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:**	NCT00933842
		Study Code:	LACAC_L_04805
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_FL – Stay on Floral (LACAC_L_04805)		
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 the absence of photo irritation and Photosensitization potential of the product tested (Dermacyd PH_DESILSTY_FL – Stay on Floral).		
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. 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).
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:	02-Aug—2010