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:**	NCT00370162
		Study Code:	**LACTO_L_01839**
Generic drug name:	**LACTIC ACID**	**Date:**	15-May-2008

Title of the study:	Safety Dermatological evaluation: acceptability with gynecological follow up – Dermacyd Delicata (LACTO_L_01839)		
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: 12-Jun-2006 Date last subject completed: 10-Jul-2006		**Phase of development:** III	
Objectives:	To evaluate in female volunteers, the safety of the formulation Dermacyd Delicata in normal and usual usage conditions.		
Methodology:	Single-center, open label, non-comparative study.		
Number of subjects:	Planned: 30	Randomized: NA	Treated: 29
Evaluated:		Safety: 29	
Diagnosis and criteria for inclusion:	Female volunteers, aged between 18 and 60 years old, with integral skin in the region tested, willingness in following the study procedures and signature of ICF.		
Investigational product:	Lactic acid		
Dose:	Wipes to be used at least four times per day.		
Administration:	Topical usage.		
Duration of treatment: 21 days		**Duration of observation:** 21 days	

Reference therapy:	NA
Criteria for evaluation:	
Safety:	- Acceptability 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 30 female volunteers were enrolled to the study. Only one did not complete the treatment due to reasons not related to the study. None of them present skin reaction in the tested region concerning dermatological and gynecological monitoring.
Safety results:	No volunteer presented skin reaction in the tested region concerning dermatological and gynecological monitoring.
Date of report:	23-Feb-2008