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:**	NCT00497692
Generic drug name:	Lactic Acid	**Study Code:**	LACTO_L_02948
		Date:	19/May/2008

Title of the study:	Dermatological evaluation of topic compatibility (primary and accumulated dermical irritability, dermical sensibility)– Dermacyd Femina Delicata (LACTO_L_02948)		
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: 14-May-2007 Date last subject completed: 21-Jun-2007		**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 Femina Delicata.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 50	Randomized: NA	Treated: 55
Evaluated:		Safety: 55	
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 signature of ICF.		
Investigational product: Dose: Administration:	Lactic acid Wipes to be used at least during 48 hours. Topical usage.		
Duration of treatment: 06 weeks		**Duration of observation:** 06 weeks	

Reference therapy: Dose: Administration:	NA NA NA
Criteria for evaluation:	
Safety:	-Compatibility 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.
Statistical methods:	In case of occurrence of adverse reaction, it will be used the "Evaluation scale of cutaneous answer", by ICDRG (International contact Dermatitis Research Group). -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. -Percentage of volunteers with adverse reaction, taking in consideration the number, intensity and causality.
Summary:	A total of 55 female volunteers were enrolled to the study. All of them completed the treatment period of 06 weeks. Any patient had cutaneous reaction.
Safety results:	No volunteer presented skin reaction.
Date of report:	23-Apr-2008