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	**ClinialTrials.gov Identifier:**	NCT00933946
		Study Code:	LACAC_L_04842
Generic drug name:	Lactic acid	**Date:**	13 September 2010

Title of the study:	Dermatological evaluation of topic compatibility, primary dermic irritability, accumulated and dermic sensitivity– Dermacyd Silver Frutal (LACAC_L_04842)		
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: 15-Jun-2009 Date last subject completed: 23-Jul-2009	Phase of development: III		
Objectives:	To demonstrate the absence of potential irritability (primary dermic irritability and cumulated dermic irritability) and allergy (sensibilization) by the product Dermacyd Silver Frutal.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 50-60	Randomized: 55	Treated: 55
Evaluated:		Safety: 55	
Diagnosis and criteria for inclusion:	Volunteers 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 to be present at the clinic during the days and timing scheduled and Informed Consent Form signed.		
Investigational product: Dose: Administration:	Lactic acid Patients received small quantity applications over the skin. Topical usage.		
Duration of treatment: 6 weeks	**Duration of observation:** 6 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 with causality as follow: No reaction, Reaction not related to the study product, Reaction remotely related to the study product, Reaction probably related to the study product or Reaction definitely related to the study product. -Level of skin irritation in the tested region, evaluated by the presence of erythema, edema, desquamation, vesiculation, ardor and itching and their intensity and causality: - Causality: not related, possible related, probably related or definitely related. - Intensity: Mild, Moderate or Severe. It is important to point out that the prototype Fitzpatrick scale was used to classify the skin colour and the sensibilization according to the skin colour.
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). However, it is important to point out that it was not observed skin reaction.
Summary:	A total of 55 female volunteers were enrolled in the study. All of them finished the study. Any patient enrolled had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	30-Aug-2010