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Consumption and exposure assessment to sunscreen products: A key point for safety assessment

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1. Introduction

The sun is the principal source of exposure to ultraviolet (UV) radiation. Although the sun is necessary for life, too much exposure to solar ultraviolet radiation has important public health implications. Evidence of harm associated with overexposure to UV radiation has been demonstrated in many studies. Sunburn (erythema) is a sign of short-term overexposure, while premature aging, suppression of immune responses, eye cancer and skin cancer are side effects of prolonged UV exposure (FDA, 2015; IARC, 1992; Sample and He, 2017; WHO, 2006). Furthermore, UV radiation is the main cause of skin cancer development (Reichrath and Rass, 2014; US EPA, 2010).

The use of sunscreen products is one of several ways to protect the skin from the harmful effects of UV radiation. Sunscreen protection is expressed by the sun protection factor (SPF), the UVA-Protection Factor (UVA-PF) and the critical wavelength. The SPF can be defined as the numerical ratio between the minimal erythemal dose with photoprotection and the minimal erythemal dose without photoprotection (ISO 24444:2010; Petersen and Wulf, 2014). SPF is equivalent to a standardized degree of protection against UVB radiation: “low protection” (SPF equal to 6 or 10), “medium protection” (SPF equal to 15, 20 or 25), “high protection” (SPF equal to 30 or 50) and “very high protection” for a labelled SPF equal to 50+ (EU, 2006). The UVA-PF is calculated as the ratio of the Minimal Persistent Pigment Darkening Dose (MPPDD) on product-protected skin to the MPPDD on unprotected skin (ISO 24442:2011). The critical wavelength is defined as the point where 90% of the area of UV radiation is absorbed or reflected by the sunscreen product. According to the EU Commission recommendations on the efficacy of sunscreen products, the UVA-PF have to represent at least 1/3 of the SPF value and the critical wavelength at least 370. *In vivo* determination of the SPF and the UVA-PF is performed using a quantity of 2 mg/cm^2 nm (European Commission, 2006). However, a literature has demonstrated that this amount was rarely respected under natural conditions (Petersen and Wulf, 2014).

Sunscreens are cosmetic products according to the European Regulation (EC) No 1223/2009. As mentioned in the European Regulation, cosmetic products available on the market must be safe for human health when used under normal or reasonably foreseeable conditions. In order to perform a safety evaluation, exposure data to the finished cosmetic product is required (EU, 2009). Exposure (mg/kg bw/day) can be determined by dividing the daily consumption of a finished product by the body weight of the studied population. Exposure data to the finished product is essential for determining the systemic exposure dose (SED) for each ingredient found in the product. This SED value is then used for the calculation of margin of safety (MoS) (SCCS, 2016).

The Scientific Committee on Cosmetic Products and Non-Food Products intended for Consumers (SCCNFP) suggested a consumption value of 18 g per day for sunscreen product in the calculation of the MoS. However, this single value was proposed only for adult consumers who used sunscreen product on the whole body, and no data was

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mentioned for children (SCCNFP, 2003). Few other consumption and/or exposure data is available for sunscreen products. Biesterbos et al. (2013) assessed the consumption of sunscreen and after-sun products by Dutch adults. Consumption of sunscreen and after-sun products was assessed in French children and adults; exposure was evaluated in babies aged 0-3 (Ficheux et al., 2015, 2016a and 2016b). Lee et al. (2017) assessed the consumption and the exposure of sunscreen product depending on season in Korean babies aged 0-36 months.

In a previous work, we studied the consumption and the exposure to sunscreen products in adults and in children. The consumption data were obtained from clinical safety studies carried out according to a specific protocol. Therefore, these previous studies could not fully reflect the real use of the products (Gomez-Berrada et al., 2017). Thus, the aim of the present study was to assess the consumption and the exposure of French consumers to sunscreen product, leaving the consumers free to use the cosmetic product according to their habits during the summer holidays. Consumption and exposure were assessed by sex and by age.

2. Material and methods

Two consumption studies were conducted. A schematic representation of the protocol was presented in Fig. 1.

2.1. Preliminary web-based questionnaire

2.1.1. Study design

The aim of the survey was to collect general information on usage patterns of sunscreen products by French families. The enquiry was made among families composed of adults living as a couple and having children. Families were members of a panel of consumers. 567 adult panel members from different families were invited to complete a web-based questionnaire for their entire household. For example, if a woman was interviewed, she answered the questionnaire for her consumption, for the consumption of her partner/husband and for the consumption of her child (ren) (only one response was permitted for all children in the household).

Questions were related to the usage patterns of sunscreen products during holidays out of home such as the percentage of users, the duration of holidays, the usual type of sunscreen products according to the SPF (≤ 20, 30-40 and ≥ 50) and according to the galenic form (spray, cream, milk or oil), and the usual application area (face and/or body).

Respondents resided in the Northwest of France in the city of Rennes and surrounding area. The questionnaire was conducted in March 2014.

2.1.2. Data analysis

Usage pattern data were presented as percentages for adult men, for adult women and for children.

2.2. Real-life conditions study

2.2.1. Study design

The aim of the study was to assess the real consumption of French families to sunscreens. Families were selected according to their answers previously obtained in the web-based questionnaire (section 2.1.1). The first inclusion criterion was the regular use of a high protection sunscreen product in a pump spray form. The others inclusion criteria were as follow:

- Between 1 and 3 children with an age ranging from 3 to 13 per

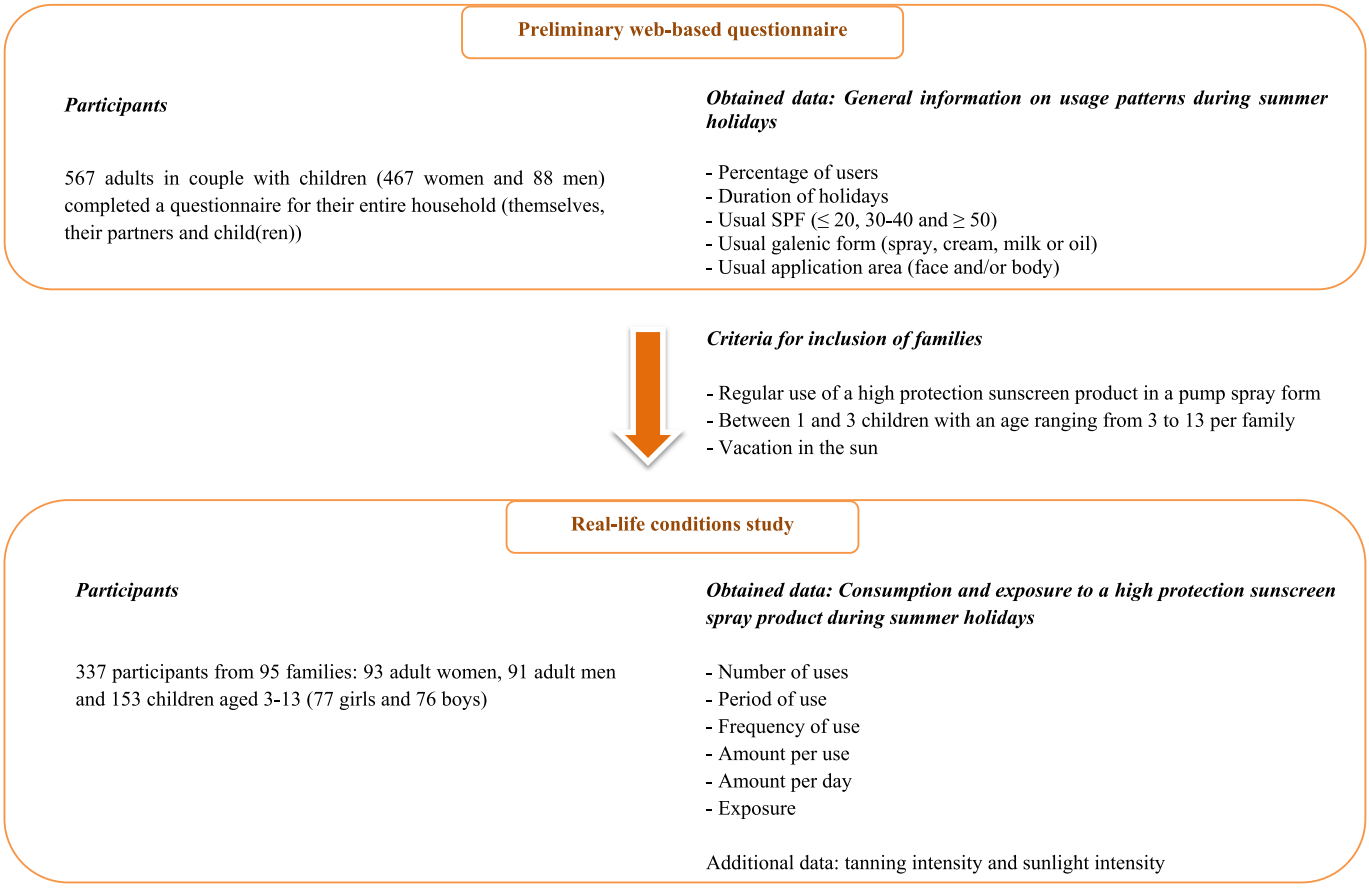

Fig. 1. Schematic representation of the study protocol: number of participants and generated data.

Table 1
Body weight parameters used in exposure assessment.

	Body weight parameters (kg bw)			Mean	Standard deviation	Reference
	French population	Number of data	Distribution type			
Boys	Boys aged 3-13	1226	Lognormal	29.2	13.1	Ficheux et al., 2015 and 2016c
Girls	Girls aged 3-13	1161	Lognormal	28.3	12.6	
Adult women	Women ≥ 15	6881	Lognormal	64.0	12.1	
Adult men	Men ≥ 15	6699	Lognormal	78.6	13.8	

Literature data were used in this study for body weight parameter (Ficheux et al., 2015 and 2016c).
Example: For boys, body weight data obtained from 1226 French boys aged 3-13 were adjusted to a Lognormal distribution, with a mean distribution value equal to 29.2 kg bw and a standard deviation equal to 13.1 kg bw.

family;
- Vacation in the sun

The exclusion criteria were drug, food or cosmetic product allergies, skin diseases, serious medical condition, pregnancy and breast-feeding. Based on these criteria, 95 out of the 567 families were included in this study.

All volunteers signed a study information form and a volunteer consent form. A SPF 50 face and body sunscreen pump spray was provided to each member of the 95 families. Participants were invited to use the product in the closest possible way to their personal usage patterns during summer holidays 2014.

Volunteers were asked to record in a diary the daily usage of sunscreen spray during holidays. Adults filled information for their children. At the end of holidays, the participants returned the completed diaries and the tested products. The diaries were reviewed and checked to ensure they were correctly and completely filled out. All the cosmetic products were weighed with a precision balance with sensitivity equal to 10 mg at the beginning and at the end of the study to determine the individual total amount of product used.

At the end of this study, families were asked to complete a questionnaire about the circumstances of the product use during their holidays, especially about the intensity of tanning before the first use (not tanned, slightly tanned or tanned) and the sunlight intensity when the participants applied the product (low, moderate, strong and very strong).

2.2.2. Consumption data analysis

Consumption parameters (number of uses, period of use, frequency of use, amount per use and amount per day) were analysed according to gender in adults and children only in consumers. Mean, standard deviation, and median values were calculated using Microsoft Excel 2010 Software. 90th and 95th percentile values were also presented when the number of data was sufficient.

- *Period of use:* The period of use corresponded to the number of days during which the product was applied at least once (day).
- *Number of uses:* The number of sunscreen spray uses was obtained depending of the body surface area (face and body, face only and body only) (without unit).
- *Frequency of use:* The frequency of use was calculated by dividing the total number of use by the period of use (day^{-1}).
- *Amount per use:* The amount of product per use was obtained by dividing the total amount of sunscreen spray consumed during holidays by the total number of use (g/use).
- *Amount per day*: The amount of cosmetic product used per day was calculated by dividing the total amount of product used during holidays by the period of use (g/day).

Statistical analysis was performed on the five consumption parameters. A Mann-Whitney test was conducted between girls and boys, and between women and men. A Mann-Whitney test was also performed on data collected for children and adults. Only p-values less than 0.05 were considered to be significant.

Consumption parameter previously obtained (period of use, number of uses, frequency of use, amount per use and amount per day) were analysed according to tanning intensity and sunlight intensity. Data were analysed by sex in adults and regardless of sex in children. Only p-values less than 0.05 were considered to be significant.

- *Tanning intensity:* A Kruskal-Wallis test was performed on consumption data obtained for people not tanned, slightly tanned and tanned before the first use of sunscreen spray.
- *Sunlight intensity:* the response modalities were grouped into two categories: low (including “low” and “moderate” responses) and strong (including “strong” and “very strong” responses). A Mann-Whitney test was conducted between consumption data obtained in low and strong sunlight intensity categories.

2.2.3. Exposure assessment

The cutaneous exposure to sunscreen spray was assessed only in consumers using the following equation:

$$Exposure\ (mg/kgbw/day) = (AD \times 1000 \times RF)/BW$$

AD: Amount per day (g/day), RF: Retention factor and BW: body weight (kg bw).

Amount per day data were obtained as described in section 2.2. Sunscreen spray was a leave-on product. Consequently, a retention factor equal to 1 was applied. As the body weight of each participant was not available, literature data were used for the assessment of exposure by unit of weight. Body weight data obtained on 2387 French children aged 3-13 and 13 580 French adults (≥15 years old) were used (See Ficheux et al., 2015 and 2016c for more details concerning the data collection). Body weight distribution parameters were presented in Table 1.

Amount per day and body weight values were adjusted to the theoretical distribution with the chi-squared goodness of fit test using the @risk 7.5 software (Palisade Corp.). The probabilistic exposure assessment was performed using Monte Carlo random simulations (@risk 7.5 software). The exposure distributions were assessed by 10 000 iterations according to recommendations of the US EPA (US EPA, 2001). Exposure calculations were performed by sex and by age class.

3. Results

3.1. Demographics

Preliminary web-based questionnaire: The enquiry was performed on 567 parents from 567 different families: 479 women and 88 men. Parents responded to complete a questionnaire for their family. Consequently, 567 data were obtained for adult women, adult men and children.

Real-life conditions study: This study was conducted on 95 families. Among participants of each family, data were analysed for people who

correctly followed the protocol i.e. volunteers who used the sunscreen spray and recorded it in a diary. In total, 337 participants were included in the study: 93 adult women, 91 adult men and 153 children (77 girls and 76 boys).

Women were from 29 years to 52 years, with mean and median values equal to 39 years. Men were from 23 years to 60 years, with mean and median values equal to 41 years and 40 years, respectively. Children were from 3 years to 13 years, with mean and median values equal to 7 years and 8 years, respectively.

51% of families were composed of 1 child between 3 and 13 years old, 35% had 2 children between 3 and 13 years old and 14% were composed of 3 children between 3 and 13 years old.

3.2. Preliminary web-based questionnaire (Figs. 2 and 3)

Among the 567 families included in this web enquiry, 542 reported going on holiday on summer (96%). The following information was therefore collected on these 542 families.

Percentage of users of sunscreen products during holidays: 98% of adult women, 97% of children and 89% of adult men were consumers of sunscreens.

Duration of holidays: 47% of families indicated going on holidays over a 2-week period; 24% during 3 weeks, 20% during 1 week and 9% during at least 4 weeks.

Consumption of sunscreen according to the SPF: Adult women mainly applied a sunscreen product with a SPF ≥50 on face (37%) and with a SPF between 30 and 40 on body (39%). Adult men mainly used a sunscreen product with a SPF between 30 and 40 on face and on body (37%). Children mostly used a sunscreen product with a SPF ≥50 on face (67%) and on body (64%) (Fig. 2).

Consumption of sunscreen according to the galenic form: Volunteers indicated favouring spray and cream forms than milk and oil forms. 47% of adult women declared using a sunscreen product in spray and 26% consumed a cream form. 46% of adult men applied a sunscreen product in spray and 27% consumed a product in cream. 55% of children used a sunscreen product in spray and 25% applied a product in cream form (Fig. 3).

Usual application area: Sunscreen products were applied on face and on body by 100% of children. 97% of adult women used sunscreen products on face and on body, 1% applied it on face only and 2% used it on body only. 96% of adult men used sunscreen products on face and on body, 2% applied it on face only and 2% used it on body only.

3.3. Real-life conditions study

The duration of families' summer holidays was on average equal to 17 ± 6 days, with minimum and maximum values equal to 6 days and 36 days, respectively.

3.3.1. Consumption data (Tables 2 and 3)

The consumption data of sunscreen spray (period of use, number of use, frequency of use, amount per use and amount per day) are presented by sex in adults and children in Table 2. For example, adult women used sunscreen spray for 11 days on median, with a P95 value equal to 20 days. Sunscreen spray was applied 16 times (median), with a P95 value equal to 58 times. The frequency of use was equal to 1.43 day^{-1} (P50 value) and 3.70 day^{-1} (P95 value). Adult women applied in median 1.57 g of product per use, with a P95 value equal to 5.32 g per use. The daily use of sunscreen spray was equal to 2.56 g/day (P50 value) and 9.44 g/day (P95 value) (Table 2).

Results of statistical analyses are described below. All p values are presented in Table 3.

Period of use: The period of use was higher in women than in men (11 days *versus* 8 days for median values and 20 days *versus* 17 days for P95 values). This difference was statistically significant ($p = 0.025$). A statistical significant difference was also observed according to gender in children. The period of use was equal to 12 days and 19 days for girls, and equal to 10 days and 20 days for boys (P50 and P95 values, respectively) ($p = 0.031$). A statistical significant difference was shown between children and adults, with median and P95 values respectively equal to 11 days and 20 days in children; and equal to 9 days and 20 days in adults ($p = 0.015$).

Number of uses: The number of sunscreen spray uses was higher in women than in men (16 times *versus* 11 times for median values and 58 times *versus* 43 times for P95 values). This difference was statistically significant ($p = 0.009$). A statistical significant difference was also observed according to gender in children. The number of uses was equal to 18 times and 60 times for girls, and equal to 14 times and 65 times for boys (P50 and P95 values, respectively) ($p = 0.020$). The number of uses was higher in children than in adults: median and P95 values were respectively equal to 17 times and 62 times in children; and equal to 13 times and 57 times in adults ($p = 0.001$).

The number of sunscreen spray uses was obtained depending of the body surface area (face and body, face only and body only). As it was shown in Fig. 4, sunscreen spray was mostly applied on the whole body. For example in adult women, the product was on median applied 7 times on face and body, 2 times on face only and 1 time on body only. P95 values were equal to 30 times (face and body), 26 times (face only) and 19 times (body only).

Frequency of use: A statistically difference was shown concerning gender for adults ($p = 0.022$) and children ($p = 0.023$). Frequency data were higher in women than in men (1.43 day^{-1} *versus* 1.29 day^{-1} for

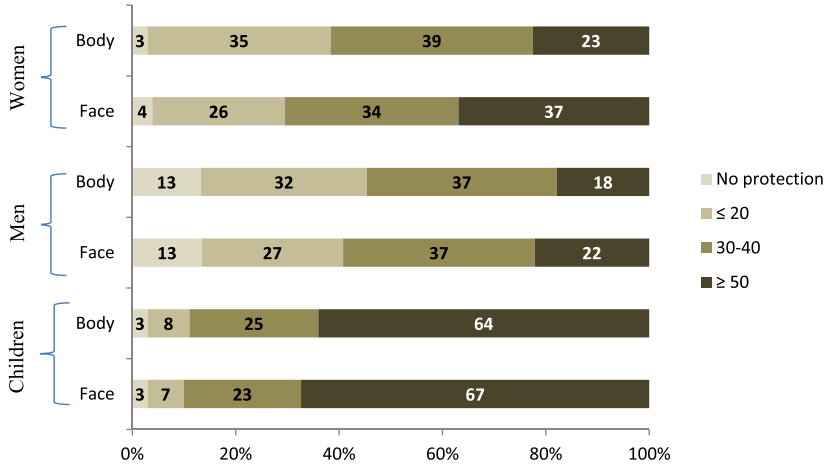

Fig. 2. Percentage of sunscreen product users depending on the SPF (≤20, 30-40 and ≥ 50).
Usage patterns data were obtained from the web-based questionnaire.
The results are presented for each family member (adult women, adult men and children) according to the application area (face and body).
Data were obtained from all families who reported going on summer holidays. 542 data were collected for adult women, for adult men and for children.

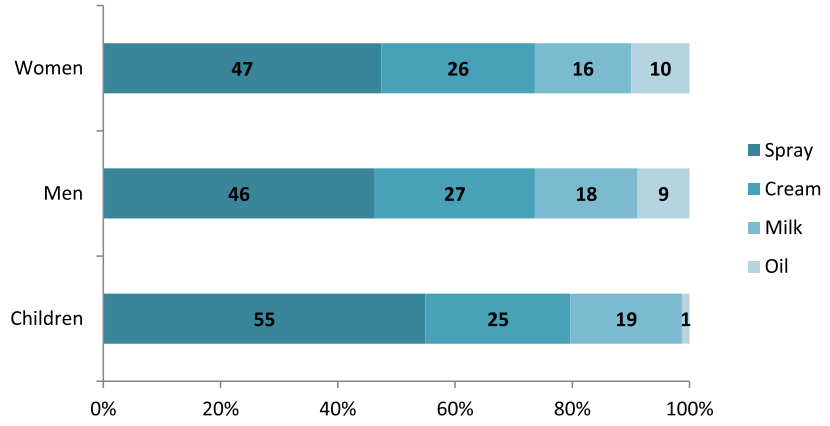

Fig. 3. Percentage of sunscreen product users depending on the galenic form (spray, cream, milk and oil).
Usage patterns data were obtained from the web-based questionnaire.
Parameter was calculated only for users of sunscreen products. The results are presented for each family member (men, women and children).
Data were obtained from all families who reported going on summer holidays. 542 data were collected for adult women, for adult men and for children.

median values and 3.70 *versus* 3.30 for P95 values) and higher in girls than in boys (1.85 day^{-1} *versus* 1.50 day^{-1} for median values and 3.42 *versus* 2.98 for P95 values). A statistical significant difference was also observed between adults and children ($p = 0.0002$).

Amount per use: No statistically significant difference was shown between gender for adults and for children ($p = 0.198$ and $p = 0.975$, respectively); and between adults and children ($p = 0.600$).

Amount per day: No statistically significant difference was shown concerning gender for adults and for children ($p = 0.855$ and $p = 0.374$, respectively). No statistically significant difference was observed between adults and children ($p = 0.384$).

3.3.1.1. Effect of tanning intensity (Table 4). In general, the consumption of sunscreen spray decreased with the increase of tanning intensity.

In adults, this difference was statistically significant only for amount per day and number of uses (in men) parameters. For example with men, the number of uses was on median equal to 12 times, 10 times and 6 times with the increase of tanning intensity ($p = 0.040$). In men, the daily consumption of sunscreen spray was on median equal to 3.7 g/day (persons not tanned), 2.1 g/day (persons slightly tanned) and 2.1 g/day (persons tanned) ($p = 0.011$). The daily consumption of sunscreen spray in women was on median equal to 2.9 g/day (not tanned), 2.2 g/day (slightly tanned) and 1.5 g/day (tanned) ($p = 0.037$).

In children, the diminution of consumption was statistically significant for all tested parameters. For example by comparison of median values, the period of use was equal to 12 days (not tanned), 11 days (slightly tanned) and 7 days (tanned) ($p = 0.005$); the number of uses was equal to 22 times (not tanned), 15 times (slightly tanned) and 9 times (tanned) ($p = 0.0001$); the frequency of use was equal to 1.9 day^{-1} (not tanned), 1.6 day^{-1} (slightly tanned) and 1.0 day^{-1} (tanned) ($p < 0.0001$); the amount used per application was equal to 1.4 g (not tanned), 2.0 g (slightly tanned) and 1.5 g (tanned) ($p = 0.029$); and the daily consumption was equal to 2.8 g/day (not tanned), 3.1 g/day (slightly tanned) and 1.5 g/day (tanned) ($p = 0.002$) (Table 4).

3.3.1.2. Effect of sunlight intensity (Table 5). In general, all consumption parameters (period of use, number of uses, frequency of use, amount per use and the amount per day) were higher when the sunlight intensity was strong. All p values are presented in Table 5.

In children and in women, this difference was statistically significant for period of use, number of uses, frequency of use and amount per day parameters. For example with children, the period using sunscreen spray was on median equal to 8 days (P50 value) when the sunlight intensity was low and was equal to 12 days when the sunlight intensity was strong ($p < 0.0001$). The number of uses was on median equal to 13 times when the sunlight intensity was low and was equal to 25 times when the sunlight intensity was strong ($p < 0.0001$). The frequency of use was on median equal to 1.45 day^{-1} when the sunlight intensity was low and was equal to 1.93 day^{-1} when the sunlight intensity was strong ($p = 0.002$). The amount of sunscreen spray used per day was on median equal to 2.24 g/day when the sunlight intensity was low and was equal to 3.47 day^{-1} when the sunlight intensity was strong ($p = 0.001$) (Table 5).

In adult men, the difference of consumption was statistically significant only for the period of use and the number of uses parameters. The period using sunscreen spray was equal to 6 days (P50 value) when the sunlight intensity was low and was equal to 9 days (P50 value) when the sunlight intensity was strong ($p = 0.030$). The number of uses was equal to 8 times (P50 value) when the sunlight intensity was low and was equal to 13 times (P50 value) when the sunlight intensity was strong ($p = 0.043$) (Table 5).

3.3.2. Exposure data (Table 2)

Exposure to sunscreen spray was assessed according to gender in adults and in children. Children aged 3-13 were the most exposed to sunscreen spray according to the P50 and P95 values: 96.36 mg/kg bw/day and 368.21 mg/kg bw/day respectively. Data obtained for girls and boys were in the same order of magnitude: median exposure values were respectively equal to 102.90 mg/kg bw/day and to 92.29 mg/kg bw/day; P95 exposure values were respectively equal to 367.99 mg/kg bw/day and to 381.68 mg/kg bw/day (Table 2).

The exposure to sunscreen spray was higher in adult women than in adult men according to P90 and P95 values: P90 exposure values were respectively equal to 111.42 mg/kg bw/day and to 85.88 mg/kg bw/day. P95 exposure values were respectively equal to 152.91 mg/kg bw/day and to 114.38 mg/kg bw/day. However, median exposure values were similar (36.38 mg/kg bw/day in women and 30.12 mg/kg bw/day in men, respectively) (Table 2).

4. Discussion

4.1. Design of the study

The preliminary web-based questionnaire permitted to collect general data on usage patterns of sunscreen products during summer holidays by 567 French families. This enquiry showed that the percentage of users was very high, especially in children and in adult women. Sunscreen products were mostly applied on the whole body. The sun protection factor was different depending on family member, with very high sun protection factor mostly used by children and mothers and high sun protection factor consumed by fathers (Fig. 2). The favouring galenic form was spray for the whole family (Fig. 3). According to results obtained in this enquiry, 95 families who consumed a

Table 2
Consumption and exposure assessment to sunscreen spray.

	Adults			Children		
	Women	Men	Women and men	Girls	Boys	Girls and boys
Period of use (day)						
Mean	10,59	8,87	9,74	11,78	10,43	11,11
SD	5,62	5,59	5,66	5,05	5,78	5,45
Median	11,00	8,00	9,00	12,00	10,00	11,00
P90	17,00	16,00	16,00	17,00	17,00	17,00
P95	20,00	17,00	20,00	19,00	20,00	20,00
N	93	91	184	77	76	153
Number of uses (without unit)						
Mean	20,65	14,97	17,84	24,49	20,22	22,37
SD	18,81	15,15	17,29	19,27	18,49	18,95
Median	16,00	11,00	13,00	18,00	14,00	17,00
P90	48,00	32,00	39,00	46,00	47,00	47,00
P95	58,00	43,00	57,00	60,00	65,00	62,00
N	93	91	184	77	76	153
Frequency of use (day $^{-1}$)						
Mean	1,75	1,53	1,64	1,96	1,73	1,85
SD	0,99	0,92	0,96	1,05	0,89	0,98
Median	1,43	1,29	1,33	1,85	1,50	1,63
P90	2,72	2,08	2,58	2,57	2,69	2,62
P95	3,70	3,30	3,69	3,42	2,98	3,38
N	93	91	184	77	76	153
Amount per use (g)						
Mean	2,06	2,23	2,14	1,83	2,01	1,92
SD	1,74	1,62	1,68	1,03	1,54	1,31
Median	1,57	1,82	1,68	1,79	1,59	1,74
P90	4,15	4,03	4,15	3,34	3,71	3,51
P95	5,32	5,30	5,54	3,67	5,12	3,92
N	93	90	183	77	76	153
Amount per day (g/day)						
Mean	3,17	2,97	3,07	3,18	3,19	3,18
SD	2,69	1,94	2,35	1,77	2,53	2,17
Median	2,56	2,87	2,65	2,94	2,55	2,81
P90	6,02	5,18	5,89	5,82	6,21	6,02
P95	9,44	6,96	7,73	6,49	7,41	6,77
N	93	90	183	77	76	153
Exposure (mg/kg bw/day)						
Mean	53,56	41,88	48,12	139,77	133,29	136,32
SD	55,49	40,59	49,78	128,12	140,98	137,99
Median	36,38	30,12	33,23	102,9	92,29	96,36
P90	111,42	85,88	99,44	278,9	275,55	276,04
P95	152,91	114,38	135,99	367,99	381,68	368,21

Consumption and exposure parameters were obtained from the real-life conditions study.
Consumption data (period of use, number of use, frequency of use, amount per use and amount per day) and exposure values were presented according to gender in adults and in children.
Consumption values were calculated using Microsoft Excel 2010 Software.
Exposure values were calculated by a probabilistic method using Monte Carlo random simulations (@risk 7.5 software).
N: Number of values.

high protection sunscreen product in a spray form were selected to participate in a real-life conditions study. Families were free to use the cosmetic product according to their own habits during their summer holidays, which is the main period of sunscreen use. Information concerning the tanning intensity and the sunlight intensity were collected.

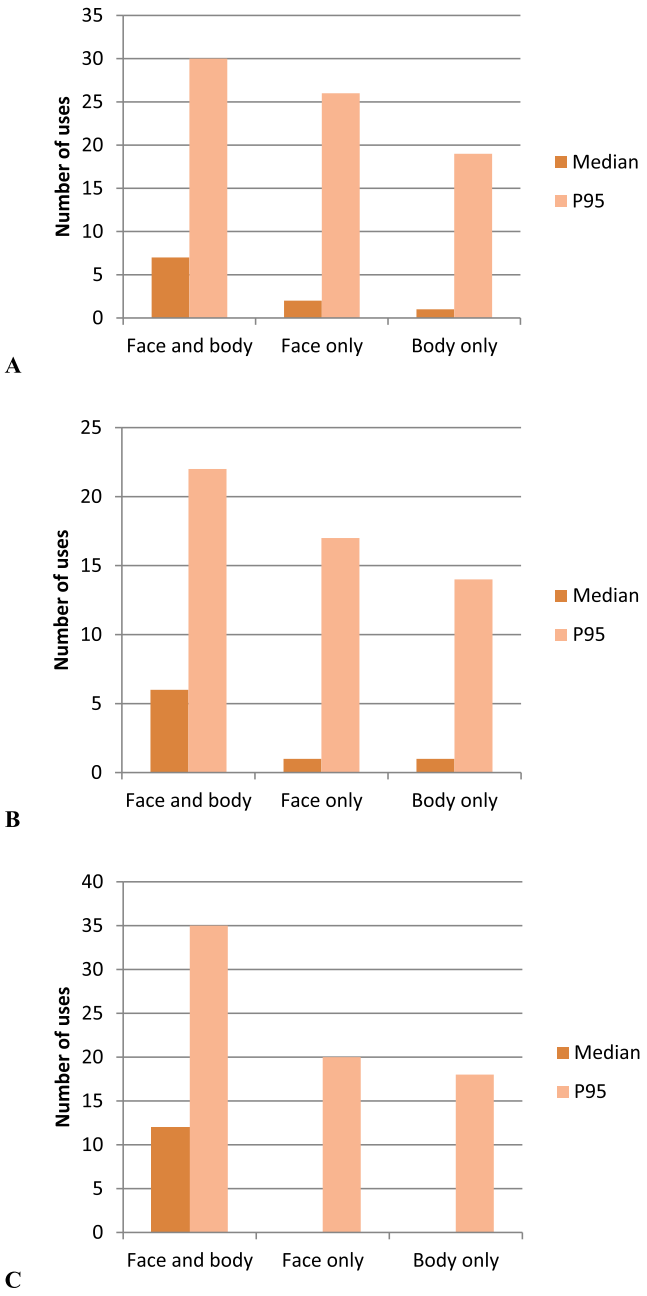

Fig. 4. Number of sunscreen spray uses depending of the body surface area (face and body, face only and body only).
Consumption parameters were obtained from the real-life conditions study.
93 data were collected for adult women, 91 for adult men and 153 for children.
Median and P95 values were calculated using Microsoft Excel 2010 Software.
A: women, B: men and C: children.

Few data are available on consumption and on exposure to sunscreen products. As mentioned above, various usage patterns and

Table 3
Consumption of sunscreen spray according to gender and to age.

	Period of use (day)	Number of uses (without unit)	Frequency of use (day^{-1})	Amount per use (g)	Amount per day (g/day)
Women versus men	**0.025**	**0.009**	**0.022**	0.198	0.855
Girls versus boys	**0.031**	**0.020**	**0.023**	0.975	0.374
Adults versus children	**0.015**	**0.001**	**0.0002**	0.600	0.384

Consumption and exposure parameters were obtained from the real-life conditions study.
p values are presented in the table in bold when a statistically significant effect was observed.

Table 4
Consumption of sunscreen spray depending on the tanning intensity before the first use (not tanned, slightly tanned or tanned).

	Women			Men			Children		
	Not tanned	Slightly tanned	Tanned	Not tanned	Slightly tanned	Tanned	Not tanned	Slightly tanned	Tanned
Period of use (day)									
Mean	10.65	10.64	10.18	10.06	8,89	6,00	12,97	10,09	8,62
SD	5.35	5.73	6.91	6.08	5,32	4,40	6,34	4,13	4,46
Median	10.00	11.00	8.00	9.00	8,00	5,50	12,00	11,00	7,00
N	49	33	11	33	44	14	65	67	21
p value	0.907			0.052			**0.005**		
Number of uses (without unit)									
Mean	20.73	18.82	25.73	16.15	16,27	8,00	29,97	18,16	12,29
SD	18.69	14.66	29.19	11.49	18,67	7,09	23,65	12,42	8,69
Median	16.00	17.00	8.00	12.00	10,00	6,00	22,00	15,00	9,00
N	49	33	11	33	44	14	65	67	21
p value	0.903			**0.040**			**0.0001**		
Frequency of use (day $^{-1}$)									
Mean	1.77	1.60	2.10	1.59	1,58	1,24	2,19	1,68	1,32
SD	0.90	0.72	1.80	0.89	1,06	0,34	1,27	0,59	0,44
Median	1.50	1.42	1.14	1.33	1,28	1,04	1,93	1,56	1,00
N	49	33	11	33	44	14	65	67	21
p value	0.659			0.246			$<$ **0.0001**		
Amount per use (g)									
Mean	2.30	2.01	1.14	2.58	1,91	2,24	1,77	2,21	1,46
SD	1.83	1.77	0.78	1.61	1,43	2,13	1,28	1,42	0,73
Median	1.63	1.47	1.28	2.25	1,63	1,70	1,42	2,04	1,48
N	49.00	33	11	33	44	14	65	67	21
p value	0.077			0.086			**0.029**		
Amount per day (g/day)									
Mean	3.73	2.81	1.80	3.54	2,57	2,66	3,38	3,38	1,97
SD	3.10	2.18	1.14	1.79	1,92	2,19	2,59	1,78	1,41
Median	2.93	2.22	1.49	3.68	2,13	2,05	2,84	3,12	1,48
N	49	33	11	33	44	14	65	67	21
p value	**0.037**			**0.011**			**0.002**		

Consumption and exposure parameters were obtained from the real-life conditions study.
Consumption data (period of use, number of use, frequency of use, amount per use and amount per day) were presented according to gender in adults and regardless of sex in children.
Consumption values (mean, standard deviation and median) were calculated using Microsoft Excel 2010 Software.
p values are presented in the table in bold when a statistically significant effect was observed.
N: Number of values.

consumption data were generated in this work. Some information, such as the relation between the tanning intensity and the consumption of sunscreen or the relation between the sun intensity and the consumption of sunscreen was obtained for the first time. It would have been relevant to assess the effect of sunlight intensity and tanning together on sunscreen consumption. However, the number of data points available *per* variable (i.e. the number of participants) in this study was not sufficient to perform a robust statistical analysis.

Consumption data were analysed only during the period of use (and not reported to the whole year) to detect maximum consumption behaviors. This choice allows being as protective as possible in terms of safety evaluation. In fact, in a safety assessment, consumption data are involved in the Margin of Safety calculation (MoS). The higher the consumption values, the consumer will be protected. The study was performed on adult and children, with a number of subjects fairly high: 184 adults and 153 children. However, the sampling may not be representative of the French population. In fact, sampling was performed in the Northwest of France. In the future, it could be interesting to perform a higher scale study in order to refine data obtained here.

4.2. Data analysis

4.2.1. Consumption

Depending on age: Various results obtained in this work showed different behaviours depending on age. Generally, children were the most protected to UV radiation by sunscreen product use.

In fact, parents declared mostly using for their children a sunscreen product with a very high protection factor (SPF $\geq$ 50) on face (67%) and on body (64%). Adult women mainly applied a sunscreen product with a SPF $\geq$50 on face (37%), but most of these women consumed sunscreen product with a high protection factor (SPF 30-40) on body (39%) and on face (34%). Adult men mainly used a sunscreen product with a SPF between 30 and 40 on face and on body (37%) (Fig. 2). The period of use, the number of uses and the frequency using sunscreen spray during summer holidays were higher in children than in adults (Table 3). In children, the consumption of sunscreen spray increased with the decrease of tanning intensity. This increase was statistically significant for all consumption parameters. This effect has also been observed in adults, but was statistically significant only for the amount per day parameter (Table 4). Sunscreen spray consumption parameters increased with the increase of sunlight intensity. In children and in women, this effect was statistically significant for the period of use, the number of uses, the frequency of use and the amount per day parameters. In adult men, the difference of consumption was statistically significant only for the period of use and the number of uses parameters (Table 5).

These results showed the positive influence of parents in sun protection of their children. Their guidance is essential for avoiding excessive exposure to ultraviolet radiation. Similar observations on parent's sun-protective behaviors for their child have been observed in literature (Gefeller et al., 2014, 2016; Hamilton et al., 2016). It was interesting to note that the behavior of women was closer to that of children than to men.

Depending on gender: Results highlighted difference of sunscreen consumption depending on gender, especially on adults. Generally, adult women were most protected to UV radiation by sunscreen product than adult men.

The percentage of sunscreen product users during holidays was

Table 5
Consumption of sunscreen spray depending on the sunlight intensity (low or strong).

	Women		Men		Children	
	Low	Strong	Low	Strong	Low	Strong
Period of use (day)						
Mean	8.19	12.18	7.09	9.83	9.16	13.19
SD	4.31	5.84	4.34	5.98	4.01	6.02
Median	7.00	12.00	6.00	9.00	8.00	12.00
N	37	56	32	59	79	74
p value	**0.001**		**0.030**		**< 0.0001**	
Number of uses (withour unit)						
Mean	12.16	26.25	10.38	17.44	16.59	28.54
SD	8.36	21.58	8.78	17.24	15.40	20.48
Median	10.00	19.00	8.00	13.00	13.00	25.00
N	37	56	32	59	79	74
p value	**0.0004**		**0.043**		**< 0.0001**	
Frequency of use (day $^{-1}$)						
Mean	1.40	1.98	1.42	1.59	1.68	2.03
SD	0.55	1.15	0.83	0.97	0.87	1.05
Median	1.14	1.56	1.23	1.29	1.45	1.93
N	37	56	32	59	79	74
p value	**0.002**		0.238		**0.002**	
Amount per use (g)						
Mean	1.63	2.35	1.89	2.37	1.69	2.18
SD	0.88	2.09	1.12	1.84	0.96	1.56
Median	1.47	1.66	1.69	1.84	1.60	1.83
N	37	56	32	59	79	74
p value	0.399		0.381		0.301	
Amount per day (g/day)						
Mean	2.31	3.74	2.53	3.16	2.60	3.81
SD	1.53	3.12	1.48	2.14	1.55	2.54
Median	1.68	3.12	2.47	2.92	2.24	3.47
N	37	56	32	59	79	74
p value	**0.015**		0.301		**0.001**	

Consumption and exposure parameters were obtained from the real-life conditions study. Consumption data (period of use, number of use, frequency of use, amount per use and amount per day) were presented according to gender in adults and regardless of sex in children.
Consumption values (mean, standard deviation and median) were calculated using Microsoft Excel 2010 Software.
p values are presented in the table in bold when a statistically significant effect was observed.
N: Number of values.

higher in women than in men: 98% in adult women and 89% in adult men. Women mainly applied a sunscreen product with a SPF ≥50 on face, and between 30 and 40 on body. Adult men mainly used a sunscreen product with a SPF between 30 and 40 on face and on body (Fig. 2). The period of use, the number of uses and the frequency using sunscreen spray during summer holidays were higher in women than in men (Table 3). A difference of consumption was also observed between girls and boys for the same parameters.

As in children, the consumption of sunscreen spray increased with the decrease of tanning intensity in adults. This increase was statistically significant for the amount per day parameter for both sexes. A statistically significant increase was also shown for the number of uses parameter in men (Table 4).

Sunscreen spray consumption parameters increased with the increase of sunlight intensity. In women, this effect was statistically significant for period of use, number of uses, frequency of use and amount per day parameters. In adult men, the difference of consumption was statistically significant only for the period of use and the number of uses parameters (Table 5).

Differences observed here between men and women were also shown in a study performed in the US adults where men tended to use sunscreen less frequently than women, and many of them did not use sunscreen at all (Holman et al., 2015). Men could view sunscreen as non-masculine or inconvenient (Courtenay, 2000). Moreover, sunscreen ads target women more often than men (Courtenay, 2000).

Interesting usage patterns were highlighted in this work. The consumption of sunscreen spray increased with the increase of sunlight intensity, especially in children. The consumption of sunscreen spray increased with the decrease of tanning intensity, especially in children. These results were corroborated findings from previous studies that parental attitudes towards tanning are associated with protective measures employed for young children (Gefeller et al., 2014).

4.2.2. Exposure

Depending on age: The amount of sunscreen spray applied per use was in the same order or magnitude between children and adults. As parents usually apply sun care products on their children, they probably apply the same amount of product to themselves as for their children. Children were the most exposed to sunscreen spray. This result was

Table 6
Comparison of consumption (g/use and g/day) and exposure (mg/kg bw/day) data with literature data.

	Children	*Current study*		Gomez-Berrada et al., 2017		Ficheux et al.. 2016a
	Age (years old)	3–13	3–13	3–9	10–14	4–14
	Sex	Girls	Boys	Mixed	Mixed	Girls
	Number	77	76	72	46	10
	Galenic form of sunscreen	Spray	Spray	Spray	Spray	Spray
	Values	P50/P95	P50/P95	P50/P95	P50/P95	P50/P95
	Consumption per use (g/use)	1.79/3.67	1.59/5.12	4.72/7.36	5.10/8.36	3.1/5.6
	Consumption per day (g/day)	2.94/6.49	2.55/7.41	6.39/16.65	6.12/16.56	
A	Exposure (mg/kg bw/day)	102.90/367.99	92.29/381.68	255.84/1016.41	132.99/521.10	

	Adults	*Current study*		Gomez-Berrada et al., 2017		Biesterbos et al., 2013	Ficheux et al.. 2016a	
	Age (years old)	≥29	≥23	≥15	≥15	≥18	Women ≥ 15	Men ≥ 15
	Sex	Women	Men	Women	Men	Mixed		
	Number	93	90	372	107	516		
	Galenic form of sunscreen	Spray	Spray	Spray	Spray	Not mentioned	Spray	Spray
	Values	P50/P95	P50/P95	P50/P95	P50/P95	Mean	P50/P95	P50/P95
	Consumption per use (g/use)	1.57/5.32	1.82/5.30	3.77/7.70	4.16/7.96	9.2	1.4–4.3/5.0–11.1	1.9–2.9/3.0–8.9
	Consumption per day (g/day)	2.56/9.44	2.87/6.96	6.62/16.69	8.76/16.24	0.4		
B	Exposure (mg/kg bw/day)	36.38/152.91	30.12/114.38	99.01/317.4	95.94/3114.85			

A Data obtained in children.
B Data obtained in adults.

explained by the differences in body weight. For example, children were exposed to 368.21 mg of sunscreen spray/kg bw/day versus 135.99 mg of sunscreen spray/kg bw/day for adults. A factor equal to 2.7 was therefore observed between these two subpopulations.

Depending on gender: The amount of sunscreen spray applied per day was in the same order or magnitude between girls and boys. In consequence, the exposure values were in the same order of magnitude. The exposure to sunscreen spray was higher in adult women than in adult men according to P90 and P95 values.

It is therefore essential to assess the exposure of different subpopulations, rather than of the entire population, to detect the most exposed subpopulations and thereby protect all consumers.

4.3. Comparison to literature data (Table 6)

The SCCS suggested a single value of sunscreen lotion equal to 18 g per day in adult for safety assessment, which correspond to an exposure value equal to 300 mg/kg bw/day (SCCS, 2016). These consumption and exposure values were much higher than those obtained in this work, where the daily consumption was estimated to 7.7 g/day (P95) and the exposure to 136.0 mg/kg bw/day (P95). No data was proposed by the SCCS for children safety assessment.

Few sunscreen consumption and exposure data are available in literature. In addition, published data came from studies carried out with different protocols which make the comparison difficult. The present study was performed during the summer holidays to detect high consumption behaviors. As mentioned in the first section of discussion, this choice allows being as protective as possible in terms of safety evaluation. However, sunscreen products can also be used in everyday life, apart from summer holidays. In consequence, the differences shown with other publication available in literature have to be taken with caution.

Sunscreen spray consumption and exposure values were about 2 times lower than those previously obtained for children and adults in our previous study (Gomez-Berrada et al., 2017). In the present study, consumers were free to use the product according to their habits during the summer holidays. In Gomez-Berrada et al. (2017) study, consumption values were obtained from clinical studies for which the objective was to assess the tolerance of the sunscreen spray with precise directions of use. In addition, sunscreen product was tested by people of different countries with different sunshine, and most of clinical studies were conducted in Mauritius where sunshine is important. These differences could explain the variation of consumption observed in our studies.

The consumption of sunscreen was assessed in Dutch adults (Biesterbos et al., 2013). The amount of product applied per use was much greater than values obtained here: 9.2 g on average in Biesterbos et al. (2013) study; and 2.1 g on average for adults in this study. This difference could be explained by the fact that in Biesterbos et al. (2013) study, photographs were used to visualize the amount of sunscreen per application. Moreover, the galenic form was not taken into account. The daily amount of sunscreen (0.4 g per day on average) was much lower than that generated here (3.1 g per day on average). In fact, in Biesterbos et al. (2013) study, the consumption data were calculated over a year, and include periods of use and non-use of the sun care products. In this study, the consumption data were obtained during only the summer period using sunscreen products.

Consumption of sunscreen spray was assessed in French adults according to exposed body area (small, intermediate or large) (Ficheux et al., 2016a). Values were higher than those obtained in this study. For example in women: P50 value was between 1.4 g/use (small area) and 4.3 g/use (large area) in Ficheux et al. (2016a) study, and was equal to 1.6 g/use here. P95 values were between 5.0 g/use (small area) and 11.1 g/use (large area) in Ficheux et al. (2016a) study; and was equal to 5.3 g/use here. Values obtained in girls were higher than those obtained here, with P50 and P95 values respectively equal to 3.1 g/day and 5.6 g/day in Ficheux et al. study (2016a); versus 1.8 g/day and 3.7 g/day in the present study. In Ficheux et al. (2016a) study, amount data were estimated from a single application per subject, most often on the beach when the sun intensity is strong, which differed from this study where amount data were obtained on the whole holiday period, where the solar intensity varies according to the activities practiced.

5. Conclusion

Unlike many cosmetic products daily used by consumers such as moisturizers, sunscreen products are used for a very limited period of time. A great variation in the use of sunscreens can exist between consumers according, for example, to their natural susceptibility to the sun, their perception of skin cancer risk, their attraction to sunlight or their holiday habits (IARC, 2001). Few data are available on consumption and on exposure to sunscreen products. Thus, accurate exposure data can improve the reliability of the risk assessment. This study provided relevant information regarding consumption and exposure to sunscreen product. These new information will be useful for safety assessors.

Transparency document

Transparency document related to this article can be found online at http://dx.doi.org/10.1016/j.fct.2018.02.035.

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