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## Oral exposure of children to chemicals via hand-to-mouth contact

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## Rapport in het kort

#### Orale blootstelling van kinderen aan stoffen door hand-mondcontact

Het RIVM stelt nieuwe waarden voor om in te schatten in welke mate kinderen blootstaan aan bepaalde chemische stoffen wanneer zij hun handen in hun mond steken (dus bij handmondcontact). Voorbeelden zijn blootstelling aan chemische stoffen die in bestrijdings- of schoonmaakmiddelen in en rond het huis worden gebruikt. Vooral jonge kinderen komen op deze manier in aanraking met chemische stoffen, omdat zij hun handen vaak in hun mond stoppen.

De nieuwe waarden zijn wetenschappelijk onderbouwd; de oude waren veelal gebaseerd op beperkte gegevens en veronderstellingen. Het RIVM adviseert de nieuwe waarden als standaard op te nemen in reguliere beleidskaders om chemische stoffen te beoordelen op risico's. Momenteel ontbreekt een uniforme beoordeling, omdat verschillende beleidskaders eigen methoden gebruiken om de blootstelling door hand-mondcontact te berekenen.

Trefwoorden: hand-mondcontact, bestrijdingsmiddelen, stoffen, blootstelling, standaardwaarden, kinderen.

### **Abstract**

### Oral exposure of children to chemicals via hand-to-mouth contact

The National Institute for Public Health and the Environment of the Netherlands (RIVM) proposes new default values for assessing the degree of exposure of children to chemicals following hand-to-mouth contact. One example of such exposure is the hand-to-mouth transfer of chemicals found in common household biocides and/or cleaning products. This route of transferring chemicals is especially relevant for young children, because they frequently put their hands into their mouth.

The new default values have an empirical basis, whereas the currently used values are generally based on limited data and assumptions. The RIVM advises using the new default values in risk assessments of chemicals within the relevant policy frameworks. A standardized approach is currently lacking because – within the different policy frameworks – various assessment methods are used to calculate exposure to chemicals via hand-to-mouth contact

Key words: hand-to-mouth (HTM) contact, children, chemicals, biocides, exposure assessment.

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## **Samenvatting**

In huidige risicobeoordelingen van chemische stoffen nemen kinderen vaak een bijzondere plaats in. De blootstelling van kinderen is hoger dan van volwassenen in verhouding tot hun lichaamsgewicht. Ook kan gedrag van kinderen leiden tot een relevante blootstelling aan stoffen. Een voorbeeld van specifiek gedrag is hand-mondcontact van kinderen. Hand-mondcontact kan leiden tot orale opname van chemische stoffen (naast opname via de voeding). Het in de mond brengen van de hand, de frequentie en het oppervlak van de hand in contact met de mond zijn van invloed op de mate van orale blootstelling De blootstelling als gevolg van hand-mondcontact is afhankelijk van het feit of, en in welke mate, de hand 'geladen' is met chemische stoffen.

In verschillende kaders van risicobeoordeling, bijvoorbeeld op het gebied van bestrijdingsmiddelen, bodembeleid, consumentenproducten en diergeneesmiddelen, worden standaardwaarden gebruikt om blootstelling als het gevolg van hand-mondcontact te berekenen. Deze standaardwaarden zijn veelal gebaseerd op aannames of op summiere data, behalve bij bodembeleid waar meetgegevens van grond inname ten grondslag liggen. Echter, gegevens met betrekking tot hand-mondcontact zijn steeds meer voorradig. Een overzicht van aanwezige literatuur met betrekking tot hand-mondcontact van kinderen is opgesteld. Over het algemeen omvatten de studies relatief weinig personen en is de variatie in het hand-mondcontact groot. Uit de literatuur bleek dat zowel de frequentie van hand-mondcontact als de mate waarin de hand in de mond wordt gebracht, afneemt naarmate kinderen ouder worden.

Op basis van de aanwezige literatuur zijn standaardwaarden voor frequentie van handmondcontact en oppervlakte van de hand afgeleid voor verschillende leeftijdscategorieën (tot elf jaar oude kinderen). Door het combineren van deze standaardwaarden is het mogelijk om de orale blootstelling via hand-mondcontact te berekenen per lichaamsgewicht. Er is geconcludeerd dat de afgeleide standaardwaarden voldoende wetenschappelijke basis hebben en leiden tot een verbeterde blootstellingschatting. Om deze reden is het aanbevolen om de afgeleide standaardwaarden te gebruiken in de verschillende beleidskaders.

## **Summary**

Children are often regarded separately in risk assessments. They are exposed in different ways than adults, because their physiology and behaviour is different. For example, hand-to-mouth contact is a child specific behaviour that can lead to a relevant exposure for children. Hand-to-mouth contact is defined as all activities in which hands or fingers are touched by the mouth or put into the mouth, except for dietary activities. The extent of oral exposure as a result of hand-to-mouth contact is influenced by the frequency of contacts, insertion of the hand into the mouth and hand surface area which is contacted by the mouth. The oral exposure is also dependent on the extent of amount of chemicals on the hands. In different policy frameworks of risk assessment, e.g. biocide use, soil, consumer products and veterinary medicines, default values are used to calculate the oral exposure via hand-to-mouth contact. These default values are, however, based on assumptions or on limited data, except for soil ingestion where measured data on soil ingestion are available. To date, data on hand-to-mouth contact have become available. In this report, an overview of available data on hand-to-mouth contact is provided. In general, the studies included a

To date, data on hand-to-mouth contact have become available. In this report, an overview of available data on hand-to-mouth contact is provided. In general, the studies included a relative low number of subjects and observed variations in hand-to-mouth contacts are large. Based on the study results, it could be concluded that as children grow older, the frequency of hand-to-mouth contacts and hand-in-mouth contacts decreases.

Default values for hand-to-mouth contact and hand surface area contacted with the mouth are derived for children to the age of eleven years old. Combining these default values it is possible to calculate the oral exposure via hand-to-mouth contact per body weight for the specified age groups.

It is concluded that derived default values have a sufficient scientific basis. Therefore, it is advised using the derived default values in the different policy frameworks to improve future exposure assessments.

### 1. Introduction

Children are exposed in different ways than adults, because their physiology and behaviour is different (see section 1.1). For this reason, children are often regarded separately in risk assessments. Oral exposure to certain chemicals may occur via mouthing of the hands or objects (referred to as non-dietary ingestion), which is considered as a specific exposure route for children. Therefore, non-dietary ingestion of chemicals by children has been included in a number of exposure scenarios in risk assessments as secondary (oral) exposure. In determining non-dietary ingestion of chemicals, Hand-to-mouth (HTM) contact behaviour of children is one of the parameters that play an important role. However, data availability to assess this kind of exposure to biocides or pest control products is mostly not sufficient and thus defaults have been suggested.

In this report, an attempt was made to determine whether these defaults are adequate to assess non-dietary exposure from HTM contact or whether they should be adjusted based on currently available data.

In addition, data, approaches and defaults used in other policy frameworks are integrated to obtain a more complete overview of HTM contact behaviour. These frameworks are consumer products (e.g. toys), soil ingestion, and veterinary medicines.

Hereto, a literature search was conducted to obtain a state of the art overview of Hand-to-mouth contact. Mouthing behaviour (in general), HTM contact and other parameters will be described and discussed. To study HTM contact behaviour of children several methods have been used, i.e. questionnaires, diaries and videotape techniques. These methods are briefly evaluated. In addition, relevant information concerning HTM contact behaviour, such as anthropometric data, was also collected.

## 1.1 Non-dietary exposure of children

### 1.1.1 Rationale for considering non-dietary exposure of children

As mentioned above, children are often considered as a separate subpopulation in risk assessment, because of their different physiology and behaviour compared to adults (Cohen Hubal et al., 2000). Considering children's physiology; due to their continuous growth (or discontinuous when taking growth spurts into consideration) children's organs, which are developing, can function differently from adults. In some cases this can make children more (or less) vulnerable to chemical exposures (Wolterink et al., 2007). In addition, relative to their body weight, children breathe more air, drink more water, and, for certain food commodities, consume more (Cohen Hubal et al., 2000, Moya et al., 2004). Furthermore, young children breathe and play close to the floor due to their physiology, i.e. children that are not able to walk yet. This may result in specific exposure scenarios, e.g. dermal exposure to chemicals present on the floor whereupon infants crawl.

Behaviour of children is also an important reason for considering children separately from adults in risk assessment. Children explore, learn and are involved in active play and thus exhibit different behaviour than adults. White (1975; as cited in (Groot et al., 1998)) describes that infants till the age of six weeks mouth as a reflex and habit when lips are touched. After that period, infants start to explore their environment by mouthing their own fists and fingers and eventually everything they can take hold of. At an age of about 8 months the teething process starts, to which children respond with mouthing to sooth the pain (Tulve

et al., 2002). Mouthing behaviour as a result from exploring continues until an age of about 24 months is reached (Groot et al., 1998).

Taking the physiology and children's behaviour together, it can be expected that mouthing behaviour and HTM contact of children may result in potentially significant non-dietary exposure to certain chemicals.

#### 1.1.2 Definitions of types of contact

The use of biocides and pest control products in and around the residence may cause deposition and/or adsorption of a chemical on floors and objects. From contact with these surfaces or objects chemicals can be transferred to the mouth resulting in non-dietary exposure. Four definitions that describe a (specific) type of contact leading to non-dietary exposure are listed below:

- mouthing behaviour
- hand-to-mouth contact and object-to-mouth contact
- soil ingestion

#### Mouthing behaviour

Mouthing behaviour was defined by Groot et al., (1998) as follows: 'Mouthing behaviour includes all activities in which objects, including fingers, are touched by the mouth or put into the mouth except for eating and drinking, and includes licking, sucking, chewing, and biting'. This definition of mouthing behaviour is widely accepted and used. Exposure to chemicals may occur from deposits of chemicals on children's hands and the object they are mouthing. Considering the definition for mouthing behaviour by Groot et al., this would also include hand-to-mouth contact and object-to-mouth contact. Therefore, it is not possible to derive values on either types of contact from data on mouthing behaviour. Principally, a distinction is made between hand-to-mouth contact and object-to-mouth contact on the one side, and mouthing behaviour on the other side. With mouthing behaviour (in Dutch: sabbelen) generally a more prolonged contact with either objects or fingers is described, although there is no general rule for the duration of contact considered in the definition by Groot et al. The prolonged contact is associated with the explorative behaviour or comforting of young children up to approximately three years who put their fingers and objects (e.g. toys meant for mouthing) for relatively long periods in their mouth. This may result in exposure to chemicals from the object itself (i.e. chemicals that leach from an object), rather than chemicals that are deposited on the object. This type of prolonged contact is expected to decrease as children age and is not expected to occur amongst children above six years of age. Furthermore, children older than three will start mouthing other objects relatively more.

#### Hand-to-mouth and object-to-mouth contact

Hand-to-mouth (HTM) contact specifically describes the contact of the hand with the mouth. No distinction is made between touching the mouth or insertion fingers into the mouth (see section 1.3). Object-to-mouth contact describes the contact of an object (fingers are not considered as objects) with the mouth or insertion into the mouth.

In general, hand-to-mouth contact and object-to-mouth contact are fast and intermittent contacts (Zartarian et al., 1997), however also prolonged contact is possible. If reported in terms of min/h no distinction can be made between short contacts with high frequency or long contact with low frequency (see section 1.3).

#### **Soil ingestion**

Soil ingestion is mainly the result of HTM contact behaviour. Exposure to chemicals may occur via this route. In general, the hand is not loaded with soil homogeneously. Determining soil ingestion as a result of HTM contact is therefore difficult. The extent of soil ingestion is usually expressed in terms of mg per day. Exposure due to soil ingestion mainly occurs outdoors during play time, but household dust also consists of 30-70% soil (Oomen et al., 2007) which can contribute to the exposure as well.

Children with 'pica' behaviour exhibit habitual ingestion of soil (or other non-food objects). This is a very uncommon behaviour which may result in unusual high levels of soil ingestion. However, this kind of soil ingestion is not considered to be the result of normal HTM contact behaviour and is therefore not covered in the present report.

In this report, the focus is on HTM contact behaviour and how this influences exposure. It has been hypothesized that hand-to-mouth (HTM) contact activity is one of the major sources of non-dietary exposure of children (HESI, 2004). However, exposure to biocides and pest control products may also occur from object-to-mouth contact as chemicals from these products are deposited or adsorbed to the surface of objects. For this reason, object-to-mouth contact was also taken into consideration.

## 1.2 Hand loading

The exposure via hand-to-mouth contact behaviour is preceded by another process, i.e. loading of the hands with contaminants. Young children are frequently situated close to the ground, where they crawl or play. Being on or close to the floor, carpet or soil (lawns) can lead to significant hand loadings of chemicals, such as biocides (Moya et al., 2004). The presence of pets in dwellings may also play an important role in hand loadings of biocides. The pet or his basket may have been treated with a veterinary medicine or biocide, respectively. Subsequently, this biocide or veterinary medicine may be transferred on to the hands after contact with the animal. In addition, soil can be loaded onto the hands during outdoor play or as mentioned before can be loaded as a part of household dust. The extent of hand loading is dependent on a number of aspects, such as the type of application, children's behaviour, hand surface, the product (matrix) or chemical and unloading activities. A brief explanation why these aspects influence hand loading is given in Appendix I. For further reading on this topic is referred to US EPA (2006). The basic assumption in this report is that the hand is always loaded with chemicals even upon repeated contact (see Appendix I).

# **1.3** Factors that influence exposure via hand-to-mouth contact

In the present report, the process of hand loading is not extensively discussed. It is assumed that HTM contact occurs with a hand already loaded with a certain amount of chemical. This section focuses exclusively on the HTM contact activity, and not on the processes before loading.

Starting with the definition of hand-to-mouth (HTM) contact a number of factors can be discerned. The definition for HTM contact is as follows: 'HTM contact behaviour includes all activities in which hands or fingers are touched by the mouth or put into the mouth, except for dietary activities'.

Following the definition, the following issues are of relevance:

- includes all activities frequency of contact and/or duration of contact
- touched by the mouth or put into the mouth specific type of contact
- hands or fingers surface area which is contacted
- unloading of the hands by HTM contact

#### **Frequency of contact**

HTM contact behaviour can be expressed in terms of frequency of hand-to-mouth contact, e.g. events/hr. Another way of expressing HTM contact is by the total time of contact per specified period of time (as a rate), e.g. minutes per day. Logically, the higher the frequency of contact the higher the potential exposure from HTM contact, considering an already loaded hand. Therefore a positive correlation can be expected between HTM contact frequency and oral exposure. On the other hand, HTM contact is considered to be fast and intermittent (US EPA, 2006, Zartarian et al., 1997). It is questionable whether this fast contact can lead to significant oral exposure.

When expressing HTM contact as duration of contact per day it is difficult or even impossible to assess the potential exposure, since it is unclear how many contacts there were. If there was only one contact that lasted for 15 minutes the hand could not be reloaded. For this reason, dealing with mouthing behaviour (prolonged insertion of fingers, unknown frequency) is difficult. For exposure from HTM contact to chemicals on hands it is recommended to describe mouthing as events/hr. In the case where leaching from objects (and thus not from surface) is considered, describing mouthing behaviour in min/d is more relevant.

The total time per day a child exhibits HTM contact is relevant to determine the number of contacts per day (events/hr \* hrs/day = events/day).

#### **Specific type of contact**

The definition of HTM contact includes touching of the mouth and insertion of hands or fingers into the mouth. However, some researchers define HTM contact as at least insertion of (part of) the hand in mouth (Freeman et al., 2001, Kissel et al., 1998). It is questionable whether merely touching the mouth or lips can cause relevant exposure from mouthing via the non-dietary route. Actual insertion of the hand or part of the hands seems a more relevant parameter (Freeman et al., 2001). For this reason, an additional parameter is used to describe the insertion of hands or fingers *in* to the mouth. This phenomenon is referred to as hand-in-mouth (HIM) contact for clarity purposes.

The extent of insertion (of fingers or whole hand) is relevant for determining more accurately the potential dose that is available for non-dietary digestion. Furthermore, during insertion the fingers become moistened. Camann et al. (1996) and Rodes et al. (2001) (all cited in (Freeman et al., 2001) have observed that dust loadings on moist hands can increase up to 100-fold compared to dry hands. Because the transfer efficiency may also be greater with saliva than without, it is worth specifying whether contact refers to HTM or HIM contact (HESI, 2004).

To summarize, the definition of HTM contact as stated above remains unchanged. HIM contact only describes activities in which hands or fingers are put *into* the mouth, and is part of the total HTM contact.

#### Hand surface area in contact with the mouth

Surface area of hands or fingers that are contacted with the mouth will influence the exposure via HTM contact. It is likely that not the entire hands are contacted with the mouth, but rather a part of the hand or fingers. Following the basic assumption that the entire hand is loaded, it is of relevance to determine the contact area, because the area of contact will directly relate to the exposure that is expected from HTM contact (see also unloading of the hands by HTM contact).

#### Unloading of the hands by HTM contact

The unloading of the hands by HTM contact corresponds to the fraction of the amount of chemical that is effectively removed by HTM contact activity. As a default, it has been assumed that either 50% (in Pest Control Products Fact Sheet) or 100% (by US EPA) of chemical residue on the skin (of hands and fingers) is taken up (see Appendix I). In this report, it is assumed that the unloading of the hands of chemical residue by HTM contact equals the amount of chemical on the hand surface area which is contacted. In other words, the unloading of the hands is 100% effective for the hand surface area that is contacted.

In chapter 2, some of the factors above will be described in more detail based on findings in literature. In section 2.1 a state of the art overview of HTM contact will be given. In section 2.2 relevant literature on the controversy between HTM and HIM contact will be discussed. The degree to which hands and/or fingers are contacted or inserted is discussed in section 2.3.

## 1.4 Hand-to-mouth contact dealt with in different policy frameworks

In Europe, exposure through non-dietary ingestion from mouthing behaviour is taken into account in at least four policy frameworks, i.e. biocide use, soil contamination, consumer products and veterinary medicines.

#### 1.4.1 Defaults used in biocide exposure assessments

#### 1.4.1.1 Technical Notes for Guidance

For assisting exposure and risk assessments for biocides the Technical Notes for Guidance (TNsG) document (European Commission, 2002a) was drawn up by the European Chemicals Bureau. This guidance includes concepts developed in the report of the Biocides Steering Group (97/505/3040/DEB/E2) and refers to guidance on exposure assessment being developed for New and Existing Substances. The exposure to biocides from non-dietary ingestion was considered in the second part of the TNsG on human exposure. The TNsG itself does not provide default values for mouthing behaviour or HTM contact leading to exposure to biocides. Instead, the document provides examples of secondary exposures (worked examples from part III) which are described in more detail in a supporting document of TNsG; 'User Guidance to report 2002' (European Commission, 2002b). One relevant example was given in the latter document, i.e. infant playing on weathered structure and mouthing (for a wood preservative).

#### Infant playing on weathered structure and mouthing

The exposure to a wood preservative is considered for an infant. A specific age range is not provided in the TNsG. Below the assumptions that were made for calculating the exposure to wood preservative are presented. The justification for these assumptions was not given. The mouthing considered in this scenario exclusively involves object-to-mouth contact. It is assumed that an infant would ingest the surface deposit on  $50 \text{ cm}^2$  ( $5 \times 10 \text{ cm}^2$ ) of wood. In the TNsG there is no explanation given for presenting the surface deposit area contacted by the mouth by  $5 \times 10 \text{cm}^2$ . Possibly, it indicates the surface area contacted by the mouth each time the structure is contacted ( $10 \text{ cm}^2$ ) and the frequency (5 times).

The scenario does not take into account the potential oral exposure from HTM contact.

Assumptions: Wood preservative residue on surface = gross assumption 0.01 mg/cm<sup>2</sup>

Hand surface area = 200 cm<sup>2</sup>, prolonged and repeated contact 20% of hand contaminated at 100% of surface concentration

10% dermal uptake

100% ingestion of surface deposit on 5 x 10cm<sup>2</sup> of wood

bodyweight = 10 kg

Exposure via skin:  $= 0.01 \text{ mg x } 200 \text{ x } 20\% \text{ cm}^2 \text{ x } 10\%$ 

= 0.04 mg uptake

Exposure via ingestion:  $= 0.01 \text{ mg/cm}^2 \text{ x } 50 \text{ cm}^2 = 0.5 \text{ mg uptake}$ 

= total 0.54 mg = 0.05 mg/kg bw/day

#### 1.4.1.2 Pest Control Products Fact Sheet

The Pest Control Products Fact Sheet (Bremmer et al., 2006a) provides guidance on how to assess exposure from HTM contact. Defaults in the fact sheet are aimed to be reasonably worst case. The defaults for oral exposure through HTM contact is described as follows: 'If dermal exposure of children occurs after the application of a pest control product, those children can also be exposed orally due to hand-mouth contact. Dermal exposure of children can take place on any uncovered skin, that is, on the head, the arms and hands, and on the legs and feet. The hands form about 20% of the total uncovered skin. It is assumed that 50% of the product that ends up on the hands is taken in orally due to hand-mouth contact. This means that via hand-mouth contact 10% of the external dermal exposure is ingested. The ingestion rate can be calculated based on the assumption that from the total dermal exposure 10% is taken in orally due to hand-mouth contact'.

Underlying assumption is that the 20% of uncovered skin (which resembles hand-surface area) is completely contaminated with a pest control product. Furthermore, half of the area of the hands is assumed to be effectively unloaded by mouthing.

#### 1.4.1.3 Residential non-dietary oral exposure to pesticides – US EPA

The US EPA applies different defaults in determining non-dietary exposure of pesticides from mouthing in a residential area. To this end, US EPA issued Standard Operating Procedures for Residential Exposure Assessment in which defaults are given (US EPA, 1997b). Exposure scenarios are described in which default parameters are derived to assess the exposure when no actual data is available. Relevant scenarios were lawn applications (turf), indoor surfaces and pet treatment. The defaults (see Table 1) are set for a (average) three year old toddler with a body weight of 15 kg (represents 1 to 6 year olds). The HTM contact activity for toddlers (3 to 5 years old) is based on a time-activity study performed by

US EPA (published in 1996 as cited in SOP for residential exposure assessment) and equals 1.56 events/h.

It should be noted that using the same HTM contact frequency for children ranging from 1 to 6 years old, based on children ranging from 3 to 5 years old, is not correct. Children under the age of 3 can behave much differently than children ranging from 3 to 5 years old. However, at that time data on children under the age of 3 might not have been present.

Dislodgeable amounts and exposure durations are based on professional judgment and experience of the OPP staff. The exposure is then calculated as follows:

$$PDR = DR * SA * FQ * ET$$

Where, PDR is potential dose rate (mg/day); DR is dislodgeable residue on pet or floor (mg/cm<sup>2</sup> pet or floor); SA is surface area of the hands (cm<sup>2</sup>); FQ is frequency of HTM activity (events/h) and ET is exposure duration (hrs/day).

Table 1: Overview of default values used for residential non-dietary exposure to pesticides by US EPA (US EPA, 1997b).

|                         | Lawn application     | Indoor surfaces     | Pet treatment <sup>a</sup> |
|-------------------------|----------------------|---------------------|----------------------------|
| HTM contact activity    | 0.026 events/min     | 0.026 events/min    | 0.026 events/min           |
|                         | (1.56 events/h)      | (1.56 events/h)     | (1.56 events/h)            |
| Age of child considered | 1 to 6 years         | 1 to 6 years        | 1 to 6 years               |
| Dislodgeable amount     | 20 % of application  | One-to-one          | 20 % of application        |
|                         | rate                 | Relationship        | rate applied to            |
|                         |                      | dislodgeable amount | surface                    |
|                         |                      | and concentration   |                            |
|                         | One-to-one           |                     | One-to-one                 |
|                         | Relationship         |                     | Relationship               |
|                         | dislodgeable amount  |                     | dislodgeable amount        |
|                         | and concentration on |                     | and concentration on       |
|                         | hands                | _                   | hands                      |
| Surface area hand       | 350 cm <sup>2</sup>  | 350 cm <sup>2</sup> | 350 cm <sup>2</sup>        |
| Exposure duration       | 2 hrs/d              | 4 hrs/d             | 2 hrs/d                    |

<sup>&</sup>lt;sup>a</sup> Assumed one animal contacted per day. In Europe, products which are used to treat pets are always referred to as veterinary medicines.

In 1999, US EPA evaluated the use of certain default parameters for non-dietary exposure assessment (US EPA, 1999a). Amongst others, pet treatment was considered in the report where the 20% dislodgeable amount per application rate was point of discussion. Reason for discussion was submission of a study to Health Canada in which a dislodgeable amount of 2.8% (average) was observed. On the other hand, the study by Boone et al., (2001) obtained a dislodgeable amount of 16% for the same chemical, chlorpyrifos. The difference in both figures can be explained by comparing the sampling techniques applied, where Boone applied a more vigorous rubbing method compared to the more gentle stroking method applied in the other study (US EPA, 1999a). Nevertheless, US EPA (1999) concluded that 20% is still (over) protective and can be continued for use in exposure assessments based on findings by Boone et al.

The Health and Environmental Sciences Institute (HESI) issued a report on residential exposure factors with input from US EPA (HESI, 2004). HESI reported an age limit below which children are not expected to be exposed. As children less than 4 months of age are not mobile, hand to treated object contact is considered unlikely and therefore this age group was excluded.

Defaults from US EPA using the same equation for residential exposure are used to determine the exposure via HTM contact. Generally, this formula is used in a first tier assessment. Defaults for HTM contacts were provided for acute and chronic exposure which are 20 contacts/h and 8.5 contacts/h, respectively. The age category for which these figures were derived was not stated. Therefore, it cannot be stated whether these alternative values used by US EPA replace the default of 0.026 events/min (from US EPA SOP) mentioned above.

For more accurate estimates US EPA uses different HTM frequencies (data not shown).

HESI also reported a default on the finger area inserted into the mouth with each HTM contact. A default finger area inserted into the mouth of  $20 \text{ cm}^2$  was assumed by US EPA's pesticide program. This assumption was based on the estimate that a child puts three fingers up to the palm in their mouth,  $\approx 20 \text{ cm}^2$  (Smegal 2001, as cited in (HESI, 2004)) (Hemond and Solo-Gabriele, 2004).

From this figure, the LifeLine group (2000) estimated the fraction which is inserted into the mouth. The fraction of a 2-3 year old total hand area (both hands) that corresponds to 20 cm<sup>2</sup> is 0.06.

#### 1.4.2 Soil contamination

Because measurement data on soil ingestion by children is available, there is no need to determine the non-dietary exposure to soil via the use of HTM contact data. As a result, no defaults for HTM contact in this policy framework have been established. The defaults used for determining oral exposure to soil from HTM contact were derived from a number of tracer studies (selected key studies). This means that a tracer, which is a chemical that is not absorbed in the gastro-intestinal tract and found in soil, but not in food or non-food products, is measured in faeces to estimate the amount of soil a child has ingested (Lijzen et al., 2001). From these tracer studies a weighted average with percentiles were derived by RIVM (Lijzen et al., 2001, Otte et al., 2001) and US EPA (2006).

In an RIVM report on 'Technical evaluation of the Intervention Values for Soil/sediment and Groundwater' (Lijzen et al., 2001) and an RIVM report on 'Evaluation and revision of the CSOIL parameter set' (Otte et al., 2001), parameter values, amongst other soil ingestion, were evaluated and revised according to available data. The average daily soil ingestion (including ingestion of dust containing soil) default values derived were 50 mg/d for adults (lifelong exposure) and 100 mg/d for children (1-7 years of age). The 95% confidence limits of the average soil ingestion of children were 75 to 125 mg/d. The 95th percentile of the soil ingestion by children is about 200 mg/d. Formerly, an average soil ingestion of 150 mg/d was suggested, which was lowered to 100 mg/d based on the available data, because deliberate intake of soil, so-called 'pica'-behaviour, was not included in calculations of soil ingestion.

In a report by US EPA (2006) recommendations were made for default values for soil ingestion by children. From the studies considered, mean values ranged from 38 mg/d to 193 mg/d with a weighted average of 93 mg/d. A weighted average of 106 mg/d was derived when soil ingestion from dust was included. Recommended values for the average and

95<sup>th</sup> percentile soil ingestion were 100 mg/d and 400 mg/d, respectively.

For the indoor and outdoor ingestion of lead from soil and dust US EPA (1999b) used the standard default value for ingestion of soil as starting point and modeled the exposure for several age groups. Thus, the derived ingestion rates are age dependent. The calculated ingestion rates of soil and dust were: 85 mg/day for the 0-1 year olds and 6-7 year olds, 135 mg/day for 1-4 year olds, 100 mg/day for 4-5 year olds and 90 mg/day for 5-6 year olds (US EPA, 1999b).

For children with pica behaviour, the Centers for Disease Control used a value of 10 g/d. This value was based on multiple observations of one child, where the intake rate of soil was 10-14 g/d (Calabrese et al., 1989; as cited in (US EPA, 2006)). Therefore, the value of 10 g/d was considered reasonable by US EPA (2006). However, not much is known about the number of children exhibiting this kind of behaviour and whether they exhibit this behaviour on a daily basis for a prolonged period of time.

All default values were derived for children ranging in age from 1-7 years old. It was noted that the tracer studies had insufficient lengths to determine usual ingestion of a child over a longer time period. Therefore, uncertainty is large in the recommended values for its use in chronic exposure assessments.

#### 1.4.3 Defaults for consumer products

In the second edition of the Technical Guidance Document (TGD) (European Commission, 2003) in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, no default values for HTM contact are provided.

In the article by Babich et al., (2004) a table was provided in which used default mouthing durations were shown. For consumer product safety the presence of hazardous chemicals in the product and whether or not they can be released from their matrix are relevant in exposure assessment. Consumer products considered for mouthing are teethers, pacifiers and toys. The parameter of interest is the mouthing duration of objects (e.g. toys) which is combined with migration rates of the chemical of interest to perform an exposure assessment. In Table 2, default mouthing durations are provided. A mouthing duration of 180 min/day is often used as default value in exposure and risk assessments. In an advisory report prepared by RIVM/SIR (van Engelen et al., 2006) for DG Enterprise, the default of 180 min/day was adopted, based on observations where children displayed mouthing durations over three hours per day. It is, however, widely acknowledged that the default of 180 min/d is a worst case estimate (CSTEE, 1998, van Engelen et al., 2006).

Table 2: Default values used for mouthing duration by three agencies

| Agency            | Object          | Age group | Mouthing duration |
|-------------------|-----------------|-----------|-------------------|
|                   |                 | (months)  | (min/day)         |
| Health Canada     | Teethers / toys | 3-12      | 60-180            |
|                   | Pacifiers       | 3-12      | 120-360           |
| CHAP <sup>a</sup> | Toys            | 0-18      | 180               |
|                   |                 | 19-36     | 60                |
| France            | Toys            | 3-12      | 180               |

<sup>&</sup>lt;sup>a</sup> Chronic Hazard Advisory Panel from the U.S.

In a report by US EPA on Standard Operating Procedure for Residential Exposure Assessment (US EPA, 1997b) defaults are provided for impregnated materials. Mouthing of toys was considered for impregnated matter for toddlers. For these toys a surface area of 500 cm<sup>2</sup> was proposed, which is mouthed entirely once per day.

In the Children's Toy Fact Sheet (Bremmer and van Veen, 2002) exposure to chemicals from HTM contact is described for three consumer products, i.e. chalk, finger paint and face paint. The oral exposure from HTM contact to chalk and finger paint was based on comparisons with soil ingestion. In this report the average soil ingestion of children was 100 mg/d and the 75<sup>th</sup> percentile was set at 300 mg/d based on available data from nine published studies. Note, that these studies are not (at least not all) the same studies considered by Lijzen et al. (2001) or by US EPA (1997b), thereby explaining the differences in found values. As a starting point for calculating the oral exposure the 75<sup>th</sup> percentile of soil ingestion (300 mg/d) was used in combination with exposure duration of 50 minutes. Chalk ingestion was considered similar to soil ingestion, however finger paint was considered more comparable with mud (stickier to the hands). For this reason and based on the difference between soil and mud intake a factor of 5 was applied for ingestion of finger paint. Correcting for use durations of the products (both 45 minutes) the daily intake was calculated to be 45/50 \* 300 mg/d = 270 mg/d for chalk and 270 \* 5 = 1350 mg/d. For face paint, the starting point was the total amount on the skin (1.4 g) of which it was assumed that 15% is ingested per day caused by HTM contact providing 210 mg per day (see Table 3).

Table 3: Overview of default values used for HTM contact with respect to children's toys from the Children's Toy Fact Sheet.

|                         | Children's toys    |              |                     |
|-------------------------|--------------------|--------------|---------------------|
|                         | Piece of chalk     | Finger paint | <b>Face paint</b>   |
| Point of departure      | 270 mg, 45 minutes | 270 mg * 5,  | 210 mg, 480 minutes |
|                         |                    | 45 minutes   | _                   |
| HTM contact             | 6 mg/min           | 30 mg/min    | 0.44 mg/min         |
| Ingestion rate (mg/day) | 270 mg/day         | 1350 mg/day  | 210 mg/day          |

#### 1.4.4 Veterinary medicines

The guideline on user safety for pharmaceutical veterinary medicinal products (CVMP, 2005) states that with certain scenarios, HTM contact needs to be considered. However, defaults (in general) are not given in the guideline. For this it is referred to the appendix II of part I of the second edition of the Technical Guidance Document (European Commission, 2003) in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market.

Also, it is referred to the US EPA's Exposure Factors Handbook (US EPA, 1997a) and the ECETOC Exposure Factors Sourcebook for European populations (ECETOC, 2001). Data on mouthing behaviour from these last two sources are however limited.

## 1.5 Methods that have been used to generate HTM contact data

Several methods have been used to generate data on HTM contact:

- questionnaires; filled in by parents
- diaries; filled in by parents
- observational studies
  - o real time observations (by parents or researchers)
  - o videotape observations (by researchers)
- combination of the methodologies.

In the sections below the methodologies will be described and advantages and disadvantages are discussed. It must be noted that some methodologies are not focused only on collection of HTM contact data. Children's behaviour is in general the main point of interest.

#### 1.5.1 Questionnaire (surveys)

In questionnaires specific questions can be posed concerning the children's behaviour, including mouthing behaviour. With questionnaires, information regarding product use can be requested, anthropometric data can be gathered, and relevant background information on housing, socio-economic status, hygiene, physical status, and so on can be obtained. When including different age groups questionnaires can also capture trends in children's behaviour. Follow-up may be required to validate previous results and/or verify observed trends. A large population can be reached with questionnaires. Costs to perform this kind of research are relatively low, because no sophisticated techniques are needed. Furthermore, completing questionnaires will generally not require much time. Processing completed questionnaires, however, can be labour intensive.

With questionnaires it is possible to obtain quantitative and qualitative data, but that requires a well designed questionnaire (Steenbekkers, 2001). Disadvantage of using questionnaire are that microactivities such as HTM contacts and temporal variations (variations in behaviour on a time basis) cannot be extracted from questionnaires. Also, a relatively high number of subjects have to be addressed to obtain a sufficient number of participants, because of a generally low response to questionnaires. For the reasons above, with respect to HTM contact, questionnaires are mainly used for supporting and/or validating results from observational studies.

Questionnaires can also be performed via interviews to obtain rather qualitative data, although quantitative data can also be obtained. A major advantage of an interview is that additional questions can be posed for clarification (Steenbekkers, 2001).

#### 1.5.2 Diaries

Diaries are used to record children's behaviour on a daily basis, e.g. for multiple (consecutive) days or even weeks. The diaries are filled in by parents, or in case of relatively older children (often not relevant here) by children themselves. A diary may contain information about time spent outdoors, playing on the ground, and more specifically whether there was contact with certain surfaces, consumption habits, and children's hygiene. Investigators must clarify prior to handing out diaries what is expected to be filled in and where the focus lies. It must be noted that Juberg et al., (2001) used observational diaries in

which parents were asked to observe their children for one entire day (pilot) or on multiple days (phase III) to record all things that were put into the mouth and for what duration. This study demonstrates the thin line between diary recording and observational study by parents. A major advantage of using diaries is that a large number of children can be covered. Templates of diaries can be sent by post and also replied by post. As the diaries are filled in by the parents no observers are required. After receiving completed diaries, results have to be worked out, which is labour intensive. Another advantage is that temporal variability in activities of the child can be collected from a diary (Cohen Hubal et al., 2000). Because diaries function on a recall basis (unless observations are noted directly), its use is limited to macro-level activities. Specific activities such as HTM contact cannot be recorded and if so, probably not reliable due to recall bias. Therefore, diaries are more generally used to support/validate findings in an observational study. For instance, major activities caught on videotape can be compared with diaries to see if results are consistent.

#### 1.5.3 Observational studies

Observational studies are studies during which children (in the present context) are directly observed for their behaviour by either their parents or researchers. Observational studies can be performed for both macro- and micro-activity levels, making observational studies very suitable for studying HTM contact behaviour. There are two methods to observe children, which are real-time observations (by parents or researchers) and videotaping (by researchers). In general, observational studies are time consuming, labour intensive and costly to implement, therefore observational studies are typically carried out with smaller groups of subjects (Steenbekkers, 2001).

#### 1.5.3.1 Real-time observational studies

Real-time observation means that children's behaviour is being hand recorded during observation. Prior to observations the observers need to be trained and instructed. Trained observers may recognize certain behaviour easier and more accurate than parents, but children's behaviour may be also more affected by the presence of a stranger, i.e. the trained observer (Groot et al., 1998). Furthermore, although parents may be distracted more than a trained observer, parents are diligent in their observations (Groot et al., 1998). In addition, mostly parents observe their child on voluntary basis making costs low.

The mobility of the observer in a real-time observation is high, which enables the observer to

The mobility of the observer in a real-time observation is high, which enables the observer to follow a child and to view from the desired angle. Because observations are immediately recorded, the chance to miss an activity is rather low. A disadvantage of real-time recording is that observations have to be processed afterwards. This generally includes inserting all data into computer programs from the scoring card.

#### 1.5.3.2 Videotape observations

During videotape observations trained observers/cameramen will videotape children. In contrast to real-time recording, videotaping methodology allows the observers to score the behaviour with advanced equipment directly onto computer (or computer compatible files, see below). This requires observing the child 'twice', because observations are not directly noted. On the one hand, chance of missing an activity or behaviour is rather low. On the other hand, videotaping requires focusing on the child and capturing its entire behaviour. Due to the behaviour of the child this may be troublesome. Training of the observer/cameraman is very important. Also the behaviour of a child may be affected by the presence of a stranger. On the other hand, children will adapt to the presence of others quickly (Ferguson et al.,

2006). Observers have to become aware when children are play-acting or distracted by the observer. Parents can facilitate by indicating different behaviour.

In 1993 a pilot field study was conducted by Zartarian and colleagues during which videotape software was evaluated and refined. This software is able to translate videotaped micro-level activities into computer text files. A template with grids is used where locations, activity levels and object (or object groups) are designated. The output files can subsequently be scanned by a computer program which sums/separates all input data for a certain child (Zartarian et al., 1997). Others have adopted/adapted the videotape method to describe micro-level activity patterns (Ferguson et al., 2006). A translation palette that can be tailored to meet the study design was introduced. Furthermore, grids were expanded with more options and also to indicate whether the behaviour was constant or repetitive (Black et al., 2005, Ferguson et al., 2006).

An additional purpose of videotape observations are for training purposes or more importantly for shadow observations. In this way, observations (and observers) are checked for consistency in the results (Groot et al., 1998, Zartarian et al., 1997). Ferguson et al., (2006) mentions that inter-observer (as describe above) and intra-observer checks can be carried out. Intraobserver check being the measurable agreement between recordings of the same videotape on two different occasions. Reliability of results from videotaping is therefore considered high.

Also, archiving videotapes containing children's behaviour enables researchers to re-use the videotapes for studying other types of behaviour.

#### **Overall**

These methodologies have in common that gathering of data is time consuming and labour intensive, and thus expensive. Selection procedures, paperwork and training (e.g. explaining terminology) have to be performed prior to actually sending out surveys or conducting observations.

The methods described above are often combined with each other in one study. In this way, resources and costs are combined and reduced, respectively. Questionnaires and diaries are in many studies used to support or validate observational studies. Doing so, it is easier to obtain a complete picture of the child. It provides the opportunity to combine results on a macrolevel with results on micro-level. Furthermore, a larger number of subjects can be reached with a questionnaire than during observations. Observing subjects selected from questionnaires provides not only a more complete picture, but also validates extrapolation of findings to a larger population. Care must be taken that selection bias by the researcher is ruled out (Freeman et al., 2001).

Table 4: Overview of methodologies to generate HTM contact data and their advantages and disadvantages.

| Method                | Advantage                       | Disadvantage                  |
|-----------------------|---------------------------------|-------------------------------|
| Questionnaire         | Low costs                       | Cannot be used for recording  |
|                       | Large number of subjects        | HTM contact                   |
|                       | Low labour intensive            | Low response                  |
| Diaries               | Low costs                       | Mostly suited for macro-level |
|                       | Temporal variation included     | activity                      |
|                       | Large number of subjects        | Much work required to extract |
|                       |                                 | relevant data.                |
| 01 1 . 1:             | NC 1 1 2 2 2                    | TT: 1                         |
| Observational studies | Micro-level activities are      | High costs                    |
|                       | included                        | Low number of subjects        |
| - real time           | Parents can observe, no         | Reliability is relatively low |
|                       | interference with child         | Labour intensive              |
|                       | Relatively (to videotaping) low |                               |
|                       | costs                           |                               |
| - videotaping         | Accurate, reliable              | Very labour intensive         |
|                       | Direct computational            | Interference with child       |
|                       | processing                      |                               |
|                       | Observations can be re-used     |                               |
|                       | and put into databases          |                               |

# 2. Derivation of defaults for exposure via HTM contact

The exposure via HTM contact is determined by the number of contacts with the mouth, the surface area of the hand which is contacted and body weight. A relatively small number of published studies were found, in which results on HTM contact activities are reported. An overview of the derived results will be provided, where similarities and discrepancies will be discussed (section 2.1).

In section 2.2 hand-in-mouth contacts and the extent of contact of the hands by the mouth will be discussed. Anthropometric data such as surface areas of hands and fingers and body weight are given in section 2.3.

Based on available information default values will be recommended for parameters that are required to determine the oral exposure via HTM contact. Where possible, default parameters are set in such way that they would either represent the 75<sup>th</sup> percentile or 25<sup>th</sup> percentile of a parameter distribution. The 75<sup>th</sup> percentile is used for parameters which give a higher exposure for higher values, and the 25<sup>th</sup> percentile is used in the reverse case, e.g. body weight. Given the number of parameters and the relationship between the parameters, it is expected that, in general, the calculated values for oral exposure via HTM contact will result in a reasonable worst case estimate (approximating 99<sup>th</sup>-percentile).

#### 2.1 Hand-to-mouth contact data

Eight studies reporting HTM contact, of which the original articles could be retrieved, were found during a literature search. A short summary is given per study (in Appendix II), where attention has been paid to study design, methods used, and important results and/or conclusions derived in these studies. Based on these studies an overview is given (Table 5).

#### **HTM** contact

A small number of studies were performed to elucidate the behaviour of children including HTM contact. With exception of the study by Groot et al., (1998), all studies were performed in the US. Generally, these studies included children from relatively small geographical regions. Therefore it has been remarked by US EPA (2006) that outcomes may not be representative for the entire population. On the other hand, differences between children from different geographical regions in mouthing behaviour are not expected to be large within a country or even between the US and the Netherlands (or Europe). For this reason, it is assumed that data from the studies above are representative for the Dutch (European) region.

Three general observations can be made based on the studies. The first observation is that relatively small sample sizes (per age group) were used in most studies. Furthermore, dependent on the study design, the number of observations and observation times are relatively low. In most studies, the total duration of observation per child was about four hours on a single day. This can be explained by the fact that these kinds of studies are often expensive and very time consuming. In addition, children engage in more activities than adults do, leading to extensive observations (Cohen Hubal et al., 2000). Therefore, including more children will not be feasible in most cases.

As a result, the influence of possible outliers on the outcome can be significant, thereby possibly explaining the large variability within studies. Also, scoring methodology related to the observation time (e.g. score behaviour every 15 seconds or per hour) can attribute to large variability and uncertainty, because certain behaviour is counted twice (i.e. when child mouths his fingers for 30 minutes) or missed completely (outside time frame).

Table 5: Overview of HTM contact data.

| Age   | No. of<br>children  | HTM duration <sup>a</sup> (SD or range)                                      | HTM<br>frequency <sup>a</sup><br>(contact/h)<br>mean (SD) or | Reference (remarks)   |
|---|---------------------|--|--|---|
| 29-50 months  | 4                   |  | 3-10<br>9-19   | Zartarian et al., 1997<br>(one hand and two<br>hands summed)            |
| 3-6 months<br>6-12 months<br>12-18 months<br>18-36 months                 | 5<br>14<br>12<br>11 | 20.5 min/d (18.8)<br>7.5 min/d (11.6)<br>5.8 min/d (14.9)<br>6.3 min/d (9.1) |  | Groot et al., 1998  |
| 2-6 years   | 30                  | 0.0 0.000  | 9.5<br>(0.4-25.7)  | Reed et al., 1999   |
| 3-4 years<br>5-6 years<br>7-8 years<br>10-12 years                        | 3<br>7<br>4<br>5    |  | 4 (4)<br>8 (13)<br>5 (7)<br>4 (6)                            | Freeman et al., 2001<br>(only data from<br>videotaping, HIM<br>contact) |
| 24-55 months  | 10                  |  | 10.2 (6.0)   | Freeman et al., 2005  |
| 11-24 months<br>25-60 months  | 28<br>44            |  | 18<br>16   | Tulve et al., 2002  |
| 1-year olds<br>2-6 years  | 8 30                | 2.7 min/h (0-14.7)<br>0.4 min/h (0-2.2) <sup>b</sup>                         | 13.0 (1.3-47.7)<br>11.3 (0.2-<br>39.5) <sup>b</sup>          | AuYeung et al., 2004;<br>2006 (outdoor results)                         |
| 1-year olds<br>2-6 years  | 1 9                 | 10.7 min/h<br>0.7 min/h (0-1.8)  | 73.5<br>13.9 (2.2-34.1)                                      | AuYeung et al., 2004;<br>2006 (indoor results)                          |
| Infants (7-12 months) 1-year olds 2-year olds preschoolers (37-53 months) | 13<br>12<br>18<br>9 |  | 19.8 (14.5)<br>15.8 (8.7)<br>11.9 (9.3)<br>22.1 (22.1)       | Black et al., 2005  |

<sup>&</sup>lt;sup>a</sup> all figures are means.

The second observation is the large variability and/or uncertainty in HTM contact. In most studies this was apparent by the large ranges and high standard deviations. These high variability and uncertainty does not only result from study designs. The mouthing behaviour itself contributes to the uncertainty as well. It is acknowledged that mouthing behaviour is fast intermittent and non-uniform (Moya et al., 2004, Zartarian et al., 1997), which might also explain the large variability in HTM contact amongst and between age groups in a number of studies.

Inter-observer agreement percentages were found ranging from 88 to 96% (Black et al., 2005, Zartarian et al., 1997) indicating that differences in recordings of the same observation by different observers are not of major influence.

<sup>&</sup>lt;sup>b</sup> range is from 5<sup>th</sup> percentile to 99<sup>th</sup> percentile.

A third observation is that most studies used videotaping methodology to investigate the mouthing behaviour of children. Zartarian et al., (1997) stated that because most object contacts were 2-3 seconds in duration videotape methodologies should be used, as diaries or questionnaires cannot capture such detail. Most studies were conducted with videotaping methodologies, albeit generally in combination with other methodologies.

Overall results of the studies were that HTM contact seems to be age dependent, but not gender dependent. The location of children in the house or outdoors also seems to influence the mouthing behaviour.

HTM contact was lower in the older age groups (Auyeung et al., 2006, Black et al., 2005, Groot et al., 1998, Hemond and Solo-Gabriele, 2004, Tulve et al., 2002). This was not only stipulated by the decrease in frequency, but also by the total time spent mouthing hands (Auyeung et al., 2004; 2006). It seems that mouthing behaviour is inversely related to age. This trend in mouthing behaviour is more apparent when children ranging in age from about 6-48 months are included. Explorative behaviour is then included, which is supposed to have an effect on mouthing frequencies (Groot et al., 1998). According to Juberg et al., (2001) mouthing is positively correlated with teething and inversely with increasing mobility.

Age group categories differed per study, which makes comparisons difficult. Tulve et al., (2002) made a clear distinction between children over and under the age of two. However, Groot et al., found highest mouthing durations for the age groups 3-6 months (fingers only) and 6-12 months (including objects), suggesting that more age groups should be considered. Smith and Norris (2003; as cited in (US EPA, 2006)) and Black et al., (2005) also observed highest mouthing durations in this specific age group. Above the age of two the mouthing behaviour seems to drop, although results found by Black et al., contradict this statement. Black et al. included dietary activities in their study; whether the HTM contact frequency observed in preschoolers remains high after correction for dietary activities cannot be predicted.

Some researchers also studied the relation between gender or right/left handedness and mouthing behaviour. No relation between gender and mouthing behaviour was found (Tulve et al., 2002). It was noted that boys spent more time on outdoor play than girls (Auyeung et al., 2004). Slight differences in right or left hand use were observed by Freeman et al., (2005), although these differences were not significantly different. Earlier, Zartarian et al. (1997) investigated HTM contact separately for the left and right hand, but did not make a distinction. Reed et al., did not find a difference with respect to HTM contacts for left and right hand. However, for object-to-mouth contacts a clear preference for the right hand was observed (ratio right/left was 6.8). Auyeung et al. (2006) further elucidated that the right hand was predominantly used to manipulate objects (i.e. toys) and the left hand had longer hourly contact durations with objects that did not need to be manipulated (i.e. surfaces).

In a comprehensive study by Xue et al. (2007) a meta-analysis of children's HTM contact frequency data was performed. Authors from nine studies were contacted to gather HTM contact data (in contacts/h; per individual), thereby including 429 subjects and more than 2,000 hours of observation from nine studies. All studies that were included by Xue et al. were performed using videotape methodologies (for references see Xue et al., 2007). Xue et al. investigated differences in HTM contact across studies by age (using US EPA (2005) recommended age grouping), gender and location. It was acknowledged by the authors that differences in study design and methodologies applied were not accounted for in their meta-analysis. However, meta-analysis revealed that there was not a statistical

significant difference in HTM contact frequency across studies (no statistical test and condition for significance was given). In Table 6 HTM contact distributions per study and age group is given for indoor and outdoor locations. Xue and colleagues fitted the data (in Table 6) to lognormal, Weibull and normal distributions. From these analyses it appeared that Weibull distributions fitted HTM contact data the best for all analyses conducted, although not all fitted Weibull distributions passed the chi square test (not shown). It is noted that reported values in Table 6 from the same study may differ from what is reported in Table 5. This is explained by the fact that Xue et al. requested the raw data from

reported in Table 5. This is explained by the fact that Xue et al. requested the raw data from the authors of the studies and subsequently analysed the data themselves. This also explains why the number of observations may differ, because Xue et al. used different age groups than those which were used in the original studies.

Table 6: HTM contact data per study and age group for indoor and outdoor locations

(adapted from Xue et al., 2007). a

|                          | Age Group     | No. of       | Mean         |      |        |           |      |      |          |
|--------------------------|---------------|--------------|--------------|------|--------|-----------|------|------|----------|
| Study                    | (years)       | Observations | (contacts/h) | Std  | Median | <b>p5</b> | p75  | p95  | Location |
| Greene, 2002 b           | 0.25 to < 0.5 | 23           | 28.0         | 21.7 | 23.0   | 3.0       | 48.0 | 65.0 | Indoor   |
| Greene, 2002 b           | 0.5 to <1     | 88           | 19.8         | 17.8 | 14.5   | 2.0       | 29.0 | 50.0 | Indoor   |
| Tulve et al., 2002       | 0.5 to <1     | 9            | 14.4         | 23.6 | 5.0    | 0.1       | 15.0 | 71.0 | Indoor   |
| Black et al., 2005       | 0.5 to <1     | 11           | 19.1         | 17.1 | 13.7   | 3.3       | 19.7 | 56.8 | Indoor   |
| Beamer et al., in prep b | 0.5 to <1     | 11           | 14.6         | 7.9  | 17.0   | 2.0       | 20.8 | 26.4 | Indoor   |
| Greene, 2002 b           | 1 to <2       | 132          | 20.1         | 21.0 | 14.0   | 0.1       | 26.0 | 65.0 | Indoor   |
| Tulve et al., 2002       | 1 to <2       | 84           | 18.5         | 19.2 | 14.0   | 0.1       | 27.0 | 54.0 | Indoor   |
| Black et al., 2005       | 1 to <2       | 20           | 17.1         | 9.6  | 14.6   | 4.7       | 23.6 | 35.4 | Indoor   |
| Greene, 2002 b           | 2 to <3       | 87           | 13.6         | 16.3 | 8.0    | 0.1       | 20.0 | 39.0 | Indoor   |
| Tulve et al., 2002       | 2 to <3       | 41           | 12.1         | 13.6 | 8.0    | 0.1       | 15.0 | 36.0 | Indoor   |
| Black et al., 2005       | 2 to <3       | 24           | 11.6         | 8.7  | 10.5   | 1.6       | 16.2 | 31.5 | Indoor   |
| Reed et al., 1999        | 3 to <6       | 25           | 10.1         | 6.6  | 9.0    | 2.0       | 13.0 | 25.0 | Indoor   |
| Greene, 2002 b           | 3 to <6       | 12           | 11.8         | 9.8  | 10.0   | 0.1       | 17.5 | 30.0 | Indoor   |
| Tulve et al., 2002       | 3 to <6       | 104          | 15.5         | 21.2 | 7.5    | 0.1       | 22.0 | 62.0 | Indoor   |
| Hore, 2003 b             | 3 to <6       | 9            | 22.0         | 13.2 | 19.4   | 8.9       | 26.1 | 47.8 | Indoor   |
| Black et al., 2005       | 3 to <6       | 13           | 20.5         | 20.3 | 14.8   | 4.9       | 22.5 | 83.9 | Indoor   |
| Freeman et al., 2001     | 6 to <11      | 12           | 6.7          | 6.0  | 4.2    | 1.7       | 10.2 | 20.6 | Indoor   |
|                          |               |              |              |      |        |           |      |      |          |
| Tulve et al., 2002       | 1 to <2       | 10           | 13.3         | 9.7  | 11.0   | 0.1       | 17.0 | 35.0 | Outdoor  |
| Black et al., 2005       | 1 to <2       | 12           | 12.6         | 13.7 | 7.0    | 1.3       | 15.6 | 42.2 | Outdoor  |
| Tulve et al., 2002       | 2 to <3       | 17           | 5.5          | 9.1  | 4.0    | 0.1       | 7.0  | 38.0 | Outdoor  |
| Black et al., 2005       | 2 to <3       | 20           | 5.3          | 8.2  | 2.2    | 0.1       | 6.7  | 26.6 | Outdoor  |
| Leckie et al., 2000 b    | 3 to <6       | 9            | 2.5          | 3.8  | 1.1    | 0.1       | 3.0  | 11.5 | Outdoor  |
| Tulve et al., 2002       | 3 to <6       | 33           | 10.1         | 10.4 | 7.0    | 0.1       | 16.0 | 36.0 | Outdoor  |
| Black et al., 2005       | 3 to <6       | 10           | 10.4         | 14.9 | 5.8    | 0.1       | 8.7  | 40.9 | Outdoor  |
| Freeman et al., 2001     | 6 to <11      | 12           | 2.6          | 4.4  | 0.1    | 0.1       | 3.5  | 11.9 | Outdoor  |

<sup>&</sup>lt;sup>a</sup> The study by Zartarian et al., 1997 was not analysed separately, because a condition for inclusion was to have at least nine observations.

The authors concluded that age and location are of influence to HTM contact, but study and gender are not. For this reason, data from several studies were pooled based on age groups for the indoor and outdoor location (Table 8). It was concluded that increasing age led to a decrease in frequency of HTM contact for both locations. HTM contact frequencies for same age groups were consistently lower in outdoor locations. Furthermore, the authors highlighted the need for more data for children aged from birth to < 6 months old and for 3 to <6 year olds to reduce uncertainty in the results.

<sup>&</sup>lt;sup>b</sup> All studies are as cited in Xue et al., 2007.

In the study by Xue et al., some other studies than described in Appendix II were included in the analysis. On the other hand, the studies by Auyeung et al., (2004; 2006) were not included in the meta-analyses. However, most studies from the overview were included in the meta-analyses. The conclusions made previously in the overview (see above) are supported by the findings of Xue et al.

Recently, recommendations for HTM contact were made by US EPA (2006) to be used in exposure assessments for children. The defaults derived by US EPA (see Table 7) do not differ much from the means recommended in this report (see Table 8), which were based on the study by Xue et al., (2007). However, the means reported by Xue et al. are based on pooled data including a relatively large number of children, whereas US EPA based their recommended values on either one study or the weighted mean of several studies. Another similarity was the decline in HTM contact when children aged, although an increase can be observed in the report by US EPA for the default HTM contact set for 3-6 year olds (see below). Differences can be seen in the choice of age groups, where US EPA (2006) in addition used the birth-1 month, 1-3 months and 2-6 years age groups. For the first two age groups (including children from birth to 3 months old) no defaults were recommended as there were no data for those age groups. In this report, it was also decided not to have overlapping age groups, to avoid confusion.

*Table 7: Default HTM contact frequencies recommended by US EPA (2006).* 

|                | 2 ( )                     |
|----------------|---------------------------|
| Age group      | Default HTM contact by US |
|                | EPA (contacts/h)          |
| 6 to 12 months | 20                        |
| 1 to 2 years   | 16                        |
| 2 to 3 years   | 12                        |
| 2 to 6 years   | 12                        |
| 3 to 6 years   | 14                        |
| 6 to 11 years  | 4                         |

#### 2.1.1 Recommended defaults for HTM contact

Considering the overviews of studies it can be concluded that HTM contact is age and location related. Based on these conclusions it was decided to recommend defaults for several age groups per location (indoors and outdoors). Because Xue et al., (2007) gathered and analysed a large number of HTM contact data from several studies, it was decided to use HTM contact frequencies derived by Xue for the derivation of defaults in this report. Although differences in studies were not accounted for, it appeared that there were no significant differences between studies. Therefore, pooling of data was considered a valid approach. Data was pooled per age group and location. Age groups were based on recommendations from US EPA resulting in the following age groups: 0.25 to <0.5 year olds, 0.5 to <1 year olds, 1 to <2 year olds, 2 to <3 year olds, 3 to <6 year olds and 6 to <11 year olds (Table 7). In the present report, the same age groups will be considered. For derivation of the defaults in this report, the 75<sup>th</sup> percentile of the derived HTM contact frequency distribution by Xue et al. was used as point of departure. The recommended default values are rounded values of the 75<sup>th</sup> percentile of the HTM contact frequency distribution (Table 8).

Table 8: HTM contact frequencies from pooled data and derived default values for specified age groups and the indoor and outdoor location are given.

| Age Group<br>(vears) | No. of<br>Observations | Mean<br>(contacts/h) | Std  | Median | р5  | p75  | p95  | Location | Default HTM<br>contact<br>(contacts/h) |
|----------------------|------------------------|----------------------|------|--------|-----|------|------|----------|--|
| 0.25 to <0.5         |                        | 28                   | 21.7 | 23     | 3.0 | 48.0 | 65.0 | Indoor   | ` ′                                    |
|                      | 23                     |                      |      |        | 3.0 |      |      |          | 50                                     |
| 0.5 to <1            | 119                    | 18.9                 | 17.4 | 14     | 1.0 | 26.4 | 52.0 | Indoor   | 30                                     |
| 1 to <2              | 245                    | 19.6                 | 19.6 | 14     | 0.1 | 27.0 | 63.0 | Indoor   | 30                                     |
| 2 to <3              | 161                    | 12.7                 | 14.2 | 9      | 0.1 | 17.0 | 37.0 | Indoor   | 20                                     |
| 3 to <6              | 169                    | 14.7                 | 18.4 | 9      | 0.1 | 20.0 | 54.0 | Indoor   | 20                                     |
| 6 to <11             | 14                     | 6.7                  | 5.5  | 5.7    | 1.7 | 10.2 | 20.6 | Indoor   | 10                                     |
|                      |                        |                      |      |        |     |      |      |          |  |
| 0.5 to <1            | 10                     | 14.5                 | 12.3 | 11.6   | 2.4 | 16.0 | 46.7 | Outdoor  | 20                                     |
| 1 to <2              | 32                     | 13.9                 | 13.6 | 8      | 1.1 | 19.2 | 42.2 | Outdoor  | 20                                     |
| 2 to <3              | 46                     | 5.3                  | 8.1  | 2.6    | 0.1 | 7.0  | 20.0 | Outdoor  | 10                                     |
| 3 to <6              | 55                     | 8.5                  | 10.7 | 5.6    | 0.1 | 11.0 | 36.0 | Outdoor  | 10                                     |
| 6 to <11             | 15                     | 2.9                  | 4.3  | 0.5    | 0.1 | 4.7  | 11.9 | Outdoor  | 5                                      |

## 2.1.2 Recommended defaults for object-to-mouth contact Object-to-mouth contact

In some studies, also other hand and mouth contact activities of children were reported, such as object-to-mouth contact. Object-to-mouth contact behaviour shows a similar trend as HTM contact. Both contact behaviours show a decreasing trend in contact frequency as children age. Object-to-mouth contact is a broad subject including contacts with all kinds of objects (toys and non-toys) and surfaces. In some studies distinction was made between touching surfaces or objects, but these contacts are summed in the summary table below (see Table 9). For details on studies in which these results were found it is referred to sections above and Appendix I.

Deriving default values for object-to-mouth contact is more complicated than for HTM contact. Object-to-mouth contact is meant to describe contacts of objects with the mouth. However, in most studies mouth contact with surfaces is also included. Because object-to-mouth contact is described differently in the studies, it is difficult to compare results. Furthermore, the results do not show consistency between the studies, while within studies a decreasing trend in object-to-mouth contact frequency can be detected when children grow older. It is therefore concluded that, at present, there is insufficient data to derive defaults for different age groups for object-to-mouth contact.

*Table 9: Overview of object-to-mouth contact data.* 

| Age                         | No. of children | Object-to-mouth (means)    | Reference (remarks)           |
|-----------------------------|-----------------|----------------------------|-------------------------------|
|                             |                 | (SD or range)              |                               |
| 3-6 months                  | 5               | 37 min/d (19.1)            | Groot et al., 1998            |
| 6-12 months                 | 14              | 44 min/d (44.7)            | (mouthing duration, including |
| 12-18 months                | 12              | 16 min/d (18.2)            | HTM contact)                  |
| 18-36 months                | 11              | 9 min/d (9.8)              |                               |
| 2-6 years                   | 30              | 16.3 contacts/h (0.0-86.2) | Reed et al., 1999             |
| 3-4 years                   | 3               | 6 contacts/h (7)           | Freeman et al., 2001          |
| 5-6 years                   | 7               | 1 contacts/h (2)           | (only data from videotaping)  |
| 7-8 years                   | 4               | 1 contacts/h (2)           |                               |
| 10-12 years                 | 5               | 1 contacts/h (1)           |                               |
| 24-55 months                | 10              | 4.5 contacts/h (3.1)       | Freeman et al., 2005          |
| 0-18 months                 | 146             | 70 min/d                   | Juberg et al., 2001 (do-ers   |
| 18-36 months                | 40              | 56 min/d                   | only) a                       |
| ≤ 24 months                 | 28              | 62 contacts/h              | Tulve et al., 2002 b          |
| older than 24 months        | 44              | 26 contacts/h              |                               |
| ≤ 24 months                 | 9               | 1 contact/h                | Auyeung et al., 2004; 2006    |
| older than 24 months        | 38              | 8 contacts/h               | (indoor results)              |
| ≤ 24 months                 | 9               | 1 min/d <sup>c</sup>       |                               |
| older than 24 months        | 38              | 1 min/d <sup>c</sup>       |                               |
| Infants (7-12 months)       | 13              | 24.4 contacts/h (11.6)     | Black et al., 2005            |
| 1-year olds                 | 12              | 9.8 contacts/h (6.3)       |                               |
| 2-year olds                 | 18              | 7.8 contacts/h (5.8)       |                               |
| preschoolers (37-53 months) | 9               | 10.1 contacts/h (12.4)     |                               |

<sup>&</sup>lt;sup>a</sup> 'Do-ers only' means that children who did not display this behaviour were excluded from further calculations to obtain minutes of event per day. Includes non-pacifier objects only.

#### 2.2 Hand-in-mouth contact data

Most studies did not make a distinction between HTM and HIM contact in published HTM contact data using videotape methodologies (Kissel et al., 1998). It is obvious from articles cited in section 2.1 that insertion of fingers/hands into the mouth is studied to a much lesser degree compared to HTM contact. In fact, only the studies by Freeman and colleagues regarded HIM contact. Their findings do not differ much (generally slightly lower contact frequencies) (see section 2.1) from other studies which investigated HTM contact (including HIM contact). In a recently published study, Ko et al., (2007) studied the relationship between video assessments and parental perceptions of child touching and mouthing behaviours during outdoor play. In that study, HIM contact was one of the parameters selected. Thirty-seven children (aged 1 to 5) were videotaped. The average HIM contact was 6 contacts/h with an SD of 0.55 (log-normal distributed) and a range of 0 to 67 contacts/h. However, Ko et al. included food activities as HIM contact and did not separate HIM contact for different age groups. They also included HTM area contacts and observed an average of 28 contacts/h. (n=37, aged 1 to 5). For HTM contacts touching the area around the mouth and food activities were counted as HTM contact. This study seems to support the finding that on average the number of HIM contacts/h does no differ much from HTM contact data found,

<sup>&</sup>lt;sup>b</sup> Data from Tulve et al. (2002) are based on the sum of hand-body, hand-surface and hand-toys contacts.

<sup>&</sup>lt;sup>c</sup> Mouthing time per day was estimated by US EPA using awake times of 10 hours per day and 10.7 hours a day for children under two years of age and above, respectively.

however it is difficult to compare the results of Ko et al. to others because food activity was included.

HIM/HTM ratios that were observed by Leckie et al. (2000; as cited in HESI 2004) reflect that children contact their lips more often than they insert fingers into their mouth. Leckie et al. used videotape methodology to investigate the degree of hand insertion (HESI, 2004). The researcher used data from another study (from Zartarian et al., 1997) and from the SHEDS database (later on published in SHEDS, 2002) to obtain a reasonably large dataset. Leckie and colleagues found that for individual children hands touching lips constituted 2-100% of HTM contacts, with an average of 62%. This implies that on average 38% of HTM contacts is HIM contact. According to Leckie et al., (2000; as cited in HESI 2004) the percentage declines with age: 'Children at age 1-2 have on average 46% HIM contacts of the HTM contact events. This decreases to 42% for children 4-6 years old and 24% for children 5-6 years old'. However, details on which information these statements were based are not provided in the report by HESI (2004). It also seems that the second age group 4-6 years should be 3-4 years.

#### 2.2.1 Derivation of defaults for HIM contact

HIM contact is considered a more relevant parameter than HTM contact. Very little data are available for HIM contact and degree of insertion. Comparing HIM data from Freeman et al., with other data is not possible, because only a low number of children have been observed per age group and HTM contact data is not available for the children in the study by Freeman (to compare HTM contacts with other studies to see whether children displayed 'extreme' HTM behaviour). Data derived by Ko et al. (2007) could not be used for deriving default values for HIM contact, because food activities were included as HIM contact and in addition all children were pooled into one age group. The range in found HIM contact frequencies may be caused by the range in childrens' ages.

Because data on HIM contact is not sufficient to derive default values for exposure assessments, default values for HIM/HTM ratios were derived. This ratio can be applied as a correction factor to HTM contact to obtain the HIM contact. The HIM/HTM ratios derived by Leckie et al., (2000; as cited in HESI, 2004) are based on a relatively extensive dataset, but the quality of this data could not be checked.

Nevertheless, defaults will be based on HIM/HTM ratios observed by Leckie, taking into account the different age groups considered in the present report (based on EPA recommendations (Xue et al., 2007). Children below the age of one are included in this report for which a higher HIM/HTM ratio is expected. Therefore, a slightly higher ratio was assigned to the age groups of 0.25 to <0.5 years, 0.5 to <1 years and 1 to <2 years (50% vs. 46% (age 1-2 years)). The HIM/HTM ratio is then expected to decline when children age, based on results from Leckie et al (HESI, 2004). For this reason, a similar decrease in HIM/HTM ratio was taken up in the defaults where the value for age group 4-6 years (0.42) was adapted to 0.4 (rounded) for 2 to <3 year olds. The HIM/HTM ratios for 3 to <6 years and 6 to <11 year olds was adapted (rounded to 0.3) from Leckie et al (see Table 10), because the different age groups considered are overlapping. It is noted that for the age group 6 to <11 year the default ratio may be conservative considering the data from Leckie et al. Because no raw data is available, it was not possible to derive 75<sup>th</sup> percentiles for the HIM/HTM ratios. The presented default values are averages.

| Age group    | Default HIM/HTM ratios (fraction) |
|--------------|-----------------------------------|
| 0.25 to <0.5 | 0.5                               |
| 0.5 to <1    | 0.5                               |
| 1 to <2      | 0.5                               |
| 2 to <3      | 0.4                               |
| 3 to <6      | 0.3                               |
| 6 to <11     | 0.3                               |

Table 10: Default HIM/HTM ratios that can be used to derive the HIM contact from HTM contact data.

#### 2.2.2 Degree of insertion

Currently, in exposure assessments it is assumed that all HTM contacts involve insertion of (part of) the hands into the mouth as a default. This assumption can be refined by applying the HIM/HTM ratio which was derived by Leckie et al (as cited in HESI, 2004). Further refinement can be achieved by elucidating the degree of finger contact with the mouth. To this end, Leckie et al. scored frequencies of single finger or palm versus multiple fingers to mouth contacts from videotape observations (see Table 11). Based on results shown in Table 11 it can be concluded that children contact their mouth infrequently with palm, three, four or five fingers. More often either one or two fingers are inserted (Leckie et al., 2000; as cited in HESI, 2004). Seventy-four per cent of the HTM contacts were with one or two fingers for 1-3 olds, this figure was 69% for children aged 1-6 years.

*Table 11: HTM contact frequency scored for palm, one finger and multiple fingers (HESI, 2004).* 

| Palm and fingers contacting mouth (contacts/h) |      |     |     |      |     |       |  |  |
|--|------|-----|-----|------|-----|-------|--|--|
| Age (yrs)                                      | Palm | 1   | 2   | 3    | 4   | 5     |  |  |
| 1-3  | 1.1  | 4.9 | 5.6 | 0.78 | 1.5 | 0.26  |  |  |
| 4-6  | 1.4  | 3.4 | 2.5 | 1.5  | 1.2 | 0.067 |  |  |
| 1-6  | 1.2  | 4.2 | 4.3 | 1.1  | 1.4 | 0.18  |  |  |

In the HESI report, surface area contacting the mouth per HTM event as a function of age was calculated. Calculations were made using an equation that multiplies frequency, degree of insertion (fraction) and surface area per event. Results show a range of hand area contacted per HTM event of 4.1 cm²/event to 7.9 cm²/event for a 1-year old and 3-year old child, respectively. Children older than three were calculated to have lower contacted areas per event. It should be noted that the input data from which the results were derived were not reported.

The degree of insertion is not extensively studied up until now. Leckie et al., (2000; as cited in HESI, 2004) scored frequencies of hand palm or multiple fingers inserted into the hand. From the results it can be concluded that during contact in most occasions only one or two fingers are contacted. In some occasions the palm or more fingers are contacted. As a default US EPA considers that three fingers are inserted up to the palm in exposure assessment for pesticides (Hemond and Solo-Gabriele, 2004, HESI, 2004). However, based on the results shown above (Table 11), it appears that generally two fingers are contacted by the mouth in all age groups. For this reason, as a default the surface area that equals to two fingers will be considered the contacted hand surface area for all age groups. The contacted area is also

defined per contact, thereby no distinction is made whether the same hand surface area is contacted or not.

## 2.3 Anthropometric data

Non-dietary exposure to chemicals from mouthing behaviour is the result of placing either hands (fingers and/or thumbs) or objects into the mouths. Hand loading of chemicals is expected to be a continuous process, because children are very active. This is strengthened by high hand-to-object contact frequencies (amongst which also included surfaces). Hence, the surface areas of the hands as to determine the potential dermal and oral exposure are important parameters. In the previous section as a default it was decided to consider the surface area of two fingers to be the contacted hand area.

The surface area of two fingers will be given in this section as a default. In addition, surface areas of the hand derived from different sources will be given as background information.

#### 2.3.1 Hand surface area

Hand surface area is related to the age of a child. As the child grows larger the surface area of their hands will increase as well. Furthermore, as HTM contact is also age related (highest among 0.25 to <0.5 year old children) it is relevant to provide hand surface areas for similar age categories. In the draft Appendix for 'Non-food- products: How to assess children's exposure?' anthropometric data concerning children are collected. Data for the Dutch child population on body weight and surface areas for body and hands (as percentage of total body area), amongst other body parts, are shown in Tables 12 and 13 For full overview of anthropometric data concerning children is referred to Bremmer et al.(2006b) and (van Engelen and Prud'homme de Lodder, 2004).

| Table 12: Rody | weights   | for infants and | children | in the   | Netherlands | (Bremmer et al  | 2006h            |
|----------------|-----------|-----------------|----------|----------|-------------|-----------------|------------------|
| Tuble 12. Dou  | y weights | joi injunis ana | Chilaren | iii iiic | remerianas  | Dienniel et al. | , <b>2</b> 0000) |

| Age     |       | Boys  |         | Girls       |     | Children    |      | ren              |
|---------|-------|-------|---------|-------------|-----|-------------|------|------------------|
| Months  | Years | Weigl | nt (kg) | Weight (kg) |     | Weight (kg) |      | (kg)             |
|         |       | Mean  | SD      | Mean        | SD  | Mean        | SD   | Default value a) |
| 1.5     |       | 4.8   | 0.5     | 4.5         | 0.5 | 4.65        | 0.52 | 4.30             |
| 4.5     |       | 7.0   | 0.8     | 6.5         | 0.7 | 6.75        | 0.79 | 6.21             |
| 7.5     |       | 8.6   | 1.0     | 8.0         | 0.9 | 8.30        | 1.0  | 7.62             |
| 10.5    |       | 9.8   | 1.1     | 9.1         | 1.0 | 9.45        | 1.1  | 8.69             |
| 13.5    |       | 10.7  | 1.2     | 9.9         | 1.1 | 10.3        | 1.2  | 9.47             |
|         | 1.5   | 11.5  | 1.9     | 10.8        | 1.9 | 11.1        | 1.9  | 9.85             |
|         | 2.5   | 14.2  | 2.0     | 13.5        | 2.1 | 13.9        | 2.1  | 12.5             |
|         | 3.5   | 16.1  | 2.8     | 16.0        | 2.9 | 16.0        | 2.9  | 14.1             |
|         | 4.5   | 18.7  | 3.0     | 18.0        | 3.2 | 18.4        | 3.1  | 16.3             |
|         | 6.5   | 23.5  | 3.9     | 22.8        | 3.7 | 23.1        | 3.8  | 20.6             |
|         | 9.5   | 32.1  | 6.2     | 32.7        | 5.7 | 32.4        | 6.0  | 28.4             |
|         | 12.5  | 44.2  | 8.2     | 45.3        | 7.9 | 44.8        | 8.1  | 39.3             |
|         | 13.5  | 49.4  | 9.2     | 50.6        | 8.8 | 50.0        | 9.0  | 43.9             |
|         | 16.5  | 65.6  | 8.6     | 60.2        | 8.6 | 62.9        | 9.0  | 56.8             |
| a) - th | 17.5  | 69.7  | 10.5    | 60.9        | 7.9 | 65.3        | 10.0 | 58.2             |

a) 25<sup>th</sup> percentile

| Age    | Surface area     | Surface area by body part |  |  |
|--------|------------------|---------------------------|--|--|
|        | $(m^2)$          | $(m^2)$                   |  |  |
|        |                  |                           |  |  |
| Months | Default value a) | Hands <sup>b)</sup>       |  |  |
| 1.5    | 0.270            | 0.014                     |  |  |
| 4.5    | 0.346            | 0.018                     |  |  |
| 7.5    | 0.398            | 0.021                     |  |  |
| 10.5   | 0.437            | 0.023                     |  |  |
| 13.5   | 0.467            | 0.025                     |  |  |
|        |                  |                           |  |  |
| Years  |                  |                           |  |  |
| 1.5    | 0.480            | 0.025                     |  |  |
| 2.5    | 0.575            | 0.030                     |  |  |
| 3.5    | 0.640            | 0.035                     |  |  |
| 4.5    | 0.709            | 0.039                     |  |  |
| 6.5    | 0.841            | 0.046                     |  |  |
| 9.5    | 1.05             | 0.058                     |  |  |
| 12.5   | 1.31             | 0.075                     |  |  |
| 13.5   | 1.40             | 0.080                     |  |  |

Table 13: Surface areas by body part for infants and children in the Netherlands

The percentage of surface area for the hands ranges from 5.0 to 5.8% of the body surface area (corresponding to 0.014 to 0.080 m<sup>2</sup>) for children ranging in age from 1.5 month to 13.5 years (Table 13). This shows that the hand surface area increases with age.

Note that figures for hand surface area in Table 13 are derived from the default body surface area values. However, the correlation between the body surface area distribution and hand surface area distribution is not known. Therefore, it cannot be said that derived values for hand surface area in Table 13 represent the 25<sup>th</sup> percentiles of the hand surface area distribution. It is assumed that the derived hand surface areas approximate the 25<sup>th</sup> percentile.

Other methods to obtain the hand surface area are simply by calculating. This means measuring the length and width of the hands. Multiplying both provides, roughly, the surface area.

#### Palm surface area = length \* width

Multiplying obtained palm hand surfaces by a factor of 4 will roughly provide the total hand surface area. The length of the hand is determined by taking the line from tip middle finger to where the hand meets the wrist. The width of the hand is determined by taking the concavity near the palm-digital crease to where the medial thumb diverges from the index finger (thumb is excluded but compensated by taking the length from tip of middle finger) (Steenbekkers, 1993).

Studies by Amirsheybani et al., Snyder et al., Lioy et al., and Leckie et al., (all cited in (HESI, 2004)) conducted hand palm measurements with children ranging from 1 to 6 years of age. Hand palm surface areas were obtained using the same formula as Steenbekkers (1993). Table 14 provides surface areas of hand palms derived from these four studies.

a) 25<sup>th</sup> percentile

b) Calculated from percentages given by Bremmer et al. (2006b)

|             | Hand palm SA<br>Amirsheybani et<br>al. (cm <sup>2</sup> ) | Hand palm SA<br>Snyder et al.<br>(cm <sup>2</sup> ) | Hand palm SA<br>Lioy et al. (cm <sup>2</sup> ) | Hand palm SA<br>Leckie et al.<br>(cm <sup>2</sup> ) |
|-------------|---|---|--|---|
| N           | 101   | 89-648  | 35   | 1   |
|             | (total 2-6 yrs old)                                       | (per age group)                                     | (total 3-6 yrs old)                            | (per age group)                                     |
| Age (years) |   |   |  |   |
| 1           | ND  | 41  | ND   | 55  |
| 2           | 51  | 50  | ND   | 70  |
| 3           | 62  | 55  | 54   | 64  |
| 4           | 66  | 60  | 64   | 76  |
| 5           | 70  | 68  | 72   | 76  |
| 6           | 76  | 75  | 78   | 82  |

*Table 14: Calculations of hand palm surface areas from several studies (all cited in HESI, 2004).* 

ND = not determined

From the data above, it can be concluded that surface area of the hands (or palm of hands) increases proportionally with age. Leckie et al., only measured the surface area of one child per age group, which might explain the higher observed surface area for the two year old than for the three year old.

Allometric scaling can also be used to determine the surface area of the hands, although it is generally preferred to use measured data. Anderson et al., (1985) (as cited in (Kissel et al., 1998)) described two formulas used for calculating the surface area based on body weight and height of the subject for males and females separately.

$$SA_{hands, male} = 0.0257 * W^{0.573} * H^{-0.218}$$
 
$$SA_{hands, female} = 0.0131 * W^{0.412} * H^{0.0274}$$

Where SA is surface area (m²), W is weight in kg, and H is height in centimetres. The allometric equations were based on data on three males and one female and describe the surface area of both hands. The equations were based on adults; therefore it is uncertain whether the correlations are valid for children as well. The percentage of the hands as part of total surface area remains almost the same over the age categories, ranging from 5.0 to 5.8%. Thus, it seems that the correlation between body weight and height with surface area will not be affected much by age. In Table 15 hand surface areas were calculated using allometric scaling. The equation for females was used in combination with data from the Dutch Growth Study (Fredriks et al., 2000) taking body weights and height (all averages) for girls into consideration.

*Table 15: Calculated hand surface area based on allometric scaling.* 

| Age | Body weight (kg) | Height (cm) | Hand surface area (m <sup>2</sup> ) |
|-----|------------------|-------------|-------------------------------------|
| 1   | 9.6              | 75.1        | 0.037                               |
| 2   | 12.3             | 87.5        | 0.042                               |
| 3   | 14.7             | 96.7        | 0.045                               |
| 4   | 16.9             | 104.5       | 0.048                               |
| 5   | 19.2             | 111.8       | 0.050                               |
| 6   | 21.8             | 118.7       | 0.053                               |

Comparing the data from Bremmer et al. (2006b) with data generated with allometric scaling shows that the values derived with allometric scaling are overall slightly lower. Nevertheless, allometric scaling could be used when underlying data is sufficient to derive the equation. In this case, the underlying data was insufficient (the equation is based on adults) and it is therefore not recommended to use the equations for children.

#### 2.3.2 Finger surface area

The part of the hand that mostly is inserted into the mouth is the fingers. Although there are data concerning the surface area of the hands, this is not the case for fingers. Finger surface areas can be estimated by taking the finger length and width and subsequent multiplication of both figures. In HESI (2004) average calculated and measured surface areas for fingers were provided. The average finger widths were derived by taking the hand with and divide this by five, which was conducted with data from Amirsheybani et al., (2001). Data on finger length was obtained from studies by Snyder et al., (1975) and Gefferth (1972). Remarkably, data from Gefferth was obtained by X-raying fingers, thereby missing the part which of finger length from the top of the bone to the tip of the finger. Finger length may be underestimated as a result. In Table 16, the average finger surface area of children ranging from 1 to 6 years old are provided as calculated from data from Amirsheybani and Gefferth (all cited in HESI, 2004).

#### 2.3.3 Default for contacted area with the mouth per event

In subsection 2.2.2 it was concluded that the contacted area per event is the surface area of two fingers. In addition, no discrimination was made between the age groups. In section 2.3 hand surface areas and finger surface area are provided. Following the conclusion in subsection 2.2.2 data on finger surface area should be used to determine the contact area per contact. The calculated average finger area based on two studies was chosen as point of departure (HESI, 2004).

The default contact areas are derived by multiplying the average surface area of a finger by two. Because some age groups considered in this report are different from the age groups in Table 16, estimations were made of the average finger surface area for those age groups. The default contacted finger areas per age group are listed below (see Table 16). Because there was no data for children under one year of age on the surface area, the average surface area of one finger for this age group was estimated, 2.5 cm<sup>2</sup> (personal estimation).

Table 16: Finger surface area of the average fingers (calculated) for different age groups (adapted from HESI, 2004) and derived default values for surface area contacted by the mouth (assumed surface area of two fingers).

| Age group<br>(years) |                    | Average finger SA (calculated) | Average finger<br>SA (rounded) | Default contacted area with the mouth      |  |
|----------------------|--------------------|--------------------------------|--------------------------------|--|--|
| HESI (2004)          | Default age groups | (cm <sup>2</sup> )             | (cm²)                          | (sum of two fingers)<br>(cm <sup>2</sup> ) |  |
| -                    | 0.25 to <0.5       | ND                             | 2.5                            | 5.0  |  |
| -                    | 0.5 to <1          | ND                             | 2.5                            | 5.0  |  |
| 1                    | 1 to <2            | 2.93                           | 3.0                            | 6.0  |  |
| 2                    | 2 to<3             | 3.48                           | 3.5                            | 7.0  |  |
| 3                    |                    | 4.26                           |                                |  |  |
| 4                    | 3 to <6            | 5.04                           | 5.0                            | 10   |  |
| 5                    |                    | 5.32                           |                                |  |  |
| 6                    | 6 to <11           | 6.03                           | 7.5                            | 15   |  |
| -                    | 6 to <11           | -                              | 7.5                            | 15   |  |

### 3. Discussion and conclusions

Scenario based approaches have been used in exposure assessments for biocides by both EU (or national) agencies and the US EPA. In specific scenarios non-dietary ingestion from HTM contact is considered a relevant route of secondary exposure to children. In those scenarios simplified approaches and/or default values have been applied to assess the exposure from HTM contact behaviour of children. In Europe, it appeared that HTM contact data were not used to calculate exposure, but basic assumptions were used (see section 1.4). US EPA applies HTM contact data to determine the exposure to biocides. The default used was based on one study performed in 1996.

The use of default values in exposure assessment is widely accepted and even required when data are lacking or insufficient. When new data are available it may replace default values or can be used to set new default values. In this report new default values for HTM contact have been proposed for its use in exposure assessments based on currently available data.

#### 3.1 Combined data and recommended default values

Data has been collected for several parameters. For these parameters defaults have been recommended per age group based on available data (see sections 2.1 to 2.3). The default values are combined in Table 17, where also default body weights are added. Note that body weights were not specifically derived for an age group, but for a certain age of the child instead. As a default the body weight (25<sup>th</sup> percentile) associated with the age group is taken up. For instance, for two-year olds the age of 2.5 was selected and consequently the body weight was rounded to 12.5 kg. For some age groups it was not possible to match an appropriate age from Table 12, in those cases the body weight was estimated, taking the body weights of surrounding age groups into account.

Table 17: Combined recommended defaults for HTM contact, HIM/HTM ratio, contact area and body weight.

| Age group | HTM contact<br>(contacts/h) |         | HIM/HTM<br>ratio<br>(fraction) | Contact<br>area per<br>event | Body<br>weight <sup>a</sup><br>(kg) | Total contact area (cm²/kg bw/h) (cm²/h) |         |
|-----------|-----------------------------|---------|--------------------------------|------------------------------|-------------------------------------|--|---------|
|           | Indoor                      | Outdoor |                                | (cm <sup>2</sup> )           |                                     | Indoor                                   | Outdoor |
| 0.25 to   | 50                          | -       | 0.5                            | 5.0                          | 6.0                                 | 20.8                                     | -       |
| < 0.5     |                             |         |                                |                              |                                     | (125)                                    |         |
| 0.5 to <1 | 30                          | 20      | 0.5                            | 5.0                          | 9.0                                 | 8.3                                      | 5.6     |
|           |                             |         |                                |                              |                                     | (75)                                     | (50)    |
| 1 to <2   | 30                          | 20      | 0.5                            | 6.0                          | 10                                  | 9.0                                      | 6.0     |
|           |                             |         |                                |                              |                                     | (90)                                     | (60)    |
| 2 to <3   | 20                          | 10      | 0.4                            | 7.0                          | 12.5                                | 4.5                                      | 2.3     |
|           |                             |         |                                |                              |                                     | (56)                                     | (28)    |
| 3 to <6   | 20                          | 10      | 0.3                            | 10                           | 16                                  | 3.8                                      | 1.9     |
|           |                             |         |                                |                              |                                     | (60)                                     | (30)    |
| 6 to <11  | 10                          | 5       | 0.3                            | 15                           | 25                                  | 1.8                                      | 0.9     |
|           |                             |         |                                |                              |                                     | (45)                                     | (23)    |

<sup>&</sup>lt;sup>a</sup> Default body weights were based on Bremmer et al., (2006). Rounded values are given.

The defaults for HTM contact are based on results from Xue et al., (2007), who gathered, pooled and analysed data on HTM contact from a number of studies. Xue and colleagues included a number of studies, which were also described in this report, and some additional studies, thereby providing an almost complete view of available data on HTM contact. A description of the study by Xue et al. and the way the defaults were derived is provided in section 2.1.

Combining the HTM contact, HIM/HTM ratio, contact area per event and body weight the total contact area per hour per kg body weight for each age group can be derived (see Table 17). The youngest age group shows the highest contact area expressed in contact area per hour and in contact per hour per kg body weight. This can be explained by the relatively high HTM contact frequency.

Results for the other age groups show a slight increase to the age of two and decrease in contact area per hour when older age groups are considered. The total contact area per body weight decreases with increasing age of children, except for the 1 to <2 age group under specified basic assumptions. These assumptions are that every HTM contact event will lead to oral exposure and that the contacted area per event remains the same per age group, i.e. the surface area of two fingers. Considering the relatively high frequencies for hand-to-object contact (data not shown); then assuming that the hand will be loaded every time the hand is contacted might not be too worst case.

Three important aspects were revealed from reviewing the studies. 1) Relatively small sample sizes and short observation times were used which affects the representativeness of the results, 2) large variability was observed in HTM contact behaviour between children, which is difficult to handle in deriving defaults and 3) day-to-day variation was not studied enlarging the uncertainty for its use for exposures from HTM contact.

Next to the HTM contact frequencies, defaults were derived for HIM/HTM ratios and anthropometric data. Since for exposure assessment HIM contact is probably a more important parameter than HTM contact, using HIM contact data is preferred. However, sufficient HIM contact data is lacking. Therefore, default HIM/HTM ratios can be used to derive HIM contact frequencies. Unfortunately, the defaults for HIM/HTM ratios are based on one study only and are therefore considered of low reliability. The anthropometric data (surface areas and body weights of children) are considered to be of much higher quality, because it is supported by sufficient data.

Although the recommended defaults in this report are subject to uncertainty and data gaps still exist (see section 3.5), we recommend using these defaults in exposure assessments with regard to exposure via HTM contact. The recommended defaults are based on available (measured) data and are therefore considered more appropriate than currently used default methods, which are mainly based on assumptions.

# 3.2 Recommended default values versus currently used default values

Recommended default values are summarized in Table 17. The defaults have been derived for a number of age groups, because differences between children from different age groups are significant. Moreover, in a specific exposure scenario a decision can be made on which age group should be considered and more importantly which age group should not be considered. As an example for pet treatment, US EPA (1997b) considers a toddler in their exposure scenario, which should represent children ranging from 1-6 years of age. For pet

treatment there is no use in taking children, aged less than one year, into account as they will generally not pet animals. In other words, these children will not be the highest exposed subjects. On the other hand, using an age group of 1-6 year olds might potentially undermine high exposed subjects (subgroups) in that age group, for instance the two year olds.

A comparison is made between the approaches used until now according to the Pest Control Product Fact Sheet (A) and the approach using recommended default values in the present report (B) (see Appendix III). The results from both approaches do not differ much from each other. This can be explained partially, because the same subject (10.5 month old child) was considered in the assessment. Furthermore, the same point of departure was used, i.e. the total dermal exposure (or the amount on hands) where the same assumption was made for the oral ingestion (i.e. all compounds on contacted area).

On the other hand, in the second approach the oral exposure is directly linked to the behaviour of the child, which is clearly not the case in the first approach. The difference in both approaches originates from the difference in contacted hand area. In the first approach (A) this is based on 50% of the total hand surface of a child. In approach (B) the contacted area is based on HTM contact behaviour and surface area contacted per event, which is set for all ages to the equivalent of two fingers. As can be seen from Table 17 the total contacted area will increase up until two years of age. After that a decrease is observed for the contacted hand area, due to a decrease in HTM frequency.

The default values recommended in this report are set in such way that they should provide a reasonable worst case estimate. As shown above, approach (A) will provide even higher outcomes. This will be even more apparent when considering older children, because the contacted area will increase using approach (A), i.e. the contacted surface area with the mouth remains 50% of the total hand surface area of the child. Therefore, it is suggested using the recommended defaults instead of the defaults used in the Pest Control Products Fact Sheet.

A larger difference in exposure can be expected when the defaults from US EPA were used. US EPA would consider a toddler for this scenario to represent 1-6 year olds. One can imagine that the exposure as a result from HTM contact would become much lower using the specifications for a three year old. In that case the exposure for a one year old could be underestimated. Therefore, it is very important to select subjects that are expected to have the highest exposures. Using the recommended defaults in this report, it is possible to make separate exposure assessments for different age groups.

# 3.3 Soil ingestion data

The recommended defaults in this report could be used to assess the oral exposure to soil or contaminants present in the soil, because HTM contact is expected to be similar when hand loading of soil is only superficial. In that case the dermal load can be described in terms of mg/cm<sup>2</sup>. A comparison is made between the currently used default for soil ingestion and how this would correspond to recommended default values. In order to make that comparison a few assumptions have to be made. First, it is assumed that HTM contact behaviour can be used for outdoor activities and secondly a child plays outdoors one hour per day.

The current default is 100 mg/day soil ingestion (see subsection 1.4.2). This default is derived for children in the range from one to six years of age. Furthermore, the soil ingestion is the

result of indoor and outdoor activities where both soil and dust (containing soil particles) are ingested. On average a three hour outdoor activity per day is considered (Lijzen et al., 2001, Otte et al., 2001, Oomen et al., 2007).

For comparison purposes, it is assumed that a one year old child plays one hour outdoors resulting in ingestion of 100 mg soil from HTM contact. In one hour the child has contacted  $60 \text{ cm}^2$  of the hand surface area (20 \* 0.5 \* 6 = 60) based on the defaults in Table 17 (HTM contact for outdoor location was considered). The dermal load required to obtain 100 mg ingestion, assuming that all soil on the contacted area is ingested, should be  $100 / 60 = 1.67 \text{ mg/cm}^2$ . Obviously, when contacted areas are decreasing, the dermal load should be higher to obtain 100 mg/d ingestion. For a six year old this would correspond to a dermal load of  $4.3 \text{ mg/cm}^2$ , but six year olds may play longer in outdoor environments. In that case, the total soil ingestion per day is spread over a longer contact time, thereby increasing the potential contacted hand area. Logically, dividing 100 mg/day soil ingestion by a larger contacted hand area provides a lower dermal load.

Corresponding dermal loads required to obtain similar soil ingestion from HTM contact does not provide unrealistic results. For this reason, it is concluded that the recommended default values do not contradict the default for soil ingestion. However, current defaults on soil ingestion are based on a relatively large number of data. Use of this data is preferred over the recommended default values.

## 3.4 Object-to-mouth contact

Object-to-mouth contact behaviour shows a similar trend as HTM contact. Due to insufficient information it was decided not to derive default values for object-to-mouth contact. Instead, as default the deposited amount on an object is the point of departure for assessing the exposure. In that case, the surface area of the object contacted determines the total oral exposure. A clear difference between exposure from HTM contact and object-to-mouth contact is that objects are assumed not be reloaded if there is no repeated treatment. On the other hand, other objects can be contacted as well. For this reason, future research on object-to-mouth contact should focus more on what objects are contacted by a child's mouth to determine whether repeated exposure may occur (from different objects).

# 3.5 Data gaps

To obtain more insight in non-dietary chemical exposure of children a (limited) number of studies have been performed. Topics of interest were children's behaviour and transferable amounts of pesticides or biocides post-application. However, these studies were not aimed to determine the exposure as a result of child behaviour, but merely to describe the behaviour. This might explain for the larger part as to why data gaps still exist to date. In this section, the major data gaps are identified.

#### 3.5.1 Insufficient data on HTM and HIM contact data

Studies have been performed to obtain insight in the behaviour of children. This relatively small number of studies investigated behaviour such as mouthing and hand contacts with all

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kinds of objects and/or surfaces. These studies have already filled an important gap concerning our (lack of) knowledge of children's behaviour.

From the overview of studies it can be concluded that most studies did not observe children of less than 12 months of age, especially for the outdoor location. During that stage of life, children often start to crawl or even walk, which places them close to the ground where contact with contaminants can be expected. In addition, infants start teething around 8 months of age; this is behaviour that is positively correlated with mouthing behaviour. For this reason, more information should be gathered for children less than 12 months of age. Furthermore, children ranging in age from two to six years are often placed in one group. Having data for smaller defined age groups is useful in determining age trends or dependencies for, for instance, HTM contact and HIM contact.

In most studies, the mouthing behaviour is presented as a frequency (contacts/h) rather than in terms of duration (min/d). The frequency of mouthing behaviour indicates the extent of mouthing behaviour compared to other children, but lacks any information on how effectively these contacts are. For example, contacting a toy with the mouth 20 times per hour does not indicate whether or not transfer of chemicals is possible during those contacts. Knowing the average contact duration in combination with the total awake time of a child can provide the mouthing duration in minutes per day. This also enables us to compare the different representation of results.

The question remains whether or not contacts are effective in transferring chemicals from the hand into the mouth. In the case a hand is inserted into the mouth effective transfer of chemicals is expected to be much higher than for just touching lips. For this reason, the hand-in-mouth (HIM) contact is of interest and also how this relates to HTM contact. Currently, only HESI (2004) gives an indication of HIM contact for children of 1-6 years old. Also, the degree of insertion is a point of interest, which has not been studied sufficiently thus far.

# 3.5.2 Data gap for link between children's activities and exposure scenario

Children's activities play a major role in exposure assessment, because it places them in certain situations where exposure to chemicals can be predicted. Up until now, no link has been made between certain exposure scenarios with children's activity, for example, application of a biocide in the kitchen or on a lawn. Only two studies have been performed which included the amount of time spent indoors and outdoors, time spent in locations in the house and outside the house (e.g. kindergartens) and what kind of behaviour is related to those microenvironments (Freeman et al., 2001; Auyeung et al., 2004). Xue et al., (2007) included data from four studies for outdoor HTM contact showing that children display less HTM contact behaviour outdoors. However, older children can play for significant durations outdoors making the outdoor HTM contact frequencies relevant.

At present, information on children's activity on where they crawl, walk or play and what micro-level activities children exhibit in a specified microenvironment is insufficient. For this reason, linking location to children's activity is difficult.

Therefore, it is important to obtain a complete picture what children's behaviour is at a certain age or life stage. Data on HTM contact, children's activity, data on microenvironment, children's anthropometrics, potential dermal (hand) loading should be combined and linked together. It is noted that this mainly concerns refinement of exposure assessments to obtain more predictive exposure assessments than worst case exposure assessments.

## 3.6 Recent developments / work in progress

Videotaping methods as were used by Auyeung et al. (2004, 2006) are relatively new. A lot of effort is put in the reliability of the results where inter- and intra-observer agreement checks are performed. The refinements of the videotaping techniques gathered over the years have resulted in major improvements. Methodologies can be tailored to gather micro-level activity patterns for specified exposure or risk assessments (Ferguson et al., 2006). Videotaping devices have a large set of input possibilities which make the tailor-made approach possible. Results of the observations are scored in computer files and read-out according to requirements. In this way a link can be made between children's activities and location and thus also a link with exposure scenarios.

Another effort concerning videotaping methodology is standardizing output files. This makes it possible to combine children's activity data in large databases, such as in the Consolidated Human Activity Database (CHAD) and in the Stochastic Human Exposure and Dose Simulations (SHEDS) database. In these databases it would also become possible to combine macro-level activity data from diaries and questionnaires with micro-level activity data. An example of the usefulness of combining data in databases is shown in a companion paper (Xue et al., 2006, Zartarian et al., 2006). A probabilistic exposure assessment was performed for children exposed to arsenics from CCA treated wood. CCA treated wood is used for construction of playgrounds and decks. The use of input data from the above databases in their exposure assessment enabled the authors to model the exposure to CCA for children.

In an internal report (Rodewijk, 2003) a study was described where children were divided in 'life-stage' groups, e.g. children that 'tiger', children that crawl, and children able to walk. For these groups investigations were made for their different types of behaviour and locations. Although data from this study cannot be compared with data from other studies it can be helpful in deciding what children (in what life-stage) should be considered in exposure assessment.

# 3.7 Concluding remarks

Deriving default values for HTM contact per age group was possible based on available literature. Uncertainties concerning derived recommended default values primarily result from lack of data on HTM contact behaviour for specific age groups. Furthermore, differences in study design, relatively small sample sizes and short observation times, and large variation in HTM contact amongst children result in uncertainty. On the other hand, data from available studies did show similarities in their results, which was supported by findings of Xue et al. after meta-analysis of the data. Therefore, it is concluded that the recommended default values have a sufficient scientific basis.

#### 3.7.1 Recommendations / future research

• It is recommended to use the proposed default values in this report for determining the exposure to chemicals via HTM contact. It is emphasized to carefully consider which

- age group to select for exposure assessment. The selection of an age group to consider should always be scenario based.
- It is suggested to substitute current defaults in the Pest Control Products Fact Sheet with the in this report recommended default values, where exposure to chemicals via HTM contact of children is considered.
- It is recommended to the Dutch Board for the authorization of pesticides (CTB) and European Authority to implement into their protocols the use of the derived defaults to determine the oral exposure to children via HTM contact. Also, in other policy frameworks (except for soil ingestion) it is advised to use the derived default values.
- It is noted that HTM contacts described in this report are not directly to be used for adult exposure via HTM contact. The use of these recommended defaults in the report are restricted to its use in exposure assessments for children.
- In some policy frameworks, such as authorization for pesticides, exposure via HTM contact of adults can be a relevant route of exposure, especially for worker environments. Therefore, it is suggested to focus future research into HTM contact of adults, because this potential exposure route for adults/workers is usually not considered in exposure assessment.
- There are data gaps in HTM contact data for children that can be filled leading to a refinement of the proposed defaults. Future research should focus on very young children (less than one year of age) and on deriving more information on HIM contact, which is considered the more relevant type of contact.
- Hand (un)loading of chemicals was beyond the scope of this report. Future research should focus on the relation between product use and hand loading potentially leading to oral exposure via HTM contact.

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# **Appendix I: Hand loading**

#### **Determinants for hand loading**

#### **Application**

Biocides can be applied in different ways. Here, we make a distinction whether the product is applied onto surfaces (e.g. floors, lawn, and play decks) or onto pets (veterinary medicine) or animal bedding. For the former, contact with these surfaces is relevant for hand loading meaning that a child should be close to the floor or on the lawn. Consequently, the chemical can be rubbed off from the surface. The frequency of contact with these surfaces is relevant, which is described with Hand-to-Surface contact frequency. Also the dispersive use of the product (for instance multiple locations) seems to positively influence the potential hand loading, since a positive correlation was found between hand loadings and multiple locations of HTM contact (Freeman et al., 2005). The amount of chemical applied may also influence hand loading. Up until now, it is unknown which correlation exists between applied product amount and potential hand loading for consumers.

When a pet is treated with a veterinary medicine like a flea powder, exposure may result from petting the animal. In this case, the number of contacts with the pet is of interest. Hand loading can expected to be lower when only the animal bedding is treated. In this case, first the animal must have contact with the bedding before hands can be loaded from petting the animal.

#### Behaviour and hand surface

One can imagine that the very young children (approximately up to one year) will not pet an animal. Hence, their hand loading will be negligible after treatment of the pet. Some children are more active during play and have more contacts with contaminated surfaces (Freeman et al., 2005). Behaviour and/or activities of younger children are different from those of older children leading to different hand loadings. The difference in hand loading between younger and older children can also be due to differences in hand surfaces. The potential dermal load is higher for children with larger hand surface areas.

Hemond and Solo-Gabriele (2004) have shown that moist hands can lead to higher hand loadings than dry hands. From a number of studies it became apparent that moist hands have a positive effect on the hand loading potential. For children who exhibit mouthing behaviour, it reasonably can be assumed that their hands will be moistened. Moist hands in combination with petting or direct dermal contact to contaminated surfaces are potentially significant exposure sources.

#### **Chemical characteristics**

Chemical characteristics can influence the exposure to a compound in general. The distribution of a chemical or product over a room is dependent on for instance its molecular weight, vapour pressure and density. Also, some chemicals adsorb easily to surfaces. This influences the dislodgeable (or transferable) amount of a chemical, which can be loaded upon contact. These characteristics may differ significantly amongst various chemicals.

#### **Unloading of the hands**

Another relevant parameter for the dermal load on hands is unloading of a chemical. By mouthing, washing hands, and rubbing off, the chemical may be partially or entirely removed from the hands. For example, children wash their hands between three and five times a day

according to observations by Freeman et al. (2001) and Black et al. (2005). In those cases, reloading of the hands with contaminants is important.

#### **Basic assumptions for hand loading**

In current exposure assessments generally basic assumptions are made for hand loading. It is assumed that the hands (or hand palms) are entirely loaded with a chemical. As briefly described in section 1.2.1 it can be anticipated that the dermal load depends on the amount of product (biocide or pesticide) used. This relation will probably be non-linear, but still positive proportional. US EPA (1997b) assumes that 20% of the application rate is dislodgeable and thus potential dermal load. The US EPA assumes that all chemical loaded upon the hands will be taken up orally (see also sections 1.4.3.2 and 1.4.3.3).

In the Pest Control Products Fact Sheet (Bremmer et al., 2006a) another approach is taken: first the dermal exposure is calculated and then it is assumed that hands form 20% of uncovered skin. This mounts up to the potential dermal load. A fraction of the chemical that is loaded upon the hands can be taken up orally by HTM contact. In the Pest Control Products Fact Sheet (Bremmer et al., 2006a), this percentage is set to 50%.

In principle, two different cases can be considered:

- 1. Hands are loaded in one occasion (single hand loading). Subsequently, this amount is taken up orally by HTM contact. The total oral exposure is then determined by multiplication of the amount on the skin (mg/cm²) by total hand surface (cm²) placed into the mouth.
  - Oral exposure = Amount on skin \* hand surface area put in mouth
- 2. In a worst case scenario it is assumed that hands are constantly reloaded after hands were unloaded by HTM contact (at least that percentage of the hands which is placed into the mouth) (repeated hand loading). This implies that on every occasion a child mouths its hands, he or she will be exposed orally. The oral exposure is then determined by multiplication of the amount on the skin (mg/cm²) by total hand surface (cm²) placed into the mouth and by the frequency of HTM contact (events/time period).
  - Oral exposure = Amount on skin \* hand surface area put in mouth \* frequency

In both cases it is assumed that the hand is always loaded and also that all chemical on the contacted hand surface area will be ingested. These are, in fact, the basic assumptions for hand loading in this report.

#### Hand loading: work in progress

Ideally, new studies should include hand wipes of the children observed to create a direct link with children's activity and hand loadings. Other techniques than hand wipes could be used as well. In Ivancic et al., (2004) transfer of surrogate pesticide residues was monitored via a video-fluorescence imaging system. Tracers were used to quantify the residual transfer to the hands upon repeated contact. These kinds of techniques can provide input on the surface area that is loaded and the amount loaded upon hands. In occupational settings this method has already been applied (Ivancic et al., 2004). Riley et al., (2004) studied the effectiveness of unloading activities of amongst others mouthing and found that there were 8 effective unloadings of the hands by mouthing. Their findings were based on HTM contact studies and

the study by Ivancic et al., (2004). These kinds of studies can lead to more insight on hand residual levels after hand contacts.

# Appendix II: Summary of selected published studies

A short summary is given of the relatively small number of published studies, in which results on HTM contact activities are reported. Attention is paid to study design, methods used, and important results and/or conclusions derived in these studies. Note that this overview only contains the studies which were available to us and therefore do not include all the studies mentioned in this report.

#### Zartarian et al., 1997

In 1993 a pilot study was performed where 4 children of farm workers were videotaped to gather dermal activity data. Two girls and two boys (age ranging from 29 to 50 months) were videotaped for one day each resulting in a total observation time of 33 hours. Results were presented for every child individually and for both hands separately (Zartarian et al., 1997).

Age groups considered: 1 (29-50 months); 4 children observed.

*Duration of observation*: In total 33 hours of observation spread over four children. The exact time per child was the waking hours of the day (6, 7, 9 and 11 hours).

Results and conclusions: Average HTM contact activities ranged from 3 to 10 contacts/h regarding hands separately. Adding the figures for the left and right hand will provide a range from 9 to 19 contacts/h (data not provided by original author). Highest contact rates were found for touching hard (smooth) surfaces and toys. This study aimed at evaluating methodology of data gathering, therefore a small sample size was used. Therefore, this study has limited value for the estimation of contact frequency.

#### Groot et al., 1998

Mouthing behaviour of 42 infants (aged 3 to 36 months) was examined in an observational study. Parents were asked by investigators to observe their children. The observations were used to gather information on time spent mouthing per day. This study was part of a larger study to determine whether mouthing of PVC toys containing phthalates would pose a risk for children. A distinction was made between toys meant for mouthing and toys not meant for mouthing (Groot et al., 1998).

Age groups considered: 4; (3-6 months (5); 6-12 months (14); 12-18 months (12) and 18-36 months (11)), 42 children observed.

*Duration of observation*: 15 minutes per interval, ten times per day for two (separate) days. In total the observation time per child was 300 minutes.

Results and conclusions: Average mouthing durations per day were estimated to be 20.5 min/day (3-6 months), 7.5 min/day (6-12 months), 5.8 min/day (12-18 months) and 6.3 min/day (18-36 months) (data shown for fingers only, raw data obtained from US EPA (1999a)). The youngest children (3-6 months) mouth their fingers the most, while children of age 6-12 months, mouth toys the most and to lesser extent fingers. Older children still mouth their fingers to a high extend, but 'non-toys' are mouthed most above the age of 12 months. It was stated that mouthing toys is probably the result of the child's desire to ease the pain from teeth coming through or just to explore objects. Limitations of the study were small size of the study, study was not representative for population due to inclusion of children from mostly higher-educated parents, and limited days of observation. The latter may be a limitation for most studies.

#### Reed et al., 1999

Reed et al., (1999) used videotaping methodology to examine the mouthing behaviour of children. The children were divided in location and age group (day care, age 3-6 years, n = 20; residences, age 2-5 years, n = 10). Parents and day care keepers were asked to fill in questionnaires describing the behaviour of the children. In addition to HTM contact, hand-to-hand, object-to-hand, object-to-mouth, and hand to surfaces (smooth, textured, dirt, and clothing) were studied using videotape observations.

Age groups considered: 2; (2-5 years (20) and 3-6 years (10)), 30 children observed. Duration of observation: Total observation durations of 112 hrs and 56 hrs were realized for children in day cares and at residences, respectively. This resulted in individual observations in the range of 3 to 7 hrs and 5 to 6 hrs in day cares and at residences, respectively. Contact frequencies were averaged over 1 hour periods.

Results and conclusions: An average HTM frequency of 9.5 contacts/h was observed for all children. This result is in concordance with Zartarian et al., (1997). Highest contact rates were observed for hand-to-surfaces contact (123 contacts/h; including objects). The results indicate that the hand is continuously being loaded due to the high contact frequencies with surfaces or objects. Object-to-mouth contact rate was found to be on average 16.3 contacts/h. Limitations of the study were small sample size and not including children younger than two years of age.

#### Freeman et al., 2001

The study was part of the Minnesota Children's Pesticide Exposure Study (MNCPES) where macroactivity and microactivity data were collected for 168 children. Questionnaires were sent out to all children and a subset of 19 children was videotaped for four consecutive hours (awake time). Time/activity diaries were completed by families of 102 children for one week (data not reported). Children in the study were of age 3 to 12 years and living in urban and rural areas. Videotaping was performed similar to methodology of Reed et al., (1999). For both the left and right hand six microactivity behaviours were recorded: hand-to-mouth, object-to-hand, object-to-mouth, and hand to surfaces (smooth, textured, and clothing). It must be noted that Freeman et al., regard mouthing as to insertion of fingers, thumb or hand in mouth, also referred to as HIM. For clarity reasons his findings will be described as HIM contacts (Freeman et al., 2001).

Age groups considered: 4; (3-4 years (3); 5-6 years (7); 7-8 years (4) and 10-12 years (5)), 19 children observed (results from videotape observations only).

Duration of observation: Four consecutive hours of videotaping. Time/activity diaries were filled in for one week.

Results and conclusions: The researchers found a significant higher activity for object-to-mouth contact amongst 3 year olds compared to other age groups. A mean of 6 contacts/h was observed for this group, based on videotape observations. HIM contacts did not differ significantly amongst the age groups and means ranged from 4 to 8 contacts/h. Further it was observed that both object-to-mouth and HIM contacts were less frequent outdoors than indoors. Limitation of the study was not including children younger than three years of age. Advantage of the study was the combination of three methods to generate and compare data on children's behaviour, i.e. questionnaire, videotaping, and filling in of a diary.

#### Freeman et al., 2005

In the study by Freeman and colleagues (2005), 10 children ranging in age from 24 to

55 months were videotaped for four hours. The investigators studied the link between pesticide use and exposure through non-dietary ingestion from mouthing behaviour. Two days prior to videotaping pesticides were used indoors (professional crack and crevice application). Hands of children were washed before and rinsed after videotaping to determine the dermal load of pesticide on their hands. Videotapes were transcribed for both hands separately and coded for location, activity level and contact activities.

Age groups considered: 1 (24-55 months), 10 children observed. Duration of observation: Four consecutive hours of videotaping. Results and conclusions: HIM contact was found to be on average 10.2 contact/h, while object-to-mouth contact was less frequent amongst the children: 4.5 contacts/h. For both contacts the right hand was slightly preferred over the left hand (median ratio right/left hand was 1.4 and 1.2 for HIM and object-to-mouth contacts). No strong correlation could be drawn up for hand loading and activities, because probably few contacts are needed to load maximally and/or a small sample size was used in the study.

#### Tulve et al., 2002

Mouthing behaviour of 90 children from an unpublished data set, recorded by trained observers (real-time observations), was analysed in this study. Data was originally collected by the Fred Hutchinson Cancer Research Centre, where observations were focused on mouth and tongue contacts with hands, other body parts, natural objects, surfaces and toys. Final data set used in this study (by Tulve et al., 2002) included only those children who were coded as engaging in quiet play indoors. Children (n = 72) ranged in age from 11 to 60 months. A total of 186 observations were included (Tulve et al., 2002).

Age groups considered: 2 (11-24 months (28) and 25-60 months (44)), 72 children observed. Duration of observation: Children were observed between 5 and 60 min/d for 1-6 days (original data set). Instructions were to observe and record every 15 seconds for a minimum duration of 15 minutes. In the reduced data set the number of observations ranged from 1 to 6 per child.

Results and conclusions: Children  $\leq$  24 months had the highest frequency of mouthing behaviour (81 events/h) compared to the older children which had a frequency of 42 events/h. Regarding all children, highest contact frequencies were observed for mouth-toy contacts followed by HTM contact. HTM contacts for all children, children  $\leq$  24 months and older children were 16 contacts/h, 18 contacts/h and 16 contacts/h, respectively. No difference in mouthing behaviour was observed between the sexes. Limitation of the study was exclusion of children in active play, but they appeared to exhibit less HTM activity than children involved in quiet play according to the author (personal communication of Tulve with HESI, as cited in HESI, 2004).

#### Auyeung et al., 2004; 2006

In this study, 38 children were videotaped for two hours during indoor and outdoor play. Children ranged in age from 1 to 6 years old. Micro-level activity time series (MLATS) data were gathered on hand contacts with mouth where a distinction was made between touching, inserting and licking of the hands. Both studies (Auyeung et al., 2006) used the same data set, but in 2004 only HTM contacts and other mouthing contacts were reported while in 2006 specifically hand contacts were reported.

Age groups considered: 2 (1 year olds (8) and 2-6 years (30)), 38 children observed. Duration of observation: children were videotaped during two consecutive hours.

Results and conclusions: The investigators made a difference between outdoor and indoor play. However, for indoor play only a limited number, nine in total of which one under 24 months, of observations was recorded. Nevertheless, it can be concluded that the frequency of HTM contacts outdoor is lower than observed for indoor HTM contacts. For children ≤ 24 months mean HTM contact frequencies were 73.5 contacts/h (10.7 min/h) and 13.0 contacts/h (2.7 min/h) for indoor and outdoor HTM contact, respectively. For children older than 24 months; 13.9 contacts/h (0.7 min/h) and 11.3 contacts/h (0.4 min/h) for indoor and outdoor HTM contact, respectively. A gender difference was also observed in this study where girls had significantly higher frequencies of mouthing contacts, but also significantly shorter contact durations.

#### Black et al., 2005

Fifty-two children in age ranging from 7 to 53 months (from mid-Rio Grande Valley, US) were videotaped to gather data on their mouthing behaviour. In addition, questionnaires were collected wherein information about residences, mouthing behaviour activities, and pesticide and cleaner use was noted. Three behaviours were scored taking both frequency and duration into account, i.e. HTM contact, object-to-mouth contact and food handlings (Black et al., 2005).

Age groups considered: 4 (infants, 7-12 months (13); 1-year olds, 13-24 months (12); 2-year olds, 25-36 months (18); and preschoolers 37-53 months (9)), 52 children observed. *Duration of observations*: Each child was videotaped for four hours. *Results and conclusions*: HTM contacts in terms of frequency were highest amongst the preschoolers (mean 22.1 contacts/h), while two-year olds displayed the lowest frequency of HTM contact (mean 11.9 contact/h). Infants and one-year olds had mean HTM contact frequencies of 19.8 contacts/h and 15.8 contacts/h, respectively. However, the duration of HTM contact was highest for the infants, which on average was 4.6% of tape time. Object-to-mouth activities ranged in frequency from 7.8 contacts/h (two-year olds) to 24.4 contacts/h for infants. Food handlings were included in this study, which seemed to have a positive effect on the HTM contact frequency, particularly for children over one year of age (Black et al., 2005). It was suggested that this impact was more pronounced amongst preschoolers since they often got snacks independently.

# Appendix III: Comparison between currently used defaults and recommended defaults in exposure assessment

The point of departure is an exposure scenario where a child (10.5 months old) crawls over a biocide treated surface (indoors). From the Pest Control Products Fact Sheet defaults for the exposure scenario are used to derive the total dermal load from applying biocides. For details see Bremmer et al., (2006a). The exposure refers to exposure on one day.

Transfer coefficient  $0.6 \text{ m}^2/\text{h}$ 

Dislodgeable amount 15.3 g/m<sup>2</sup> (based on 30% of total amount: 60 g/m<sup>2</sup>)

Contact time 60 min/day

Using the data from the fact sheet total dermal exposure is than: 0.6 \* 15.3 = 9.18 g/day. According to the fact sheet 20% of the total amount ends up on the hands: 1.84 g/day. Dermal concentration of the hand is determined by dividing the total amount by the surface area of the hands of a 10.5 month old child. According to Bremmer et al. (2006b) this equals to  $230 \text{ cm}^2$ . The resulting amount on the hands is  $0.008 \text{ g/cm}^2$ .

These values are used as starting points to determine the oral exposure from HTM contact. In both approaches it is assumed that all compounds per contacted area will be taken up orally.

(A)

The Pest Control Products Fact sheet describes that 10% of total dermal exposure is taken in orally by HTM contact, while 90% of dermal exposure is dermally absorbed. The 10% is based on the assumption that 20% of the total dermal exposure ends up on the hands of which 50% is orally ingested. This equals to the amount on half of both hands (=  $230 \text{ cm}^2$ ):  $0.5 * 230 = 115 \text{ cm}^2$ , which is contacted.

The oral exposure can be calculated by taking the contact area: 0.008 \* 115 = 0.92 g/day or the oral exposure is calculated by fraction of total dermal exposure: 0.1 \* 9.18 = 0.92 g/day (or 0.5 \* 1.84 g/day) from HTM contact.

(B)

In order to compare the results, the same starting point was used, i.e. 0.008 g/cm<sup>2</sup>. From the presently recommended default values the following data for a child 0.5 to <1 year old were used.

HTM contact frequency 30 contacts/h

HIM/HTM ratio 0.5 Surface area (2 fingers) 5 cm<sup>2</sup> Concentration on hand 0.008 g/cm<sup>2</sup>

The oral exposure from HTM contact is than: 30 \* 0.5 \* 5 \* 0.008 = 0.6 g/day. The assumption made is that all chemical is taken up orally during each contact, regardless whether or not the same area is contacted. The difference between both approaches is made obvious by comparing the contacted hand area, which is 75 cm<sup>2</sup> in approach (B), 30 \* 0.5 \* 5 cm<sup>2</sup> = 75 cm<sup>2</sup> versus the contacted hand area in (A) of 115 cm<sup>2</sup>.