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Children's Toys Fact Sheet

To assess the risks for the consumer

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Summary

Mathematical models are available to assess and estimate the exposure and uptake of substances in consumer products. Calculations are performed with a computer program called CONSEXPO. Since the huge number of consumer products does not allow exposure models and parameter values to be determined for every product separately, a limited number of main categories containing similar products are defined. Examples are paint, pesticides, cosmetics and floor covering. The information on each main category is described in a fact sheet .
This particular fact sheet deals with the use of children's toys, classifying the ways in which children can be exposed and defining the different exposure categories. One or several representative examples are given for each of the 17 exposure categories defined. Default models were chosen for these examples to determine the exposure to, and the uptake of, substances from the toys. The default parameter values were also filled in. On the basis of these representative defaults for the examples chosen, the default values for an exposure route of any type of toy can be derived. Because some parameters depend on the type of toy, these should still be filled in for every type of toy.

It appears that suitable models for every exposure category are available, allowing us to describe the exposure reliably. In our analysis, it was in most cases impossible to fill in all default-parameter values reliably enough to soundly estimate the exposure and the uptake of substances from the toys.
The crucial parameter, for which we have too little information for a sound estimate, is usually the factor that describes the migration of the substance under investigation from the product. The substance-dependent migration parameter referred to here will depend on the migrating substance and on the material from which it migrates. Empirically determining this parameter is the best way of arriving at a sound exposure estimate. This migration parameter is not known for mouthing, skin contact with solid products and eye contact for almost all substance/material combinations.

CONSEXPO does not only have the capacity to calculate the amount of substance taken up on the basis of contact, exposure and uptake models, but it can also do the reverse. If the amount taken up is known (e.g. the maximum amount which may be taken up, as defined in a standard), CONSEXPO can back-calculate and therefore calculate one of the other parameters. If the amount that a child can take up is known for a particular type of toy, CONSEXPO can calculate the associated migration factor as long as all the other parameters are known.

Samenvatting

Om de blootstelling aan stoffen uit consumentenproducten en de opname daarvan door de mens te kunnen schatten en beoordelen zijn wiskundige modellen beschikbaar. Voor de berekening wordt gebruik gemaakt van het computerprogramma CONSEXPO. Het grote aantal consumentenproducten verhindert dat voor elk afzonderlijk product blootstellingsmodellen en parameterwaarden vastgesteld kunnen worden. Daarom is een beperkt aantal hoofdcategorieën met gelijksoortige producten gedefinieerd. Voorbeelden van hoofdcategorieën zijn verf, bestrijdingsmiddelen, cosmetica en vloerbedekking. Voor elke hoofdcategorie wordt de informatie in een factsheet weergegeven. In deze factsheet wordt informatie gegeven over het gebruik van kinderspeelgoed.
Het gebruik van kinderspeelgoed wordt beschreven met behulp van een indeling van de manieren waarop kinderen kunnen worden blootgesteld. Er zijn 17 verschillende blootstellingscategorieën gedefinieerd. Van elke blootstellingscategorie worden één of enkele representatieve voorbeelden gegeven. Voor deze voorbeelden worden voor de blootstelling aan en de opname van stoffen uit het speelgoed defaultmodellen gekozen en zijn de default-parameterwaarden ingevuld. Uitgaande van deze representatieve voorbeeld-defaults is het mogelijk de defaultwaarden voor een blootstellingsroute van een willekeurig type speelgoed af te leiden. Gezien het zeer grote aantal soorten speelgoed is het niet mogelijk voor alle soorten speelgoed defaultwaarden weer te geven. Uitgaande van de representatieve voorbeeld-defaults is het mogelijk de defaultwaarden voor een blootstellingsroute van een willekeurig type speelgoed af te leiden. Enkele parameters zijn afhankelijk van het type speelgoed, deze dienen voor elk soort speelgoed nog te worden ingevuld.

Het blijkt dat er voor elke blootstellingscategorie geschikte modellen zijn om de blootstelling op een verantwoorde manier te beschrijven. Het invullen van alle default-parameterwaarden, die voldoende betrouwbaar zijn om tot een verantwoorde schatting van de blootstelling en de opname van stoffen uit speelgoed te kunnen komen bleek echter in de meeste gevallen niet mogelijk.
De cruciale parameter waarvan te weinig informatie voorhanden is om een verantwoorde schatting te kunnen maken is veelal de factor die de migratie van de te onderzoeken stof uit het product beschrijft. Het betreft steeds een stof-afhankelijke parameter, die afhankelijk is van de stof die migreert en van het materiaal waaruit de stof migreert. Om tot een verantwoorde blootstellingsschatting te kunnen komen is het empirisch te bepalen van deze parameter de beste oplossing. Deze migratie-parameter is bij sabbelen, bij huidcontact met vaste stoffen en bij oogcontact voor bijna alle stof/materiaal combinaties niet bekend.

CONSEXPO is niet alleen in staat om uitgaande van de contact-, de blootstellings- en de opnamemodellen de hoeveelheid stof te berekenen die wordt opgenomen, maar CONSEXPO kan ook de omgekeerde route bewandelen. Als de hoeveelheid die wordt opgenomen bekend is (bijvoorbeeld als norm, de hoeveelheid die maximaal mag worden opgenomen) kan CONSEXPO terugrekenen en zo één van de andere parameters berekenen.
Als voor een bepaald type kinderspeelgoed de hoeveelheid die een kind mag opnemen bekend is kan CONSEXPO de bijbehorende migratiefactor berekenen, op voorwaarde dat alle andere parameters bekend zijn.

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1. Introduction

1.1 General

Descriptive models have been developed as part of the “Risk assessment for the consumer” project, to estimate and assess the exposure to substances from consumer products and the uptake of these by humans. A PC-based computer program called CONSEXPO is used for the calculations. When a model is chosen in CONSEXPO, and the required parameters are filled in, the program calculates the exposure to, and the uptake of, the substance involved.

The large number of consumer products means that it is not possible to determine exposure models and parameter values for each individual product. A limited number of main categories of similar products have therefore been defined. Examples of the main categories are: paint, pesticides, cosmetics and floor covering. The relevant information with respect to the estimate of exposure to, and the uptake of, substances from consumer products is given in a fact sheet for each of the main categories. This fact sheet gives information for the main category children’s toys. The fact sheets are set up to act as a source of data for the users of CONSEXPO. Basic information is collected in the fact sheets to be able to assess the exposure to, and the uptake of, substances from toys.

Hazardous substances can occur in children’s toys and relatively little is known about the exposure via toys. A risk-analysis might be necessary for toys, as health problems could arise due to the release of substances from toys.. The questions that arise with respect to the exposure are:
- how children handle toys,
- which toys are put in the mouth,
- with which toys children have intensive contact,
- to what extent substances are released from the toys.

1.1.1 Reading guide

Section 1.2 gives more details on the CONSEXPO computer model. The way in which the calculations of exposure to, and the uptake of, substances from children’s toys are carried out in practice is discussed in section 1.3. In section 1.4, the principles behind the fact sheets are described, including the boundary conditions under which the data is estimated and the way in which the reliability of the data is indicated. Section 1.5 is dedicated to the inhomogeneity of substances in children’s toys. Finally, section 1.6 deals with the length, weight and surface of body parts of children of various ages.

Each of the exposure categories, ingestion, mouthing, inhalation, skin contact and eye contact, is then treated in a separate chapter (chapters 2 to 6). The conclusions about the methods used and the filling in of the parameter values are given in chapter 7.

1.2 Use of the modeling tool CONSEXPO

CONSEXPO is a set of coherent, general models to be able to estimate and assess the exposure to substances from consumer products and their uptake by humans. The program is built up using data about the use of products and from mathematical concentration models. The program is based on relatively simple exposure and uptake models. The starting point for these models is the route of exposure, i.e. the inhalatory, dermal or oral route. The most appropriate exposure scenario and uptake model is chosen for each route. The parameters needed for the exposure scenario and the uptake models are then filled in. It is possible that exposure and uptake occur simultaneously by different routes. In addition to data about the exposure and uptake, contact data is also needed, such as the frequency of use and the duration of use. Using the data mentioned above, CONSEXPO calculates the exposure and uptake. The model is described in detail in Van Veen[34].

The version 3 of CONSEXPO is also able to do the reverse. It can calculate back, based on some (toxicological) limit value of the substance, and so can work out one of the other parameters. For children's toys, we can make use of this possibility by starting with the amount of a particular substance that a child may take (e.g. the maximum amount which may be taken in, as defined in a standard) and calculating one of the other parameters. In this way, we can determine the relationship between the amount of a certain substance that may be taken in and the migration or the leaching factor, for example. This is visualized in figure 1.

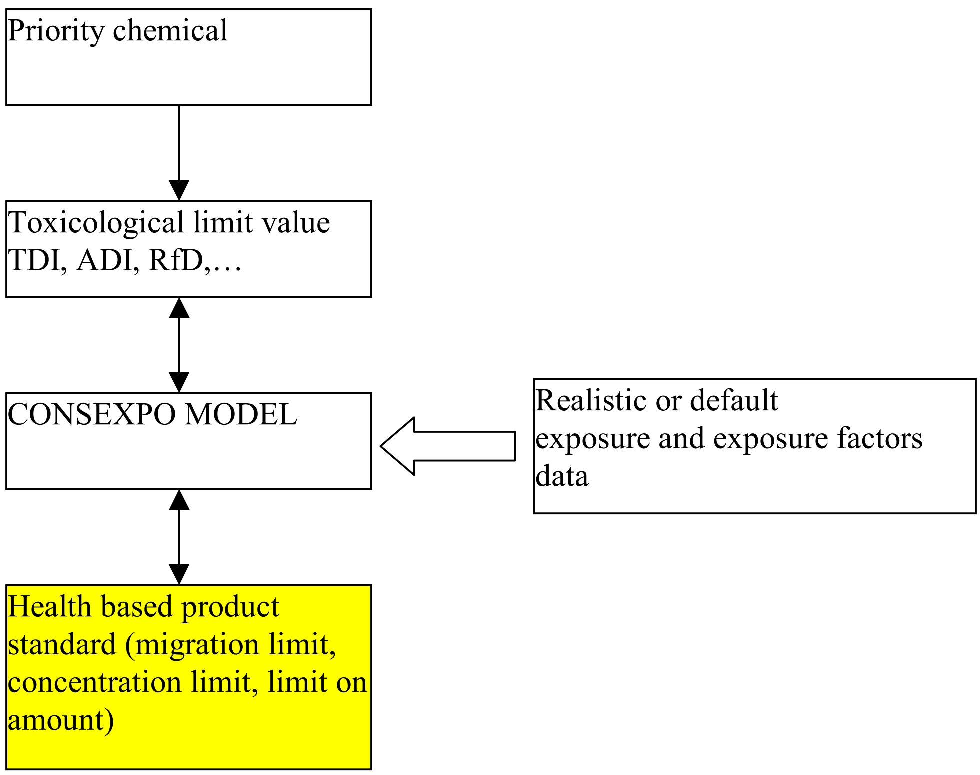

Figure 1: information flow for the calculation of health based standards

CONSEXPO calculates the release of substances from toys in a standardized manner. It does not only perform point calculations, but it is also able to perform distributional analysis and sensitivity analysis. The program is publicly available.

1.3 Exposure characterization

For the fact sheet on children's toy's, we have classified the ways in which children can be exposed. The previous fact sheets were based on main categories of product groups (such as paint and cosmetics), defined with a similar exposure (examples of product categories are latex masonry paint and sun tan lotions).
We have not chosen this approach here, since there is only a marginal relationship between the groups of products and exposure to those products, or in other words a marginal relationship between the type of toy and the exposure which that type of toy causes. A large number of toys are mouthed (sucked and chewed), including toys which are not made for that purpose, such as cars, pens and clothes. In a classification into the type of toy, almost every category would have to list "mouthing" as the exposure method. It is much easier to describe the exposure method itself, i.e. mouthing, and to categorize the different types of toys in that way. Table 1 shows all possible methods of exposure in the form of exposure categories. If other scenarios and models and used for a certain exposure, a new exposure category is defined. If methods of exposure can be distinguished on essential points, for example, because the duration or intensity varies significantly, a separate exposure category is also defined. One or several representative examples are given for each exposure category. Default models are chosen for these representative examples, and the default parameter values are filled in. Using these representative example defaults, it is possible to deduce the default values for an exposure route of any random type of toy.

The default models and default parameter values are available for users and computer applications via a database.

The categorization into relevant routes of contact that is used by the European committee for standardization, the CEN (Comité Européen de Normalisation) (Technical committee 52/Working Group 9) is similar to the one used in this study. The CEN uses the subdivisions: ingestion, mouthing, inhalation, skin contact and eye contact. This classification is refined in exposure categories, so that all methods of exposure to children's toys can be shown. The exposure categories are shown in table 1.

1.3.1 Link between exposure category and type of toy

An individual toy can cause exposure in different ways. A cuddly toy can be mouthed, but there will also be intensive dermal contact with the hands and face. In table 2 (page 10-11), the link between the type of toy and possible methods of exposure are indicated. Types of toys are linked to exposure categories, whereby exposure to, and uptake of, substances from the toy in question is possible. In table 2, this link is given for all representative examples mentioned in table 1, i.e. for all types of toy for which a default is described.

Table 1: exposure categories

Exposure category	Examples [age category[1)]]
Mouthing	
toys meant for mouthing	teething ring [1]
other toys	cuddly toy [2], plastic doll [2]
Ingestion	
direct ingestion	modeling clay [5], paint from toy car [4], ball pen [6]
hand-mouth contact, direct	finger paint [4], chalk[5]
hand-mouth contact, indirect	face paint[4]
Inhalation	
evaporation from liquids	felt pen[5]
evaporation from solid products	tent [2]
dust	chalk [5], cosmetics (blusher) [5]
Skin contact	
leaching from solid products	cowboy suit [5], tent ground sheet [1] cuddly toy [2]
rubbing off	tent canvas [2], preserved wood[5]
application on the skin	cosmetics [5], face paint[5]
intensive hand contact	modeling clay [5], finger paint [4]
spillage	poster paint [5]
Eye contact	
leaching from solid products	diving goggles [5]
application on the skin near the eyes	cosmetics (eye shadow) [5], face paint[5]
evaporation from solid products	diving goggles [5]
hand-eye contact	finger paint [4], chalk[5]

1) see table 4 for the age categories

1.3.2 Method of working

The following method is used to estimate the exposure to, and the uptake of, substances from a certain toy.

- For a particular individual toy, the methods of exposure that can occur are defined and described using the link between the exposure and type of toy (in table 2).
- The most appropriate representative examples are chosen for each exposure category.
  Default models with default parameter values are given for the exposure category (or categories). The chosen default models of the exposure category in question can always be used. Most of the default parameter values can also be applied.
- Some parameters depend on the type of toy; these should still be filled in for every type of toy.

For example, the default is described for paint that is mouthed from a toy car and is directly ingested (see section 3.2.2). The default can also be used for a pencil from which the paint is sucked off.

Table 2: relationship between exposure category and type of toy (from the representative examples)

type of toy / exposure category	teething ring	cuddly toy	plastic doll	modeling clay	paint from a car	ball pen	finger paint	chalk	face paint
Mouthing									
toys meant for mouthing	X								
other toys		X	X			X			
Ingestion									
direct ingestion				X	X	X	X	X	
hand-mouth contact, direct				X			X	X	X
hand-mouth contact, indirect									X
Inhalation									
evaporation from liquids									
evaporation from solid products									
dust								X	
Skin contact									
leaching from solid products		X	X		X				
rubbing off									
application on the skin									X
intensive hand contact				X			X		
spillage									
Eye contact									
leaching from solid products									
application on the skin near the eyes									X
evaporation from solid products									
hand-eye contact				X			X	X	X

Table 2 (contd.): relationship between exposure category and type of toy (from the representative examples)

type of toy / exposure category	felt pen	tent, canvas	cosmetics	cowboy suit	tent, ground sheet	preserved wood	poster paint	diving mask
Mouthing								
toys meant for mouthing								
other toys	X							
Ingestion								
direct ingestion	X							
hand-mouth contact, direct			X				X	
hand-mouth contact, indirect			X					
Inhalation								
evaporation from liquids	X							
evaporation from solid products		X						
dust			X					
Skin contact								
leaching from solid products				X	X			
rubbing off		X				X		
application on the skin			X					
intensive hand contact								
spillage							X	
Eye contact								
leaching from solid products								X
application on the skin near the eyes			X					
evaporation from solid products								X
hand-eye contact			X					

In fact, some default parameter values should then be adapted, such as the amount which is taken in daily and the age and associated body weight.
It is not possible to show default values for all types of toys, due to the huge numbers involved. In chapters 2 to 6, guidelines are given for each of the exposure categories ingestion, mouthing, inhalation, skin contact and eye contact, to be able to carry out the above-mentioned changes to the default values.

1.4 Fact sheets

1.4.1 General

This report is one of a series of fact sheets that describe main categories of consumer products, such as paint, cosmetics and pest control products. The fact sheets give information that is necessary when estimating and assessing the exposure to, and the uptake of, substances from consumer products.

A separate general fact sheet gives general information about the fact sheet [19], and deals with subjects that are important for several main categories. The general fact sheet gives details of:

- the boundary conditions under which the defaults are estimated,
- the way in which the reliability of the data is shown,
- ventilation and room sizes,
- the surface of (parts of) the human body.

The fact sheets follow the principle described in the general fact sheet[19)]. This means that the fact sheets bring together information about the exposure to chemical substances for a product or an exposure category. These categories are chosen so that products with similar exposures can be combined. On the one hand, the fact sheet gives general background information, while on the other hand, it quantifies exposure parameters, which together with an exposure model produce a quantitative estimate of the exposure.

1.4.2 Boundary conditions

Toy definition
This report describes the exposure and the uptake of substances by children, caused by playing with toys. Children also play with materials that do not fall into the ‘toys’ category; these are generally referred to by the term "play goods". Examples of these are: an item of clothing, a piece of paper, a book for adults, and flatware (knives, forks or spoons). Play goods are not investigated in this fact sheet.

Children can also be exposed to substances from products other than toys. Think, for example, of substances that are released when camping in a tent. This exposure is not dealt with in the current fact sheet. The exposure caused by playing in a toy tent is included. There are considerable differences between camping and playing in a tent, with regards to the duration and the frequency of exposure, for example.

“Reasonable worst-case” estimate
The parameter values are chosen such that a relatively high exposure and uptake are calculated, between the 95th and 99th percentile of the distribution. To achieve this goal, the 75th or the 25th percentile is calculated or estimated for all parameters. The 75th percentile

is used for parameters which give a higher exposure for higher values, and the 25th percentile is used in the reverse case. For a significant number of parameters, there is too little data to calculate the 75th or 25th percentile. An estimate is then made which corresponds to the 75th or 25th percentile. In such cases, the 75th/25th percentile should be seen as a guideline. The end result is a "reasonable worst-case" estimate for children who play with a certain type of toy relatively often, and then under less favorable circumstances. It is also assumed that children play with certain toys from a relatively young age. Uptake is usually expressed in amounts per kilo of body weight. For the same exposure, this uptake is larger for younger children because they have a lower body weight. In the general fact sheet[19)], the boundary conditions under which these defaults are estimated are dealt with in more depth.

1.4.3 Reliability of the data

A number of parameters are difficult to estimate based on the literature sources, published and unpublished research. If we choose not to include these parameters, no quantitative exposure estimates can be carried out. This is why a quality factor (Q-factor) is introduced in the general fact sheet, which is, in fact, a grading system for the value of the estimate of the exposure parameter. These Q-factors are shown in table 3. A low Q-factor indicates that the default is based on insufficient (or no) data, and is an obvious worst-case estimate. If such a default is used in an exposure analysis, it should be looked at and actually adapted. High Q-factors indicate that the defaults are based on sufficient (or a lot of) data. These defaults generally require less attention. It is possible that they will need to be adapted if the exposure scenarios require it. For example, an exposure estimate might be carried out for a room of a particular size; the well-founded default room size would then need to be replaced by the required value.

A Q-factor is given to all parameter values in the fact sheets, indicating the reliability of the estimate of the default value. The quality factor can have a value of between 1 and 9. Table 3 shows a summary of the meaning of the values of the quality factor. The value of the quality factor is examined in more detail in the general fact sheet[19)].

Table 3: value of quality factor Q

Q	value
9	ample and good quality data
8	good quality data
7	quality and number of studies satifactory
6	good useable, but open to improvement
5	few data, parameter value is usable as default value
4	single data source supplemented with expert judgment, parameter value doubtfull as default value
3	single data source supplemented with expert judgment, parameter value not reliable as default value
2	educated guess from similarities with other products
1	educated guess, no data

1.5 Toy composition, inhomogeneity

The substances to be examined in toys are not always homogeneously distributed. The toy can be made up of several materials, whereby the substance to be investigated is present in one or more of the materials. In a painted toy metal car, there is a metal layer and a paint layer. Another example is a cuddly toy which is made from different sorts of textile and which is filled with a synthetic foam filling. There are also types of toys where the substance to be investigated is not homogeneously distributed in the material. An example of this is wooden playground equipment, whereby the wood has been preserved using a preservative. From the time of treatment, the concentration of the preservative in the wood will decrease with the distance from the surface.

Multiple materials
For toys made from several materials, which have no influence on each other, we only consider those materials that contain the substance to be investigated. In the example of the painted metal car, whereby the substance to be investigated is present in the paint layer, the paint layer is taken to be the object under investigation.

Inhomogeneous distribution
From the remainder of this study (chapters 2 to 6), we learn that if a substance to be investigated is inhomogeneously distributed in a material, the parameter which describes the migration of the substance to be investigated from the product to man is the crucial parameter, allowing us to make a sound estimate of the exposure. This is a parameter that depends on the substance that migrates and the material from which it migrates. It is not possible to make an estimate of this parameter based on the currently available data. To make

a sound estimate of the exposure, the migration parameter should be empirically determined. Because the migration parameter is empirically determined, any inhomogeneous distribution of the substance to be investigated is of secondary importance. Any inhomogeneity is initially important since an estimate of this parameter is made for a new substance/product combination, based on a number of conditions of the migration-parameter.

1.6 Length, weight and surface of body parts

In the representative examples in table 1, one or more age categories are shown. Default models for default parameter values have been worked out for these ages. In each case, we have chosen the age category for which the highest exposure is expected. In practice, it means that the youngest children who played with a certain type of toy were chosen for the defaults. The youngest children are the lightest and, barring exceptions, have the highest uptake per kg of body weight for the same exposure. The age categories are shown in table 4. When applying default values, it is not possible to work with time periods. For example, you cannot attribute a body weight to a child of 3 to 6 months, you must choose a point in time (4.5 months).

In the age periods, as given in table 4, the legal limit of 3 years is taken into account; other standards apply below this age for certain types of toy. In addition we also have taken into account the exposure of older children as requested by of the Ministry of Health Welfare and Sport. We also looked at the age categories used in the literature, so that data from the literature does not have to be "translated" to a different age group. The body weight and body surface corresponding to the chosen body categories are shown in table 5. The data comes from the general fact sheet. When choosing the ages for the body category defaults, we have taken into account the data that is known about the body weight and body surface of children. In the general fact sheet, the relative body surfaces "arms and legs" and "legs and feet" are not split up for children. This division however is necessary for this fact sheet.

In the EPA's "Exposure factors handbook" [12)], the surfaces of arms and hands, and of legs and feet are given separately. The measurements for each age group concern only one or a few children. For this reason, the determinations for children from 0-3 years, from 3-9 years, and from 9-14 years have been combined. For these age categories, we calculated the relative proportion of the hands with respect to the total of the hands and arms. Using this data, and based on the data from the general fact sheet, the data for hands and arms was split into the surface for the hands and the surface for the arms. For "legs and feet", the splitting up into "legs" and "feet" was carried out in a similar way.

Table 4: age categories

age category	period	default value
1	3 - 6 months	4.5 months
2	6 -12 months	7.5 months
3	12-18 months	13.5 months
4	18-36 months	18 months
5	3- 9 year	4.5 year
6	,,	6.5 year
7	9-14 year	12.5 year

Table 5: defaults of body weight and body surface of children

age category	age	body weight		body surface		body surface in %						
		[kg]	Q	[m^2]	Q	head	trunk	arms	hands	legs	feet	Q
1	4.5 months	6.21	8	0.346	7	19.5	32.8	12.1	5.1	23.5	7.0	5
2	7.5	7.62	8	0.398	7	18.5	33.5	12.2	5.2	23.6	7.0	5
3	13.5	9.47	8	0.467	7	16.9	34.3	12.6	5.3	23.8	7.1	5
4	1.5 years	9.85	8	0.480	7	16.2	34.0	13.0	5.15	25.05	6.6	6
5	4.5	16.3	8	0.709	7	13.4	33.05	14.0	5.5	26.95	7.1	6
6	6.5	20.6	8	0.841	7	12.5	33.45	13.95	5.5	27.35	7.2	6
7	12.5	39.3	8	1.31	7	9.8	33.15	13.9	5.7	30.0	7.4	6

2. Mouthing

2.1 General

When we talk about mouthing, we should think of:
- purposefully mouthing a teething ring or pacifier
- mouthing a cloth or a cuddly toy in bed,
- mouthing an item of clothing during the day.

Mouthing defines everything whereby children put an object in the mouth, except food and drink; sucking, biting and licking therefore also fall under mouthing.

For toys that are mouthed, the "leaching from product" scenario is suitable to calculate the exposure. The parameters below are needed for this scenario:
- concentration in the product [mg/kg]
- initial leaching rate [g/(cm^2 x min)
- weight of the toy[g]
- density of the individual toy [g/cm^3]
- the surface in contact with the mouth [cm^2]
- duration of contact [min]

2.1.1 Duration of contact

In an extensive study by Groot et al[1)], the time for which children up to 3 years of age mouth is separated into 4 age categories. The length of time that various types of toys are mouthed is indicated. The most important data for the current study is shown in table 6. In total, the mouthing times of 42 children are involved in the study. Note that it concerns the mouthing time during the day.
A cloth that is mouthed is counted as "non toys", as are all items of clothing that are mouthed. A cuddly toy that is mouthed falls into the category "other toys". Groot et al[1)] researched mouthing behavior during the day; mouthing a cloth or a cuddly toy during the night was not included.

Table 6: mouthing time of children per age category, during the day (Groot et al[1)])

age [months]	average mouthing time, during the day [minutes a day] (s.d.)					
	pacifier	toys meant for mouthing	other toys	non toys	fingers	total
3-6	94.9	3.4 (5.1)	11.3 (10.0)	2.8 (2.8)	20.5 (18.8)	131.8
6-12	27.3	5.8 (11.4)	22.1 (28.5)	9.4 (8.4)	7.5 (11.6)	71.3
12-18	17.3	0.0 (0.1)	3.6 (3.5)	7.2 (14.2)	5.8 (14.9)	33.6
18-36	20.8	0.0 (0.0)	1.1 (1.2)	2.0 (3.4)	6.3 (9.1)	30.1

Toys meant for mouthing: all kinds of teething rings, some rattles.
Other toys: cloth books, plastic books, cuddly toy
Non toys: a piece of cloth, a piece of paper, a book for adults, flatware

Juberg et al.[35] recently published an investigation into mouthing behaviour of young children, summarized in table 7. Except for the pacifier, the mouthing durations are similar to those published by Groot et al. Mouthing durations for pacifiers are much longer in Juberg et al., perhaps due to the fact that Juberg et al. studied mouthing for 24 hours, while Groot et al. took only diurnal durations in consideration. The data from Groot et al. have been used to develop defaults.

The default values for the mouthing times for children were calculated based on the data from Groot et al. in table 6. The defaults are shown in table 8. The 75th percentile is calculated from the mouthing times as shown by Groot et al. Results are multiplied by a factor of 1.5 to include the nighttime. For mouthing times on a pacifier, only average times are known and no standard deviations. For toys, non toys and other toys, it turned out that there was a factor 3 between the default value and the average mouthing times during the day. This factor is also used to calculate the default values for the mouthing times on a pacifier based on the average mouthing times during the day.

Table 7: average daily mouthing time of children (Juberg et al.[35])

age [months]	average daily mouthing duration [min]			
	pacifier	teether	plastic toy	other objects
0-18				
all participants (n=107)	108	6	17	9
only those who mouthed object (number)	221 (52)	20 (34)	28 (66)	22 (46)
19-39				
all participants (n=110)	126	0	2	2
only those who mouthed object (number)	462 (52)	30 (1)	11 (21)	15 (18)

Table 8: default mouthing times for children

age [months]	default mouthing times [minutes a day]				Q
	pacifier	toys for mouthing	other toys	non toys	
4.5	285	11	27	8	7
7.5	82	21	63	23	7
13.5	52	0	9	26	7
18	62	0	3	6	7

2.1.2 Leaching rate

The leaching rate is the amount of a substance that is released from a certain product by mouthing, per unit time. The leaching rate depends on the sort of material that is mouthed and on the substance that is leached. The way of mouthing, and the shape and thickness of material, are also important. For exposure characterisation, the leaching rate is an essential parameter. The leaching of a substance from a certain product is only known for a few substance/product combinations. We will summarize the data found about the leaching rate below.
For standard setting, the leaching rate is the end result of the calculations. The standard setting procedures results in an upper limit for the leaching rate.

In Könemann [4)], a study of volunteers (using 20 adult volunteers) is described to determine the leaching rate of the plasticizer DINP (di-isononylphthalate) from PVC by mouthing. An area of 10 cm^2 was mouthed on three objects for 15 minutes. The leaching rate of the three PVC objects turned out to be 0.138, 0.244, and 0.163 µg/ (cm^2 x min), respectively. The pH of the saliva was determined repeatedly; for the three objects it was on average 7.31, 7.26, and 7.38, respectively.

The leaching of textile dyestuffs with synthetic saliva is described by the "Ecological and Toxicological Association of the Dyes and organic pigment manufacturers" (ETAD) [22)]. An acidic (pH 2.5) and basic (pH 8.6) synthetic saliva were used. Sixteen grams of fiber were shaken for 4 hours in 60 ml of simulated saliva at 37 °C. The average results are shown in table 9. In section 5.2.2, a similar extraction procedure is described for the leaching of clothes due to sweat.

In this study, we assume that regularly washed clothing will result in a total exposure to a substance which is a maximum of 10 times the amount extracted during the leaching tests, such as the one described above. This factor of 10 is derived from this and another study by the ETAD[21)], where leaching tests are described after the clothing has been washed many times (up to 29 times). This factor of 10 is also used for the leaching of AZO-dyestuffs from clothes by Zeilmaker et al[6)].

During the ETAD test[22)], the product is shaken for 4 hours with a saliva simulant. The leached amount will probably not increase further after 4 hours; an equilibrium is reached. The tests do not indicate how quickly any equilibrium can be reached. It is not possible to give a reliable estimate of the leaching of this dyestuff per unit time using this data.

Table 9: leaching parameters of extraction of dyestuffs from textiles with saliva simulant

product	material	dyestuff-class	leaching factor [µg/cm^2]	leach rate [µg/(cm^2 x min)]	Q
baby-wear	wool	acid	0.54	3.6×10^{-2}	3
baby-blankets	wool	acid	0.075	5.0×10^{-3}	3
toy textiles	PA	acid	0.070	4.7×10^{-3}	3
toy textiles	PAC	basic	0.027	1.8×10^{-3}	3
fabric	wool	acid (1:2 Cr. complex)	0.037	2.5×10^{-3}	3

To be able to the make an estimate about the leaching per unit time based on the leaching factors, it is assumed that the situation as measured after 4 hours shaking with saliva stimulant is already reached after 15 minutes. The value of the leaching rate is calculated based on this assumption.

The leaching rate is calculated here for a *dyestuff class*, while the leaching rate is a substance-parameter which depends on the substance which is leached and the material from which the leaching takes place. The leaching rate is therefore substance-dependent, depending on the dyestuff class and the group of substances. The calculated value is not more than a crude indication, showing the order of magnitude.

The calculated values in table 9 are given a quality factor Q of 3, based on the considerations above.

2.2 Defaults for mouthing

2.2.1 Teething ring (DINP from PVC)

	default value	Q	references, comments
Child 4.5 months			
body weight	6.21 kg	8	see 1.6
Contact			
frequency	365/year	7	see table 8, toys for mouthing
total duration	11 min	7	see table 8, toys for mouthing
use duration	11 min	7	see table 8, toys for mouthing
Oral			
Exposure: leaching from product			
product volume	20 cm^3	4	estimation 20 g, density 1g/cm^3
leach rate DINP from PVC	0.244 μg/(cm^2 x min)	7	see above
area	10 cm^2	6	4)
uptake: fraction model			
absorbed fraction	1	7	potential dose

2.2.2 Cuddly toy (acid dyestuff from wool)

	default value	Q	references, comments
Child 4.5 months			
body weight	6.21 kg	8	see 1.6
Contact			
frequency	365/year	7	see table 8, other toys
total duration	27 min	7	see table 8, other toys
use duration	27 min	7	see table 8, other toys
Oral			
Exposure: leaching from product			
product volume	50 cm^3	4	estimation, "skin" cuddly toy 45 g, density 0.9 g/cm^3
leach rate of acid dyestuff from wool	$3.6x10^{-2}$ $\mu g/(cm^2 x min)$	3	see table 9
area	10 cm^2	6	4)
uptake: fraction model			
absorbed fraction	1	7	potential dose

2.2.3 Plastic doll (DINP from PVC)

	default value	Q	references, comments
Child 7.5 months			
body weight	7.62 kg	8	see 1.6
Contact			
frequency	365/year	7	see table 8, other toys
total duration	63 min	7	see table 8, other toys
use duration	63 min	7	see table 8, other toys
Oral			
Exposure: leaching from product			
product volume	100 cm^3	4	estimation, doll 100 g, density 1 g/cm^3
leach rate DINP from PVC	0.244 $\mu g/(cm^2$ x min)	7	see above
area	10 cm^2	6	4)
uptake: fraction model			
absorbed fraction	1	7	potential dose

3 Ingestion

3.1 General

If a child puts an object in its mouth, pieces of the object can break away, and these can be swallowed. We should think here of instances such as the more or less conscious eating of a little piece of chalk, or the ink out of a felt pen, and the chewing of a pencil or a ball pen. When toys are mouthed, pieces can also break off and be swallowed, such as paint from the metal toy car, for example. Apart from putting objects in the mouth, substances can be taken in by hand-mouth contact. Here, we distinguish between direct hand-mouth contact, for example by playing with finger paint, and indirect hand-mouth contact, for example face paint which is applied by een third party and rubbed off by hand through the child.

3.2 Defaults for direct ingestion

The exposure via the direct ingestion of amounts of a product can be calculated using the "single ingestion" scenario. The parameters are:
- the composition of the ingested product
- the density of the product,
- the dilution of the product before it is ingested,
- the amount of product taken in.

No measurement data was found with respect to the amount ingested, which is why estimates are made for a few specific type of toys: modeling clay, paint from a toy car, and a ball pen. For 'paint from a toy car', the default age of a child is taken to be 18 months; the mouthing time of "other toys" for children of 18 months (see tabel 8) is taken as the default contact time.

3.2.1 Modeling clay

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	52 /year	4	estimation
total duration	60 min	4	estimation
use duration	60 min	4	estimation
Oral			
single ingestion			
product volume	0,5 cm^3	4	estimation
density	2 g/cm^3	5	estimation
uptake: fraction model			
absorbed fraction	1	7	potential dose

3.2.2 Paint from a toy car

	default value	Q	references, comments
Child 18 months			
body weight	9.85 kg	8	see 1.6
Contact			
frequency	150/year	4	estimation, 3x/week
total duration	3 min	4	see table 8, other toys
use duration	3 min	4	see table 8, other toys
Oral			
single ingestion			
product volume paint	0.05 cm^3	4	estimation
density	2 g/cm^3	5	estimation
uptake: fraction model			
absorbed fraction	1	7	potential dose

3.2.3 Ball pen

	default value	Q	references, comments
Child 6.5 years			
body weight	20.6 kg	8	see 1.6
Contact			
frequency	365/year	4	estimation
total duration	30 min	4	estimation
use duration	30 min	4	estimation
Oral			
single ingestion			
product volume	0.2 cm^3	4	estimation
density	1.5 g/cm^3	5	estimation
uptake: fraction model			
absorbed fraction	1	7	potential dose

3.3 Hand - mouth contact

The "hand to mouth contact" scenario can be used in CONSEXPO to describe the exposure of substances from products which are taken in orally via the hands. The parameters in this scenario are:

- the composition of the product,
- the ingestion rate (in volume-units per unit time)

No measurement data was found for substances from children's toys that are taken in orally via the hands. With regards to the oral intake of substances by hand-mouth contact, data was only found for the ingestion of soil. A significant amount of research has been carried out into this exposure. Section 3.3.1 gives the measurement data with regard to the amount of soil that children ingest per day, and the amount of soil which remains on the hands in various situations. Based on the data for the daily intake of soil, defaults are derived for the intake of substances from toys by hand-mouth contact.

Two approaches can be used to estimate the exposure by hand-mouth contact.

- The macro approach,
  whereby an estimate is made of the amount of product transferred per unit time. All processes which contributed to the transfer of a substance from the surface to the mouth are therefore described with the help of one sum-parameter.
- The micro approach,
  whereby estimates are made of all parameters which influence the process of hand-mouth contact. Here, we should think of the transfer of a substance from a surface on the hand, the hand-mouth contact frequency, and the amount of product that is transferred from the hand to the mouth each time. This last parameter depends, among other things, on the structure of the skin, the adhesion of the substance to the skin, and the condition of the skin (wet/sticky or dry).

CONSEXPO uses the macro approach. There is too less data to use the micro-approach. Of the parameters that are needed to describe hand-mouth contact via the micro-approach, we only found measurement data for the contact frequency. This data is shown in section 3.3.2.

3.3.1 Ingestion from soil

Studies have been carried out by significant number of researchers[23-29)], with relation to the ingestion of soil by children. Based on all the data, the average ingestion of soil by children is estimated at 100 mg/day, with a 75th percentile of 300 mg/day, and a 90th percentile of 500 mg/day. The various studies were carried out on children between 1 and 7 years of age.

As for mouthing, the ingestion of soil depends on the age of the child. The amount of soil ingested per day by children older than 7 years of age will be significantly less than the amount ingested by children between 1 and 7 years of age. No measurements have been found whereby the relationship between the age and the amount of soil ingested by children has been studied. The default value for the ingestion of soil is based on a child of 18 months. The default value for the amount of soil ingested by children is set at 300 mg per day.

Since the ingestion rate is important for the "hand to mouth contact scenario", i.e. the amount which is taken up per unit time, a default value of the time for which those children are in contact with the soil is also estimated. Section 5.3.1 indicates that the default value for the time which children spend outside is set at 240 minutes. A value of 60 min/day is given for the time that children between the ages of 2 and 5 spend in parks and playgrounds[15)]; for preschool children, a value of 30 - 150 minutes is given[13)]; for children between 6 and 11 years of age, 87-108 minutes is given[15)]; for children between 9 and 11 years of age 64-119 minutes is given. It is assumed that children spend 50 % of the time in these playgrounds and parks in contact with the soil. Based on these assumptions, the default value for the time that children between 1 and 7 years of age are in contact with the soil, is set at 50 minutes per day. The default value for the ingestion rate of soil by children between 1 and 7 years of age is calculated at 6 mg/min.

In addition to the amount of soil which is ingested, several studies have been carried out into the amount of adhering soil. In an overview article by Finley et al. [24)], values of 0.1 - 1.5 mg soil/ cm^2 of skin were found. The values per cm^2 of skin were comparable for adults and children. From the combined data of children and adults, an average of 0.52 was found, a median of 0.25, and a 75th percentile of 0.6 mg soil/ cm^2 skin.

Kissel et al [30)] found differences in the adhering soil with the differing soil types and different activities. Children who played in the mud had an amount of adhering soil from 6.7 mg soil/cm^2 on their feet up to 58 mg soil/cm^2 on their hands.

3.3.2 Frequency of contact

Zartarian et al.[33)] and Reed et al.[5)] have quantified the behavior of children, with respect to hand and mouthing behavior, using a videotape method. Reed et al.[5)] quantified 9 activities by a total of 30 children from 2 to 6 years of age. From this data, shown in table 10, it appears that hand-mouth contact takes place 9.5 times per hour.

Table 10: frequency of contacts per hour (Reed et al.[5])

variable	contacts per hour	90 percentile
hand to clothing	66.6	103.3
hand to dirt	11.4	56.4
hand to hand	21.1	43.5
hand to mouth	9.5	20.1
hand to object	122.9	175.8
object to mouth	16.3	77.1
hand to "other" (paper, grass, pets)	82.9	199.6
hand to smooth surface	83.7	136.9
hand to textured surface	22.1	52.2

3.3.3 Approach

The macro approach that is applied in CONSEXPO is also used for soil by the US-CPSC[11)] and the US-EPA[12)]. The US-CPSC[11)] bases its calculations on the amount of soil ingested per day, the amount of soil adhering to the hands and the surface of the hands that are contaminated by the soil. Using this data, they calculate the number of "handloads" taken in per day. A "handload" is the average amount of soil that is found on the hands during the exposure. The average amount of adhering soil is estimated by the US-CPSC[11)] to be 0.52 mg soil/cm^2. The surface of the hands of an 18 month old child is 247 cm^2 (see table 5).
The amount of adhering soil on the inside of the hands (half of the surface of the hand) is calculated at 123.5 x 0.52 = 64 mg. Section 3.3.1 indicates that the average amount of soil that is ingested by children is estimated at 100 mg per day. In other words, 100/64 = 1.6 handloads are taken in per day on average. Based on the default values of 300 mg/day ingested, and 0.6 mg soil/ cm^2 of adhering soil (the 75th percentile of the data from the US-CPSC[11)]), we can calculate that 4.0 handloads are ingested per day.

The US-EPA[12)] has defined an ingestion rate, a time-dependent hand-mouth transfer factor. They estimate that for children from 3 to 5 years of age, 1.56 times the amount present on a certain surface is transferred per hour. They use the inside surface of the fingers as the surface. Based on the value given by the US-EPA and the data from paragraph 3.3.1 (a child of 18 months; a quarter of the surface of the hand as the surface, or 62 cm^2; the average amount of adhering soil of 0.52 mg/ cm^2; 50 minutes for which a child is in contact with the soil), this would mean that, on average, 0.42 mg of soil is ingested per day. Based on the default value for the amount of adhering soil of 0.60 mg/ cm^2, we arrive at an amount of 50 mg per day.
In the "hand to mouth contact" scenario of CONSEXPO, the ingestion rate [in cm^3/min] is the most important parameter. The scenario is therefore comparable with that of the US-EPA.

3.4 Defaults for hand – mouth contact

3.4.1 General

In the "hand to mouth contact" scenario in CONSEXPO, in addition to the composition of the product ingested, the ingestion rate (in volume-units per unit time) is the only parameter that has to be estimated. As there is only measurement data for the ingestion of soil by hand-mouth contact, we have chosen to estimate the following:

- for "dry" products, i.e. products which do not immediately stick to the skin
  we could think here of a piece of chalk, for example. The estimate of the default is based on the values from the ingestion of soil.
- for products which stick to the skin
  we could think here of finger paint and face paint, for example. To define a relationship between "dry products" and "products which stick to the skin", we have made use of the data from Kessel et al.[30)], who carried out research into the amount of adhering soil in relation to the different types of soil and different activities.

Two defaults are described for direct hand-mouth contact: one for products that stick to the skin (finger paint) and one for products that do not immediately stick to the skin (a piece of chalk). A default for indirect hand-mouth contact is also described (face paint which is applied by a third party). Based on the currently available data, it is not possible to further distinguish between the products that do or do not stick to the skin. The defaults indicate an order of magnitude; they are not very reliable. This is indicated in the default by the quality factor of 3 for the ingestion rate.

It is estimated that children play with finger paint and chalk 2 times a week, and that they have their faces painted ones a month. It is assumed that children play with finger paint and chalk for 45 minutes per day. The estimate of the ingestion rate for the piece of chalk is based on soil, i.e. on the default of 300 mg per day (thus an ingestion of 300 mg in 50 minutes). The daily intake is calculated to be 45/50 x 300 =270 mg. This amount is ingested in 45 minutes; the ingestion rate is therefore 6 mg/min.
Based on the differences between soil and mud, the default value for products which stick to the skin is first estimated at an amount 5 times as large, i.e. the ingestion rate for finger paint is estimated at 30 mg/min.

3.4.2 Piece of chalk

	default value	**Q**	**references, comments**
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	100/year	4	see above
total duration	45 min	4	see above
use duration	45 min	4	estimation
Oral			
hand mouth contact			
ingestion rate	6 mg/min	3	see above
uptake: fraction model			
absorbed fraction	1	7	potential dose

3.4.3 Finger paint

default	default value	Q	references, comments
Child 18 months			
body weight	9.85 kg	8	see 1.6
Contact			
frequency	100/year	4	see above
total duration	45 min	4	estimation
use duration	45 min	4	estimation
Oral			
hand mouth contact			
ingestion rate	30 mg/min	3	see above
uptake: fraction model			
absorbed fraction	1	7	potential dose

3.4.4 Face paint

For the indirect contact with face paint, we should bear in mind that it concerns a substance that sticks to the skin and, in addition to dermal exposure, is taken in orally via the hands. It is assumed that the face paint is removed at the end of the day (default: after 8 hours; 480 min.). The total amount of face paint on the skin is 1.4 g (see: § 5.4.2). We estimate that 15 % of this is ingested per day, which means an ingestion rate of 210/480 = 0.44 mg/min. This value should be seen as an order of magnitude, which is why a quality factor Q of 3 is assigned.

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	12/year	4	see above
total duration	480 min	4	estimation
use duration	480 min	4	estimation
Oral			
hand mouth contact			
ingestion rate	0.44 mg/min	3	see above
uptake: fraction model			
absorbed fraction	1	7	potential dose

4 Inhalation

4.1 General

When we think of inhalation, we should think of more or less volatile organic compounds that evaporate from the toy. We use the solvent from a felt pen as the representative example. From the "representative" example, it appears that it is very rare for volatile organic compounds to be able to evaporate freely from toys; the volatile organic compounds are almost always restricted in one way or another. The substance that evaporates from toys can also be a less volatile organic compound, such as a fungicide that may be released from a cotton toy tent.

The parameters which are important for the evaporation from liquids (assumption of homogeneous mixture) and the parameters which are important during the release from solid products (assumption that substances have to migrate in the material) are not the same. We therefore make a distinction between the evaporation of substances from liquids and the release of substances from solid products. Section 4.2 gives details of the evaporation of substances from liquids, and the evaporation of substances from solid products is detailed in section 4.3.

Inhalatory exposure also comprises inhalation of particles, for example dust from chalk of cosmetic products like a blusher. The inhalatory intake of small particles is treated in section 4.4.

4.2 Evaporation from liquids

The "evaporation from mixture" scenario can be used for evaporation of substances in children's toys from liquids. This model is suitable for applications where a relatively small evaporation takes place. The "painting" scenario is also available, which describes the evaporation from a layer-based application. Both scenarios are based on Raoult's law. In this context, the most important difference is that the finiteness of the evaporated amount of liquid is taken into account in the painting scenario, as opposed to the "evaporation from mixture scenario”, where we assume an infinite amount of liquid. Toys usually only contain small amounts of more or less volatile organic compound. The painting scenario will therefore usually describe the process best.

The painting model is a relatively complicated model. It assumes a two-layer system, whereby the volatile organic compound evaporates from the top layer. Diffusion takes place from the lower layer to the upper layer. The choice of the default values for the parameters that describe the evaporation process are shown for various types of paint in the paint fact sheet [31]. This data is shown in appendix 2.

A default for the evaporating substances from a felt pen is described as the representative example. The volatile organic compounds will almost never be able to evaporate from toys freely, but will almost always be restricted in some way or other. This means that the chosen model describes a worst-case situation. The representative example describes the normal use of a felt pen, i.e. using the felt pen to draw with.

4.2.1 Ink from felt pen

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
Frequency	200 x/year	5	use: 4/week, estimation
total duration	45 min	4	estimation
use duration	30 min	4	estimation
Inhalation			
exposure: paint model			
ventilation	0.6 h^{-1}	8	[19)]
room size	20 m^3	8	[19)]
density ink	1.1 g/cm^3	5	estimation
molecular weight matrix	450 g/mol	4	[31)]
room temperature	20 ^oC	9	[19)]
fraction to upper layer	0.1	4	[31)]
exchange rate	0.4 min^{-1}	4	[31)]
amount ink	300 mg	4	estimation; total, all colors
area	450 cm^2	4	estimation; total, all colors
uptake: fraction model			
absorbed fraction	1	7	potential dose
inhalation rate	9.2 l/min	7	[38)]
respirable fraction	1	7	potential dose

The default can easily be adapted for the case when a child takes the felt pen apart. We can do this by changing the default values of the parameters below into the given values.

	default value	Q	references, comments
frequency	12 x/year	5	estimation
total duration	20 min	4	estimation
use duration	5 min	4	estimation
amount ink	4 g	4	estimation
area	10 cm^2	4	estimation

4.3 Evaporation from solid products

For evaporation from solid products, where we could think of fungicide evaporating from a tent or substances evaporating from plastic, Raoult's law is not applicable and the scenarios mentioned in section 4.2 can therefore not be used. One possibility would be to use the "source and ventilation" scenario. In this case, the evaporation rate from the matrix (in mg/min) must be estimated or calculated as the parameter. It is not possible to give an estimate of this parameter that is in any way reliable, based on the currently available information.

We could use the approach that the substance to be researched is not present in a matrix but as a pure substance. Under these conditions, the "evaporation from pure substance" scenario can be applied. The "evaporation from pure substance" scenario assumes evaporation of an indefinite amount of substance. If the application concerns a small amount of product, an adapted "painting" scenario can be used. This is the painting scenario whereby the parameter values are chosen so that, in practice, one substance evaporates. In practice this means choosing 10,000 for the "molecular weight matrix" and 0.999 for the "fraction to upper layer". In this way, a significant over-estimate of the exposure is obtained; we cannot make an estimate that is closer to reality at this time.

To describe a representative default set, the evaporation of a fungicide from canvas of a toy tent is described. We will base the default exposure on a toddler of 4.5 years of age that plays in the summer period (the middle of May till the middle of September) 3 times a week in the tent, adding up to 48 days a year. We estimate that the toddler plays for 3 hours a day in the tent.
Note again that the model does not describe the actual situation very well, and that a significant over-estimate of the exposure is therefore obtained.

4.3.1 Fungicide from canvas of a toy tent

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	48/year	4	see above
total duration	180 min	4	see above
use duration	180 min	4	see above
Inhalatory			
exposure: paint model			
ventilation	2 h^{-1}	3	estimation
room size	2 m^3	5	estimation
density	1 g/cm^3	5	estimation
molecular weight matrix	10000 g/mol	4	see above
room temperature	20 ^oC	4	temperature in tent
fraction upper layer	0.999	4	see above
exchange rate	0.4 min^{-1}	4	see appendix 2
product amount (weight canvas)	2000 g	5	estimation
area	9 m^2	5	estimation
uptake: fraction model			
absorbed fraction	1	7	potential dose
inhalation rate	9.2 l/min	7	[38])
respirable fraction	1	7	potential dose

4.4 Dust

The inhalatory exposure to fine particles is described with the “spray cloud model”. This model is developed to estimate exposure to aerosols, but exposure to particles falls within the assumptions of the model. The user of the product that produces particles is assumed, worst case, to have his “nose in the cloud”.

Section 3.4.2 describes the exposure to chalk by hand-to-mouth contact. The defaults for the contact scenario are copied here, resulting in a use duration of 45 minutes per day.
Emission rate formulation
It is assumed that 10 gram of chalk is used. For comparison, a normal chalk weights 5 gram, a large outdoor chalk 25 gram. We estimate that 5% of the used chalk is released as dust in the air, resulting in 500 mg. If this is released over 45 minutes, the average emission rate becomes 11 mg/minute.
Airborne fraction and particle size
The particle size plays an important role in the model because it determines how long a particle stays in the air. The model only uses the average particle size. The airborne fraction defines how much of the potential release of particles is actually released into air. The

respirable fraction defines which fraction of the inhaled particles descends in the lungs. The remainder, deposited in nose, throat or upper bronchial tract, is assumed to be swallowed and causes oral exposure. The respirable fraction depends on the particle size. Particles larger than 20 µm are all nonrespirable[36,37]. A percentage of 1.7 % of particles with a size of 10 µm are respirable[37].
No data is available for the particle size distribution of chalk dust. We will make the assumption that the smallest 10% of the dust particles have an average size of 25 µm, and that 5% has an average size of 10 µm. We will set the default for the airborne fraction to 0.05, the default for the particle size to 10 µm and the default for the respirable fraction to 1.7%. These defaults imply that less than 0.1% (0.05 x 0.017 = 0.00085) of the chalk dust is available for inhalatory exposure.

default piece of chalk	**default value**	**Q**	**references, comments**
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	100/year	4	see 3.4.2
total duration	45 min	4	see 3.4.2
use duration	45 min	4	see 3.4.2
Inhalatoir			
Exposure: spray cloud model			
emission rate formulation	11 mg/min.	3	see above
density	2 g/cm^3	5	estimation
airborne fraction	0.05 g/g	3	see above
droplet size	10 µm	3	see above
release height	100 cm	5	estimation
radius aerosol cloud	20 cm	3	estimation
room volume	20 m^3	8	19)
ventilation rate	0.6 h^{-1}	8	19)
target area	8 m^2	4	surface room
uptake: *fraction model*			
absorbed fraction	1	7	potential dose
inhalation rate	9.2 l/min	7	38)
respirable fraction	1.7 %	3	see above

To describe exposure to dust while using a powder blusher, we propose largely the same set of parameters. The contact scenario is described in paragraph 5.4.1. There we have estimated that 300 mg of blusher is used in 5 minutes time. It is assumed that 20% of this amount is released into air, being 60 mg. The emission rate of dust is therefore 12 mg/minute.

default blusher	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	12/year	4	see 5.4.1
total duration	480 min	4	see 5.4.1
use duration	5 min	4	see 5.4.1
Inhalatoir			
Exposure: spray cloud model			
emission rate formulation	12 mg/min	3	see above
density formulation	1.8 g/cm^3	5	estimation
airborne fraction	0.05 g/g	3	see above
droplet size	10 µm	3	see above
release height	100 cm	5	estimation
radius aerosol cloud	20 cm	3	estimation
room volume	20 m^3	8	19)
ventilation rate	0.6 h^{-1}	8	19)
target area	8 m^2	4	surface room
uptake: *fraction model*			
absorbed fraction	1	7	potential dose
inhalation rate	9.2 l/min	7	38)
respirable fraction	1.7 %	3	see above

5 Skin contact

5.1 General

For skin contact, we distinguish between solid products which will not stick to the skin, and products which can stick to the skin. For solid products we should think off cuddly toys and dolls which are pressed against the face, whereby a relatively small part of the skin comes into contact with the toy. A larger portion of skin can also come into contact with the toy. Examples of this are wearing a cowboy suit, lying on a bed or on the groundsheet of a tent. For certain types of toys, it is possible that substances are rubbed from the product, for example, dyestuffs from a tent and preservatives in preserved wood.

When considering products that stick, we should think of face paint, finger paint and ball pen ink, for example. A distinction is made between products which are applied to the skin, such as face paint and cosmetics, and products which come into contact with the hands during use, such as modeling clay and finger paint. We also define a final category of products which can be spilled onto the skin, such as ink and poster paint.

5.2 Leaching from solid products

5.2.1 General

The dermal exposure due to leaching of substances from solid products can be described using CONSEXPO's "migration to skin" and "contact rate" scenarios.

The crucial parameter in the "migration to skin" scenario is:
- the leaching factor, i.e. the amount of substance leached per unit weight of product [in g substance/g product].
  The leaching factor depends on the product from which the leaching takes place and on the substance that is released from the product.

The other parameters in this model are:
- the weight of the product from which the leaching takes place [g]
- the contact frequency F_{cont}, i.e. the number of times during the contact time that leaching actually takes place [$year^{-1}$],
- the "skin contact factor" F_{skin}, i.e. the fraction of the product that actually comes into contact with the skin [no dimension].

The parameters in the "contact rate" scenario are:
- the density of the product [g/cm^3],
- the weight fraction of the substance to be researched in the product [g/g],
- the contact rate, i.e. the amount of product which gets onto the skin per unit time [mg/min].

In the "migration to skin" scenario, the amount of substance which leaches per *unit weight* of product is the crucial parameter, and in the "contact rate" scenario, the amount of product which leaches per *unit time* is the crucial parameter. Both parameters are substance-parameters that depend on the substance that leaches and the material from which the substance leaches. Measurement data describing the leaching from solid products is shown in section 5.2.2. Leaching data is only available for a small number of substance/product combinations. It is not possible to make a reliable estimate of the leaching factors based on the currently available information.

Using the above models, all cases of exposure by leaching from solid products via the skin can be described. The leaching factor will almost always first need to be determined experimentally, to arrive at a reliable estimate of exposure.

Defaults are described for a cowboy suit, the groundsheet of a toy tent, and for a cuddly toy. The exposure from the cowboy suit is given with the help of the migration to skin scenario; the groundsheet of the tent and the cuddly toy are given using the contact rate scenario.

5.2.2 Leaching data

Zeilmaker et al.[6)] describe experiments whereby the leaching of AZO-dyestuffs from clothing and footwear is determined using synthetic sweat. The leaching factor was determined by shaking 1g of textile with 100 ml sweat simulant for 16 hours at 37 °C. The released amount of AZO dyestuff in the liquid was then determined. The results of the study carried out by Zeilmaker et al. are shown in table 11.
During washing, a substantial part of the dye disappears. Zeilmaker et al.[6)] determine the leaching before washing. They assume that the cumulative amount of the dye that is released during wearing of the product is equal to 10 times the leaching of the new unwashed product. To calculate the leaching Zeilmaker et al.[6)] use the initial leaching and set the contact frequency (F_{cont}) of products that are washed to be 10. A contact frequency of 20 or 30 (see table11) means that two or three of that products are used a year.
For the products that are not washed, the contact frequency is equal to the frequency of use
The data from table 11 gives the leaching of AZO-dyestuffs from textile and leather. The leaching factor would have to be determined again for all other substances in each material.

Table 11: leaching parameters of AZO dyes from garments and footwear (Zeilmaker et al.[6)])

product	material	AZO dye	leaching factor [g/g]	F_{cont} [year $^{-1}$]	F_{skin}
underwear	unknown	benzidine	0.0005	30	1
underwear	silk	benzidine	0.0018	30	1
legging	cotton-elastine	benzidine	0.0016	20	1
blouse	silk	o-tolidine	0.0014	20	0.55
lining of a coat	polyamide	o-dianisidine	0.0045	10	0.19
,,		o-tolidine	0.0051	10	0.19
,,		benzidine	0.037	10	0.19
slipper	textile	benzidine	0.01	150	0.1
slipper	textile	2,4-toluenediamine	0.0009	150	0.1
shoe (upper side)	leather	benzidine	0.149	150	0.1
sport shoe (upper side)	leather	o-dianisidine	0.39	150	0.01

Data about leaching after wearing and washing clothes is described by ETAD[21)]. Three parts of textile with three different dyestuffs were washed 28 times. The leaching was determined after the 1st, 2nd, 3rd, 4th, 17th and 28th time of washing, using synthetic perspiration; the leaching from the unwashed material was not determined. The leaching is shown in table 12. Leaching tests of dyestuffs from various sorts of textiles are described in ETAD[22)]. The leaching tests are carried out using two different leaching procedures and with an acidic and basic synthetic perspiration. The leaching factors shown in table 13 are the average results of these procedures.

Table 12: leaching of dyestuffs from textiles after washing (ETAD[21)])

	leaching [µg dye/cm^2] after .. times of washing with acid perspiration simulants						
product	1	2	3	4	5	17	29
disperse yellow 3	0.017	0.017	0.011	0.011	0.008	0.006	< 0.003
disperse blue 3	0.011	0.009	0.019	0.009	0.009	0.009	0.004
acid red 114 [a)]	0.023	0.009	0.009	0.009	0.009	0.009	0.009

a): synonym of AZO-dyestuff o-tolidine

Table 13: leaching parameters of extraction of dyestuffs from textiles

product	material	dyestuff-class	leaching factor [g/g]
stockings	PA 66	acid	1 e-3
socks	PA 66	acid	5 e-5
tricot bathing wear	PA 6	acid	4 e-4
socks	wool	acid	1 e-4
socks	wool-nylon	acid	1 e-3
socks	cotton	vat	nd
socks	cotton	reactive	3 e-4
stockings	PA	disperse	6 e-3
pantyhose	perlon	disperse	2 e-4
underwear	cotton	vat	nd
underwear	cotton	vat	nd
underwear	cotton	reactive	1 e-3
underwear	knitted cotton	reactive	nd
sheets	cotton/PES	vat	nd
baby wear	wool	acid	2 e-2
blankets	wool	acid	1 e-3
toy textiles	PA	acid	7 e-4
toy textiles	PAC	basic	7 e-4
fabric	wool	acid	5 e-4
yarn	polyester	disperse	nd

nd: not detectable

5.2.3 Cowboy suit (with AZO-dyestuff benzidine)

A cowboy suit is worn during play. It is assumed that such a suit is worn for 30 days in a year, for 8 hours per day. Is also assumed that the suit is washed after being worn 3 times. Based on this data, it is assumed that the contact frequency, i.e. the number of times that contact actually takes place with the benzidine, is equal to the maximum number for products which are washed periodically, i.e. 10 (see section 5.2.2). This value (10 times a year) is given as the default value of the contact frequency, and not the number of days a year (30 days a year) that the suit is worn. By defining the contact frequency in this way, the "total duration" and the "use duration" must be read as the wearing time between two washes. As indicated above, the washing time between two washes is 3 days of 8 hours, or 1440 minutes.

We will base the default exposure on a toddler of 4.5 years old. Underwear is normally worn under the cowboy suit. For the calculation of the skin-contact factor, i.e. the part of the product that is actually in contact with the skin, it is assumed that 2/3 of the suit is in direct contact with the skin (F_{skin} =1) and 1/3 is worn on top of underwear (F_{skin} = 0.1). The skin-contact factor then becomes 0.67 x 1 + 0.33 x 0.1 =0.7. The surface concerns the whole surface of the skin, excluding the head, hands, and feet; the default value for this surface is shown in table 5 and is 5247 cm^2. For the surface that is actually exposed, this value must be multiplied by the skin-contact factor of 0.7, resulting in 3673 cm^2.

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	10/year	4	see above
total duration	1440 min	4	see above
use duration	1440 min	4	see above
Dermal			
Exposure: migration			
weight cowboy suit	400 g	3	estimation
leaching factor of benzidine from cotton	0.0016 g/g	5	see: table 11
skin contact factor	0.7	4	see above
uptake: diffusion model			
exposed area	3673 cm^2	5	see above
blood volume	367 cm^3	4	20)
skin blood flow	51 cm^3/min	4	42)

5.2.4 Tent ground sheet (with plasticizer DINP)

To describe a representative case of exposure, we will use exposure to DINP (diisononyl-phthalate) in the ground sheet of a toy tent. We will base the default exposure on a toddler of 4.5 years of age that plays in the summer period (the middle of May till the middle of September) 3 times a week in the tent, adding up to 48 days a year. We estimate that the toddler plays for 3 hours a day in the tent.
The "contact rate" scenario is used as the model to describe the exposure, since this scenarios includes a time-dependent leaching factor, as opposed to the "migration to skin" scenario, which is based on a time-independent leaching factor. In the contact rate scenario, the crucial parameter is the contact rate, i.e. the total amount of product that comes on the skin per unit time (in mg per minute). For a number of applications, when applying biocides, for example, this is a very easy measure. For applications, where intensive contact takes place with part of the skin, a parameter per unit of surface is a more manageable measure. For this reason, the surface that is in direct contact with the skin is calculated first.
If indirect skin contact takes place, the exposed surface is multiplied by a weighting factor G. Indirect contact is caused by penetration of the substance though clothing. The weighting factor G indicates the fraction between exposure by indirect skin contact compared to direct skin contact. The surface with which a direct, intensive skin contact takes place is calculated in this way. The contact rate per unit surface is multiplied by this surface to calculate the contact rate for the total amount of product that comes onto the skin per unit time (in mg product per minute). The contact time is defined as the time that the child is actually in contact with the product.
It is assumed that the child stays in the tent for 3 hours a day (total duration: 180 minutes). For the default value, it is assumed that the child is actually in contact with the ground sheet during the whole period. The surface of the child's skin that actually comes into contact with the ground sheet during the contact time of 180 minutes is calculated as follows (see section 1.6 for the surfaces).
Direct contact; when crawling, 1/5 of the legs and half of the hands (577 cm^2), when lying down a third of the head, arms and hands, legs and feet (1560 cm^2).
Indirect contact; when lying down, half of the trunk (1172 cm^2), when crawling none. The weighting factor G of 0.1 is applied for indirect contact. If we assume that a child crawls for 20% of the contact time, and lies down for the rest of the time, then we can calculate that an average surface of 1457 cm^2 (0.2 x 577 + 0.8 x 1560 + 0.8 x 1172 x 0.1) is actually in contact with the ground sheet during the contact time. The contact rate (in mg/minutes) of DINP from PVC is unknown. Detailed studies have been carried out into the amount of DINP that is released by mouthing on PVC that contains DINP (see section 2.1.2). The default value for the leaching rate of DINP by mouthing is 0.244 μg/ cm^2 x min (see section 2.3). For 1457 cm^2, this means a leaching of 356 μg/min. The "contact rate" is probably considerably lower than this value. To make a reliable estimate of the exposure, the contact rate should be determined empirically. In the default, the value calculated above is shown as the upper limit, as an indication. A quality factor Q = 3 is given to indicate that this value is not reliable.

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	48/year	4	see above
total duration	180 min	4	see above
use duration	180 min	4	see above
Dermal			
Exposure: contact rate			
weight fraction	0.385 w/w	6	4)
contact rate	356 µg/min	3	see above
density	1 g/cm^3	5	estimation
uptake: diffusion model			
exposed area	1457 cm^2	5	see above
blood volume	146 cm^3	4	20)
skin blood flow	20 cm^3/min	4	42)

5.2.5 Cuddly toy, “acid” dyestuff from wool

The "contact rate" scenario is the most suitable model to estimate the dermal exposure to a cuddly toy that is held against the skin. Based on the data from table 13, the *leaching factor* of a dyestuff from the dyestuff class "acid" from wool is assumed to be no higher than 0.02 g/g. It is not possible to make an estimate of the contact rate (in mg/min) from this data. As indicated earlier, the contact rate is a substance-parameter that depends on the substance that migrates and on the material from which it migrates. To be able to estimate the dermal exposure to "acid" dyes, the contact rate must first be determined empirically.

It is assumed that there is skin contact with the cuddly toy for 4 hours a day. The surface of the skin which is in direct contact with the cuddly toy is estimated at 100 cm^2. The contact frequency is estimated to be 182 times a year. It is assumed that the cuddly toy is washed after six months, and after this time another cuddly toy becomes the "favorite". If a toy is washed more frequently, the "migration to skin" scenario is a more suitable model to describe the exposure.

	default value	Q	references, comments
Child 7.5 months			
body weight	7.62 kg	8	see 1.6
Contact			
frequency	182/year	4	see above
total duration	240 min	4	see above
use duration	240 min	4	see above
Dermal			
Exposure: contact rate			
weight fraction	-- w/w		see above
contact rate	-- µg/min		see above
density	0.9 g/cm^3	5	estimation
uptake: diffusion model			
exposed area	100 cm^2	4	see above
blood volume	10 cm^3	4	20)
skin blood flow	1,4 cm^3/min	4	42)

5.3 Rubbing off

Rubbing off relates to dermal exposure to solid products whereby the exposure takes place by the product being rubbed. We should think here of fungicides from a tent canvas and wood preservatives from impregnated wood. The "dermal transfer coefficient" exposure model is used. Parameters in this model are:

- "dislodgeable formulation", i.e. the amount of product which can be rubbed off per surface-unit (in mg/ cm^2) and
- "transfer coefficient", i.e. the factor which indicates the surface which is brushed per unit time (in cm^2/hour),
- the total surface (cm^2) that is contaminated.

5.3.1 Contact

Contact with preserved wood

In the EPA's Exposure Factors Handbook[12)], it is stated that the 90th percentile of the time that children up to 4 years of age spend outside is 210 min/day. For older children it is a little longer. In some Canadian and American studies showing questionnaires about the time that children spend outside, this time is shown to vary from 60 to 300 minutes per day[13, 14, 15)]. Based on this data, the default value for the time which children spend outside is set at 240 min/day. For the time which children spend in parks and playgrounds, 60 min/day is given for children of 2 -5 years of age[15)], 30-150 minutes is given for children in the preschool age group[13)], 87-108 minutes is given for children of 6-11 years of age[15)], and 64 - 119 minutes is given for children of 9-11 years of age[14)].

It is assumed that children spend 25% of the time in playgrounds and parks in contact with preserved wood. Based on these assumptions, a default value for the time that children are in contact with preserved wood is set at 25 minutes per day.

Contact with tent canvas
The rubbing of a fungicide of the canvas a toy tent is descrided as representative default. It is assumed that a 4.5 year old child plays in the tent during the summerperiod (the middle of May till the middle of September) for 3 times a week, or 48 days a year. It is estimated that the child plays 3 hours a day in the tent and that the child actually comes into contact with the tent canvas for 25 % of the time (25 % of 180 minutes, or 45 minutes).

5.3.2 Dislodgeable formulation

The "dislodgeable formulation" is a substance-parameter. It depends on:
- the material that is rubbed,
- the substance which is rubbed from the material.

The dislodgeable formulation is empirically determined for some substances from some products. This data is shown in this section. It is not possible to estimate this parameter accurately enough with the currently available information. To determine the dislodgeable formulation for other substances from other products, we would have to determine this parameter experimentally for each substance/product combination.

Experiments involving brushing wood that is preserved with CCA wood preservative [7,8,9,10,11)] are described in the literature. CCA wood preservatives contain copper and chrome or copper, chrome and arsenic. The amount of copper, chrome and arsenic that can be brushed off depends on a large number of factors. In addition to the composition of the CCA wood preservatives and the amount applied per m^3 of wood, other important factors include: the quality of the impregnation process, the type of wood, sapwood or heartwood, the time since the impregnation, smooth or rough wood, and the sampling techniques (the manner of brushing). Table 14 shows the range and the mean, from the recent, reliable literature. A default value (the 75th percentile) is calculated or estimated (a value similar to the 75th percentile) from these values.

Alberts and Dannen[3)] have carried out brushing experiments whereby organo-tin substances were brushed from tent canvas. The front and the back of a piece of tent canvas of 20 by 20 cm (400 cm^2) was intensively brushed with cotton wool. The amount of organo-tin substances on cotton wool was determined. The experiment was carried out both with dry and wet cotton wool. The results are shown in table 15. Based on this data, the default for the dislodgeable formulation for dibutyl and tributyl tin substances of tent canvases is taken to be 0.04 µg/ cm^2. Considering the limited size of the research, a quality factor of Q = 5 is given.

Table 14: dislodgeable formulation of metals from wood preserved with CCA wood preservative

metal	dislodgeable formulation [µg/cm^2]			reference
	range	mean	default	
Cr (total)	0.00012 - 0.658	0.119 ± 0.137	0.21[1)]	Health Canada [9)] Van Bruggen[10)]
Cu	0.014 tot 0.204	0.088 ± 0.100	0.16[1)]	Health Canada [9)]
As	0.052 -0.688	0.2	0.4[2)]	Lee and Jain[11)] Health Canada [9)]

1): calculated
2): estimated

Table 15: amounts of organo-tin substances brushed off the tent canvas (Alberts and Dannen[3)])

dislodged with:	dislodgeable formulation [µg/cm^2] dibutyltin-derivatives	dislodgeable formulation [µg/cm^2] tributyltin- derivatives
moist cotton wool 1	0.025	0.039
moist cotton wool 2	0.031	0.040
moist cotton wool, mean	0.028	0.040
dry cotton wool	0.014	0.015

5.3.3 Transfer coefficient

The Canadian PMRA assigned the following transfer coefficient for an assessment of CCA wood preservatives: for children in the age range 2-5 years, a transfer coefficient of 1040 cm^2/hour for the fingers and 14,900 cm^2/hour for the rest the body. For children in the age range 6-12 years, a transfer coefficient of 22,630 cm^2/hour is given for the whole body [9)].

A number of transfer coefficients have been determined for the use of pesticides by adults for agricultural purposes. A transfer coefficient of 450 cm^2/hour was found for picking tomatoes[16)]. For the transfer from leaves to the hands when using four different pesticides, a transfer coefficient of 4500 cm^2/hour was found[17)]. Transfer coefficients of 1200, 2400 and 4550 cm^2/hour, respectively, were found for the skin surface of the underarm and hands when using 3 pesticides. When only considering the surface of the hands, these values should be approximately halved, and to adapt the value from adults to children, the value should be halved again. In this way, transfer coefficients of 300, 600 and 1140 cm^2/hour are calculated for children. These values agree reasonably well with the value of 1040 cm ^{2}/hour from the Canadian PMRA[9)]. Based on the above, a transfer coefficient of 1000 cm^2/hour is given for preserved wood.

For tent canvas, we have kept the transfer coefficient given by the Canadian PMRA [9)] for the whole body, i.e. 15,940 cm^2/hour for children in the age range 2-5 years, and 22,630 cm^2/hour for children in the age range 6-10 years. It is assumed that 10% of the body ever comes into contact with the tent canvas, a surface equivalent to half of the hands, half of the lower and upper arms and a quarter of the head. This surface is not simultaneously in contact with the tent canvas; it is assumed that 10% of the mentioned body surface will actually come into contact. This gives a transfer coefficient of 159 cm^2/hour for children in the 2-5 age range, and 226 cm^2/hour for children in the 6-10 age range. As default value for the transfer coefficient of tent canvas for of a 4.5 years old child the above-mentioned 159 cm^2/hour is used.

5.3.4 Tent canvas

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see: 1.6
Contact			
frequency	48 /year	4	see: 5.3.1
total duration	180 min	4	see: 5.3.1
use duration	180 min	4	see: 5.3.1
Dermal			
Exposure: transfer factor			
dislodgeable formulation	0.04 µg/cm^2	5	see: 5.3.2
transfer factor	159 cm^2/hour	4	see: 5.3.3
surface	9 m^2	4	estimation
uptake: diffusion model			
exposed area	70.9 cm^2	4	1 % total body surface area, see 5.3.3 and 1.6
blood volume	7.1 cm^3	4	20)
skin blood flow	1.0 cm^3/ min	4	42)

5.3.5 Preserved wood

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see: 1.4
Contact			
frequency	365/year	4	see: 5.3.1
total duration	720 min	4	see: 5.3.1
use duration	25 min	4	see: 5.3.1
Dermal			
Exposure: transfer factor			
dislodgeable form. Cr (total)	0.21 $\mu g/cm^2$	4	see: 5.3.2
Cu	16 $\mu g/cm^2$	4	see: 5.3.2
As	0.4 $\mu g/cm^2$	4	see: 5.3.2
transfer factor	1000 cm^2/hr	4	see: 5.3.3
surface	1.5 m^2	4	estimation
uptake: diffusion model			
exposed area	195 cm^2	5	50 % surface hands see: 1.6
blood volume	19.5 cm^3	4	20)
skin blood flow	2.7 cm^3 /min	4	42)

5.4 Application on the skin

The "fixed volume" scenario is most suitable to describe the exposure to substances that are applied to the skin, such as face paint and cosmetics. The uptake is described with help of the "diffusion" model.

According to the definition, cosmetics do not actually fall into the category "children's toys"; neither does the use by children fall into the category "cosmetics". Here, we describe cosmetics used by children during play. Children use cosmetics as a game to imitate the behavior of adults. This means that a number of parameters will be different to the case when cosmetics and are used as consumer items. The "normal" use of cosmetics by children, such as the use of sun tan lotions, toothpaste and hair dyes, for example, is not described here.

The use of cosmetics during play will often take place during dressing up, at children's parties, for example. It will therefore usually occur incidentally and not periodically, as is usual with cosmetics. The sort of cosmetics usually used are those with which a color is applied. We should think here of lipsticks, nail polish, eye shadow and blusher. Defaults are described for these applications. It is assumed that if cosmetics are used during play, these 4 products will be applied one after the other. As a guideline, it is assumed that the amount that is applied is 3 times as large (unit per surface) as the amount of cosmetics that is usually used.

5.4.1 Cosmetics as toys (lipstick, nail polish, eye shadow and blusher)

Lipstick

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see: 1.6
Contact			
frequency	12x/ year	4	estimation
use duration	3 min	4	estimation
total duration	240 min	4	4 hours, estimation
Oral			
exposure: single ingestion			
amount product	0.03 g	4	see above, 32)
density	1.3 g/cm^3	5	estimation
uptake: fraction model			
absorbed fraction	1	7	potential dose

Nail polish

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	12x/ year	4	estimation
use duration	5 min	4	estimation
total duration	480 min	4	8 hours, estimation
Dermal			
exposure: fixed volume			
amount product	0.75 g total	4	see above, 32)
	0.25 g on skin	4	1/3 on skin, 2/3 on nail, estimation
density	0.9 g/cm^3	5	estimation
uptake: diffusion model			
exposed area	10 cm^2	4	on skin, estimation
blood volume	1 cm^3	4	20)
skin blood flow	0.14 cm^3/min	4	42)

Eye shadow

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	12x/ year	4	estimation
use duration	5 min	4	estimation
total duration	480 min	4	8 hours, estimation
Dermal			
exposure: fixed volume			
amount product	0.03 g	4	see above, 32)
density	1.3 g/cm^3	5	estimation
uptake: diffusion model			
exposed area	8 cm^2	3	estimation
blood volume	0.8 cm^3	4	20)
skin blood flow	0.11 cm^3/min	4	42)

Blusher

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	12x/ year	4	estimation
use duration	5 min	4	estimation
total duration	480 min	4	8 hours, estimation
Dermal			
exposure: fixed volume			
amount product	0.3 g total	4	see above; 32); 3 mg/cm^2
density	1.8 g/cm^3	5	estimation
uptake: diffusion model			
exposed area	100 cm^2	4	estimation
blood volume	10 cm^3	4	20)
skin blood flow	1.4 cm^3/min	4	42)

5.4.2 Face paint
It is assumed that the whole face, i.e. half of the surface of the head, is painted with face paint. From section 1.6 it appears that, for a child of 4.5 years of age, half of the surface of the head is 475 cm^2. No data was found on the amount of face paint used. To start with, we assume 5 times the amount per cm^2 than is used for general cream[32)], which is 1.4 g.

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	12x/ year	4	estimation
use duration	5 min	4	estimation
total duration	480 min	4	8 hours, estimation
Dermal			
exposure: fixed volume			
amount product	1.4 g total	4	see above; 5 mg/cm^2
density	1.5 g/cm^3	5	estimation
uptake: diffusion model			
exposed area	475 cm^2	4	see above
blood volume	47.5 cm^3	4	20)
skin blood flow	6.7 cm^3/min	4	42)

5.5 Intensive hand contact

When we think of intensive hand contact we should think of playing with modeling clay or painting with finger paint. Extremely intensive contact takes place between the hands and the product. The "fixed volume" scenario is chosen as the exposure scenario. It assumed that the product is continuously present on the hands. Since there is intensive hand contact for a prolonged period of time, the total amount of clay is taken as the amount of product. For the uptake, the rate at which substances from the clay or the finger paint penetrate the skin results in the choice of the "diffusion" model. The same model is used for the description of exposure and uptake by playing with modeling clay and the use of finger paint. The crucial difference is the age of the users: finger paint will be used by much younger children than for modeling clay.

5.5.1 Playing with modeling clay

	default value	Q	references, comments
Child 4.5 years			
body weight	16.3 kg	8	see 1.6
Contact			
frequency	52 x/ year	4	estimation
use duration	60 min	4	estimation
total duration	60 min	4	estimation
Dermal			
exposure: fixed volume			
amount product	350 g	3	estimation
density	2 g/cm^3	5	estimation
uptake: diffusion model			
exposed area	390 cm^2	6	area hands
blood volume	39 cm^3	4	20)
skin blood flow	5.5 cm^3/min	4	42)

5.5.2 Finger paint

The models used are the same as for modeling clay. Half of the surface of the hands is used as the surface. There is no data for the amount of finger paint used. A first estimate assumes an amount of 20 g of paint.

	default value	Q	references, comments
Child 18 months			
body weight	9.85 kg	8	see 1.6
Contact			
frequency	100 x/ year	4	estimation
use duration	45 min	4	estimation
total duration	45 min	4	estimation
Dermal			
exposure: fixed volume			
amount product	20 g	3	estimation
density	1.3 g/cm^3	5	estimation
uptake: diffusion model			
exposed area	124 cm^2	6	½ area hands
blood volume	12 cm^3	4	20)
skin blood flow	1.7 cm^3/min	4	42)

5.6 Spillage

In principle, spillage can be described in the same way and with the same models as application on the skin. The surface will be much smaller and the time that the product stays on the skin can differ from the time with cosmetics and face paint. As a representative example, the default for spilling poster paint is described.

This default is chosen because a number of simple experiments have been carried out for paint, for which an estimate could be made of the amount of paint spilt. These experiments are described in the paint fact sheet[31)]. Based on this data, we assume the default value of the amount of spilt poster paint to be 1.4 g. For the exposed surface, as in the paint fact sheet[31)], we assume a paint layer of twice the normal thickness (12 x 60 = 120 μm). The exposed surface is then 48 cm^2.

5.6.1 Poster paint

	default value	Q	references, comments
Child 6.5 years			
body weight	20.6 kg	8	see 1.6
Contact			
frequency	52 x/ year	4	estimation
use duration	90 min	4	estimation
total duration	90 min	4	estimation
Dermal			
exposure: fixed volume			
amount product	1.4 g	5	see above
density	1.23 g/cm^3	5	31); masonry paint
uptake: diffusion model			
exposed area	48 cm^2	4	see above
blood volume	4.8 cm^3	4	20)
skin blood flow	0.7 cm^3/min	4	42)

6 Eye contact

If toys come into contact with the eyes, exposure of the eyes can occur. Some examples of toys coming into contact with the eyes are face paint and cosmetics, but also diving goggles and a microscope. Exposure can occur, but seems to be less relevant on the whole. The models that describe the exposure and uptake have already been discussed in the previous chapters. In this chapter, the exposure route is indicated, and the previous chapters are referred to. No separate defaults are given for eye contact. With regards to exposure, we distinguish between semi-solid products which can stick to the skin and solid products which do not. All possible exposure routes are given below.

Leaching from solid products
Where children play with goods like a diving goggles of a microscope, some exposure may occur by leaching of a substance to skin. The model used to describe the exposure and uptake due to leaching from solid products (see section 5.2) can also be applied here. All parameters, except one, will correspond. The only difference is the surface of the skin; here it is the surface around the eyes. In this way, the exposure and uptake around the eyes is described, but not the actual eye contact.

Apply products onto the skin near the eyes
Products that are applied this way are, for example, face paint and eye shadow. The models to describe the exposure and uptake by semi-solid products, such as face paint and cosmetics, are the same as those used when applying substances to the skin (see section 5.4). The only parameter that actually deviates is the amount of product. Here, the amount of product applied near the eyes should be taken. In this way, just as for the leaching from solid products, the exposure and uptake around the eyes is described and not the actual eye contact.

Evaporation from solid products
A third possibility to describe the exposure of substances to the eyes requires the help of the models described in section 4.3, the evaporation from solid products. Here we should think of diving goggles or a microscope. If substances evaporate from the diving goggles or the eyepiece of a microscope, vapors can come into the small closed-off area between the eye and the product. Even for a small amount of evaporation, the exposure may not be negligible. The models used in section 4.3 can also be applied here. For the evaporation from solid products, it is assumed that the substance to be researched is not present in the solid matrix, but as a pure substance. In this way, a significant overestimate of the exposure can result. A more accurate estimate cannot be made at the current time.

Hand-eye contact
The fourth and last possibility to describe exposure of the eyes is rubbing in the eyes with contaminated hands, thus an exposure by hand-eye contact. For example when childern are playing with finger paint or with chalk. Section 3.3.2 shows contact frequencies for the hands. In fact, the number of times that children rub their eyes is not shown in this otherwise very detailed study. The models that describe the hand-mouth contact (see section 3.4) can also be used here. The only parameter that is actually different concerns the “ingestion rate”, which should then be seen as the amount of product which comes into the eyes per unit time.

7. Conclusions

7.1 General

In the children's toys fact sheet, we have classified the ways in which children can be exposed to compounds from children's toys in exposure categories.
The previous fact sheets used the principle of defining a main category of groups of products (such as paint and cosmetics) with a comparable exposure (examples of product categories are latex masonry paint and sun tan lotions). We did not choose this approach, since there is only a marginal relationship between the groups of products and exposure to these products, or in other words a marginal relationship between the type of toy and the exposure which that type of toy causes.
One or several representative examples are given for each exposure category, i.e. for each way in which children can be exposed to compounds from children's toys. Default models are chosen for these representative examples, and the default parameter values are filled in. Using these representative example defaults, it is possible to deduce the default values for an exposure route of any random type of toy.

The categorization into relevant routes of contact that is used by the European committee for standardization, the CEN (Comité Européen de Normalisation) (Technical committee 52/Working Group 9) is similar to the one used in this study. The CEN uses the subdivisions: ingestion, mouthing, inhalation, skin contact and eye contact. This classification is refined in exposure categories, so that all methods of exposure to children's toys can be shown. The exposure categories are shown in table 1.

There are suitable models for every exposure category, allowing us to describe the exposure adequately. However, in most cases, it turned out not to be possible to fill in all default-parameter values so that they were reliable enough to make a sound estimate of the exposure and the uptake of substances from the toys.
The crucial parameter for which we have too little information is usually the factor that describes the migration of the substance under investigation from the product. It concerns a substance-dependent parameter, which depends on the substance that migrates and on the material from which it migrates. The most practical way of arriving at a sound exposure estimate is to empirically determine this parameter. This migration parameter is not known for mouthing, skin contact with solid products, and eye contact for almost all substance/material combinations.

7.1.1 Calculation of the maximum migration factor based on toxicological limit values

CONSEXPO is not only able to calculate the amount of substance taken in based on the contact, exposure and uptake models, it can also calculate backwards. If the amount taken in is known (e.g. the maximum amount which may be taken in, as defined in a standard), CONSEXPO can calculate back and so can calculate one of the other parameters.

If the amount of a certain substance that a child may take in from a certain type of children's toy is known, CONSEXPO can calculate the associated migration factor, if all the other parameters are known.

7.2 Mouthing

The crucial parameter during mouthing is the *leaching rate*, i.e. the amount of a substance that is released from a certain product during mouthing per unit time. The leaching rate depends on the sort of material that is mouthed and the substance that is leached, in addition to the manner of mouthing, and the shape and thickness of the material. The leaching factor of a substance from a certain product is only known for a few substance/product combinations. There is actually only reliable data available for the leaching of diisononylpthalate (DINP) from PVC.

Based on the currently available information, is not possible to make a reliable estimate of the leaching factor. To determine the exposure and uptake of substances by mouthing, the most practical method is to empirically determine the leaching rate. TNO has developed a method to empirically determine the leaching rate during research into phthalate released from soft PVC baby toys[4)].

7.3 Ingestion

For the *direct ingestion* from products, the most important parameter is the parameter that indicates the amount of product that is taken in daily. No measurement data is available for this parameter. Estimates of these amounts have been made; they are not very reliable.

For oral intake by *hand-mouth contact,* the amount of product that is taken in by hand-mouth contact per unit time is the crucial parameter. The only measurement data for this parameter is for soil. Based on this data, defaults have been defined for products which do or do not stick to the skin. The defaults indicate an order of magnitude; they are not very reliable. Based on the currently available data, is not possible to make a further distinction between products that do or do not stick to the skin.

7.4 Inhalation

For inhalation we distinguish between substances which evaporate from liquids and substances which are released from solid products. Volatile organic compounds will almost never be able to evaporate from toys freely, but will be restricted in one way or another. The painting model describes the free evaporation of substances from the liquid and is based on Raoult's law. In this way, the exposure calculated is too high. This is however the best choice of the currently available models.

The painting model is also used for the evaporation from solid products. As mentioned above, the painting model is based on Raoult's law, which concerns the evaporation of liquids from liquids. Here, it concerns the release of substances from a solid product. This results in a significant overestimate of exposure. There is currently no better model to describe the evaporation from solid products.
Exposure to dust particles is described with the “spray cloud model”. There is little data about this kind of exposure, but on first principles, we estimate that less than 0.1 % of the particles is available for inhalatory exposure.

7.5 Skin contact

Substances from solid products

To be able to estimate the dermal exposure of substances from solid products, the crucial parameter is the leaching factor, i.e. the amount of substance that is leached per unit weight of the product. The leaching factor depends on the type of material from which the product is made and the substance that is leached. The leaching factor is only determined for a few combinations of material and substances. It is not possible to make a reliable estimate of the leaching factors of the other combinations of material and substances using the currently available information. The most practical way of arriving at a sound estimate for the exposure of substances from solid products is to empirically determine the leaching factor for the required combinations of substance and product.

Rubbing off

The "dermal transfer coefficient" model is used to describe the exposure by rubbing. Important parameters in this model are:

- "Dislodgeable formulation", i.e. the amount of product which can be rubbed off per unit surface (in mg/ cm^2) and
- "transfer coefficient", i.e. the factor which indicates the surface that is brushed per unit time (per cm^2/hour).

The "dislodgeable formulation" is a substance parameter which depends on the material that is rubbed and the substance that is rubbed from the material. The "dislodgeable formulation" has been empirically determined for a few substances from a few products. It is not possible to estimate this parameter sufficiently accurately with the currently available information. To calculate the exposure and uptake by rubbing, the most suitable solution is the experimental derivation of the dislodgeable formulation for each substance from each material. Based on the currently available data, a more or less accurate estimate of the "transfer coefficient" can be given.

Application on the skin, intensive hand contact and spillage

Application on the skin, intensive hand contact and spillage are described using the same models. The exposure is described using the "fixed volume" scenario and the "diffusion" model is applied for the uptake. The applied amounts are estimates in all cases, which we can assume to be of the right order of magnitude. These parameters can be accurately estimated using a number of simple tests.

7.6 Eye contact

Four possibilities describe the exposure and uptake where eye contact is concerned. The term "eye contact" should be better defined. For the leaching from solid products and the application of semi-solid products on the skin, the exposure and uptake near the eyes is described, and not the actual eye contact.

For the other two possibilities, evaporation from solid products and hand-eye contact, the parameters that describe the migration are not available. These should first be empirically determined to arrive at a sound estimate of the exposure and uptake.

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Appendix 2: painting scenario for different types of paint

The data in this appendix is from the paint fact sheet[31)].

In the painting exposure scenario, some parameters appear which depend on the type of paint and on the substance properties of the paint in question. No further details are given here on these parameters. In the paint scenario, the paint layer is modeled as a system with two layers. The substance under investigation evaporates from the upper layer; the substance is supplied from the lower layer to the upper layer.

2.1 Fraction of the upper layer and exchange rate

Product parameters that play a role in this model are the relative thickness of the two layers and the exchange rate of the substance from the lower to the upper layer. Values are filled-in in the defaults for substances that are mobile and which evaporate quickly; for paint, these are values which are applicable for volatile solvents. If research is carried out into less volatile organic compounds, these values should be adjusted. Table 16 shows the relationship between the vapor pressure of substances in a certain type of paint and the exchange rate. For less volatile organic compounds, the exchange rate decreases and the relative thickness of the upper layer is smaller. For substances with a very low vapor pressure,<10^{-5} mm Hg, evaporation is so small that any change in the thickness of the layer and the exchange rate has no influence on the exposure; only the evaporated surface is important for the exposure.

Table 16: fraction of the upper layer and the exchange rate

type of paint	substance	vapour pressure [mm Hg]	fraction upper layer	exchange rate [min^{-1}]	quality factor Q
solvent based	white spirit	4,5	0,1	0,4	6
		0,01	0,1	0,1	4
	phthalic anhydride	0,0002	1.10^{-4}	1.10^{-4}	4
water borne	Benzylbutyl phthalate	$8{,}6\ 10^{-6}$	1.10^{-4}	1.10^{-4}	4
	propyleneglycol	0,2	0,1	0,4	5

2.2 Molecular weight matrix

The "molecular weight matrix" parameter appears in the painting scenario. This parameter is used to calculate the vapor pressure of the component being researched. When calculating the evaporation of substances from paint, Raoult’s law is used. In the painting scenario, the partial vapor pressure is calculated by assuming a binary mixture, whereby x is part of the substance under investigation and y is the part of all other substances in the paint (y = 1-x).

$$P_{part} = \frac{\frac{x}{M_x}}{\frac{x}{M_x} + \frac{y}{M_y}} P_{pure\ substance}$$

P_{part} : the (partial) vapor pressure of component x in the paint
x : the part of component x in the paint
M_x : the molecular weight of component x
y : the part of the other components in the paint
M_y : molecular weight matrix
$P_{pure\ substance}$: the vapor pressure of component x

Expressed more accurately, y/M_y is the sum of the quotient of the relative part of the component in question in the paint, and the molecular weight of that component:

$$\frac{y}{M_y} = \frac{y_1}{M_{y1}} + \frac{y_2}{M_{y2}} + \ldots\ldots\ldots + \frac{y_n}{M_{yn}}$$

Only the substances with relatively low molecular weights, which are present in reasonable concentrations in paint, contribute to y/M_y. If the molecular weight of components in paint is orders of magnitude higher than the substance under investigation, the contribution is negligible, since the molecular weight appears in the denominator in the formula. Only components with a molecular weight in the same order of magnitude or smaller than the substance under investigation are important for the decreasing of vapor pressure with respect to the vapor pressure of the pure substance. The molecular weight of the binding agent in conventional solvent-based paint is 3,000 – 5,000; the molecular weight of the binding agent for water-based paint is approximately 500,000. The contribution of the lowering of the vapor pressure with respect to the vapor pressure of the pure substance of the binding agents is negligible. Other solvents are of particular importance for paint. For water based systems, it is mainly the influence of water that is so important. Water is actually polar, and the solvents in water based systems are usually polar too. Raoult's law can be applied to solvents that are not too concentrated, and to ideal solutions. During evaporation of substances from paint, we have to remember that deviations in Raoult's law can occur, particularly with water-based systems.

If data is known about the composition of paint, the formulas in this section can be used to calculate the molecular weight matrix. If this is not the case, default values can be used for a certain type of paint. For the default parameter values, it is assumed that only the solvent will contribute to the decrease in vapor pressure, with respect to the vapor pressure of the pure substance under investigation. When calculating the default values, a binary system is assumed, with the substance under investigation and the solvent.

$$\text{molecular weight matrix} = \frac{Mw_{oplosmiddel} * y}{y_1} = \frac{Mw_{oplosmiddel} * (1-x)}{y_1}$$

y : the part of the other components in paint
y_1 : solvent parts
x : the part of component x in paint
$Mw_{oplosmiddel}$: $Mw_{solvent}$

The part of the component under investigation x will be much less than 10% and will be a maximum of several tens of %. x is therefore much smaller than 1; in the calculation of the default values, x is negligible with respect to 1, or $1-x \approx 1$.

$$\text{molecular weight matrix} = \frac{Mw_{oplosmiddel}}{y_1}$$

For the default values, the molecular weight matrix is equal to the molecular weight of the solvents divided by a correction factor equal to the part of the solvent. Table 17 shows the default values calculated in this way for the molecular weight matrix of different types of paint.

Table 17: default values for molecular weight matrix

type of paint	composition	molecular weight matrix [g/mol]
solvent based	30 % solvent, mw 140	450
solvent poor	15 % solvent, mw 140	900
water borne	40 % water, mw 18	45

Appendix 3: CONSEXPO, Exposure and standard assessment methodology

The CONSEXPO-model contains a number of models to calculate exposure of consumer products via the inhalatory, dermal and oral routes[34)]. The models range from the simple models as proposed in the Technical Guidance Document for new and existing substances[39)] and European Union System for the Evaluation of Substances EUSES [40)] to complex models for a specific situation as e.g. painting (Van Veen et al., 1999)[41)]. It is extended for the CEN activities with a module that backcalculates a limit value for a parameter to ensure exposures under the exposure limit. A limit for a parameter is that value of the parameter that exactly results in an exposure at the exposure limit or TDI. Typical parameters to calculate an exposure standard for are chemical concentrations, chemical amounts and chemical migration rates.
Exposure to benzene and cyclohexanone due to their presence in a plastic toy can be attributed to evaporation and mouthing. No dermal exposure is calculated because the toxicity of the substance will be systemic of nature and the dermal bioavailability is generally much less than the oral one, while oral and dermal exposure times are equal or at least comparable. Therefore, an oral limit will cover dermal exposure. For the inhalatory route a standard on the concentration of the chemical in toy or ink printing is set assuming evaporation occurs during initial use. For the oral route, exposure will occur during mouthing and a standard is set for the leach rate and for the total amount present. The latter limit is only given for cyclohexanone because it is present in a relative small amount of printing on the outside of the toy, which might partially be taken in by a baby during mouthing. The exposure limit introduced in the calculation is the initial 15 minute average air concentration for inhalatory exposure and the oral dose in mg/kg bw on the first day of exposure. Both imply the largest doses that will occur during the use of a toy. If longer averaging times are introduced, the corresponding exposures will be lower and the parameter standard can be enlarged.

CONSEXPO

CONSEXPO

Features. The CONSumer EXPOsure models (CONSEXPO) program is being developed at the Dutch National Institute of Public Health and the Environment (RIVM) to provide estimation routines to assess exposure to consumer products including pesticides. CONSEXPO contains both simple screening models based on the European Union Technical Guidance Document accompanying new and existing substances legislation, and advanced models to describe indoor exposure caused by consumer products.

- Total exposure is defined from the combination of contact, exposure and uptake scenarios for each route of entry, and dose measures are calculated. These dose measures contain concentration estimates, and short- and long-term average doses in terms of milligram of chemical per day per kilogram of body weight.
- The program allows for stochastic parameters and each parameter can attain a normal, lognormal or uniform distribution, or an empirical distribution defined by data. Exposure and dose distributions reflect stochastic parameters and these distributions can be depicted and percentiles can be quantified.

- The program provides sensitivity analyses for each stochastic parameter, in which mean exposures or doses as a function of the value of a selected stochastic parameter are depicted and analyzed.

Theoretical. The program's operation is based on a modeling framework containing the components of 1) contact, 2) exposure and 3) uptake. For each component, the user selects a model and provides its parameters. The contact component does not contain a mathematical model but specifies duration of actual use, duration of contact with the product, and frequency of use. The duration of actual use and the duration of contact might differ if actual usage is short, as when using a spray, but substances from the product fill the air around a person, causing a prolonged exposure.

The exposure component contains multiple models to estimate the concentration of substance in the medium that directly contacts the human body. These estimation models range from simple screening models to advanced models describing specific exposures. Exposure includes the inhalatory, dermal, and oral routes, and the software provides a function of modeling exposure through multiple routes. For the inhalatory route, the advanced models include painting, evaporation, exhaust gas production, sprays, and a continuous source. For the dermal route, the models include transfer factors, contact rates and fixed volume of product. For the oral route, models include ingestion, leaching from materials into food, leaching from materials into the mouth, and hand-mouth contact.

The uptake component estimates the amount taken up through the skin, the lungs, or the gastrointestinal wall. This denotes the amount that reaches systemic circulation. If information on the fraction taken up is available, this can be specified. Otherwise, simple diffusion models can be used to estimate the fraction taken up. As an alternative, uptake can be set to 100%, in which case potential doses are calculated by the program.