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Sponsor/company: sanofi-aventis		ClinicalTrials.gov Identifier: NCT00668668	
Generic drug name: Lactic Acid		Study Code: LACAC_L_03733	
		Date: 27/Jan/2009	
Title of the study:		Monocentric Study, Phase III, for Dermatological evaluation of topic compatibility (primary and accumulated dermical irritability, dermical sensibility)– Dermacyd Tina Gel Sweet Flower (LACAC_L_03733)	
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: 03-Dec-2007 Date last subject completed: 10-Jan-2008		Phase of development: III	
Objectives:		To demonstrate the absence of irritation potential (primary dermic irritability and cumulated dermic irritability) and allergy (sensibilization) of the product Dermacyd Tina Gel Sweet Flower.	
Methodology:		Single-center, open label, non-comparative study.	
Number of subjects:		Planned: 50-60	Randomized: NA Treated: 52
Evaluated:		Safety: 52	
Diagnosis and criteria for inclusion:		Healthy volunteers, Female, aged between 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 ICF signature.	
Investigational product: Dose: Administration:		Lactic acid Patients are going to receive some applications in the skin. Topical usage.	
Duration of treatment: 6 weeks		Duration of observation: 6 weeks	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	<p>-Compatibility evaluated by the occurrence of adverse events reported by the subject or noted by the investigator with causality as follow:</p> <p>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.</p> <p>-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:</p> <p>Causality: not related, possible related, probably related or definitely related.</p> <p>Intensity: Mild, Moderate or Severe.</p> <p>These data are going to be filled out in CRF and Adverse Events Form.</p>
Statistical methods:	<p>In case of occurrence of adverse reaction, it will be used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group).</p> <p>-The sum of the occurrences will be divided by the number of volunteers that present reaction, representing the mean of positive cutaneous answer to the product. The value will be show with standard deviation, mode and median.</p> <p>-Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality.</p>
Summary:	A total of 54 female volunteers were enrolled to the study. Two of them were discontinued: one due to exposure to the sun and for this reason had an itching; the other one took forbidden medication which could modify the study result. Any patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	09-jan-09