes algorithms considered to be appropriate for calculating EHE, they are not always applicable to the wide variety of consumer products available. Therefore, after carefully considering the characteristic of the consumer product and the chemical substances contained in the product, usage pattern of the product and other such factors, it may be necessary to establish individual algorithms for the EHE calculations, by actual measurements of parameters through experimental or other methods, and scientifically reliable reference documents or sources. In addition, beside the algorithms introduced in this Appendix, there might be other similar or improved/reinforced algorithms available. Moreover, occasionally some or all of the factors required for the algorithms might be available by experiments. If the evaluator has ascertained scientifically reliable algorithms or actual measured values available, they may use them in assessments.

II Basic Exposure Scenario and Algorithm

In this section some exposure scenarios are provided for each of the exposure routes of inhalation, dermal, or oral as basic consumer product exposure scenarios. Note that this Appendix does not provide scenarios that take exposure via general environment or other consumer products into account. The initial concentrations have not been set (the initial concentration = 0), as the contribution from another products and the general environment are not considered here.

II-1 Inhalation Route

The following is a basic algorithm [1]for estimating Human Exposure through the inhalation route. That is, it estimates the respiratory intake of target substances in the air from breathing air.

$$EHE(inha) = \frac{Ca_t \times Q \times t \times n \times a(inha)}{BW} \qquad \text{(II-1-1)}$$

EHE (inha)：Uptake of Inhalation Exposure (mg/kg/day)

Ca_t: Average Air Concentration of Exposure Duration (mg/m^3)

Q: Inhalation rate of the exposed person (m^3/h)

t: Duration of Exposure per Event (h/event)

n: Mean number of events per day (events/day)

a (inha): Uptake Fraction (inhalation) (dimensionless)

*Unless the body absorbance by humans and animals used in the hazard assessment of the chemical substance has been identified, a (inha) = 1 (100 %) should be used, regardless of exposure route.

BW: Body Weight (kg)

With inhalation exposure, as the inhalation rate of the exposed person is assumed to be a constant, estimation of the concentration of the compound in the air is important. Depending on the emission characteristics of the chemical substance in the consumer product used one of the following 4 modes should be selected and used to calculate the Ca_t (Average Air Concentration of Exposure Duration).

1) Simple Estimation Mode

2) Instantaneous Evaporation Mode

a. Monotonically Decreasing

b. Consider the Time in Use

3) Steady Emission Mode

4) Saturated Vapor Pressure Mode

[1] Similar to the formula (2) described in the APPENDIX II 3.1.1 “Inhalation exposure” of the “European Union Technical Guidance Document (EU TGD) 2ed Edition Part1” (European Commission 2003).

1) Simple Estimation Mode

[Characteristics]

This model is the simplest estimation method utilizing the weight fraction of the compound in the Product, and the volume of space that the product is used in (rooms, virtual space etc). Assume that when the product is used, the chemical substance immediately diffuses uniformly into the space and that the concentration remains constant without regard to ventilation or inhalation.

Figure II-1 shows the relationship between concentration and time.

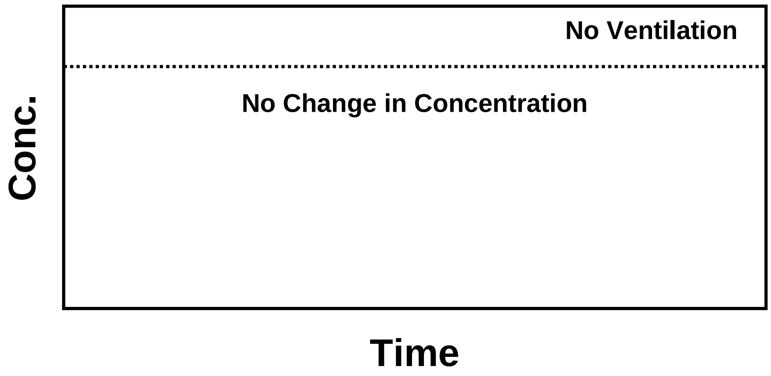


Figure II-1 Relationship between Concentration and Time with the Simple Estimation Mode

Average Air Concentration of Exposure Duration (Ca_t) should be calculated using Product amount (Ap), Weight Fraction of the compound in the Product (Wr), and Volume of Space (V). Depend on the characteristics of the product, the volume of virtual space around the body can be used instead of the volume of the whole room.

[Algorithm]

$$Ca_t = \frac{Ap \times Wr}{V} \qquad \text{(II-1-2)}$$

Ca_t: Average Air Concentration of Exposure Duration (mg/m^3)

Ap: Product Amount (mg)

Wr: Weight Fraction of the compound in the Product (dimensionless)

V: Volume of Space (m^3)

Assign this Ca_t to the formula II-1-1 to calculate the amount of inhalation exposure.

Use of the Simple Estimation Mode is most effective when the duration of use is short and ventilation rate[2] (air exchange rate) is low.

2) Instantaneous Evaporation Mode

Replacement of the air (ventilation) occurs in real room spaces. However, with the Simple Estimation Mode, this ventilation is not taken into consideration and therefore sometimes overestimation may occur. If it seems to have been overestimated, a change in concentration such as decrease of chemical substance caused by ventilation, should be considered.

The Instantaneous Evaporation Mode is based on an algorithm[3] that takes changes in concentration into account.

a. Instantaneous Evaporation Mode: Monotonically Decreasing

[Characteristics]

This mode assumes that all the chemical substances immediately diffuse into the space after the product is used, and hence similar to the Simple Estimation Mode, the concentration of the chemical substance is calculated with the Weight of Chemical Substance (Ap x Wr) used and Volume of Space (V). However, the upper limit of vapor pressure is the saturated vapor pressure. In addition, it is assumed that emission of the chemical substance is instantaneous and not continuous. The concentration in the room gradually decreases from the initial concentration, just after application has completed, caused by ventilation. This mode is applied to products whose time of use is extremely short in relation to the entire exposure time and that not emit after use.

Figure II-2 shows the relationship between concentration and time.

[2] Ventilation rate (air exchange rate) indicates how many times the air volume in the space (room volume) changes per hour. A ventilation rate of 0.5/h denotes that a volume of air equivalent to half the total volume is replaced with air from outside every hour while a ventilation frequency of 1/h denotes that a volume of air equivalent to the total volume is replaced with air from outside every hour.

[3] Based on the algorithm used in E-FAST version 2.0, the risk assessment adopted by the TSCA of the U.S. EPA. For more details regarding the algorithm refer to the “Exposure and Fate Assessment Screening Tool (E-FAST) version 2.0 Documentation Manual” (U.S. EPA, 2007). In addition, see also the “EU TGD 1st Edition Part 1, APPENDIX IV, Attachment A” (European Commission, 1996). The following is what the algorithm was based on.

$$Ca = Ca_0 \times \exp(-N \times t) + \frac{G}{N \times V} \times \left[1 - \exp(-N \times t)\right]$$

Ca: Concentration of Air (mg/m^3), Ca_0: Initial Concentration of Substance in Air (mg/m^3), N: Ventilation Rate (h^{-1}), V: Room Volume (m^3), G: Emission Rate (mg/h), t: Time (h)

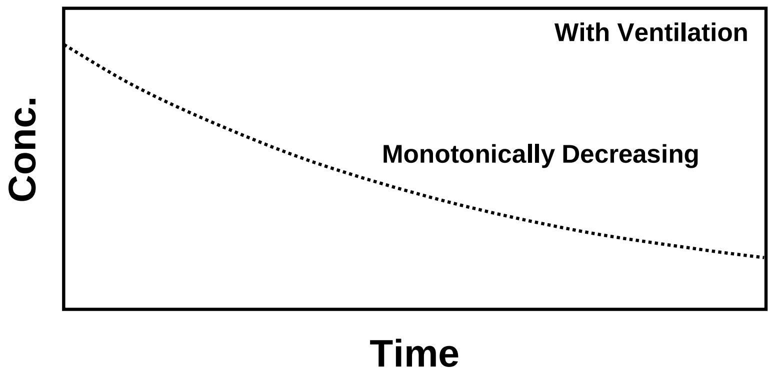


Figure II-2 Relationship between Concentration and Time during Instantaneous Evaporation Mode (Monotonically Decreasing)

[Algorithm]

The concentrations in Figure II-2 at Time (t) can be represented with the following algorithm.

$$Ca = \frac{Ap \times Wr}{V} \times \exp(-N \times t) \qquad \text{(II-1-3)}$$

Ca: Concentration of Compound in the room air (mg/m^3)

Ap: Product Amount (mg)

Wr: Weight fraction of the compound in the total product (dimensionless)

V: Volume of Space (m^3)

N: Ventilation Rate of the space (number of air exchanges/h)

t: Time (h)

The formula II-1-3 calculates the concentration at Time (t). Average Air Concentration of Exposure Duration (Ca_t) can be calculated using the following algorithm.

$$Ca_t = \frac{\frac{\left(Ap \times Wr / V \right)}{N} \times \left[1 - \exp(-N \times t)\right]}{t} \qquad \text{(II-1-4)}$$

Ca_t: Average Air Concentration of Exposure Duration (mg/m^3)

Ap: Product Amount (mg)

Wr: Weight fraction of the compound in the total product (dimensionless)

V: Volume of Space (m^3)

N: Ventilation Rate of the space (number of air changes/h)
t: Exposure Duration (h)

Assign this Ca_t value to the formula II-1-1 to calculate the amount of inhalation exposure over exposure duration (t).

b. Instantaneous Evaporation Mode: Consider the Time in Use

[Characteristics]

Figure II-3 represents the relationship between concentration and time in this mode, which is suitable for products such as paint or adhesive. The air concentration of the compound increases during use of the product, and then gradually decreases from the initial concentration by ventilation.

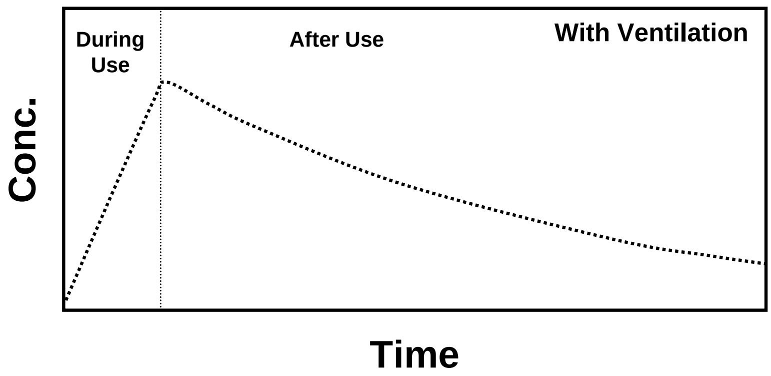


Figure II-3 Relationship between Concentration and Time during Instantaneous Evaporation Mode (Consider the Time in Use)

In this case, the total amount of inhalation should be obtained by adding the exposure amount during use and after use. They are estimated separately.

[Algorithm]

i) Calculation of Exposure During Use

To estimate the concentration of the compound during use, increase in concentration due to product use, and decrease in concentration due to ventilation must be considered. The concentration can be represented using the following algorithm.

$$Ca_i = \frac{G}{N \times V} \times \left[1 - \exp(-N \times t_i) \right] \qquad \text{(II-1-5)}$$

G：Emission Rate During Use (mg/h)
Ca_i: Concentration of Compound in the air in Time of Use t_i (mg/m^3)

N: Ventilation rate of the room (Numbers /h)

V: Volume of Space (m^3)

t_i: Time During Use (h)

The concentration at Time (t_i) can be calculated by the formula II-1-5. Average Air Concentration of Exposure Duration (Ca_{ti}) can be calculated using the following algorithm.

$$Ca_{ti} = \frac{\frac{G}{N \times V} \times \left\{ t_i - \frac{1}{N} \times \left[1 - \exp\left(- N \times t_i \right) \right] \right\}}{t_i} \qquad \text{(II-1-6)}$$

Ca_t: Average Air Concentration During Product Use (mg/m^3)

N: Ventilation rate of the room (Numbers /h)

V: Volume of Space (m^3)

G: Emission Rate (mg/h)

t_i: Exposure Duration (During Use) (h)

Assign this Ca_{ti} value to the formula II-1-1 to calculate the amount of inhalation exposure over exposure duration (t_i).

Emission Rate (G) during Use may also be calculated using the following formula.

$$G = \frac{Ap \times Wr}{t_i} \qquad \text{(II-1-7)}$$

G: Emission Rate (During Use) (mg/h)

Ap: Product Amount (mg)

Wr: Weight fraction of the compound in the total product (dimensionless)

t_i: Time During Use (h)

ii) Calculation of Exposure Amount After Use

Concentration reaches a maximum by product use, and then monotonically decreases when use of the product has ended. It can be represented using the following algorithm.

$$Ca_{ii} = Ca_1 \times \exp\left(- N \times t_{ii} \right) \qquad \text{(II-1-8)}$$

Ca_{ii}: Concentration of Compound in the air at Staying Time t_{ii} (mg/m^3)

Ca_1: Concentration of Compound in the air when use of the product ended (mg/m^3)

t_{ii}: Time During Stay (h)

Here the Air Concentration when use of the product ended (Ca_1) should be calculated by substituting the total time of use for t_i in the formula II-1-5.

Formula II-1-8 shows the concentration at time (t_{ii}). Average Air Concentration During Stay (Ca_{tii}) can be calculated using the following algorithm.

$$Ca_{tii} = \frac{\frac{Ca_1}{N} \times \left[1 - \exp\left(-N \times t_{ii}\right)\right]}{t_{ii}} \qquad \text{(II-1-9)}$$

Ca_{tii}: Average Air Concentration During Stay (mg/m^3)

Ca_1: Concentration of Compound in the air in Time of Use (mg/m^3)

N: Ventilation rate of the room (Numbers/h)

t_{ii}: Exposure Duration (During Stay) (h)

Assign this Ca_{tii} to the formula II-1-1 to calculate the amount of inhalation exposure at Exposure Duration (t_{ii}).

The total amount of inhalation exposure during and after product use, should be calculated by adding amount of each inhalation exposure.

Spray products can be considered the same as in Instantaneous Evaporation Mode. However, as use of spray products is localized in many cases, they can be classified into 2 types as follows.

1. Sprayed around a person: If the product is sprayed around a person take the “small virtual space” around the person into consideration.
2. Sprayed throughout the room: If the product is sprayed throughout the room, consider the whole room space, not the virtual space.

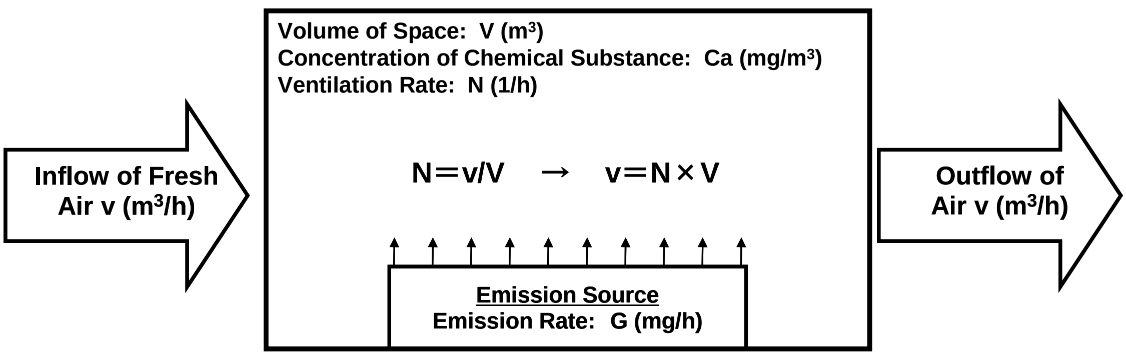
As the spray is forced to disperse, it is not necessary to set an upper limit for the saturated vapor pressure; however inhaling the mist (aerosol) in inhalation exposure must be considered. The particle size of the mist varies, and large size particle of mist is not inhaled. However, it is very difficult to predict what proportion of the mist is actually inhaled. Therefore, unless scientifically reliable value has been available, all the mist should be assumed to be of a size that is inhaled.

3) Steady Emission Mode

[Characteristics]

When usage time of the product is long and the product has a constant emission rate, use emission rate to estimate the amount of exposure. The Air Concentration (Ca) does not change over time, and shown in Figure II-1. The Air Concentration (Ca) here is constant due to the equilibrium between increasing concentration by emission of the chemical substance, and decreasing concentration by inflow of the air to the space and outflow from the space. As there is no change in the Air Concentration, Average Air Concentration of Exposure Duration (Ca_t) is the same as Ca. And therefore the amount of inhalation exposure should be calculated using Average Air Concentration of Exposure Duration (Ca_t), the inhalation rate of the exposed person (Q), and Exposure Duration (t). However, if the time of use of the product is short and use of the product ended before it reaches a certain concentration. Results using the Steady Emission Mode can be overestimate. If the measured value of the emission rate, considering the conditions of use of the product including any possible misuse, is available, it should be used.

The algorithm in figure II-4 can be obtained as it takes the mass balance of steady emission into account.



Mass Balance of Chemical Substance

Emission Rate in Space: G
Outflow Rate to Outside the Space: v×Ca
Mass Balance between Emission into the Space and Outflow to Outside the Space: G＝v×Ca

Therefore: Ca＝G/v＝G/(N×V)

Figure II-4 Algorithm of Air Concentration in Steady Emission Mode

[Algorithm]

$$Ca_t = \frac{G}{N \times V} \quad \text{(II-1-10)}$$

Ca_t: Average Air Concentration of Exposure Duration (mg/m^3)
N: Ventilation Rate of the room (Numbers s/h)
V: Volume of Space (m^3)
G: Emission Rate (mg/h)

Assign this Ca_t to the formula II-1-1 to calculate the amount of inhalation exposure.

4) Saturated Vapor Pressure Mode

[Characteristics]

For products with a fast emission rate that quickly reach saturated vapor pressure, the Air Concentration (Ca) of the chemical substance should be calculated assuming that air concentration is always at the saturated vapor pressure of the substance. In other words, regardless of ventilation rate, the concentration always reaches the saturated vapor pressure. Air Concentration does not change over time. It is similar to Figure II-1 for the Simple Estimation Mode. As there is no change in air concentration, the Average Air Concentration of Exposure Duration (Ca_t) is the same as the Ca. And therefore the amount of inhalation exposure should be calculated using Average Air Concentration (Ca_t), the inhalation rate of the exposed person (Q), and Exposure Duration (t). The following is the algorithm where the Saturated Vapor Pressure was obtained in units of Pa.

[Algorithm]

$$Ca_t = 0.4037 \times M \times P \qquad \text{(II-1-11)}$$

Ca_t: Average Air Concentration of Exposure Duration (mg/m^3)

0.4037: Unit Conversion Constant ($mg\text{-}mol/g/Pa/m^3$)

M: Molecular Weight (g/mol)

P: Saturated Vapor Pressure (Pa)[4]

Assign this Ca_t to the formula II-1-1 to calculate the amount of inhalation exposure.

II-2 Dermal Route

Differing from exposure via general environment, dermal exposure is a very important exposure route when considering direct exposure from consumer products. In the assessment of Inhalation exposure and oral exposure, external boundaries (Intake: nose, mouth) are clearly distinguished from internal boundaries (Uptake: lung, gastrointestinal tract) (Figure 1). However, in the case of dermal exposure, the skin is an external boundary as well as an internal boundary. This can make it difficult to estimate the amount of exposure when compared to exposure estimations of inhalation and oral routes.

The following two types of basic dermal exposure[5] will be considered in this Appendix.

[4] (Ref.) Unit of pressure: 1 atm = 101325 Pa, 1 bar= 100000 Pa, 1 psi = 6894.757 Pa, 1 Torr (mmHg) = 133.322 Pa, 1 at = 98066.5 Pa.

1) Dermal exposure through contact with liquid solutions (or solids) containing the substance
    a. Virtual Volume Mode that assumes a contact volume (amount)
    b. Dermal Absorption Rate Mode which uses the Absorption Rate of the contact substance
2) Dermal Exposure that assumes some or all of the chemical substance used adhere to the skin

1) Dermal exposure through contact with liquid solutions (or solids) containing the substance

a. Virtual Volume Mode that assumes a certain contact volume

[Characteristics]

To estimate the amount of dermal exposure, it is necessary to know the amount that adheres (contacts) to the skin. It is possible to consider simply that the entire product amount used is involved in exposure; however, it could result in overestimations. Therefore, assume that the product (or concentration of the product) of the Skin Contact Layer within a certain distance of the skin should be involved in exposure. To calculate the volume of that contact layer set the assumed thickness to be the section that will adhere to the skin (hereinafter referred to as the Thickness of Skin Contact Layer (Ls)). And then multiply the area adhering to the skin by the Thickness of Skin Contact Layer (Ls) to calculate the volume of the product involved in exposure.

If the assessment target product is a liquid, it can be assumed that the entire volume of the virtual volume will be involved in exposure unless scientifically reliable data is available to the contrary. That is, assume that the entire volume of the target chemical substance in the virtual volume will be exposed.

On the other hand, if the assessment target product is solid, overestimations may occur if the entire volume of the target chemical substance in the virtual volume is involved in exposure, and therefore the Transition Rate from the product to the skin should be considered. If information regarding the Transition Rate is unavailable, assume that the entire volume of the chemical substance in the virtual volume will be exposed. In addition, if the Thickness of Skin Contact Layer can not be assumed, then refer to "2) Dermal Exposure through Adherence from Some Parts used to the Skin (Constant Ratio Adherence)" that a certain part of the solid object is assumed to adhere, or use a combination of the formulas of "Virtual Volume Mode" and "Constant Ratio Adherence".

[5] The algorithm for dermal exposure in this document references the algorithm described in "ConsExpo4.0 Consumer Exposure and Uptake Models Program Manual" (RIVM 2005) and was edited according to the concept of this Appendix. The algorithm itself is basically the same as that used in ConsExpo4.0.

[Algorithm]

$$EHE(derm) = \frac{Cl\ (or\ Cs) \times Ls \times Sp \times n \times a(derm)}{BW} \qquad \text{(II-2-1)}$$

EHE (derm)：Uptake of Dermal Exposure (mg/kg/day)

Cl: Concentration of Substance in Liquid Solution (mg/cm^3) or

Cs：Concentration of Substance in Solid (mg/cm^3)

Ls: Thickness of Skin Contact Layer (cm)[6]

Sp: Skin Surface Area available for Contact (cm^2)

n: Mean number of events per day (events/day)

* If the target product is a solid and information is available regarding the Transition Rate, then multiply with the Transition Rate.

a (derm): Uptake Fraction (derm) (dimensionless)

*Unless the bodily absorbance by the humans and animals used in the hazard assessment for the chemical substance has been identified, a (derm) = 1 (100 %) should be used, regardless of exposure route.

BW: Body Weight (kg)

b. Dermal Absorption Rate Mode Which Uses the Rate of Absorption of the Contact Material

[Characteristics]

About some substances, the Dermal Absorption Rate (Ml) mg/cm^2/h, absorption rate from the skin into the body, may have already been measured or capable of being estimated. In this case the amount of exposure should be calculated using the Dermal Absorption Rate, Skin Surface Area (available for contact) (Sp) cm^2, which is the area the substances adhere to, Exposure Duration (t) h/event, and mean number of events per day (n) events/day. When Dermal Absorption Rate (Ml) mg/cm^2/h is available, the Uptake Fraction a (derm) can be excluded from the calculation. This is because the Uptake Fraction a (derm), which denotes the absorption ratio from the skin to the body, has already been considered as for the Dermal Absorption Rate. However, the Dermal Absorption Rate must also be correspondingly taken into the hazard assessment,

[Algorithm]

$$EHE(derm) = \frac{Sp \times Ml \times t \times n}{BW} \qquad \text{(II-2-2)}$$

EHE (derm): Uptake of Dermal Exposure (mg/kg/day)

[6] The Thickness of Skin Contact Layer Ls is represented as 2.14~10^{-3}cm in the “European Union Risk Assessment Report for TRICHLOROETHYLENE” (EU 2004) and 0.01cm in the “European Union Risk Assessment Report for PHENOL” (EU 2006). Use these as references in determining the appropriate Thickness of Skin Contact Layer.

Sp: Skin Surface Area available for Contact (cm^2)

Ml: Dermal Absorption Rate ($mg/cm^2/h$)

* Occasionally "cm/h (= $cm^3/cm^2/h$)" is used as the unit of dermal absorption rate; however a concentration of target substance (mg/cm^3) is similar to $mg/cm^2/h/$

t: Exposure Duration (h/event)

n: Mean number of events per day (events/day)

BW: Body Weight (kg)

Even when the substance adheres to objects then adheres to the skin (indirect adherence), it should be considered to be dermal exposure, through contact with objects containing the substance. For example, when laundry is washed using washing detergent, although it may only be a small amount, some of the detergent component will adhere to the laundry. And if the laundry is processed using softening agent, then the softening component will adhere to the laundry. Wearing the laundry, in particularly underwear, detergent component may transfer to the skin. Basically it can be calculated using the formula II-2-1; but the important points are the ways to estimate adheres to laundry, and the transfer ratio from laundry to the skin.

2) Dermal exposure through adherence from some parts used to the skin (Constant Ratio Adherence)

[Characteristics]

When adhesive or paint is used the dermal exposure from the skin, due to adherence of some parts of the product must be considered. Assume the ratio that adheres to the skin as the Skin Adhesion Ratio (Md), and calculate the adhesive amount by multiplying the Weight of Chemical Substance in the Used Product (Ap x Wr) and Skin Adhesion Rate (Md). Uptake of the Dermal Exposure (EHE (derm)) are then evaluated as follows.

[Algorithm]

$$EHE(derm) = \frac{Ap \times Wr \times Md \times n \times a(derm)}{BW} \qquad \text{(II-2-3)}$$

EHE (derm): Uptake of Dermal Exposure (mg/kg/day)

Ap: Product Amount (mg)

Wr: Weight fraction of the compound in the total product (dimensionless)

Md: Skin Adhesion Ratio (dimensionless)

n: Mean number of events per day (events/day)

a (derm): Uptake Fraction (derm) (dimensionless)

*Unless the bodily absorbance by humans and animals used in the hazard assessment of the chemical substance has been identified, a (derm) = 1 (100 %) should be used, regardless of exposure route.

BW: Body Weight (kg)

II-3 Oral Exposure

In assessment of oral exposure via environment, an exposure assessment of the substance, which are emitted from the consumer product into the environment (general air, water, and soil) and taken through food or water ingestion, should be considered. However, as it is not included in risk assessments of consumer product in GHS, assessments via environment are not considered in this Appendix. Second exposures, for example, touching mouth by hands that the substance attached, or inhaling house dust that the substance is absorbed, are also not considered here.

Hence the following two basic oral exposure[7] algorithms will be presented as examples in this Appendix.

1) Unintentional oral exposure from products with possibility to be put in mouth
2) Oral exposure of substance transferred to food via routes other than environment

1) Unintentional oral exposure of products with possibility to be put in mouth

[Characteristics]

There are some products that is not assumed to be put in the mouth, but that might be occur due to common practices such as envelopes (seal), postal stamps and so on. The amount of oral exposure should be calculated by assuming a residual ratio that remains in the mouth per event (Unintentional Intake Ratio (Mo)).

[Algorithm]

$$EHE(oral) = \frac{Ap \times Wr \times Mo \times n \times a(oral)}{BW} \qquad \text{(II-3-1)}$$

EHE (oral): Uptake of Oral Exposure (mg/kg/day)

Ap: Product Amount (mg)

Wr: Weight fraction of the compound in the total product (dimensionless)

Mo: Unintentional Intake Ratio (dimensionless/event)

n: Mean number of events per day (events /day)

A (oral): Uptake Fraction (oral) (dimensionless)

*Unless the bodily absorbance by humans and animals used in the hazard assessment for the chemical substance has been identified, a (oral) = 1 (100 %) should be used, regardless

[7] The algorithm for oral exposure in this document references the algorithm described in the “ConsExpo4.0 Consumer Exposure and Uptake Models Program Manual” (RIVM 2005) and was edited according to the concept of this Appendix. The algorithm itself is basically the same as the one used in ConsExpo4.0.

of exposure route.

BW: Body Weight (kg)

2) Intake of substances transferred to food

[Characteristics]

Oral exposure can occur when a product containing the substance contacts food and that food is eaten. For example, it is applicable if the substance in kitchen cleaner remains on dishes and then adheres to food or when washing vegetables or fruit are washed by dishwashing detergent and is then eaten. Estimates should be done using the amount of the adhered substance to kitchenware (or containers) and the Transfer Rate to food.

[Algorithm]

<Estimation from the concentration of substance in food>

This is applicable when food such as vegetables or fruit are washed using the dishwashing detergent.

$$EHE(oral) = \frac{Cf \times Wf \times a(oral)}{BW} \quad \text{(II-3-2)}$$

EHE (oral): Uptake of Oral Exposure (mg/kg/day)

Cf: Concentration of Substance in Food (mg/g)

Wf: Amount of Food Consumed (mg/day)

a (oral): Uptake Fraction (oral) (dimensionless)

*Unless the bodily absorbance by humans and animals used in the hazard assessment for chemical substance has been identified, a (oral) = 1 (100 %) should be used, regardless of exposure route.

BW: Body Weight (kg)

Although the estimation of a Concentration of Substance in Food (Cf) can be individually conducted using a variety of methods, occasionally it might be possible to estimate it by applying the algorithms or other ways as described in II-2-2 dermal exposure.

<Estimation from Transfer Rate>

When the substance adhering to a container is transferred to food and the food is consumed, the amount of Oral Exposure is calculated by multiplying the amount of the substance adhering to the container by Transfer Rate (Mfd) (formula II-3-3).

$$EHE(oral) = \frac{Cd \times Mfd \times a(oral)}{BW} \quad \text{(II-3-3)}$$

EHE (oral): Uptake of Oral Exposure (mg/kg/day)
Cd: Weight of Adhered Substance on Food Container Used per Day (mg/day)
Mfd: Transfer Rate from Container to Food (dimensionless)
a (oral): Uptake Fraction (oral)　(dimensionless)
*Unless the bodily absorbance by humans and animals used in the hazard assessment for the chemical substance has been identified, a (oral) = 1 (100 %) should be used, regardless of exposure route.
BW: Body Weight (kg)

Estimation of the Weight of Adhered Substance on Container is not described here, as it can be conducted individually using a variety of methods.

<Estimation using Transfer Rate and Contact Time>

If the amount of exposure is estimated by calculating the adhered amount to food from the Transfer Speed Mfp (the ratio at which the substance is migrated to food) and contact time t_c, the formula will be the following (Formula II-3-4).

$$EHE(oral) = \frac{Sf \times Mfp \times t_c \times a(oral)}{BW} \quad \text{(II-3-4)}$$

Sf: Area of Food Container (Adhered Section Only) Used per Day (cm^2/day)
Mfp: Transfer Rate from Container to Food (dimensionless)
t_c：Contact Time (h)
a (oral): Uptake Fraction (oral) (dimensionless)
*Unless the bodily absorbance by humans and animals used in the hazard assessment for the chemical substance has been identified, a (oral) = 1 (100 %) should be used, regardless of exposure route.
BW: Body Weight (kg)

Table II-1 Overview of Exposure Route Scenarios

Exposure Route	Exposure Scenario	Calculation Condition		Overview of scenario	Formula number
Inhalation	Inhalation Exposure	Estimation formula for basic exposure		Calculated using Average Air Concentration of Exposure Duration, Inhalation Rate, Exposure Time, Use Counts, Body Weight and Absorption Rate. The Average Air Concentration of Exposure Duration should be calculated after considering the characteristics of the product and various aspects of the substance and the appropriate mode then selected.	II-1-1
		Calculation of Average Air Concentration	Simple Estimation Mode	Assume that the assessment chemical substance in the product diffuses throughout the entire space, and then calculate the Average Air Concentration.	II-1-2
			Instantaneous Evaporation Mode Monotonically Decreasing	Assume that the assessment chemical substance in product diffuses throughout the entire space, and then calculate the Average Air Concentration during the exposure duration where the concentration decreases due to ventilation.	II-1-4
			Instantaneous Evaporation Mode Consider the Time in Use	i) Average Air Concentration During Use The concentration of the product during use must take into consideration both the increase in concentration due to product use and decrease in concentration due to ventilation in calculating the Average Air Concentration During Use.	II-1-6
				ii) Average Air Concentration After Use Same as Monotonically Decreasing, when calculating the Average Air Concentration During Stay the decrease in concentration in the air after use of the product has ended due to ventilation should be considered.	II-1-9
			Steady Emission Mode	Calculate the Average Air Concentration where the emission of the chemical substance and inflow of external air and outflow of air in the room from outside are in equilibrium. The concentration is constant because it is in equilibrium.	II-1-10
			Saturated Vapor Pressure Mode	Assume that the chemical substance is always at a saturated vapor pressure level when calculating the concentration. It should be calculated using the vapor pressure and molecular weight.	II-1-11
Dermal	Contact with target substance	Virtual Volume Mode		Assume a virtual volume on the skin surface that then involves exposure in calculating the amount of exposure.	II-2-1
		Dermal Absorption Rate Mode		If the rate of absorbance of the chemical substance from the skin to the body is already known, then use the Dermal Absorption Rate Mode to calculate the amount of exposure.	II-2-2
	Contact with target substance	Constant Ratio Adherence		Assume a ratio of adherence to the skin in calculating the amount of exposure.	II-2-3
Oral	Unintentional Intake Ratio			Where the possibility of being transferred to the mouth exists, assume a residual ratio in the mouth in calculating the amount of exposure.	II-3-1
	Transition to Food	Calculate from the Concentration in Food		This should be used when the chemical substance is attached to food due to product use and its concentration is known. Calculate the amount of exposure from the attached concentration and intake volume of food it is attached to.	II-3-2
		Consider the Transfer Rate		If the chemical substance is transferred to food due to product use, then calculate the amount of exposure from its transition rate and intake volume of food.	II-3-3
		Consider the Transfer Rate and Contact Time		If the chemical substance is transferred to food due to product use, then calculate the amount of exposure from its transition speed and intake volume of food.	II-3-4

Reference: Exposure Factors

Various factors come into play when estimating the amount of exposure using each algorithm introduced in this Appendix. Some of the factors commonly used in various substances include Weight, Inhalation Rate, and Skin Surface Area and are used as “Exposure Factors” in exposure assessments.

In maintaining consistency and ensuring transparency, the common “Exposure Factor” values are desirable. However, sufficient information is not available to determine common exposure factors for estimating the amount of exposure of consumer products.

In the Exposure Assessment Examples given in Chapter III of this Appendix (Appendix 1) and Examples of Risk Assessment in Appendix 2, “Exposure Factors” were set for assessment by referencing the following domestic and foreign reference documents. Table II-2 lists the exposure factors used in our assessment. However, these values are only reference values and appropriate exposure factors should be used in assessments on the individual responsibility of evaluators. In addition, variable values (contents, product amount, contact time etc.) must be applied properly on the individual responsibility of evaluators, in consideration of foreseeable misuse such as excessive use.

<Reference Materials>

- National Institute of Advanced Industrial Science and Technology (AIST), Research Center for Chemical Risk Management (CRM): Japanese Exposure Factors Handbook (2007)[8]
- United States Environmental Protection Agency (U.S. EPA): Exposure Factors Handbook (1997)[9]
- European Exposure Factors: The European Exposure Factors (ExpoFacts) Sourcebook[10]
- European Centre for Ecotoxicology & Toxicology of Chemicals (ECETOC)[11]: Targeted Risk Assessment (TRA) Technical Report No.93 (2004)
- Human and Environmental Risk Assessment on ingredients of household cleaning products (HERA): Guidance Document Methodology (2005)[12]

[8] http://unit.aist.go.jp/riss/crm/exposurefactors/
[9] http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20563
[10] http://expofacts.jrc.ec.europa.eu/
[11] http://www.ecetoc.org/
[12] http://www.heraproject.com/files/HERA%20TGD%20February%202005.pdf

Table II-2 Exposure Factors Used in this Appendix (Reference Values)

Item	Type	Value	Source
Human Body	Body Weight	50 kg	Initial Risk Assessment for Chemical Substances Ver. 2.0 Preparation Manual (NITE, CERI 2007)
	Inhalation Rate	0.833 m^3/h (20 m^3/day)	Initial Risk Assessment for Chemical Substances Ver. 2.0 Preparation Manual (NITE, CERI 2007)
In-room	1 tatami mat	1.62 m^2	Enforcement Regulations for Fair Competition Regarding Real Estate Descriptions Chapter 5 Section 1 Article 16 No. 16
	Room Height for Living Rooms (Building Standard Act "Minimum Value")	2.1 m	Building Standard Act Cabinet Order Article 21 (Japanese law)
	Standard living room (6 tatami mats floor)	20 m^3	6 tatami mats x 1.62 m^2/tatami x 2.1 m = 20m^3
	Volume of Lavatory	20 m^3	Average volume of apartment/studio lavatory unit type 0811, 0812, 0815 0811 type: 0.8 m x 1.1 m x 2.0 m = 1.76 m^3 0812 type: 0.8 m x 1.2m x 2.0 m = 1.92 m^3 0815 type: 0.8 m x 1.5m x 2.0 m = 2.40 m^3
	Ambient volume of product (such as sprays)	2 m^3	"Guidelines for Initial Risk Assessment" Japan Chemical Industry Association (Revised version, March 1997)
	Ventilation Rate (standard living room)	0.2 h^{-1}	Mihara et al. (2004), *Journal of RIEMAM, 52, 166-169.* This ventilation rate averaged the minimum value of a result obtained by various measurement methods.
	Ventilation Rate (toilet)	0.5 h^{-1}	The ventilation Rate stated in the Building Standards Act with the consideration that a local ventilation system or window is installed
Others	Skin Adhesion Ratio due to the adherence of paint or adhesive while working	0.5 %	European Union Risk Assessment Report TOLUENE (European Commission 2003)

III Specific Exposure Scenarios by the Application Category of the Products and Exposure Assessment Examples

This section describes examples of exposure scenarios and exposure assessment with respect to 5 categories of product application included in the scope of this Appendix (1 Household Adhesive, 2 Household Coating Material and wax, 3 Household Detergent, 4 Deodorant and Fragrance Substances, and Repellents for Nuisance Insects, and 5 Auto Products).

The summary of the following items is described for each of the 5 categories.

1. Scope of product included in the categories
2. Characteristics of the categories
3. Exposure scenario and algorithm
4. Example of assessment

One or some representative examples of exposure assessment are given.

For consumer products not included in the categories described above, and those not fit for the idea of exposure assessment in the categories, the suppliers may use an exposure assessment by setting their own exposure scenarios and algorithms based on the exposure assessment method and assessment examples in this Appendix, as well as those in scientifically reliable data etc.

The assessment examples given in this Appendix are only "examples" for use in understanding the concept of an exposure scenario and, including the estimation method for the quantity of exposure, should not be taken as the only correct method. The chemical substances selected for the assessment examples are provisional ones used to present assessment examples more specifically, and are not chosen as they are determined to pose chronic health hazards subject to the risk assessment.

Similarly, the factors used in the assessments or the adequacy of assessment results are not guaranteed.

When conducting practical exposure assessments, the characteristics of the target product, properties of the target chemical substance, foreseeable misuse etc must be carefully considered, and the most appropriate exposure scenario should be set.

III-1 Household Adhesive

III-1-1 Scope of This Category

This category includes adhesives used in the home or room by general consumers. It does not include adhesives contained in, for example, flooring or furniture, or adhesives used in a room when remodeling has taken place.

III-1-2 Characteristics of This Category

Various chemical substances are used in adhesives according their function. However, generally there are very few chances of exposure (contact) because adhesives is covered with objects. The exposure occurs mainly when the adhesive is being used (being applied, or when can is open) and while the adhesive is being cured.

Therefore, main exposure route of adhesives is limited to the following.

1. Inhalation exposure during use and after use when staying in the inhaled air
2. Dermal exposure due to unintended adherence of droplets, or adherence to the hands during use

III-1-3 Exposure Scenario and Algorithm

Assume the exposure scenario that should be considered, then select the algorithm to estimate the amount of exposure.

With household adhesives, inhalation exposure during to product use is the most important. In addition, exposure to the hands by product application and unintended adherence of droplets to the skin during use should also be considered.

<Exposure Scenario 1> Inhalation exposure to volatile adhesive components

During the application of the product, concentration increase (due to increased amount used) and concentration decrease (due to room ventilation) can both occur. After the application of adhesive, emission of chemical substances generally completes. However, emission from the generation source may continue for some time.

Secondary exposure such as the oral intake of detached pieces of solidified adhesive does not need to be considered.

<u>Algorithm</u>

If emission completes at the same time application of the product ends, use the formula II-1-6 and II-1-9 to calculate the Average Air Concentration of Exposure Duration. Then assign the value to the formula II-1-1 to calculate the amount of inhalation exposure.

If emission continues for a while after application of the product, use the formula II-1-10 to calculate the room concentration of steady emission, and then assign the value to the formula II-1-1 to calculate the amount of exposure.

<Exposure Scenario 2> Dermal exposure due to the application of the products

Select the algorithm to be used according to the amount of adhesive used or information (such as Dermal Absorption Rate) of the dermal exposure of the target component.

Algorithm

If a constant amount of the adhesive used is assumed to contact the skin, use the formula II-2-3 to calculate the amount of dermal exposure. Use the formula II-2-1 to calculate the amount of exposure, when assuming a Skin Contact Layer. If the Dermal Absorption Rate of the assessment component is available, use the formula II-2-2 to calculate the amount of exposure.

III-1-4 Example of Assessment

Example General-use adhesive (plastic model adhesive)

Chemical substance: acetone

<Acetone>

- CAS No.: 67-64-1
- Molecular Weight: 58.08 g/mol
- Vapor Pressure: 230 mmHg (25 degrees C)

<Exposure Scenario>

- General-use adhesive (plastic model adhesive) contains 35% acetone.
- Assess exposure to acetone in the adhesive when assembling plastic models.
- Assume 5g of the adhesive is used in the standard living room (20 m^3, ventilation rate: 0.2 times/h) and a plastic model is assembled once a month.
- Assume that no long term emission occurs after product use ends, and the emission of acetone stops at the same time use of the product does.
- Assume that the working time (the time the product is used for) is 0.5 hour and remains in the room for 3 hours after that.
- Skin Adhesion Ratio due to unintended adherence of adhesive during work is 0.5% of the amount used.

<Algorithm>

- Inhalation Exposure: Instantaneous Evaporation (Consider the Time in Use)
- Dermal Exposure: Constant Ratio Adherence
- Oral Exposure: Not Assumed

<Various Data>

- Amount of Product Used (Ap): 5 g
- Inhalation Rate (Q): 0.833 m^3/h
- Volume of Room (V): 20 m^3
- Time During Use (t_i): 0.5 h
- Skin Adhesion Ratio (Md): 0.5 %
- Frequency of Use (n): Once a month
- Weight Fraction of Acetone in Product (Wr): 35 %
- Body Weight (BW): 50 kg
- Ventilation Rate (N): 0.2 times/h
- Time spent After Use (t_{ii}): 3.0 h
- Uptake Fraction (a): 100 %

<Calculation>

(1) Inhalation Exposure

Calculate the amount of inhalation exposure using the <Instantaneous Evaporation Mode: Consider Time in Use>.

[Amount of Inhalation Exposure During Use]

Average Air Concentration During Use should be calculated using the formula II-1-6.

$$Ca_{ti} = \frac{\frac{Ap \times Wr / t_i}{N \times V} \times \left\{ t_i - \frac{1}{N} \times [1 - \exp(-N \times t_i)] \right\}}{t_i}$$

$$Ca_{ti} = \frac{\frac{5g \times 0.35 / 0.5h}{0.2/h \times 20m^3} \times \left\{ 0.5h - \frac{1}{0.2/h} \times [1 - \exp(-0.2/h \times 0.5h)] \right\}}{0.5h}$$

$$= 42.33mg/m^3$$

Assign this to the formula II-1-1 to calculate the amount of inhalation exposure during use.

$$EHE(inha) = \frac{Ca_t \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{42.33mg/m^3 \times 0.833m^3/h \times 0.5h \times 1 \times 12/365\text{day}}{50kg}$$

$$= 0.012mg/kg/day$$

[Amount of Inhalation Exposure After Use]

Average Air Concentration During Stay (After Use) should be calculated using the formula II-1-9.

$$Ca_{tii} = \frac{\frac{Ca_1}{N} \times [1 - \exp(-N \times t_{ii})]}{t_{ii}}$$

Here, Ca_1 represents the concentration in the air immediately after use, and therefore the air concentration immediately after use should be calculated using the formula II-1-5.

$$Ca_1 = \frac{Ap \times Wr / t_i}{N \times V} \times [1 - \exp(-N \times t_i)]$$

$$Ca_1 = \frac{5g \times 0.35 / 0.5h}{0.2/h \times 20m^3} \times [1 - \exp(-0.2/h \times 0.5h)]$$

$$= 83.267mg/m^3$$

Therefore

$$Ca_{tii} = \frac{\frac{Ca_1}{N} \times [1 - \exp(-N \times t_{ii})]}{t_{ii}}$$

$$Ca_{tii} = \frac{\frac{83.267mg/m^3}{0.2/h} \times [1 - \exp(-0.2/h \times 3h)]}{3h}$$

$= 62.62 mg/m^3$

Assign this to the formula II-1-1 to calculate the amount of inhalation exposure during stay (after use).

$$EHE(inha) = \frac{Ca_t \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{62.62 mg/m^3 \times 0.833 m^3/h \times 3.0 h \times 1 \times 12/365\text{day}}{50 kg}$$

$$= 0.103 mg/kg/day$$

[Total Amount of Inhalation Exposure]

The amount of exposures during use and after use are added to calculate the total amount of inhalation exposure:

$$EHE(inha) = 0.012 mg/kg/day + 0.103 mg/kg/day = 0.115 mg/kg/day$$

(2) Dermal Exposure

Calculate the amount of exposure using <Constant Ratio Adherence>.

Calculate the amount of dermal exposure using the formula II-2-3 assuming a constant ratio of the product has adhered to the skin.

$$EHE(derm) = \frac{Ap \times Wr \times Md \times n \times a(derm)}{BW}$$

$$EHE(derm) = \frac{5 mg \times 0.35 \times 0.005 \times 12/365 day \times 1}{50 kg} = 0.006 mg/kg/day$$

(3) Estimated Human Exposure (EHE)

The Estimated Human Exposure (EHE) should be calculated using the Amount of Inhalation Exposure (EHE (inha)) and Amount of Dermal Exposure (EHE (derm)).

Since the EHE (inha) : 0.115 mg/kg/day, EHE (derm): 0.006mg/kg/day, then the EHE will be as follows.

$$EHE = 0.115 mg/kg/day + 0.006 mg/kg/day = 0.121 mg/kg/day$$

<Results>

Amount of Inhalation Exposure: 0.115 mg/kg/day

Amount of Dermal Exposure: 0.006 mg/kg/day

Estimated Human Exposure: 0.121 mg/kg/day

III-2 Household Coating Material and Wax

III-2-1 Scope of this Category

Household coating wax and paint are included in this category as they have the same exposure route. Hence this category covers paint and wax used indoors as well as paint used outdoors such as in the garden. However, it does not include paint or wax that has already been absorbed into flooring or furniture.

III-2-2 Characteristics of this Category

Like adhesives, various chemical substances are used in paint for their function. After application was over, and a dry period passed, paint makes solid surface, and serious inhalation exposure or dermal exposure to chemical materials is not thought to be occurred.

Hence main exposure route of paints is limited to the following.

1. Inhalation exposure during application and after application when staying in the inhaled air.
2. Dermal exposure due to unintended adherence of droplets or adherence to the hands during application

III-2-3 Exposure Scenario and Algorithm

Assume the exposure scenarios that should be considered, then select the algorithm to estimate the amount of exposure.

With household paints, inhalation exposure due to product application is the most important. In addition, exposure to the hands by product application, and unintended adherence of droplets to the skin during use, should also be considered.

Secondary exposure such as oral intake due to the detachment of solidified paint after emission is not need to be considered.

<Exposure Scenario 1> Inhalation exposure to volatile components of paint

During application of the product, similar to adhesive products, concentration increase due to product application and decrease due to room ventilation occur simultaneously. After the application of paint, emission of chemical substances generally completes. However, emission from the generation source may continue for some time. In the first case, the concentration decreases due to ventilation, but in the latter case, the concentration becomes constant.

Algorithm

If emission completes at the same time application of the product ends, use the formula II-1-6 and II-1-9 to calculate the Average Air Concentration of Exposure Duration. Then assign the value to the formula II-1-1 to calculate the amount of inhalation exposure.

If emission continues for a while after application of the product, use the formula II-1-10 to calculate the room concentration of steady emission, and then assign the value to the formula II-1-1 to calculate the amount of exposure.

<Exposure Scenario 2> Dermal Exposure due to application of the products

Select the algorithm to be used according to the amount of paint applied or information (such as Dermal Absorption Rate) of the dermal exposure of the assessment component.

Algorithm

If a constant amount of paint applied is assumed to contact to the skin, use the formula II-2-3 to calculate the amount of dermal exposure. Use the formula II-2-1 to calculate the amount of exposure, when assuming a Skin Contact Layer. If the Dermal Absorption Rate of the assessment component is available, use the formula II-2-2 to calculate the amount of exposure.

III-2-4 Example of Assessment

Example 1) Household synthetic resin emulsion paint

Chemical substance: Isopropyl Alcohol (IPA)

<Isopropyl Alcohol (IPA)>

- CAS No.: 67-63-0
- Molecular Weight: 60.10 g/mol
- Vapor Pressure: 33 mmHg (20 degrees C)

<Exposure Scenario>

- Applied to walls in a room (20 m^3).
- Household synthetic resin emulsion paint (1 L, weight of product: 1200g) contains 2% IPA.
- Basically, two coats are assumed with half the product (600g) being applied for each coat.
- Assume that a coat takes 2 hours, and that a user will leave the room after the first coat until emission has complete (until completely dry), give the second coat, and leave the room again.
- Assume that ventilation was inadequate during work, and set the ventilation rate as 0.2 times/h, which is the same for a standard living room.
- Assume that the frequency of the work is once a year.
- Assume that Skin Adhesion Ratio due to unintended adherence of paint during work is 0.5% of the amount applied.

<Algorithm>

- Inhalation Exposure: Instantaneous Evaporation (Consider the Time in Use)
- Dermal Exposure: Constant Ratio Adherence
- Oral Exposure: Not Assumed

<Various Data>

- Amount of Product Used (Ap): 600 g
- Inhalation Rate (Q): 0.833 m^3/h
- Volume of Room (V): 20 m^3
- Time During Application (one time) (t_i): 2.0 h
- Skin Adhesion Ratio (Md): 0.5 %
- Description of Work: Twice
- Weight Fraction of IPA (Wr): 2 %
- Body Weight (BW): 50 kg
- Ventilation Rate (N): 0.2 times/h
- Time spent After Use (t_{ii}): 0.0 h
- Uptake Fraction (a): 100 %
- Frequency of Application (n): Once per Year

<Calculation>

(1) Inhalation Exposure

Calculate the amount of inhalation exposure using the <Instantaneous Evaporation Mode: Consider the Time in Use>.

Average Air Concentration During Application should be calculated using the formula II-1-6.

$$Ca_{ti} = \frac{\frac{Ap \times Wr / t_i}{N \times V} \times \left\{ t_i - \frac{1}{N} \times \left[1 - \exp(-N \times t_i) \right] \right\}}{t_i}$$

$$Ca_{ti} = \frac{\frac{600g \times 0.02 / 2h}{0.2/h \times 20m^3} \times \left\{ 2h - \frac{1}{0.2/h} \times \left[1 - \exp(-0.2/h \times 2h) \right] \right\}}{2h}$$

$$= 263.7mg/m^3$$

Assign this to the formula II-1-1 to calculate the amount of exposure during use (exposure period during application).

$$EHE(inha) = \frac{Ca_t \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{263.7mg/m^3 \times 0.833m^3/h \times 2.0h \times 1 \times 1/365\text{day}}{50kg}$$

$$= 0.024mg/kg/day$$

As this value is the amount of inhalation exposure from a single coat, the calculation for the amount of inhalation exposure with two coats will be as follows:

$$EHE(inha) = 0.024mg/kg/day \times 2 = 0.048mg/kg/day$$

(2) Dermal Exposure

Calculate the amount of dermal exposure using the <Constant Ratio Adherence>.

Calculate the amount of dermal exposure using the formula II-2-3 assuming a constant ratio of the product has adhered to the skin.

$$EHE(derm) = \frac{Ap \times Wr \times Md \times n \times a(derm)}{BW}$$

$$EHE(derm) = \frac{600g \times 0.02 \times 0.005 \times 1/365day \times 1}{50kg}$$

$$= 3.29 \times 10^{-3} mg/kg/day$$

As this value is the amount of dermal exposure from a single coat, the calculation for the amount of inhalation exposure with two coats will be as follows:

$$EHE(derm) = 3.29 \times 10^{-3} mg/kg/day \times 2 = 0.007mg/kg/day$$

(3) Estimated Human Exposure (EHE)

The Estimated Human Exposure (EHE) should be calculated using the Amount of Inhalation

Exposure (EHE (inha)) and Amount of Dermal Exposure (EHE (derm)). Since the EHE (inha)：0.048 mg/kg/day, EHE (derm): 0.007 mg/kg/day then the EHE will be as follows. $EHE = 0.048 mg/kg/day + 0.007 mg/kg/day = 0.055 mg/kg/day$
<Results> Amount of Inhalation Exposure: 0.048 mg/kg/day Amount of Dermal Exposure: 0.007 mg/kg/day **Estimated Human Exposure: 0.055 mg/kg/day**

Example 2) Indoor Floor Wax

Chemical Substance: Diethylene glycol monoethyl ether

<Diethylene glycol monoethyl ether (DEGEE)>

- CAS No.: 111-90-0
- Molecular Weight: 134.2 g/mol
- Vapor Pressure: 19 Pa

<Exposure Scenario>

- Wax applied on indoor flooring.
- The wax contains 7.75% DEGEE.
- Assume that 200g of the wax will be applied with a general living room (6 tatami mats floor = 20 m^3).
- Normally a mop is used when waxing. However, in this case assume that the wax is applied with bare hands with inadequate ventilation and set the ventilation rate as 0.2 times/h, which is the same for the general living room.
- Assume that no long term emission occurs after product use, and the emission of DEGEE stops at the time application has completed.
- Assume that the working period is one hour and the user stays in the room for one hour after that.
- Assume that Skin Adhesion Ratio due to unintended adherence of wax during work is 0.5% of the amount applied.
- Assume that the frequency of the work is twice a year.

<Algorithm>

- Inhalation Exposure: Instantaneous Evaporation (Consider the Time in Use)
- Dermal Exposure: Constant Ratio Adherence
- Oral Exposure: Not Assumed

<Various Data>

- Amount of Product Used (Ap): 200g
- Inhalation Rate (Q): 0.833 m^3/h
- Volume of Room (V): 20 m^3
- Working Hours (t_i): 1.0 h
- Time spent After Use (t_{ii}): 1.0 h
- Skin Adhesion Ratio (Md): 0.5 %
- Weight Fraction of DEGEE in Product (Wr): 7.75%
- Body Weight (BW): 50 kg
- Ventilation Rate (N): 0.2 times/h
- Frequency of Use (n): Twice per Year
- Uptake Fraction (a): 100 %

<Calculation>

(1) Inhalation Exposure

Calculate the amount of inhalation exposure using <Instantaneous Evaporation Mode: Consider the Time in Use>.

[Amount of Inhalation Exposure During Application]

Average Air Concentration During Application should be calculated using the formula II-1-6.

$$Ca_{ti} = \frac{\frac{Ap \times Wr / t_i}{N \times V} \times \left\{ t_i - \frac{1}{N} \times [1 - \exp(-N \times t_i)] \right\}}{t_i}$$

$$Ca_{ti} = \frac{\frac{200g \times 0.0775 / 1.0h}{0.2/h \times 20m^3} \times \left\{ 1h - \frac{1}{0.2/h} \times [1 - \exp(-0.2/h \times 1.0h)] \right\}}{1h}$$

$$= 362.9mg / m^3$$

Assign the value to the formula II-1-1 to calculate the amount of inhalation exposure during application (exposure period during application).

$$EHE(inha) = \frac{Ca_t \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{362.9mg/m^3 \times 0.833m^3/h \times 1.0h \times 1 \times 2/365\text{day}}{50kg}$$

$$= 0.033mg/kg/day$$

[Amount of Inhalation Exposure After Application Period]

Average Air Concentration During Stay (After Application) should be calculated using the formula II-1-9.

$$Ca_{tii} = \frac{\frac{Ca_1}{N} \times [1 - \exp(-N \times t_{ii})]}{t_{ii}}$$

Here Ca_1 represents the concentration in the air immediately after use Ca_1 should be calculated using the formula II-1-5.

$$Ca_1 = \frac{Ap \times Wr / t_i}{N \times V} \times [1 - \exp(-N \times t_i)]$$

$$Ca_1 = \frac{200g \times 0.0775 / 1.0h}{0.2/h \times 20m^3} \times [1 - \exp(-0.2/h \times 1.0h)]$$

$$= 702.4mg / m^3$$

Therefore

$$Ca_{tii} = \frac{\frac{Ca_1}{N} \times [1 - \exp(-N \times t_{ii})]}{t_{ii}}$$

$$Ca_{tii} = \frac{\frac{702.4mg/m^3}{0.2/h} \times [1 - \exp(-0.2/h \times 1.0h)]}{1.0h}$$

$$= 636.6mg/m^3$$

Assign the value to the formula II-1-1 to calculate the Amount of Inhalation Exposure During Stay (After Application).

$$EHE(inha) = \frac{Ca_t \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{636.6mg/m^3 \times 0.833m^3/h \times 1.0h \times 1 \times {}^{2}\!/_{365\text{day}}}{50kg}$$

$$= 0.058mg/kg/day$$

[Total Amount of Inhalation Exposure]

The amounts of exposure during application and after application are added to calculate the total amount of inhalation exposure:

$$EHE(inha) = 0.033mg/kg + 0.058mg/kg = 0.091mg/kg$$

(2) Dermal Exposure

Calculate the amount of dermal exposure using the <Constant Ratio Adherence>.

Calculate the amount of dermal exposure using the formula II-2-3 and assuming a constant ratio of the product has adhered to the skin.

$$EHE(derm) = \frac{Ap \times Wr \times Md \times n \times a(derm)}{BW}$$

$$EHE(derm) = \frac{200g \times 0.0775 \times 0.005 \times {}^{2}\!/_{365\text{day}} \times 1}{50kg} = 0.008mg/kg/day$$

(3) Estimated Human Exposure (EHE)

The Estimated Human Exposure (EHE) should be calculated using the Amount of Inhalation Exposure (EHE (inha)) and Amount of Dermal Exposure (EHE (derm)).

Since the EHE (inha) : 0.091mg/kg/day, EHE (derm): 0.008mg/kg/day then the EHE will be as follows.

$$EHE = 0.091mg/kg/day + 0.008mg/kg/day = 0.099mg/kg/day$$

<Results>

Amount of Inhalation Exposure: 0.091 mg/kg/day

Amount of Dermal Exposure: 0.008 mg/kg/day

Estimated Human Exposure: 0.099 mg/kg/day

III-3 Household Detergent

III-3-1 Scope of this Category

This category of household detergent includes laundry detergents, hand dishwashing detergents, and home cleaners for cleaning furniture and home appliances. In addition, although not detergent, fabric softener, starch, and bleach for laundry are also included in this category..

III-3-2 Characteristics of this Category

Detailed research on risk assessment methods for household detergents has taken place as voluntary efforts made by the SDA (The Soap and Detergent Association)[13] and HERA (Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products: CEFIC European Chemical Industry Council and A.I.S.E. Soap and Detergent Association of Europe)[14]and the content has already been published[15].

Referring to these existing risk assessment methods and considering how household detergents are used in Japan, the following exposures are considered important.

1. Dermal exposure to the hands from detergent (laundry, dishes)
2. Dermal exposure to compounds remaining on laundry after use of products
3. Inhalation exposure to spray products
4. Oral exposure to compounds remaining on dishes (Oral Intake of substances transferred to food)

III-3-3 Exposure Scenario and Algorithm

Assume the exposure scenario that should be considered, then select the algorithm to estimate the amount of exposure.

1. Dermal exposure to detergent (laundry, dishes)

When washing the laundry[16] or dishes using synthetic detergents dermal exposure is the main route of exposure.

(Exposure scenario) Dermal exposure from the use of detergent (laundry, dishes) when used with bare hands without rubber gloves

Algorithm

Use the formula II-2-1 which assumes a Skin Contact Layer to calculate the amount of exposure. Or if the Dermal Absorption Rate of the assessment compound is available, use the formula II-2-2 to calculate the amount of exposure.

2. Dermal exposure to the compound remaining on laundry after use of the product

When laundry is washed using detergent, although it may only be a small amount, some of the

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[13] http://cleaning101.com/files/Exposure_and_Risk_Screening_Methods_for_Consumer_Product_Ingredients.pdf
[14] http://www.heraproject.com/Library.cfm
[15] The Japan Soap and Detergent Association are also cooperating in these projects.
[16] In Japan most users use the laundry machines, however, depending on the type or form of the laundry hand washing may occur.

detergent will remain on the laundry. In addition, if the laundry is processed using a fabric softener, then the softening agent will also remain on the laundry. Therefore wearing the laundry, in particular underwear, which directly touch the skin, can result in the remnant components being transferred to the skin. The important point is how the residual amount in the laundry and the amount transferred from the laundry to the skin should be estimated.

(Exposure Scenario) Dermal exposure to the compound remaining on laundry after use of the product

Algorithm

Use the formula II-2-1 which assumes a Skin Contact Layer to calculate the amount of exposure. Or if the Dermal Absorption Rate of the assessment target component is available, use the formula II-2-2 to calculate the amount of exposure.

3. Inhalation exposure to spray products

Assume that exposure occurs in a limited space over a limited period of time. Inhalation of mist (aerosol) from the spray should be considered. Although the particle size of the mist varies and large size particles of mist will not be inhaled, it is very difficult to predict what proportion of the mist will be inhaled. Therefore, unless scientifically reliable value has been available, all the mist should be assumed to be of a size that can be inhaled.

(Exposure Scenario) Inhalation exposure to spray products (Instantaneous Evaporation)

Algorithm

Depending on the form of the product, select from the formula II-1-2 through to the formula II-1-9 and calculate the concentration for a virtual space or room (real space), which can be subject to the Exposure by spray, then use the formula II-1-1 to calculate the Amount of Inhalation Exposure.

4. Oral exposure to the compound remaining on dishes

When dishes are washed using hand dishwashing detergent, although it may only be a small amount, some of the detergent components will adhere to the dishes, and then transfer to food from the dishes, which can result in oral exposure. The adhered amount and concentration of detergent will drastically decrease after being rinsed with water. Although all of detergent components will not be transferred to food, 100 % of it is assumed to transferred in this case. In addition, washing vegetables or fruit using a detergent may cause detergent components to adhere to them. In this case, use the algorithm for dermal exposure to calculate the weight of components on the vegetables, and then calculate the amount of exposure from the Intake Amount of Food per day.

<Exposure Scenario> Oral exposure to the compound remaining on dishes

Algorithm

Select one of the formula II-3-2, II-3-3, or II-3-4 to calculate the amount of oral exposure.

III-3-4 Example of Assessment

Example 1) Hand Dishwashing Detergent

Chemical Substance: Ethanol

<Ethanol>

・ CAS No.: 64-17-5

・ Molecular Weight: 46.1

・ Vapor Pressure: 5.8 kPa (at 20 degrees C)

<Exposure Scenario>

・ Hand Dishwashing detergent contains 5% ethanol.

・ Assume dermal exposure occurs from handwashing dishes using hand dishwashing detergent and oral exposure through dishes/food.

・ Assume the frequency of hand dishwashing to be 3 times a day (45 minutes/event).

・ Assume the concentration of hand dishwashing detergent during handwashing dishes to be 100 mg/cm^3.

・ Assume that the surface area of the hands and arms exposed during handwashing dishes to be 1980 cm^2.

・ Assume the Dermal Absorption Rate of Ethanol during dishwashing to be 0.8×10^{-3} cm/h.

・ Oral exposure to dishes is caused by the transfer of washing liquid remaining on the dishes to food and then from eating that food. However, assume the Trancfer Rate from Dishes to Food to be 100 %.

・ Assume that oral exposure through food occurs from washing vegetables and fruit with hand dishwashing detergent and then in taking the remaining liquid on the vegetable and fruit.

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*1 This exposure assessment references the exposure scenarios and factors described in the "Guidance Document Methodology" from "HERA (Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products)" (2005)*2 and "SDA (The Soap and Detergent Association) Exposure and Risk Screening Methods for Consumer Product Ingredients" (2005) *3.

*2 "Guidance Document Methodology" (HERA, 2005) can be obtained from the following URL: http://www.heraproject.com/files/HERA%20TGD%20February%202005.pdf

*3 "Exposure and Risk Screening Methods for Consumer Product Ingredients" (SDA, 2005) can be obtained from the following URL: http://cleaning101.com/files/Exposure_and_Risk_Screening_Methods_for_Consumer_Product_Ingredients.pdf

*4 "About the amine oxide blended cleaning agent" from "Health Science 1989, Research regarding the safety of food cleaning agents (No. 1)" About amine oxide blended cleaning agent" (Japan Food Cleaners and Hygienic Association, 1991) was referred to in the Concentration of Substances in Vegetables and Fruit.

<Algorithm>

・ Inhalation Exposure: Not Assumed

・ Dermal Exposure: Dermal Absorption Rate Mode

・ Oral Exposure: The estimated Transfer Rate and estimated concentration of the substance in food

<Various Data>

- Body Weight (BW): 50 kg
- Weight Fraction of Ethanol (Wr): 5%
- Working Hours per Count: 0.75 h/count
- Dermal Absorption Rate (Ml): 0.8×10^{-3} cm/h
- Amount of Residual liquid on the Dish Surface: 5.5×10^{-5} cm^3/cm^2
- Transition Rate from Dish to Food (Mfd): 100 %
- Concentration of Substance in Vegetable (Cf_1): 1.4×10^{-3} mg/g
- Concentration of Substance in Fruit (Cf_2): 2.4×10^{-4} mg/g
- Concentration of Hand Dishwashing Detergent:: 100 mg/cm^3
- Exposure Surface Area (Sp): 1,980 cm^2
- Frequency of Work per day (n): 3 times/day
- Concentration of Residual Product Remaining on Dishes: 0.8 mg/cm^3
- Contact Area of Food and Dish: 5,400 cm^2/day
- Intake Amount of Vegetables (Wf_1): 263 g/day
- Intake Amount of Fruits (Wf_1): 256 g/day
- Uptake Fraction (a): 100 %

<Calculation>

(1) Dermal Exposure

Calculate the amount of dermal exposure using the <Dermal Absorption Rate Mode>.

The Dermal Absorption Rate can be determined using the formula II-2-2. As the unit used in Dermal Absorption Rate above is in "cm/h", and hence needs to be converted into "mg/cm^2/h" to consider the concentration of Ethanol in hand dishwashing detergent. The concentration of ethanol in detergent should be calculated with the following formula:

As the Concentration of Ethanol (mg/cm^3) = Concentration of the Hand Dishwashing Detergent x Weight Fraction of Ethanol in product,

Concentration of Ethanol (mg/cm^3) = 100 mg/cm^3x 0.05 = 5 mg/cm^3.

Therefore, Dermal Absorption Rate Ml (mg/cm^2/h) is as follow:

Dermal Absorption Rate Ml (mg/cm^2/h) = Concentration of Ethanol (mg/cm^3) x Dermal Absorption Rate (cm/h),

Dermal Absorption Rate Ml (mg/cm^2/h) = 5mg/cm^3 x 0.8×10^{-3} m/h = 4.0×10^{-3} mg/cm^2/h.

Assign it to the formula II-2-2:

$$EHE(derm) = \frac{Sp \times Ml \times t \times n}{BW}$$

$$EHE(derm) = \frac{1{,}980cm^2 \times 4.0 \times 10^{-3}\, mg/cm^2/h \times 0.75h \times 3/day}{50kg}$$

$$= 0.356 mg/kg/day$$

(2) Oral Exposure

[Amount of Oral Exposure from Dishes]

Calculate the amount of oral exposure using the <Estimation from Transition Rate>.

The Amount of Oral Exposure to Ethanol in cleaning solution remaining on dishes should be calculated using the formula II-3-3.

Here, Cd (mg/day) the Weight of Adhered Substance on Dishes per Day should be calculated using the following formula:

Cd (mg/day) = Concentration of Residual Product Remained on Dishes x Weight Fraction of Ethanol in Product (Wr) x Residual Fluid Amount on Dish Surface x Contact Area between Food and Dish:

Cd (mg/day) = 0.8 mg/cm^3 x $0.05 \times 5.5 \times 10^{-5}$ cm^3/cm^2 x 5,400 cm^3/day = 1.188×10^{-2} mg/day

Assign this to the formula II-3-3,

$$EHE(oral) = \frac{Cd \times Mfd \times a(oral)}{BW}$$

$$EHE(oral) = \frac{1.188 \times 10^{-2}\, mg/day \times 1 \times 1}{50kg} = 2.38 \times 10^{-4}\, mg/kg/day$$

[Amount of Oral Exposure from Vegetables]

Calculate the amount of oral exposure using the <Estimation from the Concentration of Substance in Food>.

The Amount of Oral Exposure to Ethanol in the cleaning solution remaining on the vegetables should be calculated using the formula II-3-2.

$$EHE(oral) = \frac{Cf \times Wf \times a(oral)}{BW}$$

$$EHE(oral) = \frac{0.0014\, mg/g \times 263 g/day \times 1}{50kg} = 7.36 \times 10^{-3}\, mg/kg/day$$

[Amount of Oral Exposure from Fruit]

Calculate the amount of oral exposure using the <Estimation from the Concentration of Substance in Food>.

The Amount of Oral Exposure from Ethanol in the cleaning substance remaining on the fruit should be calculated using the formula II-3-2.

$$EHE(oral) = \frac{Cf \times Wf \times a(oral)}{BW}$$

$$EHE(oral) = \frac{0.00024\, mg/g \times 256 g/day \times 1}{50kg} = 1.23 \times 10^{-3}\, mg/kg/day$$

[Total Amount of Oral Exposure]

Add each amount of each type of exposure to calculate the amount of oral exposure:

$$EHE(oral) =$$

$$2.38 \times 10^{-4} mg/kg/day + 7.36 \times 10^{-3} mg/kg/day + 1.23 \times 10^{-3} mg/kg/day$$

$$= 0.009 mg/kg/day$$

(3) Estimated Human Exposure (EHE)

The Estimated Human Exposure (EHE) should be calculated using the Amount of Dermal Exposure (EHE (derm)) and Amount of oral Exposure (EHE (oral)). Since the EHE (derm): 0.356 mg/kg/day, EHE (oral): 0.009 mg/kg/day, the EHE will be as follows:

$$EHE = 0.356 mg/kg/day + 0.009 mg/kg/day = 0.365 mg/kg/day$$

<Results>

Amount of Dermal Exposure: 0.356 mg/kg/day

Amount of Oral Exposure: 0.009 mg/kg/day

Estimated Human Exposure: 0.365 mg/kg/day

Example 2) Residual laundry detergent substances on laundry

Chemical substance: Linear Alkylbenzene Sulfonete (LAS)

<Linear Alkylbenzene Sulfonete (LAS)>

- CAS No.: 25155-30-0 (for $C_{18}H_{29}SO_3Na$) and others
- Molecular Weight: 348.48 (for $C_{18}H_{29}SO_3Na$)
- Vapor pressure: -

<Exposure Scenario>

- Assume that 0.025 mg of LAS per $1cm^2$ of laundry remains.
- Assume that the bodily surface area contacting the laundry is 17,600 cm^2 and the Transfer Ratio from Laundry to Skin is 0.01 %
- Assume the frequency of wearing the laundry with remaining detergent on it to be once a day.

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*1 This exposure assessment references the exposure scenarios and factors described in the “Guidance Document Methodology (2005)*2” and “Linear Alkylbenzene Sulphonate Human Health Risk Assessment (2007)” (HERA (Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products)) and was partially edited according to the concept of this Appendix.

*2 “Guidance Document Methodology” (HERA, 2005) can be obtained from the following URL: http://www.heraproject.com/files/HERA%20TGD%20February%202005.pdf

*3 “Linear Alkylbenzene Sulphonate Human Health Risk Assessment” (HERA, 2003) can be obtained from the following URL: http://www.heraproject.com/files/4-F-HERA_LASFinalReport2007revision10_07.pdf

<Algorithm>

- Inhalation Exposure: Not Assumed
- Dermal Exposure: Virtual Volume Mode, Partially Modified
- Oral Exposure: Not Assumed

<Various Data>

- Body Weight (BW): 50 kg
- Residual Amount of LAS on Laundry: 0.025 mg/cm^2
- Frequency of Use (n): Once/day
- Contact Area to Laundry (Sp): 17,600 cm^2
- Transfer Ratio from Laundry to Skin: 0.01 %
- Uptake Fraction (a): 100 %

<Calculation>

◆ **Dermal Exposure**

Calculate the amount of dermal exposure using the <Virtual Volume Mode>.

With the Virtual Volume Mode (the formula II-2-1), the Weight of Chemical Substance in the virtual volume is calculated using Thickness of Skin Contact Layer (Ls) and Contact Area (Sp) and Concentration (Cs) as shown below. The Amount of Exposure is then calculated by determining how many times that weight is absorbed per day.

$$EHE(derm) = \frac{Cs \times Ls \times Sp \times n \times a(derm)}{BW}$$

Here the weight of chemical substance on the skin surface is calculated using Residual Amount of LAS on Laundry (mg/cm^2), Contact Area of Laundry and the Transfer Rate from laundry to the skin surface.

Therefore Cs (mg/cm^3) x Ls (cm) x Sp (cm^2) = Residual Amount of LAS on Laundry (mg/cm^2) x Transfer Rate from Laundry to the Skin Surface x Sp (cm^2), then the amount of dermal exposure should be:

$$EHE(derm) = \frac{0.025mg/cm^2 \times 0.0001 \times 17{,}600cm^2 \times 1/day \times 1}{50kg}$$

$$= 8.80 \times 10^{-4} mg/kg/day$$

<Results>

Amount of Dermal Exposure: 8.80×10^{-4} mg/kg/day

Estimated Human Exposure: 8.80×10^{-4} mg/kg/day

III-4 Deodorant/Air Freshener and Repellents for Nuisance Insects

III-4-1 Scope of this Category

The scope of this category includes deodorant/air freshener and repellents for nuisance insects used in living rooms or lavatory.

III-4-2 Characteristics of this Category

There are different types of deodorant/air freshener and repellents for Insects: those sprayed on the object, those forced to volatilize by heat or burn , and those set in a room for emission.

Therefore, exposure through the following need to be considered:

1. Inhalation exposure to spray products
2. Inhalation exposure from products forced to volatilize by heat or burn
3. Inhalation exposure to emission/sublimation products

III-4-3 Exposure Scenario and Algorithm

Assume the exposure scenario that should be considered, then select the algorithm to estimate the amount of exposure.

1. Inhalation exposure to spray products

Sprayed on objects, nuisance insects, or in a space several times over a short period of time. Determine the total weight of the product using spray period, spray volume and frequency of spray, and then calculate the weight of the compound sprayed using the content of the compound in the product. If spray period is short, and a spray object is near a user, set virtual space around the user, assume that the sprayed compound homogeneously distributed in the space, and calculate the concentration of the compound in the virtual space.

On the other hand, if the compound to be sprayed diffuses throughout the whole room, chose the compound concentration of the whole room rather than that of the virtual space. The amount of exposure should be calculated using the concentration of the compound and frequency of use per day. As the particle of the mist ranges in size, and large mist particles will not be inhaled, it is very difficult to predict the proportion of the mist particles that will be inhaled. Therefore, all the mist should be assumed to be of a size that will be inhaled, unless scientifically reliable value has been available.

(Exposure Scenario) Inhalation exposure to components of the spray being used against the object

<u>Algorithm</u>

Depending on the type of product, use the formula II-1-2 for the Simple Estimation Mode or the formula II-1-4 for the Instantaneous Evaporation Mode (Monotonically Decreasing) to calculate the average exposure concentration in the virtual space or actual space.

2 Forced volatilization products

Forced volatilization product contains fragrance components or components with repellent effect, that vaporize through burning or heating. The rate of volatilization should be calculated using the usable life time per product and content ratio of the compound. If the rate of volatilization is relatively small compared with the space (Room volume), the component is thought to volatilize from the product by a constant rate (Emission Rate). If the rate of volatilization is large, the room concentration is thought to increase gradually, in spite of decrease due to ventilation. In both cases the concentration in rooms will gradually decrease after volatilization ends. Based on the assumption above, the amount of inhalation exposure is calculated using the room concentration and staying time, during and after volatilization.

<Exposure Scenario> Inhalation exposure from the use of forced volatilization products

Algorithm

Depending on the form of the product use, the formula II-1-10 (Steady Emission Mode) or II-1-6 (Instantaneous Evaporation Mode: Consider the Time in Use) is used to calculate the concentration during volatilization. After volatilization has ended, use the formula II-1-9 in both cases to calculate the concentration. From the concentration and staying time during and after volatilization, the amount of inhalation exposure will be calculated using the formula II-1-1. However, if the formula II-1-10 (Steady Emission) is used, depending on the situation, the time to reach steady status may become too long, and result in overestimation. Therefore, the characteristics of the product and usage pattern should be carefully considered. If it seems to have been overestimated, then compare it with a value calculated with Instantaneous Evaporation Mode (Consider the Time in Use), and then review if the exposure scenario has fitted the characteristics and usage pattern of the product, and the chemical substances.

3. Release/volatilization products

Release/volatilization products emit compounds into the space with a constant Emission Rate. Therefore, calculate the concentration of the compound emitted into the air using the Emission Rate. However, if the status of the compound reaches saturated vapor pressure, calculate the concentration in the air using the Saturated Vapor Pressure.

<Exposure Scenario> Inhalation exposure to slow-released products in rooms

Algorithm

The concentration in the space is calculated using the formula II-1-10 (Steady Emission Mode) or II-1-5 (Saturated Vapor Pressure Mode), depending on the form of the product. Use the concentration in the space and the staying time, the amount of inhalation exposure is calculated by the formula II-1-1.

III-4-4 Example of Assessment

Example 1) Aerosol type deodorant for lavatory

Chemical substance *n*-butane

＜n-butane＞
・ CAS No.: 106-97-8 ・ Molecular Weight: 58.12 g/mol ・ Vapor Pressure: 1,830mmHg (25 degrees C)
<Exposure Scenario> ・ Household aerosol type toilet deodorant (200g) for lavatory is used in lavatory. ・ Contains 59.4% *n*-butane. ・ Assume that each spray is 1 second (1g/sec)*1. ・ Assume that the ventilating rate is 0.5 time/hour considering that a local ventilation system or window is in the lavatory. ・ Assume that the frequency of using the lavatory is 6 times/day*2 and that deodorant for lavatory is used 3 of the 6 times. ・ Assume that user stays in the lavatory for 2 minutes (0.0333 h) after the spray is used. ・ Assume a virtual space as the effective range of the spray. And in this case assume that the virtual space is the same as the volume of the lavatory (2 m^3), and use the real lavatory volume in evaluations. ・ Assume the concentration soon after entering in the lavatory is 0, as a lot of air is moved around when entering. ・ All the spray components are assumed to be of a mist size that can be inhaled. ----------------------------- *1 The injection amount of spray was abstracted from the "How does it get cold? Cold spray" in Fukushima Prefecture Consumer Advice Centre (http://www.pref.fukushima.jp/syouhi/test/H15spray.htm). *2 The staying time and frequency of using toilets was abstracted from "Everyone's Lavatory: How to build a public lavatory" on the Kochi Prefecture Civil Engineering Department Building Division Home page (http://www.pref.kochi.jp/~kenchiku/kenchiku/toile_onepoint.html).
<Algorithm> ・ Inhalation Exposure: Simple Estimation Mode or Instantaneous Evaporation Mode (Monotonically Decreasing) ・ Dermal Exposure: Not Assumed ・ Oral Exposure: Not Assumed * There are two types of calculation methods: one ignores ventilation while the other takes it into consideration. In this section, [Simple Estimation Mode] and [Instantaneous Evaporation Mode (Monotonically Decreasing)] are shown respectively.
<Various Data>

- Used Amount (/count) (Ap): 1 g
- Volume of Lavatory (V): 2 m^3
- Ventilation Rate (N): 0.5 times/h
- Inhalation Rate (Q): 0.833 m^3/h
- Uptake Fraction (a): 100 %
- Weight Fraction of n-butane (Wr): 59.4 %
- Staying Time After Spray (t): 0.0333 h/count
- Body Weight (BW): 50 kg
- Frequency of Spray per Day (n): 3 times/day

<Calculation>

◆ **Inhalation Exposure**

For the [Simple Estimation Mode]:

Calculate the amount of inhalation exposure using the <Simple Estimation Mode>.

As the staying time after using splay is short (2 minutes), the Simple Estimation Mode is used here to calculate the amount of inhalation exposure during the stay. The air concentration is calculated using the formula II-1-2:

$$Ca_t = \frac{Ap \times Wr}{V} = \frac{1000mg \times 0.594}{2m^3} = 297mg/m^3$$

Assign this to the formula II-1-1 to calculate the amount of exposure during the stay in the lavatory.

$$EHE(inha) = \frac{Ca_t \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{297mg/m^3 \times 0.833m^3/h \times 0.0333h \times 1 \times 3/day}{50kg} = 0.494mg/kg/day$$

For the [Instantaneous Evaporation Mode: Monotonically Decreasing]

Calculate the amount of exposure using the <Instantaneous Evaporation Mode: Monotonically Decreasing>.

Using the formula II-1-4 calculate the average concentration in the lavatory when the spray is injected throughout the lavatory and the user then remain in the room for 2 minutes.

$$Ca_t = \frac{\dfrac{Ap \times Wr / V}{N} \times [1 - \exp(-N \times t)]}{t}$$

$$Ca_t = \frac{\dfrac{1g \times 0.594 / 2m^3}{0.5/h} \times [1 - \exp(-0.5/h \times 0.0333h)]}{0.0333h} = 294.8mg/m^3$$

Assign this to II-1-1 to calculate the amount of inhalation exposure during stay in lavatory.

Since $EHE(inha) = \dfrac{Ca_t \times Q \times t \times a(inha) \times n}{BW}$ $EHE(inha) = \dfrac{294.8mg/m^3 \times 0.833m^3/h \times 0.0333h \times 1 \times 3/day}{50kg} = 0.491mg/kg/day$ * As the exposure period per single count is only 2 minutes, there will be little difference in the results. If the ventilation frequency is large or the staying time is long, that difference will be larger. Therefore, carefully consider the characteristics and usage pattern of the product and any other factors, and then select the appropriate exposure scenario.
<Results> Amount of Inhalation Exposure: 0.494 mg/kg/day [Simple Estimation Mode] 0.491 mg/kg/day [Instantaneous Evaporation Mode (Monotonically Decreasing)] **Estimated Human Exposure:** **0.494 mg/kg/day [Simple Estimation Mode]** **0.491 mg/kg/day [Instantaneous Evaporation Mode (Monotonically Decreasing)]**

Example 2) Electric vaporizer type repellent

Chemical substance: Metofluthrin

<Metofluthrin>

- CAS No.: 240494-70-6
- Molecular Weight: 360.35 g/mol
- Vapor Pressure: 1.47×10^{-5} mmHg (25 degrees C)

<Exposure Scenario>

- Use of an electric vaporizer type repellent in 6 tatami mats floor (20 m^3).
- Amount of the product used is 1.2 mg (Assume the Weight Fraction of Metofluthrin to be 100%).
- The amount of volatilization product is 0.2 mg/h, a value that considerably exceeds the maximum value of commercial items.
- Assume the used period of electric vaporizer type repellent is 6 hours and the user stays in the room during use.
- Assume that the user stay 2 hours when use of the product has completed.
- Assume that the repellent agent is used everyday.

<Algorithm>

- Inhalation Exposure: Instantaneous Evaporation Mode (Consider the Time in Use) or Steady Emission Mode and Instantaneous Evaporation Mode (Monotonically Decreasing)
- Dermal Exposure: Not Assumed
- Oral Exposure: Not Assumed

* Two types of exposure are assumed: one where the concentration increases with use of the product (Instantaneous Evaporation considering the time in use) similar to paint and adhesives, and the other, Steady Emission during use and Monotonically Decreasing after use. In this section the [Instantaneous Evaporation Mode (Consider the Time in Use)] or [Steady Emission Mode and Instantaneous Evaporation Mode (Monotonically Decreasing)] are respectively documented.

<Various Data>

- Used Amount (Ap): 1.2 mg
- Volume of Room (V): 20 m^3
- Staying Time During Use (t_i): 6.0 h
- Inhalation Rate (Q): 0.833 m^3/h
- Uptake Fraction (a): 100 %
- Frequency of Use (n): Once/day
- Weight Fraction of Metofluthrin (Wr): 100%
- Emission Rate (G): 0.2 mg/h
- Staying Time After Use (t_{ii}): 2.0 h
- Ventilation Rate (N): 0.2 times/h
- Body Weight (BW): 50 kg

<Calculation>

◆ Inhalation Exposure

For [Instantaneous Evaporation Mode: Consider the Time in Use]

Calculate the amount of inhalation exposure using the <Instantaneous Evaporation Mode: Consider the Time in Use>.

[Amount of Inhalation Exposure During Use]

Average Air Concentration During Use should be calculated by using the formula II-1-6.

$$Ca_{ti} = \frac{\frac{Ap \times Wr / t_i}{N \times V} \times \left\{ t_i - \frac{1}{N} \times [1 - \exp(-N \times t_i)] \right\}}{t_i}$$

$$Ca_{ti} = \frac{\frac{1.2mg \times 1 / 6.0h}{0.2/h \times 20m^3} \times \left\{ 6.0h - \frac{1}{0.2/h} \times [1 - \exp(-0.2/h \times 6.0h)] \right\}}{6.0h}$$

$$= 0.02088 mg/m^3$$

Assign this to the formula II-1-1 to calculate the amount of inhalation exposure during use.

$$EHE(inha) = \frac{Ca_{ti} \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{0.02088 mg/m^3 \times 0.833 m^3/h \times 6.0h \times 1 \times 1/day}{50kg}$$

$$= 2.09 \times 10^{-3} mg/kg/day$$

[Amount of Inhalation Exposure After Use]

Average Air Concentration During Stay (After Use) should be calculated using the formula II-1-9.

$$Ca_{tii} = \frac{\frac{Ca_1}{N} \times [1 - \exp(-N \times t_{ii})]}{t_{ii}}$$

Here, Ca_1 represents the concentration in the air immediately after use. The air concentration immediately after use should be calculated using the formula II-1-5.

$$Ca_1 = \frac{Ap \times Wr / t_i}{N \times V} \times [1 - \exp(-N \times t_i)]$$

$$Ca_1 = \frac{1.2mg \times 1 / 6.0h}{0.2/h \times 20m^3} \times [1 - \exp(-0.2/h \times 6.0h)] = 0.03494 mg/m^3$$

Therefore

$$Ca_{tii} = \frac{\frac{Ca_1}{N} \times [1 - \exp(-N \times t_{ii})]}{t_{ii}}$$

$$Ca_{tii} = \frac{\frac{0.03494 mg/m^3}{0.2/h} \times [1 - \exp(-0.2/h \times 2.0h)]}{2.0h} = 0.02880 mg/m^3$$

Assign this value to the formula II-1-1 to calculate the amount of inhalation exposure during stay after use.

$$EHE(inha) = \frac{Ca_{ti} \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{0.02880 mg/m^3 \times 0.833 m^3/h \times 2.0 h \times 1 \times 1/day}{50 kg}$$

$$= 9.60 \times 10^{-4} mg/kg/day$$

[Total Amount of Inhalation Exposure]

The total amount of inhalation exposure is caluculated by the amount of exposure during use and after use:

$$EHE(inha) = 2.09 \times 10^{-3} mg/kg/day + 9.60 \times 10^{-4} mg/kg/day = 3.05 \times 10^{-3} mg/kg/day$$

For the [Steady Emission Mode and Instantaneous Evaporation Mode: Monotonically Decreasing]

Calculate the amount of inhalation exposure using the <Steady Emission Mode and Instantaneous Evaporation Mode: Monotonically Decreasing>.

[Amount of Inhalation Exposure During Use]

Average Air Concentration During Use should be calculated using the formula II-1-10.

$$Ca_t = \frac{G}{N \times V}$$

$$Ca_t = \frac{0.2 mg/h}{0.2/h \times 20 m^3} = 0.05 mg/m^3$$

Assign this value to the formula II-1-1 to calculate the amount of inhalation exposure during use.

$$EHE(inha) = \frac{Ca_{ti} \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{0.05 mg/m^3 \times 0.833 m^3/h \times 6.0 h \times 1 \times 1/day}{50 kg}$$

$$= 5.00 \times 10^{-3} mg/kg/day$$

[Amount of Inhalation Exposure After Use]

Average Air Concentration During Stay (After Use) should be calculated using the formula II-1-9.

$$Ca_{tii} = \frac{\frac{Ca_1}{N} \times [1 - \exp(-N \times t_{ii})]}{t_{ii}}$$

Here, Ca_1 is the air concentration immediately after use, As there is no concentration changes during use, the Average Air Concentration During Use (0.05 mg/m^3) can be used as Ca_1 in the formula II-1-9.

Therefore

$$Ca_{tii} = \frac{\dfrac{0.05mg/m^3}{0.2/h} \times [1 - \exp(-0.2/h \times 2.0h)]}{2.0h} = 0.04121mg/m^3$$

Assign this value to the formula II-1-1 to calculate the amount of inhalation exposure during stay after use.

$$EHE(inha) = \frac{Ca_{ti} \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{0.04121mg/m^3 \times 0.833m^3/h \times 2.0h \times 1 \times 1/day}{50kg}$$

$$= 1.37 \times 10^{-3} mg/kg/day$$

[Total Amount of Inhalation Exposure]

The total amount of inhalation exposure is calculated by the amount of exposure during use and after use.

$$EHE(inha) = 5.00 \times 10^{-3} mg/kg/day + 1.37 \times 10^{-3} mg/kg/day = 6.37 \times 10^{-3} mg/kg/day$$

<Results>

Amount of Inhalation Exposure:

3.05×10^{-3} mg/kg/day [Instantaneous Evaporation Mode : Consider the Time in Use)]

6.37×10^{-3} mg/kg/day [Steady Emission Mode and Instantaneous Evaporation Mode: Monotonically Decreasing]

Estimated Human Exposure:

3.05×10^{-3} mg/kg/day [Instantaneous Evaporation Mode : Consider the Time in Use)]

6.37×10^{-3} mg/kg/day [Steady Emission Mode and Instantaneous Evaporation Mode: Monotonically Decreasing]

III-5 Auto Products

III-5-1 Scope of this Category

Similar to living rooms, there are various products for use inside vehicles and many products are available on the market as maintenance goods. In this Appendix, those types of vehicle and maintenance products are all considered as auto products. However, adhesive and paint used in the interiors/exteriors of vehicles are excluded.

III-5-2 Characteristics of this Category

The time to spend in cars is relatively short compared to living rooms where we spend a lot of time. Although it varies with each individual, vehicles are commonly used to commute to office or school and leisure activities. It is important to assess exposure to auto products.

The temperature changes that occur in cars are large when compared to living rooms, and the temperature sometimes gets very high[17] when left the car in the sun. In addition, ventilation is extremely varied depending on the introduction of external air. Therefore, those factors must be considered when assessing exposure.

Although a wide variety of products are used in cars, exposure through the following should be considered:

1. Deodorant/Air Freshener: Inhalation exposure due to emission of chemical substances in the cars
2. Maintenance goods: Inhalation and dermal exposure due to the use of detergents and wax

III-5-3 Exposure Scenario and Algorithm

Assume the exposure scenario that should be considered, and then select the algorithm to estimate the amount of exposure.

1. Deodorant/Air freshener

Deodorant/air freshener purposefully emit (spray) chemical substances. Depending on the form of the product (spray and setting type deodorants), the appropriate algorithms should be used to calculate the concentration in cars and estimate the amount of exposure. As times of ventilation vary depending on the usage pattern of the vehicle, ignore times of ventilation or set it refer to the ventilation rate for a living room. If the usage patterns are available, set the ventilation rate using the flow rate of the air conditioning etc.

(Exposure Scenario) Inhalation exposure to air freshener in the air inside cars

Air Freshener used in cars is considered to include spray types, setting type, and types which

[17] It is known that the temperature in cars during summer can get very high, and has been reported at to 27 – 51 degrees C (average 41 degrees C) in daytime in summer (Tsuji et. al., Journal of Society of Indoor Environment, Japan, 2006, 9(2), 90-91). In addition a report made by National Consumer Affairs Center of Japan stated that the maximum temperature in a car in the hot sun during summer was 60.3 degrees C and the temperature on the dashboard was 86.7 degrees C ("Evaluating safety in passenger vehicles", National Consumer Affairs Center of Japan, 2003).

air freshener set in front of the air conditioner outlet.

With spray types the inhalation of mist (aerosol) diffused in the car need to be considered. Although the particle size of the mist varies, and large size particle of mist will not be inhaled, it is very difficult to predict what proportion of the mist that will be inhaled. Therefore, unless scientifically reliable value has been available, all the mist should be assumed to be of a size that will be inhaled.

With installed types, as it is emitted into the space at a Constant Emission Rate, calculations should be done using the Emission Rate.

Algorithm

Depending on the form of the product, choose one of the formula II-1-2, II-1-4, II-1-6, or II-1-9 to calculate the average air concentration, and then use the formula II-1-1 to calculate the amount of inhalation exposure.

Example of the type that air freshener set in front of the air conditioner outlet is shown in “III-5-4 Example of Assessment”, because it is characteristic of automotive chemical products. As the exposure scenario and algorithms of installed or spray type deodorant/air freshener are similar to that in “III-4 Deodorant/Air Freshener and Repellents”, the amount of exposure should be calculated refer to the examples in III-4 using Room Volume and Ventilation Rate for cars.

2. Maintenance goods

Although maintenance goods are classified as automotive chemical products, the same assessment method as that for adhesive, paint, and detergents can be used.

Detergents: As they use the same assessment method for household detergents refer to “III-3 Household Detergent” for more details.

Wax: As it uses the same assessment method for Coating Materials and Adhesive refer to “III-1 Household Adhesive” and “III-2 Household Coating Material and Wax” for more details.

III-5-4 Example of Assessment

Example Air Freshener for Vehicle

Chemical substance: d-limonene

<d-limonene>

- CAS No.: 138-86-3
- Molecular Weight: 136.23 g/mol
- Vapor Pressure: 1.55 mmHg

<Exposure Scenario>

- Air freshener for vehicle (10g) of the type set in front of air-conditioning outlets.
- Assume that the amount of d-limonene contained is 2.9 % (amount of entire fragrance chemical is 14 % [*1]).
- As this is the types which air freshener set in front of the air conditioner outlet, it is assumed that the air conditioning is always working while in the car.
- Assume that the intake flow rate of external air to be 9 m^3/h [*2](the flow rate of the air conditioning), the volume of the vehicle 3 m^3 [*3], and ventilation frequency 3 times/h [*4].
- Calculate the emission rate assumed from the product life (6 months at 2 hours use/day)[*5].

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*1 Value used in the “Mapping of chemical substances in air fresheners and other fragrance liberating products”, (Danish Environmental Protection Agency, 2002) was used for the product composition.

*2 Assumes that the air intake of the air conditioning comes from outside. The appropriate value for the amount was also assumed to be within the possible range.

*3 Assumes that 60 % of the space in a Standard Light Motor Vehicle (3.4 m long, 1.48 m wide, 2 m high) is within the car body and half of that is the space inside the car.

*4 The Ventilation Frequency (N) is N = 9 m^3/h/3 m^3 = 3/h as it is assumed that the external air flow into the car is 3 m^3 at a flow rate of 9 m^3/h.

*5 If calculated using the Emission Rate = Weight of Product x Content Volume of Compound/Use (Possible) time, then the Emission Rate G (mg/h) is G = 10 g × 0.029/(2 h/day × 180 day) = 0.806 mg/h. However, when the air conditioning is not used, it is assumed that no emission takes place.

<Algorithm>

- Inhalation Exposure: Steady Emission Mode
- Dermal Exposure: Not Assumed
- Oral Exposure: Not Assumed

<Various Data>

- Used Amount: 10 g
- Emission Rate of d-limonene (G): 0.806 mg/h
- Flow Rate of Air Conditioning: 9 m^3/h
- Ventilation Rate (N): 3 times/h
- Weight Fraction of d-limonene (Wr): 2.9 %
- Inhalation Rate (Q): 20 m^3/day
- Volume in Vehicle (V): 3 m^3
- Staying Time in Vehicle (t): 2.0 h/day

・ Inhalation Rate (Q): 0.833 m^3/h	・ Body Weight (BW): 50 kg
・ Uptake Fraction (a): 100 %	

<Calculation>

◆ Inhalation Exposure

Calculate the amount of inhalation exposure using the <Steady Emission Mode>.

Average Air Concentration During Staying Time in vehicle should be calculated using the formula II-1-10.

$$Ca_t = \frac{G}{N \times V}$$

$$Ca_t = \frac{0.806 mg/h}{3/h \times 3m^3} = 0.0896 mg/m^3$$

Assign this value to the formula II-1-1 to calculate the amount of inhalation exposure during riding time.

$$EHE(inha) = \frac{Ca_{ti} \times Q \times t \times a(inha) \times n}{BW}$$

$$EHE(inha) = \frac{0.0896 mg/m^3 \times 0.833 m^3/h \times 2.0h \times 1 \times 1/day}{50kg}$$

$$= 2.99 \times 10^{-3} mg/kg/day$$

<Results>

Amount of Dermal Exposure: 2.99×10^{-3} mg/kg/day

Estimated Human Exposure: 2.99×10^{-3} mg/kg/day