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:**	NCT00933257
		Study Code:	LACAC_L_04808
Generic drug name:	Lactic acid	**Date:**	13 September 2010

Title of the study:	Dermatological topic evaluation of the photo irritation and photo sensitivity potential – Dermacyd PH_DESILSTY_FR – Stay on Frutal (LACAC_L_04808)		
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: 22-Jun-2009 Date last subject completed: 23-Jul-2009	Phase of development: III		
Objectives:	To prove that the product tested (Dermacyd PH_DESILSTY_FR – Stay on Frutal) does not cause photo irritation and photo sensitivity when exposure to the light.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 25-30	Randomized: 27	Treated: 27
Evaluated:		Safety: 27	
Diagnosis and criteria for inclusion:	Volunteers aged among 18 and 60 years old; phototypes: II and III, 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 signature.		
Investigational product: Dose: Administration:	Lactic acid Patients received small quantity applications and irradiation over the skin. Topical usage.		
Duration of treatment: 5 weeks		**Duration of observation:** 5 weeks	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	- Photo irritation and photo sensitive potential were 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 color and the sensibilization according to the skin color.
Statistical methods:	In case of adverse reaction occurrence, 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 27 volunteers were enrolled in the study. All of them finished the study. Any patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	27-Aug-2010