These results are supplied for informational purposes only.
Prescribing decisions should be made based on the approved package insert in the country of prescription

Sponsor/company: sanofi-aventis	ClinicalTrials.gov Identifier: NCT00881270
Generic drug name: Lactic acid	Study Code: LACAC_L_04678
	Date: 25/Sep/2009

Title of the study:	Safety Dermatological Evaluation: acceptability with pediatric follow up – Dermacyd Infantile. LACAC_L_04678		
Investigator(s):	Sergio Schalka *MEDCIN – Instituto da Pele* Avenida Dr. Carlos de Moraes Barros, nº 304, Osasco, São Paulo		
Study center(s):	1 BR center		
Publications (reference):	None		
Study period: Date first subject enrolled: 03-Mar-2009 Date last subject completed: 25-Mar-2009		Phase of development: III	
Objectives:	To evaluate the safety of the infantile formulation in normal and usual daily hygiene conditions.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 30-35	Randomized: NA	Treated: 31
Evaluated:		Safety: 30	
Diagnosis and criteria for inclusion:	Healthy volunteers, aged between birth and 12 years old; integral skin test in the region (body); use the same category cosmetic product; willingness in following the study procedures and to be present in the clinic at the days and scheduled time and (ICF) Informed Consent Form responsible signature;		
Investigational product: Dose: Administration:	Lactic acid Liquid soup to be applied over the child body for daily hygiene during the shower, with abundantly rinse after use, during 21 days ± 2. Topical usage.		
Duration of treatment: 21 days ± 2		Duration of observation: 21 days ± 2	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	Acceptability evaluated by the occurrence of adverse events reported by the subject or noted by the investigator as follow: -Level of skin irritation in the tested region, evaluated by the presence of erythema, edema, desquamation, vesiculation, ardor and itching and their intensity: Mild, Moderate or Severe- In case of Adverse Event, these data were filled out in patient CRF (Case Report Form) and Adverse Reactions Form.
Statistical methods:	In case of occurrence of adverse reaction, it would be used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group).
Summary:	A total of 31 volunteers were enrolled to the study. One of them did not return to the final visit and for this reason, only 30 subjects were evaluated. None of this evaluated patients had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	27-Apr-09