

CALENTOL

**Tolerability and effectiveness of Calendula Nappy Change Cream and
Calendula Shampoo and Body Wash – A prospective, multicenter, paediatric
study**

STUDY REPORT

Version 1.0 du 26/02/2020

SLB PHARMA

Report Approbation

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Table of contents

1. GENERAL INFORMATIONS	8
2. STUDY PROTOCOL	9
3. DATA-MANAGEMENT AND STATISTICAL CONSIDERATIONS	15
3.1. SOFTWARES	15
3.2. BLIND REVIEW	15
3.3. STATISTICAL METHODS	15
4. ETHIC.....	17
4.1. ETHICS COMMITTEE	17
4.2. PARENT’S INFORMATION AND CONSENT	17
5. SUBJECTS INCLUDED IN THE STUDY	18
5.1. ENROLMENT PERIOD AND FLOW OF PATIENTS	18
5.2. DATA SETS ANALYZED.....	22
6. DESCRIPTION OF SUBJECTS AT BASELINE.....	26
6.1. DEMOGRAPHIC CHARACTERISTICS.....	26
6.2. ANTHROPOMETRIC DATA	27
6.3. FEEDING HABITS: MILK AND DIVERSIFIED DIET	27
6.4. DIAPER CHANGES AND CLEANSING HABITS	28
6.5. SKIN HISTORY	31
6.6. INITIAL SKIN EXAMINATION.....	32
6.7. CONCOMITANT TREATMENTS TAKEN PRIOR THE STUDY	32
7. CHANGE IN ANTHROPOMETRICS BETWEEN V1 AND V2	33
8. FREQUENCY OF USE.....	34
8.1. CALENDULA NAPPY CHANGE CREAM	34
8.2. CALENDULA SHAMPOO AND BODY WASH.....	36
9. PRIMARY OBJECTIVE: PAEDIATRICIAN RECOMMENDATION RATE – ITT POPULATION.....	38
9.1. RECOMMENDATION RATE	38
9.2. PAEDIATRICIANS OPINIONS ON WELEDA	38
10. DERMATOLOGICAL CONCOMITANT TREATMENTS TAKEN DURING THE STUDY	40
11. SECONDARY OBJECTIVE: THE PRODUCTS TOLERANCE – SAFETY POPULATION	41
11.1. SKIN EVENTS	41
11.2. EVALUATION OF THE TOLERANCE BY THE PAEDIATRICIAN	42
12. SECONDARY OBJECTIVE: THE PRODUCTS’ EFFICACY	44
12.1. EVALUATION OF THE EFFICACY BY THE PAEDIATRICIAN.....	46
13. SECONDARY OBJECTIVE: PARENTS’ SATISFACTION ON PRODUCTS.....	48

13.1. CALENDULA NAPPY CHANGE CREAM 48

13.2. CALENDULA SHAMPOO AND BODY WASH..... 54

14. SUMMARY OF RESULTS 57

15. APPENDIX..... 62

List of tables

Table 1: Disposition of included subjects per center	18
Table 2: Description of the duration of participation in the study	19
Table 3: Listing of the subjects with a study duration longer than 30 days	20
Table 4: Disposition of subjects throughout the study.....	20
Table 5: Listing of the premature withdrawal (after inclusion).....	20
Table 6: Conformity with the inclusion criteria	22
Table 7: Conformity with the non-inclusion criteria.....	22
Table 8: Listing of subjects with deviations at inclusion.....	22
Table 9: Listing of subjects with major deviations	23
Table 10: Listing of subjects included in the safety, ITT and PP populations	25
Table 11: Population sizes	25
Table 12: Description of the genders in the safety and ITT populations	26
Table 13: Description of the age in the safety and ITT populations	26
Table 14: Listing of premature births in the safety and ITT populations.....	26
Table 15: Anthropometric characteristics in the safety and ITT populations.....	27
Table 16: Description of the milk feeding habits in the safety and ITT populations	27
Table 17: Description of the dietary diversification in the safety and ITT populations	27
Table 18: Number of diaper changes per day in the safety and ITT populations.....	28
Table 19: Diaper characteristics in the safety and ITT populations.....	28
Table 20: Number of baths per week in the safety and ITT populations.....	28
Table 21: Satisfaction with the usual body and hair cleansing product assessed by the parents in the safety and ITT populations	29
Table 22: Diaper cleansing characteristics in the safety and ITT populations.....	29
Table 23: Satisfaction with the usual nappy change product assessed by the parents in the safety and ITT populations	29
Table 24: Importance of the natural composition of baby care products assessed by the parents in the safety and ITT populations	30
Table 25: Infant skin description in the safety and ITT populations.....	31
Table 26: Skin history in the safety and ITT populations.....	31
Table 27: Listing of the skin pathologies in the safety and ITT populations.....	31
Table 28: Fitzpatrick scale type in the safety and ITT populations.....	32
Table 29: Clinical examination of the skin in the safety and ITT populations	32
Table 30: Description of the anthropometric characteristics at V1, V2 and change V2-V1 in the ITT population	33
Table 31: Total use duration of Calendula Nappy Change Cream between the inclusion and the V2 control visit in the ITT population	34

<i>Table 32: Calendula Nappy Change Cream: Use duration, number of days of use and interruption based on the data from the daily log in the ITT population</i>	34
<i>Table 33: Number of daily uses (from days where Calendula Nappy Change Cream was used) per infant based on the daily log data in the ITT population</i>	35
<i>Table 34: Total use duration of Calendula Shampoo and Body Wash between the inclusion and the V2 control visit in the ITT population</i>	36
<i>Table 35: Calendula Shampoo and Body Wash: Use duration, number of days of use and interruption based on the data from the daily log in the ITT population.....</i>	36
<i>Table 36: Frequency of use per infant based on the daily log data in the ITT population</i>	37
<i>Table 37: Number of baths based on the daily log data in the ITT population</i>	37
<i>Table 38: Number of paediatricians who would recommend Calendula Nappy Change Cream to parents in the ITT population</i>	38
<i>Table 39: Number of paediatricians who would recommend Calendula Shampoo and Body Wash to parents in the ITT population.....</i>	38
<i>Table 40: Paediatricians' opinions on Weleda before their participation to the study.....</i>	39
<i>Table 41: Paediatricians' opinions on Weleda at the end of the study</i>	39
<i>Table 42: Listing of the dermatological treatments taken during the study in the ITT population.....</i>	40
<i>Table 43 : Number of skin events during the study in the safety population.....</i>	41
<i>Table 44 : Characterization of skin events during the study in the safety population</i>	42
<i>Table 45: Calendula Nappy Change Cream tolerance assessed by the paediatricians in the ITT population</i>	42
<i>Table 46: Calendula Shampoo and Body Wash tolerance assessed by the paediatricians in the ITT population</i>	43
<i>Table 47: Clinical examination of the skin at V2 control visit in the ITT population.....</i>	44
<i>Table 48 : Skin events specifications in the safety population</i>	44
<i>Table 49: Number of infants who have and have not presented a skin event in the ITT population</i>	44
<i>Table 50 : Listing of the causes of the skin events in the safety population.....</i>	45
<i>Table 51: Time interval between the inclusion and the skin event in the safety population</i>	45
<i>Table 52: Skin event duration in the safety population.....</i>	45
<i>Table 53 : Listing of the body areas (excluding nappy area) where skin events appeared in the safety population</i>	46
<i>Table 54: Calendula Nappy Change Cream efficacy assessed by the paediatrician in the ITT population.....</i>	46
<i>Table 55: Calendula Shampoo and Body Wash efficacy assessed by the paediatrician in the ITT population</i>	47
<i>Table 56: Self-administered questionnaires answers on Calendula Nappy Change Cream in the ITT population</i>	50
<i>Table 57: Description of the usual nappy change cream among all the subjects and the ones who prefer the Calendula Nappy Change Cream over their usual product in the ITT population</i>	50
<i>Table 58: Self-administered questionnaires answers on Calendula Nappy Change Cream for subjects who used the product more than 2 times a day on average</i>	53
<i>Table 59: Comparison of the percent of agreement between subjects who have used the Calendula Nappy more than 2 times a day and subjects who have used it as indicated in the notice.....</i>	53
<i>Table 60: Self-administered questionnaires answers on Calendula Shampoo and Body Wash in the ITT population....</i>	55

<i>Table 61: Description of the usual washing care among the subjects who prefer the Calendula Shampoo and Body Wash over their usual product in the ITT population</i>	<i>55</i>
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List of figures

<i>Figure 1: Enrolment curve</i>	<i>18</i>
<i>Figure 2: Distribution of the study duration of the included subjects</i>	<i>19</i>
<i>Figure 3: Participant flow diagram (infants who entered and completed the study)</i>	<i>21</i>
<i>Figure 4: Data sets analyzed</i>	<i>25</i>
<i>Figure 5: Distribution of the age in the safety and ITT populations</i>	<i>26</i>
<i>Figure 6: Tolerance of the products assessed by the paediatrician in the ITT population</i>	<i>43</i>
<i>Figure 7: Efficacy of the products assessed by the paediatrician in the ITT population</i>	<i>47</i>
<i>Figure 8: Calendula Nappy Change Cream evaluations by the parents in the ITT population</i>	<i>51</i>
<i>Figure 9: Calendula Shampoo and Body Wash evaluations by the parents in the ITT population</i>	<i>56</i>

List of abbreviations

CRF	Case Report Form
CRO	Contract Research Organisation
ITT	Intention to treat
md	Missing data
Nb	Number
NOC	Natural and Organic Cosmetic
PP	Per Protocol
SD	Standard Deviation

1. GENERAL INFORMATIONS

Title of the study	Tolerability and effectiveness of Calendula Nappy Change Cream and Calendula Shampoo and Body Wash – A prospective, multicenter, paediatric study.
Short title	CALENTOL
Version	V1.0_01/08/2019
Design	A prospective, multicenter, non-comparative study, conducted under paediatric control. This interventional study involves 2 cosmetic products.
Sponsor	Weleda Dychweg 14 4144- Arlesheim Switzerland
Investigation site	7 paediatric liberal offices
CRO	SLB Pharma 28 Bis rue du Thabor 35000 Rennes FRANCE

2. STUDY PROTOCOL

Title	"Tolerability and effectiveness of Calendula Nappy Change Cream and Calendula Shampoo and Body Wash- A prospective, multicenter, paediatric study."
Short title	CALENTOL
Version and date	V1.0_01/08/2019
Keywords	Infant; Change cream; Washing cream; Epidermis; Soothes and protects; Calendula; Weleda; Cosmetic product.
Sponsor	<p>Weleda Dychweg 14 4144- Arlesheim Switzerland</p> <p>Contact: Valérie DONNIZAUX, Global Marketing, vdonnizaux@weleda.ch Tel: (+41) 6 17 05 21 79 Mobile: (+41) 7 91 29 21 46</p>
CRO	<p>SLB PHARMA - 28 Bis rue du Thabor - 35000 Rennes, FRANCE Contact: Ophélie Flageul, Clinical Project Manager o.flageul@slbpharma.com Tel: (+33) 2 99 12 19 62</p>
Investigation sites	<p>Multi-center study carried out in France. 7 paediatric liberal offices. The investigators will be pediatricians/</p>
Design	A prospective, multicenter, non-comparative study, conducted under paediatric control. This interventional study involves 2 cosmetic products.
Duration	<p>⌚ Enrollment duration: 2 to 3 months ⌚ Duration of follow-up /infant: 2 weeks ⌚ Data processing: 1.5 months ⌚ Total study: 5 months</p>
Cosmetic products under study	<p><u>Calendula Nappy Change Cream:</u></p> <ul style="list-style-type: none"> - For the care of the infant's nappy area, it protects, soothes and regenerates the epidermis. - Marketed since 1985 and 2006 in Germany and France respectively. <p><i>Composition: water, sweet almond oil, sesame oil, zinc oxide, beeswax, lanolin, fatty acid esters, clay, extract of calendula and chamomile flowers, essential oils.</i></p> <p>Ingredients (INCI): Water (Aqua), Prunus Amygdalus Dulcis (Sweet Almond) Oil, Sesamum Indicum (Sesame) Seed Oil, Zinc Oxide, Beeswax (Cera Alba), Lanolin, Glyceryl Linoleate, Hectorite, Calendula Officinalis Flower Extract, Chamomilla Recutita (Matricaria) Flower Extract, Fragrance (Parfum)*, Limonene*, Linalool*, Benzyl Benzoate*, Benzyl Salicylate*, Geraniol*, Farnesol*. *from natural essential oils</p> <p><u>Calendula Shampoo and Body Wash:</u></p> <ul style="list-style-type: none"> - Aimed at the daily toilet (body and hair) of infants and young children thanks to a mild plant-based washing base.



	<p>- Marketed since 2007.</p> <p><i>Composition: water, sugar esters, sweet almond oil, alcohol, coconut fat glutamates, sesame oil, glycerin, carrageen, calendula flower extract, xanthane, lactic acid, essential oils.</i></p> <p>Ingredients (INCI): Water (Aqua), Coco-Glucoside, Prunus Amygdalus Dulcis (Sweet Almond) Oil, Alcohol, Disodium Cocoyl Glutamate, Sesamum Indicum (Sesame) Seed Oil, Glycerin, Carrageenan, Sodium Cocoyl Glutamate, Calendula Officinalis Flower Extract, Xanthan Gum, Lactic Acid, Fragrance (Parfum)*, Limonene*, Linalool*. *from natural essential oils</p>						
<p>Objectives & outcomes</p>	<p><u>Main objective and outcome:</u> The main objective of this clinical study is to evaluate, in the medium term, the recommendation rate by paediatricians of Calendula Nappy Change Cream and Calendula Shampoo and Body Wash.</p> <p>The main outcome will therefore be the proportion of paediatricians who answered "Yes" to the question -presented in the end-of-study questionnaire - "<i>Do you recommend... [product name]?</i>" for each product.</p> <p><u>Secondary objectives and outcomes:</u></p> <table border="1" data-bbox="443 974 1536 2004"> <thead> <tr> <th data-bbox="443 974 754 1014">Secondary objectives</th> <th data-bbox="754 974 1536 1014">Secondary outcomes</th> </tr> </thead> <tbody> <tr> <td data-bbox="443 1014 754 1328"> <p>Products tolerance:</p> </td> <td data-bbox="754 1014 1536 1328"> <p><u>The occurrence of skin side effects:</u> Table of cutaneous events completed from the end-of-study clinical examination and the parent daily log.</p> <p><u>The paediatrician's evaluation of overall tolerance:</u> Using a 4-point Likert scale (<i>Very good, Good, Moderate, Bad</i>). The proportion of infants with good or very good tolerance will be calculated for each product.</p> </td> </tr> <tr> <td data-bbox="443 1328 754 2004"> <p>Efficacy on skin protection:</p> </td> <td data-bbox="754 1328 1536 2004"> <p><u>The number of children who did not present cutaneous events in the nappy area and the rest of the body (excluding adverse effects) and the number, average duration and causes of cutaneous events (nappy area and rest of the body):</u> At the end-of-study visit, from the clinical examination and the daily log completed by the parents, the paediatrician will complete the table of cutaneous events. For each cutaneous event, the nature, duration, severity and causes will be described. Also, the proportion of infants who did not present cutaneous events (excluding adverse effects due to study products) will be calculated.</p> <p><u>Parental assessment of the variation in the frequency of redness/irritation on the nappy area compared to the 2 weeks before using Calendula Nappy Change Cream:</u> By means of a question in the parental self-questionnaire at the end of the study: "Compared to the 2 weeks before using Calendula Nappy Change Cream, do you find that your baby's</p> </td> </tr> </tbody> </table>	Secondary objectives	Secondary outcomes	<p>Products tolerance:</p>	<p><u>The occurrence of skin side effects:</u> Table of cutaneous events completed from the end-of-study clinical examination and the parent daily log.</p> <p><u>The paediatrician's evaluation of overall tolerance:</u> Using a 4-point Likert scale (<i>Very good, Good, Moderate, Bad</i>). The proportion of infants with good or very good tolerance will be calculated for each product.</p>	<p>Efficacy on skin protection:</p>	<p><u>The number of children who did not present cutaneous events in the nappy area and the rest of the body (excluding adverse effects) and the number, average duration and causes of cutaneous events (nappy area and rest of the body):</u> At the end-of-study visit, from the clinical examination and the daily log completed by the parents, the paediatrician will complete the table of cutaneous events. For each cutaneous event, the nature, duration, severity and causes will be described. Also, the proportion of infants who did not present cutaneous events (excluding adverse effects due to study products) will be calculated.</p> <p><u>Parental assessment of the variation in the frequency of redness/irritation on the nappy area compared to the 2 weeks before using Calendula Nappy Change Cream:</u> By means of a question in the parental self-questionnaire at the end of the study: "Compared to the 2 weeks before using Calendula Nappy Change Cream, do you find that your baby's</p>
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	<p>redness/irritations are: less frequent, identical, more frequent? ».</p> <p><u>The paediatrician's assessment of overall efficacy:</u> Using a 4-point Likert scale (<i>Very good, Good, Moderate, Bad</i>). The proportion of infants with good or very good efficacy will be calculated for each product.</p>	
	<p>Taking dermatological treatments:</p>	<p>From a questioning and the daily log completed by the parents, the paediatrician will complete the table of dermatological treatments used during the study phase.</p>
	<p>Frequency of use:</p>	<p>Obtained from the number of uses of the 2 studied products and the number of baths carried out, notified each day on the parents' daily log.</p> <p>Based on this data, the total number of days of use of each product, the number of days of interruption, the number of daily uses of Calendula Nappy Change Cream and the number of uses of Calendula Shampoo and Body Wash will be calculated.</p>
	<p>Parents' satisfaction:</p>	<p>By product-specific self-questionnaire, parents will evaluate the efficacy, tolerance, practicality and their level of satisfaction with the two cosmetic products.</p> <p>The proportion of responses will be described for each question.</p>
<p>Eligibility criteria</p>	<p><u>Inclusion criteria:</u></p> <ul style="list-style-type: none"> - Aged between 3 and 36 months, healthy, born at term or up to 1 month before term, - A skin phototype I-III according to Fitzpatrick scale, - Wearing diapers daily with at least 2 daytime changes and a night port, - Taking at least 3 baths per week (daily bath or 1 day out of 2), - Of which at least one parent has given its written informed consent regarding its participation in the clinical study. <p><u>Non-inclusion criteria:</u></p> <ul style="list-style-type: none"> - Taking more than 7 baths per week, - Presenting an ongoing cutaneous event (infants with mild redness or irritation are eligible), - Presenting a skin pathology known, - Under medication that may interfere with the products under study and/or the skin, - Child and/or parent(s) under official guardianship, - Simultaneous participation in other clinical research or participation in another clinical study in the past month. 	
<p>Sample size</p>	<p>The minimum number of infants to be included is 60 for the main criteria. In order to prevent any loss to follow-up, an additional 10% of infants will be included for a total of 66 infants.</p>	

Clinical evaluations	<p>The research will take place in liberal paediatric offices.</p> <p><u>Inclusion Visit - V1 (J0)</u></p> <ul style="list-style-type: none"> - Pre-screening of infants by the paediatrician during consultations. - Informative poster displayed if necessary, in the waiting room to broadcast the conduct of this study to parents. - At this visit, the investigator will explain orally the objectives, the procedure and the terms of participation in this research. - The investigator will also give an information note which contains these information. - After a sufficient period of reflection, the parents will give their written consent or not, in 2 copies, regarding the participation of their child in this research. The child's participation in the protocol must be notified in his medical file. - After obtaining the parents' consent: clinical examination of the infant + parent's questioning carried out by the paediatrician + filling of V1 module in the CRF (demographic and anthropometric data, skin pathology, etc.) + verification of eligibility criteria. - If the infant is included, a daily log + the 2 products under study + instructions notes for use will be given to parents; the daily log should be completed each day by the parents. - V2 follow-up visit scheduled within 14 days (± 2 days) depending on the availability of the paediatrician and parents. <p style="text-align: center;">•</p> <p><u>Follow-up end visit - V2 (J14 - 2)</u></p> <ul style="list-style-type: none"> - The investigator collects and checks the daily log completed by the parents. - Controlling the good use of studied products by the paediatrician. - Infant's clinical examination + parent's questioning + filling of V2 module by the paediatrician. - Evaluation of the tolerance and efficacy of each product by the paediatrician using a 4-point Likert scale. - 2 self-questionnaires given to parents to assess their satisfaction with the 2 products used. - Giving compensatory allowances to the family: a pack of WELEDA products (Liniment, massage oil and shower gel) for the whole family. - Filling of the study end form (also in case of early exit from the protocol). <p>At the end of the protocol, the infant will be followed by his pediatrician in accordance with the usual practice.</p> <p><u>End of study</u></p> <p>A final-study questionnaire will be sent to each paediatrician to evaluate their opinion on the WELEDA brand and the 2 products under study to determine the recommendation rate of products by paediatricians.</p>
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Vigilance	<p>Tolerance to cosmetics under study will be assessed by the paediatrician during the follow-up end visit, scheduled to 14 days, using a clinical examination, parent interrogation and information collected by parents in the daily log.</p> <p>Also, a hotline will be provided by the medical office in order that parents can inform the investigator in case of an adverse event.</p> <p>For each adverse event, the cause of the event will be evaluated by the investigator to determine if the event is related to an intolerance to the product or any other cause. Known side effects (minor events) related to the use of Weleda products Calendula Nappy Change Cream and Calendula Shampoo and Body Wash are redness, itching and spots.</p> <p>Any serious adverse event must be notified by the investigator to the sponsor using a paper form "Notification of a serious adverse event by the investigator to the sponsor" (<i>provided by SLB Pharma</i>) which will indicate the date of occurrence, intensity, relationship with the product under study (or research) and follow-up.</p>
Statistical analysis	<p><u>Statistical methods:</u> The analysis will be descriptive. Clinical data collected at inclusion and at 2 weeks will be described. Descriptive statistics will be presented based on the nature of the criteria analyzed:</p> <ul style="list-style-type: none"> • Quantitative variable: average, effective, standard deviation, minimum, maximum and median of observed data, number of missing data. • Qualitative variable: numbers and percentages per class in each group, number of missing data. <p>Charts will be provided according to the variables.</p> <p>The analysis of product efficacy and satisfaction of parents and paediatricians will focus on the ITT population and a supportive analysis on the PP population will be carried out to verify the stability of the results (only if the number gap between 2 populations is more than 10%).</p> <p>The tolerance analysis will focus on the Safety population. Tolerance data will be expressed in number of adverse events (EI) and in number of subjects having reported at least one adverse event. The severity, cause and timing of their occurrence will be described.</p> <p><u>Comparative analyses:</u> because the study is non-comparative, there is no expected comparison between two groups. However, comparative analyses between different subgroups may be conducted if necessary, based on factors of interest that need to be defined at the latest in the data review meeting. In this case, the comparison of averages will use the Student test for independent data (2 groups), after checking the conditions of application (normality of distribution by the Kolmogorov-Smirnov test and equality of variances by Fischer's test). Failing that, Mann-Whitney's non-parametric test will be used; the percentages will be compared using the Chi-2 test (for 2 percentages) or the Cochran test (more than 2 percentages). Statistical tests will be conducted in bilateral situations with a degree of significance for the risk of alpha error set at 5%.</p>

Flow-chart of the trial:

	Inclusion visit V1 (D0)	End-of-follow-up visit V2 (D14±2)
Introducing the study to parents: oral + information note	X	
Obtaining written consent from at least one parent	X	
Clinical examination by paediatrician	X	X
Collection of concurrent treatments and skin history	X	X
Delivery of products	X	
<u>Use of products:</u> -Calendula Nappy Change Cream: 1 to 2 times/day -Calendula Shampoo and Body Wash: at each bath		
<u>Collecting with a daily log:</u> -number of baths, -number of use of products, -events of life, -skin adverse events, -treatment.		
Parent's satisfaction (1 parental self-administered questionnaire/product)		X
Collecting of skin events		X
Tolerance evaluation (by paediatrician)		X
Efficacy evaluation (by paediatrician)		X
Paediatrician recommendation rate		X <i>(at the end of the study)</i>

3. DATA-MANAGEMENT AND STATISTICAL CONSIDERATIONS

3.1. Softwares

- ENNOV Clinical version 8.0: design and configuration of the CRF for data entry and export.
- JMP® from SAS Institute, version 15.0.0: data analysis.

3.2. Blind review

Cf. the Data Review Report (see [APPENDIX I](#) - EXTRACT).

3.3. Statistical methods

Definition of the populations:

Safety population: is defined as all subjects who have used one of the products at least once.

Intention To Treat population (ITT population): includes every included subject who were delivered the products and for whom efficacy and safety data are available.

Per Protocol population (PP population): is defined as a subset of the ITT population who completed the study without any major eligibility and/or protocol violations. PP population excludes patients with major deviations.

Protocol deviations (minor or major) have been discussed in the data review report.

Descriptive analysis:

The analysis will be descriptive. The clinical data collected at inclusion and 2 weeks, as well as their variations between these two periods, will be described according to the nature of the criterion analyzed:

- quantitative parameters will be presented in terms of mean, standard deviation, median, extreme values (min and max), number of subjects and missing data;
- qualitative parameters will be presented in terms of number and percentage of each modality and the number of missing data will be given.

In the text, to ease the reading, some data can be rounded.

Graphs will be provided as needed.

The variations of parameters will be calculated as: latest measure – initial measure. *Example: variation of weight is “weight measured at V2 – weight measured at V1”.*

The duration variables will be calculated as a date difference: latest date – initial date + 1. An event that lasts “1 day” is then an event who lasts 24 hours at most.

Evaluation of efficacy and satisfaction

The analysis of product efficacy and satisfaction of parents and paediatricians will focus on the ITT population and a supportive analysis of the PP population will be carried out to verify the stability of the results (only if the number gap between 2 populations is more than 10%).

The proportions of agreement (“Very Good” + “Good” answers) will be calculated and compared to 70% (theoretical proportion threshold to approve the claim) with a two-sided binomial test performed at a 0.05 significance level.

The proportions of agreement between subjects who used Calendula Nappy Change Cream ≤ 2 times a day and subjects who used it more than 2 times a day will be compared with a Pearson chi-square test performed at a 0.05 significance level.

Evaluation of safety

The tolerance analysis will focus on the safety population. Tolerance data will be expressed in the number of skin events and the number of subjects having reported at least one skin event. Skin event characteristics (type, grade, relationship with the investigational products, action, duration, causes, and timing of their occurrence) will be described.

4. ETHIC

4.1. Ethics Committee

In accordance with the *“Décret n° 2017-884 du 9 mai 2017 modifiant certaines dispositions réglementaires relatives aux recherches impliquant la personne humaine”*, satisfaction studies on cosmetic products aimed to clean, perfume, modify the appearance, protect, maintain the human body in good condition or correct body odors are not considered as *“recherche impliquant la personne humaine”* in France. So, no ethics committee was solicited for this study. Nevertheless, the study was conducted in accordance with Helsinki declaration and French Good Clinical Practices (décision du 24 novembre 2006).

4.2. Parent’s Information and Consent

65 parents received oral and written information about the investigation in the national language (French) and signed a consent (French version of Informed Consent Form is provided in *Appendix II*).

5. SUBJECTS INCLUDED IN THE STUDY

5.1. Enrolment period and flow of patients

5.1.1. Enrolment period

Seven centers (paediatric liberal offices) enrolled infants (**Table 1**). In total, in accordance with the protocol, 66 infants were included in the CALENTOL study. However, the inclusion announced by Dr. Souweine was false.

Center number	City	Investigator name	Number of included subjects n = 66
01	Draguignan (83)	D'Andrea	14
02	Paris (75)	Joseph Gaudry	20
03	La Rochelle (17)	David-Henriau	6
04	Bischheim (67)	Dagrenat	11
05	Lyon (69)	Touboul	10
06	Rennes (35)	Arberet	4
07	Saintes (17)	Souweine	1

Table 1: Disposition of included subjects per center

Infants were included between 22/08/2019 and 28/11/2019 (3 months to complete the recruitment). **Figure 1** shows the recruitment curve. The last infant completed the last visit (Visit V2, D28) on 12/12/2019.

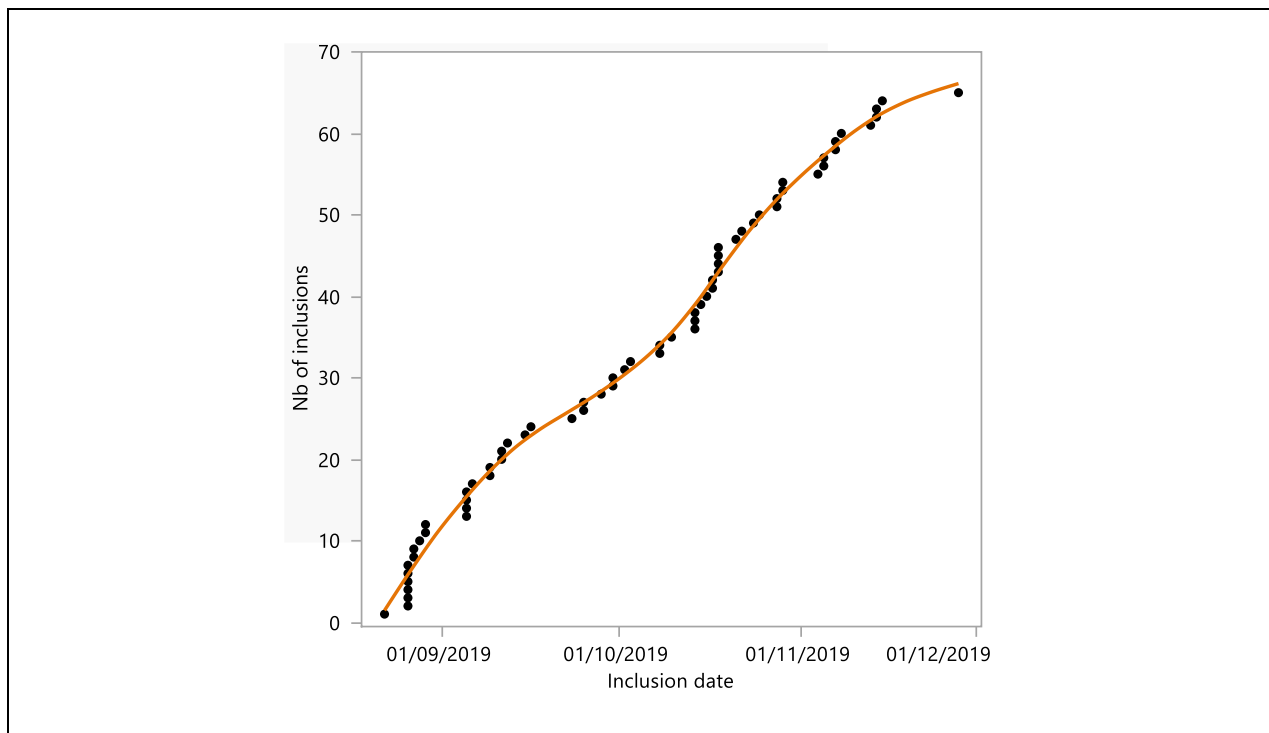


Figure 1: Enrolment curve

5.1.2. Duration of participation in the study

The observed duration of participation in the study is longer than the duration intended by the protocol (i.e. 20.1 ± 13.9 days - **Table 2**). Indeed, paediatricians who participated in the study receive in general their patients every month and it was difficult for some families to add a consultation at 2 weeks. So, on average, infants were followed for 6 more days than planned by the protocol.

During the data review meeting, these deviations concerning the duration of participation had been characterized as a minor deviation.

Included subjects (n = 66)		
Duration of participation (days)	N (md)	61 (5)
	Mean	20.1
	SD	13.87
	Median	15
	Minimum	11
	Maximum	100

Table 2: Description of the duration of participation in the study

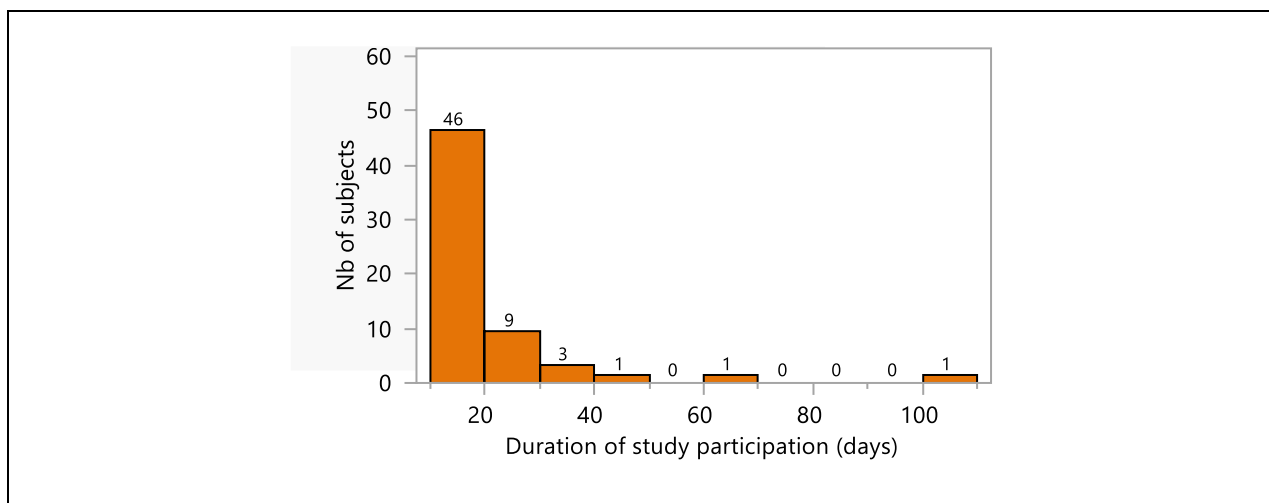


Figure 2: Distribution of the study duration of the included subjects

As described on the graph above, for 3 patients, the period between V1 and V2 visits is more than 1 month (i.e. monthly consultation). The reasons are described in **Table 3** and are unavailability of parents (02-07, 02-10) and a transient illness of the mother (04-06).

Despite the long period of follow-up, parents of subjects 02-07 and 02-10 respected the duration of use (14 ± 2 d).

Subject ID	Study duration (days)	Use duration (days)		Reason for study duration longer than 30 days
		Calendula Nappy Change Cream	Calendula Shampoo and Body Wash	
02-07	100	17	16	PARENTS PAS DISPONIBLES
02-10	68	16	16	DISPONIBILITE DES PARENTS
04-06	41	42	41	EVENEMENT DE SANTE DE LA MAMAN LA VEILLE DU RENDEZ-VOUS PREVU ET REPORTE AU 23/10/2019

Table 3: Listing of the subjects with a study duration longer than 30 days

5.1.3. Flow of subjects

As shown in **Table 4** and **Figure 3**,

- 66 infants were included in the study,
- 65 infants received the products under study (delete of the patient “included” by Dr. Souweine),
- 61 infants completed the study (Visit V2, D14).

Four (4) infants were withdrawn prematurely from the study (**Table 5**): all infants were lost to follow-up. For subject n°02-02, the paediatrician got the mother on phone; data on tolerance and efficacy were collected.

For the other 3 patients (01-13, 02-16, 05-07), the paediatrician had no news despite some contacts, thus no data on efficacy and tolerance were collected so they are not analyzed in the Safety and ITT population (more details in the following chapter).

	Number of subjects
Nb of included (enrolled) subjects	66 (7 centers)
Nb of subjects who were delivered the products	65 (6 centers)
Nb of treated subjects	62
Nb of completed subjects (control visit done)	61
Nb of subjects with premature withdrawal (after inclusion)	4

Table 4: Disposition of subjects throughout the study

Subject ID	Premature discontinuation reason specification	Date of last news
01-13	Subject lost to follow-up without product use date	14/11/2019
02-02	Subject lost to follow-up with efficacy and tolerance data available	10/12/2019
02-16	Subject lost to follow-up without product use date	14/10/2019
05-07	Subject lost to follow-up without product use date	29/10/2019

Table 5: Listing of the premature withdrawal (after inclusion)

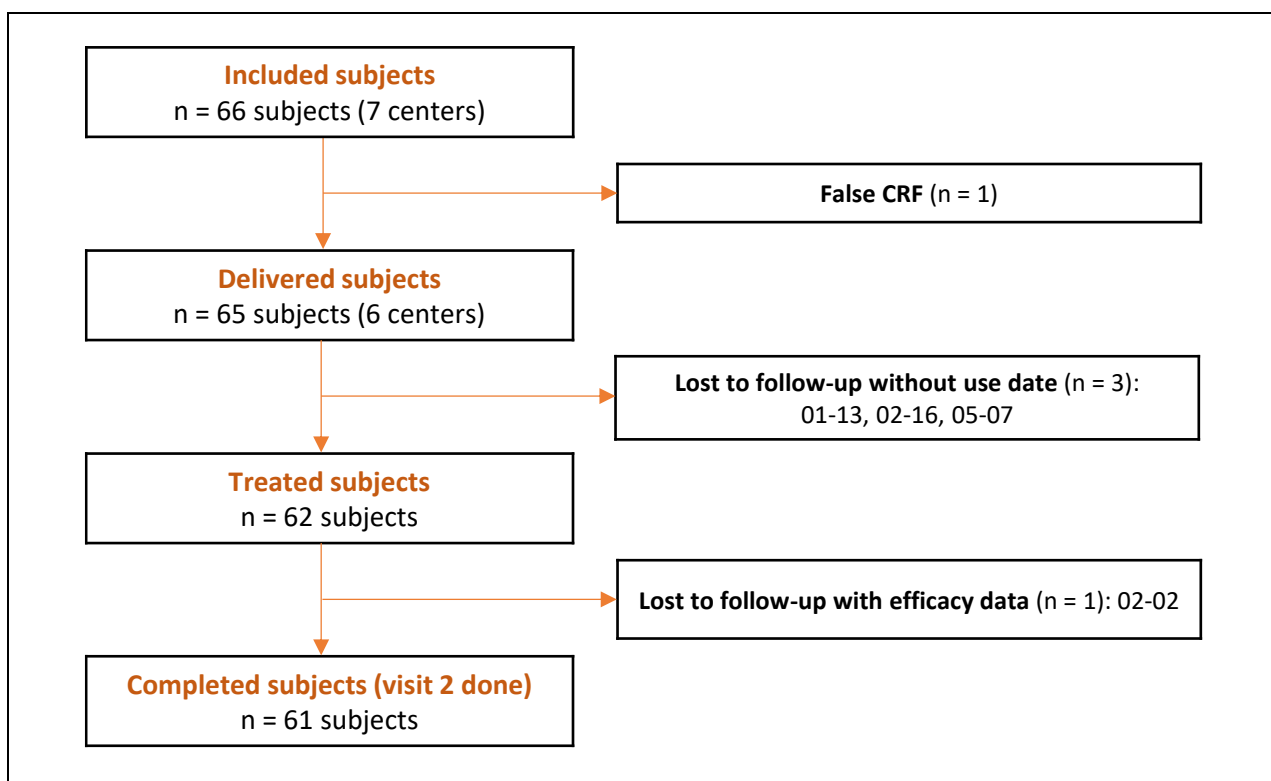


Figure 3: Participant flow diagram (infants who entered and completed the study)

5.2. Data sets analyzed

5.2.1. Compliance with eligibility criteria

Table 6 and **Table 7** describe the list of inclusion and non-inclusion criteria with the percentage of conformity. Seven (7) infants had deviation at inclusion (**Table 8**). Among these deviations:

-4 deviations are characterized as Minor deviation,

-3 deviations are characterized as Major deviation: skin pathology (n=2 - eczema) and skin event (n=1 - dryness).

Inclusion criteria number	Inclusion criteria description	Conformity (Nb of "Yes")
1	Aged between 3 and 36 months, healthy, born at term or up to 1 month before term	64 (98.5%)
2	A skin phototype I-III according to Fitzpatrick scale	65 (100.0%)
3	Wearing diapers daily with at least 2 changes during the day and a night port	65 (100.0%)
4	Taking at least 3 baths per week (daily bath or 1 day out of 2)	64 (98.5%)
5	Of which at least one parent has given its written informed consent regarding its participation in the clinical study	65 (100.0%)

Table 6: Conformity with the inclusion criteria

Non-inclusion criteria number	Non-inclusion criteria description	Conformity (Nb of "No")
1	Taking more than 7 baths per week	65 (100.0%)
2	Presenting an ongoing cutaneous event (infants with mild redness or irritation are eligible)	62 (95.4%)
3	Presenting a skin pathology	63 (96.9%)
4	Under medication that may interfere with the products under study and/or the skin	65 (100.0%)
5	Child and/or parent(s) under official guardianship	65 (100.0%)
6	Simultaneous participation in other clinical research or participation in another clinical study in the past month	65 (100.0%)

Table 7: Conformity with the non-inclusion criteria

Subject ID	Deviation at inclusion	Deviation type	Inclusion in the population		
			Safety	ITT	PP
01-08	Does not take at least 3 baths per week at inclusion (Parents indicated 2 baths per week)	Minor	Yes	Yes	Yes
02-17	Skin pathology (eczema)	Major	Yes	Yes	No
02-19	Skin pathology (eczema)	Major	Yes	Yes	No
02-20	Irritation and redness at inclusion	Minor	Yes	Yes	Yes
04-04	Skin event (dryness) at inclusion	Major	Yes	Yes	No
04-10	Born more than 1 month before the term (Birth was 35 days before the term)	Minor	Yes	Yes	Yes
05-03	Redness at inclusion	Minor	Yes	Yes	Yes

Table 8: Listing of subjects with deviations at inclusion

5.2.2. Major protocol deviations

Table 9 describes the list of subjects with a major deviation to the protocol (during the follow-up); nine (9) infants had a deviation.

The subjects with no data on tolerance were not analyzed in the Safety population (01-13, 02-16, 05-07). They were lost to follow-up, so no data were collected at V2 visit. For subject 02-16, the V2 visit was not realized but the paediatrician got the mother on phone and collected data on tolerance and efficacy.

Subject ID	Major deviation	Inclusion in the population		
		Safety	ITT	PP
01-05	Has not used both products	Yes	Yes	No
01-13	Lost to follow-up (no use data available)	No	No	No
02-02	Lost to follow-up (efficacy and tolerance data available)	Yes	Yes	No
02-16	Lost to follow-up (no use data available)	No	No	No
02-17	Skin pathology (eczema)	Yes	Yes	No
02-19	Skin pathology (eczema)	Yes	Yes	No
04-04	Skin event (dryness) at inclusion Used Dexeryl during the study	Yes	Yes	No
05-04	Has not used both products	Yes	Yes	No
05-07	Lost to follow-up (no use data available)	No	No	No

Table 9: Listing of subjects with major deviations

5.2.3. Populations for analyses

In accordance with deviations to the protocol, **Table 10** describes the patients' distribution on the three populations: Safety population, ITT population, and PP population.

As shown in **Table 11** and **Figure 4**, from 66 subjects included on the protocol:

- 62 subjects were integrated into the safety population,
- 62 subjects were integrated into the ITT population,
- and 56 subjects were integrated into the PP population.

Since the Safety and the ITT populations represent the same subjects, their statistics will be equal.

Also, to verify the stability of results, the protocol foresees for a supportive analysis on the PP population if the difference in the number of subjects between the ITT population and the PP population was more than 10%.

The difference between the ITT and the PP populations is less than 10%; as a result, no supportive analyses on the PP population will be performed.

So, in this report, all analyses will be done on the same population: Safety / ITT population (n=62).

Subject ID	Safety population	ITT population	PP population
01-01	YES	YES	YES
01-02	YES	YES	YES
01-03	YES	YES	YES

Subject ID	Safety population	ITT population	PP population
01-04	YES	YES	YES
01-05	YES	YES	NO
01-06	YES	YES	YES
01-07	YES	YES	YES
01-08	YES	YES	YES
01-09	YES	YES	YES
01-10	YES	YES	YES
01-11	YES	YES	YES
01-12	YES	YES	YES
01-13	NO	NO	NO
01-14	YES	YES	YES
02-01	YES	YES	YES
02-02	YES	YES	NO
02-03	YES	YES	YES
02-04	YES	YES	YES
02-05	YES	YES	YES
02-06	YES	YES	YES
02-07	YES	YES	YES
02-08	YES	YES	YES
02-09	YES	YES	YES
02-10	YES	YES	YES
02-11	YES	YES	YES
02-12	YES	YES	YES
02-13	YES	YES	YES
02-14	YES	YES	YES
02-15	YES	YES	YES
02-16	NO	NO	NO
02-17	YES	YES	NO
02-18	YES	YES	YES
02-19	YES	YES	NO
02-20	YES	YES	YES
03-01	YES	YES	YES
03-02	YES	YES	YES
03-03	YES	YES	YES
03-04	YES	YES	YES
03-05	YES	YES	YES
03-06	YES	YES	YES
04-01	YES	YES	YES
04-02	YES	YES	YES
04-03	YES	YES	YES
04-04	YES	YES	NO
04-05	YES	YES	YES
04-06	YES	YES	YES
04-07	YES	YES	YES
04-08	YES	YES	YES
04-09	YES	YES	YES
04-10	YES	YES	YES
04-11	YES	YES	YES
05-01	YES	YES	YES
05-02	YES	YES	YES
05-03	YES	YES	YES
05-04	YES	YES	NO
05-05	YES	YES	YES

Subject ID	Safety population	ITT population	PP population
05-06	YES	YES	YES
05-07	NO	NO	NO
05-08	YES	YES	YES
05-09	YES	YES	YES
05-10	YES	YES	YES
06-01	YES	YES	YES
06-02	YES	YES	YES
06-03	YES	YES	YES
06-04	YES	YES	YES

Table 10: Listing of subjects included in the safety, ITT and PP populations

	Nb of subjects
Inclusion	66
Safety population	62
ITT population	62
PP population	56

Table 11: Population sizes

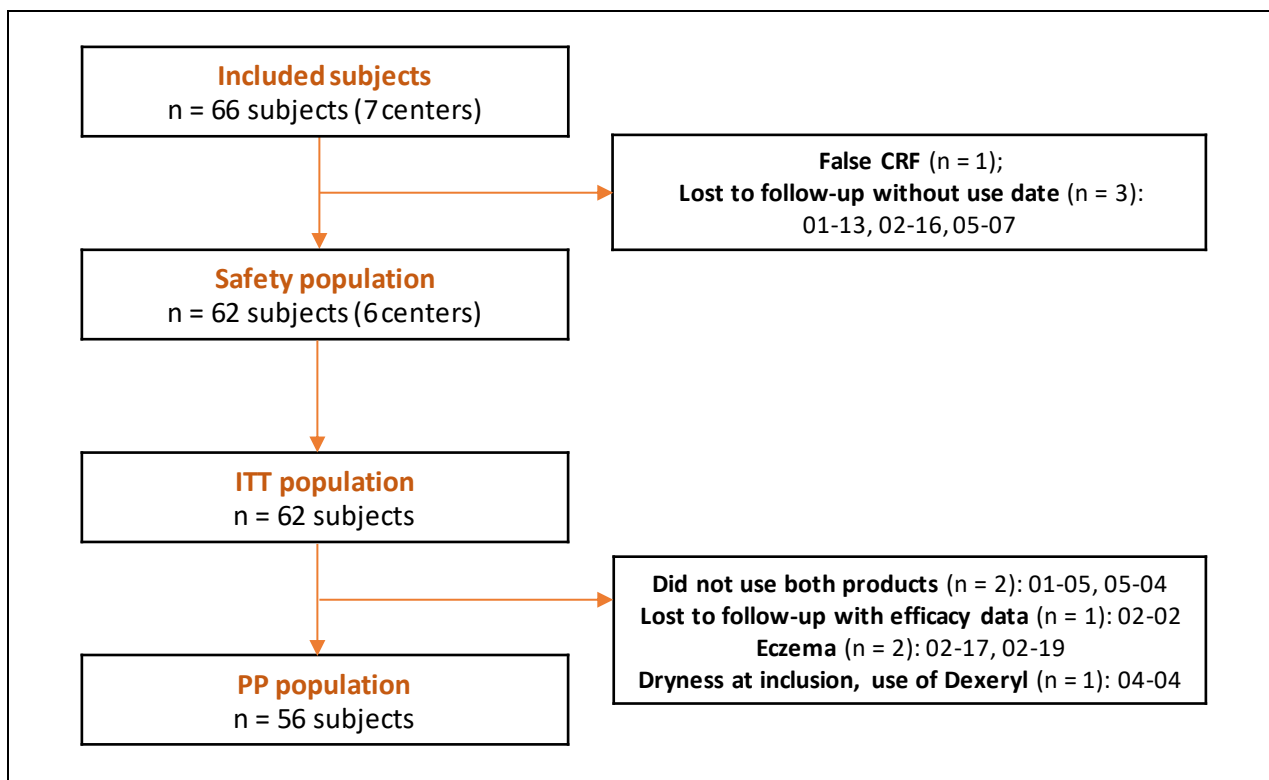


Figure 4: Data sets analyzed

6. DESCRIPTION OF SUBJECTS AT BASELINE

Baseline data are described for the Safety / ITT population.

6.1. Demographic characteristics

As described in **Table 12**, the sex ratio is **51.6 % girls / 48.4 % boys**.

Infants who took part in the research are aged **between 3 and 34 months** and the **mean age is 10.0 ± 7.4 months**; the median age is 7.5 months (**Table 13** and **Figure 5**).

Most patients are born at term; four (4) patients were born prematurely (between 7 and 35 days before term) - **Table 14**.

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Gender	N	62 (0)	
	Female	32	51.6%
	Male	30	48.4%

Table 12: Description of the genders in the safety and ITT populations

Safety and ITT populations (n = 62)		
Age (months)	N (0)	62 (0)
	Mean	10.0
	SD	7.39
	Median	7.5
	Minimum	3
	Maximum	34

Table 13: Description of the age in the safety and ITT populations

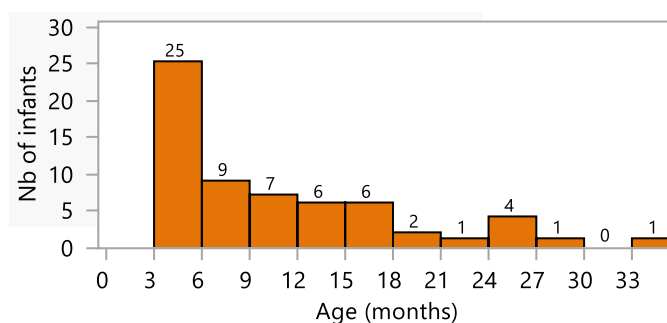


Figure 5: Distribution of the age in the safety and ITT populations

Subject ID	Nb of days before term
01-12	7
04-08	24
04-10	35
04-11	28

Table 14: Listing of premature births in the safety and ITT populations

6.2. Anthropometric data

As described in **Table 15**, the **mean height is 71.1 ± 10.8 cm** and the **mean weight is 8.4 ± 2.6 kg**.

Safety and ITT populations (n = 62)		
Height (cm)	N (md)	62 (0)
	Mean	71.06
	SD	10.759
	Median	68.75
	Minimum	44.5
	Maximum	95
Weight (kg)	N (md)	62 (0)
	Mean	8.40
	SD	2.617
	Median	7.7
	Minimum	2.1
	Maximum	16.5

Table 15: Anthropometric characteristics in the safety and ITT populations

6.3. Feeding habits: milk and diversified diet

Table 16 and **Table 17** show that:

- less than 10% of infants are exclusively breastfed,
- almost 25% of infants have an exclusive milk powder diet,
- diversified diet is introduced in almost 60% of infants.

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Milk feeding	Exclusive breast feeding	6	9.7%
	Exclusive milk powder diet	15	24.2%
	Exclusive milk feeding (breast + formula)	4	6.5%

Table 16: Description of the milk feeding habits in the safety and ITT populations

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Diversified diet	Yes	37	59.7%
	No	25	40.3%

Table 17: Description of the dietary diversification in the safety and ITT populations

6.4. Diaper changes and Cleansing habits

6.4.1. Diaper

As described in **Table 18** and **Table 19**, the mean number of **diaper changes per day** was **5.4 ± 1.2** and all infants (100%) wore diapers at night. Most infants (93.5%) wore disposable diapers. Brands are detailed in *Appendix III*.

Safety and ITT populations (n = 62)		
Diaper changes (Nb/day)	N (md)	62 (0)
	Mean	5.4
	SD	1.18
	Median	5
	Minimum	2
	Maximum	10

Table 18: Number of diaper changes per day in the safety and ITT populations

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Wearing diapers at night		62 (0)	100.0%
Diaper type	N	62 (0)	
	Disposable diapers	58	93.5%
	Washable diapers	2	3.2%
	Disposable and washable diapers	2	3.2%

Table 19: Diaper characteristics in the safety and ITT populations

6.4.2. Cleansing

Number of Baths & Products used to cleanse the body and hair

On average, infants took 4.8 baths per week, which is more than 1 day out of 2 (**Table 20**).

The product brands used to cleanse the body and hair are described in *Appendix III*.

Based on an oral questionnaire, more than 95% of parents are satisfied or very satisfied with their usual body and hair cleansing product (**Table 21**).

Safety and ITT populations (n = 62)		
Baths (Nb/week)	N (md)	62 (0)
	Mean	4.8
	SD	1.62
	Median	4.5
	Minimum	2
	Maximum	7

Table 20: Number of baths per week in the safety and ITT populations

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Satisfaction with the usual body and hair cleansing product	N	62 (0)	
	Very Satisfied	19	30.7%
	Satisfied	41	66.1%
	Moderately Satisfied	1	1.6 %
	Not Satisfied	1	1.6 %

Table 21: Satisfaction with the usual body and hair cleansing product assessed by the parents in the safety and ITT populations

Product used to cleanse diaper area

As described in **Table 22**, the usual products to cleanse the diaper area are very diversified. Liniment, used alone or in combination, is the most used product to cleanse the diaper area. The product brands used to cleanse the diaper area are described in *Appendix III*.

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Usual product to cleanse the diaper area	N	62 (0)	
	Cleansing milk + Liniment + Wipes	1	1.6%
	Cleansing milk + Water	2	3.2%
	Cleansing water	4	6.5%
	Liniment	30	48.4%
	Liniment + Water	3	4.8%
	Liniment + Wipes	4	6.5%
	Nappy change cream	2	3.2%
	Paste of water	1	1.6%
	Soap + Water	1	1.6%
	Water	7	11.3%
	Water + Wipes	2	3.2%
	Wipes	3	4.8%
Not determined	2	3.2%	

Table 22: Diaper cleansing characteristics in the safety and ITT populations

Products used to care the diaper area

The product brands used to care for the diaper area are described in *Appendix III*. Before the study, about 14% of parents didn't use a product to care for the diaper area.

Based on an oral questionnaire, 90% of parents are satisfied or very satisfied with their usual nappy change product (**Table 23**).

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Satisfaction with the usual nappy change product	N	52 (10)	
	Very Satisfied	16	30.8%
	Satisfied	31	59.6%
	Moderately Satisfied	5	9.6%
	Not Satisfied	0	0.0%

Table 23: Satisfaction with the usual nappy change product assessed by the parents in the safety and ITT populations

Also based on an oral questionnaire, most parents who took part in the protocol attach importance or big importance to the natural composition of baby care products (**Table 24**).

To note, Dr. Laurent David-Henriau proposed the participation in the protocol to a mother. The mother was interested, and she consulted the Yuka application. The application gave a bad note to Calendula Nappy Change Cream (43/100) due to the presence of Benzyl salicylate. So, the mother decided not to participate in the study.

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Importance of the natural composition of baby care products	N	62 (0)	
	Very Important	33	53.2%
	Important	22	35.5%
	Neutral / Without Opinion	7	11.3%
	Unimportant	0	0.0%
	Very unimportant	0	0.0%

Table 24: Importance of the natural composition of baby care products assessed by the parents in the safety and ITT populations

6.5. Skin history

As describe in **Table 25**, most of the infants have normal or occasionally sensitive skin (40.3% for both).

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Infant skin description	N	62 (0)	
	Normal	25	40.3%
	Occasionally sensitive	25	40.3%
	Sensitive	11	17.7%
	Very sensitive	1	1.6%

Table 25: Infant skin description in the safety and ITT populations

To be eligible for the protocol, infants shouldn't have a skin pathology.

As described in **Table 26** and **Table 27**, two (2) infants have a skin pathology: eczema; this skin pathology is considered as a major deviation to the protocol (subjects 02-17 and 02-19). Also, seventeen (17) infants have skin pathology on their family (parents or siblings) without having a skin pathology themselves.

Safety and ITT populations (n = 62)	Nb of subjects (md)	%
Infant with skin pathology	2 (0)	3.2%
Parents with skin pathology	13 (0)	21.0%
Siblings with skin pathology	5 (0)	8.1%

Table 26: Skin history in the safety and ITT populations

Subject ID	Skin pathology
01-04	Siblings: Eczema
01-05	Father: Psoriasis
01-06	Father: Psoriasis
01-07	Brother: Baby eczema
01-08	Father: Eczema
01-10	Mother: Eczema
02-12	Mother: Seborrhoeic dermatitis
02-17	Infant: Eczema
02-19	Infant: Eczema
03-04	Father: Impetigo
03-06	Siblings: Eczema
04-01	Parent: Psoriasis
04-04	Parent: Infant eczema
04-05	Father and brother: Vitiligo
04-07	Siblings: Eczema
04-09	Father: Vitiligo
05-02	Parent: Eczema
05-03	Mother: Psoriasis
05-05	Father: Eczema

Table 27: Listing of the skin pathologies in the safety and ITT populations

6.6. Initial skin examination

To be eligible for the protocol, infants should have fair skin (Type I, II or III regarding the Fitzpatrick scale) to evaluate easily the skin integrity. All infants respect this criterion (**Table 28**).

Safety and ITT populations (n = 62)		Nb of subjects (md)	%
Phototype (Fitzpatrick scale)	N	62 (0)	
	Type I	31	50.0%
	Type II	26	41.9%
	Type III	5	8.1%

Table 28: Fitzpatrick scale type in the safety and ITT populations

At baseline, the paediatrician performed a clinical examination of the skin. To be eligible for the protocol, infants shouldn't have a skin event; slight redness or irritations were accepted. As described in **Table 29**, nine (9) infants present redness and five (5) infants present irritation. As discussed during the data review meeting, all these skin events were characterized as no deviation or minor deviation.

The comments made by paediatricians are listed in **Appendix IV**.

Safety and ITT populations (n = 62)	Nb of subjects (md)	%
Redness	9 (0) ^a	11.3%
Irritation	5 (0) ^b	6.5%
Dryness	0 (0)	0.0%
Peeling	0 (0)	0.0%
Cracks	0 (0)	0.0%
Papule	0 (0)	0.0%
Pustule	0 (0)	0.0%
Oedema	0 (0)	0.0%
Vesicle	0 (0)	0.0%
Oozing	0 (0)	0.0%

Table 29: Clinical examination of the skin in the safety and ITT populations

^a01-06, 01-10, 01-14, 02-18, 02-20*, 04-01, 04-06, 04-09, 05-03*

^b01-06, 01-14, 02-18, 02-20*, 04-01

*=minor deviation; despite the redness ± irritation at baseline, the infants had a good frequency and duration of use and have not discontinued the study.

6.7. Concomitant treatments taken prior the study

In this trial, regarding the nature of the product under study, only dermatological treatments were collected. To be eligible for the protocol, infants shouldn't take treatments that can interfere with the skin.

None of the infants was under dermatological treatment at inclusion; the treatment history was not gathered.

7. CHANGE IN ANTHROPOMETRICS BETWEEN V1 AND V2

Anthropometrics data at each visit (V1 and V2) are described in the table below (Table 30). In the last column the changes from baseline are presented (V2- V1).

The paediatricians considered that all infants (n=61; md=1) had a harmonious development during the study. Globally, the height increased by 0.9 cm and the weight increased by 0.3 kg. Six (6) infants lost weight (0.1 to 0.3 kg) during the study but this loss is not abnormal for a young infant; no clinical data explained this loss.

ITT population n = 62		V1	V2	Variation $\Delta V2 - V1$
Height (cm)	N (md)	62 (0)	61 (1)	61 (1)
	Mean	71.06	72.10	0.89
	SD	10.759	10.137	1.795
	Median	68.75	71	0.5
	Minimum	44.5	57	0
	Maximum	95	95	12.5
Weight (kg)	N (md)	62	61 (1)	61 (1)
	Mean	8.40	8.71	0.28
	SD	2.617	2.483	0.388
	Median	7.7	8.1	0.2
	Minimum	2.1	4.7	-0.3
	Maximum	16.5	16.4	2.6

Table 30: Description of the anthropometric characteristics at V1, V2 and change V2-V1 in the ITT population

8. FREQUENCY OF USE

As a reminder, the parents had to complete the daily log every day. The document permitted to report data for 16 days. However, some infants were clinically monitored for more than 16 days so parents have continued to use the Calendula Nappy Change Cream and the Calendula Shampoo and Body Wash without being able to collect all data on their daily log. The total use duration has been recorded during the V2 visit, but the frequency of use statistics can only be computed with the daily log data.

8.1. Calendula Nappy Change Cream

As described in **Table 31**, the total use duration is, on average, **16.4 ± 6.0 days** and the median is 15 days. For some infants, the use duration of Calendula Nappy Change Cream is not conform to the protocol; in general, this minor deviation is due to an incompatibility between the agenda of parents and pediatrician.

The use duration is also described in **Table 32** but as said before, these data are not exact because the daily log did not allow parents to collect data after the sixteenth day of follow-up. Regarding data collected on the daily log, on 14.5 days, the product was on average used 13.8 days with 0.7 day of interruption.

ITT population (n = 62)		
Total use duration <i>from inclusion to V2 visit</i> (days)	N (md)	59 (3)
	Mean	16.4
	SD	5.96
	Median	15
	Minimum	11
	Maximum	42

Table 31: Total use duration of Calendula Nappy Change Cream between the inclusion and the V2 control visit in the ITT population

ITT population (n = 62)		
Use duration <i>based on the daily log</i> (days)	N (md)	59 (3)
	Mean	14.5
	SD	1.45
	Median	15
	Minimum	11
	Maximum	17
Nb of days of use per infant	N (md)	59 (3)
	Mean	13.8
	SD	2.02
	Median	14
	Minimum	8
	Maximum	16
Nb of days of interruption per infant	N (md)	59 (3)
	Mean	0.7
	SD	1.33
	Median	0
	Minimum	0
	Maximum	6

Table 32: Calendula Nappy Change Cream: Use duration, number of days of use and interruption based on the data from the daily log in the ITT population

The **Table 33** describes the number of daily uses of Calendula Nappy Change Cream. On average, the product has been used **2.4 ± 1.2 times per day** and the median is 2 times per day.

For some infants (n=25), despite oral and written notice provided by the paediatrician, Calendula Nappy Change Cream was used more than 2 times per day, and more precisely at each change. In the section 13.1 (satisfaction regarding Calendula Nappy Change Cream), complementary analyses will be done to evaluate if the number of daily uses impacts the satisfaction of parents (efficacy + tolerance).

ITT population (n = 62)		
Nb of daily uses	N (md)	59 (3)
	Mean	2.39
	SD	1.153
	Median	2
	Minimum	1.1
	Maximum	6.3

Table 33: Number of daily uses (from days where Calendula Nappy Change Cream was used) per infant based on the daily log data in the ITT population

8.2. Calendula Shampoo and Body Wash

As described in **Table 34**, the total use duration is, on average, **16.0 ± 6.0 days** and the median is 14 days. For some infants, the use duration of Calendula Shampoo and Body Wash is not conform to the protocol; in general, this minor deviation is due to an incompatibility between the agenda of parents and pediatrician.

The use duration is also described in **Table 35** but as said before, these data are not exact because the daily log did not allow parents to collect data after the sixteenth day of follow-up. Regarding data collected on the daily log, on 14.1 days, the product was on average used **10.4 days with 3.7 days of interruption**. These data are correlated with the number of baths taken (**Table 36**). As presented in Table 36, the average number of uses of Calendula Shampoo and Body Wash per bath is more than 1; this result can be explained by the fact that some parents used Calendula Shampoo and Body Wash without taking a bath (ex: washing with a glove).

Moreover, as described in **Table 37**, Calendula Shampoo and Body Wash has not always been used for baths; indeed, as notified by parents, it happened that the baby was cared by the family who had no access to the product under study but this case is very exceptional (98.4% of baths were taken with Calendula Shampoo and Body Wash).

ITT population (n = 62)		
Total use duration from inclusion to V2 visit (days)	N (md)	61 (1)
	Mean	16.0
	SD	5.97
	Median	14
	Minimum	7
	Maximum	41

Table 34: Total use duration of Calendula Shampoo and Body Wash between the inclusion and the V2 control visit in the ITT population

ITT population (n = 62)		
Use duration based on the daily log (days)	N (md)	61 (1)
	Mean	14.1
	SD	1.74
	Median	14
	Minimum	7
	Maximum	16
Nb of days of use per infant	N (md)	61 (1)
	Mean	10.4
	SD	3.78
	Median	10
	Minimum	4
	Maximum	16
Nb of days of interruption per infant	N (md)	61 (1)
	Mean	3.7
	SD	3.11
	Median	3
	Minimum	0
	Maximum	10

Table 35: Calendula Shampoo and Body Wash: Use duration, number of days of use and interruption based on the data from the daily log in the ITT population

ITT population (n = 62)		
Nb of uses per infant	N (md)	61 (0)
	Mean	10,9
	SD	4.45
	Median	10
	Minimum	4
	Maximum	25
Nb of baths per infant	N (md)	61 (0)
	Mean	10.3
	SD	4.01
	Median	9
	Minimum	4
	Maximum	19
Nb of uses of Calendula Shampoo and Body Wash per bath	N (md)	61 (0)
	Mean	1.08
	SD	0.360
	Median	1
	Minimum	1
	Maximum	3.6

Table 36: Frequency of use per infant based on the daily log data in the ITT population

ITT population (n = 61; md=1 ¹)	Nb of baths (md)	%
Nb of baths took	627 (0)	
Nb of baths took with Calendula Shampoo and Body Wash	617 (0)	98.4%

Table 37: Number of baths based on the daily log data in the ITT population

¹ Patient 02-02 did not come to V2 visit so the daily log is missing.

9. PRIMARY OBJECTIVE: PAEDIATRICIAN RECOMMENDATION RATE – ITT POPULATION

9.1. Recommendation rate

The main objective of this clinical study is to evaluate, in the medium term, the recommendation rate by paediatricians of Calendula Nappy Change Cream and Calendula Shampoo and Body Wash.

The main outcome is therefore the proportion of paediatricians who answered "Yes" to the question - presented in the end-of-study questionnaire - "Do you recommend... [product name]?" for each product.

The results presented below concern paediatricians who have clinically monitored patients in CALENTOL study (n=6). Indeed, the end-of-study questionnaire was not sent to Dr. Souweine in view of the false patient declared.

Table 38 and **Table 39** show that **all paediatricians (100%) who collaborated in CALENTOL study recommend Calendula Nappy Change Cream and Calendula Shampoo and Body Wash.**

ITT population (n = 62)		Nb of paediatricians (md)	%
Calendula Nappy Change Cream recommendation	N	6 (0)	
	Yes	6	100.0%
	No	0	0.0%

Table 38: Number of paediatricians who would recommend Calendula Nappy Change Cream to parents in the ITT population

ITT population (n = 62)		Nb of paediatricians (md)	%
Calendula Shampoo and Body Wash recommendation	N	6 (0)	
	Yes	6	100.0%
	No	0	0.0%

Table 39: Number of paediatricians who would recommend Calendula Shampoo and Body Wash to parents in the ITT population

9.2. Paediatricians opinions on Weleda

Before the study and at the end of the study, a questionnaire was sent to paediatricians to evaluate their feelings regarding the composition of infant care products in general and regarding the Weleda brand. The answers are summarized in **Table 40** (before the study) and **Table 41** (after the study).

Before the study, all paediatricians knew the Weleda brand. Five (5) paediatricians had a good or very good opinion regarding the brand and had confidence in the brand. One (1) paediatrician was neutral/without opinion regarding the brand and its trust in it. All paediatricians considered that the quality of the composition of infant care products is very important.

At the end of the study, the opinion regarding the Weleda brand seems to have improved: five (5) paediatricians had a very good opinion regarding the brand and one (1) had a good opinion. The trust has remained relatively stable.

		Nb of paediatricians (md)	%
Weleda brand knowledge	N	6 (0)	
	Yes	6	100.0%
	No	0	0.0%
	Have already heard about it	0	0.0%
Opinion of Weleda brand at the beginning of the study	N	6 (0)	
	Very good	2	33.3%
	Good	3	50.0%
	Neutral / Without Opinion	1	16.7%
	Somewhat bad	0	0.0%
Very bad	0	0.0%	
Trust in Weleda brand at the beginning of the study	N	6 (0)	
	Trust	2	33.3%
	Rather trust	3	50.0%
	Neutral / Without Opinion	1	16.7%
	Don't trust	0	0.0%
Composition quality of the infant care products	N	6 (0)	
	Very Important	6	100.0%
	Important	0	0.0%
	Neutral / Without Opinion	0	0.0%
	Unimportant	0	0.0%
	Very unimportant	0	0.0%

Table 40: Paediatricians' opinions on Weleda before their participation to the study

		Nb of paediatricians (md)	%
Opinion of Weleda brand at the end of the study	N	6 (0)	
	Very good	5	83.3%
	Good	1	16.7%
	Neutral / Without Opinion	0	0.0%
	Somewhat bad	0	0.0%
	Very bad	0	0.0%
Trust in Weleda brand at the end of the study	N	6 (0)	
	Trust	4	66.7%
	Rather trust	1	16.7%
	Neutral / Without Opinion	1	16.7%
	Don't trust	0	0.0%

Table 41: Paediatricians' opinions on Weleda at the end of the study

10. DERMATOLOGICAL CONCOMITANT TREATMENTS TAKEN DURING THE STUDY

As described in **Table 42**, thirteen (13) infants took one or more dermatological treatments during the study. Details are described in *Appendix V*.

During the study, the subject 04-04 has used Dexeryl (medical device). It was assessed as a major deviation during the data review since the indication is a chronic dryness of almost all the body. This information was not provided at the inclusion. Indeed, at the end of the study, the paediatrician has told to SLB Pharma that the infant has a “chronic” dryness and used Dexeryl very often; the mother had stopped the use of Dexeryl at the beginning of their participation but this product was reused after 9 days of follow-up due to the presence of dryness.

The other treatments were all judged as minor deviations because they were taken during a short period or had no influence on the principal outcome.

Subject ID	Class of product	Inclusion date	Treatment starting date	Treatment end date	Indication
01-04	Chlorhexidine	02/10/2019	16/10/2019	Still in progress at the end of the study	Impetigo
01-04	Mupirocine	02/10/2019	16/10/2019	Still in progress at the end of the study	Impetigo
01-09	Cosmetic product	04/11/2019	07/11/2019	07/11/2019	Dryness
01-09	Cosmetic product	04/11/2019	12/11/2019	12/11/2019	Dryness
02-01	Cosmetic product	26/08/2019	29/08/2019	29/08/2019	Dryness
02-03	Dexpanthenol	26/08/2019	09/09/2019	10/09/2019	Redness
02-06	Cosmetic product	27/08/2019	29/08/2019	30/08/2019	Papule
02-09	Homeopathy	29/08/2019	02/09/2019	02/09/2019	Hematoma
02-12	Mupirocine	05/09/2019	08/09/2019	14/09/2019	Infected mosquito bite
02-17	Cosmetic product	14/10/2019	05/11/2019	Still in progress at the end of the study	Eczema
02-18	Cosmetic product	15/10/2019	28/10/2019	29/10/2019	Irritation + Redness
02-19	Betamethasone	17/10/2019	18/11/2019	Still in progress at the end of the study	Eczema
02-19	Medical device	17/10/2019	18/11/2019	Still in progress at the end of the study	Eczema
04-04	Medical device	11/09/2019	20/09/2019	Still in progress at the end of the study	Dryness
04-06	Cosmetic product	12/09/2019	19/09/2019	20/09/2019	Irritation + Redness
05-01	Dexpanthenol	17/10/2019	28/10/2019	01/11/2019	Diaper rash

Table 42: Listing of the dermatological treatments taken during the study in the ITT population

11. SECONDARY OBJECTIVE: THE PRODUCTS TOLERANCE – SAFETY POPULATION

11.1. Skin events

Thirty-six (36) infants, i.e 58.1%, had at least one skin event during the study (Table 43).

A total of 70 skin events were reported between V1 and V2 visits. The list and their description are given in Appendix VI.

The majority of skin events are redness (70%), irritation (18.6%), buttons (12.9%) and dryness (10.0%) - Table 48. No serious skin event was notified.

Among the skin events (Table 44):

- 2 events led to the temporary interruption of the use of products (subjects 02-06 and 05-04),
- 1 event led to the termination of the use of products (subject 02-04: buttons on testicles),
- 13 events required a corrective treatment.

No skin event is related to the use of Calendula Nappy Change Cream and/or Calendula Shampoo and Body Wash (no adverse effect).

Safety population (n = 62 subjects)	Nb (dm)	%
Nb of subjects with at least 1 skin event	36 (0)	58.1%
Nb of subjects with at least 1 serious skin event	0 (0)	0.0%
Nb of subjects with at least 1 skin event leading to the temporary interruption of the use of the products	2 (0)	3.2%
Nb of subjects with at least 1 skin event leading to the termination of the use of the product	1 (0)	1.6%
Nb of skin events	70	

Table 43 : Number of skin events during the study in the safety population

Safety population (n = 62 subjects)		Nb of skin events (dm)	%
Number of skin events		70	
Skin event body area	N (dm)	70 (0)	
	Diaper area	46	65.7%
	Other area	24 (details in Table 53)	34.3%
Skin event severity	N (dm)	70 (0)	
	Grade 1	58	82.9%
	Grade 2	12	17.1%
Serious skin events		0 (0)	0.0%
Skin event relationship to the products	N (dm)	70 (0)	
	Bad tolerance to the investigational products	0	0.0%
	Other cause	70 (details in Table 50)	
Action	N (dm)	70 (0)	
	Temporary interruption	2	2.9%
	Termination	1	1.4%
	Treatment	13	18.6%

Table 44 : Characterization of skin events during the study in the safety population

11.2. Evaluation of the tolerance by the paediatrician

For each infant, regarding the clinical exam, daily log and questioning of parents, paediatricians have evaluated the tolerance of products.

As described in **Table 45**, paediatricians have evaluated the tolerance of Calendula Nappy Change Cream for sixty (60) infants. In total, for **95.0% of the infants**, paediatricians considered that **tolerance is good or very good**.

The tolerance is considered as bad for subject 02-04. In fact, after 8 days of use, one button appeared on testicles. At the appearance of a second button, the mother stopped the use of Calendula Nappy Change Cream; buttons disappeared three days later. On the CRF, paediatrician has considered that this event is not due to the product under study but still considered that tolerance is bad.

ITT population (n = 62)		Nb of subjects (md)	%
Calendula Nappy Change Cream tolerance	N	60 (2) ^a	
	Agreement	57	95.0%
	Very good	42	70.0%
	Good	15	25.0%
	Moderate	2	3.3%
	Bad	1	1.7%

Table 45: Calendula Nappy Change Cream tolerance assessed by the paediatricians in the ITT population

^a Subjects 01-05 and 05-04 had not used Calendula Nappy Change Cream so the paediatrician couldn't evaluate the tolerance for these two subjects.

As described in **Table 46**, paediatricians have evaluated the tolerance of Calendula Shampoo and Body Wash for sixty-two (62) infants. For **all patients**, tolerance was considered as **good or very good**.

ITT population (n = 62)		Nb of subjects (md)	%
Calendula Shampoo and Body Wash tolerance	N	62 (0)	
	Agreement	62	100.0%
	Very good	48	77.4%
	Good	14	22.6%
	Moderate	0	0.0%
	Bad	0	0.0%

Table 46: Calendula Shampoo and Body Wash tolerance assessed by the paediatricians in the ITT population

The graphs below illustrate the tolerance of products:

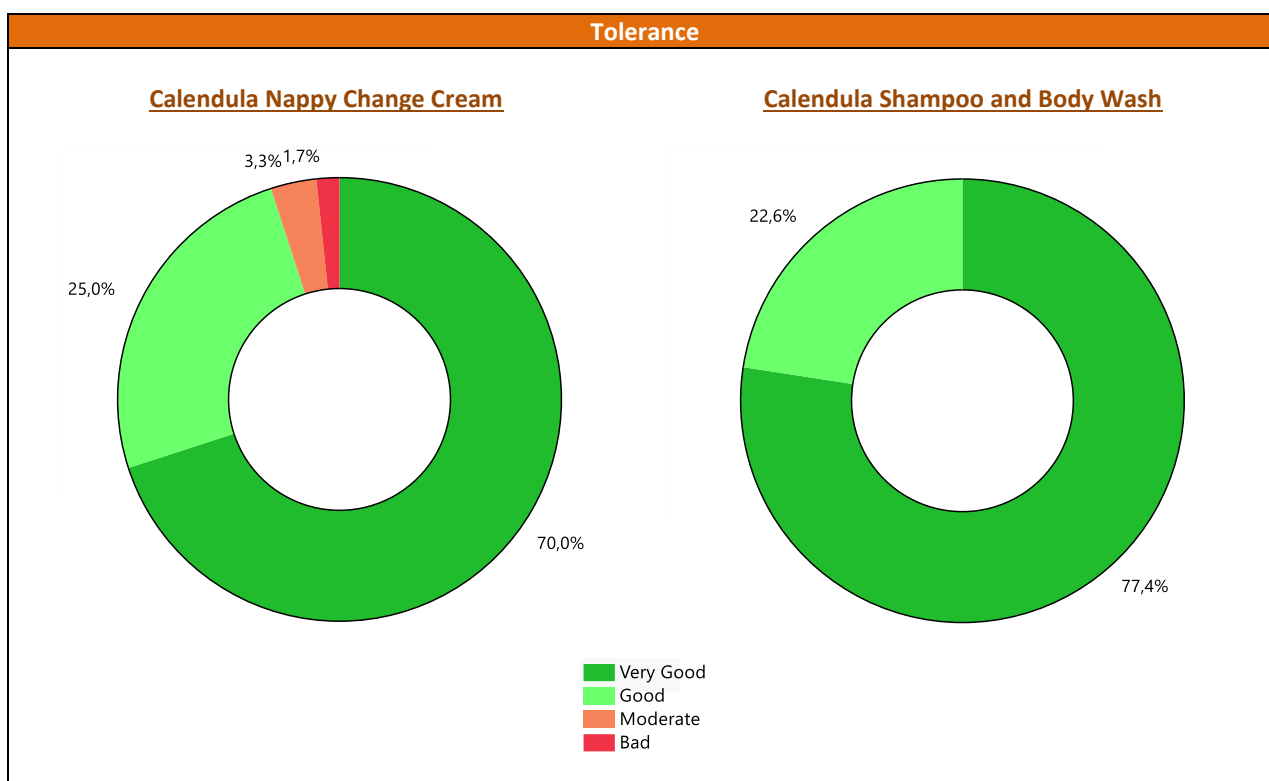


Figure 6: Tolerance of the products assessed by the paediatrician in the ITT population

12. SECONDARY OBJECTIVE: THE PRODUCTS' EFFICACY

At V2 visit (= end of follow-up), the paediatrician did a clinical exam of the skin to evaluate the tolerance and efficacy of the products. The skin events reported at V2 visit are listed in **Table 47**; *Appendix IV* listed the associated comments.

Also, **Table 48** describes the classes of skin event notified by parents and paediatricians throughout the study; 70 skin events were reported between V1 and V2 visits.

Most of the skin events are **redness** (70%), irritation (18.6%), buttons (12.9%) and dryness (10.0%).

ITT population (n = 62)	Nb of subjects (md)	%
Redness	7 (1)	11.5%
Irritation	2 (1)	3.3%
Dryness	5 (1)	8.2%
Peeling	0 (1)	0.0%
Cracks	0 (1)	0.0%
Papule	1 (1)	1.6%
Pustule	0 (1)	0.0%
Oedema	0 (1)	0.0%
Vesicle	2 (1)	3.3%
Oozing	1 (1)	1.6%

Table 47: Clinical examination of the skin at V2 control visit in the ITT population

Safety population (n = 62 subjects)	Nb of skin events (dm)	%
Buttons	9 (0)	12.9%
Dryness	7 (0)	10.0%
Hematoma	1 (0)	1.4%
Irritation	13 (0)	18.6%
Redness	49 (0)	70.0%
Vesicle	1 (0)	1.4%
Papule	1 (0)	1.4%
Diaper rash	1 (0)	1.4%
Impetigo	1 (0)	1.4%

Table 48 : Skin events specifications in the safety population

At total, twenty-six (26) infants had not presented a skin event (**Table 49**):

ITT population (n = 62 subjects)	Skin event on diaper area		Skin event on the rest of the body		Total	
	Nb (dm)	%	Nb (dm)	%	Nb (dm)	%
Nb of infants who have presented at least one skin event	27 (0)	43.5%	16 (0)	25.8%	36 (0)	58.1%
Nb of infants who have not presented a skin event	35 (0)	56.5%	46 (0)	74.2%	26 (0)	41.9%

Table 49: Number of infants who have and have not presented a skin event in the ITT population

Description of skin events

As described in the previous section (**Table 44**), no skin event was related to the products under study (no adverse effect). Most of them are related to **teething** (**Table 50**) and for 22 skin events, the cause is unknown.

Table 51 and **Table 52** describe the time interval between inclusion/emergence of the skin event and the duration of the skin event; on average, the duration of a skin event is **2.3 ± 2.2 days**. Thirteen (13) skin events required a corrective treatment.

Almost 65% of skin events appeared on the **diaper area**; the other areas are listed in **Table 53**.

Safety population (n = 62 subjects)	Nb of skin events (md)
Teething	28
Unknown	22
Other cause	10
Diarrhea	8
Poor hygiene	2
Infectious disease	2
Sweat	1
Dietary modification	0
Skin pathology	0

Table 50 : Listing of the causes of the skin events in the safety population

Time interval between skin event & inclusion

Safety population (n = 62 subjects)		Skin event on diaper area	Skin event on the rest of the body	Total
Time interval between inclusion and the skin event (days)	N (md)	46 (0)	24 (0)	70 (0)
	Mean	8.5	9.4	8.8
	SD	5.61	5.76	5.64
	Median	8.5	9	9
	Minimum	1	1	1
	Maximum	29	23	29

Table 51: Time interval between the inclusion and the skin event in the safety population

Skin event duration

Safety population (n = 62 subjects)		Skin event on diaper area	Skin event on the rest of the body	Total
Skin event duration (days)	N (md)	43 (3)	18 (6)	61 (9)
	Mean	2.3	2.2	2.3
	SD	2.33	2.07	2.24
	Median	1	1	1
	Minimum	1	1	1
	Maximum	13	8	13

Table 52: Skin event duration in the safety population

Safety population (n = 62 subjects)	Nb of skin events
Face	10
Diaper area + Face	3
Genitals	2
Leg	2
Arm	1
Arm + Back + Leg	1
Arm + Leg	1
Hand	1
Trunk	1
Whole body	1

Table 53 : Listing of the body areas (excluding nappy area) where skin events appeared in the safety population

12.1. Evaluation of the efficacy by the paediatrician

For each infant, regarding the clinical exam, daily log and questioning of parents, paediatricians have evaluated the efficacy of the products.

As described in **Table 54**, paediatricians have evaluated the efficacy of Calendula Nappy Change Cream for sixty (60) infants. In total, for **86.7% of the infants**, paediatricians considered that the **efficacy is good or very good**.

The efficacy is considered as bad for:

- subject 02-03: during its participation, the infant had 3 episodes of redness ± irritations with the use of Bepanthen for the first episode.
- subject 02-04: during its participation, buttons appeared on testicles.

ITT population (n = 62)		Nb of subjects (md)	%
Calendula Nappy Change Cream efficacy	N	60 (2) ^a	
	Agreement	52	86.7%
	Very good	41	68.3%
	Good	11	18.3%
	Moderate	6	10.0%
	Bad	2	3.3%

Table 54: Calendula Nappy Change Cream efficacy assessed by the paediatrician in the ITT population

^a Subjects 01-05 and 05-04 had not used Calendula Nappy Change Cream so the paediatrician couldn't evaluate the efficacy for these two subjects.

As described in **Table 55**, paediatricians have evaluated the efficacy of Calendula Shampoo and Body Wash for sixty-two (62) infants. In total, for **96.8% of the infants**, paediatricians considered that the **efficacy is good or very good**.

The efficacy is considered as bad for:

- subject 02-05: parents don't recommend the product; "it's difficult to rinse" and "the smell is strong for a soap".
- subject 02-19: after 7 days of use, buttons, redness, and dryness appeared on the face and diaper area. In fact, this infant has eczema, so the Calendula Shampoo and Body Wash is not suitable for this infant.

ITT population (n = 62)		Nb of subjects (md)	%
Calendula Shampoo and Body Wash efficacy	N	62 (0)	
	Agreement	60	96.8%
	Very good	42	67.7%
	Good	18	29.0%
	Moderate	0	0.0%
	Bad	2 ^a	3.2%

Table 55: Calendula Shampoo and Body Wash efficacy assessed by the paediatrician in the ITT population

The graphs below illustrate the tolerance of products:

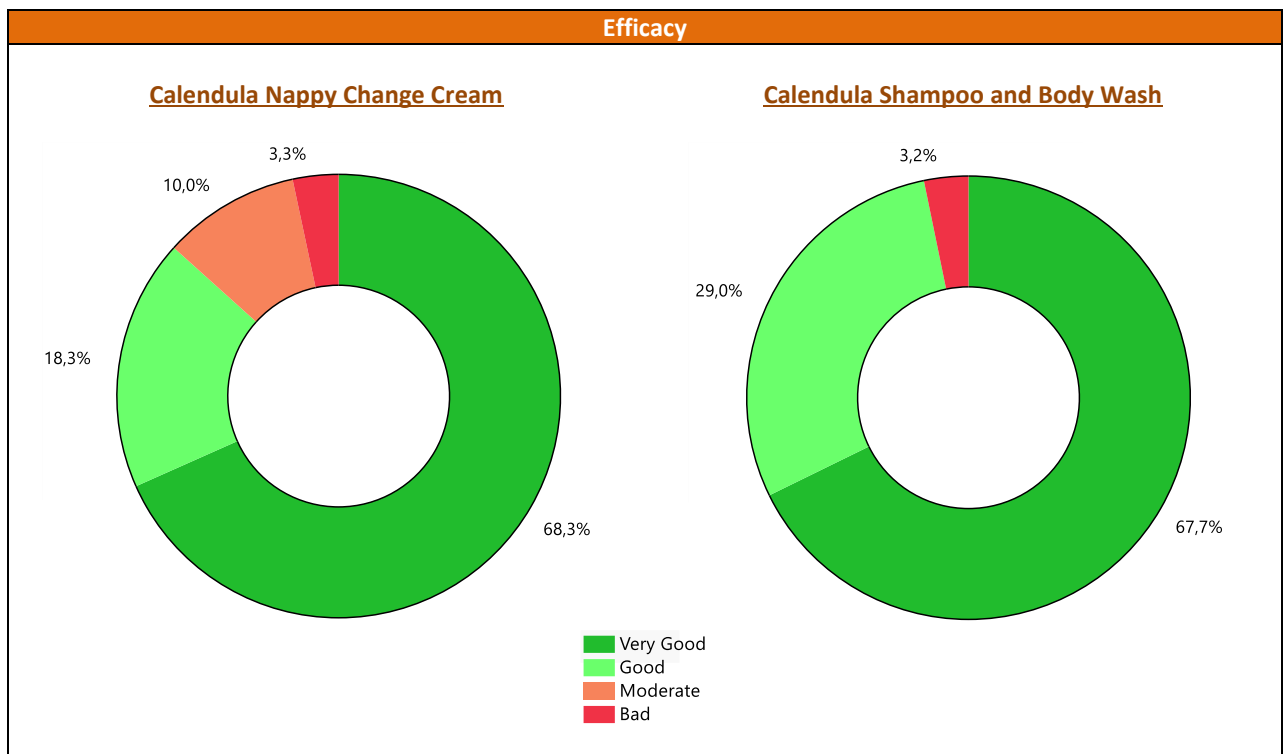


Figure 7: Efficacy of the products assessed by the paediatrician in the ITT population

13. SECONDARY OBJECTIVE: PARENTS' SATISFACTION ON PRODUCTS

13.1. Calendula Nappy Change Cream

At the end of the follow-up, parents had to complete a self-questionnaire regarding the Calendula Nappy Change Cream.

Table 56 describes the answers (6 parts); for each item, answers are presented in terms of number and percentage. The last columns (green columns) present the percentage of agreement (sum of “totally agree” and “agree”). Also, as described in section 3, a test to compare the percentage of agreement observed with the theoretical percentage of 70% was done and a p-value was calculated for each item.

N°	Question	Totally agree	Agree	Neither Agree nor disagree	Disagree	Not agree at all	Agreement
1	The product is easy to apply (means that it is easy to get the product out of the tube and it does not drop of the finger) (<i>md = 2</i>)	36 60.0%	13 21.7%	9 15.0%	2 3.3%	0 0.0%	49 81.7%
2	The product can be easily spread (means the consistency is soft enough that the product can be distributed easily on the skin) (<i>md = 2</i>)	34 56.7%	16 26.7%	6 10.0%	4 6.7%	0 0.0%	50 83.3%
3	I like the smell of the product (<i>md = 2</i>)	35 58.3%	9 15.0%	13 21.7%	2 3.3%	1 1.7%	44 73.3%
4	The product forms a protective layer (<i>md = 3</i>)	37 62.7%	13 22.0%	9 15.3%	0 0.0%	0 0.0%	50 84.7%
5	The skin of my baby looks healthy (<i>md = 2</i>)	38 63.3%	17 28.3%	4 6.7%	1 1.7%	0 0.0%	55 91.7%
6	The product left my baby's skin feeling soft and smooth (<i>md = 2</i>)	37 61.7%	10 16.7%	12 20.0%	1 1.7%	0 0.0%	47 78.3%
7	The skin is intensively cared for and nourished (<i>md = 2</i>)	32 53.3%	17 28.3%	10 16.7%	1 1.7%	0 0.0%	49 81.7%
8	The product protects from wetness in the nappy area (<i>md = 2</i>)	26 43.3%	16 26.7%	17 28.3%	1 1.7%	0 0.0%	42 70.0%
9	The product protects against redness / irritation in the area covered by the diaper (<i>md = 3</i>)	30 50.8%	17 28.8%	9 15.3%	3 5.1%	0 0.0%	47 79.7%
10	The product is especially suitable for sensitive baby's skin (<i>md = 2</i>)	39 65.0%	12 20.0%	7 11.7%	2 3.3%	0 0.0%	51 85.0%

Among infants who took part in the protocol, half of them presented redness or irritation in the nappy area during the participation. For them:

-73.3% of parents consider that the **product soothes the skin** of their baby,

-76.7% of parents consider that the **product cares the irritated and reddened skin** of their baby,

-53.3% of parents consider that their baby seems to better endure the diaper changing when using the Calendula Nappy Change Cream.

N°	Question	Yes	No
11	Did your baby have any redness or irritation in the nappy area at the time of the study? (<i>md = 2</i>)	30 50.0%	30 50.0%

N°	Question	Totally agree	Agree	Neither Agree nor disagree	Disagree	Not agree at all	Agreement
12	The product soothes the skin of my baby (<i>md = 0</i>)	12 40.0%	10 33.3%	6 20.0%	2 6.7%	0 0.0%	22 73.3%
13	The product cares the irritated and reddened skin of my baby (<i>md = 0</i>)	12 40.0%	11 36.7%	3 10.0%	4 13.3%	0 0.0%	23 76.7%
14	When using the product, in case of redness and irritations, my baby seems to better endure the diaper changing (means my baby seems to have less pain during the change) (<i>md = 0</i>)	5 16.7%	11 36.7%	13 43.3%	1 3.3%	0 0.0%	16 53.3%

As described below, **94.9%** of parents consider that the **skin tolerance** of the Calendula Nappy Change Cream is **good or very good**.

For three infants (02-04, 04-06, 05-08), parents considered that skin tolerance is bad. All these three patients had skin event(s) during their participation in the study, but these skin events are not due to the product.

N°	Question	Very good	Good	Bad	Very Bad	Agreement
15	How do you judge the skin tolerance of the product? (<i>md = 3</i>)	36 61.0%	20 33.9%	3 5.1%	0 0.0%	56 94.9% <i>p < 0.0001</i>

Globally, most parents are **satisfied** (89.8%) with the Calendula Nappy Change Cream and they are likely to **recommend the product** to other parents (86.4%). Near than 80% of parents **prefer the Calendula Nappy Change Cream** to their usual cream used to care for the nappy area.

N°	Question	Yes	No
16	Are you satisfied with the product? (<i>md = 3</i>)	53 89.8%	6 ^a 10.2%
17	Would you recommend the product to other parents? (<i>md = 3</i>)	51 86.4%	8 ^b 13.6%

^a 02-03, 02-04, 04-02, 04-06, 05-01, 05-08

^b 02-03, 02-04, 02-07, 02-20, 04-02, 04-06, 05-01, 05-08

N°	Question	Calendula Nappy Change Cream (used in this protocol)	Your usual cream	No decision
18	Which product do you prefer for the prevention of redness and irritation of the diaper area? (<i>md = 3</i>)	47 79.7%	11 18.6%	1 1.7%

Table 56: Self-administered questionnaires answers on Calendula Nappy Change Cream in the ITT population

On question 19 of this self-questionnaire, parents could add a comment regarding the Calendula Nappy Change Cream. All comments are listed in [Appendix VII](#).

As shown in [Table 57](#), among parents who prefer the Calendula Nappy Change Cream (compared to their usual product), 76.2% were using a conventional nappy change cream prior to their participation in the study.

ITT population (n = 62 subjects)		Subjects who prefer the Calendula Nappy Change Cream	
Usual nappy change cream	N (md)	42 (5)	
	Conventional	32	76.2%
	NOC	10	23.8%

Table 57: Description of the usual nappy change cream among all the subjects and the ones who prefer the Calendula Nappy Change Cream over their usual product in the ITT population

The graphs below illustrate some important claims regarding the Calendula Nappy Change Cream:

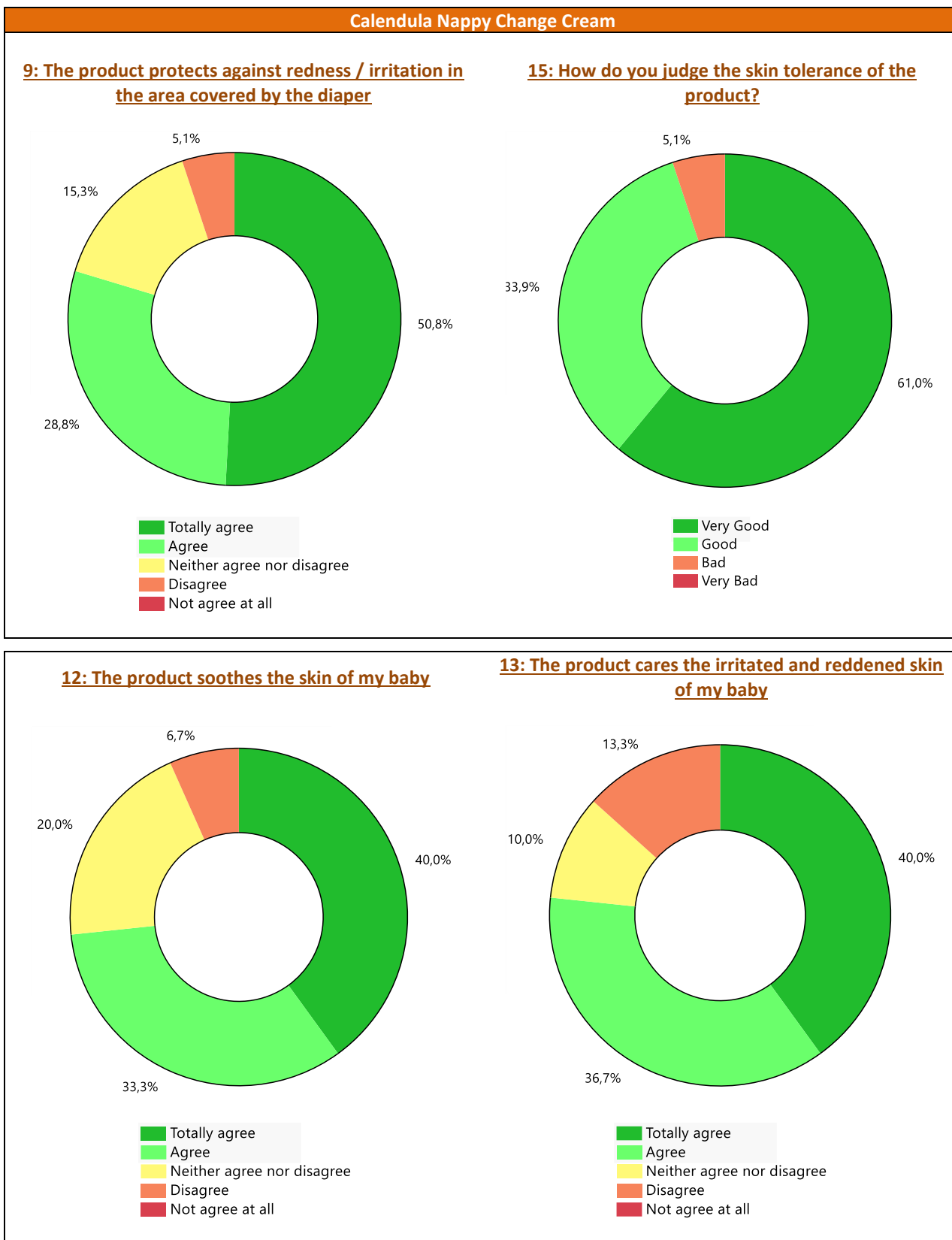


Figure 8: Calendula Nappy Change Cream evaluations by the parents in the ITT population

ADDITIONAL ANALYSIS

As described in section 8, 25 subjects have used the Calendula Nappy Change Cream more than 2 times a day on average. Hence, for these infants, it seems interesting to study in more detail the satisfaction of parents regarding efficacy and tolerance.

Table 58 presents some answers to the self-questionnaire of parents who used more than 2 times a day Calendula Nappy Change Cream.

N°	Question	Totally agree	Agree	Neither Agree nor disagree	Disagree	Not agree at all	Agreement
7	The skin is intensively cared for and nourished (<i>md = 0</i>)	13 52.0%	7 28.0%	4 16.0%	1 4.0%	0 0.0%	20 80.0%
9	The product protects against redness / irritation in the area covered by the diaper (<i>md = 0</i>)	11 44.0%	6 24.0%	6 24.0%	2 8.0%	0 0.0%	17 68.0%

N°	Question	Yes	No
11	Did your baby have any redness or irritation in the nappy area at the time of the study? (<i>md = 0</i>)	14 56.0%	11 44.0%

N°	Question	Totally agree	Agree	Neither Agree nor disagree	Disagree	Not agree at all	Agreement
12	The product soothes the skin of my baby (<i>md = 0</i>)	3 21.4%	5 35.7%	4 28.6%	2 14.3%	0 0.0%	8 57.1%
13	The product cares the irritated and reddened skin of my baby (<i>md = 0</i>)	3 21.4%	6 42.9%	2 14.3%	3 21.4%	0 0.0%	9 64.3%
14	When using the product, in case of redness and irritations, my baby seems to better endure the diaper changing (means my baby seems to have less pain during the change) (<i>md = 0</i>)	1 7.1%	3 21.4%	9 64.3%	1 7.1%	0 0.0%	4 28.6%

N°	Question	Very good	Good	Bad	Very Bad	Agreement
15	How do you judge the skin tolerance of the product? (<i>md = 0</i>)	15 60.0%	8 32.0%	2 8.0%	0 0.0%	23 92.0%

N°	Question	Yes	No
16	Are you satisfied with the product? <i>(md = 0)</i>	20 80.0%	5 20.0%
17	Would you recommend the product to other parents? <i>(md = 0)</i>	19 76.0%	6 24.0%

N°	Question	Calendula Nappy Change Cream (used in this protocol)	Your usual cream	No decision
18	Which product do you prefer for the prevention of redness and irritation of the diaper area? <i>(md = 0)</i>	16 64.0%	8 32.0%	1 4.0%

Table 58: Self-administered questionnaires answers on Calendula Nappy Change Cream for subjects who used the product more than 2 times a day on average

Table 59 presents the comparison of parent’s agreement between subjects who have used the Calendula Nappy Change Cream more than 2 times a day and subjects who have used it as indicated in the notice. Except question n°14, there are no difference between the 2 subgroups.

According to this statistical analysis, it seems that infants who have used the product as indicated in the notice better endure the diaper changing.

AQ	Agreement ≤ 2 daily uses on average	Agreement > 2 daily uses on average	p-value
7	29 82.9%	20 80.0%	1.0000 (Fisher exact test)
9	30 88.2%	17 68.0%	0.0564 (Chi2 test)
12	14 87.5%	8 57.1%	0.1010 (Fisher exact test)
13	14 87.5%	9 64.3%	0.2040 (Fisher exact test)
14	12 75.0%	4 28.6%	0.0110 (Chi2 test)
15	33 97.1%	23 92.0%	0.5686 (Fisher exact test)

Table 59: Comparison of the percent of agreement between subjects who have used the Calendula Nappy more than 2 times a day and subjects who have used it as indicated in the notice

13.2. Calendula Shampoo and Body Wash

At the end of the follow-up, parents had to complete a self-questionnaire regarding the Calendula Shampoo and Body Wash.

Table 60 describes the answers (4 parts); for each item, answers are presented in terms of number and percentage. The last columns (green columns) present the percentage of agreement (sum of “totally agree” and “agree”).

As described below, **93.4%** of parents consider that the **skin tolerance** of the Calendula Shampoo and Body Wash is **good or very good**.

N°	Question	Very good	Good	Without opinion	Bad	Very Bad	Agreement
1	How do you evaluate the perfume of Calendula Shampoo and Body Wash? (<i>md = 1</i>)	27 44.3%	24 39.3%	6 9.8%	3 4.9%	1 1.6%	51 83.6%
2	How do you evaluate the efficacy of Calendula Shampoo and Body Wash? (nourishing power) (<i>md = 1</i>)	27 44.3%	27 44.3%	7 11.5%	0 0.0%	0 0.0%	54 88.5%
3	How do you evaluate the rinsing (means: does the product is easy to rinse)? (<i>md = 1</i>)	30 49.2%	22 36.1%	5 8.2%	3 4.9%	1 1.7%	52 85.2%
4	How do you judge the skin tolerance of the product? (<i>md = 1</i>)	43 70.5%	14 23.0%	4 6.6%	0 0.0%	0 0.0%	57 93.4%

N°	Question	Totally agree	Agree	Neither Agree nor disagree	Disagree	Not agree at all	Agreement
5	The skin of my baby is supple and soft after product use (<i>md = 1</i>)	31 50.8%	20 32.8%	10 16.4%	0 0.0%	0 0.0%	51 83.6%
6	The skin of my baby is gently cleaned (<i>md = 1</i>)	34 55.7%	23 37.7%	3 4.9%	1 16.4%	0 0.0%	57 93.4%
7	The product doesn't dry out the skin (<i>md = 1</i>)	35 57.4%	20 32.8%	6 9.8%	0 0.0%	0 0.0%	55 90.2%
8	The skin of my baby smells good after use (<i>md = 1</i>)	27 44.3%	17 27.9%	13 21.3%	2 3.3%	2 3.3%	44 72.1%

Globally, most parents are **satisfied** (93.4%) with the Calendula Shampoo and Body Wash and more than 80% want to continue using Calendula Shampoo and Body Wash. Also, they are likely to **recommend the product** to other parents (88.1%). Nearly 70% of parents **prefer the Calendula Shampoo and Body Wash** to their usual product used to cleanse the body and hair.

N°	Question	Yes	No
9	Are you satisfied with the product? (<i>md = 1</i>)	57 93.4%	4 ^a 6.6%
10	After the test, would you like to continue using Calendula Shampoo and Body Wash? (<i>md = 1</i>)	49 80.3%	12 ^b 19.7%
11	Would you recommend the tested product to other parents? (<i>md = 3</i>)	52 88.1%	7 ^c 11.9%

^a 02-19, 05-04, 05-08, 05-10

^b 01-14, 02-01, 02-14, 02-19, 03-01, 03-05, 04-02, 05-04, 05-08, 05-09, 05-10, 06-02

^c 02-05, 02-10, 02-19, 03-01, 05-08, 05-09, 05-10

N°	Question	Calendula Shampoo and Body Wash (used in this protocol)	Your usual washing care	No decision
12	Which product do you prefer to clean your baby gently? (<i>md = 1</i>)	41 67.2%	18 29.5%	2 3.3%

Table 60: Self-administered questionnaires answers on Calendula Shampoo and Body Wash in the ITT population

On question 19 of this self-questionnaire, parents had the possibility to add a comment regarding the Calendula Shampoo and Body Wash. All comments are listed in [Appendix VIII](#). Globally, the main comment is regarding the container; parents suggest a push-button to deliver easily the product during the cleansing.

As shown in [Table 61](#), among parents who prefer the Calendula Shampoo and Body Wash (compared to their usual product), three quarters were using a conventional cleansing product prior to their participation in the study.

ITT population (n = 62 subjects)		Subjects who prefer the Calendula Shampoo and Body Wash	
Usual washing care	N (md)	40 (1)	
	Conventional	30	75.0%
	NOC	10	25.0%

Table 61: Description of the usual washing care among the subjects who prefer the Calendula Shampoo and Body Wash over their usual product in the ITT population

The graphs below illustrate some important claims regarding the Calendula Shampoo and Body Wash:

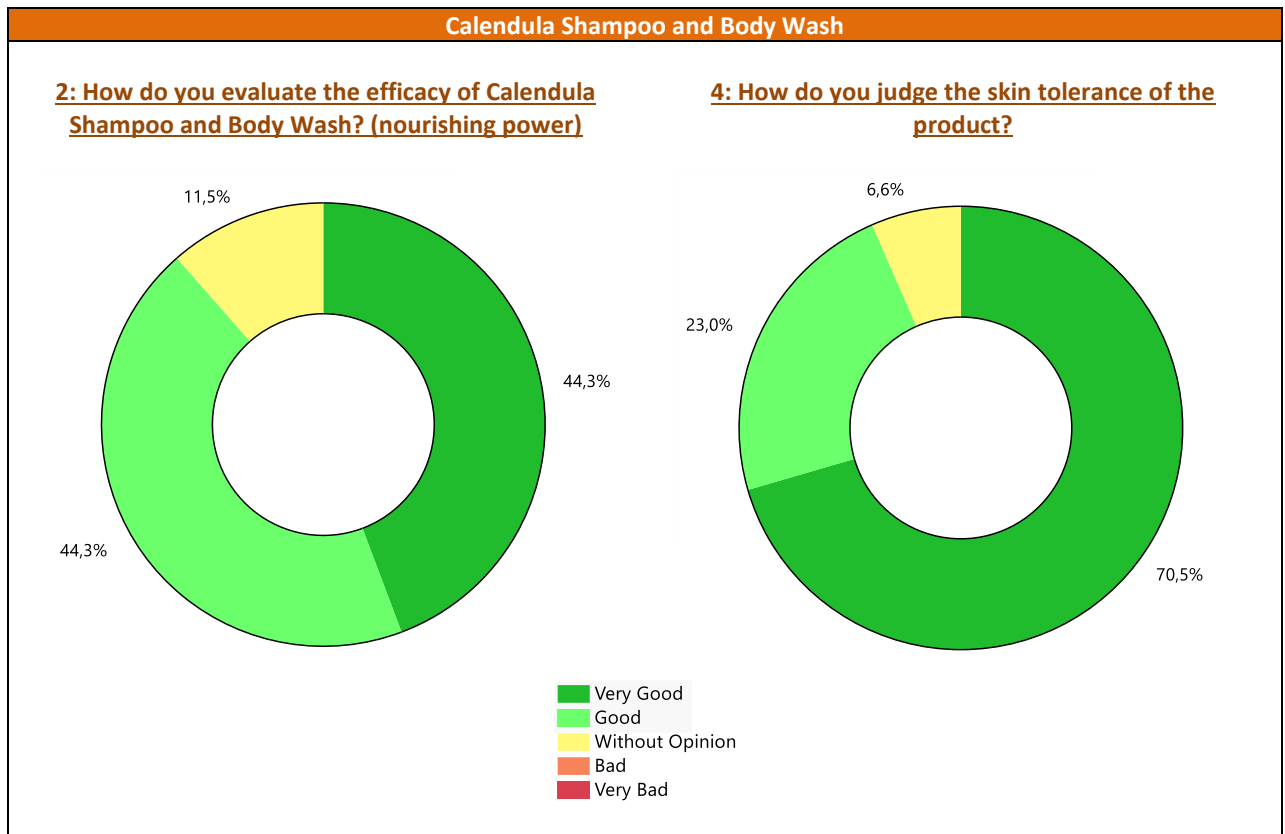


Figure 9: Calendula Shampoo and Body Wash evaluations by the parents in the ITT population

14. SUMMARY OF RESULTS

The CALENTOL study entitled “Tolerability and effectiveness of Calendula Nappy Change Cream and Calendula Shampoo and Body Wash – A prospective, multicenter, paediatric study”, conducted within seven pediatric liberal offices shows the following results:

The clinical investigation was performed from August to December 2019, with 3 months for the recruitment period.

In total, 66 infants were included, 65 infants received the products under study and ultimately, 61 infants completed the study. Four infants were withdrawn prematurely from the study; they were lost-to-follow-up.

All analyses were done on the same population: Safety/ ITT population (n=62)

Characteristics at Baseline

Demographic and anthropometric data

- The sex ratio is **51.6% girls/ 48.4% boys**,
- Most infants were born at term; 4 infants were born prematurely,
- The mean age is **10.0 ± 7.4 months** and the median age is 7.5 months,
- The mean **height is 71.1 cm** and the mean **weight is 8.4 ± 2.6 kg**.

Feeding habits

- Less than 10% of infants are exclusively breastfed,
- Almost 25% of infants have an exclusive milk powder diet,
- A diversified diet is introduced in almost 60% of infants.

Cleansing habits

- Most infants wear **disposable diapers**,
- All infants wear diapers at night and the mean number of diaper changes per day is **5.4 ± 1.2**.
- On average, infants **take a bath more than 1 day out of 2**,
- Liniment, used alone or in combination, is the product the most used to cleanse the diaper area,
- Before their participation in CALENTOL study, about 14% of parents didn't use products to care for the diaper area.

Skin history and initial skin examination

- Most infants have **normal or occasionally sensitive skin** (80.6%) and all infants have fair skin,
- 2 infants present a skin pathology at inclusion (eczema) and 17 infants have a skin pathology on their family (parents or siblings) without having a skin pathology themselves,
- 9 infants present redness and 5 infants present irritations at baseline; these skin events are considered as a minor deviation.

Concomitant treatments

No infant was under dermatological treatment at inclusion.

Frequency of use

Calendula Nappy Change Cream

-The total use duration (from V1 to V2) is **16.4 ± 6.0 days** and the median is 15 days,

-Based on the data collected in the daily log, on 14.5 days, the product was on average used **13.8 days** with **0.7 day of interruption**.

-On average, the product is used **2.4 ± 1.2 times per day** and the median is 2 times per day.

Calendula Shampoo and Body Wash

-The total use duration is **16.0 ± 6.0 days** and the median is 14 days,

-Based on the data collected in the daily log, on 14.1 days, the product was on average used **10.4 days** with **3.7 days of interruption**; these data are correlated with the number of baths taken.

Dermatological concomitant treatments

-**13 infants took one or more dermatological treatments** (n=16) during the study.

-Most of these treatments are considered as a minor deviation because they were taken during a short period or had no influence on the principal outcome; except for subject 04-04 who used Dexeryl (medical device) for a chronic dryness of almost all the body (the mother had stopped the use of Dexeryl before their participation to the protocol but this product was reused after 9 days of follow-up due to the presence of dryness).

Tolerance

Skin event

-36 infants (58.1%) had at least one skin event during the study,

-**70 skin events** were reported between V1 and V2 visits. **No serious skin event** was notified.

-**No skin event is related to the use of Calendula Nappy Change Cream and/ or Calendula Shampoo and Body Wash** (= no adverse effect).

Evaluation by the paediatrician

Calendula Nappy Change Cream

Paediatricians evaluate the **tolerance of Calendula Nappy Change Cream as Good or Very Good for 95% of the infants included in the study.**

Calendula Shampoo and Body Wash

Paediatricians evaluate the **tolerance of Calendula Shampoo and Body Wash as Good or Very Good for all infants** (100%) included in the study.

Evaluation by the parents

Calendula Nappy Change Cream

94.9% of parents consider that the **skin tolerance of Calendula Nappy Change Cream is Good or Very Good.**

Calendula Shampoo and Body Wash

93.4% of parents consider that the **skin tolerance of Calendula Shampoo and Body Wash is Good or Very Good.**

Efficacy

-**70 skin events** were reported between V1 and V2 visits. Most of the skin events are redness (70.0%), irritation (18.6%), buttons (12.9%) and dryness (10.0%).

-Most of them are **related to teething** and on average the duration of a skin event is 2.3 ± 2.2 days. 13 skin events required a corrective treatment.

-Almost 65% of skin events appeared **on the diaper area.**

-26 infants (41.9%) have not presented a skin event.

*Evaluation by the paediatrician*Calendula Nappy Change Cream

Paediatricians consider that the **efficacy of Calendula Nappy Change Cream is Good or Very Good for 86.7% of the infants included in the study.**

Calendula Shampoo and Body Wash

Paediatricians consider that the **efficacy of Calendula Shampoo and Body Wash is Good or Very Good for 96.8% of the infants included in the study.**

Evaluation by the parents

According to the guidelines provided by WELEDA, a claim is proven either when the data show the relevance and significance. The significance goes also along with a consent of around 70%.

Calendula Nappy Change Cream

The table below summarizes the claims with an agreement of 70% or more:

Question	Totally agree	Agree	Neither Agree nor disagree	Disagree	Not agree at all	Agreement
The product is easy to apply (means that it is easy to get the product out of the tube and it does not drop of the finger) (<i>md = 2</i>)	36 60.0%	13 21.7%	9 15.0%	2 3.3%	0 0.0%	49 81.7%
The product can be easily spread (means the consistency is soft enough that the product can be distributed easily on the skin) (<i>md = 2</i>)	34 56.7%	16 26.7%	6 10.0%	4 6.7%	0 0.0%	50 83.3%
I like the smell of the product (<i>md = 2</i>)	35 58.3%	9 15.0%	13 21.7%	2 3.3%	1 1.7%	44 73.3%
The product forms a protective layer (<i>md = 3</i>)	37 62.7%	13 22.0%	9 15.3%	0 0.0%	0 0.0%	50 84.7%
The skin of my baby looks healthy (<i>md = 2</i>)	38 63.3%	17 28.3%	4 6.7%	1 1.7%	0 0.0%	55 91.7%
The product left my baby's skin feeling soft and smooth (<i>md = 2</i>)	37 61.7%	10 16.7%	12 20.0%	1 1.7%	0 0.0%	47 78.3%
The skin is intensively cared for and nourished (<i>md = 2</i>)	32 53.3%	17 28.3%	10 16.7%	1 1.7%	0 0.0%	49 81.7%
The product protects from wetness in the nappy area (<i>md = 2</i>)	26 43.3%	16 26.7%	17 28.3%	1 1.7%	0 0.0%	42 70.0%
The product protects against redness / irritation in the area covered by the diaper (<i>md = 3</i>)	30 50.8%	17 28.8%	9 15.3%	3 5.1%	0 0.0%	47 79.7%
The product is especially suitable for sensitive baby's skin (<i>md = 2</i>)	39 65.0%	12 20.0%	7 11.7%	2 3.3%	0 0.0%	51 85.0%
The product soothes the skin of my baby (<i>md = 0</i>)	12 40.0%	10 33.3%	6 20.0%	2 6.7%	0 0.0%	22 73.3%
The product cares the irritated and reddened skin of my baby (<i>md = 0</i>)	12 40.0%	11 36.7%	3 10.0%	4 13.3%	0 0.0%	23 76.7%

-89.8% of parents are satisfied, and they are likely to recommend the product to other parents (86.4%).

-Near 80% of parents prefer Calendula Nappy Change Cream to their usual cream used to care for the nappy area. Among these parents, more than three quarters were using a conventional nappy change cream prior to their participation in the study.

Calendula Shampoo and Body Wash

The table below summarizes the claims with an agreement of 70% or more:

Question	Very good	Good	Without opinion	Bad	Very Bad	Agreement
How do you evaluate the perfume of Calendula Shampoo and Body Wash? (<i>md = 1</i>)	27 44.3%	24 39.3%	6 9.8%	3 4.9%	1 1.6%	51 83.6%
How do you evaluate the efficacy of Calendula Shampoo and Body Wash? (nourishing power) (<i>md = 1</i>)	27 44.3%	27 44.3%	7 11.5%	0 0.0%	0 0.0%	54 88.5%
How do you evaluate the rinsing (means: does the product is easy to rinse)? (<i>md = 1</i>)	30 49.2%	22 36.1%	5 8.2%	3 4.9%	1 1.7%	52 85.2%
Question	Totally agree	Agree	Neither Agree nor disagree	Disagree	Not agree at all	Agreement
The skin of my baby is supple and soft after product use (<i>md = 1</i>)	31 50.8%	20 32.8%	10 16.4%	0 0.0%	0 0.0%	51 83.6%
The skin of my baby is gently cleaned (<i>md = 1</i>)	34 55.7%	23 37.7%	3 4.9%	1 16.4%	0 0.0%	57 93.4%
The product doesn't dry out the skin (<i>md = 1</i>)	35 57.4%	20 32.8%	6 9.8%	0 0.0%	0 0.0%	55 90.2%
The skin of my baby smells good after use (<i>md = 1</i>)	27 44.3%	17 27.9%	13 21.3%	2 3.3%	2 3.3%	44 72.1%

-93.4% of parents are satisfied, and they are likely to recommend the product to other parents (88.1%).

-80% of parents want to continue using Calendula Shampoo and Body Wash,

-70% of parents prefer Calendula Shampoo and Body Wash to their usual product to cleanse the body and hair. Among these parents, three quarters were using a conventional cleansing product prior to their participation in the study.

Paediatrician recommendation

In this study, 6 paediatricians have included and clinically monitored 62 infants. Based on the questioning of parents, the daily log and a clinical exam, paediatricians have evaluated their recommendation. All paediatricians (100%) recommend Calendula Nappy Change Cream and Calendula Shampoo and Body Wash.

15. APPENDIX

Appendix I	Data review report V1.2 (Extract; pages 1, 49 and 50)
Appendix II	Informed Consent form
Appendix III	Listing of the cleansing habits (verbatim and classes)
Appendix IV	Listing of the investigator’s comments during V1 and V2 clinical examinations
Appendix V	Listing of the dermatological concomitant treatments taken during the study
Appendix VI	Listing of the skin events
Appendix VII	Listing of the parent’s comments about Calendula Nappy Change Cream (verbatim of the AQ19 Calendula Nappy Change Cream self-administered questionnaire)
Appendix VIII	Listing of the parent’s comments about Calendula Shampoo and Body Wash (verbatim of the AQ19 – Calendula Shampoo and Body Wash self-administered questionnaire)

APPENDIX I: Data review report V1.2 (Extract; pages 1, 49 and 50)



DATA REVIEW REPORT

Protocol: CALENTOL

Date: 10/01/2020 and 14/01/2020

Location: Telephone meeting

Attendees:

Name	Role	10/01/2020	14/01/2020
Eva-Maria Lohmüller	Scientific and Regulatory Affairs Manager Weleda AG		X
Valérie Donnizaux	Global Category Manager Mother&Child- Weleda AG	X	X
Ophélie Flageul	Project Manager SLB Pharma	X	X
Claude Pellen	Biostatistician SLB Pharma	X	X



SUBJID	Deviation specification	Deviation type		Population		
		Min	Maj	Saf.	ITT	PP
01-01				Y	Y	Y
01-02	V2 visit occurred before the 14th \pm 2 days More than 2 nappy change cream use per day	X X		Y	Y	Y
01-03	Calendula Nappy Change Cream used less than 12 days	X		Y	Y	Y
01-04	Calendula Nappy Change Cream used less than 12 days	X		Y	Y	Y
01-05	Has not used both the products		X	Y	Y	N
01-06	More than 2 nappy change cream use per day	X		Y	Y	Y
01-07	V2 visit occurred before the 14th \pm 2 days	X		Y	Y	Y
01-08	Does not take at least 3 baths per week at inclusion	X		Y	Y	Y
01-09	Dermatological treatment used during the study	X		Y	Y	Y
01-10				Y	Y	Y
01-11				Y	Y	Y
01-12	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days	X X		Y	Y	Y
01-13	Lost to follow-up (no use data available) Study duration is not 14 +/-2 days		X	N	N	N
01-14	More than 2 nappy change cream use per day	X		Y	Y	Y
02-01				Y	Y	Y
02-02	Lost to follow-up (efficacy and tolerance data available) Study duration is not 14 +/-2 days	X	X	Y	Y	N
02-03	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days Dermatological treatment used during the study	X X X		Y	Y	Y
02-04	Stopped the nappy change cream (vesicles on testicle) Study duration is not 14 +/-2 days Calendula Nappy Change Cream used less than 12 days	X X X		Y	Y	Y
02-05	Study duration is not 14 +/-2 days	X		Y	Y	Y
02-06	Dermatological treatment used during the study	X		Y	Y	Y
02-07	Study duration is not 14 +/-2 days	X		Y	Y	Y
02-08	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days	X X		Y	Y	Y
02-09	Study duration is not 14 +/-2 days	X		Y	Y	Y
02-10	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days	X X		Y	Y	Y
02-11	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days	X X		Y	Y	Y
02-12	Dermatological treatment used during the study Study duration is not 14 +/-2 days	X X		Y	Y	Y
02-13	Study duration is not 14 +/-2 days	X		Y	Y	Y
02-14				Y	Y	Y
02-15	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days	X X		Y	Y	Y
02-16	Lost to follow-up (no use data available) Study duration is not 14 +/-2 days	X	X	N	N	N
02-17	Study duration is not 14 +/-2 days Skin pathology (eczema)	X	X	Y	Y	N
02-18	Study duration is not 14 +/-2 days Dermatological treatment used during the study	X X		Y	Y	Y
02-19	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days Skin pathology (eczema) Dermatological treatment used during the study	X X X	X	Y	Y	N
02-20	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days Irritation and redness at inclusion	X X X		Y	Y	Y
03-01				Y	Y	Y
03-02				Y	Y	Y
03-03	More than 2 nappy change cream use per day	X		Y	Y	Y

SUBJID	Deviation specification	Deviation type		Population		
		Min	Max	Saf.	ITT	PP
03-04	Calendula Nappy Change Cream used less than 12 days	X		Y	Y	Y
03-05	Study duration is not 14 +/-2 days	X		Y	Y	Y
03-06				Y	Y	Y
04-01				Y	Y	Y
04-02	More than 2 nappy change cream use per day	X		Y	Y	Y
04-03				Y	Y	Y
04-04	Skin event (dryness) at inclusion More than 2 nappy change cream use per day Used Dexeryl during the study	X	X X	Y	Y	N
04-05				Y	Y	Y
04-06	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days Dermatological treatment used during the study	X X X		Y	Y	Y
04-07	More than 2 nappy change cream use per day	X		Y	Y	Y
04-08	More than 2 nappy change cream use per day	X		Y	Y	Y
04-09	Study duration is not 14 +/-2 days	X		Y	Y	Y
04-10	Born more than 1 month before the term V2 visit occurred before the 14th ± 2 days More than 2 nappy change cream use per day	X X X		Y	Y	Y
04-11	More than 2 nappy change cream use per day	X		Y	Y	Y
05-01	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days Dermatological treatment used during the study	X X X		Y	Y	Y
05-02	Study duration is not 14 +/-2 days Calendula Nappy Change Cream used less than 12 days	X X		Y	Y	Y
05-03	Study duration is not 14 +/-2 days Redness at inclusion	X X		Y	Y	Y
05-04	Temporary interruption because of vesicles on the hands Has not used both the products Study duration is not 14 +/-2 days	X X	X	Y	Y	N
05-05	Study duration is not 14 +/-2 days	X		Y	Y	Y
05-06				Y	Y	Y
05-07	Lost to follow-up (no use data available) Study duration is not 14 +/-2 days		X	N	N	N
05-08	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days	X X		Y	Y	Y
05-09	Calendula Nappy Change Cream used less than 12 days	X		Y	Y	Y
05-10	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days	X X		Y	Y	Y
06-01	Calendula Nappy Change Cream used less than 12 days	X		Y	Y	Y
06-02	More than 2 nappy change cream use per day Study duration is not 14 +/-2 days	X X		Y	Y	Y
06-03	V2 visit occurred before the 14th ± 2 days More than 2 nappy change cream use per day Calendula Nappy Change Cream used less than 12 days	X X X		Y	Y	Y
06-04	More than 2 nappy change cream use per day	X		Y	Y	Y

Table 1 : Listing of included subjects and deviations

	Nb of subjects
Safety population	62
ITT population	62
PP population	56

Table 2 : Population sizes

APPENDIX II: Informed consent form**NOTE D'INFORMATION**

« Tolérance et efficacité de Calendula Crème pour le Change et Calendula Crème lavante Corps et Cheveux- Etude prospective, multicentrique sous contrôle pédiatrique »

Étude CALENTOL

Promoteur et Responsable du Traitement de données : Weleda AG (Dychweg 14, 4144 Arlesheim Switzerland)

Madame, Monsieur,

Nous vous proposons de participer à la recherche CALENTOL, portant sur deux produits destinés au soin et au nettoyage cutané du nourrisson : CALENDULA Crème pour le Change et CALENDULA Crème lavante Corps et Cheveux de la marque WELEDA.

Avant de prendre une décision quant à la participation de votre enfant, prenez le temps de lire et de comprendre les informations qui suivent et de poser toutes les questions que vous souhaitez à votre pédiatre.

CONTEXTE & OBJECTIFS DE L'ÉTUDE

La peau de bébé, très fine et immature, est particulièrement fragile. Elle nécessite donc des soins adaptés avec une utilisation de produits formulés spécifiquement pour le soin du nourrisson.

Soucieux du bien-être des nourrissons, WELEDA commercialise en France, depuis 2006, un produit pour le soin du siège des bébés : « CALENDULA Crème pour le Change » à utiliser sur la zone de contact avec la couche ; et depuis 2008, un nettoyant cutané pour bébé : « CALENDULA Crème lavante Corps et Cheveux ». De par leur teneur en huile d'amande douce et d'extrait de fleur de Calendula bio, ces produits ont pour objet de nettoyer en douceur, protéger, régénérer et apaiser la peau du nourrisson afin de prévenir la survenue de rougeurs, d'irritations et de sécheresse de la peau.

Dans une démarche de qualité, cette étude vise à évaluer le ressenti du pédiatre et des parents au regard de l'efficacité et de la praticité des produits, auprès de 66 nourrissons.

CRITÈRES D'ÉLIGIBILITÉ & DÉROULEMENT DE L'ÉTUDE

Pour y participer, votre enfant doit :

- Être âgé entre 3 et 36 mois, en bonne santé (né à terme ou 1 mois avant terme),
- Avoir une peau saine,
- Porter des couches quotidiennement et prendre au moins 3 bains par semaine.

La recherche se déroulera au sein du cabinet de votre pédiatre. Si votre enfant est éligible à l'étude, le pédiatre vous remettra un carnet de suivi journalier ainsi que les 2 produits à l'étude accompagnés d'une notice d'utilisation. Vous devrez compléter le carnet de suivi quotidiennement (*nombre de bains, d'application des produits...*) et le rapporter à la visite de fin de suivi prévue à 14 jours. A cette visite, le pédiatre réalisera un examen clinique cutané de votre enfant et vous remettra un auto-questionnaire afin d'évaluer votre satisfaction au regard des 2 produits utilisés.

Entre les visites, pour toute question ou remarque, vous pourrez contacter votre pédiatre via le numéro de téléphone du cabinet.

BÉNÉFICES & RISQUES DE L'ÉTUDE

Aucun effet indésirable, ni risque n'est attendu en participant à cette recherche. Les bénéfices attendus pour votre nourrisson participant à la recherche sont la prévention des rougeurs et irritations de la zone de la couche grâce à une action apaisante du Calendula et de la Camomille et la prévention du dessèchement cutané.

En compensation des contraintes de l'étude, et dans la mesure où vous aurez respecté le protocole de l'étude, le pédiatre vous remettra un panier de produits de la marque WELEDA, d'une valeur de 40€, à destination de toute la famille.

VOS DROITS

Le pédiatre investigateur doit vous fournir, de façon claire et précise, toutes les explications nécessaires concernant cette étude et vous êtes absolument libres de refuser la participation de votre enfant à l'étude sans justification et sans compromettre sa prise en charge médicale.

En donnant votre consentement à la participation de votre enfant, vous acceptez expressément que les données personnelles qui le concernent et qui sont nécessaires pour répondre aux finalités de l'étude, soient collectées par le pédiatre, ou le personnel qui lui est rattaché. Un traitement informatisé des données personnelles de votre enfant sera mis en œuvre par le Laboratoire WELEDA – Responsable du traitement - pour permettre d'analyser les résultats de la recherche au regard de l'objectif de cette dernière. Les données seront pseudonymisées (identifiant = code à 4 chiffres) et seront enregistrées dans une base de données électronique ; aucune identité ou information directement identifiante ne sera recueillie. Ces données seront ensuite transmises au promoteur ou aux personnes ou sociétés agissant pour son compte, dans l'Union Européenne ; ces personnes sont soumises à un engagement de confidentialité. Ces données pourront également, dans des conditions assurant leur confidentialité, être transmises aux Autorités de Santé.

Les données ne seront pas transférées à des destinataires se trouvant dans des pays hors de l'Union Européenne.

Conformément à la réglementation relative aux recherches sur les produits cosmétiques, ces données anonymisées seront conservées jusqu'au rapport final de l'étude ou la publication des résultats de l'étude puis seront archivées pendant au moins 10 ans (et plus précisément pendant toute la durée de vie des produits WELEDA étudiés). Conformément à la loi relative à l'informatique, aux fichiers et aux libertés (*loi n°78-17 du 6 janvier 1978 modifiée par la loi n°2018-493 du 20 juin 2018 relative à la protection des données personnelles*) et au Règlement Général de Protection des Données (RGPD – Règlement (UE) 2016/679 du 27 avril 2016), vous disposez à tout moment d'un droit d'accès, de rectification et de portabilité des données concernant votre enfant, ainsi que le droit à la limitation de leur traitement, auprès de votre pédiatre. Par ailleurs, vous pouvez également saisir la Commission Nationale de l'Informatique et des Libertés (CNIL) – Autorité française de protection des données personnelles- si vous considérez que le traitement des données à caractère personnel de votre enfant constitue une violation des droits en matière de protection des données à caractère personnel. Le Laboratoire Weleda a désigné un Délégué à la Protection des Données (DPO) que vous pouvez également contacter par mail (jhimpel@weleda.de) ou par voie postale à l'adresse :Weleda AG An den Datenschutzbeauftragten (DPO) Möhlerstraße 3 – 5 73525 Schwäbisch Gmünd Deutschland.

Par ailleurs, si vous souhaitez interrompre la participation de votre enfant à l'essai à quelque moment que ce soit, vous n'aurez à fournir aucune justification et cette décision ne modifiera en rien la suite de la prise en charge de votre enfant. Aucune nouvelle donnée ne sera collectée. Afin de ne pas compromettre la méthodologie statistique de l'étude, les données déjà collectées ne pourront pas être effacées ; seules les données collectées avant votre retrait de consentement seront utilisées pour les besoins de l'étude. Par ailleurs, votre enfant pourra éventuellement être sorti d'étude sur décision du pédiatre ou du promoteur, s'il l'estime nécessaire.

Après avoir lu cette note d'information, n'hésitez pas à poser à votre pédiatre toutes les questions que vous désirez. Après un délai de réflexion, si vous acceptez de participer à cette étude, vous devrez compléter et signer ce document attestant de votre consentement à participer à l'étude. Une copie du présent document vous sera remise et l'autre copie sera conservée dans le dossier médical de votre enfant dans des conditions garantissant la confidentialité.

Toute nouvelle information importante, qui pourrait modifier votre consentement vis-à-vis de la participation de votre enfant à l'étude, vous sera communiquée. Votre consentement ne décharge en rien les organisateurs de l'étude de leurs responsabilités à l'égard de votre enfant.

Nous vous remercions de l'attention que vous avez bien voulu porter à cette note d'information.

Nous soussignés, Mme et/ou Mr
(nom et prénom de la mère) (nom et prénom du père)
parents de, certifions que le Dr
(nom et prénom de l'enfant) (nom et prénom du pédiatre)
nous a proposé la participation de notre enfant à l'étude CALENTOL.

Ayant disposé d'un temps de réflexion suffisant avant de prendre notre décision, nous acceptons librement et volontairement que notre enfant participe à cette étude citée ci-dessus et que des données personnelles le concernant et concernant sa santé soient traitées pour répondre aux objectifs de cette étude :

Oui Non

Fait à Fait à
Le/...../..... Le/...../.....

Signature du/ des parent(s) : Nom de l'investigateur :.....
Signature de l'investigateur :

Ce document est dupliqué : l'exemplaire original est à conserver par l'investigateur, la copie rose est remise au(x) parent(s).

APPENDIX III: Listing of the cleansing habits (verbatim and classes)

Subject ID	Diaper brand	Usual shampoo and body wash	Usual product to cleanse the diaper area		Usual nappy change product
			Verbatim	Class	
01-01	PAMPERS	MUSTELA	LINIMENT OLEOCALCAIRE COOPER	Liniment	BEPANTHENE
01-02	PAMPERS	MUSTELA	LINIMENT OLEOCALCAIRE GIFRER	Liniment	KLORANE POMMADE
01-03	BLUMCHEN	ALPHANOVA BEBE	LINIMENT OLEOCALCAIRE BABY SOIN	Liniment	ERYPLAST
01-04	LILLYDOO	TIDOO	LINIMENT OLEO-CALCAIRE GIFRER	Liniment	ARGILE BLANCHE
01-05	PAMPERS	JONZAC	LINIMENT OLEO-CALCAIRE COOPER	Liniment	MITOSYL
01-06	PAMPERS	JONZAC	LINIMENT OLEO-CALCAIRE COOPER	Liniment	MITOSYL
01-07	LUPILU	MUSTELA	LINIMENT OLEOCALCAIRE COOPER	Liniment	MITOSYL
01-08	PAMPERS	DODDIE	LINIMENT OLEO-CALCAIRE GIFRER	Liniment	LAIT MATERNEL
01-09	PAMPERS	BEBE CADUM OU MUSTELA	LINIMENT OLEO-CALCAIRE CARREFOUR	Liniment	MITOSYL OU MUSTELA
01-10	NATY	JONZAC	LINIMENT OLEO-CALCAIRE JONZAC	Liniment	
01-11	POMMETTE	CADUM HYPOALLERGIQUE	LINIMENT OLEO-CALCAIRE GIFRER	Liniment	MYTOSYL
01-12	HYPER U	MUSTELA	LINIMENT OLEOCALCAIRE GIFRER	Liniment	MIXA BEBE
01-13	PAMPERS	MUSTELA "PEAU NORMALE"	LINIMENT OLEOCALCAIRE BIOLANE	Liniment	BEPANTHENE
01-14	PAMPERS	MUSTELA	LINIMENT OLEO6CALCAIRE GIFRER	Liniment	BEPANTHENE
02-01	LOVE AND GREEN	CATTIER	LINIMENT OLEOCALCAIRE GIFRER	Liniment	RIEN
02-02	LOTUS	WELEDA	CA CHANGE (PAS DE MARQUE SPECIFIQUE DE LINIMENT)	Liniment	WELEDA
02-03	LOVE AND GREEN	MIXA	GIFRER	Liniment	WELEDA
02-04	PAMPERS	DOVE	PAMPERS LINGETTE + LINIMENT GRANDE SURFACE	Liniment + Wipes	CICAPLAST B5
02-05	LOTUS / PAMPERS	MUSTELA	LINGETTE PAMPERS, LINIMENT OLEOCALCAIRE GIFRER OU LAIT DE TOILETTE MUSTELA	Cleansing milk + Liniment + Wipes	BEPANTHENE
02-06	PAMPERS	ROGER CAVAILLES	LINIMENT GIFRER	Liniment	BEPANTHENE
02-07	PAMPERS	KLORANE	LINIMENT OLEO CALCAIRE GIFRER OU EAU	Liniment + Water	RIEN
02-08	PAMPERS	KLORANE	LINGETTES LOVE AND GREEN	Wipes	MITOSYL
02-09	PAMPERS	KLORANE	EAU + COTON	Water	RIEN OU LINIMENT
02-10	LOVE AND GREEN / PAMPERS	MIXA BEBE HUILE LAVANTE	EAU + COTON	Water	MUSTELA
02-11	LOVE AND GREEN / PAMPERS	CATTIER	EAU + COTON	Water	RIEN

Subject ID	Diaper brand	Usual shampoo and body wash	Usual product to cleanse the diaper area		Usual nappy change product
			Verbatim	Class	
02-12	PAMPERS	MIXA BB	LINIMENT WELEDA OU LINGETTE MIXA	Liniment + Wipes	BEPANTHENE
02-13	PAMPERS	MUSTELA	LINIMENT WELEDA OU MIXA	Liniment	BEPANTHENE
02-14	PAMPERS	KLORANE	LINIMENT ET LINGETTES URIAGE	Liniment + Wipes	BEPANTHENE
02-15	LOVE AND GREEN / LOTUS / PAMPERS	SEBIO	EAU	Water	LINIMENT GIFRER OU AUTRE
02-16	CARREFOUR / PAMPERS (NUIT)	ABCDERM	EAU	Water	BEPANTHENE
02-17	PAMPERS	ABCDERM (BIODERMA)	LINIMENT (MARQUE VARIABLE) + COTON + EAU	Liniment + Water	ERYPLAST
02-18	LOVE AND GREEN	CATTIER BEBE	LINIMENT OLEO CALCAIRE GIFRER	Liniment	RIEN
02-19	PAMPERS	BIOLANE BEBE	LAIT BIOLANE + COTON PUIS EAU	Cleansing milk + Water	MUSTELA SI IRRITATION
02-20	PAMPERS / LOTUS	KLORANE BEBE	EAU KLORANE + COTON	Cleansing water	CREME KLORANE
03-01	PAMPERS	CADUM	CADUM + MUSTELA	Not determined	MUSTELA
03-02	PAMPERS	LEA NATURE NATESSANCE	LINIMENT MUSTELA	Liniment	
03-03	TIDOO	LOVE AND GREEN	LINIMENT OLEO-CALCAIRE MITOSYL	Liniment	ALPHANOVA_ERYZINC
03-04	MARQUE REPERE "MOT D'ENFANT"	CADUM BEBE	EAU NETTOYANTE	Cleansing water	BEPANTHENE
03-05	INTERMARCHE	GAMARDE	LINGETTES GILBERT	Wipes	
03-06	DIVERS	CADUM - GEL NETTOYANT	CADUM - EAU NETTOYANTE	Cleansing water	LINIMENT OU CHANGE WELEDA
04-01	BABYLONE	BIOLANE	LINGETTE BABYLONE, LINIMENT DE MUSTELA	Liniment + Wipes	ERYPLAST SI IRRITEE
04-02	PAMPERS	MUSTELA GEL LAVANTE DOUX	LINIMENT GILBERT	Liniment	LINIMENT GILBERT
04-03	BABYLOVE	BEBE CADUM	LINIMENT MUSTELA	Liniment	OXYPLASTINE
04-04	HIPP	GEL LAVANT BIO U TOUTS PETIT A GLYCERINE ET ALOE VERA	EAU AVEC LINGETTE EN COTON LAVABLE. LINGETTE U BIO SECTION TOUTS PETITS	Water + Wipes	LEA NATURE EAU THERMALE JONZAC. BEBE BIO CREME CHEZY
04-05	BABYLONE	HIPP BAIN-DOUCHE BEBES	LINGETTE BABYLONE	Wipes	BEPANTHEN
04-06	MOT D'ENFANT LECLERC	BIOLANE	ERYPLAST	Paste of water	ERYPLAST
04-07	PAMPERS SENSITIVE	BIOLANE CORPS ET CHEVEUX	LINGETTES BIOLANE ET NETTOYANT SANS RINCAGE BIOLANE	Not determined	BEPANTHEN
04-08	PAMPERS PANTS	MUSTELA CORPS CHEVEUX	MUSTELA 12.3	Nappy change cream	CICAPLAST LAROCHE POSAY

Subject ID	Diaper brand	Usual shampoo and body wash	Usual product to cleanse the diaper area		Usual nappy change product
			Verbatim	Class	
04-09	BABYLONE JOUR + LILLYDOO NUIT	BABYLONE	LINIMENT DE BABYLONE	Liniment	CYTELIUM
04-10	BABYLOVE	MUSTELA PEAU NORMALE CORPS CHEVEUX	MUSTELA LINIMENT	Liniment	CREME CHANGE MUSTELA
04-11	PAMPERS BABYDRY	MUSTELA CORPS CHEVEUX	MUSTELA 123	Nappy change cream	CREME CHANGE MUSTELA OU CICAPLAST
05-01	PAMPERS	NIVEA	EAU	Water	BEPANTHENE
05-02	CHERUBIN	MUSTELA	LINIMENT OLEO-CALCAIRE	Liniment	BEPANTHENE
05-03	CHERUBIN	MUSTELA	LINIMENT OLEO CALCAIRE LABORATOIRE GILBERT	Liniment	BEPANTHENE
05-04	PAMPERS	A.DERMA	LINGETTES - EAU	Water + Wipes	BEPANTHENE
05-05	PAMPERS	RIVADOUCE	LINIMENT OLEO CALCAIRE LABORATOIRE GILBERT	Liniment	BEPANTHENE
05-06	LILLYDOO	SAVON DOUX	LINIMENT OLEO-CALCAIRE LABORATOIRE GILBERT	Liniment	BEPANTHENE
05-07	PAMPERS	SAVON DOVE BIO	EAU	Water	MITOSYL SI ROUGEURS
05-08	LIEDL	NIVEA BEBE	EAU + SAVON	Soap + Water	AUCUN
05-09	PAMPERS	BIODERMA GEL LAVANT	BIODERMA - EAU	Cleansing water	BEPANTHEN SI ROUGEURS
05-10	LILLYDOO	MUSTELA SAVON LIQUIDE	MUSTELA + EAU	Cleansing milk + Water	AUCUN
06-01	PAMPERS	GEL LAVANT WELEDA	LINIMENT WELEDA	Liniment	CREME CHANGE WELEDA
06-02	PAMPERS / POMMETTE	VARIABLE	EAU	Water	WELEDA CREME CHANGE
06-03	POMMETTE	VARIABLE	EAU OU LINIMENT GIFRER	Liniment + Water	CREME WELEDA POUR LE CHANGE
06-04	POMMETTE	SAVON AVENE COLD CREAM	EAU	Water	BEPANTHENE

Listing of the cleansing habits (verbatim and classes)

APPENDIX IV: Listing of the investigator's comments during V1 and V2 clinical examinations

Subject ID	Visit	Investigator's comment during the clinical examination
01-01	V2	MALGRE UNE POUSSEE DENTAIRE EN COURS D'ETUDE ACCOMPAGNEE D'UNE RHINO PAS D'ERYTHEME FESSIER !
01-04	V2	DECOUVERTE LORS DE LA V2 DE 3 LESIONS PERIBUCCALES EVOQUANT IMPETIGO, CONTAGION COLLECTIVITE
01-06	V1	ROUGEURS ET IRRITATIONS DU SIEGE BEGNINES MAIS FREQUENTES
01-10	V1	ROUGEURS LEGERES SUR LES FESSES.
01-14	V1	PETIT ERYTHEME FESSIER ACCOMPAGNANT POUSSEE DENTAIRE
03-04	V1	PAS DE PROBLEME CUTANE
04-01	V1	DERMITE PERIBUCCAL SUR TETINE
04-06	V1	ROUGEUR PAUPIERE SUPERIEURE DROITE
04-09	V1	TRES LEGERES ROUGEURS ANALES
05-01	V2	A EU 5 JOURS DE ROUGEURS DU SIEGE + POUSSEE DENTAIRE. AUJOURD'HUI, PLUS DE ROUGEURS.
05-04	V2	SYNDROMES PIED-MAINS-BOUCHE = QUELQUES VESICULES SUR LES MAINS ET AVANT BRAS (FIN D'ERUPTION).

Listing of the investigator's comments during V1 and V2 clinical examinations

APPENDIX V: Listing of the dermatological concomitant treatments taken during the study

Subject ID	Drug name	Drug name 2	Dose	Total daily dose	Starting date	End date	Indication 2
01-04	DIASEPTYL 0..5%	Chlorhexidine		4	16/10/2019		Impetigo
01-04	MUPIDERM	Mupirocine	POMMADE	2	16/10/2019		Impetigo
01-09	CREME EUCERIN	Cosmetic product	1 APPLICATION	2 FOIS PAR JOUR	07/11/2019	07/11/2019	Dryness
01-09	CREME EUCERIN	Cosmetic product	1 APPLICATION	2 FOIS PAR JOUR	12/11/2019	12/11/2019	Dryness
02-01	CREME WELEDA BEBE VISAGE CALENDULA	Cosmetic product			29/08/2019	29/08/2019	Dryness
02-03	BEPANTHEN	Dexpanthenol		2 A 3 APPLICATIONS / JOUR	09/09/2019	10/09/2019	Redness
02-06	CICALFATE	Cosmetic product			29/08/2019	30/08/2019	Papule
02-09	ARNICA	Homeopathy			02/09/2019	02/09/2019	Hematoma
02-12	MUPIDERM	Mupirocine	POMMADE 2%		08/09/2019	14/09/2019	Infected mosquito bite
02-17	DEXYANE BAUME	Cosmetic product	SUR LE TRONC	2	05/11/2019		Eczema
02-18	CICALFATE CREME	Cosmetic product	A CHAQUE CHANGE	A CHAQUE CHANGE	28/10/2019	29/10/2019	Irritation + Redness
02-19	BETAMETHASONEA	Betamethasone	1 GOUTTE DE 2.3	1	18/11/2019		Eczema
02-19	DEXYANE MED	Medical device		2	18/11/2019		Eczema
04-04	GLYCEROL 15% PARAFINE LIQUIDE 2% VASELINE 8%	Medical device	1 TUBE 250G	1 APPLIC 2*/J	20/09/2019		Dryness
04-06	CYTELIUM	Cosmetic product	1 PULVERISATION	3	19/09/2019	20/09/2019	Irritation + Redness
05-01	BEPANTHENE	Dexpanthenol	1 APPLICATION	2	28/10/2019	01/11/2019	Diaper rash

Listing of the dermatological concomitant treatments taken during the study

APPENDIX VI: Listing of the skin events

Subject ID	Skin event specification	Skin event body area	Other skin event body area	Starting date	End date	Grade	Relationship to study treatment	Cause	Therapeutic attitude	Treatment
01-01	ROUGEURS ET IRRITATIONS DU SIEGE	Diaper area		07/09/2019	09/09/2019	1	Other cause(s)	Theething	None	No
01-04	LESIONS PERIBUCCALES EVOQUANT IMPETIGO	Other	PERIBUCCALE	14/10/2019	Still in progress	2	Other cause(s)	Infectious disease	None	Yes
01-06	PETITE ROUGEUR VULVE ET IRRITATIONS	Diaper area		19/10/2019	Still in progress	1	Other cause(s)	Other cause	None	No
01-06	ROUGEURS VULVE ET FESSES ET IRRITATIONS	Diaper area		08/10/2019	14/10/2019	1	Other cause(s)	Unknown	None	No
01-06	PETITES ROUGEURS VULVE	Diaper area		16/10/2019	16/10/2019	1	Other cause(s)	Unknown	None	No
01-07	IRRITATIONS/ROUGEURS + PETITS BOUTONS A L'ANUS	Diaper area		03/11/2019	04/11/2019	1	Other cause(s)	Other cause	None	No
01-08	ROUGEURS ET SECHERESSES	Other	JOUES	08/11/2019	Still in progress	1	Other cause(s)	Other cause	None	No
01-09	BOUTONS FESSES ET JOUES	Other	FESSES ET JOUES DROITE ET GAUCHE	07/11/2019	07/11/2019	1	Other cause(s)	Unknown	None	Yes
01-09	PLAQUES DROITE ET GAUCHE	Other	JOUES DROITE ET GAUCHE	12/11/2019	12/11/2019	1	Other cause(s)	Theething	None	Yes
01-10	PETITES ROUGEURS AUX FESSES	Diaper area		07/11/2019	08/11/2019	1	Other cause(s)	Theething	None	No
01-10	PETITES PLAQUES DE SECHERESSE	Other	MOLLETS	18/11/2019	19/11/2019	1	Other cause(s)	Other cause	None	No
01-10	PETITES PLAQUES DE SECHERESSE	Other	BRAS	19/11/2019	20/11/2019	1	Other cause(s)	Other cause	None	No
01-14	ROUGEURS	Diaper area		20/11/2019	20/11/2019	1	Other cause(s)	Theething	None	No
01-14	ERYTHEME FESSIER (ROUGEURS + IRRITATIONS)	Diaper area		15/11/2019	17/11/2019	1	Other cause(s)	Theething	None	No

Subject ID	Skin event specification	Skin event body area	Other skin event body area	Starting date	End date	Grade	Relationship to study treatment	Cause	Therapeutic attitude	Treatment
02-01	SECHERESSE VISAGE	Other	VISAGE	29/08/2019	29/08/2019	2	Other cause(s)	Unknown	None	Yes
02-01	LEGERE ROUGEUR SIEGE	Diaper area		29/08/2019	29/08/2019	1	Other cause(s)	Theething	None	No
02-01	LEGERE ROUGEUR DU SIEGE	Diaper area		03/09/2019	03/09/2019	1	Other cause(s)	Theething	None	No
02-03	ROUGEURS / IRRITATIONS	Diaper area		05/09/2019	11/09/2019	2	Other cause(s)	Diarrhea + Theething	None	Yes
02-03	ROUGEURS	Diaper area		23/09/2019	Still in progress	1	Other cause(s)	Theething	None	No
02-03	ROUGEURS	Diaper area		14/09/2019	14/09/2019	1	Other cause(s)	Diarrhea	None	No
02-04	BOUTONS ROUGES SUR LES TESTICULES	Other	TESTICULES	02/09/2019	08/09/2019	1	Other cause(s)	Unknown	Output study	No
02-06	PAPULES (DE TYPE BOUTON DE PIQURE)	Diaper area		29/08/2019	10/09/2019	2	Other cause(s)	Theething	Temporary Interruption	Yes
02-07	ROUGEURS	Diaper area		02/09/2019	02/09/2019	1	Other cause(s)	Diarrhea	None	No
02-07	ROUGEURS	Diaper area		05/09/2019	05/09/2019	1	Other cause(s)	Diarrhea	None	No
02-07	ROUGEURS	Diaper area		07/09/2019	08/09/2019	1	Other cause(s)	Diarrhea	None	No
02-08	LEGERES ROUGEURS	Diaper area		02/09/2019	03/09/2019	1	Other cause(s)	Diarrhea + Theething	None	No
02-08	LEGERES ROUGEURS	Diaper area		07/09/2019	07/09/2019	1	Other cause(s)	Unknown	None	No
02-09	ROUGEURS	Other	CUISSES	30/08/2019	31/08/2019	1	Other cause(s)	Other cause	None	No
02-09	BLEU	Other	K	02/09/2019	02/09/2019	2	Other cause(s)	Other cause	None	Yes
02-09	ROUGEURS SUR LES FESSES	Diaper area		07/09/2019	07/09/2019	1	Other cause(s)	Diarrhea	None	No

Subject ID	Skin event specification	Skin event body area	Other skin event body area	Starting date	End date	Grade	Relationship to study treatment	Cause	Therapeutic attitude	Treatment
02-09	ROUGEURS	Other	JOUES	11/09/2019	11/09/2019	1	Other cause(s)	Theething	None	No
02-09	BOUTON DE CHALEUR SUR LE CORPS	Other	SUR LE CORPS	13/09/2019	15/09/2019	1	Other cause(s)	Sweat	None	No
02-10	ROUGEURS AU SIEGE	Diaper area		03/09/2019	04/09/2019	1	Other cause(s)	Theething	None	No
02-10	ROUGEURS AU SIEGE	Diaper area		07/09/2019	08/09/2019	1	Other cause(s)	Theething	None	No
02-11	ROUGEURS LE MATIN SUR LE PUBIS	Diaper area		10/09/2019	10/09/2019	1	Other cause(s)	Unknown	None	No
02-11	ROUGEURS AUTOUR DE L'ANUS	Diaper area		13/09/2019	14/09/2019	1	Other cause(s)	Unknown	None	No
02-11	QUELQUES ROUGEURS AUTOUR DE L'ANUS ET SUR PUBIS	Diaper area		18/09/2019	18/09/2019	1	Other cause(s)	Unknown	None	No
02-13	PETITS BOUTONS	Other	VISAGE	10/09/2019	12/09/2019	1	Other cause(s)	Unknown	None	No
02-13	ROUGEURS SUR LES FESSES	Diaper area		12/09/2019	15/09/2019	1	Other cause(s)	Theething	None	No
02-13	PETITE IRRITATION FESSE	Diaper area		05/09/2019	05/09/2019	1	Other cause(s)	Theething	None	No
02-13	JOUES ROUGES	Other	JOUES	07/09/2019	07/09/2019	1	Other cause(s)	Theething	None	No
02-13	ROUGEURS FESSES PLIS	Diaper area		16/09/2019	16/09/2019	1	Other cause(s)	Other cause	None	No
02-14	ROUGEURS	Other	JAMBES BRAS	16/09/2019	16/09/2019	1	Other cause(s)	Unknown	None	No
02-15	ROUGEURS VULVE ET FESSES	Diaper area		17/09/2019	19/09/2019	1	Other cause(s)	Unknown	None	No
02-15	ROUGEURS VULVE ET FESSES	Diaper area		28/09/2019	29/09/2019	1	Other cause(s)	Unknown	None	No
02-17	ROUGEURS ET SECHERESSES	Other	TRONC	05/11/2019	Still in progress	2	Other cause(s)	Other cause	None	Yes

Subject ID	Skin event specification	Skin event body area	Other skin event body area	Starting date	End date	Grade	Relationship to study treatment	Cause	Therapeutic attitude	Treatment
02-18	ROUGEURS ET IRRITATIONS	Diaper area		25/10/2019	Still in progress	2	Other cause(s)	Theething	None	Yes
02-19	ROUGEURS ET PETITS BOUTONS ET SECHERESSE	Other	MENTON, COU, JOUES ET FESSIER	25/10/2019	Still in progress	2	Other cause(s)	Other cause	None	Yes
02-20	ROUGEURS ET IRRITATIONS	Diaper area		22/10/2019	24/10/2019	1	Other cause(s)	Theething	None	No
03-05	IRRITATIONS AU NIVEAU DU CHANGE	Diaper area		30/09/2019	30/09/2019	1	Other cause(s)	Theething	None	No
03-05	ROUGEURS AU NIVEAU DU CHANGE	Diaper area		08/10/2019	08/10/2019	1	Other cause(s)	Unknown	None	No
04-03	FESSES ROUGES	Diaper area		16/09/2019	16/09/2019	2	Other cause(s)	Theething	None	No
04-04	SECHERESSE	Other	CUISSES - JAMBES - GENOUX - BRAS - DOS	11/09/2019	Still in progress	2	Other cause(s)	Unknown	None	Yes
04-06	PETITES ROUGEURS SUR LES FESSES ET BOUTON SUR LE ZIZI	Other	ERYTHEME ZIZI ET DU SIEGE ET DES PLIS	14/09/2019	21/09/2019	2	Other cause(s)	Theething	None	Yes
04-06	ROUGEURS AUX FESSES	Diaper area		26/09/2019	26/09/2019	1	Other cause(s)	Unknown	None	No
05-01	ROUGEURS (FESSE)	Diaper area		28/10/2019	01/11/2019	2	Other cause(s)	Theething	None	Yes
05-02	ROUGEURS / IRRITATIONS	Diaper area		20/10/2019	25/10/2019	1	Other cause(s)	Poor hygiene	None	No
05-03	ROUGEURS	Diaper area		18/10/2019	19/10/2019	1	Other cause(s)	Poor hygiene	None	No
05-04	VESICULES	Other	2 MAINS	28/10/2019	Still in progress	1	Other cause(s)	Infectious disease	Temporary Interruption	No
05-05	ROUGEURS	Diaper area		31/10/2019	03/11/2019	1	Other cause(s)	Theething	None	No
05-05	PETITS BOUTONS	Other	VISAGE	05/11/2019	05/11/2019	1	Other cause(s)	Unknown	None	No
05-05	ROUGEURS	Other	JOUES	10/11/2019	10/11/2019	1	Other cause(s)	Theething	None	No

Subject ID	Skin event specification	Skin event body area	Other skin event body area	Starting date	End date	Grade	Relationship to study treatment	Cause	Therapeutic attitude	Treatment
05-05	PETITS BOUTONS	Other	VISAGE ET COU	11/11/2019	12/11/2019	1	Other cause(s)	Unknown	None	No
05-08	IRRITATIONS	Diaper area		11/11/2019	11/11/2019	1	Other cause(s)	Unknown	None	No
05-08	IRRITATIONS	Diaper area		18/11/2019	18/11/2019	1	Other cause(s)	Unknown	None	No
05-08	IRRITATIONS	Diaper area		20/11/2019	20/11/2019	1	Other cause(s)	Unknown	None	No
05-09	ROUGEURS	Diaper area		08/11/2019	08/11/2019	1	Other cause(s)	Theething	None	No
05-09	ROUGEURS	Diaper area		10/11/2019	10/11/2019	1	Other cause(s)	Unknown	None	No
06-02	ROUGEURS	Diaper area		24/10/2019	24/10/2019	1	Other cause(s)	Diarrhea + Theething	None	No
06-02	ROUGEURS	Other	ZONE DE LA COUCHE + JOUES	03/11/2019	03/11/2019	1	Other cause(s)	Theething	None	No

Listing of the skin events

APPENDIX VII: Listing of the parent's comments about Calendula Nappy Change Cream (verbatim of the AQ19 – Calendula Nappy Change Cream self-administered questionnaire)

Subject ID	Comments about Calendula Nappy Change Cream
01-01	JE PREFERE MAINTENANT UTILISER CETTE CREME (AUX AUTRES HABITUELLEMENT UTILISEES) CAR LA PEAU DE MON BEBE EST BIEN PROTEGE DES IRRITATIONS EN PERIODE DE POUSSEE DENTAIRE ET LES COMPOSANTS SONT BIO ET CERTIFIE COSMETIQUE NATUREL.
01-02	LE PRODUIT GLISSE DES DOIGTS
01-03	LA CREME EST TRES PARFUMEE, EST-CE NECESSAIRE ?
01-05	PAS EU BESOIN D'UTILISER LA CREME POUR LE CHANGE.
01-06	TEXTURE AU TUBE UN PEU GLISSANTE SI L'ON A LES MAINS PLEINES DE CREME ET TUBE PAS ASSEZ SOUPLE POUR POUVOIR FAIRE SORTIR LA FIN DE LA CREME.
01-08	/!\ IMPRESSION DE FROMAGE DANS LA VULVE, MAIS C'EST LA CREME.
02-04	APRES QUELQUES JOURS D'UTILISATION MON BEBE A SORTI DES BOUTONS SUR LES TESTICULES ET QUI ONT DISPARU DES L'ARRET DE LA CREME.
02-05	L'ODEUR EST TROP FORTE. TOUTES LE AUTRES CREMES QUE NOUS UTILISONS NE SENTENT PAS.
02-09	PARFAIT MAIS TEXTURE TRES EPAISSE ET DIFFICILE DE BIEN L'ETALER DANS LES TRIPLES PLIS DES CUISSES.
02-11	PRODUIT DE QUALITE. ODEUR AGREABLE.
02-12	LE PRODUIT POURRAIT ETRE UN TOUT PETIT PLUS FLUIDE, MAIS PAS TROP NON PLUS CAR IL PROTEGERAIT MOINS. NOUS UTILISONS LE LINIMENT WELEDA OU CALENDULA ET NOUS AURIONS AIME PLUS D'INDICATIONS POUR UNE UTILISATION SIMULTANEE DES DEUX PRODUITS.
02-13	J'AIME BEAUCOUP CE PRODUIT.
02-18	OUI UN BON PRODUIT MAIS UNE ODEUR ASSEZ FORTE D'HUILES ESSENTIELLES. POUR LES 'JEUNES BEBES" UN PARFUM/COMPOSITION UN PEU PLUS DOUX SERAIT MIEUX.
03-02	PRODUIT NON INDIPENSABLE MAIS QUI APPORTE DU CONFORT.
04-03	TRES SATISFAITE
04-04	REVOIR LA MANIABILITE DU TUBE (RACORDER LE TUBE AU CAPUCHON POUR EVITER DE VISSER-DEVISSER)
04-06	N'APaise PAS LES ROUGEURS ET IRRITATIONS LIEES A LA POUSSE DENTAIRE
04-07	LA CREME PENETRE PLUS ET RESTE PLUS LONGTEMPS PAR RAPPORT A UNE AUTRE CREME.
04-09	JE SUIS GLOBALEMENT SATISFAITE DE L'ODEUR ET DU PRODUIT QUI A TRES BIEN REAGIT SUR MON BEBE. JE RECOMMANDE CE PRODUIT QUI EST NATUREL CE QUI EST IMPORTANT POUR MOI.
04-10	J'AIME TROP L'ODEUR EN PLUS IL PROTEGE BIEN LA PEAU DE MON BEBE.
05-01	PRODUIT UTILE POUR TOUT LES JOURS, MAIS PAS QUAND LE BEBE A UNE IRRITATION ET LES GROS ROUGEURS.
05-06	TRES BIEN - BON PRODUIT
06-01	EGALEMENT UTILISEE POUR LES IRRITATIONS DES PLIS DE LA PEAU --> COU, OREILLE ETC... RESULTAT SUPER. UNE FOIS LE TUBE CONSOMME A MOITIE LA MATIERE RIGIDE DU TUBE N'EST PAS FACILE A UTILISER, PARFOIS UN PLI DU TUBE PEUT CASSER ET FAIRE UN TROU.
06-02	JE SUIS UNE ADEPTE D ECE PRODUIT QUE JE RECOMMANDE DEJA VIVEMENT A D'AUTRES PARENTS. LA CRECHE DE MA FILLE L'UTILISAIT AUSSI. MA FILLE A DEPUIS CHANGE DE CRECHE POUR UNE CRECHE MUNICIPALE DANS LAQUELLE ILS NE L'UTILISENT PAS.
06-03	SUPER, NE CHANGEZ RIEN

Listing of the parents' comments about Calendula Nappy Change Cream (verbatim of the AQ 19 – Calendula Nappy Change Cream self-administered questionnaire)

APPENDIX VIII: Listing of the parent's comments about Calendula Shampoo and Body Wash (verbatim of the AQ19 – Calendula Shampoo and Body Wash self-administered questionnaire)

Subject ID	Comments about Calendula Shampoo and Body Wash
01-01	COMME POUR LA CREME DE CHANGE, JE VAIS CONTINUER AVEC LE GEL LAVANT (BIO, COSMETIQUE NATUREL), LE SEUL BEMOL C'EST QU'APRES LE BAIN, LA PEAU DE MON BEBE N'EST PAS "PARFUMEE".
01-02	TRES BIEN
01-03	LA CREME LAVANTE SE RINCE MOINS BIEN QUE MON SOIN HABITUEL MAIS PEUT-ETRE EST-CE A CAUSE DE LA QUANTITE DE PRODUIT UTILISE/MOUSSE.
01-07	LE GRAND FRERE A APPRECIÉ L'ODEUR.
01-08	TEXTURE GENIALE, BONNE MOUSSE.
01-14	LE CONDITIONNEMENT SERAIT PREFERABLE EN POUSSE MOUSSE ET L'AUTRE N'EST PAS TRES ATTRACTIVE.
02-01	LA DISTRIBUTION DU GEL N'EST PAS FACILITE DE PART LE FORMAT DU TUBE. UN "POUSSE MOUSSE" SERAIT PLUS PRATIQUE, SURTOUT LORSQU'ON NE PEUT UTILISER QU'UNE SEULE MAIN (L'AUTRE TENANT LE BEBE DANS LE BAIN). L'EAU SE TEINTE AVEC LE PRODUIT, SE TROUBLE.
02-03	CELA PIQUE UN PEU LES YEUX DU BEBE
02-04	TRES BONNE CREME LAVANTE.
02-05	TROPS DIFFICILE A RINCER. ODEUR FORTE POUR 1 SAVON. NOUS AVONS APRECIE LE PRODUIT EN TANT QUE SHAMPOING.
02-09	JUSTE UN POINT D'AMELIORATION SUR LE FLACON = INTEGRER UN "BOUTON POUSSOIR" (CF LOVE AND GREEN) PLUS PRATIQUE PENDANT LE BAIN. SINON JE SUIS CONQUISE ! JE TROVE AUSSI QUE L'ODEUR (OU LE CALENDULA ET SES VERTUES) APAISE MON BEBE PENDANT SON BAIN.
02-11	PRODUIT DE QUALITE. PARFUM AGREABLE.
02-13	ODEUR UN PEU FORTE A L'APPLICATION (NE SENT PAS TROP LE "BEBE"). LE PRODUIT N'EST PAS TRES ONCTUEUX, PAS "DOUX". TROP PETITE CONTENANCE DU TUBE. TUBE PAS TRES PRATIQUE A UTILISER.
02-15	J'UTILISE HABITUELLEMENT UN SAVON SOLICE. IL SERAIT BIEN D'AVOIR DEUX VERSIONS DU PRODUIT : SOLIDE ET CREME. SOLIDE = MOINS DE DECHET PLASTIQUE.
02-17	RENDRE LE RINCAGE PLUS FACILE.
02-18	NON, TRES BON PRODUIT.
02-19	GROSSE DIFFICULTE DE RINCAGE DU PRODUIT. 1 FLACON POMPE SERAIT PLUS FACILE D'UTILISATION. UNE HUILE LAVANTE CALENDULA SERAIT PEUT-ETRE PLUS FACILE D'UTILISATION.
03-01	CE PRODUIT EST TRES BIEN MAIS JE N'APPRECIÉ PAS L'ODEUR QUE JETROUVE TROP FORTE.
03-02	LE TUBE N'EST PAS PRATIQUE ET UN FLACON AVEC UN POUSSOIR SERAIT PREFERABLE, QUAND ON A QU'UNE MAIN POUR LAVER ET UNE POUR TENIR BEBE.
03-05	SOIN LAVANT HABITUEL SAVON SANS GRAS SAPONIFIE A FROID.
04-01	ODEUR UN PEU FORTE
04-03	CA NE SENT PAS TROP SUR LE CORPS UNE FOIS RINCE. C'EST DOMMAGE CAR CA SENT TRES BON AU LAVAGE DU CORPS OU DES CHEVEUX.
04-04	FAIRE UN TUBE POUSSOIR POUR EXTRACTION DU PRODUIT A UNE MAIN
04-07	LA CREME LAVANTE SERAIT PLUS PRATIQUE EN FLACON AVEC POUSSOIR.
04-09	LE PRODUIT SENT TRES BON ET S'ETALE FACILEMENT. IL A L'AIR D'ETRE APPRECIÉ EGALEMENT PAR MON BEBE. JE RECOMMANDE.
04-10	TRES BON PRODUIT, PARFUM TROP BON J'AIME LE PRODUIT.
05-01	TRES BON PRODUITS IL MANQUE JUSTE UN PEU D'ODEUR DE FRAICHEUR.
05-02	FRANCHEMENT J'APREANDEZ CES PRODUITS MES JE CROIX QUE JE VAIS UTILISER CETTE GAMES LA MERCI DE M'AVOIR FAIT DECOUVERT D'AUTRE PRODUITS PLUS EFFICASSE.
05-03	ELLE SENS TRES BON ET PRATIQUE A UTILISER.
05-04	RINCAGE TRES RAPIDE ET SE DILUE TROP FACILEMENT DANS L'EAU.
05-05	TEXTURE CREME QUI TROUBLE L'EAU APRES RINCAGE --> PAS IDEAL QUAND BEBE CONTINUE A SE BAIGNER APRES LA DOUCHE.
05-06	REMARQUE PAS RAPPORT AUX EMBALLAGES EN PLASTIQUE (RECYCLAGE ?).
05-10	POUR LECORPS JE SUIS SATISFAITE, PAR CONTRE POUR LES CHEVEUX PAS DU TOUT APRES UTILISATION, CHEVEUX SEC ET RECHES.
06-01	L'ODEUR EST BONNE (ET NON TB) MAIS C'EST AUSSI POSITIF CAR LE PRODUIT NE FAIT PAS TROP "CHIMIQUE" AVEC AJOUT DE PARFUM INUTILE. UN PEU DIFFICILE A RINCER MAIS C'EST NEGLIGEABLE. A QUAND LA RECHARGE POUR CONSOMMER MOINS DE PLASTIQUE ?

Subject ID	Comments about Calendula Shampoo and Body Wash
06-02	JE SUIS TRES CONVAINCUE DE LA CREME POUR LE CHANGE. UN PEU MOINS DE LA CREME LAVANTE. JE N'AIME PAS TROP LA TEXTURE, J'AI RECU PLUSIEURS FOIS DES BOUTS D ECREME DANS LES YEUX EN OUVRANT LE TUBE QUE JE NE TROUVE PAS FACILE A MANIER.
06-03	SUPER, TRES SATISFAITE

Listing of the parents' comments about Calendula Shampoo and Body Wash (verbatim of the AQ 13 – Calendula Shampoo and Body Wash self-administered questionnaire)