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: NCT00761800
	Study Code: LACAC_L_04087
Generic drug name: Lactic acid	Date: 28/May/2009

Title of the study:	Study for dermatological evaluation of topic compatibility (primary and accumulated dermical irritability, dermical sensitivity) of Dermacyd Teen care Tangerina Mix. (LACAC_L_04087)		
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: 12-May-2008 Date last subject completed: 30-May-2008		Phase of development: III	
Objectives:	To prove the absence of irritation potential (primary dermic irritability and cumulated dermic irritability) of the product Dermacyd Teen Care Tangerina Mix.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 50-60	Randomized: NA	Treated: 51
Evaluated:		Safety: 51	
Diagnosis and criteria for inclusion:	Aged among 18 and 60 years old, Phototypes: I, II, III and IV, with integral skin in the region tested, willingness in following the study procedures and Informed Consent Form (ICF) signature.		
Investigational product: Dose: Administration:	Lactic acid Liquid soap. Patients received some sample applications on the skin, like a curative. Topical usage.		
Duration of treatment: 3 weeks		Duration of observation: 3 weeks	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	-Compatibility was 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, vesicles, ardor and itching and their intensity and causality: -Causality: not related, possible related, probably related or definitely related. -Intensity: Absent, Mild, Moderate or Severe. These data were filled out in CRF and Adverse Reactions Form.
Statistical methods:	In case of occurrence of adverse reaction, 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 present 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 in consideration the number, intensity and causality.
Summary:	A total of 51 female volunteers were enrolled in the study. No patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	19-May -09