

**In-Use Skin Tolerance Observation (Repeated Open Application  
Test) on Infants / Small Children Conducted With  
“Sansin Baby shampoo and bath Pink Duck”  
(09.04.2021)**

**(Cosmetic Trial)**

**Summary**

Study Sponsor .....: **ChemCore Impex Kft.**  
1022 Budapest  
Szemlőhegy utca 6.  
Hungary

Performance of Test .....: Derma Consult Concept GmbH  
and Evaluation by Hermann-Wandersleb-Ring 4  
53121 Bonn  
Germany

Date of Order.....: 20.05.2020

Study Code .....: DCC20U051

Study Objective .....: To evaluate skin tolerance of the test product and its suitability  
for regular use on infants / small children as shampoo and bath  
additive.

Supervisors of Study .....: Dr. med. H. Prieur, Dermatologist – Allergist  
B. Nissen, Manager Derma Consult Concept

Test Product.....: The test product, which was coded as follows, was provided by  
ChemCore Impex Kft. in May 2020 in retail packaging:

**A. Sansin Baby shampoo and bath Pink Duck (09.04.2021)**  
Samples received labeled as “Sansin Baby Shampoo for her”

Subjects .....: Number of individuals.: 30  
Sex.....: 16 female, 14 male  
Age range (at study start) : 6 month - 4 years (average: 2,3)

manager: Boris Nissen  
bank account: Sparkasse KölnBonn BIC: COLSDE33XXX  
IBAN: DE89 3705 0198 1902 2876 38

district court Bonn HRB 12566  
VAT-REG.No. DE 209873944  
Tax No. 205/5711/0927

Test Area .....: Hair (use as shampoo) / Body & hair (use as bath additive)

Application.....: Duration....: 28 days  
Frequency.: Min. 2 times weekly (incl. min. once weekly as bath additive)  
(sole replacement for any shampoo & bath additive)

Test Period.....: June / July 2020

Result.....: Overall, the test product showed good skin compatibility under the given test conditions and it can be concluded that in normal use the test product is safe and can be used on infants / small children as shampoo and bath additive.

## Study Objective

To evaluate skin tolerance of the test product and its suitability for the use on infants / small children in conditions of regular use as shampoo and bath additive.

## Performance of Test

To respect the SARS-CoV-2 related legal requirements in place at the time of conduct of the study, a contact minimized study protocol was employed.

For ethical reasons, the test was only started after successful completion of a prior patch test (test report Derma Consult GmbH, 08.07.2019: “Sansin Baby Shampoo for Her” Batch No.: 1/27/05/2019). The subjects were selected from the Derma Consult Concept GmbH database. The respective guardians were informed about importance and meaning of the study and written informed consent was obtained prior to entry of their child into the trial. The following criteria were used for selection of the children:

*for inclusion in study:*

- between 6 month and 4 years of age
- fundamentally clinically healthy
- ability to comply with the requirements of the study

*for exclusion from study:*

- skin diseases or any other medical condition interfering with the objectives of the study
- planned medical treatment or vaccination during study period
- planned vacation during study period

On the initial visit to the test institute, the guardians were questioned on the medical history of their child and the skin condition of the children was examined; only children in good health matching the in- and exclusion criteria were permitted to participate in the study. The guardians could withdraw their children from the study at any time without giving any reason. Study participation was limited to one child per household.

On infants / small children a complete discontinuation of the regular treatment regime and sole use of the test product could ethically not be justified. In order to minimize interference of concurrent product use with the study objective, the test product was introduced to the guardians as replacement for the shampoo and bath additive they commonly used for their child and apart from this change to maintain their regular treatment regime (products & application frequency – e.g. sunscreen, nappy rash cream, face wash) with cosmetic care and cleansing products throughout the entire study.

After examination and collection of demographic data, the guardians were provided the test product along with the usage instructions and were asked to return to the test institute after 28 days of home use. They were reminded to use the provided test product as sole replacement for any shampoo and bath additive for their child. The usage frequency of the test product was set to minimum twice weekly, including minimum once weekly use as bath additive. The application amount was not standardized and the guardians instructed to shake the product before each use and to thoroughly rinse after each use. A more frequent use was expressly allowed, but not required. In case of any problems with the test product, suspected incompatibility or any change in the medical condition of the child, the guardians were instructed to immediately contact the study supervisor and schedule a visit to the test institute. Any such events were recorded.

The guardians of subjects completing the full treatment period were, on their concluding visit after 28 days of home use, questioned on their experience with the test product in use on their child with regard to skin tolerance or any other product related problems and the skin condition of the children was examined for any signs of irritative or allergic responses to the test product.

Questioning and data recording were conducted digitally using Keypoint 5.54 (MU + Data Entry, Cambridge Software Publishing, UK), a printout of the data recording instrument is included in appendix II.

## **Drop-outs / Incompatibilities**

All children completed the study; they were, at the start of the study, between 6 month and 4 years of age (average: 2,3; 16 females, 14 males). No problems were observed in or reported by any of the guardians and in the examination of the children no signs of irritative or allergic responses to the test product could be detected.

At the beginning and end of the study, two of the children respectively showed minor redness on the bottom – reactions at a level commonly found and at the end of the study not attributable to the use of the test product.

The concluding study visit of subject 12 was delayed by 2 days for personal reasons unrelated to the conduct of the study – the guardians continued product treatment on their child. Considering the short delay of 2 days in relation to the overall planned for application phase of the study (28 days), the study supervisors accepted the timing deviation as preferable to a reduced subject number by excusing the subject from the study.

## **Conclusion**

Overall, the test product showed good skin compatibility under the given test conditions and it can be concluded that in normal use the test product is safe and can be used on infants / small children as shampoo and bath additive.

Signature:

B. Nissen Manager Derma Consult Concept
--

Signature:

Dr. med. H. Prieur Dermatologist - Allergist
---

Appendix I: Tabulated subject data  
Appendix II: Data recording instrument (printout)

## **Appendix I:**

Tabulated subject data

Sansin Baby shampoo and bath Pink Duck  
(09.04.2021)

Subject	Sex	Age (y / m)		Inclusion criteria	Exclusion criteria	Anomalies – Start	Regular completion	Unplanned termination - reason	Problems	Reported Problems		
										Obs. discomfort	Redness	Dryness/Scaling
1	M	3	3	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
2	F	4	0	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
3	M	3	2	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
4	F	2	10	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
5	M	1	11	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
6	F	3	5	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
7	M	2	0	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
8	M	0	7	Yes/Yes/Yes/Yes	No/No/No/No	Minor reddening in nappy area	Yes	-	No	-	-	-
9	M	0	11	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
10	F	2	0	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
11	F	1	11	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
12*	M	3	6	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
13	F	0	10	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
14	F	2	1	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
15	F	1	5	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
16	M	1	3	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
17	F	0	8	Yes/Yes/Yes/Yes	No/No/No/No	Minor reddening in nappy area	Yes	-	No	-	-	-
18	F	3	3	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
19	M	2	6	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
20	M	4	5	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
21	F	0	8	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
22	F	0	11	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
23	F	3	2	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
24	M	2	6	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
25	M	4	3	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
26	F	2	8	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
27	M	0	10	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
28	F	4	0	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
29	F	1	8	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-
30	M	1	4	Yes/Yes/Yes/Yes	No/No/No/No	-	Yes	-	No	-	-	-

\* concluding study visit delayed

**Sansin Baby shampoo and bath Pink Duck**  
(09.04.2021)

Subject	Reported Problems					Problem description	Anomalies – End
	Rash	Edema	Eye irritation	Tearing	Other problems		
1	-	-	-	-	-	-	-
2	-	-	-	-	-	-	-
3	-	-	-	-	-	-	-
4	-	-	-	-	-	-	-
5	-	-	-	-	-	-	-
6	-	-	-	-	-	-	-
7	-	-	-	-	-	-	-
8	-	-	-	-	-	-	-
9	-	-	-	-	-	-	-
10	-	-	-	-	-	-	-
11	-	-	-	-	-	-	-
12*	-	-	-	-	-	-	-
13	-	-	-	-	-	-	Minor reddening in nappy area
14	-	-	-	-	-	-	-
15	-	-	-	-	-	-	-
16	-	-	-	-	-	-	-
17	-	-	-	-	-	-	Minor reddening in nappy area
18	-	-	-	-	-	-	-
19	-	-	-	-	-	-	-
20	-	-	-	-	-	-	-
21	-	-	-	-	-	-	-
22	-	-	-	-	-	-	-
23	-	-	-	-	-	-	-
24	-	-	-	-	-	-	-
25	-	-	-	-	-	-	-
26	-	-	-	-	-	-	-
27	-	-	-	-	-	-	-
28	-	-	-	-	-	-	-
29	-	-	-	-	-	-	-
30	-	-	-	-	-	-	-

\* concluding study visit delayed

## **Appendix II**

Data recording instrument (printout)



## Verträglichkeit / Skin Compatibility

### Sansin Baby shampoo and bath Pink Duck - Start

Q1. Probandennummer / Subject No. \_\_\_\_\_

Q2. Alter des Kindes (J/M) / Age of child (y/m) \_\_\_\_\_

Q3. Geschlecht / Gender  weiblich / female  männlich / male

#### Q4. Einschlusskriterien / Inclusion Criteria

	Ja / Yes	Nein / No
Q4.1. 6 Monate <= Alter <= 4 Jahre / 6 month <= age <= 4 years	<input type="checkbox"/>	<input type="checkbox"/>
Q4.2. Grundsätzlich klinisch gesund / fundamentally clinically healthy	<input type="checkbox"/>	<input type="checkbox"/>
Q4.3. Bedingungen der Studie erfüllbar / ability to comply with study requirements	<input type="checkbox"/>	<input type="checkbox"/>
Q4.4. Einverständniserklärung der Erziehungsberechtigten liegt vor / written consent of the legal guardians is available	<input type="checkbox"/>	<input type="checkbox"/>

#### Q5. Ausschlusskriterien / Exclusion Criteria

	Ja / Yes	Nein / No
Q5.1. Alter / Age > 4 Jahre / years oder / or < 6 Monate / month	<input type="checkbox"/>	<input type="checkbox"/>
Q5.2. (Haut-)Erkrankung, die mit den Zielen dieser Untersuchung nicht vereinbar ist / (Skin-)disease incompatible with the goals of the study	<input type="checkbox"/>	<input type="checkbox"/>
Q5.3. Geplante medizinische Behandlung oder Impfung in nächsten 4 Wochen / planned medical treatment or inoculation during next 4 weeks	<input type="checkbox"/>	<input type="checkbox"/>
Q5.4. Geplanter Urlaub in nächsten 4 Wochen / planned vacation during next 4 weeks	<input type="checkbox"/>	<input type="checkbox"/>

Q6. Auffälligkeiten Start / Anomalies start:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## Verträglichkeit / Skin Compatibility

### Sansin Baby shampoo and bath Pink Duck - Ende / End

**Q7.** Reguläre Beendigung der Studie / Regular completion of study  Ja / Yes  Nein\* / No\*

**Q8.** \*Unplanmäßige Beendigung - Begründung / Unplanned termination - reason

---

---

---

**Q9.** Probleme während der Studie / Problems during study  Ja\* / Yes\*  Nein / No

**Q10.** Probleme während der Studie (bei zuvor bestehenden Symptomen verstärktes oder vermehrtes Auftreten) / Problems during study (in case of previously present symptoms intensified or more frequent occurrence)

<input type="checkbox"/>	<i>Beob. Missempfindung (Brennen / Jucken)* / Observed discomfort (stinging / itching)*</i>	<input type="checkbox"/>	<i>Ödem* / Edema*</i>
<input type="checkbox"/>	<i>Rötung* / Redness*</i>	<input type="checkbox"/>	<i>Irritation der Augen* / Eye irritation*</i>
<input type="checkbox"/>	<i>Schuppung o. Austrocknung* / Dryness o. Scaling*</i>	<input type="checkbox"/>	<i>Tränende Augen* / Tearing*</i>
<input type="checkbox"/>	<i>Ausschlag* / Rash*</i>	<input type="checkbox"/>	<i>Sonstige Probleme* / Other problems*</i>

**Q11.** \*Beschreibung Probleme od. Unverträglichkeiten / Description problems or incompatibilities

---

---

---

---

---

**Q12.** Auffälligkeiten Ende / Anomalies end:

---

---

---