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Sponsor/company: sanofi-aventis		clinicaltrials.gov Identifier: NCT00784160	
Generic drug name: Lactic acid		Study Code: LACAC_L_04308	
		Date: 21/Aug/2009	
Title of the study:		Dermatological evaluation of topic compatibility (primary and accumulated dermal irritability, dermal sensibility)– Dermacyd PH_DETINBACK Tangerine Mix (LACAC_L_04308)	
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: 28-Jul-2008 Date last subject completed: 04-Sep-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 PH_DETINBACK Tangerine Mix.	
Methodology:		Single-center, open label, comparative study.	
Number of subjects:		Planned: 50-60	Randomized: NA Treated: 53
Evaluated:		Safety: 53	
Diagnosis and criteria for inclusion:		Female volunteers, 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 to be present in the clinic at the days and scheduled time and Informed Consent Form (ICF) signature.	
Investigational product: Dose: Administration:		Lactic acid Patients received some applications over the skin. Topical usage.	
Duration of treatment: 6 weeks		Duration of observation: 6 weeks	

Reference therapy:	Dermacyd PH_DETINLYN Tangerine Mix
Dose:	Patients received some applications over the skin.
Administration:	Topical usage.
Criteria for evaluation:	
Safety:	<p><u>-Compatibility evaluated by the occurrence of adverse events reported by the subject or noted by the investigator with causality as follow:</u></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><u>-Level of skin irritation in the tested region, evaluated by the presence of:</u></p> <ul style="list-style-type: none"> - erythema, edema, desquamation, vesiculation, ardor and itching and their intensity and causality: - <u>Causality:</u> not related, possible related, probably related or definitely related. - <u>Intensity:</u> Mild, Moderate or Severe.
Statistical methods:	<p>In case of occurrence of adverse reaction, it was used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group).</p> <p>-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.</p> <p>-Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality.</p>
Summary:	A total of 53 female volunteers were enrolled to the study. None of the patients analyzed had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	03-Aug-2009