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Safety of toys — Children´s mouthing behaviour in contact with toys

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National foreword

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European foreword

This document (CEN/TR 16918:2015) has been prepared by Technical Committee CEN/TC 52 “Safety of toys”, the secretariat of which is held by DS.

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Introduction

This CEN Technical Report presents the results of a European Study on “Children's mouthing behaviour in contact with toys”. The objective of the study was the measurement and quantification of the duration and frequency that children under 36 months introduce toys into their mouths spontaneously.

It presents information about the literature review focused on children's mouthing behaviour, including commonly used methodologies in addition to a review of significant results from previous research. It also includes the design of the research; methodology; data on the children and toy sample; complete results obtained in the frequency and duration that children mouthed toys and estimated data on the time children under 36 months spend mouthing toys each day.

Up to now, the study was the one with the largest sample (245 children and a total number of 1 680 observations) and the only one to be carried out in three different European countries (Germany, France and Spain). It was also the study with the highest representation of specific toys (54 different products) for children up to 36 months.

In addition to the results on the mouthing behaviour with regard to toys, Annex B contains information concerning children's mouthing behaviour in contact with childcare articles. This informative annex is, however, just a first approach, and of limited value.

Clause 7 of this CEN Technical Report contains a more detailed summary of the results of the European Study on “Children's mouthing behaviour in contact with toys”.

1 Scope

This Technical Report presents the results of a European Study on “Children's mouthing behaviour in contact with toys”. It provides statistical data on the duration and frequency that children under 36 months introduce toys into their mouths and estimated data on the time children under 36 months spend mouthing toys each day.

Furthermore, it provides information on:

— the literature focused on children's mouthing behaviour, including commonly used methodologies and significant results;

— the design and methodology of the study;

— the data on the children and toy sample;

— the forms used in data collection.

2 Literature review

2.1 General

Mouthing is an important component in childhood development. In early development, sucking provides essential nutrients in the form of breast or bottle-feeding, as well as a feeling of well-being and a sense of security (Juberg et al., 2001 [1]). If infants are not allowed unrestricted breast-feeding, they will suck on a dummy, thumb (or other fingers), blanket, or toy (Groot et al., 1998 [2]). As children develop, mouthing behaviour, in combination with looking and touching, allows children to explore and investigate their environment. Mouthing behaviour develops into an exploratory behaviour in which objects are placed into the mouth for a few seconds for purposes of discovery. During this stage of development, children will put their hands, and any object that they come in contact with, into their mouths (Ruff, 1984 [3]; Ruff and Dubiner, 1987 [4]; Davis et al., 1995 [5]; Groot et al., 1998 [2]: Tulve et al., 2002 [6]).

In the field of psychology, Freud named the stage between birth and 2 years of age the 'oral stage'. This first stage of development is characterized by the physical aspects of sucking, encompassed by the mouth, tongue and lips. During the oral stage, it is common for children to have a persistent tendency to put whatever falls into their hands into their mouths. It is the means by which they express their need to experience the world through their mouths. The pleasurable activity of sucking, biting and chewing, means the child starts to recognize objects and distinguish them as separate from himself. When a baby puts something in his mouth, he bites it with his gums, sucks it and moves it with his tongue. It is the first form of learning that children experience, as they begin to recognize textures, temperatures and forms through mouthing. Furthermore, it benefits verbalization processes, chewing and teething.

Teething is another reason that children will mouth fingers and objects. At this stage of development, mouthing alleviates the pain and discomfort associated with teething (Groot et al., 1998 [2]). Teething usually begins at 6 months to 8 months, but may start several months earlier or later. Teething continues in babies until approximately the age of 3.

The first teeth to appear are usually the two bottom front teeth, also known as the lower front incisors. Between 4 weeks to 8 weeks later, they are followed by the four upper front teeth. About a month later, the lower lateral incisors appear. Next come the first molars, and then finally the canines. Most children have their 20 milk teeth (which are the first teeth to appear) when they reach three years of age. The commencement of teething is the most important stage in babies' mouthing.

Young children's urge to suck and mouth is a natural developmental phase. Sucking may be divided into two distinct behavioural types: nutritive and non-nutritive sucking (Turgeon-O'Brien et al., 1995 [7]).

Nutritive sucking is the instinctive need to feed. Non-nutritive sucking (e.g. sucking on a dummy/soother) is thought to be adopted by infants as a response to frustration, or as a need for contact, or as a part of the child's psychological development in exploring the world around them through touching and tasting objects with the mouth and tongue (Norris and Smith, 2002 [8]).

Research on the mouthing behaviour of children has usually concentrated on the psychological development of the act, being concerned with the cause and motivation behind mouthing. There is, however, a child safety issue concerned with the safety of the items being placed into the mouths of young children. Some products, such as dummies, teething rings and bottle teats, are intended to be placed into the mouth. Unfortunately, products not intended for mouthing invariably end up in children's mouths, as this is how young children explore their world. Obviously, child safety is of paramount concern, and so products shall be as safe as possible, whether they are handled or placed into the mouth (Smith and Norris, 2003 [9]).

This is the reason why there is an increasing focus on children in exposure and risk assessments, as they are more sensitive to environmental contaminants than adults (Silvers et al., 1994 [10]). All items that are placed into a child's mouth have the potential to be a mechanical hazard. The most obvious hazards are choking or suffocation, although there is a risk of any item becoming stuck in the mouth and the resultant trauma may be serious. There is also the risk of foreign body incidents where a child swallows an item, which may then cause harm to internal systems of the body (Norris and Smith, 2002 [8]).

Because of their mouthing behaviour, children have a higher potential for exposure to available chemicals through the non-dietary ingestion route; thus, frequency of hand-to-mouth activity is an important variable for exposure assessments. Such data are limited and difficult to collect. Few published studies report such information, and the studies that have been conducted used different data collection approaches: e.g. videography vs. real-time observation, data analysis and reporting methods, ages of children, locations (indoor vs. outdoor), and even definitions of “mouthing” (Xue et al. 2007 [11]).

As children in all geographic regions spend most of their time indoors, at home, Silvers et al. (1994) [10] indicated that risk assessments should focus on indoor, on-site hazards. The same conclusion was made by Xue et al. (2007) [11], as was seen in the review of previous research. The present study is consistent with these conclusions: observing interaction with a sample of toys in the home environment (indoor parental observation). Furthermore, Hubal et al. (2000) [12] defined the general principles for studying children's exposure. In their review of factors in the Children's Exposure Assessment, they indicated that exposure assessments are developed to represent real-life situations.

Toxic chemicals can be transferred from contaminated surfaces or soil to the hand and then ingested via hand-to-mouth activity. Detailed information on children's mouthing activities helps researchers assess children's exposure to toxicants via the non-dietary ingestion route. Thus the frequency of hand-to-mouth behaviour is an important variable for children because, as part of their natural development, children mouth their fingers and other objects (Hubal et al. 2000 [12]).

2.2 Methodological review on children’s mouthing behaviour

Generally, children's mouthing behaviour is studied using both direct observation and video recording methodologies (Zartarian et al., 1996 [13]; Reed et al., 1999 [14]; Freeman et al., 2001 [15]; Ferguson et al., 2005 [16]). Data analyses from these studies are reported as either a frequency of contact (i.e. contacts/duration) or as an exposure period (i.e. minutes). Xue et al. (2007) [11] studied the frequency of hand-to-mouth contact; this research will also analyse hand-to-mouth duration data.

The general formula for estimating non-dietary ingestion of chemical residue via hand-to-mouth contact involves the product of hand residue or soil loading (μg/cm^2 or μg/g), hand-to-mouth frequency (contacts/h), hand surface mouthed per mouthing event (cm^2) and exposure duration (h/ day) (Norris and Smith, 2002 [8])

The statistical formula used by Norris and Smith (2002) [8], in which the estimated daily mouthing time is extrapolated from the mouthing behaviour recorded over the observation time, is calculated as follows:

$$t_{edmt} = \frac{t_{omt}}{t_{tto}} \cdot t_{tamp} \quad (1)$$

where

t_{edmt} estimated daily mouthing time;

t_{omt} observed mouthing time (amount of mouthing time recorded for each child);

t_{tto} total time observed (time available over the whole day for the child to mouth);

t_{tamd} time available to mouth per day.

Norris and Smith [8] calculated the average time spent mouthing per hour, multiplied by the total number of hours each day that each child has available to mouth; i.e. the number of hours they are awake during the day but not eating, or the number of hours they are awake and in contact with a toy (play time). This is based on the assumption that children are likely to mouth at the same rate throughout the day. They performed a Krustal-Wallis test, which showed no significant differences in observed mouthing between the different times of the day when children were observed.

Children's hand-to-mouth behaviour is difficult to measure for several reasons. Some of these reasons include the following: children's contact with surfaces and objects are frequent and intermittent; observational studies are labour-intensive for data collection and data analysis; and data analysis can be subjective. Interpretation of the results is also difficult. Some researchers express mouthing behaviour in terms of frequency of occurrence, others express mouthing behaviour as an exposure period (Xue et al., 2007 [11]).

Table 1 summarizes previous literature, focused on the types of activity collected by the various authors and the methodology used in their research, in order to have a complete picture of the methodological approaches used in the study of children's mouthing behaviour.

Table 1 — Summary of previous literature

Reference	Age Range	Number of children	Location of study	Activity collected	Method employed collection
AuYeung, W. et al. (2004) [17]	1 year to 6 years	38	California	Detailed information on children's mouthing activities.	Videotaping for 2 h per child during natural play time.
Norris and Smith (2002) [8]	1 month to 5 years	236	London, United Kingdom	Duration of each mouthing behaviour. What types of items were mouthed. The type of mouthing behaviour for each item mouthed. What was mouthed and in which room of the house.	5 h of observation in periods of 15 min
Black et al. (2004) [18]	7 months to 53 months	52	Texas	Hand-to-mouth Object-to-mouth Food-handling	Questionnaires to parents. Videotaping children for 4 h using a hand-held camcorder. Children were followed through the house and yard.

Reference	Age Range	Number of children	Location of study	Activity collected	Method employed collection
Ferguson et al. (2005) [16]	1 year to 12 years	83 (4 studies: 4–23–20–36)	Salinas Valley Menlo Park and Palo Alto, California	MLATS, describing intermittent dermal (i.e. a second-by-second account of contact with surfaces and objects) and non-dietary ingestion contact behaviour.	Videotaping human activity to assess exposure. 4 h/day to 8 h/day (sample 4 children) 2 h (sample 36 children) 2 h (sample 20 children)
Freeman (2000, 2001) [19]	3 years to 12 years	19	Minnesota	Mouthing behaviour	Videotaping observations
Groot et al. (1998) [2]	3 months to 36 months	42	The Netherlands	Mouthing duration	Parental Observation 2,5 h/day of 15 min periods
Juberg et al. (2001) [1]	0 months to 36 months	168	Western New York	Mouthing duration, mouthing behaviour	Parental Observation; 1 day; standard diary form
Madden et al. (1980) [20]	23 months to 33 months	3	Urban Maryland	Mouth-to-body, mouth-to-object	Trained observers 3 h to 6 h of observation; recorded mouthing activity; given a score based on frequency
Reed et al. (1999) [14]	2 years to 6 years	30	Urban New Jersey	Hand-to-clothing, hand-to-dirt, hand-to-hand, hand-to-mouth, hand-to-object, hand-to-other items (paper, grass, pets), hand-to-smooth/textured surfaces, object-to-mouth	Videotaping waking hours: approximately 1 day of tape per child; activities were quantified from 5-min periods and added up to give hourly frequency counts
Ruff (1984) [3]	6 months to 12 months	60	Undisclosed suburban location	Evaluation of exploratory behaviour	Videotaping play with specified objects; trained observer, timed interactive events
Ruff and Dubinier (1987) [4]	9 months to 12 months	29	Undisclosed suburban location	Evaluation of young children's ability to manipulate objects and their associated behaviour	Videotaping play with specified objects; trained observer, timed interactive events
KO et al. (2006) [21]	1 year to 5 years	37	Chicago	Children's touching and mouthing behaviour during outdoor play. Frequency, not amount of time.	Video observation. 2 h of video recording
Tulve et al. (2002) [6]	10 months to 60 months	90	Seattle	Describe and quantify the distribution of soil ingestion values.	Observational study in home environment by trained observers 5 min to 60 min per day for 1 day to 6 days, depending on scheduling, cooperation etc.
Xue, J. et al. (2007) [11]	review	review	review	review	Literature review.

Reference	Age Range	Number of children	Location of study	Activity collected	Method employed collection
Zartarian et al. (1998) [22]	29 months to 50 months	4	Salinas Valley, CA	Left and right hand contact frequency and duration for numerous categories of objects	Videotape of waking hours: approximately 1 day of tape per child; computerised translation software
NOTE SOURCE: Update of Tulve et al. (2002) [6].					

2.3 Main results on the duration and frequency of children's mouthing behaviour in previous literature

2.3.1 General

There is more literature on the time and frequency of hand-to-mouth behaviour than on object–to-mouth behaviour. Furthermore, there is great uniformity in the conclusions that instances of indoor mouthing behaviour are always higher than outdoor mouthing behaviour. Xue et al. (2007) [11] indicated that the variation between indoor and outdoor behaviour is 60 %.

In their review of previous research, Xue et al. (2007) [11] indicated that average indoor hand-to-mouth behaviour ranged from 6,7 contacts/hour to 28,0 contacts/hour, with the lowest value corresponding to the 6 to < 11 year olds and the highest value corresponding to the 3 to < 6 month olds. Average outdoor hand-to-mouth frequency ranged from 2,9 contacts/hour to 14,5 contacts/hour, with the lowest values corresponding to the 6 to < 11 year olds and the highest values corresponding to the 6 to < 12 month olds. However, the authors stated that the analysis highlighted the need for additional hand-to-mouth data for the < 3 months, 3 to < 6 months, and 3 to 6 year age groups.

The results of the meta-analysis carried out by Xue et al. (2007) [11] and Tulve et al. (2002) [6] indicate that age and location are important for hand-to-mouth frequency, but type of study and gender are not. As age increases, both indoor and outdoor hand-to-mouth frequencies decrease. All research concludes that mouthing behaviour is significantly greater indoors than outdoors. The frequency and duration of hand-to-mouth, object-to-mouth and food-handling behaviours were all greater indoors than outdoors.

Another widely accepted coincident result is the clear trend that mouthing duration decreases as age increases. This is consistent with patterns of child development, which show a peak period for mouthing activity that is positively correlated with teething and negatively correlated with increased mobility (Juberg el al. 2001 [1], Groot et al. 1998 [2], Xue et al. 2007 [11], Norris and Smith, 2002 [8]).

One more accepted premise is that no significant differences in mouthing times were found between the sexes, and no significant difference was found for mouthing times at different times of the day (Xue et al. 2007 [11], Norris and Smith, 2002 [8]).

For this study, results that focused on object-to-mouth contact and the surface area of the objects mouthed are of primary interest, with a specific focus on toy-to-mouth contact. However, the majority of results obtained from previous literature featured data on objects in general (sometimes including toys, but not always).

The results of research indicate that children's mouthing behaviour depends on age and the items mouthed (e.g. teethers, dummies, toys, etc.). Dummies clearly dominated as the single item most frequently mouthed by children of all ages (Juberg et al., 2001 [1], Norris and Smith, 2002 [8]).

All studies demonstrated that children mouth many items other than dummies, teethers, and toys expected to be mouthed (i.e. those products specifically designed for mouthing). A huge variety of items are mouthed, particularly by children under 1 year, due to teething and using mouthing as a method of exploring their environment. The variety of objects mouthed indicates that young children have access to a wide range of non-toy objects, some of which could pose an immediate hazard to them.

Nevertheless, this study will focus exclusively on results concerning toys and mouthing behaviour in children under 3 years.

2.3.2 Daily time available to mouth not spent sleeping or eating

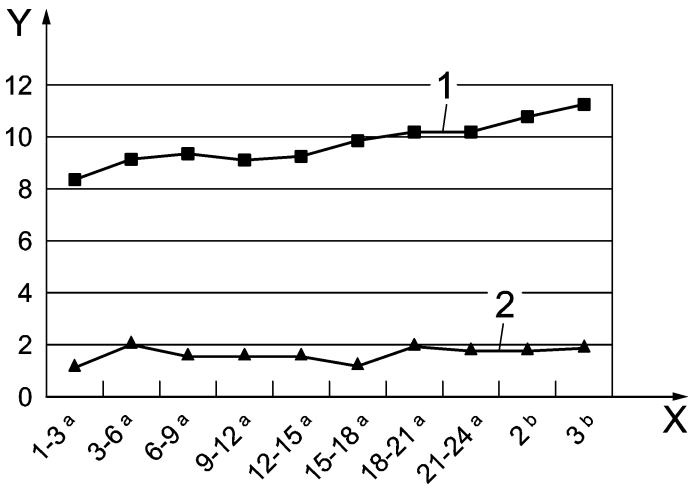
Around 9 h to 10 h is the average time each day not spent eating or sleeping, as obtained in the Norris and Smith research (2002) [8]. This is the time during a typical day that a child would have available to spend mouthing, that is, the time spent neither sleeping nor eating.

Table 2 — Mean, maximum and minimum times available to mouth not spent sleeping or eating

Age group	**Mean** (Hours:Minutes)	**Minimum** (Hours:Minutes)	**Maximum** (Hours:Minutes)
1 month to 3 months	8:22	3:51	13:30
3 months to 6 months	9:09	6:20	12:48
6 months to 9 months	9:21	7:10	11:50
9 months to 12 months	9:06	6:45	11:23
12 months to 15 months	9:15	7:20	11:05
15 months to 18 months	9:50	6:57	12:42
18 months to 21 months	10:10	8:30	12:15
21 months to 24 months	10:12	6:50	13:39
2 years	10:45	7:35	13:20
3 years	11:10	9:35	13:50
NOTE SOURCE: Norris and Smith, 2002 [8]			

In the data obtained there were no significant differences observed in mouthing between the different times of the day that children were observed. Neither were significant differences in mouthing time found between the sexes.

However, as can be observed in the following graph, Norris and Smith (2002) [8] found a great difference between the time available to mouth per day and the duration of children's mouthing behaviour in contact with objects.



Key

X age group

Y number of hours

1 time available to mouth per day (awake but not eating)

2 estimated children's mouthing behaviour in contact with objects

a months

b years

NOTE Based on Norris and Smith 2002 [8] data.

Figure 1 — Time available to mouth per day vs. mouthing behaviour in contact with objects

2.3.3 Frequency of mouthing objects

In their study to quantify children's handling and mouthing activities through a videotaping methodology, Reed et al. (1999) [14] found the mean frequency of contacts per hour: objects-to-mouth (including toys and other objects), was 16,3 objects, 90th percentile 77,1, and maximum contacts was 86,2 (for a sample of 30 3- to 6-year-olds, and 10 children aged 2 years to 5 years).

Analysis of the data collected by Tulve et al. (2002) [6] suggests that the mouthing data can, and should, be broken into two subsets based on age: < 24 months and > 24 months. The data further showed that toys and hands were preferentially mouthed compared with other body parts and household surfaces. They have obtained a more realistic estimate of a child's mouthing behaviour by using data collected on multiple observation days. The results reported in this study are focused on children who engaged in quiet play in an indoor environment. The data presented by Tulve et al. (2002) [6] shows that young children may mouth specific objects (e.g. toys) up to 48 events/hour.

The research by Black et al. (2004) [18] is presented as a table of results of the frequency of object-to-mouth events (see Table 3).

Table 3 — Results of the frequency of object-to-mouth events per hour

Age	Frequency	Time %
Infant	18,1 (24,4 + 11,6)	3,1 (4,0 + 2,4)
1-year-old	8,4 (9,8 + 6,3)	1,3 (1,6 + 1,2)
2-year-old	5,5 (7,8 + 5,8)	0,9 (1,3 + 1,1)
Preschool	8,4 (10,1 + 12,4)	1,9 (3,0 + 3,9)
NOTE SOURCE: Black et al. 2004 [18].		

Regarding the number of items mouthed (all kinds of items), Norris and Smith (2002) [8] concluded that children aged 6 months to 9 months mouth the greatest number of items: the average number of items mouthed each day per child peaks at age 6 months to 9 months (26 items) and then gradually decreases as the age of the child increases (at 3 years old 12 items are mouthed). Children aged 1 month to 3 months mouth the fewest number of items on average (3 items).

Concerning the material of the toys and other objects mouthed, plastic was the most common material to be mouthed, followed by fabrics; approximately half of all the toys and other objects mouthed were made of plastic (Norris and Smith, 2002 [8]).

Childcare products, such as teethers and rattles, were mouthed by nearly all age groups. However, the most significant data from Norris and Smith [8] showed that an estimated minimum of 75 % of the items mouthed by children in their study were considered as not intended to be mouthed. Around just 25 % of all the toys and other objects mouthed in this study were considered as intended to be mouthed, and around 30 % (after age 3 months) of these were made of plastic. Whereas, for the 1 month to 3 months age group, all the plastic items mouthed were intended for mouthing. After this age a maximum of only 31 % of the plastic items mouthed were considered as intended for mouthing (Norris and Smith 2002 [8]).

They list the categories of toys and others objects mouthed by the sample in their study. Looking at the category of toys mouthed, it features all types of toys: animals, foods, vehicles, blocks, dolls, soft toys, books, toy figures, balls, tools, musical instruments, bath toys, cameras, teethers, rattles, letters, walkers, puzzles, balloons, etc. Regarding other objects, they include: clothing, cups, magazines, kitchen utensils, pens, shoes, remote controls, packaging, sofas, bottles, keys, TVs and videos, chairs, straps, boxes, watches, carpets, bags, flowers, pet foods, etc. In conclusion, there is a wide assortment of objects that children mouth at home, the majority of them being not intended for mouthing (Norris and Smith, 2002 [8]).

Focusing on children's mouthing habits, 29 % of children leave bite marks on toys, and 25 % of children damage items by biting (Norris and Smith, 2002 [8]).

2.3.4 Amount of the time spent mouthing objects

In the study by Juberg et al. (2001) [1], the average daily time spent mouthing (all objects except dummies) was 36 min. For the 0 months to 18 months age group, the average daily duration of introducing objects into the mouth was: plastic toys (17 min), teethers (6 min) and other objects (9 min). The results for children aged 19 months to 36 months were: plastic toys (2 min), teethers (0 min) and other objects (2 min).

Health Canada (quoted by Juberg et al., 2001 [1]) used average daily mouthing duration estimates for plastic toys of 2 h for children aged 3 months to 12 months and 2,5 h for children aged 12 months to 36 months. The results obtained in this study are significantly higher than the Juberg [1] results, with an average of 23 min for plastic toys with children aged 3 months to 12 months, and an average of 5 min for plastic toys amongst children aged between 13 months and 36 months.

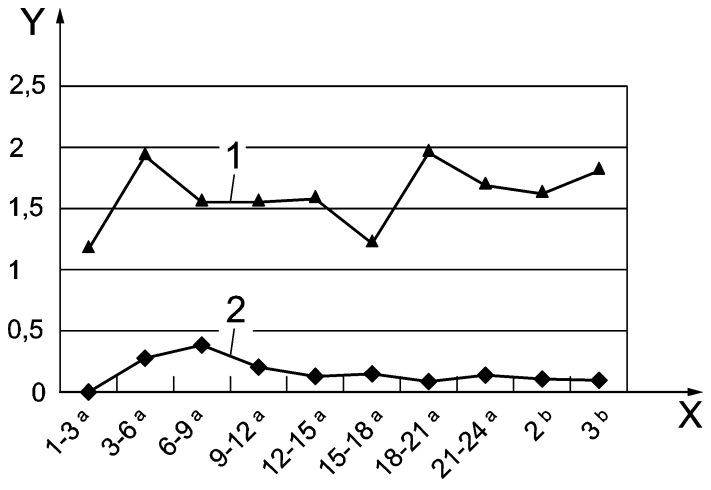
The CPSC relied on the Groot et al. (1998) [2] data to estimate geometric means of 12 min for 3 months to 12 months old children and 2 min for 13 months to 26 months old children, for teethers, rattles, and toys, assuming that the data are distributed lognormally.

Concerning the average time that a child in each group could be expected to mouth a given item over the course of a normal day, Norris and Smith (2002) [8] presented a table of the time (hours: minutes: seconds) spent mouthing dummies, fingers, toys, and other objects. No clear age patterns exist for total mouthing time. However, when they estimated the daily mean mouthing of toys and other objects, a much clearer pattern of changes with age emerges.

Table 4 — Estimated mean and maximum daily mouthing time for toys and other objects

	Toys		**Other objects**	
Age group	**Mean**	**Maximum**	**Mean**	**Maximum**
1 month to 3 months	0:00:14	0:00:59	0:05:14	0:28:11
3 months to 6 months	0:28:20	2:34:45	0:12:29	0:36:39
6 months to 9 months	0:39:10	3:46:46	0:24:30	1:10:23
6 months to 9 months	0:23:10	1:04:49	0:16:25	1:31:00
12 months to 15 months	0:15:18	0:44:01	0:12:02	1:03:03
15 months to 18 months	0:16:34	0:58:28	0:23:01	1:38:02
18 months to 21 months	0:11:07	0:32:49	0:19:49	1:06:21
21 months to 24 months	0:15:46	1:42:04	0:12:53	0:40:20
2 years	0:12:23	2:05:48	0:21:46	2:57:58
3 years	0:11:37	1:34:36	0:15:16	1:25:29
NOTE SOURCE: Norris and Smith, 2002 [8].				

They found no general trend of an increase or decrease in mouthing, across all items, from the ages of 1 month to 5 years, although there were differences between age groups within that range. Nevertheless, mouthing toys and other objects (which are most likely to be a hazard) shows a trend with age. Mean estimated daily mouthing peaks at age 6 months to 9 months (approximately one hour) and decreases as children grow older. For the maximum estimated daily mouthing, 2-year-olds mouth for as long as 6 months to 9 months old children (approximately 5 hours/day), (Norris and Smith, 2002 [8]).



Key

X age group
Y number of hours
1 estimated children's mouthing behaviour in contact with objects
2 estimated children's mouthing behaviour in contact with toys
a months
b years

Figure 2 — Mouthing behaviour in contact with all items mouthed vs. in contact with toys

In classifying the type of mouthing, various authors talk about using three categories to classify mouthing behaviour, namely: licking, sucking and biting/chewing. Analysing results concerning the variable "how the object was mouthed", Norris and Smith [8] found sucking was the most commonly observed mouthing behaviour, accounting for approximately two thirds of all observed mouthing behaviours (2002).

Annex A contains a summary of results of previous quantitative studies on children's mouthing behaviour.

3 Design of the research

3.1 General objective

The overall aim of this research is the measurement and quantification of the times and frequency that children aged 0 months to 36 months, introduce toys into their mouths spontaneously.

Additionally, another objective is to obtain qualitative information on how children behave when they put the toys in their mouths.

3.2 Data collection

The main methodology used in previous research on children's mouthing behaviour is observation. Two main methods are employed to capture data: video recording and parental observation. As methodological recommendations suggested, this study used parental observation in a natural environment combined with video recording sessions.

The presence of a stranger in the home recording children's activities is likely to alter the behaviour of the child being observed to a greater or lesser extent; so while the reliability of the data may be high, the circumstances are less "realistic" and lower the validity of the data. Another problem with video recording is that young children are often on the move, which would make capturing each example of

behaviour extremely difficult. For these reasons this research used parents/carers as observers, to ensure that children's mouthing behaviour, and their behaviour in general, is as natural as possible, to guarantee high data validity.

Concerning the amount of time of observation, this depends on which methodology is used. Using video recording methodology the amount of time observed is very high, but with parental observation the amount of time decreases. In relation to parental observation, based on previous research, about 15' of observation per day is the most accurate amount of time. To increase the amount of time observed in parental observation, various authors have split their observation into different days, or at least into different times during the same day. The amount of time observed per child in previous research, for statistical estimates, is around two hours.

On the other hand, it was noted that there are no recent studies on children's mouthing behaviour; very little literature could be found on children's mouthing focused on toy-to-mouth behaviour (the last observational study was in 2002). Furthermore, a great deal of studies concluded that there was a high frequency of mouthing objects, but there were very few consistent conclusions on the amount of time spent mouthing them.

It is not possible to understand the exact characteristics of the toys used in the studies carried out. There is neither data on the parts of toys mouthed nor on the materials of the product mouthed. The only available information is on the percentage of the materials that were rubber or plastic, as noted in the explanations of the material mouthed.

Finally, there are no clear explanations of the qualitative process of mouthing toys in children under 3 years, even though they are consistent in that a lot of mouthing behaviour occurs during this period of age (and specifically under 12 months). There is no graphic information on how toys were mouthed by babies or children and there is an evident lack of knowledge about how children are mouthing toys.

Based on the review of literature, it can be concluded that the variability between different samples was very high, and the qualitative focus of the methodology employed resulted in very low samples – only a few studies had a sample higher than 100 children.

The present study is the one with the largest sample (245 children and a total number of 1 680 observations) and the only one, up to now, to be carried out in three different European countries (Germany, France and Spain). It is also the study with the highest representation of specific toys (54 different products) for children aged 0 months to 36 months.

Parents made observations of their children playing at home for 18 min/day, resulting in 126 min of observation per child at the end of the week. In total, 511,8 h of adult observation of children's activities with toys were collected, together with a total of 16 h of video recording sessions, in order to carry out qualitative and quantitative analysis of children's mouthing behaviour.

The next sub-clause describes the methodology of this study in detail.

3.3 Methodology

3.3.1 General

The quantitative and observational qualitative study involved families with children under 3 years. This study included 3 different methodologies combined: Ethnographic, Home environment and Free Play environment (see Table 5).

Table 5 — Methodologies of the study

1. Ethnographic	2. Home environment	3. Free play environment
a) Parental observation b) 24 h study c) 245 families d) 3 European countries: France, Germany, Spain e) Gathering information: 1) App for quantitative study 2) Training protocols	a) Parental observation b) Friendly environment: home c) 54 selected toys d) 3 European countries: France, Germany, Spain e) 245 families f) 126 min observation per child (18 min for 7 days) g) Gathering information: 1) App for quantitative study 2) Video recording for qualitative study 3) Training protocols	a) Educators observation b) Friendly environment: nursery school c) Free play with selected toys d) Spain e) 50 children (5 children per session) f) 12 sessions – 30 min per day of video recording g) Gathering information: 1) Video recording
Outcomes: Number of hours per day in contact with toys.	**Outcomes:** Amount of time and frequency of children's mouthing behaviour. Analysis of the most relevant mouthing behaviours.	**Outcomes:** Analysis and video selection of the most relevant behaviours.

3.3.2 Ethnographic

The study consisted of parental observations of their children's usual activities in a whole week, taking into account working as well as non-working days. It was a 24-h study, to determine the number of minutes/hours that a child can be in contact with toys per day (not sleeping and not eating). After this week, parents answered some questions related to their children's activities in 24 h, using the observational tool. This study was carried out by all 245 children in the sample, with representatives from all age groups (based on the EPA standard) from 0 months to 36 months, with families from 3 countries (Germany, France and Spain).

Figure 3 — Example of children activities

3.3.3 Home environment

This study consisted of parental observation (at home) of children's mouthing behaviour when they were in contact with specific toys, to obtain the times and frequency that children (0 months to 36 months) introduce toys into their mouths.

A sample of 245 families (from Germany, France and Spain) observed their children's use of specific toys. Each family had 3 toys, selected according to the age of their child, and observed their child's use of the toys for 126 min over the course of a week. Each toy was tested by 12 different families.

Children should be in a "normal" state of relaxation/excitement during observation. To this end, it was necessary to minimize the excitement that the appearance of a new toy might suppose for a child. To

achieve this, the parents let their children play freely and spontaneously with the toys being studied on the same day they were delivered, without making any type of record of the information. Subsequently, at least once a day for a week, they observed children using the allocated toys for 18 min and registered if there was mouthing behaviour, along with the frequency, time and type of mouthing (licking, sucking or biting).

The present study defined 3 types of mouthing behaviour, which were explained to the family participants in order to classify their observations:

— Licking/lip-touching: This is where an item touches the front of the mouth, without actually entering into the mouth itself. The child may be licking the object, or touching the object to their lips or tongue.

— Sucking/trying to bite: The item is put directly into the child's mouth. The child may be sucking, holding the object in their mouth or trying to bite (gumming) the object.

— Biting/chewing: The item is directly inside the child's mouth. It is clear that the child is biting it or chewing on it.

Furthermore, they classified their child's mouthing behaviour according to different levels of salivation:

— High salivation: Saliva present on the lips and dribbling.

— Medium salivation: Saliva present and observed directly on the child's lips.

— Low salivation: Slight saliva observed on the toy, but not on the child's lips.

This study was carried out on all children in the sample, with representatives from all age groups (based on EPA Standard classification of children for mouthing behaviour studies).

Table 6 — Sample age groups

AGE	Germany	France	Spain	All countries
< 3 months	10 children	10 children	10 children	30 children
≥ 3 months and < 6 months	10 children	10 children	10 children	30 children
≥ 6 months and < 10 months	12 children	10 children	10 children	32 children
≥ 10 months and < 13 months	10 children	10 children	11 children	31 children
≥ 13 months and < 19 months	10 children	10 children	10 children	30 children
≥ 19 months and < 25 months	9 children	10 children	11 children	30 children
≥ 25 months and < 31 months	10 children	10 children	11 children	31 children
≥ 31 months and < 37 months	10 children	10 children	11 children	31 children
Total children (0 months to 36 months)	81 children	80 children	84 children	245 children

Finally, the total sample was 245 families because, in order to ensure a minimum 240 families, more families were selected in the 3 countries (a characterization of the sample can be found in 3.4.2).

To ensure the quality of the results of parental observation and video recording, the observations were broken down into equal periods per day:

— Child waking up to 12:00;

— 12:01 to 18:00;

— 18:01 to child going to bed.

To carry out their observations, they used the observational tool and protocols documented in 3.3.6.

Figure 4 — Home environment observation

3.3.4 Free play environment

This study consisted in video recordings of how children behave when they put the selected toys in their mouths, in order to obtain qualitative information on how this behaviour occurs in a free play environment.

To carry out the video recordings, selected toys (from the toy sample) were placed in a classroom. These toys were available for everyone in the group (maximum 10 children per session) in a free play session with their usual teachers or carers. Children used toys spontaneously. These toys were selected according to the children's age group. They used all the different toys in the sample.

Video recordings were made of 12 sessions of children using toys in nursery schools in Spain: 30 min/day (total: 360 min). The recordings featured children under 3 years:

— up to 1 year (4 sessions);

— 1 year to 2 years (4 sessions);

— 2 years to 3 years (4 sessions).

Figure 5 — Free play environment observation

Finally, video recordings were conducted in two environments: at home and in nursery schools. The reason was due to the difficulties in following children when they are playing in a school environment, and the inability of making good video recordings of mouthing behaviour.

For this reason, 100 families from three countries – Germany (20 families), France (20 families) and Spain (60 families) – were asked to video record 6 min of parental observation at home following the same methodology, in order to determine the most relevant mouthing behaviours (total: 600 min).

These video recordings have been analysed by technical experts that classified children behaviour into three different mouthing behaviours: Licking/lip-touching, sucking/trying to bite, biting/chewing.

Experts have selected video recordings that illustrate various examples of these 3 types of mouthing behaviours, compiled in a final videotape as part of this report.

Figure 6 — Examples of mouthing behaviour

3.3.5 Pilot test

To ensure that the protocols, methodology and data collection systems were appropriate for the intended objectives, a pilot phase of the study was performed with a sample of 8 families.

Following this pilot test, the methodology was adjusted and the following changes were made:

— The amount of time per observation was increased from the 15 min/day initially planned to 18 min/day. From 105 min to 126 min per child. In this way, a total of 30 708 min were observed (511,8 h).

— Video recordings were made of 12 sessions of 30 min in a “free play environment” instead of the initially planned 10 sessions, in order to acquire 4 sessions for each age group (360 min).

— Serious difficulties were detected when observing the mouthing behaviour of individual children in the free play environment sessions. For this reason an additional 100 sessions of individual children playing in the home environment were recorded (600 min).

— Parents' comprehension of the question regarding salivation level and types of mouthing behaviour were checked.

— In order to take into account that children could display different states of aptitude, alertness or concentration over the day, together with parents' availability to play with their children, observations were broken down into the following periods:

  — Child wakes up to 12:00.

  — 12:01 to 18:00.

  — 18:01 to child goes to bed.

3.3.6 Observational tool and protocols

To carry out the parental observation at home and to obtain ethnographic data, an app for smartphones/tablets for use as an observational tool by parents was developed, which allowed observational data to be received in real-time.

This tool included data about the following variables:

— **Children's data:** Age, gender, child/family code, dummy use.

— **Toy data:** Category, brand, product name, specific hazards, material (elastomeric/not elastomeric), parts of the toy that are mouthed, toy intended to be mouthed or not, etc.

— **Mouthing behaviour**: Number of times, amount of time, type of mouthing behaviour, level of salivation.

Every day parents watched how their children used the toys and recorded data regarding their mouthing behaviour: whether it occurred or not, the times that it occurred, and also the type of mouthing behaviour (as can be seen in the following image from the observational tool).

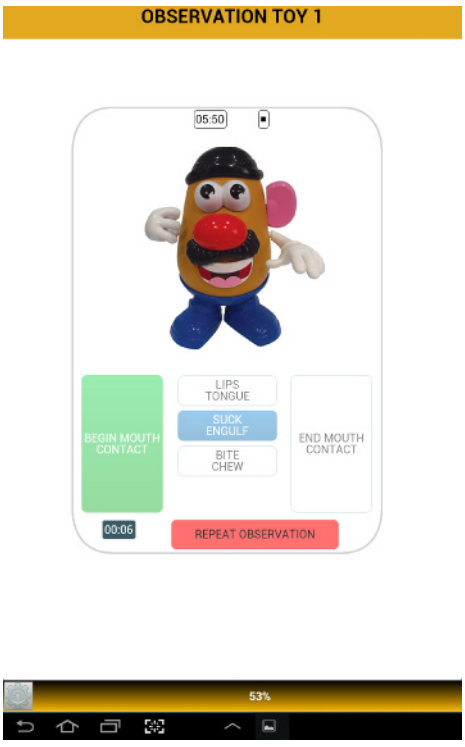


Figure 7 — Observational tool app

At the end of the week, once the 126 min of observation of their child was complete, parents were asked to finish by completing the final data validation with the tool. This involved specific questions regarding the condition of the toys, if their children had left bite marks on them, and if they had encountered any problems or had any comments they wanted to make.

Furthermore, the tool asked parents for observations about their child's daily routines and activities, as well as the times they used or were in contact with toys on each day of the week.

Each family was assigned an identification code, in order to ensure anonymity while being able to register their family characteristics, the age of the child observed and the assigned toys.

Families were provided with information and instructions so they had a better understanding of the observational process.

Additionally, various protocols were developed for parents in order to guarantee all the ethical issues: informed consent, authorisations for research and also for video recordings, and to transfer the rights of the images in this study.

3.3.7 Training sessions

To ensure that the process of observation by parents was exactly the same in all families, several training sessions were conducted where the objectives and the most relevant characteristics of the research were explained.

The observation process was explained to each family and the observational tool was presented in detail. It was verified that they had properly installed the app on their smartphone or tablet, and test runs were performed to familiarise them with the tool.

At this point the signed authorization forms were collected, the toys assigned to each family were handed over along with the quick guide for the tool, and the most frequent questions were dealt with.

These training sessions were conducted exactly the same way in all 3 countries. Each and every one of the families who participated in the research attended a session.

In addition to the training sessions, the tool itself included a section that reminded users of the observation procedure. Additionally, a FAQ sheet was distributed so they could resolve the most common uncertainties. Finally, all families had direct access to a contact person in each country (via telephone, WhatsApp and email) in order to deal with any additional issues that might have arisen during their observations.

a) Spain **b) France** **c) Germany**

Figure 8 — Training sessions

3.4 Sample description: Children and toys

3.4.1 General

3.4.2 describes the characteristics of the sample of 245 families that participated in the study, making home observations with a total of 663 toys. The selection process and the final sample of toys are described in 3.4.3. Table 7 contains an overview on the number of families and toys by country.

Table 7 — Sample description

Scope	Number of families	Number of toys
Germany	81	219
France	80	216
Spain	84	228
Total	**245**	**663**

3.4.2 Children sample

3.4.2.1 **Age of children**, Amount in the 8 age brackets:

a) < 3 months: 30 families

b) ≥ 3 months and < 6 months: 30 families

c) ≥ 6 months and < 10 months: 32 families

d) ≥ 10 months and < 13 months: 31 families

e) ≥ 13 months and < 19 months: 30 families

f) ≥ 19 months and < 25 months: 30 families

g) ≥ 25 months and < 31 months: 31 families

h) ≥ 31 months and < 37 months: 31 families

3.4.2.2 **Gender of children:** Almost equal halves of the sample of each gender (girls 51 % and boys 49 %)

3.4.2.3 **Household size:** The sizes of the households in the sample ranged from 2 to 6 people. The most common sizes were 3 or 4 people households (47 % of households were of 3 people, 34 % were households of 4 people).

3.4.2.4 **Number of children:** In 51 % of cases the families who participated in the study had only one child, 33 % had 2 children and 11 % were families with 3 children. However, even if they had more than one child the families carried out all the observations on only one child (the child who was designated to participate in the study).

3.4.2.5 **Country:** Families from the 3 countries participated (Germany: 81 families / France: 80 families / Spain: 84 families).

3.4.2.6 **Population sizes:** The population size of the place where the families lived ranged from: 5 000 to 30 000 inhabitants (30 %) / 30 000 to 200 000 inhabitants (23 %) / More than 200 000 inhabitants (43 %). As can be seen in Figure 14, in France there was less involvement of families from big cities than in Germany or Spain.

3.4.2.7 **Relationship:** 85 % of the observers were the mothers, while 14 % were the fathers, and 1 % were the grandparents or the children's carers.

3.4.2.8 **Observer ages:** In 43 % of cases the observers were parents between 31 years and 35 years / 24 % were between 36 years and 40 years / 19 % between 26 years and 30 years. The observer

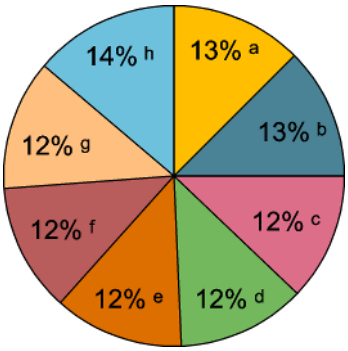
mothers in Spain had the highest age (39 % between 36 years and 40 years). This may be because the average age for having a child in Spain is the highest in the 3 countries studied.

3.4.2.9 Level of education: 51 % of the sample had a university education, 39 % a secondary education level, and 10 % a primary education or other. There was a greater representation of families with a secondary education in Germany (60 %) than in the other two countries, as can be seen in Figure 17.

3.4.2.10 Social Class: There were fewer lower class families in the German sample compared with the other two countries (Figure 18).

3.4.2.11 Observation periods: 45 % of the observations were made between 18:01 until the child went to bed / 27 % observed children between 12:01 to 18:00 / 28 % between the time the child woke up until 12:00. These periods were the times of day that the parents were available to watch their children playing and for this reason they could not be performed equally (i.e. it was not possible to have exactly a third of the observations in each period). However, it does at least provide data for the 3 different times of day, in order to evaluate differences. A Kruskal-Wallis test showed no significant differences in observed mouthing behaviour (duration and frequency) between these 3 observational periods (C.4).

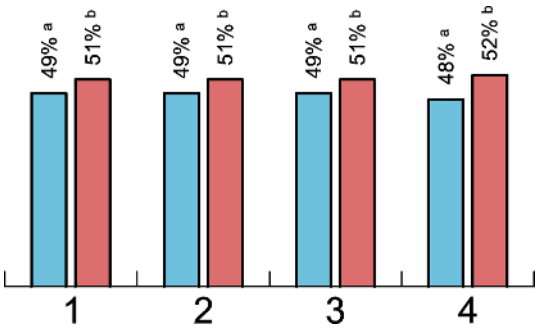
3.4.2.12 Use Dummy: 66 % of the children observed used a dummy and 34 % did not use one (Figure 20). Looking at the same data by age (Figure 21) it can be seen that from between 0 months to 18 months use of dummies rises to over 80 % of children, whereas for 18 months to 36 months the percentage falls to about 50 %. Information is not available on the reasons for using or not using a dummy, but a clear uniformity is seen in the results according to country and age.



Key

a < 3 months
b ≥ 3 months and < 6 months
c ≥ 6 months and < 10 months
d ≥ 10 months and < 13 months
e ≥ 13 months and < 19 months
f ≥ 19 months and < 25 months
g ≥ 25 months and < 31 months
h ≥ 31 months and < 37 months

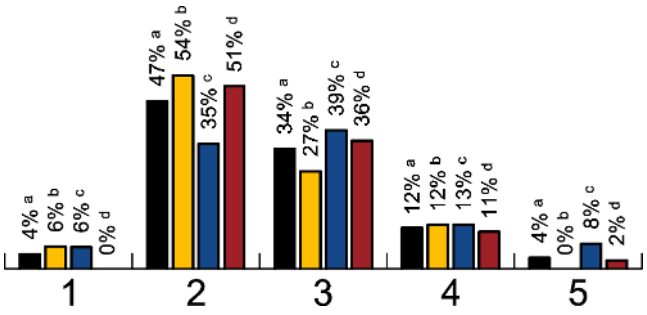
Figure 9 — Age of children



Key

1 global
2 Germany
3 France
4 Spain
a boys
b girls

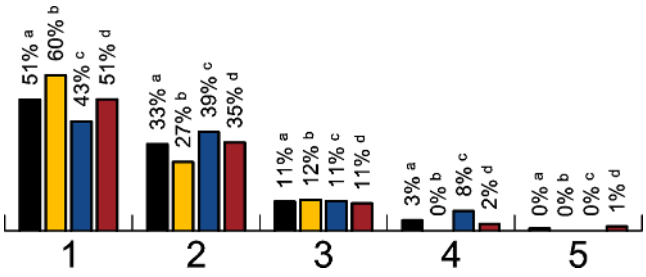
Figure 10 — Gender of children



Key

1 2 people
2 3 people
3 4 people
4 5 people
5 6 people
a global
b Germany
C France
d Spain

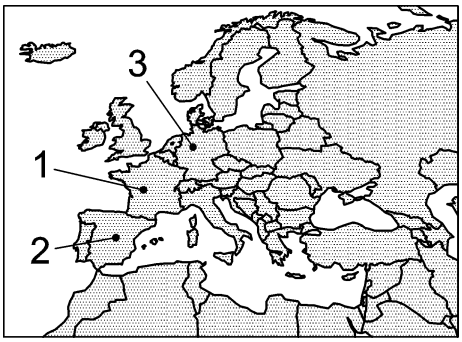
Figure 11 — Household size



Key

1 1 child
2 2 children
3 3 children
4 4 children
5 more than 5 children
a global
b Germany
C France
d Spain

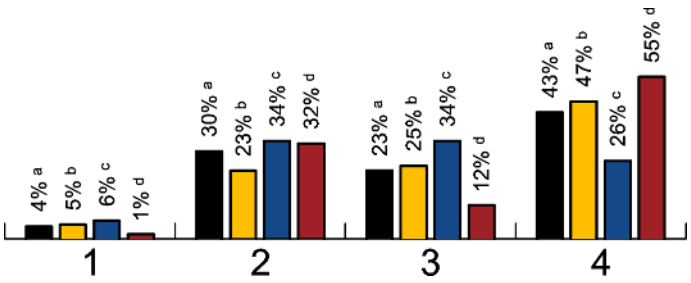
Figure 12 — Number of children



Key

1 France
2 Spain
3 Germany

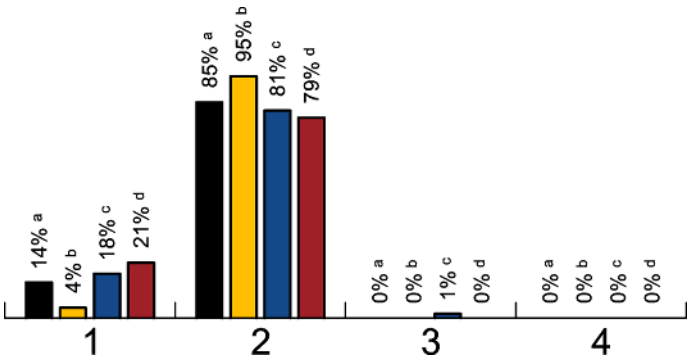
Figure 13 — Country



Key

1 less than 5 000 inhabitants
2 5 000 inhabitants to 30 000 inhabitants
3 30 000 inhabitants to 200 000 inhabitants
4 more than 200 000 inhabitants
a global
b Germany
C France
d Spain

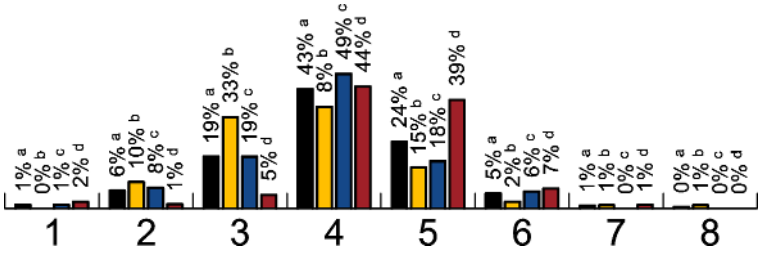
Figure 14 — Population sizes



Key

1 father
2 mother
3 grandparent
4 carer
a global
b Germany
C France
d Spain

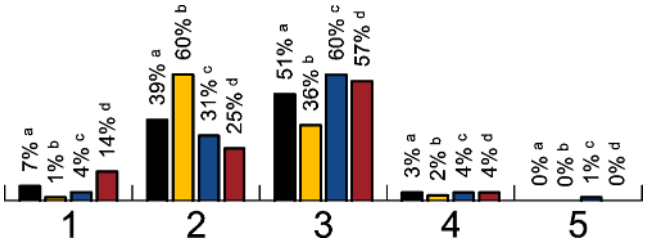
Figure 15 — Relationship



Key

1 under 20 years
2 20 years – 25 years
3 26 years – 30 years
4 31 years – 35 years
5 36 years – 40 years
6 41 years – 45 years
7 46 years – 50 years
8 over 65 years
a global
b Germany
C France
d Spain

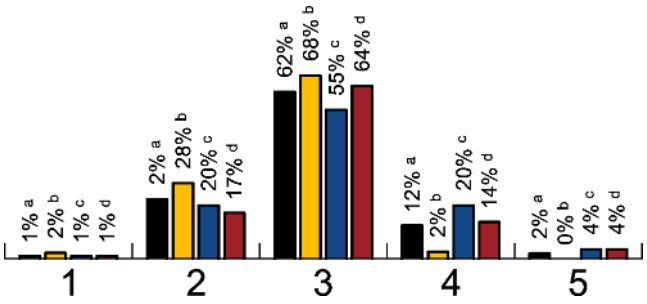
Figure 16 — Observer age



Key

1 primary education
2 secondary education
3 university education
4 other
5 no education/unfinished
a global
b Germany
c France
d Spain

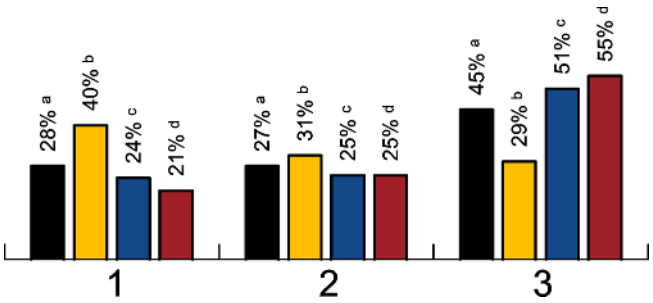
Figure 17 — Level of education



Key

1 upper
2 upper middle
3 middle
4 lower middle
5 lower
a global
b Germany
C France
d Spain

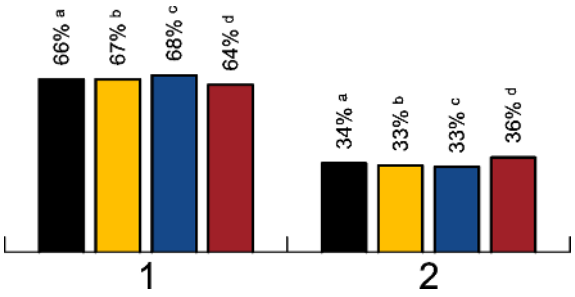
Figure 18 — Social class



Key

1 child wakes up to 12:00
2 12:00 to 18:00
3 18:00 to child goes to bed
a global
b Germany
C France
d Spain

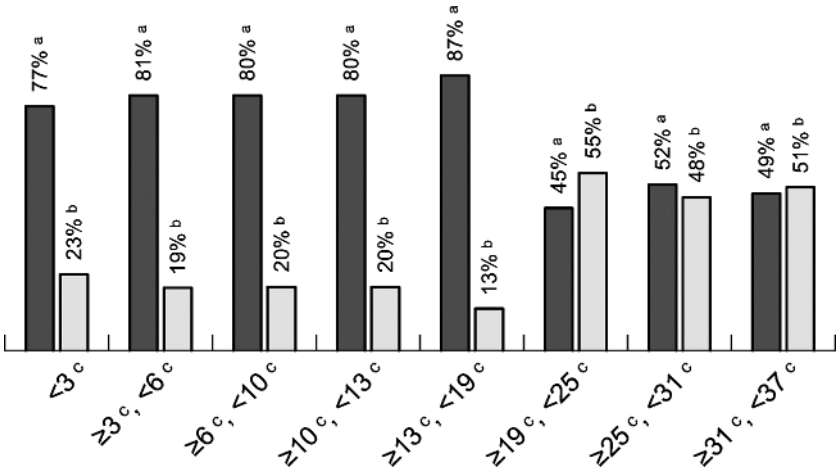
Figure 19 — Observation periods



Key

1 yes
2 no
a global
b Germany
C France
d Spain

Figure 20 — Use of dummy



Key

a months
b yes
c no

Figure 21 — Use of dummy by age

3.4.3 Sample

The results of this study served as input for the revision of EN 71-12:2013, which is applicable to toys made from elastomers (and finger paints). The selection process of the toy samples carried out is explained below:

Phase 1: In September 2013, a first selection of toys was made. This selection was initially based on the interpretation found in the "Guidance Document on the interpretation of the concept "which can be placed in the mouth"" [23]. However, solely using this guidance document, the representation of toys was very low. For this reason they were combined with products based on CEN report CR 14379:2002 *Classification of toys – Guidelines*, in order to have representation from various categories of toys presently on the market. As the study focuses on children under 36 months toys classified for children

above 3 years were not included, for safety reasons. This initial proposal included a list of toys, some of which were probably made from elastomeric materials. This proposal was discussed by the responsible CEN working group.

Phase 2: Subsequent to the comments made by this committee, a second selection of toys was made. The following aspects were considered:

— It was decided to reinclude the musical category in the sample, even though they do not include elastomeric materials.

— It was finally decided not to include arts and crafts materials in the sample.

— It was decided to include toys that imitate foodstuffs in the sample.

— It was decided to introduce a new variable that allows to separate the toys that are designed for children to put into their mouths from those that are not: toys intended to be mouthed (teethers, foodstuffs, microphones musicals, toys that represent phones) and toys not intended to be mouthed (others).

— it is important to distinguish if the part of the toy involved in the children's mouthing behaviour is made of elastomeric material or not.

— The presence of elastomeric material should be a certainty, not a probability. It was necessary to have a sample of toys made mostly with elastomeric materials. If not the whole toy, at least some parts of the product should be made of elastomeric material (silicon, rubber, etc). Products such as teethers had to be taken into account. The chemical nature of the elastomeric toys was analysed in order to verify whether the toys in the sample (or at least some part of them) were made of elastomeric material or not. The available information only states if the product was elastomeric or not. It does not provide information on the classification of types of elastomeric materials used in each toy.

Phase 3: The final selection of the toy sample consisted of 54 products that met the above requirements. Verification was carried out on the presence of elastomeric materials in the selected toys. In addition, a uniform number of toys were selected for each age group of children in the sample. All the toys were observed in the 3 countries in an equal fashion.

Table 8 lists the toys in the sample according to toy categories.

Table 8 — Toy sample

Category	Number of products
1. Push-along toys, pull-along toys and walking aids	2
2. Dolls and soft filled toys	4
3. Role-playing toys (foodstuffs included)	8
4. Toys for babies, for looking at, grasping and/or squeezing	14
5. Books with play value and bath books	3
6. Audio/visual equipment	3
7. Construction toys and puzzles	4
8. Mechanically and/or electrically driven	2
9. Play scenes and constructed models	3
10. Sand-water and bath toys	4
11. Toy musical instruments	2
12. Toy sports equipment and balls	3
13. Toys intended to bear the mass of a child	2
Total	**54**

Of the 54 toys in the sample, 50 % were toys made with elastomeric materials and 50 % without elastomeric materials. These toys had been tested to ensure the presence of elastomeric materials.

Figure 22 — Toys with elastomeric materials

Figure 23 — Toys without elastomeric materials

Furthermore, 33 % of the toys were “Intended to be mouthed”, whereas 67 % were toys “Not intended to be mouthed”.

Figure 24 — Toys intended to be mouthed

Finally, Figure 25 shows the distribution of toys to the various age groups, in accordance with the manufacturer's age recommendations.

Age groups months	**Uniformity in the number of products for each age group**
< 3	
≥ 3, < 6	
≥ 6, < 10	
≥ 10, < 13	
≥ 13, < 19	
≥ 19, < 25	
≥ 25, < 31	
≥ 31, < 37	

Figure 25 — Uniformity in the number of products for each age group

3.5 Statistical analysis

The children were grouped into eight age categories (following EPA Standards): 0-2 months/ 3-5 months/ 6-9 months/ 10-12 months/ 13-18 months/ 19-24 months/ 25-30 months/ 31-36 months. Additionally, data was grouped into two groups: Under 1 year / 2–3 years. Finally data was grouped into three categories: 1 year / 2 years / 3 years. All statistical analysis was made using the same chronological age categories.

Microactivity data and questionnaire results of frequency and duration of mouthing behaviour in contact with toys were analysed using SPSS version 15,0 (Statistical Package for the Social Sciences). All data were presented with: mean, standard deviation, 75th percentile, 85th percentile and 95th percentile, 99th percentile, maximum and minimum.

Even though some authors support the use of parametric analysis for samples of over 100 subjects (the present study has a sample of 245 subjects and 1 680 observations analysed), non-parametric tests were used to analyse differences between data (see Table 9 for details); this was due to the lack of a normal distribution of the data (see C.1). Mann-Whitney and Kolmogorov-Smirnov were applied to determine significant differences between two variables (e.g. gender/ elastomeric vs. not elastomeric/ intended or not intended). Kruskal-Wallis was used to determine significant differences between more than two variables (age groups, countries, toy categories). For more information related to these analyses please see Annex C.

Table 9 — Sample error

Global study		245 Families (±6,26 %)
Age of children	< 3 months	30 Families (±17,89 %)
	≥ 3 months and < 6 months	30 Families (±17,89 %)
	≥ 6 months and < 10 months	32 Families (±17,32 %)
	≥ 10 months and < 13 months	31 Families (±17,6 %)
	≥ 13 months and < 19 months	30 Families (±17,89 %)
	≥ 19 months and < 25 months	30 Families (±17,89 %)
	≥ 25 months and < 31 months	31 Families (±17,6 %)
	≥ 31 months and < 37 months	31 Families (±17,6 %)
Gender	Boys	118 Boys (±9,02 %)
	Girls	126 Girls (±8,73 %)
Country	Germany	81 Families (±10,89 %)
	France	80 Families (±10,96 %)
	Spain	84 Families (±10,69 %)

4 Results of children's mouthing behaviour in contact with toys

4.1 Frequency children mouthed toys

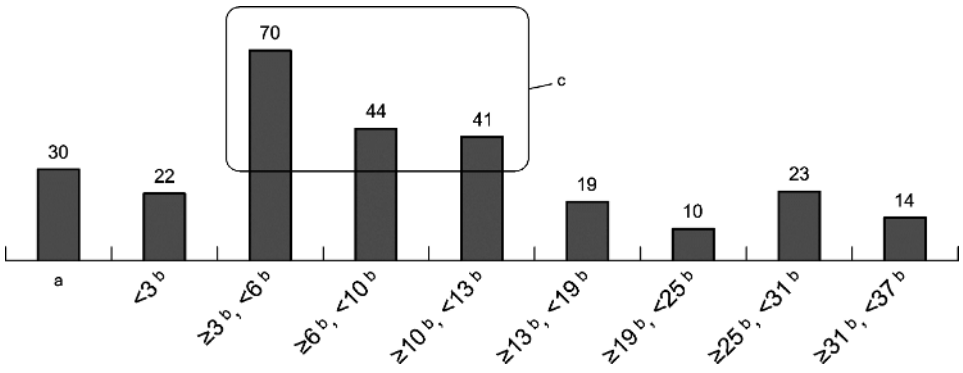
4.1.1 General

4.1 presents data related to frequency ("Number of times children mouthed toys per hour"). This information is analysed by: age, gender and country.

4.1.2 By age

Table 10 — Frequency children mouthed toys per hour by age

Age groups months	**Mean**	**SD**	**Per. 75**	**Per. 85**	**Per. 95**	**Per. 99**	**Max.**	**Min.**
< 3	22	19	37	41	58	65	66	0
≥ 3, < 6	70	53	105	127	165	210	228	0
≥ 6, < 10	44	42	45	69	123	191	201	1
≥ 10, < 13	41	35	51	73	93	150	173	1
≥ 13, < 19	19	21	24	39	62	82	87	0
≥ 19, < 25	10	16	11	16	48	67	67	0
≥ 25, < 31	23	22	38	50	60	72	75	0
≥ 31, < 37	14	15	25	29	37	53	59	0
Total sample	**30**	**36**	**41**	**55**	**91**	**171**	**228**	**0**



Key

a global

b months

c age range with highest frequencies of mouthing behaviour

Figure 26 — Frequency of mouthing behaviour per hour by age (based on means of Table 10)

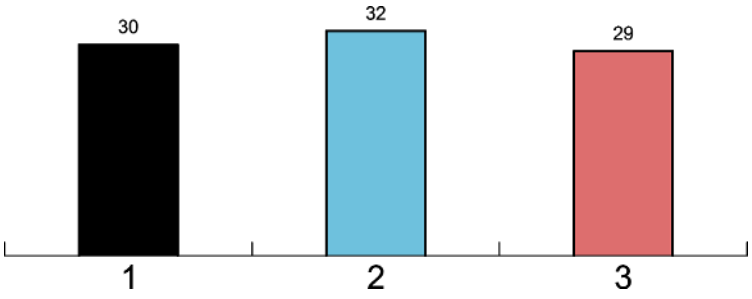
The average number of times children mouthed toys was 30 times/hour for the total sample (26 times/hour, weighted by year). The highest frequencies were in children aged 3 months to 12 months (52 times/hour), especially in those aged ≥ 3 months and < 6 months (70 times/hour).

The average number of times children under 12 months mouthed toys (44 times/hour) is significantly different compared with children from 13 months to 36 months (17 times/hour). This difference is significant, based on the non-parametric test results: Mann-Whitney and Kolmogorov-Smirnov (see C.2).

4.1.3 By gender

Table 11 — Frequency children mouthed toys per hour by gender

Gender	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Boys	32	38	41	57	111	172	201	0
Girls	29	34	41	53	86	159	228	0
Total sample	**30**	**36**	**41**	**55**	**91**	**171**	**228**	**0**



Key

1 global

2 boys

3 girls

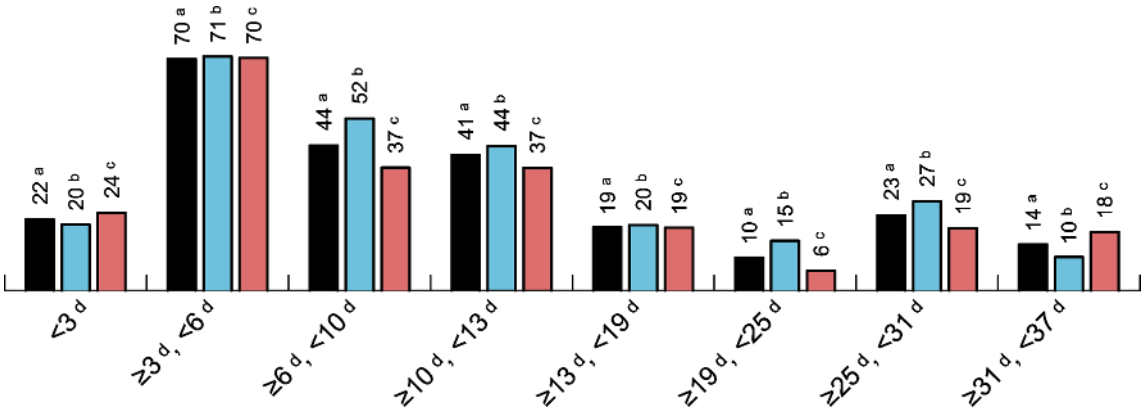
Figure 27 — Frequency of mouthing behaviour per hour by gender (based on means in Table 11)

No significant gender differences were observed when analysing the number of times children put toys into their mouths (based on the non-parametric test results: Mann-Whitney and Kolmogorov-Smirnov, see C.2).

4.1.4 By gender and age

Table 12 — Frequency of mouthing behaviour per hour by gender and age (mean values)

Age groups months	**Mean**	**Boys**	**Girls**
< 3	22	20	24
≥ 3, < 6	70	71	70
≥ 6, < 10	44	52	37
≥ 10, < 13	41	44	37
≥ 13, < 19	19	20	19
≥ 19, < 25	10	15	6
≥ 25, < 31	23	27	19
≥ 31, < 37	14	10	18
Total sample	**30**	**32**	**29**



Key

a global
b boys
c girls
d months

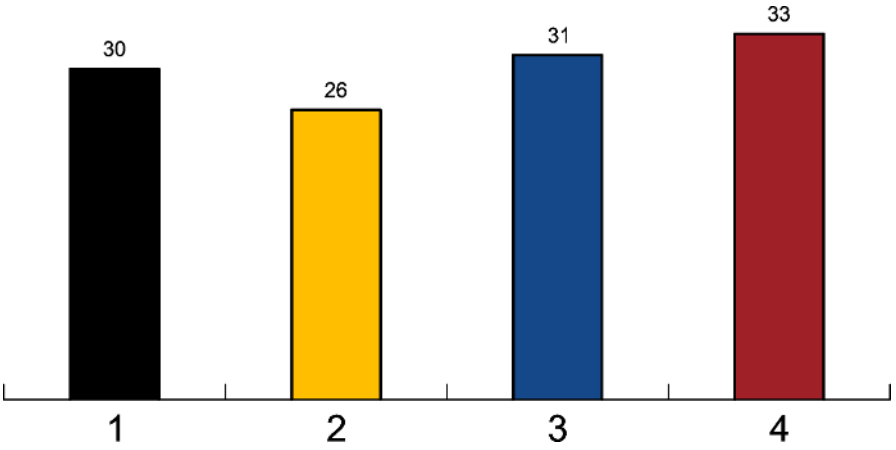
Figure 28 — Frequency of mouthing behaviour per hour by gender and age (based on means in Table 12)

Similar frequencies were found for both, boys and girls, in the different age groups. The frequencies are slightly higher for boys in some age brackets.

4.1.5 By country

Table 13 — Frequency children mouthed toys per hour, by country

Country	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Germany	26	32	41	53	67	79	87	0
France	31	33	47	62	91	145	173	0
Spain	33	47	38	52	157	206	228	0
Total sample	**30**	**36**	**41**	**55**	**91**	**171**	**228**	**0**



Key

1 global
2 Germany
3 France
4 Spain

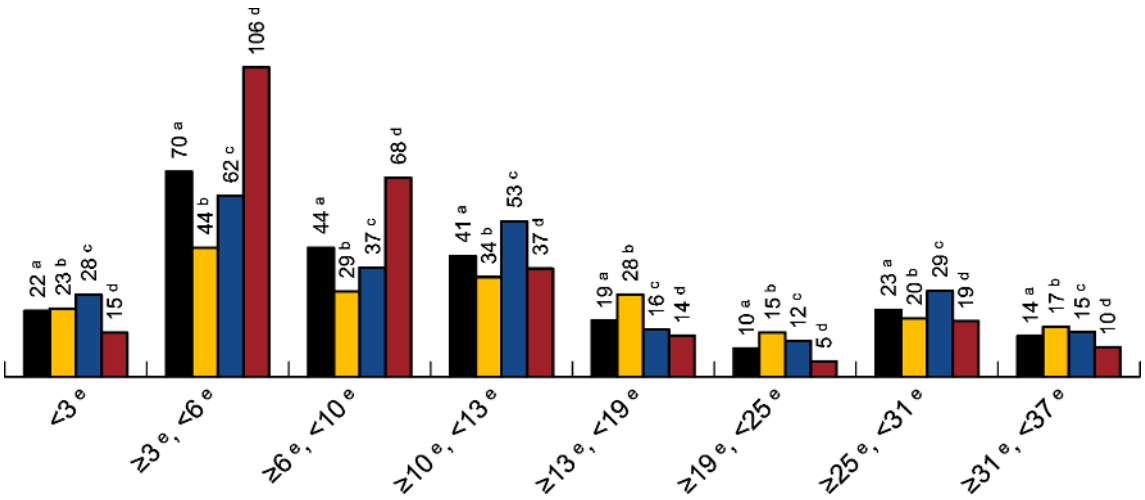
Figure 29 — Frequency of mouthing behaviour per hour by country (based on means in Table 13)

No significant differences were observed when analysing the frequency according to country (based on the results of a Kruskal-Wallis non-parametric test, see C.2).

4.1.6 By country and age

Table 14 — Frequency of mouthing behaviour per hour by country and age (mean values)

Age groups months	Mean	Germany	France	Spain
< 3	22	23	28	15
≥ 3, < 6	70	44	62	106
≥ 6, < 10	44	29	37	68
≥ 10, < 13	41	34	53	37
≥ 13, < 19	19	28	16	14
≥ 19, < 25	10	15	12	5
≥ 25, < 31	23	20	29	19
≥ 31, < 37	14	17	15	10
Total Sample	**30**	**26**	**31**	**33**



Key

a global
b Germany
c France
d Spain
e months

Figure 30 — Frequency of mouthing behaviour per hour by country and age (based on means in Table14)

The highest frequency was observed for Spanish babies, aged ≥ 3 months and < 6 months and ≥ 6 months and < 10 months.

4.2 Time children spent mouthing toys

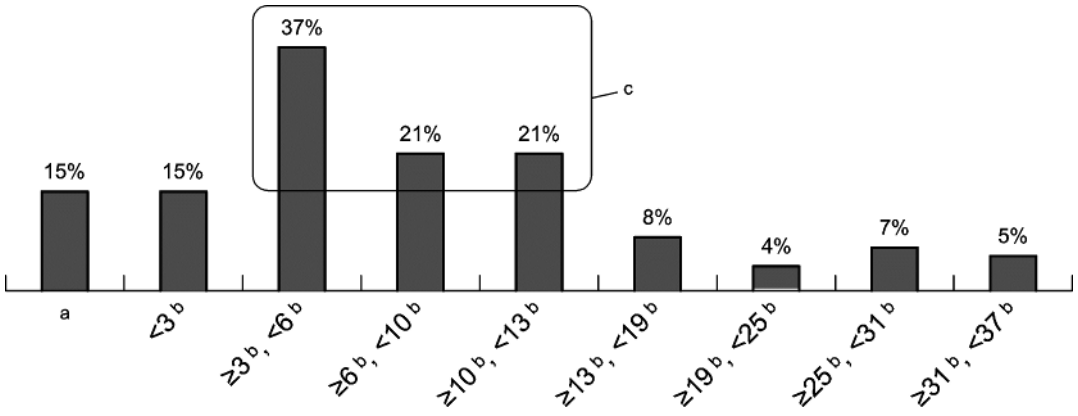
4.2.1 General

4.2 presents data related to the "percentage of time children mouthed a toy in the total time observed". This information is analysed by: age, gender and country.

4.2.2 By age

Table 15 — Percentage of time children mouthed a toy in the total time (511,8 h) by age

Age groups months	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
< 3	14,9 %	17,1 %	21,4 %	40,6 %	43,5 %	54,8 %	59,3 %	0 %
≥ 3, < 6	36,9 %	18,5 %	50,6 %	57,0 %	60,3 %	65,1 %	67,0 %	0 %
≥ 6, < 10	20,9 %	16,2 %	34,2 %	40,2 %	47,9 %	53,7 %	55,9 %	0 %
≥ 10, < 13	20,9 %	17,4 %	29,0 %	34,9 %	52,0 %	70,1 %	74,8 %	0,2 %
≥ 13, < 19	8,0 %	10,5 %	12,0 %	16,4 %	19,3 %	43,6 %	53,0 %	0 %
≥ 19, < 25	3,9 %	6,9 %	3,8 %	5,6 %	16,8 %	29,9 %	33,6 %	0 %
≥ 25, < 31	6,5 %	8,8 %	9,0 %	11,9 %	16,6 %	37,2 %	45,7 %	0 %
≥ 31, < 37	5,2 %	7,4 %	8,7 %	10,9 %	16,2 %	30,1 %	36,0 %	0 %
Total sample	**14,7 %**	**17,2 %**	**21,0 %**	**36,2 %**	**50,6 %**	**60,3 %**	**74,8 %**	**0 %**



Key

a global

b months

c age range with highest percentage of time children mouthed a toy

Figure 31 — Percentage of time children mouthed a toy in the total time (511,8 h) by age (based on means of Table 15)

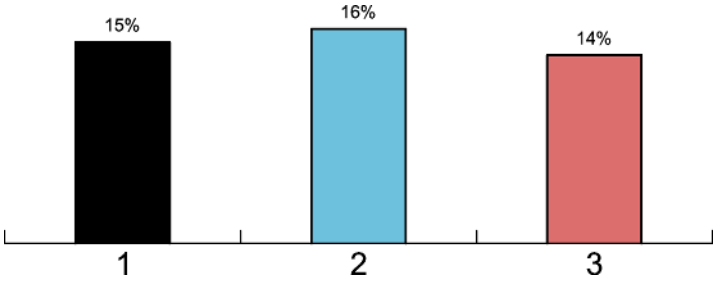
Children mouthed toys for 14,7 % (75,2 h; weighted by year: 11,7 % (59,9 h)) of the total time observed (511,8 h). However, there were considerable differences between ages: babies under 12 months, mouth between 15 % and 37 % of their time in contact with a toy. Based on the results of a Kruskal-Wallis analysis, there are significant differences between different age brackets, with a peak in children of ≥ 3 months and < 6 months (for more information see C.2).

The behaviour of children under 12 months (23,4 %) in this variable is significantly different to that of children aged between 13 months to 36 months (5,9 %). This difference is significant, based on the results of non-parametric tests: Mann-Whitney and Kolmogorov-Smirnov (see C.2).

4.2.3 By gender

Table 16 — Percentage of time children mouthed a toy in the total time (511,8 h) by gender

Gender	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Boys	15,6 %	18,9 %	25,3 %	42,6 %	55,6 %	65,8 %	74,8 %	0 %
Girls	13,9 %	15,5 %	20,3 %	34,2 %	46,8 %	57,8 %	60,5 %	0 %
Total sample	14,7 %	17,2 %	21,0 %	36,2 %	50,6 %	60,3 %	74,8 %	0 %



Key

1 global
2 boys
3 girls

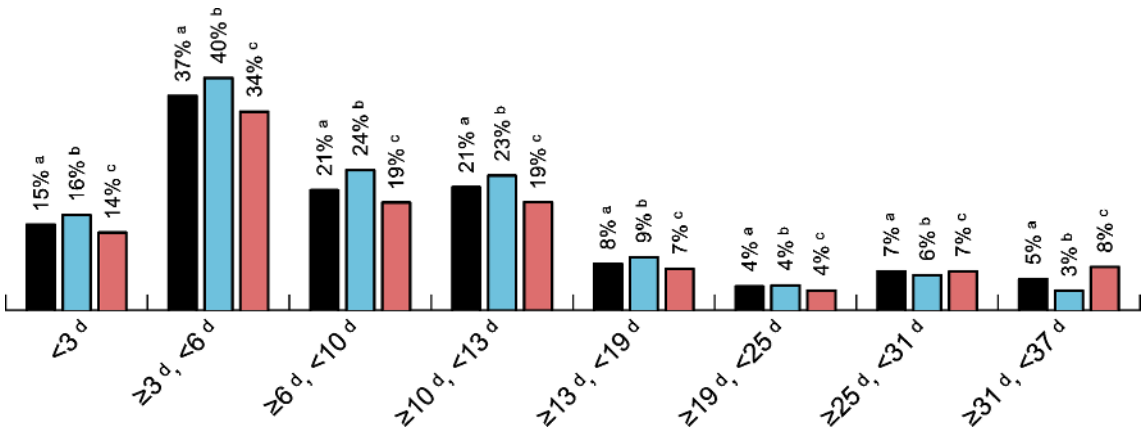
Figure 32 — Percentage of time children mouthed a toy in the total time (511,8 h) by gender (based on means of Table 16)

No significant differences between genders were observed in the duration of mouthing behaviour (based on the results of non-parametric tests: Mann-Whitney and Kolmogorov-Smirnov, see C.2).

4.2.4 By gender and age

Table 17 — Percentage of time children mouthed a toy in the total time (511,8 h) by gender and age (mean values)

Age groups months	**Mean**	**Boys**	**Girls**
< 3	14,9 %	16,4 %	13,5 %
≥ 3, < 6	36,9 %	40,0 %	34,3 %
≥ 6, < 10	20,9 %	24,0 %	18,5 %
≥ 10, < 13	20,9 %	23,2 %	18,5 %
≥ 13, < 19	8,0 %	9,0 %	7,1 %
≥ 19, < 25	3,9 %	4,4 %	3,5 %
≥ 25, < 31	6,5 %	6,0 %	6,9 %
≥ 31, < 37	5,2 %	3,1 %	7,5 %
Total sample	14,7 %	15,6 %	13,9 %



Key

a global
b boys
c girls
d months

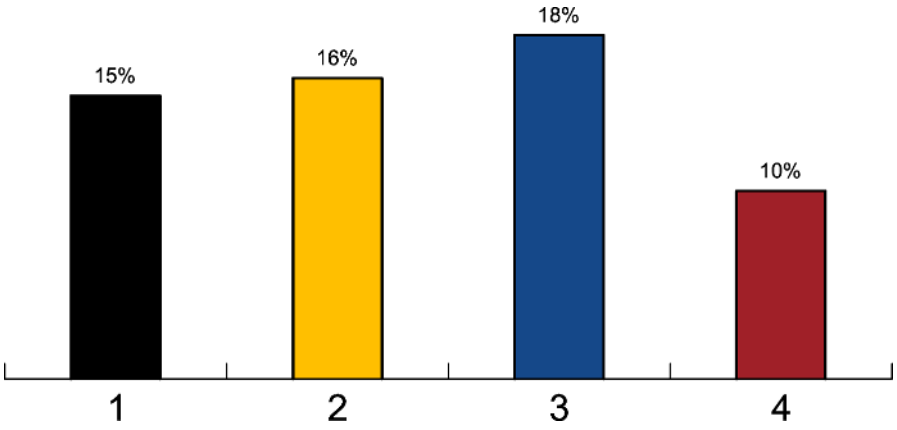
Figure 33 — Percentage of time children mouthed a toy in the total time (511,8 h) by gender and age (based on means of Table 17)

The differences between boys and girls in the time that children mouthed a toy are constant throughout the different ages.

4.2.5 By country

Table 18 — Percentage of time children mouthed a toy in the total time (511,8 h) by country

Country	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Germany	16,3 %	18,4 %	29,0 %	42,4 %	54,0 %	59,3 %	59,9 %	0 %
France	17,8 %	18,2 %	27,0 %	39,2 %	55,6 %	68,7 %	74,8 %	0 %
Spain	10,0 %	13,5 %	13,3 %	20,2 %	42,1 %	52,3 %	60,5 %	0 %
Total sample	14,7 %	17,2 %	21,0 %	36,2 %	50,6 %	60,3 %	74,8 %	0 %



Key

1 global
2 Germany
3 France
4 Spain

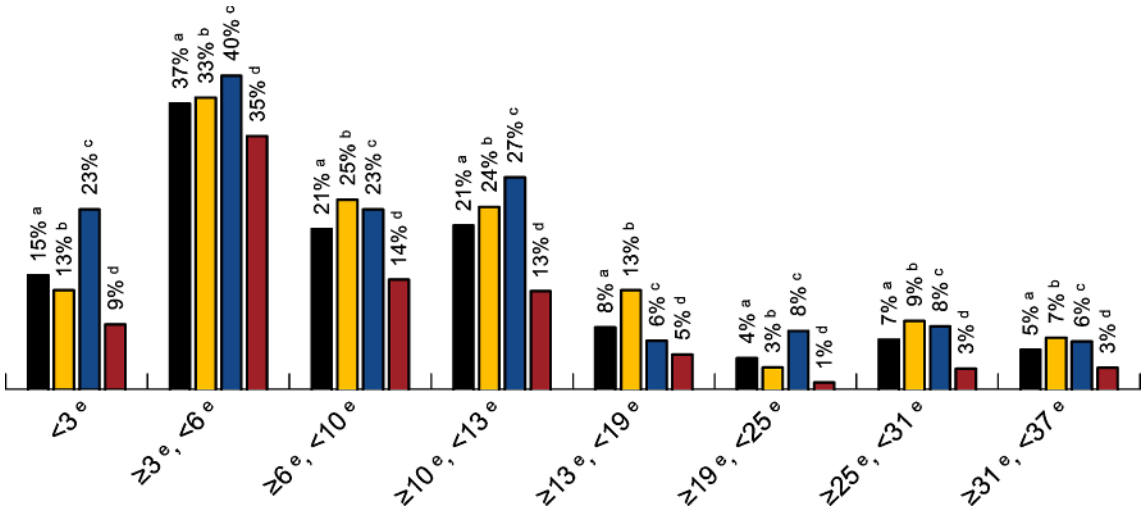
Figure 34 — Percentage of time children mouthed a toy in the total time (511,8 h) by country

Spanish children spent less time mouthing toys than German and French children, and this difference is significant (based on the results of a Kruskal-Wallis analysis, see C.2). This significant difference (not observed in the frequency variable, see 4.1.5) cannot be tested, given the absence of previous cross-cultural studies.

4.2.6 By country and age

Table 19 — Percentage of time children mouthed a toy in the total time (511,8 h) by country and age (mean values)

Age groups months	**Mean**	**Germany**	**France**	**Spain**
< 3	14,9 %	12,9 %	23,3 %	8,5 %
≥ 3, < 6	36,9 %	37,7 %	40,3 %	32,8 %
≥ 6, < 10	20,9 %	24,6 %	23,3 %	14,2 %
≥ 10, < 13	20,9 %	23,5 %	27,3 %	12,7 %
≥ 13, < 19	8,0 %	12,9 %	6,4 %	4,6 %
≥ 19, < 25	3,9 %	3,2 %	7,7 %	1,1 %
≥ 25, < 31	6,5 %	8,9 %	8,2 %	2,7 %
≥ 31, < 37	5,2 %	6,7 %	6,2 %	2,9 %
Total Sample	14,7 %	16,3 %	17,8 %	10,0 %



Key

a global
b Germany
c France
d Spain
e months

Figure 35 — Percentage of time children mouthed a toy in the total time (511,8 h) by country and age (based on means of Table 19)

The age pattern observed in total mouthing time by age is common to the three countries.

However, there are slight differences in trends in the total percentage of time spent mouthing:

— Spain, lowest percentage in time spent mouthing;

— France, highest percentage of time in the 3 months to 12 months bracket;

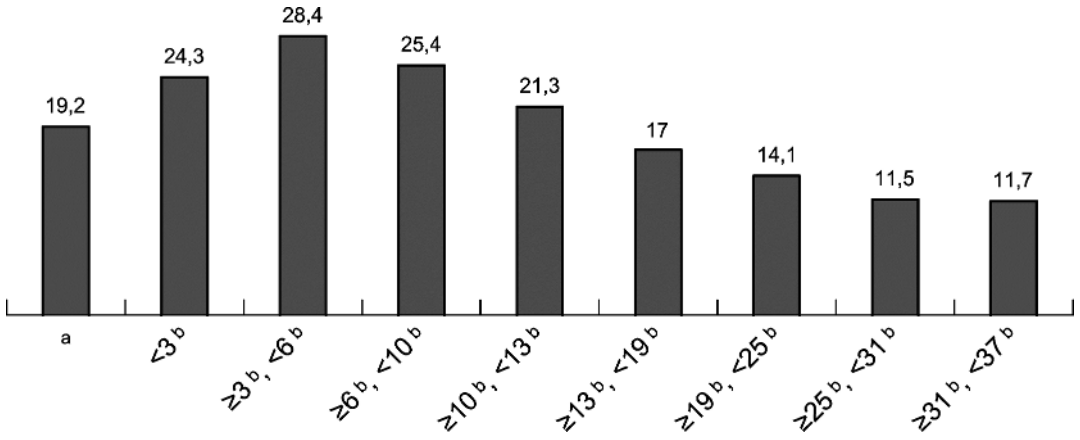
— Germany, medium position.

4.2.7 Toy-to-mouth contact duration by age

4.2.7 presents data related to the “number of second in each mouthing action” (from the toy coming into contact with the child's mouth until the end of this contact).

Table 20 — Toy-to-mouth contact duration by age

Age groups months	**Mean** s	**SD** s	**Per. 75** s	**Per. 85** s	**Per. 95** s	**Per. 99** s	**Max.** s	**Min.** s
< 3	24,3	15,7	36,1	41,5	52,7	53,7	53,9	5,3
≥ 3, < 6	28,4	24,6	37,3	55,4	74,3	98,2	106,5	5,4
≥ 6, < 10	25,4	24,3	41,5	55,6	64,1	91,3	103,3	0,7
≥ 10, < 13	21,3	17,8	25,1	35,5	61,6	71,1	73,0	4,7
≥ 13, < 19	17,0	19,4	16,9	28,2	42,5	86,1	103,0	2,5
≥ 19, < 25	14,1	11,5	16,3	21,9	30,8	53,7	61,0	4,3
≥ 25, < 31	11,5	10,4	14,1	18,7	36,2	42,3	43,0	2,0
≥ 31, < 37	11,7	6,3	14,6	19,7	21,9	24,7	25,7	3,9
Total sample	**19,2**	**18,6**	**24,1**	**35,0**	**56,5**	**94,6**	**106,5**	**0,7**



Key

a global

b months

Figure 36 — Toy-to-mouth contact duration in seconds by age (based on means of Table 20)

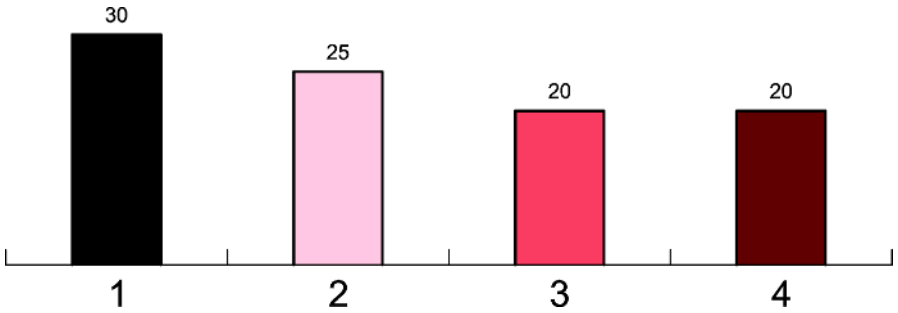
Children under 36 months spent 19,2 s in each mouthing action (17,3 s weighted by year). Analysing this data by age, after the second age bracket (≥3 months and < 6 months) the number of seconds in each mouthing action decreases with the age. The age group of under 12 months (24,9 s) is significantly different from those of 13 months to 24 months (15,6 s) and from 25 months to 36 months (11,6 s). This difference is significant based on the results of a non-parametric test: Mann-Whitney and Kolmogorov-Smirnov (see C.2).

4.3 Type of mouthing: lip/tongue, suck/engulf, bite/chew

4.3.1 Frequency by type of mouthing

Table 21 — Frequency children mouthed toys per hour by type of mouthing (multiple answer)

Type of mouthing	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Lip/ tongue	25	33	36	48	85	165	228	0
Suck/ engulf	20	29	27	44	77	124	210	0
Bite/ chew	20	32	26	42	75	160	228	0
Total sample	30	36	41	55	91	171	228	0



Key

1 global
2 lip
3 suck
4 bite

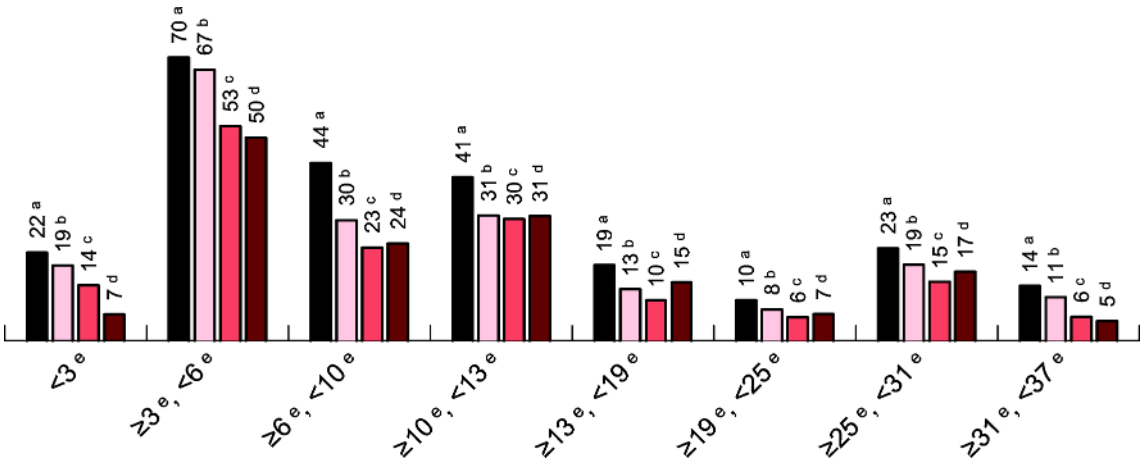
Figure 37 — Frequency children mouthed toys per hour by type of mouthing (based on means of Table 21)

Lip-touching was the most frequent type of mouthing behaviour observed in children's contact with toys (25 times/hour for the total sample, weighted by year: 21 times/hour), followed by sucking and biting (20 times/hour each, 16 times/hour for sucking and 17 times/hour for biting, weighted by year). The most common mouthing behaviour form was a combination of different types of mouthing (lip+suck, or suck+bite, or even lip+suck+bite).

4.3.2 Frequency by type of mouthing and age

Table 22 — Frequency children mouthed toys per hour by type of mouthing and age (mean values)

Age groups months	Mean	Lip/ tongue	Suck/ engulf	Bite/ chew
< 3	22	19	14	7
≥ 3, < 6	70	67	53	50
≥ 6, < 10	44	30	23	24
≥ 10, < 13	41	31	30	31
≥ 13, < 19	19	13	10	15
≥ 19, < 25	10	8	6	7
≥ 25, < 31	23	19	15	17
≥ 31, < 37	14	11	6	5
Total Sample	**30**	**25**	**20**	**20**



Key

a global
b lip
c suck
d bite
e months

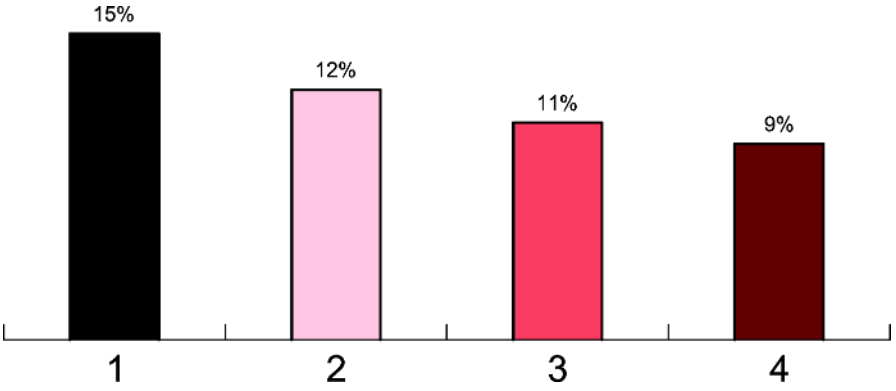
Figure 38 — Frequency children mouthed toys per hour by type of mouthing and age (based on means of Table 22)

Based on the results of a Kruskal-Wallis analysis (see C.2), there are significant differences between age brackets for lip-touching behaviour, with a peak in the ≥ 3 months and < 6 months group (67 times per hour).

4.3.3 Time children spent mouthing, by type of mouthing

Table 23 — Percentage of time children mouthed a toy in the total time (511,8 h) by type of mouthing (multiple answer)

Type of mouthing	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Lip/ tongue	11,8 %	15,8 %	16,1 %	29,5 %	47,1 %	59,0 %	74,8 %	0 %
Suck/ engulf	10,5 %	15,3 %	14,8 %	26,9 %	45,3 %	57,2 %	67,0 %	0 %
Bite/ chew	9,4 %	13,7 %	13,0 %	23,1 %	40,4 %	58,5 %	61,7 %	0 %
Total sample	14,7 %	17,2 %	21,0 %	36,2 %	50,6 %	60,3 %	74,8 %	0 %



Key

1 global
2 lip
3 suck
4 bite

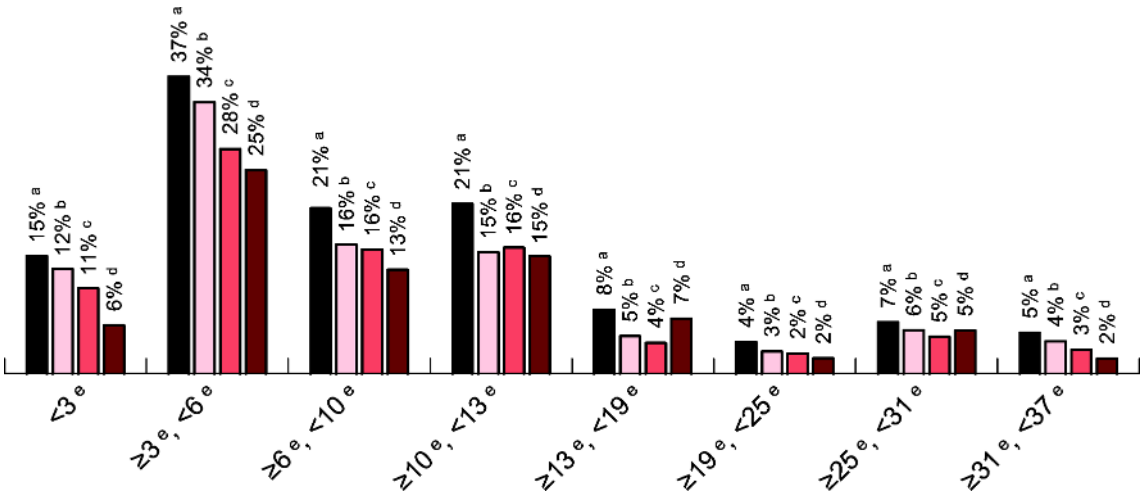
Figure 39 — Percentage of time children mouthed a toy in the total time (511,8 h) by type of mouthing

Lip-touching and sucking were the most common types of mouthing observed. Lip-touching 12 %, sucking 11 % and biting 9 % of the total mouthing time (9,3 %, 8,1 % and 7,6 % weighted by year, respectively). The most common mouthing behaviour form was a combination of different types of mouthing (lip+suck, or suck+bite, or even lip+suck+bite).

4.3.4 Time children spent mouthing toys by type of mouthing and age

Table 24 — Percentage of time children mouthed a toy in the total time (511,8 h) by type of mouthing and age (mean values)

Age groups months	Mean	Lip/ tongue	Suck/ engulf	Bite/ chew
< 3	14,9 %	11,7 %	10,5 %	5,5 %
≥ 3, < 6	36,9 %	33,6 %	28,1 %	25,2 %
≥ 6, < 10	20,9 %	16,2 %	15,9 %	13,0 %
≥ 10, < 13	20,9 %	15,3 %	15,6 %	14,5 %
≥ 13, < 19	8,0 %	4,8 %	4,0 %	6,9 %
≥ 19, < 25	3,9 %	3,1 %	2,0 %	2,4 %
≥ 25, < 31	6,5 %	5,5 %	4,7 %	5,3 %
≥ 31, < 37	5,2 %	4,1 %	2,9 %	2,0 %
Total Sample	**14,7 %**	**11,8 %**	**10,5 %**	**9,4 %**



Key

a global
b lip
c suck
d bite
e months

Figure 40 — Percentage of time children mouthed a toy in the total time (511,8 h) by type of mouthing and age (based on means of Table 24)

Based on the results of a Kruskal-Wallis analysis, there are significant differences in lip-touching behaviour between age brackets, with a peak in the ≥ 3 months and < 6 months group (34 % of toy mouthing time). This data was consistent with higher mouthing behaviour in children of this age bracket.

4.4 Elastomeric vs. not elastomeric material

4.4.1 General

4.4 analyses the differences in children's mouthing behaviour in contact with toys by comparing elastomeric and not elastomeric materials. The results of this study served as input for the revision of EN 71-12:2013, which is applicable to toys made from elastomers (and finger paints). For this reason the toy sample was separated into two different groups: toys with a presence of elastomeric material, and toys with no presence of elastomeric material (see toy sample selection, 3.4.3).

This data has been analysed by:

— Frequency children mouthed toys per hour;

— Time children spent mouthing toys in the total time observed with toys;

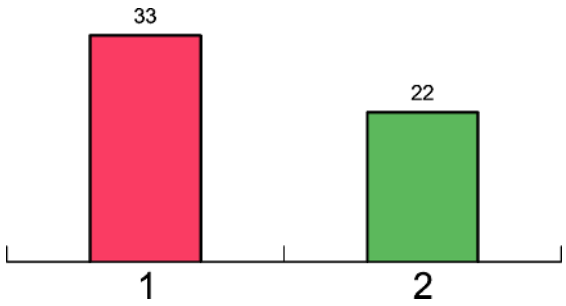
— Toy-to-mouth-contact duration.

For the calculation of frequency, time spent and toy-to-mouth contact duration by elastomeric and not elastomeric material data, observations by children were split by product (remember that the number of products observed per child was 3). This implies a change of the base and weight of the data; for this reason the mean values of the total sample are sometimes slightly different from those of previous data. In order to avoid confusion, mean values for the total sample have been omitted in the following tables and graphs.

4.4.2 Frequency by elastomeric and not elastomeric material

Table 25 — Frequency children mouthed toys per hour by material (elastomeric vs not elastomeric)

Material	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Elastomeric	33	39	48	62	103	180	228	0
Not elastomeric	22	27	33	47	69	124	163	0



Key

1 elastomeric

2 not elastomeric

Figure 41 — Frequency children mouthed toys per hour by material (based on means of Table 25)

The average number of times children mouthed an elastomeric toys was 33 times/hour (26 times/hour weighted by year, assuming a frequency value of 23 times/hour for the ≥ 25 months and < 31 months age bracket). Not elastomeric toys are mouthed an average of 22 times/hour (22 times/hour, weighted

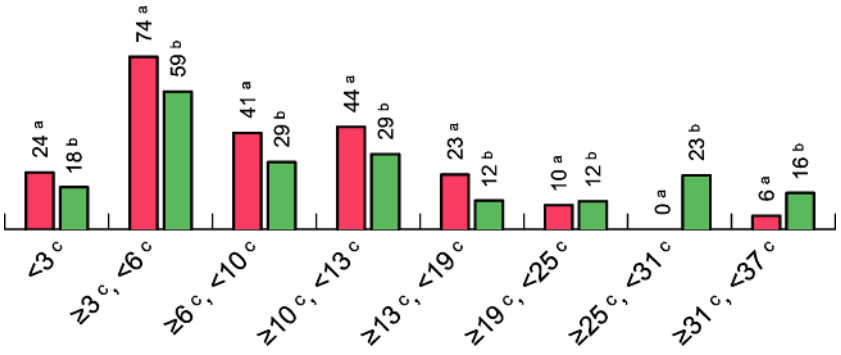
by age). This difference is significant based on the results of a non-parametric test: Mann-Whitney and Kolmogorov-Smirnov, see C.2.

Children under 12 months mouth elastomeric toys an average of 46 times/hour, and not elastomeric toys an average of 35 times/hour, this difference is significant. Not significant differences were observed analysing the same data for children from 13 months to 36 months, who mouth elastomeric toys an average of 16 times per hour and the same amount of times for not elastomeric toys.

4.4.3 Frequency by elastomeric and not elastomeric material and age

Table 26 — Frequency children mouthed toys per hour by material and age (mean values)

Age groups months	**Elastomeric**	**Not elastomeric**
< 3	24	18
≥ 3, < 6	74	59
≥ 6, < 10	41	29
≥ 10, < 13	44	32
≥ 13, < 19	23	12
≥ 19, < 25	10	12
≥ 25, < 31	No data	23
≥ 31, < 37	6	16
Total Sample	**33**	**22**



Key

a elastomeric

b not elastomeric

C months

Figure 42 — Frequency children mouthed toys per hour by material and age (based on means of Table 26)

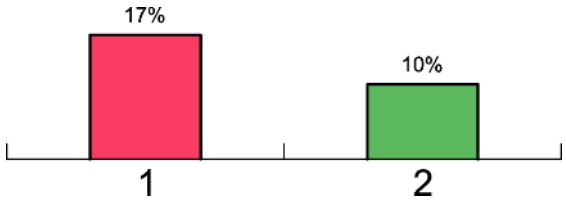
A higher frequency of mouthing behaviour with elastomeric toys is observed in the majority of age brackets.

NOTE There is a lack of data for elastomeric toys in the ≥ 25 months and < 31 months bracket due to difficulties in finding and providing elastomeric toys intended for children over 2 years of age.

4.4.4 Time children spent mouthing by elastomeric and not elastomeric material

Table 27 — Percentage of time children mouthed a toy in the total time (511,8 h) by material

Material	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Elastomeric	17,5 %	19,1 %	31,5 %	43,1 %	55,6 %	63,5 %	74,8 %	0 %
Not elastomeric	9,9 %	13,5 %	14,2 %	22,8 %	39,3 %	52,1 %	53,2 %	0 %



Key

1 elastomeric

2 not elastomeric

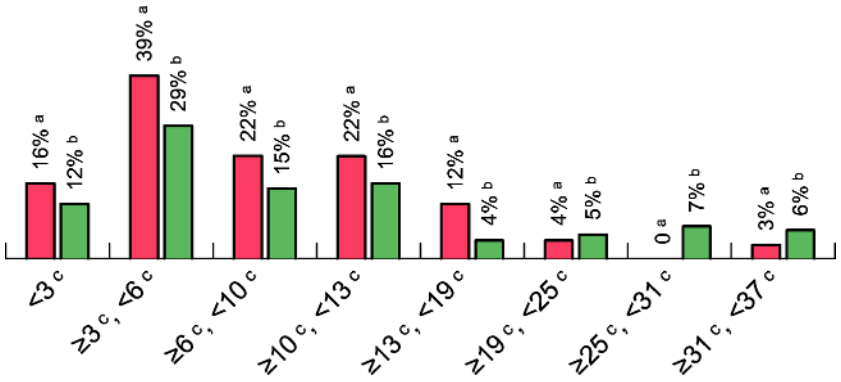
Figure 43 — Percentage of time children mouthed a toy in the total time (511,8 h) by material

In the time spent mouthing toys, significant differences were observed between elastomeric (17,5 % of time observed, 12,4 % weighted by year and assuming a value of 6,5 % for the ≥ 25 months and < 31 months age bracket) and not elastomeric materials (9,9 % of time observed, 9,7 % weighted by year). This difference is significant based on the results of a non-parametric test: Mann-Whitney and Kolmogorov-Smirnov (see C.2).

4.4.5 Time children spent mouthing, by elastomeric and not elastomeric material and age

Table 28 — Percentage of time children mouthed a toy in the total time (511,8 h) by material and age (mean values)

Age groups months	**Elastomeric**	**Not elastomeric**
< 3	15,9 %	11,8 %
≥ 3, < 6	38,8 %	29,3 %
≥ 6, < 10	21,6 %	15,2 %
≥ 10, < 13	22,1 %	15,9 %
≥ 13, < 19	11,7 %	4,3 %
≥ 19, < 25	3,9 %	5,2 %
≥ 25, < 31	No data	6,5 %
≥ 31, < 37	2,8 %	6,0 %
Total Sample	**17,5 %**	**9,9 %**



Key

a elastomeric

b not elastomeric

c months

Figure 44 — Percentage of time children mouthed toys in the total time (511,8 h) by material and age (based on means of Table 28)

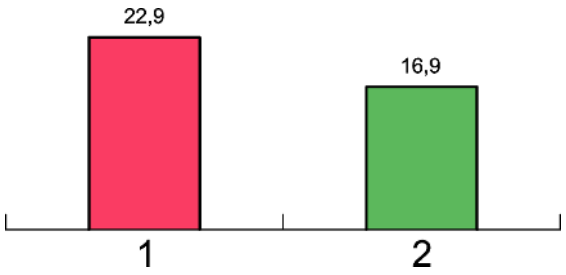
A higher time of mouthing behaviour is observed with elastomeric toys in the majority of age brackets.

NOTE There is a lack of data for elastomeric toys in the ≥ 25 months and < 31 months bracket due to difficulties in finding and providing elastomeric toys intended for children over 2 years of age.

4.4.6 Toy-to-mouth contact duration by elastomeric and not elastomeric material

Table 29 — Toy-to-mouth contact duration by material

Material	Mean s	SD s	Per. 75 s	Per. 85 S	Per. 95 s	Per. 99 s	Max. s	Min. s
Elastomeric	22,9	21,3	31,4	41,7	64,1	99,7	119,9	0,7
Not elastomeric	16,9	18,5	20,0	26,5	54,5	95,1	114,0	1,7



Key

1 elastomeric

2 not elastomeric

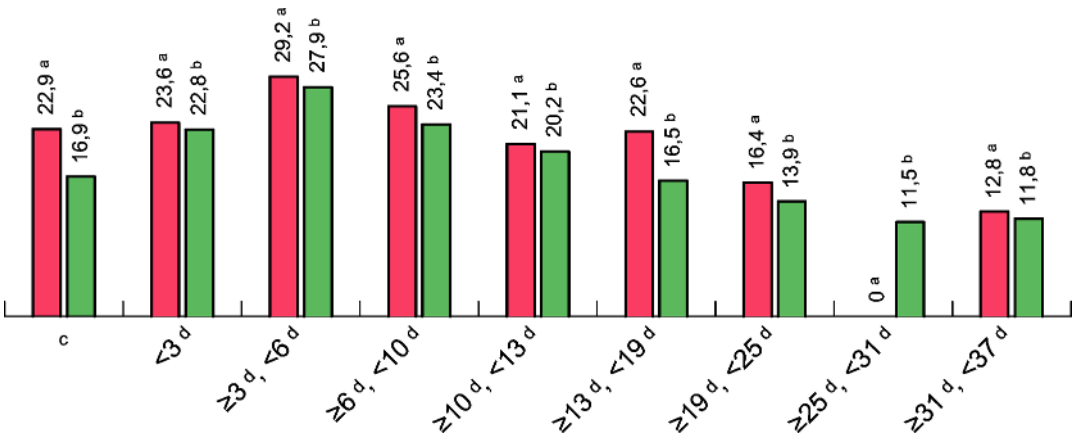
Figure 45 — Toy-to-mouth contact duration in seconds by material (based on means of Table 29)

The duration of toy-to-mouth contact in elastomeric material (22,9 s, 18,8 s weighted by year) is significantly higher than with not elastomeric materials (16,9 s, 16,8 s weighted by year). This difference is significant based on the results of a non-parametric test: Mann-Whitney and Kolmogorov-Smirnov (see C.2).

4.4.7 Toy-to-mouth duration by elastomeric and not elastomeric material and age

Table 30 — Toy-to-mouth contact duration by material and age (mean values)

Age groups months	**Elastomeric** s	**Not elastomeric** s
< 3	23,6	22,8
≥ 3, < 6	29,2	27,9
≥ 6, < 10	25,6	23,4
≥ 10, < 13	21,1	20,2
≥ 13, < 19	22,6	16,5
≥ 19, < 25	16,4	13,9
≥ 25, < 31	NO DATA	11,5
≥ 31, < 37	12,8	11,8
Total Sample	22,9	16,9



Key

a elastomeric
b not elastomeric
c mean
d months

Figure 46 — Toy-to-mouth contact duration in seconds by material and age (based on means of Table 30)

Toy-to-mouth contact duration for children aged 0 months to 12 months revealed a mean of 25 s for elastomeric toys and 24 s for not elastomeric toys. And this difference is not significant.

NOTE There is a lack of elastomeric data in ≥ 25 months and < 31 months bracket due to difficulties in finding and providing elastomeric toys intended for children over 2 years of age.

4.4.8 Qualitative approach of the influence of elastomeric material in children's mouthing behaviour

Qualitative research aims to understand certain behaviours and the reasoning behind such behaviours. It is the opposite of quantitative research, which studies measurable data that can be counted and

analysed in the form of numbers. Qualitative research studies the intangible factors that drive specific outcomes. It is commonly used in sociological research.

The present qualitative analysis employed the content analysis methodology. This is a form of data analysis in which a database is scrutinised for significant and recurring themes, based on researcher-developed codes containing brief descriptions of the recurring themes. Content analysis is a systematic procedure for the quantification and objective examination of qualitative data—such as written messages—by the classification and evaluation of terms, themes, or ideas in order to determine their meaning or effect.

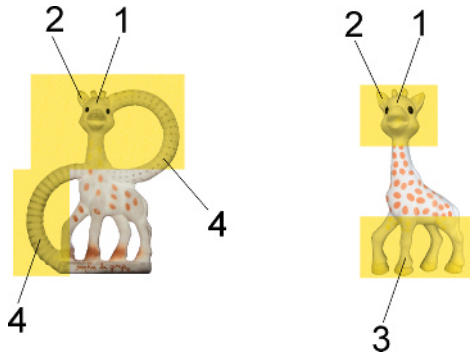
The results of this process were obtained through the analysis of an open question made to the 245 families following their last day of observation. The specific question was: "Which part of the toy has your child placed in his/her mouth most?" The answers to this question were analysed by toy, and grouped by coincidence of answer and recurring similarities between the products.

The results of this analysis showed that not only the type of material (elastomeric or not), but also the shape of the toy have a bearing on mouthing behaviour. The protruding/accessible parts of the toy, such as elements that replicate handles, heads, legs, wings, antennae, etc., further stimulate mouthing behaviour—whether they are of elastomeric material or not.

The following images show the parts of toys most frequently mouthed, as mentioned by the parents (Figure 47).

Figure 47 — Parts of toys most frequently mouthed

Even in toys made entirely with elastomeric material, the protruding parts are those that stimulate greater mouthing behaviour (Figure 48).



Key

1 head
2 bars
3 legs
4 handle

Figure 48 — Protruding parts that stimulate greater mouthing behaviour

In toys that have elastomeric materials in accessible parts, the mouthing behaviour is higher in the elastomeric parts, including toy types such as walkers (Figure 49).

Figure 49 — Elastomeric material in accessible parts of toys

In contrast, those toys that had elastomeric materials in less accessible parts of the toy did not increase children's mouthing behaviour (Figure 50).

Figure 50 — Elastomeric material in less accessible parts of toys

Therefore, following qualitative data analysis, it was concluded that the toys that most stimulate mouthing behaviour are those manufactured in elastomeric material (almost entirely), with accessible parts (due to size or design), which are intended for children under 12 months (Figure 51).

Figure 51 — Toys manufactured in elastomeric material with accessible parts

4.5 Toys intended vs not intended to be mouthed

4.5.1 General

4.5 analyses the differences in children's mouthing behaviour in contact with toys by comparing toys intended to be mouthed vs. toys not intended to be mouthed. This data has been analysed by:

— Frequency children mouthed toys per hour;

— Time children spent mouthing toys in the total time observed with toys;

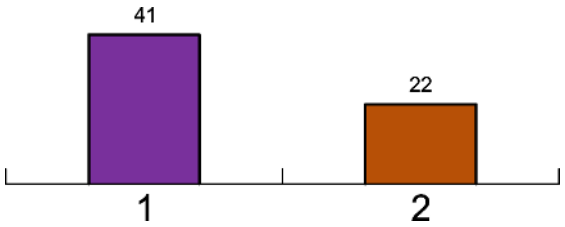
— Toy-to-mouth-contact duration.

For the calculation of frequency, time spent and toy-to-mouth contact duration for toys intended vs not intended to be mouthed, observations by children were split by product (remember that the number of products observed per child was 3). This implies a change of the base and weight of the data; for this reason the mean values of the total sample are sometimes slightly different from those of previous data. In order to avoid confusion, mean values for the total sample have been omitted in the following tables and graphs.

4.5.2 Frequency children mouthed toys intended vs not intended to be mouthed

Table 31 — Frequency children mouthed toys per hour by intended vs not intended to be mouthed

	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Intended	41	42	56	74	133	197	228	0
Not intended	22	28	33	46	69	139	172	0



Key

1 intended to be mouthed

2 not intended to be mouthed

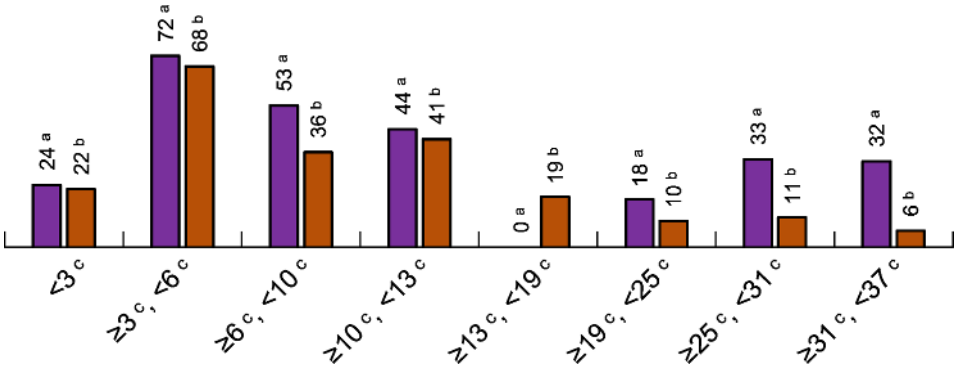
Figure 52 — Frequency children mouthed toys intended vs not intended to be mouthed per hour (based on means of Table 31)

In the frequency of mouthing toys, significant differences were observed between those intended to be mouthed (41 times/hour, weighted by year: 33 times/hour) and toys not intended to be mouthed (22 times/hour, weighted by year: 22 times/hour). This difference is significant based on the results of a non-parametric test: Mann-Whitney and Kolmogorov-Smirnov (see C.2).

4.5.3 Frequency children mouthed toys intended vs not intended to be mouthed by age

Table 32 — Frequency children mouthed toys intended vs not intended to be mouthed per hour by age (mean values)

Age groups months	Intended to be mouthed	Not intended to be mouthed
< 3	24	22
≥ 3, < 6	72	68
≥ 6, < 10	53	36
≥ 10, < 13	44	41
≥ 13, < 19	NO DATA	19
≥ 19, < 25	18	10
≥ 25, < 31	33	11
≥ 31, < 37	32	6
Total Sample	**41**	**22**



Key

a intended to be mouthed

b not intended to be mouthed

c months

Figure 53 — Frequency children mouthed toys intended vs not intended to be mouthed per hour by age (based on means of Table 32)

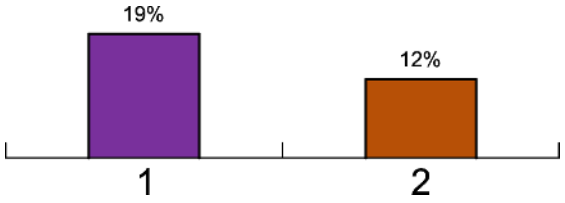
The greatest differences were found in older children (13 months to 36 months). In earlier ages (under 12 months), children put any toy in their mouth, whether it was intended to be mouthed or not.

NOTE There is a lack of data for toys intended to be mouthed for the ≥ 13 months and < 19 months age bracket, due to difficulties in finding and providing toys intended to be mouthed by children of this age.

4.5.4 Time children spent mouthing toys intended vs not intended to be mouthed

Table 33 — Percentage of time children mouthed a toy (intended vs not intended to be mouthed) in the total time (511,8 h)

Type of toy	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Intended to be mouthed	18,8 %	19,3 %	30,5 %	43,6 %	57,8 %	66,5 %	74,0 %	0 %
Not intended to be mouthed	11,5 %	15,2 %	17,7 %	29,3 %	43,2 %	55,4 %	75,3 %	0 %



Key

1 intended to be mouthed

2 not intended to be mouthed

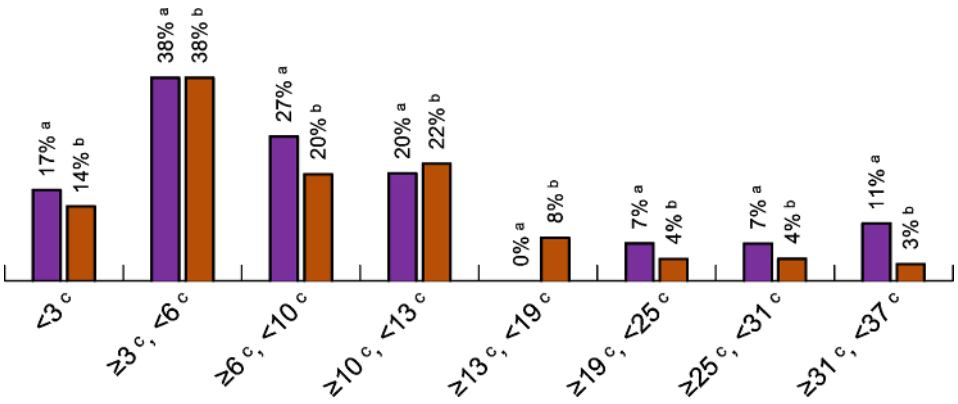
Figure 54 — Percentage of time children mouthed a toy (intended vs not intended to be mouthed) in the total time (511,8 h) (based on means of Table 33)

In the time children spent mouthing, significant differences were observed between toys intended to be mouthed (18,8 % of observed time, 14 % weighted by year and assuming a value of 8 % for the ≥ 13 months and < 19 months age bracket) and toys not intended to be mouthed (11,5 % of observed time, 11 % weighted by year). This difference is significant based on the results of a non-parametric test: Mann-Whitney and Kolmogorov-Smirnov (see C.2).

4.5.5 Time children spent mouthing toys intended vs not intended to be mouthed by age

Table 34 — Percentage of time children mouthed toys intended vs not intended to be mouthed in the total time (511,8 h) by age (mean values)

Age groups months	Intended to be mouthed	Not intended to be mouthed
< 3	17,0 %	14 %
≥ 3, < 6	37,5 %	37,6 %
≥ 6, < 10	27,0 %	19,8 %
≥ 10, < 13	19,9 %	21,8 %
≥ 13, < 19	NO DATA	8,0 %
≥ 19, < 25	6,6 %	4,3 %
≥ 25, < 31	7,0 %	4,4 %
≥ 31, < 37	11,0 %	2,5 %
Total Sample	**18,8 %**	**11,5 %**



Key

a intended to be mouthed

b not intended to be mouthed

c months

Figure 55 — Percentage of time children mouthed toys intended vs not intended to be mouthed in the total time (511,8 h) by age (based on means of Table 34)

Children from 0 months to 12 months spent an average of 25 % of the time mouthing toys intended to be mouthed vs 23 % for not intended to be mouthed. In earlier ages (under 12 months), not significant differences were found. Children spent a similar amount of time mouthing, whether the toy was intended to be mouthed or not.

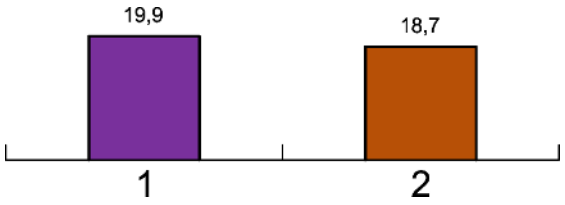
Children from 13 months to 36 months spent an average of 8 % of the time mouthing toys intended to be mouthed vs 5 % for not intended to be mouthed. And this difference is significant.

NOTE There is a lack of data for toys intended to be mouthed for the ≥ 13 months and < 19 months age bracket, due to difficulties in finding and providing toys intended to be mouthed by children of this age.

4.5.6 Toy-to-mouth contact duration for toys intended vs not intended to be mouthed

Table 35 — Toy-to-mouth contact duration for toys intended vs not intended to be mouthed

Type of toy	Mean s	SD s	Per. 75 s	Per. 85 s	Per. 95 s	Per. 99 s	Max. s	Min. s
Intended to be mouthed	19,9	19,2	26,9	39,8	58,7	77,9	106,5	1,4
Not intended to be mouthed	18,7	17,8	23,6	33,8	56,2	74,8	103,3	0,7



Key

1 intended to be mouthed

2 not intended to be mouthed

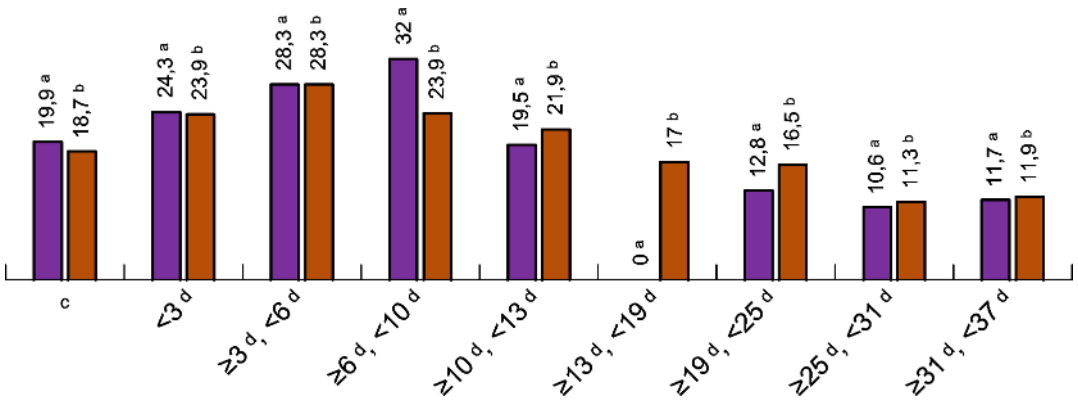
Figure 56 — Toy-to-mouth contact duration in seconds for toys intended vs not intended to be mouthed (based on means of Table 35)

Although toy-to-mouth contact duration is slightly higher for toys intended to be mouthed (19,9 s, weighted by year: 17 s) than toys not intended to be mouthed (18,7 s, weighted by year: 17 s), this difference is not significant.

4.5.7 Toy-to-mouth contact for toys intended vs not intended to be mouthed by age

Table 36 — Toy-to-mouth contact duration for toys intended vs not intended to be mouthed by age (mean values)

Age groups months	**Intended to be mouthed** s	**Not intended to be mouthed** s
< 3	24,3	23,9
≥ 3, < 6	28,3	28,3
≥ 6, < 10	32,0	23,9
≥ 10, < 13	19,5	21,9
≥ 13, < 19	NO DATA	17,0
≥ 19, < 25	12,8	16,5
≥ 25, < 31	10,6	11,3
≥ 31, < 37	11,7	11,9
Total Sample	**19,9**	**18,7**



Key

a intended to be mouthed

b not intended to be mouthed

c mean

d months

Figure 57 — Toy-to-mouth contact duration for toys intended vs not intended to be mouthed in seconds by age (based on means of Table 36)

Toys intended and not intended to be mouthed follow the same age pattern in toy-to-mouth contact duration.

NOTE There is a lack of data for toys intended to be mouthed for the ≥ 13 months and < 19 months age bracket, due to difficulties in finding and providing toys intended to be mouthed by children of this age.

4.6 Toy categories

4.6.1 General

As the toys were initially classified into these 13 categories when the sample selection was made, this section analyses the differences in children's mouthing behaviour in contact with toys by comparing toy categories. It is only a first approach, merely to offer some data related to toy categories.

This data has been analysed by: frequency and time children spent mouthing toys.

4.6.2 Frequency children mouthed toys by toy category

Table 37 — Frequency children mouthed toys per hour, by toy category

Toy category	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
1. Push-along toys, pull-along toys and walking aids	13,4	15,2	18,2	27,1	44,0	53,4	55,7	0
2. Dolls and soft filled toys	15,4	19,3	21,4	45,4	51,4	65,7	65,7	0
3. Role-playing toys (foodstuffs included)	24,2	27,4	38,6	56,8	84,3	97,3	100,0	0
4. Toys for babies, for looking at, grasping and/or squeezing	46,2	45,1	60,0	74,0	159,1	193,7	235,7	0
5. Books with play value and bath books	33,2	36,6	40,7	48,9	107,7	156,4	162,9	0
6. Audio/visual equipment	31,8	43,2	40,8	53,6	88,3	191,2	225,7	0
7. Construction toys and puzzles	18,9	25,3	26,4	40,7	69,3	97,9	105,7	0
8. Mechanically and/or electrically driven	9,1	15,3	10,0	12,0	23,2	63,3	74,3	0
9. Play scenes and constructed models	9,6	16,3	8,6	17,1	50,3	58,7	62,9	0
10. Sand-water and bath toys	45,3	38,4	67,5	81,3	120,8	152,4	178,6	2,5
11. Toy musical instruments	33,8	36,6	55,4	82,5	99,9	112,4	115,7	0
12. Toy sports equipment and balls	13,8	21,3	21,4	32,6	59,3	74,8	78,6	0
13. Toys intended to bear the mass of a child	6,8	15,5	5,7	6,7	45,7	58,2	60,0	0
Total sample	**30**	**36**	**41**	**55**	**91**	**171**	**236**	**0**

The number of times children mouthed toys per hour was significantly higher in category 4 (toys for babies, for looking at, grasping and/or squeezing) and category 10 (Sand-water and bath toys).

4.6.3 Time children spent mouthing toys by toy category

Table 38 — Percentage of time children mouthed a toy in the total time (511,8 h) by toy category

Toy category	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
1. Push-along toys, pull-along toys and walking aids	6,5 %	8,2 %	9,9 %	16,9 %	22,4 %	26,4 %	27,4 %	0 %
2. Dolls and soft filled toys	6,7 %	11,4 %	5,5 %	14,6 %	37,3 %	44,0 %	47,5 %	0 %
3. Role-playing toys (foodstuffs included)	6,9 %	9,0 %	10,5 %	14,9 %	22,5 %	42,2 %	51,2 %	0 %
4. Toys for babies, for looking at, grasping and/or squeezing	25,8 %	21,3 %	43,4 %	51,8 %	62,7 %	66,8 %	76,8 %	0 %
5. Books with play value and bath books	16,4 %	17,1 %	31,5 %	33,8 %	51,5 %	52,9 %	53,2 %	0 %
6. Audio/visual equipment	15,0 %	19,3 %	26,3 %	32,3 %	59,0 %	68,7 %	74,0 %	0 %
7. Construction toys and puzzles	11,0 %	17,4 %	16,7 %	21,4 %	48,4 %	70,1 %	76,0 %	0 %
8. Mechanically and/or electrically driven	6,1 %	10,2 %	4,5 %	16,7 %	24,5 %	35,5 %	38,5 %	0 %
9. Play scenes and constructed models	3,7 %	8,2 %	3,0 %	6,5 %	16,2 %	34,9 %	43,9 %	0 %
10. Sand-water and bath toys	24,4 %	18,8 %	36,4 %	43,8 %	56,2 %	70,7 %	74,5 %	0,4 %
11. Toy musical instruments	10,2 %	13,1 %	15,6 %	25,7 %	33,0 %	42,3 %	45,0 %	0 %
12. Toy sports equipment and balls	7,3 %	13,0 %	8,1 %	16,3 %	39,9 %	45,0 %	46,3 %	0 %
13. Toys intended to bear the mass of a child	2,4 %	6,5 %	1,2 %	1,9 %	11,0 %	26,0 %	30,3 %	0 %
Total sample	**14,7 %**	**17,2 %**	**21,0 %**	**36,2 %**	**50,6 %**	**60,3 %**	**76,8 %**	**0 %**

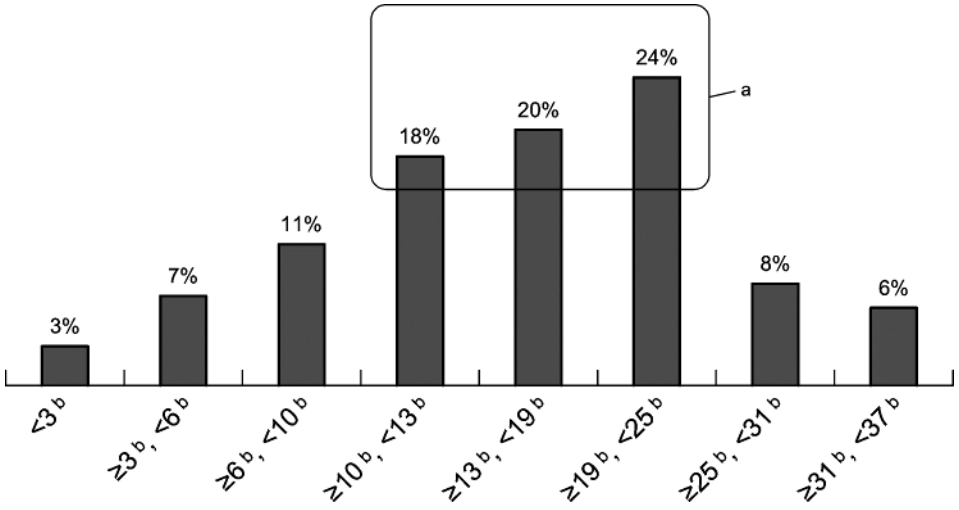
The percentage of time children spent mouthing toys was significantly higher in category 4 (toys for babies, for looking at, grasping and/or squeezing: 25,8 %) and category 10 (sand-water and bath toys: 24,4 %). This result demonstrates similar behaviour to that observed in the frequency vs. category section.

4.7 Bite marks left on toys

Table 39 — Bite marks left on toys by age

Age groups months	**Bite marks**	**No bite marks**
< 3	3 %	97 %
≥ 3, < 6	7 %	93 %
≥ 6, < 10	11 %	89 %
≥ 10, < 13	18 %	82 %
≥ 13, < 19	20 %	80 %
≥ 19, < 25	24 %	76 %
≥ 25, < 31	8 %	92 %
≥ 31, < 37	6 %	94 %
Total Sample	**10 %**	**90 %**

Children left bite marks on only 10 % of the toys mouthed.



Key

a age range with highest percentage of bite marks left on toys

b months

Figure 58 — Bite marks left on toys

There is a correlation between age and the percentage of bite marks left on toys, up to 24 months (when teething often stops). This is followed by a decrease towards lower levels.

The toys children left most bite marks on were these elastomeric ones, with EVA material (see Figure 59).

Figure 59 — Toys with EVA material

4.8 Degree of salivation

4.8.1 General

Following each observation of mouthing behaviour, subjects were asked to give their opinion on the degree of salivation of their child. For this purpose, the following levels were established.

— No salivation observed

— Salivation observed

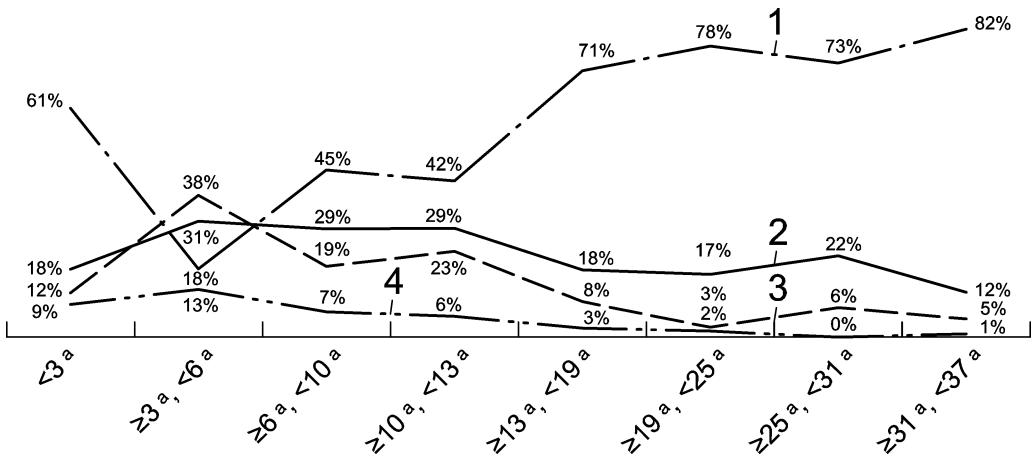
  — Low: Slight amount of saliva observed on the toy, but not on the child's lips.

  — Medium: Saliva present and observed directly on the child's lips.

  — High: Saliva present on the lips and dribbling.

Table 40 — Degree of salivation

Age groups months	**No salivation**	**Low**	**Medium**	**High**
< 3	61 %	18 %	12 %	9 %
≥ 3, < 6	18 %	31 %	38 %	13 %
≥ 6, < 10	45 %	29 %	19 %	7 %
≥ 10, < 13	42 %	29 %	23 %	6 %
≥ 13, < 19	71 %	18 %	8 %	3 %
≥ 19, < 25	78 %	17 %	3 %	2 %
≥ 25, < 31	73 %	22 %	6 %	0 %
≥ 31, < 37	82 %	12 %	5 %	1 %
Total Sample	**60 %**	**22 %**	**13 %**	**4 %**



Key

1 no salivation
2 low salivation
3 medium salivation
4 high salivation
a months

Figure 60 — Degree of salivation in toy mouthing behaviour

60 % of mouthing behaviour occurred without salivation, as perceived by parents, 22 % low salivation, 13 % medium salivation, and only 4 % high salivation. Children under 12 months exhibited higher levels of salivation than those aged 13 months and older. ≥ 3 months and < 6 months was the only age group where medium levels of salivation were higher than low levels.

4.8.2 Toys that contributed to high degrees of salivation

Toys with higher levels of salivation were usually toys made in elastomeric materials (see Figure 61).

Figure 61 — Toys with higher levels of salivation

5 Estimations

5.1 General

This clause presents the final estimation of children's mouthing behaviour in terms of frequency (number of times children mouth toys) and the time they spend mouthing toys.

Two different scenarios were considered to make the estimation:

— SCENARIO 1: Multiplying the two variables analysed by the total amount of hours that children are not sleeping and not eating.

— SCENARIO 2: Multiplying the two variables analysed by the total amount of hours that children are in contact with toys.

As was explained in the methodology section, an ethnographic study was carried out to obtain this data. The results of this study are presented in 5.2. The estimation formula used in this study is presented in 5.3. The estimation of mouthing frequency is presented in 5.4. Finally, an estimation of the time children spend mouthing is presented in 5.5.

5.2 Results of ethnographic study

5.2.1 Time children are awake and not eating

The following tables include data about times (hours per day) children are awake (not sleeping) and not eating for working and non-working days.

Table 41 — Time children are awake and not eating (non-working days)

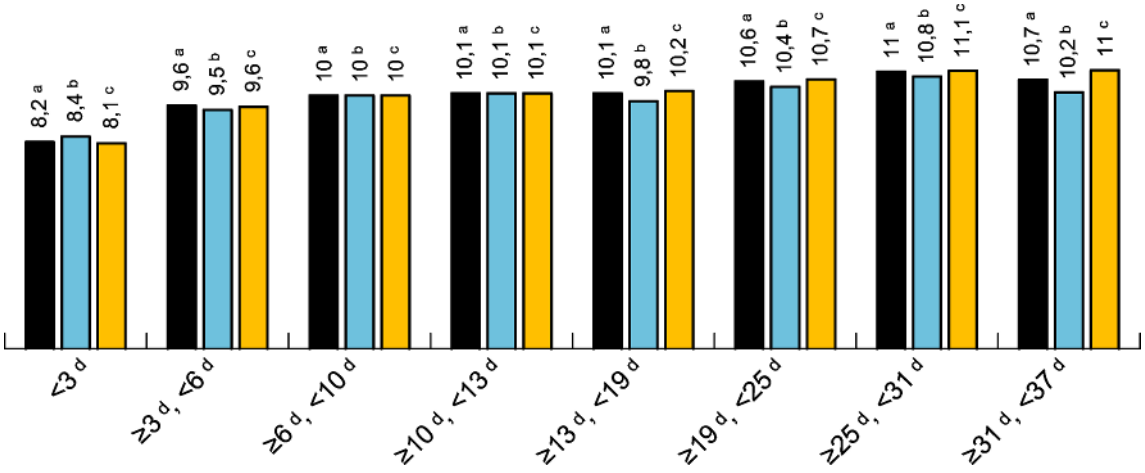
Age groups months	**Mean** hours	**Per. 75** hours	**Per. 85** hours	**Per. 95** hours	**Per. 99** hours	**Max.** hours	**Min.** hours
< 3	8,4	9,5	11,5	15,5	17,5	17,5	4,5
≥ 3, < 6	9,5	10,8	11,8	15,8	16,8	16,8	4,8
≥ 6, < 10	10	11,5	12,5	13,5	15,9	16,5	6,5
≥ 10, < 13	10,1	11,6	11,6	12,6	13,9	14,6	7,6
≥ 13, < 19	9,8	10,8	12,8	12,8	13,2	13,8	6,8
≥ 19, < 25	10,4	10,5	12,5	14,5	15,2	15,5	7,5
≥ 25, < 31	10,8	12,4	12,4	13,4	16,3	17,4	7,4
≥ 31, < 37	10,2	10,5	11,5	12,5	15,6	16,5	4,5
Total sample	**9,9**	**11,0**	**12,1**	**13,8**	**15,6**	**17,5**	**4,5**

Table 42 — Time children are awake and not eating (working days)

Age groups months	**Mean** hours	**Per. 75** hours	**Per. 85** hours	**Per. 95** hours	**Per. 99** hours	**Max.** hours	**Min.** hours
< 3	8,1	8,5	10,5	13,5	16,5	16,5	4,5
≥ 3, < 6	9,6	11	13	16	17	17	5
≥ 6, < 10	10	10,5	12,5	15,5	16,2	16,5	7,5
≥ 10, < 13	10,1	11,7	11,7	12,7	13,2	13,7	7,7
≥ 13, < 19	10,2	11,7	12,7	13,7	13,7	13,7	6,7
≥ 19, < 25	10,7	10,7	11,7	14,7	16,1	16,7	7,7
≥ 25, < 31	11,1	12,4	12,4	14,4	16,6	17,4	7,4
≥ 31, < 37	11	11,6	12,6	13,6	15,6	16,6	4,6
Total sample	**10,1**	**11,0**	**12,1**	**14,3**	**15,6**	**17,4**	**4,5**

Table 43 — Time children are awake and not eating (non-working days vs working days)

Age groups months	**Total mean** hours	**Non-working days** hours	**Working days** hours
< 3	8,2	8,4	8,1
≥ 3, < 6	9,6	9,5	9,6
≥ 6, < 10	10,0	10,0	10,0
≥ 10, < 13	10,1	10,1	10,1
≥ 13, < 19	10,1	9,8	10,2
≥ 19, < 25	10,6	10,4	10,7
≥ 25, < 31	11,0	10,8	11,1
≥ 31, < 37	10,7	10,2	11,0
Total sample	**10,0**	**9,9**	**10,1**



Key

a global
b non-working day
c working day
d months

Figure 62 — Time children are awake and not eating in hours (based on means in Table 43)

Children under 3 years are awake and not eating for an average of 10 h per day. By age, this time changes from 8,2 h at 2 months up to 10,7 h at 36 months. No significant differences were found between working and non-working days.

5.2.2 Time children are in contact with toys

Table 44 — Time children are in contact with toys (non-working days)

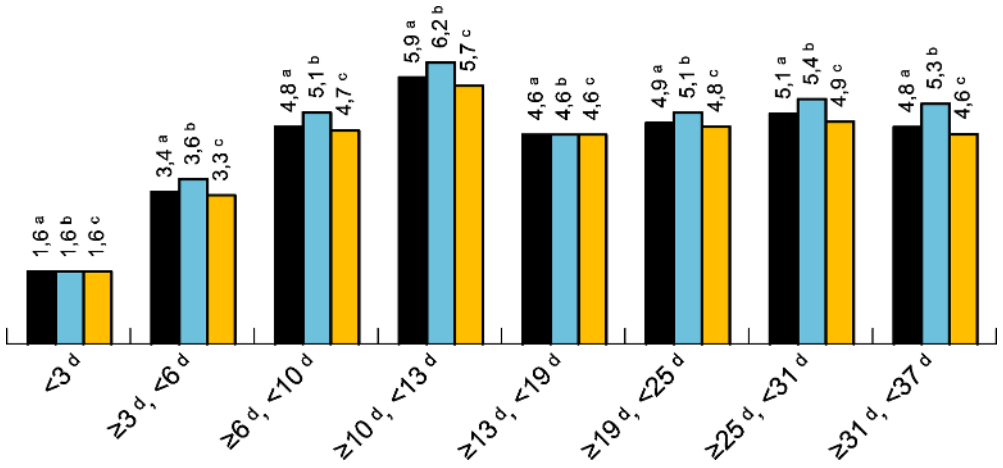
Age groups months	**Mean** hours	**Per. 75** hours	**Per. 85** hours	**Per. 95** hours	**Per. 99** hours	**Max.** hours	**Min.** hours
< 3	1,6	2	3	4	5	5	1
≥ 3, < 6	3,3	4	5	8	9	9	1
≥ 6, < 10	4,7	6	7	9	10	10	2
≥ 10, < 13	5,7	8	9	11	11	11	1
≥ 13, < 19	4,6	6	7	9	9	9	2
≥ 19, < 25	4,8	6	8	9	10	11	2
≥ 25, < 31	4,9	6	7	8	10	11	2
≥ 31, < 37	4,6	6	7	8	9	10	2
Total sample	**4,3**	**6**	**7**	**9**	**11**	**11**	**1**

Table 45 — Time children are in contact with toys (working days)

Age groups months	**Mean** hours	**Per. 75** hours	**Per. 85** hours	**Per. 95** hours	**Per. 99** hours	**Max.** hours	**Min.** hours
< 3	1,6	2	3	4	5	5	1
≥ 3, < 6	3,6	4	5	9	10	10	1
≥ 6, < 10	5,1	7	8	9	10	10	1
≥ 10, < 13	6,2	8	9	11	11	11	1
≥ 13, < 19	4,6	6	7	9	9	9	2
≥ 19, < 25	5,1	7	8	10	11	11	1
≥ 25, < 31	5,4	7	8	10	11	11	2
≥ 31, < 37	5,3	6	7	10	10	10	2
Total sample	**4,6**	**6**	**8**	**10**	**11**	**11**	**1**

Table 46 — Time children are in contact with toys (non-working days vs working days)

Age groups months	**Total mean** hours	**Non-working days** hours	**Working days** hours
< 3	1,6	1,6	1,6
≥ 3, < 6	3,4	3,6	3,3
≥ 6, < 10	4,8	5,1	4,7
≥ 10, < 13	5,9	6,2	5,7
≥ 13, < 19	4,6	4,6	4,6
≥ 19, < 25	4,9	5,1	4,8
≥ 25, < 31	5,1	5,4	4,9
≥ 31, < 37	4,8	5,3	4,6
Total sample	**4,4**	**4,6**	**4,3**



Key

a global
b non-working day
c working day
d months

Figure 63 — Time children are in contact with toys in hours (based on means in Table 46)

The average amount of minutes that children under 3 years are able to mouth toys because they are in contact with them, is 264 min (4,4 h) per day.

By age, a pattern emerges: the time in contact with toys increases in the first year (1,6 h at < 3 months up to 5,9 h at ≥ 10 months and < 13 months). From 13 months to 36 months it remains at a similar level (4 h to 5 h per day). Contact with toys is slightly higher on non-working days.

5.3 Estimation formula

This is the estimation formula to obtain the frequency and amount of time children spend mouthing toys. From this, two different scenarios were defined on the time available to mouth per day.

$$t_{total} = \frac{t_{omt}}{t_{tto}} \cdot t_{tamd}$$

where

t_{total} is the total amount of time children mouth toys per day, in minutes;

t_{omt} is the amount of mouthing time recorded for each child (observed mouthing time);

t_{tto} is the total amount of time that the children were observed (total time observed = 511,8 h);

t_{tand} is the time available to mouth per day (scenario 1: time available for mouthing per day (awake and not eating); scenario 2: time per day in contact with toys).

5.4 Estimation of frequency children mouth toys

5.4.1 General

Frequency is the number of times children mouth a toy. In Scenario 1, it is estimated that children mouth objects in general 301,1 times per day. In Scenario 2 it is estimated that children mouth toys 131,9 times per day.

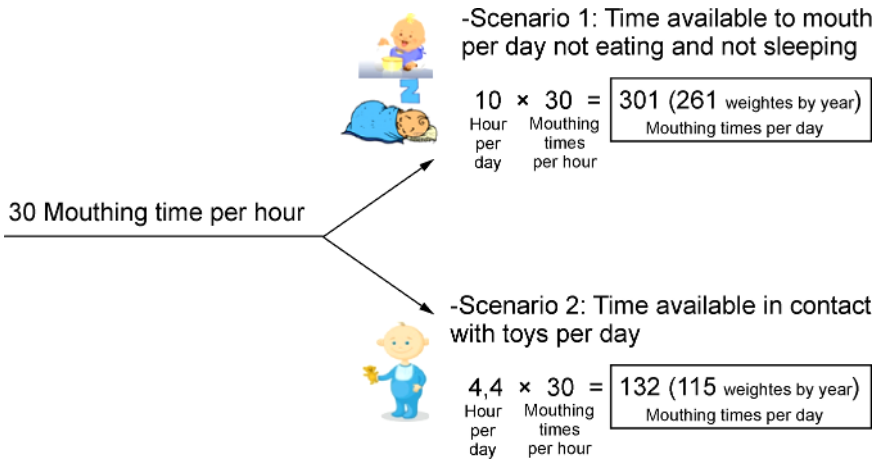


Figure 64 — Mean frequency children mouth toys for each scenario

5.4.2 Estimation of frequency children mouth toys by age

Table 47 — Frequency children mouth objects (scenario 1), total time 511,8 h

Age groups months	**Mean**	**Per. 95**	**Per. 99**	**Max.**
< 3	180	820	1 093	1 110
≥ 3, < 6	670	2 630	3 557	3 861
≥ 6, < 10	440	1 828	3 076	3 317
≥ 10, < 13	417	1 178	2 013	2 420
≥ 13, < 19	195	832	1 110	1 195
≥ 19, < 25	106	703	1 060	1 093
≥ 25, < 31	249	845	1 188	1 305
≥ 31, < 37	150	490	827	978
Total sample	**301**	**1 285**	**2 668**	**3 861**

Final estimation for scenario 1, based on mean values:

- **Total sample:** 301 objects-to-mouth per day.
- **Children under 3 years (weighted by year):** 259 objects-to-mouth per day.
- **Children aged 0 months to 12 months:** 427 objects-to-mouth per day.
- **Children aged 13 months to 36 months:** 175 objects-to-mouth per day

Final estimation for scenario 1, based on 95th percentile values:

- **Total sample:** 1 285 objects-to-mouth per day.
- **Children aged 0 months to 12 months:** 1 982 objects-to-mouth per day.
- **Children aged 13 months to 36 months:** 811 objects-to-mouth per day

Table 48 — Frequency children mouth toys (scenario 2), total time 511,8 h

Age groups months	**Mean**	**Per. 95**	**Per. 99**	**Max.**
< 3	35	218	312	330
≥ 3, < 6	238	1 322	1 896	2 125
≥ 6, < 10	212	1 116	1 910	2 010
≥ 10, < 13	240	977	1 650	1 903
≥ 13, < 19	89	530	738	783
≥ 19, < 25	49	428	710	737
≥ 25, < 31	115	520	749	825
≥ 31, < 37	68	307	508	590
Total sample	**132**	**748**	**1 881**	**2 125**

Final estimation for scenario 2, based on mean values:

- **Total sample:** 132 toys-to-mouth per day.
- **Children under 3 years (weighted by year):** 115 toys-to-mouth per day.
- **Children aged 0 months to 12 months:** 181 toys-to-mouth per day.
- **Children aged 13 months to 36 months:** 80 toys-to-mouth per day.

Final estimation for scenario 2, based on 95th percentile values:

- **Total sample:**. 748 toys-to-mouth per day
- **Children aged 0 months to 12 months:** 1 271 toys-to-mouth per day.
- **Children aged 13 months to 36 months:** 507 toys-to-mouth per day.

5.5 Estimation of time children spend mouthing toys

5.5.1 General

Time refers to the percentage of time children mouthed a toy in the total time observed with toys. In scenario 1, it was estimated that children mouth objects in general for 71 min per day (weighted by year). In scenario 2, it was estimated that children mouth toys for 30 min per day (weighted by year).

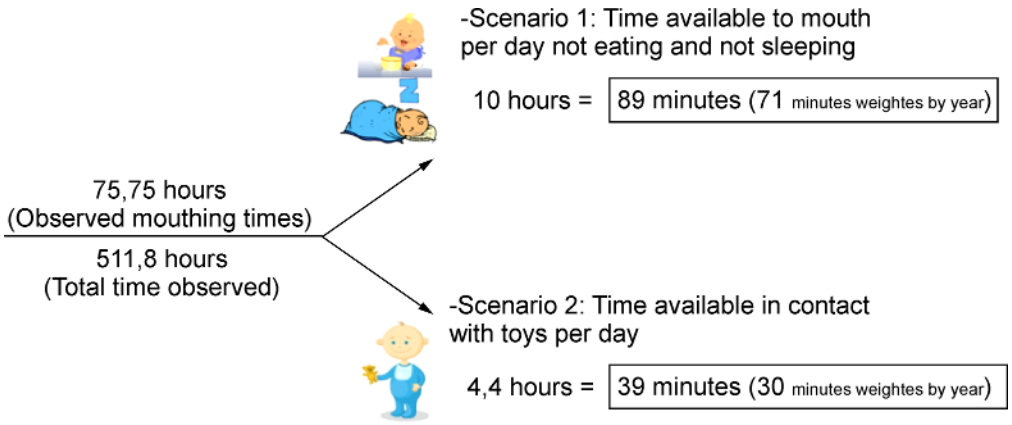


Figure 65 — Mean time children spend mouthing toys for each scenario

5.5.2 Estimation of time children spend mouthing toys by age

Table 49 — Time children spend mouthing objects (scenario 1), total time 511,8 h

Age groups months	**Mean** min	**Per. 95** min	**Per. 99** min	**Max.** min
< 3	73,3	368,9	553,0	598,4
≥ 3, < 6	212,0	576,6	661,5	680,8
≥ 6, < 10	125,4	427,2	518,9	553,4
≥ 10, < 13	126,7	395,2	564,6	627,7
≥ 13, < 19	48,1	155,3	354,2	436,7
≥ 19, < 25	24,8	147,5	283,7	329,0
≥ 25, < 31	42,9	140,3	368,4	477,1
≥ 31, < 37	33,5	128,8	281,4	357,9
Total sample	**88,5**	**428,8**	**564,1**	**680,8**

Final estimation for scenario 1, based on mean values:

- **Total sample:** 89 min per day mouthing objects in general.
- **Children under 3 years (weighted by year):** 71 min per day mouthing objects in general
- **Children aged 0 months to 12 months:** 134 min per day mouthing objects in general.
- **Children aged 13 months to 36 months:** 37 min per day mouthing objects in general

Final estimation for scenario 1, based on 95th percentile values:

- **Total sample:** 429 min per day mouthing objects in general.
- **Children aged 0 months to 12 months:** 503 min per day mouthing objects in general.
- **Children aged 13 months to 36 months:** 149 min per day mouthing objects in general

Table 50 — Time children spend mouthing toys (scenario 2), total time 511,8 h

Age groups months	**Mean** min	**Per. 95** min	**Per. 99** min	**Max.** min
< 3	14,3	98,1	157,7	177,9
≥ 3, < 6	75,2	289,8	352,6	374,6
≥ 6, < 10	60,5	260,8	322,6	335,4
≥ 10, < 13	73,5	327,6	462,7	493,7
≥ 13, < 19	22,0	99,0	235,4	286,2
≥ 19, < 25	11,5	89,9	190,0	221,8
≥ 25, < 31	19,7	86,3	232,3	301,6
≥ 31, < 37	15,0	80,6	173,2	216,0
Total sample	38,8	249,6	398,0	493,7

Final estimation for scenario 2, based on mean values:

- **Total sample:** 39 min per day mouthing toys.
- **Children under 3 years (weighted by year):** 30 min per day mouthing toys.
- **Children aged 0 months to 12 months:** 56 min per day mouthing toys.
- **Children aged 13 months to 36 months:** 17 min per day mouthing toys.

Final estimation for scenario 2, based on 95th percentile values:

- **Total sample:** 250 min per day mouthing toys.
- **Children aged 0 months to 12 months:** 322 min per day mouthing toys.
- **Children aged 13 months to 36 months:** 93 min per day mouthing toys.

6 Discussion

6.1 Frequency children mouthed toys

In the present study, the average number of times children under 36 months mouthed toys was 26 times/hour (weighted by year). The maximum frequency was 228 times/hour. This maximum value was in children aged ≥ 3 months and < 6 months.

Due to the high amount of variability in previous studies concerning the frequency of mouthing behaviour, the sample age or even the objects that are mouthed, the results cannot be compared (see Annex A).

If only the comparable data from previous research is taken into account (that related to frequency of toy-contacts by age in children under 36 months), a mean of 45 times/hour for children aged 11 months to 24 months was recorded by Tulve et al. (2002) [6]; while in the present study the mean for children aged 10 months to 24 months was 23,3 times/hour. No other comparable frequency data was found in any other previous studies because they observed other objects (dummies or hands), and there was no detailed information about mouthing frequency with toys (see Annex A).

Not significant differences were observed in the present study when analysing frequency according to country, gender, or period of observations time. These results are in line with the conclusions of previous literature, except for data about country, due to the absence of previous cross-cultural studies.

Similarities were found with previous studies in that there was an age pattern. The clear trend that mouthing duration decreases as age increases (after 1 year old) is consistent with patterns of child development, which show a peak period for mouthing activity that is positively correlated with teething and negatively correlated with increased mobility (Juberg el al. 2001 [1], Groot et al. 1998 [2], Xue et al. 2007 [11], Norris and Smith, 2002 [8]). The mouthing behaviour of children under 12 months is completely different from that of children of 13 months to 36 months. In the present study, the average number of times children under 1 year mouthed toys (44 times) is significantly different compared with data on children of 13 months to 36 months (17 times). For this reason, safety specifications related to mouthing behaviour should be aware of differences in these two age groups.

6.2 Time children spent mouthing toys

The present results showed that children mouthed toys for 11,7 % (weighted by year) of the total time observed (511,8 h), which gives a mean of 30 min per day, weighted by year. As has also been shown for the frequency children mouthed toys, the time children spent mouthing toys decreased significantly after 1 year of age. It was estimated that children mouth toys an average of 30 min per day (children aged 0 months to 12 months: 56 min per day mouthing toys, and children aged 13 months to 36 months: 17 min per day mouthing toys). Based on 95th percentile values, this value increases to 250 min per day (children aged 0 months to 12 months: 322 min, and children aged 13 months to 36 months: 93 min per day mouthing toys).

No significant differences were observed in the present study when analysing time spent mouthing toys according to gender or period of observation time. These results are consistent with the conclusions of previous literature. Similarities were found with previous studies, like Norris and Smith (2002) [8], in that there was an age pattern: time spent mouthing toys decreases as age increases, after 1 year of age.

Compared with other studies, the results are quite similar to Juberg et al. (2001) [1], bearing in mind that they consider toys in addition to other objects. A mean of 30 min mouthing toys per day was found for children under 3 years in the present study vs. 36 min per day in children under 3 years recorded by Juberg [1] (which includes teethers, toys and other objects, and excludes dummies).

The general results of the present study (mean and maximum) showed higher data than the results from Norris and Smith [8]. The maximum time children mouth toys per day in the present study (based on maximum results from scenario 2) was 493,7 min per day (8:13:00); whereas in Norris and Smith [8], the maximum value for the time children mouth toys was 226 min per day (3:46:46). A collection and structuring of Norris and Smith's [8] results are shown in Table 51.

Table 51 — Comparison of results of Norris and Smith 2002 [8] and this study on time children spent mouthing toys

Age groups months	**Mean (this study)** min	**Mean (Norris and Smith 2002 [8])** min	**Max. (this study)** min	**Max. (Norris and Smith 2002 [8])** min
< 3	14,3	0,2	177,9	1
≥ 3, < 6	75,2	28	374,6	150
≥ 6, < 10	60,5	39	335,4	226
≥ 10, < 13	73,5	23	493,7	65
≥ 13, < 19	22,0	15,5	286,2	58
≥ 19, < 25	11,5	13	221,8	102
≥ 25, < 31	19,7	12	301,6	126
≥ 31, < 37	15,0	12	216,0	126
Total sample weighted by year	**30,0**	**16,2**	**493,7**	**226**

On the other hand, both studies revealed the clear trend that mouthing duration decreases as age increases (after 1 year of age), when mean values are observed. These results are consistent with other previous literature.

Inconsistencies were found in some age brackets when maximum values were considered. Maximum values seem not to be age dependent, but due to the high variability of data when the exceptional mouthing activity of one particular case is included. If only the mean and 95thpercentile are taken into account, the age dependence is clearly visible (See Table 15).

Regarding the duration of toy-to-mouth contact, the average of number of seconds in each mouthing action—from the toy coming into contact with the child's mouth until the end of this contact—was 17,3 s, weighted by year in the present study. Again the age group of children under 12 months (24,9 s) is significantly different from those of 13 months to 24 months (15,6 s) and 25 months to 36 months (11,6 s). Maximum duration of toy-to-mouth contact was 106,5 s. There are no data available from other previous studies to compare.

6.3 Time available to mouth toys per day

Based on the results of the present study, children under 36 months are awake and not eating for an average of 600 min (10 h) per day. Norris and Smith (2002) [8] defined “time available to mouth per day” as the time available over the whole day for the child to mouth, i.e. the time during the day when they were awake but not eating. They obtained similar results to the present study in this variable, if their data about the mean in children under 36 months (9,73 h per day) is taken into consideration.

It should be noted that these authors were talking about children's mouthing behaviour in general. However, this project is focused on toys so it is necessary to consider the time children are able to be in contact with toys per day. The present study results showed that the amount of minutes that children under 36 months are available to mouth toys, because they are in contact with them, is 264 min (4,4 h) per day.

Through the ethnographic study, two scenarios were determined:

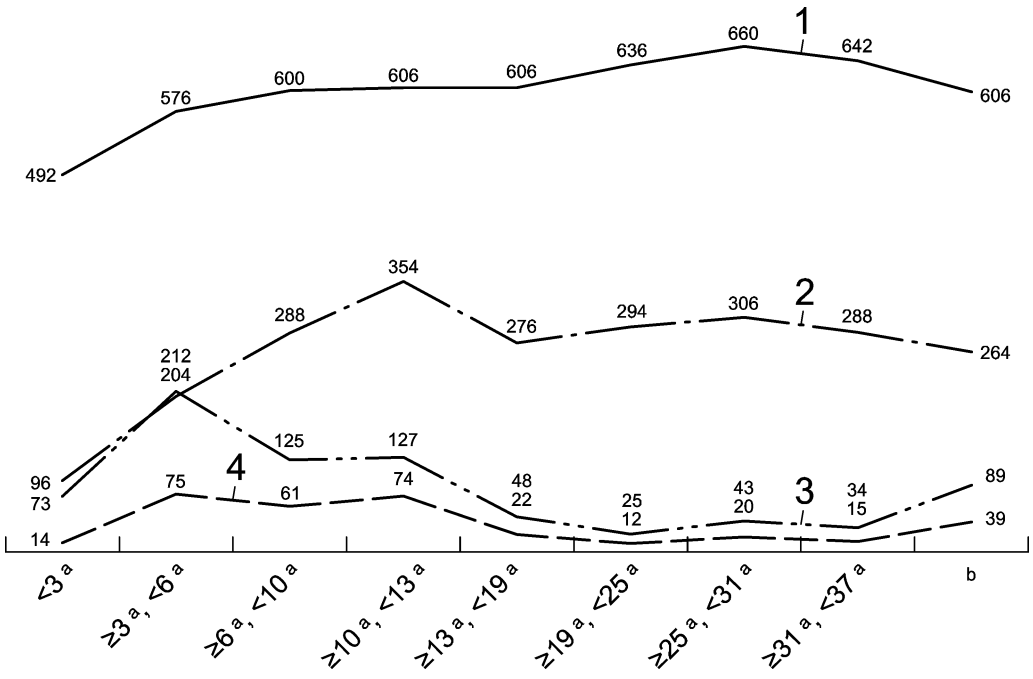
- SCENARIO 1: The amount of time that children are awake and not eating.

- SCENARIO 2:The amount of time that children are in contact with toys.

To obtain a general description of children's mouthing behaviour in relation to toys, it was considered that scenario 2 related more to the amount of time that children could mouth toys; whereas scenario 1 relates more to the amount of time that children could mouth objects in general (hands, dummies, toys, and other miscellaneous objects).

In the present study, parental observations were made by taking into account a single condition: that the children were in contact with a toy during the observation period (when the contact with a toy stopped, the observation also stopped). When children are awake and not eating, they are not always in contact with toys, rather they are in contact with other home objects, their hands or their dummies, more than with toys. For these reasons, scenario 2 is related to mouthing toys and scenario 1 is more related to mouthing objects in general. It is important to consider that, by using scenario 1 of the present study, the data on mouthing toys are extrapolated from data on general objects.

The following graph presents an estimation of the number of minutes of mouthing behaviour with toys per day under both scenarios.



Key

1	minutes not sleeping and not eating	a	months
2	time in contact with toys	b	global
3	mouthing general objects scenario 1		
4	mouthing toys scenario 2		

Figure 66 — Estimation of number of minutes of mouthing behaviour with toys per day

The final results (means, percentiles and maximum data) are shown in relation to the two different scenarios in this report, so experts who use the data will be able to choose the data most applicable to them.

6.4 Type of mouthing

Based on the results of the present study, lip-touching was the most frequent type of mouthing behaviour observed in children's contact with toys (average of 21 times/hour weighted by year), followed by sucking (16 times/hour) and biting (17 times/hour). Regarding the amount of time children spent mouthing; lip-touching and sucking were the most common types of mouthing observed: lip-touching 9,3 %, sucking 8,1 % and biting 7,6 % of total mouthing time (average weighted by year). Lip-touching frequency for children under 36 months is higher than sucking, but the number of minutes of both types of mouthing behaviour are quite similar. However, the distinction between different types of mouthing behaviour is sometimes not obvious. As in the results from Norris and Smith [8], the most common form was a combination of different types of mouthing (lip+suck, or suck+bite, or even lip+suck+bite).

6.5 Elastomeric toys

All results obtained with elastomeric toys showed significantly higher mouthing behaviour than with not elastomeric toys. Toys with elastomeric materials had a higher frequency (mean 26 times/hour weighted by year vs. 22 times/hour weighted by year).

If the maximum values are considered, the present study showed that the maximum frequency of mouthing was with an elastomeric toy (228 times/hour), whereas with not elastomeric toys, the maximum frequency was 163 times/hour.

The time spent mouthing with elastomeric toys resulted in a mean of 12,4 % of total time, weighted by year, and a maximum of 74,8 % of total mouthing time (vs. a mean of 9,7 % and a maximum of 53,2 % with not elastomeric toys). The results of the present study showed significant differences in the time children mouth elastomeric toys in comparison with not elastomeric toys.

Additionally, a slightly higher duration in individual events of toy-to-mouth contact was observed with elastomeric toys (mean 19 s, weighted by year, and a maximum of 120 s) vs. not elastomeric toys (mean 17 s and a maximum of 114 s). This difference is significant. Toy-to-mouth contact duration for children aged 0 months to 12 months revealed a mean of 25 s for elastomeric toys and 24 s for not elastomeric toys. And this difference is not significant.

The toys children left most bite marks on were the elastomeric toys, and those that produced the highest levels of salivation were also usually in elastomeric materials.

6.6 Toys intended and not intended to be mouthed

Significant differences in the time children spent mouthing toys were observed between toys intended to be mouthed (14 % of observed time, weighted by year) and toys not intended to be mouthed (11 % of observed time, weighted by year).

In addition, significant differences were observed in the frequency children mouthed toys between those intended to be mouthed (mean weighted by year of 33 times/hour, a maximum of 228 times/hour) and the toys not intended to be mouthed (mean weighted by year of 22 times/hour, a maximum of 172 times/hour).

However, no significant differences were found in the variable of duration of toy-to-mouth contact.

The greatest differences were found in older children (13 months to 36 months). In earlier ages (under 12 months), children put any toy into their mouth, whether it was intended to be mouthed or not.

6.7 Mouthing toys by categories

The frequency and the percentage of time children spent mouthing toys were significantly higher in category 4 (toys for babies, for looking at, grasping and/or squeezing) and in category 10 (sand-water and bath toys). For this reason, safety specifications related to mouthing behaviour should be aware of

the relevance of these two categories in toys aimed at children under 3 years, and pay special attention to those toys directed at children under 12 months.

6.8 Bite marks left on toys

In the present study, 10 % of children left bite marks on toys. More children's bite marks were observed in EVA toys. Children aged 13 months to 24 months left the most bite marks on toys. This pattern is completely different from the other variables analysed in this study, which showed differences in children under 1 year of age and over 2 years of age. However, it is consistent with teething development.

Norris and Smith (2002) [8] found that 29 % of children left bite marks on toys. This result differs with the outcome of the present study, but it shall be taken into consideration that the age sample and toy sample were not the same.

6.9 Degree of salivation

High levels of salivation were not detected in toy mouthing behaviour: 60 % of mouthing behaviour (as perceived by parents in the present study) occurred without salivation, 22 % with low, 13 % with medium and only 4 % with high salivation. In children under 12 months of age, higher levels of salivation were observed than in children aged over 13 months. The children aged ≥ 3 months and < 6 months was the only age group where medium levels of salivation were higher than low levels (38 % medium salivation and 13 % high salivation).

This is consistent with paediatric knowledge. Babies begin to drool at around three to four months of age. Drooling occurs at this age (≥3 months and < 6 months) because more saliva is made in the mouth and the baby does not swallow it all. Drooling (or “high salivation” in the study) is a normal behaviour that may occur in healthy children under two years of age (Leung, 1999 [24]). However, there is no literature with data to compare on the presence of drool in mouthing behaviour with toys. As drooling is commonly observed in neurologically impaired children of all ages, most studies on drooling focus on considering the presence of saliva in areas external to the oral cavity as a barrier to social integration (Mc Clure et al. 1986 [25]), and not as part of normal mouthing behaviour.

7 Summary

7.1 Introduction

This report presents the study “Children's mouthing behaviour in contact with toys” which was managed by CEN/TC 52/WG 5 “Safety of toys – Chemical properties” and funded by the European Commission. The objective of the study was the measurement and quantification of the times and frequency that children aged 0 months to 36 months, introduce toys into their mouths spontaneously. The results of this study also served as input for the revision of EN 71-12:2013.

Up to now, the study is the one with the largest sample (245 children and a total number of 1 680 observations) and the only one which was carried out in three different European countries (Germany, France and Spain). It is also the study with the highest representation of specific toys (60 different products) for children aged 0 months to 36 months.

7.2 Literature review

Mouthing is an important component in childhood development. In early development, sucking provides essential nutrients in the form of breast or bottle-feeding, as well as a feeling of well-being and a sense of security (Juberg et al., 2001 [1]). As children develop, mouthing behaviour, in combination with looking and touching, allows children to explore and investigate their environment (Ruff, 1984 [3]; Ruff and Dubiner, 1987 [4]; Davis et al., 1995 [5]; Groot et al., 1998 [2]: Tulve et al., 2002 [6]). Teething is another reason that children will mouth fingers and objects. Mouthing alleviates the pain and discomfort associated with teething (Groot et al., 1998 [2]).

There is an increasing focus on children in exposure and risk assessments, as they are more sensitive to environmental contaminants than adults (Silvers et al., 1994 [10]). Some products, such as dummies, teething rings and bottle teats, are intended to be placed into the mouth. Unfortunately, products not intended for mouthing invariably end up in children's mouths. Obviously, child safety is of paramount concern, and so products shall be as safe as possible, whether they are handled or placed in the mouth (Smith and Norris, 2003 [9]).

Children's mouthing behaviour is difficult to measure for several reasons. Some of these reasons include the following: children's contact with surfaces and objects are frequent and intermittent; observational studies are labour-intensive for data collection and data analysis can be subjective. Interpretation of the results is also difficult. Some researchers express mouthing behaviour in terms of frequency of occurrence, others express mouthing behaviour as an exposure period (Xue et al., 2007 [11]).

The high amount of variability in previous studies concerning the methodology, the sample number, the sample age, the objects or even the mouthing concept, makes it difficult to compare the results of the present study with those of previous literature.

7.3 Design of the research

The methodology used in this study was parental observation in a natural environment (the children's own home) combined with video recording sessions. The study featured a sample of 245 children, with a total number of 1 680 observations, and was carried out in three different European countries (Germany, France and Spain). In total 511,8 h of adult observation of children's activities with toys were collected, together with a total of 16 h of video recording sessions, in order to carry out qualitative and quantitative analysis of children's mouthing behaviour.

The final selection of the toy sample consisted of 54 different products. All the toys were observed in the 3 countries in an equal fashion. Of the 54 toys in the sample, 50 % were toys made with elastomeric materials and 50 % without elastomeric materials. Furthermore, 33 % of the toys were “intended to be mouthed”; whereas 67 % were toys “not intended to be mouthed.”

7.4 Results

7.4.1 Frequency children mouthed toys

The average number of times children mouthed toys was 30 times/hour for the total sample (26 times/hour, weighted by year). The average number of times children aged under 12 months mouthed toys (44 times) was significantly different compared to children from 13 months to 36 months of age (17 times). The maximum frequency recorded was 228 times/hour.

The average number of times children mouthed an elastomeric toy was 26 times/hour (weighted by year). For not elastomeric toys, it was 22 times/hour (weighted by year).

Significant differences were observed in the frequency between those intended to be mouthed (33 times/hour, weighted by year), and toys not intended to be mouthed (22 times/hour, weighted by year).

7.4.2 Time spent mouthing toys

Children mouthed toys for 14,7 % (75,2 h) weighted by year: 11,7 % (59,9 h) of the total time observed (511,8 h). The behaviour of children under 12 months (23,4 %) in this variable is significantly different compared with that of children from 13 months to 36 months (5,9 %).The maximum time children spent mouthing was 74,8 % of the total time observed.

In the time spent mouthing toys, significant differences were observed between elastomeric (12,4 % of time observed, weighted by year), and not elastomeric materials (9,7 % of time observed, weighted by year).

In the time children spent mouthing, significant differences were observed between toys intended to be mouthed (14 % of observed time, weighted by year), and toys not intended to be mouthed (11 % of observed time, weighted by year).

The duration of toy-to-mouth contact was 17,3 s (weighted by year) in the present study. Again the age group of children under 12 months (24,9 s) is significantly different from those of 13 months to 24 months (15,6 s) and 25 months to 36 months (11,6 s). The maximum duration of toy-to-mouth contact was 106,5 s.

7.5 Estimations

7.5.1 The frequency children mouthed toys

It is estimated that children under 36 months mouth toys an average of 115 times/day (181 toys-to-mouth/day for children from 0 months to 12 months and 80 toystomouth/day for children from 13 months to 36 months). Based on 95th percentile values, this data increases to 748 toys-to-mouth/day for the total sample (1 271 toys-to-mouth/day for children from 0 months to 12 months and 507 toys-to-mouth/day for children from 13 months to 36 months).

7.5.2 Time spent mouthing toys

It is estimated that children mouth toys an average of 30 min per day (56 min/day for children from 0 months to 12 months, and 17 min/day for children from 13 months to 36 month). Based on 95th percentile values, this data increases to 250 min/day (322 min for children from 0 months to 12 months and 93 min/day for children from 13 months to 36 months).

7.6 Childcare articles

Annex B of this report features information related to children's mouthing behaviour in contact with childcare articles. This section is just a first approach, of limited value.

Annex A
(informative)

Summary of previous quantitative studies on children's mouthing behaviour

Table A.1 — Summary of previous quantitative studies on children's mouthing behaviour

Sample	Range of age	Type Sample	Mouthing frequency		Mouthing contact duration		Hourly mouthing duration	
			Total	Toys	Total	Toys	Total	Toys
AuYeung et al. (2004) [17]								
			Contacts/hour		seconds		Minutes/hour	
n = 1	18 months to 24 months	Mean	84,8		5		11,1	
		Median	84,8		1		11,1	
		Maximum						
		95th Percentile	84,8		25		11,1	
		99th Percentile	84,8		32,6		11,1	
n = 8	25 months to 82 months	Mean	22,7	3,3	3,2	5,8	1,2	0,3
		Median	19,5	0[a]	1	6	0,9	0[a]
		Maximum						
		95th Percentile	47,6	15,6	9,9	9	3,3	1,4
		99th Percentile	51,3	21,5	13,1	9	3,6	2
Norris and Smith (2002) [8]								
							(hour/day)	
n = 9	1 month to 3 months	Mean					1:11:48	0:00:14
		Median						
		Maximum					0:00:59	3:31:50
		95th Percentile						
		99th Percentile						
n = 14	3 months to 6 months	Mean					1:57:41	0:28:20
		Median						
		Maximum					3:36:24	2:34:45
		95th Percentile						
		99th Percentile						
n = 15	≥ 6 months and < 10 months	Mean					1:35:11	0:39:10
		Median						
		Maximum					5:16:59	3:46:46

Sample	**Range of age**	**Type Sample**	**Mouthing frequency**		**Mouthing contact duration**		**Hourly mouthing duration**	
			Total	Toys	Total	Toys	Total	Toys
		95th Percentile						
		99th Percentile						
n = 17	9 months to 12 months	Mean					1:35:16	0:23:04
		Median						
		Maximum					6:53:01	1:04:49
		95th Percentile						
		99th Percentile						
n = 16	12 months to 15 months	Mean					14:36:16	0:15:18
		Median						
		Maximum					4:17:09	0:44:01
		95th Percentile						
		99th Percentile						
n = 14	15 months to 18 months	Mean					1:15:13	0:16:34
		Median						
		Maximum					5:14:42	0:58:28
		95th Percentile						
		99th Percentile						
n = 16	18 months to 21 months	Mean					1:58:49	0:11:07
		Median						
		Maximum					6:52:18	0:32:49
		95th Percentile						
		99th Percentile						
n = 12	21 months to 24 months	Mean					1:43:39	0:15:46
		Median						
		Maximum					6:35:01	1:42:04
		95th Percentile						
		99th Percentile						
n = 39	2 years	Mean					1:39:27	0:12:23
		Median						
		Maximum					7:41:31	2:05:48
		95th Percentile						
		99th Percentile						
n = 31	3 years	Mean					1:50:19	0:11:37
		Median						
		Maximum					8:30:12	1:34:36

Sample	Range of age	Type Sample	Mouthing frequency		Mouthing contact duration		Hourly mouthing duration	
			Total	Toys	Total	Toys	Total	Toys
		95th Percentile						
		99th Percentile						
Juberg et al. 2001 [1]								
							(minutes/day)	
n = 107	0 months to 18 months	Mean					108 (dummy) 6 (teethers) 9 (other objects) 33 (non-dummy)[b]	17
		Median					0 (dummies) 16 (non-dummy)[b]	
		Maximum						
		95th Percentile						
		99th Percentile						
n = 110	19 months to 36 months	Mean					126 (dummies) 0 (teethers) 2 (other objects) 0 (non-dummy)[b]	2
		Median					0 (dummies) 0 (non-dummy)[b]	
		Maximum						
		95th Percentile						
		99th Percentile						
Daily mouthing time for all objects (excluding dummies) (*n* = 168, 3 months to 18 months) • Mean: 36 min/day • Median: 17 min/day								
Xue et al. 2007 [11]								
			(contacts/hour)[c]					
n = 23	3 months to 6 months	Mean	28					
		Median						
		Maximum						
		95th Percentile	65					
		99th Percentile						
n = 119	3 months to 12 months	Mean	18,9					
		Median						
		Maximum						

Sample	**Range of age**	**Type Sample**	**Mouthing frequency**		**Mouthing contact duration**		**Hourly mouthing duration**	
			Total	Toys	Total	Toys	Total	Toys
		95th Percentile	52					
		99th Percentile						
n = 245	1 year to 2 years	Mean	19,6					
		Median						
		Maximum						
		95th Percentile	63					
		99th Percentile						
n = 161	2 years to 3 years	Mean	12,7					
		Median						
		Maximum						
		95th Percentile	37					
		99th Percentile						
n = 169	3 years to 6 years	Mean	14,7					
		Median						
		Maximum						
		95th Percentile	54					
		99th Percentile						
n = 14	6 years to 11 years	Mean	6,72					
		Median						
		Maximum						
		95th Percentile						
		99th Percentile						
Tulve et al. 2002 [6]								
			(contacts/hour)[c]					
n = 28, 69 observations	11 months to 24 months	Mean	81	45				
		Median	73	39				
		Maximum	88					
		95th Percentile						
		99th Percentile						
n = 44, 117 observations	25 months to 60 months	Mean	42	17				
		Median	31	9				
		Maximum	39					
		95th Percentile						
		99th Percentile						

Sample	**Range of age**	**Type Sample**	**Mouthing frequency**		**Mouthing contact duration**		**Hourly mouthing duration**	
			Total	Toys	Total	Toys	Total	Toys
Reed et al. 1999 [14]								
			(contacts/hour)[d]					
n = 30	2 years to 6 years	Mean	16,3					
		Median	3,6					
		Maximum	86,2					
		95th Percentile						
		99th Percentile						
Black et al. 2004 [18]								
			(contacts/hour)[e]				(minutes/hour)[f]	
n = 13	7 months to 12 months	Mean						
		Median	18,1				1,9	
		Maximum						
		95th Percentile						
		99th Percentile						
n = 12	13 months to 24 months	Mean						
		Median	8,4				0,8	
		Maximum						
		95th Percentile						
		99th Percentile						
Black et al. 2004 [18]								
			(contacts/hour)[e]				(minutes/hour)[f]	
n = 18	25 months to 36 months	Mean	5,5					
		Median						
		Maximum						
		95th Percentile						
		99th Percentile						
n = 9	37 months to 53 months	Mean	8,4				0,5	
		Median						
		Maximum						
		95th Percentile						
		99th Percentile						
Freeman et al. 2004 [26]								
			(contacts/hour)[e]		(seconds)[e]			
n = 10	24 months	Mean						

Sample	Range of age	Type Sample	Mouthing frequency		Mouthing contact duration		Hourly mouthing duration	
			Total	Toys	Total	Toys	Total	Toys
	to 55 months	Median	4,8		2 - 4			
		Maximum						
		95th Percentile						
		99th Percentile						
Freeman et al. 2001 [15]								
			(contacts/hour)[e]					
n = 3	3 years to 4 years	Mean						
		Median	34					
		Maximum						
		95th Percentile						
		99th Percentile						
n = 7	5 years to 6 years	Mean						
		Median	0					
		Maximum						
		95th Percentile						
		99th Percentile						
n = 4	7 years to 8 years	Mean						
		Median	0					
		Maximum						
		95th Percentile						
		99th Percentile						
Freeman et al. 2001 [15]								
			(contacts/hour)[e]					
n = 4	7 years to 8 years	Mean						
		Median	0					
		Maximum						
		95th Percentile						
		99th Percentile						
n = 5	10 years to 12 years	Mean						
		Median	0					
		Maximum						
		95th Percentile						
		99th Percentile						
Groot et al. 1998 [2]								

Sample	**Range of age**	**Type Sample**	**Mouthing frequency**		**Mouthing contact duration**		**Hourly mouthing duration**	
			Total	Toys	Total	Toys	Total	Toys
							(minutes/hour)[g,h]	
n = 5	3 months to 6 months	Mean						
		Median					5,6	
		Maximum						
		95th Percentile						
		99th Percentile						
n = 14	6 months to 12 months	Mean						
		Median					2,1	
		Maximum						
		95th Percentile						
		99th Percentile						
n = 12	12 months to 18 months	Mean						
		Median					0,83	
		Maximum						
		95th Percentile						
		99th Percentile						
n = 11	18 months to 36 months	Mean						
		Median					0,42	
		Maximum						
		95th Percentile						
		99th Percentile						
Mean daily mouthing duration (excluding dummies) • 3 months to 6 months: 37 min • 6 months to 12 months: 44 min • 12 months to 18 months: 16 min • 18 months to 32 months: 9 min Mean mouthing duration for teethers, rattles and toys • 3 months to 12 months: 12 min • 13 months to 26 months: 2 min Mean most often mouthed items (in order of preference): • 3 months to 6 months: fingers, toys. • 6 months to 12 months: toys, non-toys, fingers. • 18 months to 36 months: fingers.								
Zartarian et al. (1996, 1998) [13], [22]								
			(contacts/hour)[i]		seconds			
n = 4	2 years to	Mean						

Sample	**Range of age**	**Type Sample**	**Mouthing frequency**		**Mouthing contact duration**		**Hourly mouthing duration**	
			Total	Toys	Total	Toys	Total	Toys
	4 years	Median	16,5		3			
		Maximum						
		95th Percentile						
		99th Percentile						

[a] Zero ("0") represents contacts that lasted less than 1 s. Contacts of less than 1 s were treated as contacts with 0 s for the purpose of calculating the mean.

[b] Including teethers and toys.

[c] Total mouthing events include: mouth-body, mouth-hand, mouth-surface and mouth-toy.

[d] Object-to-mouth.

[e] Total non-dietary. It is not include hand-to-mouth-contacts.

[f] Converted by multiplying percent of observed time by 60 min/h.

[g] Estimated from graph in paper. Values presented are based on extrapolation from 5 h of observation.

[h] Computed by dividing minutes per day by 24 h/day.

[i] Computed adding the median frequencies for left-hand to mouth and right-hand to mouth contacts.

Annex B
(informative)

Results of children's mouthing behaviour in contact with childcare articles

B.1 Introduction

Data relating to childcare articles, irrespective whether they are intended to be mouthed (soothers and bottle teats, cup spouts etc.) or not intended to be mouthed, is not necessarily comparable with the data for toys. The objective of Annex B is merely a first approximation (exploratory study) of children's mouthing behaviour in contact with childcare articles. The sample is so small that the statistical error is very high (±11,55 %) and even higher when the sample is split into different groups by age, country, etc.

The results of the toy sample and the childcare articles sample have been treated as two different studies to ensure the validity of the data.

This annex presents data related to:

— B.3: Frequency, the "Number of times children mouthed childcare articles per hour". This information was analysed by: age and country;

— B.4: Time spent, the "Percentage of time children mouthed childcare articles in the total time observed". This information was analysed by: age and country.

— B.5: Type of Mouthing: Lip/Tongue, Suck/Engulf, Bite/Chew. This information was analysed by frequency and time spent mouthing childcare articles.

— B.6: Childcare article categories, this section analyses the differences in children's mouthing behaviour in contact with childcare articles by comparing the childcare articles category. This data was analysed by: frequency and time children spent mouthing childcare articles.

B.2 Design of the research

B.2.1 General objective

The overall aim of this research is the measurement and quantification of the duration and frequency that children aged 0 months to 36 months introduce child care articles into their mouths spontaneously. However, it should be taken into account that is merely a first approximation (exploratory study). The sample is so small that the statistical error is very high (±11,55 %) and even higher when the sample is split into different groups by age, country, etc. (see Table B.1).

Table B.1 — Sample error

Global study		72 Families (±11,55 %)
Children age	< 3 months	12 Families (±28,29 %)
	≥ 3 months and < 6 months	21 Families (±21,39 %)
	≥ 6 months and < 10 months	27 Families (±18,86 %)
	≥ 10 months and < 19 months	12 Families (±28,29 %)
Country	Germany	24 Families (±20 %)
	France	24 Families (±20 %)
	Spain	24 Families (±20 %)
Childcare category	Bouncer balance	13 Families (±27,18 %)
	Changing table pillow	12 Families (±28,29 %)
	Bathtub	23 Families (±20,43 %)
	Feeding	24 Families (±20 %)

B.2.2 Data collection

The present study used parental observation in a natural environment (the children's own home), which is one of the main methodologies used in previous research into children's mouthing behaviour.

The presence of a stranger in the home environment is likely to alter the behaviour of the child being observed to a greater or lesser extent; so while the reliability of the data may be high, the circumstances are less "realistic" and lower the validity of the data. For this reason, this research used parents/carers as observers, to ensure that children's mouthing behaviour, and their behaviour in general, was as natural as possible, to guarantee high data validity.

The following specific instructions were given to the parents in order to carry out the study properly:

— **I Love My Bear changing mat:** The observation of this product should be carried out at the time of dressing and/or changing your baby's nappy, in the usual manner. We recommend the presence of two adults, one to use the product and the other to make observations.

— **Bouncing reclined cradle:** The observation of this product should be carried out when the baby is sleeping or relaxing, in the usual manner. We recommend the presence of two adults, one to use the product with the baby and the other to make observations.

— **Flexibath bath:** The observation of this product should be carried out at the time of bathing your baby, in the usual manner. We recommend the presence of two adults, one to use the product and the other to make observations.

— **Easy Meal spoon:** The observation of this product should be carried out at meal times, when feeding your baby, in the usual manner. We recommend the presence of two adults, one to use the product and the other to make observations. The child may also use this product.

— **Shampoo rinser:** The observation of this product should be carried out at bath time, in the usual manner. We recommend the presence of two adults, one to use the product and the other to make observations. You can give it to your baby to play with, and then use it to rinse their hair.

— **Explora rollable bib:** The observation of this product should be carried out at meal times, in the usual manner. We recommend the presence of two adults, one to use the product and the other to make observations.

Parents made observations of their children in contact with childcare articles at home for 6 min/day, resulting in 42 min of observation per child at the end of the week. In total 50,2 h of adult observation of children's mouthing activities with these items were collected, with the aim of carrying out a first approach of children's mouthing behaviour in contact with childcare articles.

Methodology: Parental observation of children under 18 months of age in the home environment (see also Table B.2).

Table B.2 — Methodology

Type of observation	Parental observation
Environment (Place)	Home environment
Countries	Germany, France, Spain
Number of children	72 children
Gathering information	(24:Germany / 24:France / 24:Spain)

This study consisted of parental observation of children's mouthing behaviour when they were in contact with childcare articles, to obtain the times and frequency that children (0 months to 18 months) introduce childcare articles into their mouths.

B.2.3 Sample of children and products

A sample of 72 families (from Germany, France and Spain) observed their children's use of childcare articles. Each family had 1 childcare article selected according to the age of their child and observed their child's use over the course of a week. Each childcare article was tested by 12 different families.

The selection of the sample of childcare products consisted of 6 products: I Love My Bear changing mat, Bouncing reclined cradle, Flexibath bath, Easy Meal spoon, Shampoo rinser, Explora rollable bib.

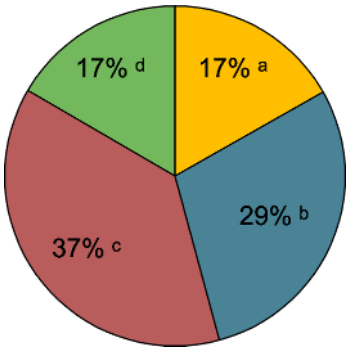
Summary of data about the children and families sample:

1) **Age of children:** Sample age group was adjusted according to the product characteristics in 4 age brackets, defined as:

   i) below 3 months: 12 children
   ii) ≥ 3 months and < 6 months: 21 children
   iii) ≥ 6 months and < 10 months: 27 children
   iv) ≥ 10 months and < 19 months: 12 children

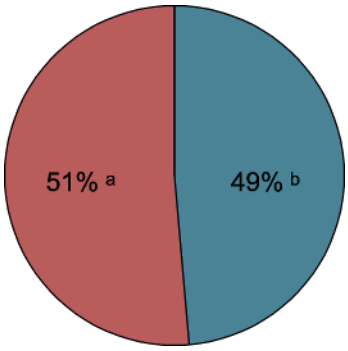
2) **Gender of children:** Almost equal halves of the sample of each gender (girls 51 % and boys 49 %).

3) **Country:** Families from the 3 countries that participated (Germany: 24 families / France: 24 families / Spain: 24 families).



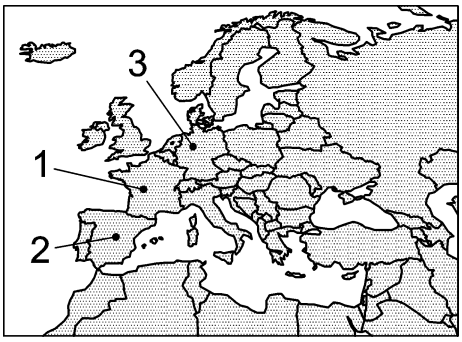
Key
a < 3 months
b ≥ 3 months and < 6 months
c ≥ 6 months and < 10 months
d ≥ 10 months and < 19 months

Figure B.1 —Children age



Key
a girl
b boy

Figure B.2 — Children gender



Key
1 France (24 families)
2 Spain (24 families)
3 Germany (24 families)

Figure B.3 — Country

Table B.3 — Childcare article sample

Childcare article category	Number of products	
1. Changing table pillow	1	
2. Bouncer balance, hammock	1	
3. Bathtub	2	
4. Feeding	2	

B.3 Frequency children mouthed childcare articles

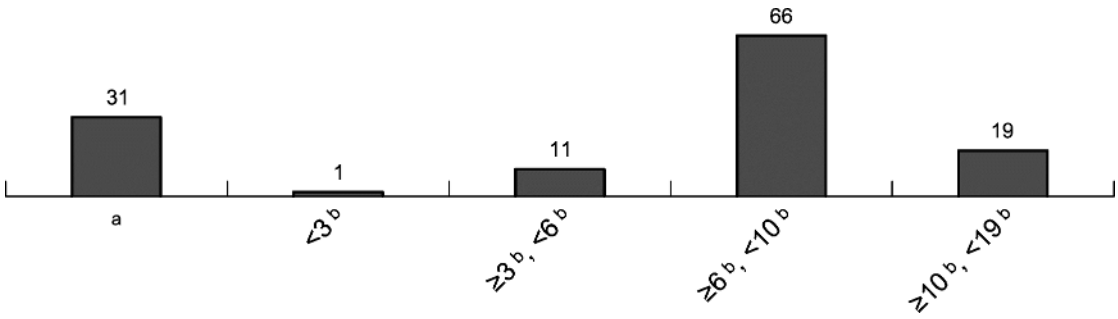
B.3.1 General

This sub-clause presents data related to frequency, the “Number of times children mouthed childcare articles per hour”. This information is analysed by: age and country.

B.3.2 By age

Table B.4 — Frequency children mouthed childcare articles per hour by age

Age groups months	**Mean**	**SD**	**Per. 75**	**Per. 85**	**Per. 95**	**Per. 99**	**Max.**	**Min.**
< 3	1	2	0	0	3	5	6	0
≥ 3, < 6	11	26	13	17	20	102	123	0
≥ 6, < 10	66	89	69	100	241	377	410	0
≥ 10, < 19	19	30	20	44	77	94	99	0
Total sample	**31**	**64**	**34**	**54**	**131**	**319**	**410**	**0**



Key

a global

b months

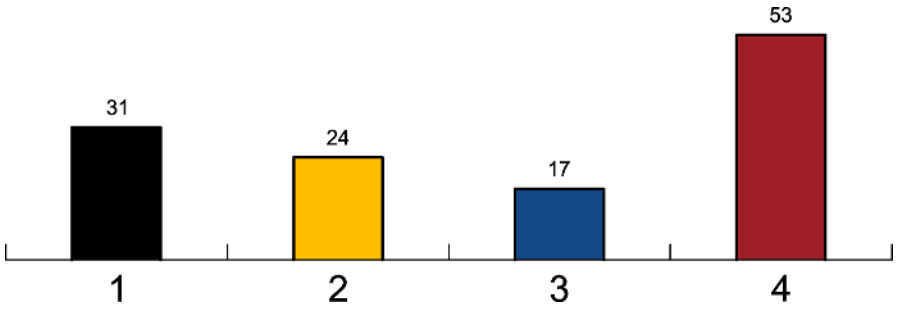
Figure B.4 — Frequency of mouthing behaviour of childcare articles per hour (based on means of Table B.4)

The average number of times children mouthed childcare articles was 31 times/hour. The highest frequencies were in children aged ≥ 6 months and < 10 months (66 times).

B.3.3 By country

Table B.5 — Frequency children mouthed childcare articles per hour by country

Country	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Germany	24	29	41	50	90	98	99	0
France	17	28	21	31	67	111	123	0
Spain	53	99	43	110	261	380	410	0
Total sample	**31**	**64**	**34**	**54**	**131**	**319**	**410**	**0**



Key

1 global

2 Germany

3 France

4 Spain

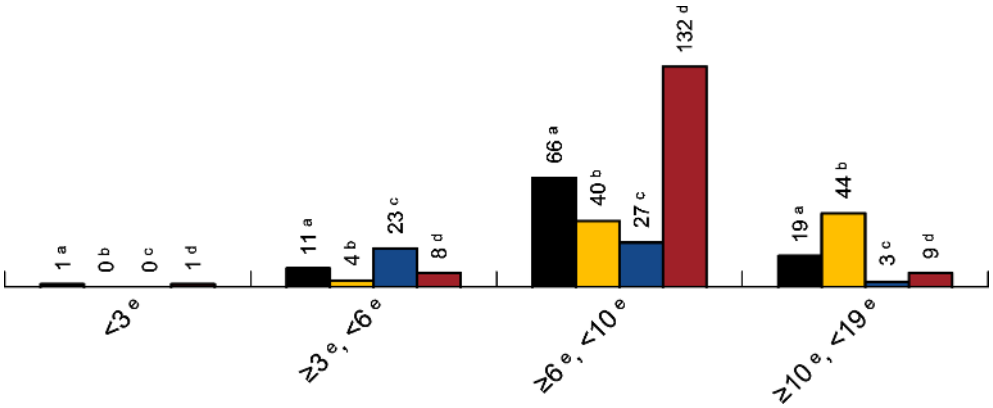
Figure B.5 — Frequency of mouthing behaviour for childcare articles per hour (based on means of Table B.5)

The country with the highest frequency was Spain (53 times). However, these differences were not significant.

B.3.4 By age and country

Table B.6 — Frequency of mouthing behaviour for childcare articles per hour by country and age (mean values)

Age groups months	Mean	Germany	France	Spain
< 3	1	0	0	1
≥ 3, < 6	11	4	23	8
≥ 6, < 10	66	40	27	132
≥ 10, < 19	19	44	3	9
Total Sample	**31**	**24**	**17**	**53**



Key

a global
b Germany
c France
d Spain
e months

Figure B.6 — Frequency of mouthing behaviour for childcare articles per hour (based on means of Table B.6)

The highest frequency was observed for Spanish babies, aged ≥ 6 months and < 10 months. However, it should be noted that these results are from only 9 children and the variability of the data are very high.

B.4 Time children spent mouthing childcare articles

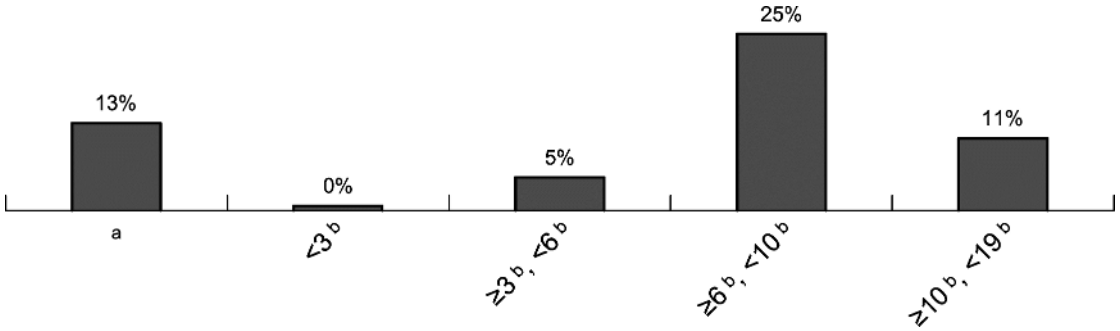
B.4.1 General

This section presents data related to the "Percentage of time children mouthed a childcare article in the total time observed". This information is analysed by: age and country.

B.4.2 By age

Table B.7 — Percentage of time children mouthed a childcare article in the total time observed (50,2 h) by age

Age groups months	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
< 3	0,1 %	0,4 %	0 %	0,1 %	0,7 %	1,2 %	1,3 %	0 %
≥ 3, < 6	4,5 %	8,5 %	4,3 %	5,2 %	23,6 %	31,8 %	33,9 %	0 %
≥ 6, < 10	25,2 %	19,6 %	37,0 %	43,6 %	62,5 %	71,7 %	73,6 %	0 %
≥ 10, < 19	10,6 %	17,8 %	11,8 %	25,2 %	44,8 %	56,4 %	59,3 %	0 %
Total sample	12,6 %	18 %	21,2 %	32,7 %	50,6 %	68,5 %	73,6 %	0 %



Key

a global
b months

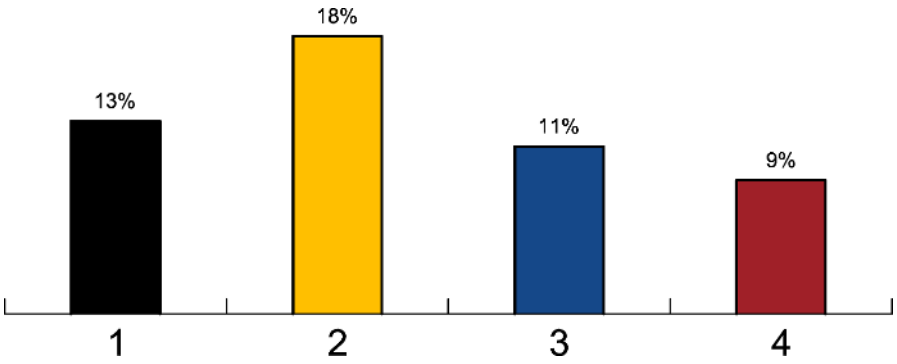
Figure B.7 — Time children spent mouthing childcare articles (total time 50,2 h) based on means of Table B.7

Children mouthed childcare articles for 12,6 % of the total time observed (50,2 h). The highest instance, found in children of ≥ 6 months and < 10 months, is significantly higher than in the other age groups analysed.

B.4.3 By country

Table B.8 — Percentage of time children mouthed a childcare articles in the total time observed (50,2 h) by country

Country	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Germany	18,1 %	23,5 %	34,5 %	45,9 %	65,3 %	72 %	73,6 %	0 %
France	10,8 %	15,1 %	19,2 %	31,0 %	34,5 %	49,2 %	53,6 %	0 %
Spain	8,7 %	11,8 %	13,9 %	22,6 %	29,9 %	38,3 %	40,8 %	0 %
Total sample	12,6 %	18 %	21,2 %	32,7 %	50,6 %	68,5 %	73,6 %	0 %



Key

1 global
2 Germany
3 France
4 Spain

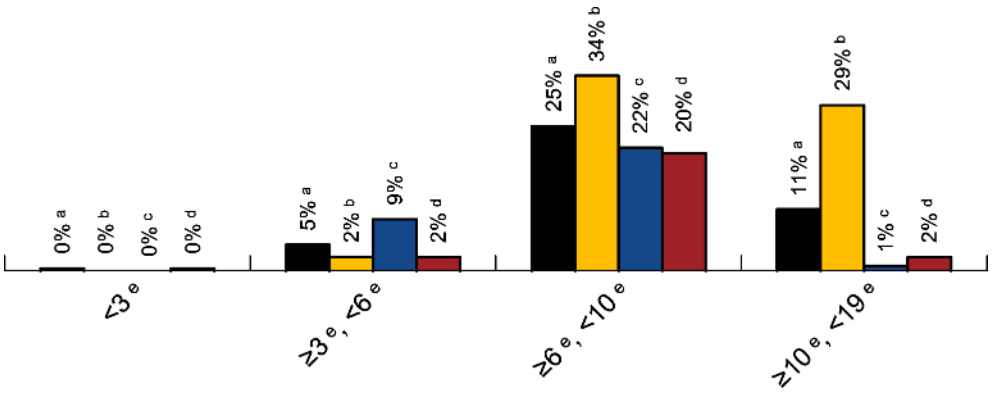
Figure B.8 — Time children spent mouthing childcare articles (total time 50,2 h) based on means of Table B.8

Spanish and French children spent less time mouthing childcare articles than German children, but these differences were not significant.

B.4.4 By country and age

Table B.9 — Percentage of time children spent mouthing childcare articles in the total time observed (50,2 h) by country and age

Age groups months	**Mean**	**Germany**	**France**	**Spain**
< 3	0,1 %	0,1 %	0 %	0,3 %
≥ 3, < 6	4,5 %	2,2 %	8,9 %	2,3 %
≥ 6, < 10	25,2 %	33,8 %	21,6 %	20,4 %
≥ 10, < 19	10,6 %	28,8 %	0,7 %	2,2 %
Total Sample	12,6 %	18 %	10,8 %	8,7 %



Key

a global
b Germany
c France
d Spain
e months

Figure B.9 — Percentage of time children spent mouthing childcare articles in the total time observed (50,2 h) by country and age (based on means of Table B.9)

The age pattern in total mouthing time by age is similar for France and Spain.

However, there are slight differences in trends in the total percentage of time spent mouthing:

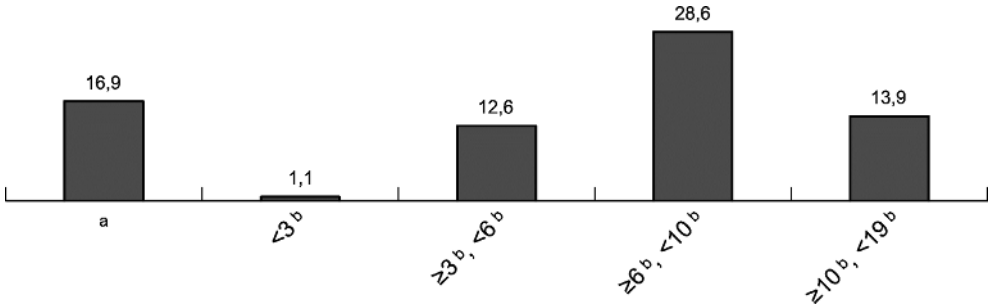
— Spain and France, lowest percentage in time spent mouthing childcare articles.

— Germany, highest percentage in time spent mouthing childcare articles, and not many differences between the age brackets “≥6 months and <10 months” and “≥10 months and <19 months”.

B.4.5 Childcare-article-to-mouth contact duration by age

Table B.10 — Childcare-article-to-mouth contact duration by age

Age groups months	**Mean** s	**SD** s	**Per. 75** s	**Per. 85** s	**Per. 95** s	**Per. 99** s	**Max.** s	**Min.** s
< 3	1,1	2,6	0,0	1,8	6,6	7,9	8,3	0,0
≥ 3, < 6	12,6	16,6	16,4	33,9	49,5	55,0	56,3	0,0
≥ 6, < 10	28,6	39,2	34,6	53,8	91,1	164,3	185,5	0,0
≥ 10, < 19	13,9	23,0	11,2	20,9	57,4	77,8	83,0	0,0
Total sample	**16,9**	**29,1**	**16,6**	**34,7**	**60,4**	**127,5**	**185,5**	**0,0**



Key

a global

b months

Figure B.10 — Childcare-article-to-mouth contact duration in seconds by age (based on means of Table B.10)

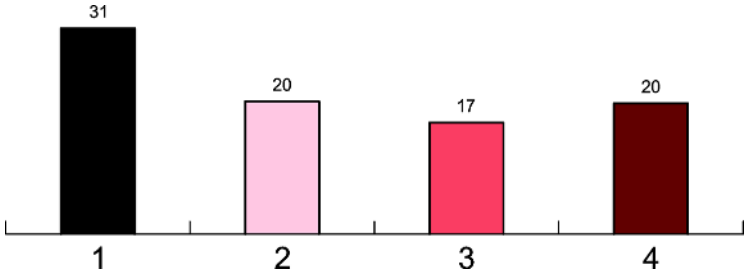
Children under 18 months spent 16,9 s in each mouthing action. Analysing this data by age, the highest averages were found in the third age bracket (≥6 months and < 10 months).

B.5 Type of mouthing lip/tongue, suck/engulf, bite/chew

B.5.1 Frequency by type of mouthing

Table B.11 — Frequency children mouthed childcare articles per hour by type of mouthing (multiple answer)

Type of mouthing	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Lip/ tongue	20	42	20	38	97	186	281	0
Suck/ engulf	17	41	12	33	92	169	281	0
Bite/ chew	20	53	19	38	78	219	410	0
Total sample	**31**	**64**	**34**	**54**	**131**	**319**	**410**	**0**



Key

1 global

2 lip

3 suck

4 bite

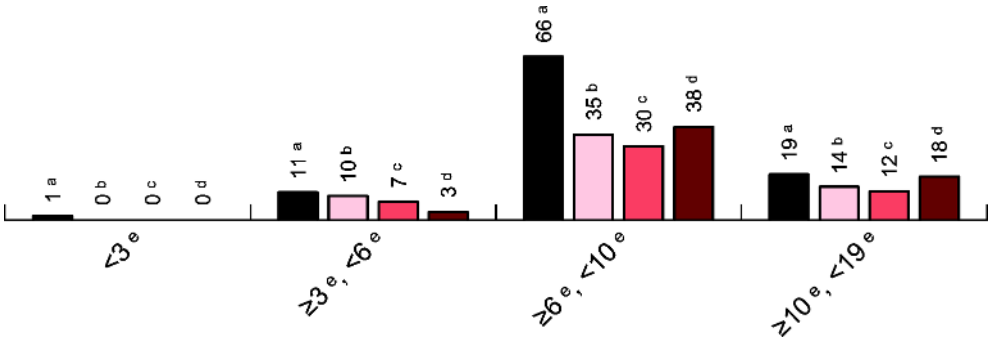
Figure B.11 — Frequency children mouthed childcare articles per hour by type of mouthing (based on means of Table B.11)

Lip-touching and biting were the most frequent type of mouthing behaviour observed in children's contact with childcare articles (20 times/hour), followed by sucking, with a similar result (17 times/hour).

B.5.2 Frequency by type of mouthing and age

Table B.12 — Frequency children mouthed childcare articles per hour by type of mouthing and age (mean values)

Age groups months	Mean	Lip/ tongue	Suck/ engulf	Bite/ chew
< 3	1	0	0	0
≥ 3, < 6	11	10	7	3
≥ 6, < 10	66	35	30	38
≥ 10, < 19	19	14	12	18
Total Sample	**31**	**20**	**17**	**20**



Key

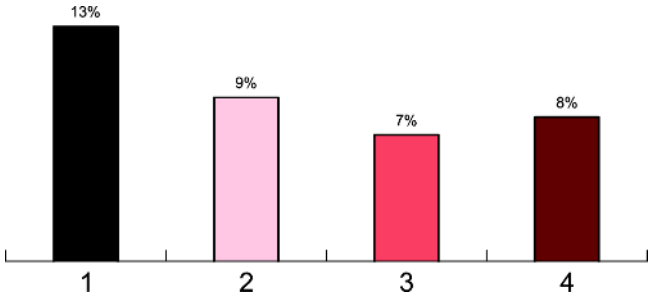
a global
b lip
c suck
d bite
e months

Figure B.12 — Frequency children mouthed childcare articles per hour by type of mouthing and age (based on means of Table B.12)

B.5.3 Time children spent mouthing by type of mouthing

Table B.13 — Percentage of time children mouthed childcare articles in the total time (50,2 h) by type of mouthing (multiple answer)

Type of mouthing	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
Lip/ tongue	9,0 %	14,0 %	16,8 %	23,6 %	38,1 %	52,3 %	63,5 %	0 %
Suck/ engulf	7,1 %	13,1 %	8,7 %	20,7 %	31,4 %	57,3 %	66,4 %	0 %
Bite/ chew	7,6 %	13,4 %	10,6 %	21,2 %	36,5 %	55,2 %	59,3 %	0 %
Total sample	12,6 %	18 %	21,2 %	32,7 %	50,6 %	68,5 %	73,6 %	0 %



Key

1 global
2 lip
3 suck
4 bite

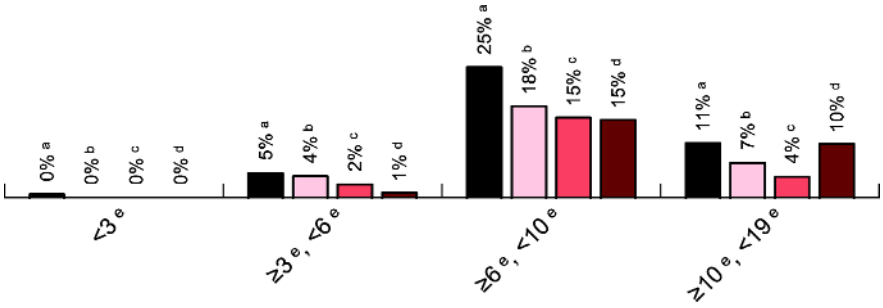
Figure B.13 — Percentage of time children mouthed childcare articles in the total time (50,2 h) by type of mouthing

Lip-touching was the most common type of mouthing observed. Lip-touching 9 %, sucking 7,1 %, and biting 7,6 % of the total mouthing time.

B.5.4 Time children spent mouthing childcare articles by type of mouthing and age

Table B.14 — Percentage of time children mouthed childcare articles in the total time (50,2 h) by type of mouthing and age (mean values)

Age groups months	Mean	Lip/ tongue	Suck/ engulf	Bite/ chew
< 3	0,1 %	0,1 %	0,0 %	0,0 %
≥ 3, < 6	4,5 %	4,2 %	2,4 %	0,8 %
≥ 6, < 10	25,2 %	17,7 %	15,4 %	15,1 %
≥ 10, < 19	10,6 %	6,6 %	3,9 %	10,4 %
Total Sample	12,6 %	9,0 %	7,1 %	7,6 %



Key

a global
b lip
c suck
d bite
e months

Figure B.14 — Percentage of time children mouthed childcare articles in the total time (50,2 h) by type of mouthing and age (based on means of Table B.14)

Lip-touching behaviour was higher in the ≥ 6 months and < 10 months group (17,7 % of childcare articles mouthing time). This data was consistent with significantly higher mouthing behaviour in children of this age bracket.

B.6 Childcare article category

B.6.1 General

B.6 analyses the differences in children's mouthing behaviour in contact with childcare articles by comparing the childcare article categories. This data has been analysed by: frequency and time children spent mouthing childcare articles.

B.6.2 Frequency children mouthed childcare articles by childcare article categories

Table B.15 — Frequency children mouthed childcare articles per hour by childcare article category

Childcare article category	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
1. bouncer balance	17	31	17	18	61	111	123	0
2. changing table pillow	1	2	0	0	3	5	6	0
3. bathtub	29	36	40	65	93	131	141	0
4. feeding	56	96	50	84	261	380	410	0
Total sample	31	64	34	54	131	319	410	0

The number of times children mouthed childcare articles per hour was significantly higher in category 4 (feeding).

B.6.3 Time children spent mouthing childcare articles by childcare article categories

Table B.16 — Percentage of time children mouthed childcare articles in the total time (50,2 h) by childcare article category

Childcare article category	Mean	SD	Per. 75	Per. 85	Per. 95	Per. 99	Max.	Min.
1. bouncer balance	6,8 %	10,0 %	4,7 %	13,7 %	27,7 %	32,7 %	33,9 %	0 %
2. changing table pillow	0,1 %	0,4 %	0,0 %	0,1 %	0,7 %	1,2 %	1,3 %	0 %
3. bathtub	10,2 %	13,7 %	13,8 %	25,5 %	39,6 %	46,6 %	48,2 %	0 %
4. feeding	24,2 %	22,4 %	35,8 %	48,9 %	65,3 %	72,0 %	73,6 %	0 %
Total sample	12,6 %	18 %	21,2 %	32,7 %	50,6 %	68,5 %	73,6 %	0 %

The percentage of time children spent mouthing childcare articles was higher in category 4 (feeding). This result demonstrates similar behaviour to that observed in frequency.

B.7 Summary

As has already been stated, the objective of this annex is merely a first approximation (exploratory study) of children's mouthing behaviour in contact with childcare articles. The data shown in this annex is only an initial approach, of limited value, on the issue of children's mouthing behaviour in contact with childcare articles.

The following paragraphs summarize some data related to this study:

— The average number of times children mouthed childcare articles was 31 times/hour. The highest frequencies were found in the age group of ≥ 6 months and < 10 months (66 times).

— Children were mouthing childcare articles 12,6 % of the total time observed (50,2 h). The highest instance was found for children of ≥ 6 months and < 10 months. Spanish and French children spent less time mouthing childcare articles than German children.

— Children under 18 months spent 16,9 s in each mouthing action. Analysing this data by age, the highest averages were found in the third age bracket (≥6 months and < 10 months).

— In terms of frequency, lip-touching and biting were the most frequent type of mouthing behaviour observed in children's contact with childcare articles (20 times/hour), followed by sucking with a similar result (17 times/hour). In terms of time children spent mouthing childcare articles, lip-touching was the most common type of mouthing observed.

— The frequency and time children spent mouthing childcare articles was significantly higher for category 4 (feeding).

Annex C
(informative)

Statistical results

C.1 Normal distribution test

Table C.1 — Toy-to-mouth contact duration - Normal distribution test

Quantitative variable	Statistical test	Outcome
Age (Months)	Kolmogorov-Smirnov	0 to 12m Sig. 0,000 13 to 24m Sig. 0,000 25 to 36m Sig. 0,007
	Shapiro-Wilk	0 to 12m Sig. 0,000 13 to 24m Sig. 0,000 25 to 36m Sig. 0,000

Table C.2 — Frequency children mouthed toys - Normal distribution test

Quantitative variable	Statistical test	Outcome
Age (Months)	Kolmogorov-Smirnov	0 to 12m Sig. 0,000 13 to 24m Sig. 0,000 25 to 36m Sig. 0,000
	Shapiro-Wilk	0 to 12m Sig. 0,000 13 to 24m Sig. 0,000 25 to 36m Sig. 0,000
Gender	Kolmogorov-Smirnov	Boys Sig. 0,000 Girls Sig. 0,000
	Shapiro-Wilk	Boys Sig. 0,000 Girls Sig. 0,000
Country	Kolmogorov-Smirnov	Germany Sig. 0,000 France, 0,000 Spain Sig. 0,000
	Shapiro-Wilk	Germany Sig. 0,001 France, 0,000 Spain Sig. 0,000
Elastomeric	Kolmogorov-Smirnov	Elastomeric Sig. 0,000 Not Elastomeric Sig. 0,000
	Shapiro-Wilk	Elastomeric Sig. 0,000 Not Elastomeric Sig. 0,000
Intended to be mouthed	Kolmogorov-Smirnov	Intended Sig. 0,000 Not Intended Sig. 0,000
	Shapiro-Wilk	Intended Sig. 0,000

Quantitative variable	Statistical test	Outcome
		Not Intended Sig. 0,000
Toy Category	Kolmogorov-Smirnov	1. Push-along Sig. 0,021 2. Dolls Sig. 0,000 3. Role-playing Sig. 0,000 4. Toys for babies Sig. 0,000 5. Books Sig. 0,001 6. Audio/visual Sig. 0,000 7. Construction Sig. 0,000 8. Mechanical Sig. 0,000 9. Play Scenes Sig. 0,000 10. Bath toys Sig. 0,000 11. Toy musical Sig. 0,002 12. Toy sport Sig. 0,000 13. Toys intended to bear the mass of a child Sig. 0,000
	Shapiro-Wilk	1. Push-along Sig. 0,001 2. Dolls Sig. 0,000 3. Role-playing Sig. 0,000 4. Toys for babies Sig. 0,000 5. Books Sig. 0,000 6. Audio/visual Sig. 0,000 7. Construction Sig. 0,000 8. Mechanical Sig. 0,000 9. Play Scenes Sig. 0,000 10. Bath toys Sig. 0,000 11. Toy musical Sig. 0,001 12. Toy sport Sig. 0,000 13. Toys intended to bear the mass of a child Sig. 0,000

Table C.3 — Time children spent mouthing toys - Normal distribution test

Quantitative variable	Statistical test	Outcome
Age (Months)	Kolmogorov-Smirnov	0 to 12m Sig. 0,000 13 to 36m Sig. 0,000 25 to 36m Sig. 0,000
	Shapiro-Wilk	0 to 12m Sig. 0,000 13 to 24m Sig. 0,000 25 to 36m Sig. 0,000
Gender	Kolmogorov-Smirnov	Boys Sig. 0,000 Girls Sig. 0,000
	Shapiro-Wilk	Boys Sig. 0,000 Girls Sig. 0,000
Country	Kolmogorov-Smirnov	Germany Sig. 0,000 France, 0,000 Spain Sig. 0,000
	Shapiro-Wilk	Germany Sig. 0,000

Quantitative variable	Statistical test	Outcome
		France, 0,000 Spain Sig. 0,000
Elastomeric	Kolmogorov-Smirnov	Elastomeric Sig. 0,000 Not Elastomeric Sig. 0,000
	Shapiro-Wilk	Elastomeric Sig. 0,000 Not Elastomeric Sig. 0,000
Intended to be mouthed	Kolmogorov-Smirnov	Intended Sig. 0,000 Not Intended Sig. 0,000
	Shapiro-Wilk	Intended Sig. 0,000 Not Intended Sig. 0,000
Toy Category	Kolmogorov-Smirnov	1. Push-along Sig. 0,002 2. Dolls Sig. 0,000 3. Role-playing Sig. 0,000 4. Toys for babies Sig. 0,000 5. Books Sig. 0,005 6. Audio/visual Sig. 0,000 7. Construction Sig. 0,000 8. Mechanical Sig. 0,000 9. Play Scenes Sig. 0,000 10. Bath toys Sig. 0,046 11. Toy musical Sig. 0,000 12. Toy sport Sig. 0,000 13. Toys intended to bear the mass of a child Sig. 0,000
	Shapiro-Wilk	1. Push-along Sig. 0,000 2. Dolls Sig. 0,000 3. Role-playing Sig. 0,000 4. Toys for babies Sig. 0,000 5. Books Sig. 0,000 6. Audio/visual Sig. 0,000 7. Construction Sig. 0,000 8. Mechanical Sig. 0,000 9. Play Scenes Sig. 0,000 10. Bath toys Sig. 0,011 11. Toy musical Sig. 0,000 12. Toy sport Sig. 0,000 13. Toys intended to bear the mass of a child Sig. 0,000

C.2 Significance test

The significance analysis of the present study was made based on the results of non-parametric tests, because of the abnormal distribution of the data, as explained in 3.5 and shown in B.1.

Parametric tests were carried out in order to compare the results with those of the non-parametric tests. The results of the parametric tests are shown in order to add more information and because some authors support the use of parametric analysis for samples of over 100 subjects.

Table C.4 — Frequency children mouthed toys – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 10 Frequency children mouthed toys by age	0 months to 12 months 13 months to 24 months 25 months to 36 months	NON-PARAMETRIC	Kruskal-Wallis	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	0 months to 12 months 13 months to 36 months	PARAMETRIC	T Student	Sig. 0,000
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Scheffé	0 to 12m – 13 to 24m = Sig 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 0,866 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 0,866
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Bonferroni	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 1,000 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 1,000
Table 11 Frequency children mouthed toys by gender	Boys Girls	NON-PARAMETRIC	Mann-Whitney	Sig. 0,953
		NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,629
		PARAMETRIC	T Student	Sig. 0,378
Table 13 Frequency children mouthed toys by country	Germany France Spain	NON-PARAMETRIC	Kruskal-Wallis	Sig. 510
	Germany France Spain	PARAMETRIC	ANOVA Scheffé	Germany – France = Sig. 0,648 Germany – Spain = Sig. 0,436 France – Germany = Sig. 0,648 France – Spain = Sig. 0,942 Spain – Germany = Sig. 0,436 Spain – France = Sig 0,942
	Germany France Spain	PARAMETRIC	ANOVA Bonferroni	Germany – France = Sig. 1,000 Germany – Spain = Sig. 0,593 France – Germany = Sig. 1,000 France – Spain = Sig. 1,000 Spain – Germany = Sig. 0,593 Spain – France = Sig 1,000

Table C.5 — Time children spent mouthing toys – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 15 Time children spent mouthing toys by age	0 months to 12 months 13 months to 24 months 25 months to 36 months	NON-PARAMETRIC	Kruskal-Wallis	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	0 months to 12 months 13 months to 36 months	PARAMETRIC	T Student	Sig. 0,000
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Scheffé	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 0,998 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 0,998
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Bonferroni	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36 m = Sig. 0,000 13 to 24m – 0 to 12 m = Sig. 0,000 13 to 24m – 25 to 36 m = Sig. 1,000 25 to 36m – 0 to 12 m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 1,000
	< 3 months ≥ 3 months and < 6 months ≥ 6 months and < 10 months ≥ 10 months and < 13 months ≥ 13 months and < 19 months ≥ 19 months and < 25 months ≥ 25 months and < 31 months ≥ 31 months and < 37 months	PARA-METRIC	ANOVA Scheffé	3–5 vs. 0–2 m = Sig. 0,000 3–5vs. 6–9 m = Sig. 0,006 3–5vs. 10–12 m = Sig. 0,006 3–5vs. 13–18 m = Sig. 0,000 3–5vs. 19–24 m = Sig. 0,000 3–5vs. 25–30 m = Sig. 0,000 3–5vs. 31–36 m = Sig. 0,000
	< 3 months ≥ 3 months and < 6 months ≥ 6 months and < 10 months ≥ 10 months and < 13 months ≥ 13 months and < 19 months ≥ 19 months and < 25 months ≥ 25 months and < 31 months ≥ 31 months and < 37 months	PARA-METRIC	ANOVA Bonferroni	3–5 vs. 0–2 m = Sig. 0,000 3–5 vs. 6–9 m = Sig. 0,000 3–5 vs. 10–12 m = Sig. 0,000 3–5 vs. 13–18 m = Sig. 0,000 3–5 vs. 19–24 m = Sig. 0,000 3–5 vs. 25–30 m = Sig. 0,000 3–5 vs. 31–36 m = Sig. 0,000

Table	Groups	Type of test	Statistical test	Outcome
Table 16 Time children spent mouthing toys by gender	Boys Girls	NON-PARA-METRIC	Mann-Whitney	Sig. 0,760
	Boys Girls	NON-PARA-METRIC	Kolmogorov-Smirnov	Sig. 0,601
	Boys Girls	PARA-METRIC	T Student	Sig. 0,445
Table 18 Time children spent mouthing toys by country	Germany France Spain	NON-PARA-METRIC	Kruskal-Wallis	Sig. 0,002
	Germany France Spain	PARA-METRIC	ANOVA Scheffé	Germany – France = Sig. 0,916 Germany – Spain = Sig. 0,030 France – Germany = Sig. 0,916 France – Spain = Sig. 0,010 Spain – Germany = Sig. 0,030 Spain – France = Sig. 0,010
	Germany France Spain	PARA-METRIC	ANOVA Bonferroni	Germany – France = Sig. 1,000 Germany – Spain = Sig. 0,025 France – Germany = Sig. 1,000 France – Spain = Sig. 0,007 Spain – Germany = Sig. 0,025 Spain – France = Sig. 0,007
Table 20 Toy-to-mouth contact duration by age	0 months to 12 months 13 months to 24 months 25 months to 36 months	NON-PARAMETRIC	Kruskal-Wallis	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Scheffé	0 to 12 m – 13 to 24m = Sig. 0,006 0 to 12 m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,006 13 to 24m – 25 to 36m = Sig. 0,494 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 0,494
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Bonferroni	0 to 12m – 13 to 24m = Sig. 0,004 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,004 13 to 24m – 25 to 36m = Sig. 0,707 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 0,707

Table C.6 — Frequency children mouthed toys (lip) – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 22 Frequency children mouthed toys (lip)	0 months to 12 months 13 months to 24 months 25 months to 36 months	NON-PARA-METRIC	Kruskal-Wallis	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARA-METRIC	Mann-Whitney	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARA-METRIC	Kolmogorov-Smirnov	Sig. 0,000
	0 months to 12 months 13 months to 36 months	PARA-METRIC	T Student	Sig. 0,000
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARA-METRIC	ANOVA Scheffé	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,001 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 0,549 25 to 36m – 0 to 12m = Sig. 0,001 25 to 36m – 12 to 24m = Sig. 0,549
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARA-METRIC	ANOVA Bonferroni	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,001 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 0,822 25 to 36m – 0 to 12m = Sig. 0,001 25 to 36m – 13 to 24m = Sig. 0,822
	< 3 months ≥ 3 months and < 6 months ≥ 6 months and < 10 months ≥ 10 months and < 13 months ≥ 13 months and < 19 months ≥ 19 months and < 25 months ≥ 25 months and < 31 months ≥ 31 months and < 37 months	PARA-METRIC	ANOVA Scheffé	3–5 vs. 0–2 m = Sig. 0,000 3–5 vs. 6–9 m = Sig. 0,001 3–5 vs. 10–12 m = Sig. 0,075 3–5 vs. 13–18 m = Sig. 0,000 3–5 vs. 19–24 m = Sig. 0,000 3–5 vs. 25–30 m = Sig. 0,000 3–5 vs. 31–36 m = Sig. 0,000
	< 3 months ≥ 3 months and < 6 months ≥ 6 months and < 10 months ≥ 10 months and < 13 months ≥ 13 months and < 19 months ≥ 19 months and < 25 months ≥ 25 months and < 31 months ≥ 31 months and < 37 months	PARA-METRIC	ANOVA Bonferroni	3–5 vs. 0–2 m = Sig. 0,000 3–5 vs. 6–9 m = Sig. 0,000 3–5 vs. 10–12 m = Sig. 0,010 3–5 vs. 13 – 18 m = Sig. 0,000 3–5 vs. 19 –24 m = Sig. 0,000 3–5 vs. 25 –30 m = Sig. 0,000 3–5 vs. 31 – 36 m = Sig. 0,000

Table C.7 — Frequency children mouthed toys (suck) – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 22 Frequency children mouthed toys (suck)	0 months to 12 months 13 months to 24 months 25 months to 36 months	NON-PARAMETRIC	Kruskal-Wallis	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	0 months to 12 months 13 months to 36 months	PARAMETRIC	T Student	Sig. 0,000
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Scheffé	0 to 12m - 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,001 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 0,701 25 to 36m – 0 to 12m = Sig. 0,001 25 to 36m – 13 to 24m = Sig. 0,701
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Bonferroni	0 to 12m - 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 1,000 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 1,000

Table C.8 — Frequency children mouthed toys (bite) – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 22 Frequency children mouthed toys (bite)	0 months to 12 months 13 months to 24 months 25 months to 36 months	NON-PARAMETRIC	Kruskal-Wallis	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	0 months to 12 months 13 months to 36 months	PARAMETRIC	T Student	Sig. 0,000
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Scheffé	0 to 12m - 13 to 24m = Sig. 0,002 0 to 12m – 25 to 36m = Sig. 0,009 13 to 24m – 0 to 12m = Sig. 0,002 13 to 24m – 25 to 36m = Sig. 0,935 25 to 36m – 0 to 12m = Sig. 0,009 25 to 36m – 13 to 24m = Sig. 0,935
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Bonferroni	0 to 12m - 13 to 24m = Sig. 0,002 0 to 12m – 25 to 36m = Sig. 0,006 13 to 24m – 0 to 12m = Sig. 0,002 13 to 24m – 25 to 36m = Sig. 1,000 25 to 36m – 0 to 12m = Sig. 0,006 25 to 36m – 13 to 24m = Sig. 1,000

Table C.9 — Time children spent mouthing (lip) – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 24 Time children spent mouthing toys (lip)	0 months to 12 months 13 months to 24 months 25 months to 36 months	NON-PARA-METRIC	Kruskal-Wallis	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARA-METRIC	Mann-Whitney	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARA-METRIC	Kolmogorov-Smirnov	Sig. 0,000
	0 months to 12 months 13 months to 36 months	PARA-METRIC	T Student	Sig. 0,000
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARA-METRIC	ANOVA Scheffé	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 0,941 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 0,941
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARA-METRIC	ANOVA Bonferroni	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 1,000 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 1,000
	< 3 months ≥ 3 months and < 6 months ≥ 6 months and < 10 months ≥ 10 months and < 13 months ≥ 13 months and < 19 months ≥ 19 months and < 25 months ≥ 25 months and < 31 months ≥ 31 months and < 37 months	PARA-METRIC	ANOVA Scheffé	3–5 vs. 0–2m = Sig. 0,000 3–5 vs. 6–9m = Sig. 0,000 3–5 vs. 10–12m = Sig. 0,000 3–5 vs. 13–18m = Sig. 0,000 3–5 vs. 19–24m = Sig. 0,000 3–5 vs. 25–30m = Sig. 0,000 3–5 vs. 31–36m = Sig. 0,000
	< 3 months ≥ 3 months and < 6 months ≥ 6 months and < 10 months ≥ 10 months and < 13 months 13 months to 18 months ≥ 19 months and < 25 months ≥ 25 months and < 31 months ≥ 31 months and < 37 months	PARA-METRIC	ANOVA Bonferroni	3–5 vs. 0–2m = Sig. 0,000 3–5 vs. 6–9m = Sig. 0,000 3–5 vs. 10–12m = Sig. 0,000 3–5 vs. 13–18m = Sig. 0,000 3–5 vs. 19–24m = Sig. 0,000 3–5 vs. 25–30m = Sig. 0,000 3–5 vs. 31–36m = Sig. 0,000

Table C.10 — Time children spent mouthing (suck) – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 24 Time children spent mouthing toys (suck)	0 months to 12 months 13 months to 24 months 25 months to 36 months	NON-PARAMETRIC	Kruskal-Wallis	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	0 months to 12 months 13 months to 36 months	PARAMETRIC	T Student	Sig. 0,000
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Scheffé	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 0,944 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 0,944
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Bonferroni	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 1,000 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 1,000

Table C.11 — Time children spent mouthing (bite) – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 24 Time children spent mouthing toys (bite)	0 months to 12 months 13 months to 24 months 25 months to 36 months	NON-PARAMETRIC	Kruskal-Wallis	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	0 months to 12 months 13 months to 36 months	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	0 months to 12 months 13 months to 36 months	PARAMETRIC	T Student	Sig. 0,000
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Scheffé	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 0,902 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 0,902
	0 months to 12 months 13 months to 24 months 25 months to 36 months	PARAMETRIC	ANOVA Bonferroni	0 to 12m – 13 to 24m = Sig. 0,000 0 to 12m – 25 to 36m = Sig. 0,000 13 to 24m – 0 to 12m = Sig. 0,000 13 to 24m – 25 to 36m = Sig. 1,000 25 to 36m – 0 to 12m = Sig. 0,000 25 to 36m – 13 to 24m = Sig. 1,000

Table C.12 — Frequency children mouthed toys by material – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Tables 26 and 27 Frequency children mouthed toys by material	Elastomeric Not Elastomeric	NON-PARAMETRIC	Mann-Whitney	Sig. 0,008
	Elastomeric Not Elastomeric	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,003
	Elastomeric Not Elastomeric	PARAMETRIC	T Student	Sig. 0,001
	Elastomeric 0 to 12m Not Elastomeric 0 to 12m	NON-PARAMETRIC	Mann-Whitney	Sig. 0,001
	Elastomeric 0 to 12m Not Elastomeric 0 to 12m	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,001
	Elastomeric 0 to 12m Not Elastomeric 0 to 12m	PARAMETRIC	T Student	Sig. 009
	Elastomeric 13 to 36m Not Elastomeric 0 to 13m	NON-PARAMETRIC	Mann-Whitney	Sig. 0,161
	Elastomeric 13 to 36m Not Elastomeric 0 to 13m	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,016
	Elastomeric 13 to 36m Not Elastomeric 0 to 13m	PARAMETRIC	T Student	Sig. 0,830

Table C.13 — Time children spent mouthing toys by material – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Tables 28 and 29 Time children spent mouthing by material	Elastomeric Not Elastomeric	NON-PARAMETRIC	Mann-Whitney	Sig. 0,001
	Elastomeric Not Elastomeric	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	Elastomeric Not Elastomeric	PARAMETRIC	T Student	Sig. 0,000
	Elastomeric 0 to 12m Not Elastomeric 0 to 12m	NON-PARAMETRIC	Mann-Whitney	Sig. 0,03
	Elastomeric 0 to 12m Not Elastomeric 0 to 12m	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,011
	Elastomeric 0 to 12m Not Elastomeric 0 to 12m	PARAMETRIC	T Student	Sig. 0,005
	Elastomeric 13 to 36m Not Elastomeric 0 to 13m	NON-PARAMETRIC	Mann-Whitney	Sig. 0,241
	Elastomeric 13 to 36m Not Elastomeric 0 to 13m	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,006
	Elastomeric 13 to 36m Not Elastomeric 0 to 13m	PARAMETRIC	T Student	Sig. 0,607

Table C.14 — Toy-to-mouth contact duration by material – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Tables 30 and 31 Toy-to-mouth contact duration by material	Elastomeric Not Elastomeric	NON-PARAMETRIC	Mann-Whitney	Sig. 0,001
	Elastomeric Not Elastomeric	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,008
	Elastomeric Not Elastomeric	PARAMETRIC	T Student	Sig. 0,042
	Elastomeric 0 to 12 month Not Elastomeric 0 to 12 months	NON-PARAMETRIC	Mann-Whitney	Sig. 0,213
	Elastomeric 0 to 12 month Not Elastomeric 0 to 12 months	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,256
	Elastomeric 0 to 12 month Not Elastomeric 0 to 12 months	PARAMETRIC	T Student	Sig. 0,822

Table C.15 — Frequency children mouthed toys intended vs not intended to be mouthed – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Tables 32 and 33 Frequency children mouthed toys intended vs not intended to be mouthed	Intended Not intended	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	Intended Not intended	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	Intended Not intended	PARAMETRIC	T Student	Sig. 0,000
	Intended 0 to 12m Not Intended 0 to 12m	NON-PARAMETRIC	Mann-Whitney	Sig. 0,130
	Intended 0 to 12m Not Intended 0 to 12 m	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,129
	Intended 0 to 12m Not Intended 0 to 12m	PARAMETRIC	T Student	Sig. 0,030
	Intended 13 to 36m Not Intended 13 to 36m	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	Intended 13 to 36m Not Intended 13 to 36m	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	Intended 13 to 36m Not Intended 13 to 36m	PARAMETRIC	T Student	Sig. 0,000

Table C.16 — Time children spent mouthing toys intended vs not intended to be mouthed – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Tables 34 and 35 Time children spent mouthing toys intended vs not intended to be mouthed	Intended Not intended	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	Intended Not intended	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,000
	Intended Not intended	PARAMETRIC	T Student	Sig. 0,000
	Intended 0 to 12m Not Intended 0 to 12m	NON-PARAMETRIC	Mann-Whitney	Sig. 0,071
	Intended 0 to 12m Not Intended 0 to 12 m	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,069
	Intended 0 to 12m Not Intended 0 to 12m	PARAMETRIC	T Student	Sig. 0,036
	Intended 13 to 36m Not Intended 13 to 36m	NON-PARAMETRIC	Mann-Whitney	Sig. 0,000
	Intended 13 to 36m Not Intended 13 to 36m	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,001
	Intended 13 to 36m Not Intended 13 to 36m	PARAMETRIC	T Student	Sig. 0,009

Table C.17 — Toy-to-mouth contact for toys intended vs not intended to be mouthed – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 35 Toy-to-mouth contact for toys intended vs not intended to be mouthed	Intended Not intended	NON-PARAMETRIC	Mann-Whitney	Sig. 0,738
	Intended Not intended	NON-PARAMETRIC	Kolmogorov-Smirnov	Sig. 0,922
	Intended Not intended	PARAMETRIC	T Student	Sig. 0,531

Table C.18 — Frequency children mouthed toys by toy category – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 37 Frequency children mouthed toys by toy category	1. Push-along toys, pull-along toys and walking aids 2. Dolls and soft filled toys 3. Role-playing toys (foodstuffs included) 4. Toys for babies, for looking at, grasping and/or squeezing 5. Books with play value and bath books 6. Audio/visual equipment 7. Construction toys and puzzles 8. Mechanically and/or electrically driven 9. Play scenes and constructed models 10. Sand-water and bath toys 11. Toy musical instruments 12. Toy sports equipment and balls 13. Toys intended to bear the mass of a child	NON-PARAMETRIC	Kruskal-Wallis	Sig. 0,000
		PARAMETRIC	ANOVA (Scheffé)	4 vs. 1 Sig. 0,066 4 vs. 2 Sig. 0,002 4 vs. 3 Sig. 0,010 4 vs. 5 Sig. 0,972 4 vs. 6 Sig. 0,971 4 vs. 7 Sig. 0,012 4 vs. 8 Sig. 0,016 4 vs. 9 Sig. 0,000 4 vs. 10 Sig. 1,000 4 vs. 11 Sig. 0,996 4 vs. 12 Sig. 0,005 4 vs. 13 Sig. 0,003 10 vs. 1 Sig. 0,267 10 vs. 2 Sig. 0,082 10 vs. 3 Sig. 0,383 10 vs. 4 Sig. 1,000 10 vs. 5 Sig. 0,997 10 vs. 6 Sig. 0,990 10 vs. 7 Sig. 0,220 10 vs. 8 Sig. 0,110 10 vs. 9 Sig. 0,023 10 vs. 11 Sig. 1,000 10 vs. 12 Sig. 0,102 10 vs. 13 Sig. 0,038
		PARAMETRIC	ANOVA (Bonferroni)	4 vs. 1 Sig. 0,001 4 vs. 2 Sig. 0,000 4 vs. 3 Sig. 0,000 4 vs. 5 Sig. 1,000 4 vs. 6 Sig. 1,000 4 vs. 7 Sig. 0,000 4 vs. 8 Sig. 0,000 4 vs. 9 Sig. 0,000 4 vs. 10 Sig. 1,000 4 vs. 11 Sig. 1,000 4 vs. 12 Sig. 0,000 4 vs. 13 Sig. 0,000 10 vs. 1 Sig. 0,011 10 vs. 2 Sig. 0,001 10 vs. 3 Sig. 0,028 10 vs. 4 Sig. 1,000 10 vs. 5 Sig. 1,000 10 vs. 6 Sig. 1,000 10 vs. 7 Sig. 0,007 10 vs. 8 Sig. 0,002 10 vs. 9 Sig. 0,000 10 vs. 11 Sig. 1,000 10 vs. 12 Sig. 0,001 10 vs. 13 Sig. 0,000

Table C.19 — Time children spent mouthing toys by toy category – Significance test

Table	Groups	Type of test	Statistical test	Outcome
Table 38 Time children spent mouthing toys by toy category	1. Push-along toys, pull-along toys and walking aids 2. Dolls and soft filled toys 3. Role-playing toys (foodstuffs included) 4. Toys for babies, for looking at, grasping and/or squeezing 5. Books with play value and bath books 6. Audio/visual equipment 7. Construction toys and puzzles 8. Mechanically and/or electrically driven 9. Play scenes and constructed models 10. Sand-water and bath toys 11. Toy musical instruments 12. Toy sports equipment and balls 13. Toys intended to bear the mass of a child	NON-PARAMETRIC	Kruskal-Wallis	Sig. 0,000
		PARAMETRIC	ANOVA (Scheffé)	4 vs. 1 Sig. 0,003 4 vs. 2 Sig. 0,000 4 vs. 3 Sig. 0,000 4 vs. 5 Sig. 0,595 4 vs. 6 Sig. 0,257 4 vs. 7 Sig. 0,001 4 vs. 8 Sig. 0,002 4 vs. 9 Sig. 0,000 4 vs. 10 Sig. 1,000 4 vs. 11 Sig. 0,071 4 vs. 12 Sig. 0,000 4 vs. 13 Sig. 0,000 10 vs. 1 Sig. 0,065 10 vs. 2 Sig. 0,003 10 vs. 3 Sig. 0,000 10 vs. 4 Sig. 1,000 10 vs. 5 Sig. 0,950 10 vs. 6 Sig. 0,813 10 vs. 7 Sig. 0,136 10 vs. 8 Sig. 0,058 10 vs. 9 Sig. 0,001 10 vs. 11 Sig. 0,395 10 vs. 12 Sig. 0,021 10 vs. 13 Sig. 0,003
		PARAMETRIC	ANOVA (Bonferroni)	4 vs. 1 Sig. 0,000 4 vs. 2 Sig. 0,000 4 vs. 3 Sig. 0,000 4 vs. 5 Sig. 0,112 4 vs. 6 Sig. 0,010 4 vs. 7 Sig. 0,000 4 vs. 8 Sig. 0,000 4 vs. 9 Sig. 0,000 4 vs. 10 Sig. 1,000 4 vs. 11 Sig. 0,001 4 vs. 12 Sig. 0,000 4 vs. 13 Sig. 0,000 10 vs. 1 Sig. 0,001 10 vs. 2 Sig. 0,000 10 vs. 3 Sig. 0,000 10 vs. 4 Sig. 1,000 10 vs. 5 Sig. 1,000 10 vs. 6 Sig. 0,462 10 vs. 7 Sig. 0,003 10 vs. 8 Sig. 0,001 10 vs. 9 Sig. 0,000 10 vs. 11 Sig. 0,031 10 vs. 12 Sig. 0,000 10 vs. 13 Sig. 0,000

C.3 Mean weighted by year

C.3.1 Frequency children mouthed toys

Table C.20 — Frequency children mouthed toys (per hour) by age

Age groups	Mean
0 to 12 months	44
13 to 24 months	15
25 to 36 months	19
Mean weighted by year	26
Age groups	**Mean**
0 to 12 months	44
13 to 36 months	17

Table C.21 — Frequency children mouthed toys (per hour) by gender and age

Age groups	Mean	Boys	Girls
0 to 12 months	44	47	42
13 to 24 months	15	18	13
25 to 36 months	19	19	19
Mean weighted by year	26	28	24
Age groups	**Mean**	**Boys**	**Girls**
0 to 12 months	44	47	42
13 to 36 months	17	18	16

Table C.22 — Frequency children mouthed toys (per hour) by country and age

Age groups	Mean	Germany	France	Spain
0 to 12 months	44	33	45	57
13 to 24 months	15	22	14	10
25 to 36 months	19	19	22	15
Mean weighted by year	26	24	27	27
Age groups	**Mean**	**Germany**	**France**	**Spain**
0 to 12 months	44	33	45	57
13 to 36 months	17	20	18	12

C.3.2 Time children spent mouthing toys

Table C.23 — Time children spent mouthing by age

Age groups	Mean
0 to 12 months	23,4 %
13 to 24 months	6,0 %
25 to 36 months	5,9 %
Mean weighted by year	11,7 %
Age groups	**Mean**
0 to 12 months	23,4 %
13 to 36 months	5,9 %

Table C.24 — Time children spent mouthing by gender and age

Age groups	Mean	Boys	Girls
0 to 12 months	23,4 %	25,9 %	21,2 %
13 to 24 months	6,0 %	6,7 %	5,3 %
25 to 36 months	5,9 %	4,6 %	7,2 %
Mean weighted by year	11,7 %	12,4 %	11,2 %
Age groups	**Mean**	**Boys**	**Girls**
0 to 12 months	23,4 %	25,9 %	21,2 %
13 to 36 months	5,9 %	5,6 %	6,3 %

Table C.25 — Time children spent mouthing by country and age

Age groups	Mean	Germany	France	Spain
0 to 12 months	23,4 %	24,7 %	28,6 %	17,1 %
13 to 24 months	6,0 %	8,1 %	7,1 %	2,9 %
25 to 36 months	5,9 %	7,8 %	7,2 %	2,8 %
Mean weighted by year	11,7 %	13,5 %	14,3 %	7,6 %
Age groups	**Mean**	**Germany**	**France**	**Spain**
0 to 12 months	23,4 %	24,7 %	28,6 %	17,1 %
13 to 36 months	5,9 %	7,9 %	7,1 %	2,8 %

Table C.26 — Toy-to-mouth contact duration by age

Age groups	Mean
0 to 12 months	24,9 s
13 to 24 months	15,6 s
25 to 36 months	11,6 s
Mean weighted by year	17,3 s
Age groups	**Mean**
0 to 12 months	24,9 s
13 to 36 months	13,6 s

C.3.3 Type of mouthing: lip/tongue, suck/engulf, bite/chew

Table C.27 — Frequency children mouthed toys by type of mouthing and age

Age groups	Mean	Lip	Suck	Bite
0 to 12 months	44	37	30	28
13 to 24 months	15	11	8	11
25 to 36 months	19	15	11	11
Mean weighted by year	26	21	16	17
Age groups	**Mean**	**Lip**	**Suck**	**Bite**
0 to 12 months	44	37	30	28
13 to 36 months	17	13	9	11

Table C.28 — Time children spent mouthing toys by type of mouthing and age

Age groups	Mean	Lip	Suck	Bite
0 to 12 months	23,4 %	19,2 %	17,5 %	14,6 %
13 to 24 months	6,0 %	4,0 %	3,0 %	4,7 %
25 to 36 months	5,9 %	4,8 %	3,8 %	3,7 %
Mean weighted by year	11,7 %	9,3 %	8,1 %	7,6 %
Age groups	**Mean**	**Lip**	**Suck**	**Bite**
0 to 12 months	23,4 %	19,2 %	17,5 %	14,6 %
13 to 36 months	5,9 %	4,4 %	3,4 %	4,2 %

C.3.4 Elastomeric vs not elastomeric material

Table C.29 — Frequency children mouthed toys (per hour) by material and age

Age groups	Elastomeric	Not Elastomeric
0 to 12 months	46	35
13 to 24 months	17	12
25 to 36 months	15	20
Mean weighted by year	26	22
Age groups	**Elastomeric**	**Not Elastomeric**
0 to 12 months	46	35
13 to 36 months	16	16

Table C.30 — Time children spent mouthing toys by material and age

Age groups	Elastomeric	Not Elastomeric
0 to 12 months	24,6 %	18,1 %
13 to 24 months	7,8 %	4,8 %
25 to 36 months	4,7 %	6,3 %
Mean weighted by year	12,4 %	9,7 %
Age groups	**Elastomeric**	**Not Elastomeric**
0 to 12 months	24,6 %	18,1 %
13 to 36 months	6,2 %	5,5 %

Table C.31 — Toy-to-mouth contact duration by material and age

Age groups	Elastomeric	Not Elastomeric
0 to 12 months	24,9	23,6
13 to 24 months	19,5	15,2
25 to 36 months	12,2	11,7
Mean weighted by year	18,8	16,8
Age groups	**Elastomeric**	**Not Elastomeric**
0 to 12 months	24,9	23,6
13 to 36 months	15,8	13,4

C.3.5 Toys intended vs not intended to be mouthed

Table C.32 — Frequency children mouthed toys intended vs not intended to be mouthed (per hour) by age

Age groups	Intended	Not Intended
0 to 12 months	48	42
13 to 24 months	19	15
25 to 36 months	33	9
Mean weighted by year	33	22
Age groups	**Intended**	**Not Intended**
0 to 12 months	48	42
13 to 36 months	26	12

Table C.33 — Time children spent mouthing toys intended vs not intended to be mouthed by age

Age groups	Intended	Not Intended
0 to 12 months	25,4 %	23,3 %
13 to 24 months	7,3 %	6,2 %
25 to 36 months	9,0 %	3,5 %
Mean weighted by year	13,9 %	11,0 %
Age groups	**Intended**	**Not Intended**
0 to 12 months	25,4 %	23,3 %
13 to 36 months	8,2 %	4,8 %

Table C.34 — Toy-to-mouth contact for toys intended vs not intended to be mouthed by age

Age groups	Intended	Not Intended
0 to 12 months	26,0	24,5
13 to 24 months	14,9	16,8
25 to 36 months	11,2	11,6
Mean weighted by year	17,4	17,6
Age groups	**Intended**	**Not Intended**
0 to 12 months	26,0	24,5
13 to 36 months	13,0	14,2

C.4 Observational periods

To ensure the quality of the results of the parental observation, the observations were broken down into the following periods:

— Child wakes up to 12:00

— 12:01 to 18:00

— 18:01 to child goes to bed

The initial objective was to record the same amount of observations in each period. However, the differences between timetables in the different countries (especially between the times when children are in contact with toys at home in France and Spain) observed during the pilot test, complicated this objective, as it would have involved forcing parents to alter their normal routines. For this reason, priority was given to children playing in the most natural environment.

Another aspect considered was that children have their own short cycles of alertness during the day, especially during the first year of life, and these children were the age group with the greatest presence in previous literature on mouthing behaviour. For example a common cycle for children aged between ≥ 3 months and < 6 months over a three-hour period is: eat (for 20 min to 30 min), fall asleep (for 30 min to 60 min), then they become active (for 90 min to 130 min).

For all these reasons and in order to ensure the quality of the data, parents were instructed to carry out the observation when their children were alert, active and concentrated, avoiding times of day when they were becoming sleepy, after feeding, etc. Finally, the observations were classified into the 3 time periods already mentioned.

45 % of the observations were made between 18:01 until the child went to bed / 27 % observed children between 12:01 to 18:00 / 28 % between the time the child woke up until 12:00. These periods were the times of day when the parents were available to watch their children playing, for this reason they could not be performed equally (i.e. it was not possible to have exactly a third of the observations in each period). However, it does at least provide data for the 3 different times of day, in order to evaluate differences.

A Kruskal-Wallis test showed no significant differences in observed mouthing behaviour (time and frequency) between these 3 observational periods. This result is in line with previous literature. Norris and Smith (2002) [8] also made a Kruskal-Wallis analysis, and their test revealed no significant differences in observed mouthing behaviour between the different times of the day that children were observed.

Table C.35 — Normal distribution test

Classification variable	Quantitative variable	Statistical test	Outcome
Frequency children mouthed toys	Observational periods	Kolmogorov-Smirnov	Woke up - 12:00 Sig. 0,000 12:01 - 18:00 Sig. 0,000 18:01 - bed Sig. 0,000
		Shapiro-Wilk	Woke up - 12:00 Sig. 0,000 12:01 - 18:00 Sig. 0,000 18:01 - bed Sig. 0,000
Time children spent mouthing toys	Observational periods	Kolmogorov-Smirnov	Woke up - 12:00 Sig. 0,000 12:01 - 18:00 Sig. 0,000 18:01 - bed Sig. 0,000
		Shapiro-Wilk	Woke up - 12:00 Sig. 0,000 12:01 - 18:00 Sig. 0,000 18:01 - bed Sig. 0,000

Table C.36 — Significance test

Classification variable	Quantitative variable	Statistical test	Outcome
Frequency children mouthed toys	Observational periods	Kruskal-Wallis	Sig. 0,743
Time children spent mouthing toys	Observational periods	Kruskal-Wallis	Sig. 0,825

Table C.37 — Sample observations distribution

Observational periods	Total sample	Germany	France	Spain
Woke up - 12:00	28,1 %	39,7 %	24,4 %	20,5 %
12:01 - 18:00	27 %	30,9 %	25,1 %	25,0 %
18:01 - bed	44,9 %	29,3 %	50,5 %	54,5 %

Table C.38 — Results

Observational periods	% of observation	Frequency children mouthed toys	Time children spent mouthing toys
Woke up - 12:00	28,1 %	31	14,6 %
12:01 - 18:00	27 %	29	16,0 %
18:01 - bed	44,9 %	30	14,1 %
Total Sample	100 %	30	14,7 %

Annex D
(informative)

Glossary of terms and definitions

Bite marks left on toys: The percentage of toys that children left bite marks on.

Daily time available to mouth: The average time children spent each day neither eating nor sleeping.

Degree of salivation: Salivation is a term that describes the secretion of saliva, especially in anticipation of food. In little children this is very common when they mouth their hands or an object, such as a toy. This study considered 3 degrees of salivation, as perceived by parents.

— Low salivation: Slight amount of saliva observed on the toy, but not on the child's lips.

— Medium salivation: Saliva present and observed directly on the child's lips

— High salivation: Saliva present on the lips and dribbling.

Elastomer/Elastomeric material: A natural or synthetic rubber or rubberoid material, which has the ability to undergo deformation under the influence of a force and regain its original shape once the force has been removed. In the present study, a toy is considered as being elastomeric when either the whole toy or one of its parts is made of elastomeric material.

EPA: United States Environmental Protection Agency.

Ethnographic study: Ethnography is the systematic study of people and cultures. Data collection methods are meant to capture the "social meanings and ordinary activities" of people (respondents) in "naturally occurring settings". The goal is to collect data in such a way that the researcher imposes a minimal amount of personal bias on the data. In the case of this research, the study was a parental observation of their children's usual activities in a whole week, taking into account working as well as non-working days, in order to determine the number of minutes/hours that a child can be in contact with toys per day, neither sleeping nor eating.

FAQ: Frequently asked questions.

Free play: The unrestricted activity of play. This term refers to the activity of playing with toys spontaneously at home, without children being forced to play with or directed to use these toys.

Frequency of mouthing: The number of times a child mouthed an item. Measured by the number of contacts per hour.

Home environment: Activities carried out at home. This refers to indoor parental observation.

Intended to be mouthed: Articles designed with the clear intention that users introduce the product into their mouths, either wholly or partly. In this study, it refers to toys that are intended to be mouthed: teethers, toy foodstuffs, musical microphones, toys that represent phones.

Mouthing behaviour: Mouthing is the behaviour of putting something into the mouth, or touching with the mouth; it is usually used in reference to puppies or little children. Mouthing behaviour generally includes all activities in which objects or hands are inserted into or touched by the mouth, with the exception of eating or drinking (Groot et al., 1998 [2]). In this study, mouthing contact was defined as any contact with the lips, inside of the mouth, and/or the tongue. See "Types of mouthing".

Observational tool: A tool is a device or implement used to carry out a particular function. In this study, the function was to help parents to carry out the observation of mouthing behaviour and thus obtain ethnographic data. In this case, the tool was an app for smartphones/tablets that included

questionnaires, a clock, images of toys, instructions, etc. It allowed observational data to be made in real time.

Parental observation: Observation (behaviour analysis) parents made of their children.

Pilot test: Also called pilot study or pilot experiment, is a small-scale preliminary study conducted in order to evaluate feasibility, time, cost and possible adverse events in an attempt to predict some problems and improve upon the design of the study prior to performing a full-scale research project. It was carried out with a preliminary sample of 8 families, in order to ensure that the protocols, methodology and data collection system were appropriate to the objectives.

Teething: Is the process by which an infant's first teeth (the deciduous teeth, often called “baby teeth” or “milk teeth”) sequentially appear by emerging through the gums.

Time available to mouth per day: The time available for mouthing over the whole day, or the time per day in contact with toys.

Time spent mouthing: The percentage of time children mouthed an item in the total time observed. Sometimes this concept refers to the amount of time children spent mouthing a toy, per day or per hour.

Total time observed: The total amount of time that children were observed in the study (511,8 h).

Toy-to-mouth contact duration: The number of seconds in each mouthing action.

Training sessions: Sessions to teach the participating family member (father or mother) how to perform the observation, in order to ensure that the process was exactly the same in all families.

Type of mouthing: The present study defined 3 types of mouthing behaviour, which were explained to the family participants in order to classify their observations:

Licking/lip-touching: This is where an item touches the front of the mouth, without actually entering into the mouth itself. The child may be licking the object, or touching the object to their lips or tongue.

Sucking/trying to bite: The item is put directly into the child's mouth. The child may be sucking, holding the object in their mouth or trying to bite (gumming) the object.

Biting/chewing: The item is directly inside the child's mouth. It is clear that the child is biting it or chewing on it.

Videotaping/videorecording: Converted into a permanent format for subsequent reproduction or broadcast. The action of recording and subsequently reproducing visual images of children's mouthing behaviour.

Working day: Every official working day of the week. Typically, these are the days between Monday and Friday, both inclusive, not including public holidays and weekends.

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