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	ClincialTrials.gov Identifier:	NCT00881348
		Study Code:	LACAC_L_04680
Generic drug name:	Lactic Acid	Date:	05/Feb/2010

Title of the study:	Dermatological evaluation of the photo irritation and Photosensitization potential - Dermacyd Infantile (LACAC_L_04680)		
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: 09-Feb-2009 Date last subject completed: 12-Mar-2009		Phase of development: III	
Objectives:	To prove the absence of photo irritation and Photosensitization potential of the product Dermacyd Infantile.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 25-30	Randomized: NA	Treated: 27
Evaluated:		Safety: 27	
Diagnosis and criteria for inclusion:	Volunteers both sexes, aged among 18 and 60 years old; phototypes: II and III, with intact skin in the region tested, willingness in following the study procedures and ICF signature.		
Investigational product: Dose: Administration:	Lactic acid Liquid soap was applied over the skin and volunteers received irradiation over this region. Topical usage.		
Duration of treatment: 05 weeks		Duration of observation: 05 weeks	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	- Photo irritation and Photosensitization potential were evaluated by the occurrence of adverse events reported by the subject or noted by the investigator with causality as follows: - Causality related to the study product. -Level of skin irritation in the tested region, evaluated by the presence of erythema, edema, desquamation, vesiculation, burning and itching and their intensity: Mild, Moderate or Severe.
Statistical methods:	In case of adverse reaction's occurrence, it was used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group). -The sum of the occurrences was divided by the number of volunteers that presented reaction, representing the mean of positive cutaneous answer to the product. The value was shown with standard deviation, mode and median. -Percentage of volunteers with adverse reaction, taking into consideration the number and intensity.
Summary:	A total of 27 female volunteers were enrolled in the study. All of them concluded the study. No volunteer had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	04- Feb-2010