2. SYNOPSIS

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<th>Individual Study Table Referring to Part of the Dossier</th>
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<td>Pfizer, Inc.</td>
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Name of Finished Product: Desitin® Zinc Oxide Diaper Rash Ointment, Desitin Creamy® Zinc Oxide Diaper Rash Ointment

Name of Active Ingredient: 

Title of Study: A Parallel, Evaluator-Blind, Randomized Clinical Trial to Evaluate the Efficacy and Safety of Two Marketed Topical Skin Protectants Containing Zinc Oxide in Children with Diaper Rash

Investigators: W. Michael Brown, M.D.

Study Centers: Hill Top Research, Inc., 6699 13th Ave. N., St. Petersburg, FL 33710

Publication (reference): Abstract accepted at 25th Annual Fall Clinical Dermatology Conference, October 6-9, 2006

Study Period: 27 June 2005 to 23 October 2005  Phase of Development: 4

Date of first enrollment: 

Date of last completed: 

Objective: The purpose of this study was to evaluate whether Desitin® Zinc Oxide Diaper Rash Ointment (Desitin Original) and Desitin® Creamy Zinc Oxide Diaper Rash Ointment (Desitin Creamy) provide relief of the signs and symptoms associated with diaper rash after 12 and 24 hours of product application.

Methodology: This was an evaluator-blinded, two-arm, randomized, parallel trial conducted with children 2-36 months of age and wearing diapers 24 hours a day. The duration of the study was twenty-four hours from the time of first product application for each subject. Prior to enrollment each subject participated in a screening process to verify good general health.
Subjects participated in a screening visit in which informed consent was obtained from the parent/guardian and the inclusion/exclusion criteria form was completed as well as being asked about concomitant medications. At the baseline visit, the subject’s medical history and eligibility were reviewed. The subject was enrolled and randomized if they received an overall severity score of 1.5 or higher. The first application of the investigational product was administered under supervision of trial personnel after enrollment. Parents/guardians were required to bring their child back to the test facility after 12 (± 1) and 24 (± 2) hours of investigational product use for evaluation of skin condition by the trained evaluator. One hundred twelve subjects were enrolled to follow a 24-hour exposure period to the randomized investigational product. Fifty-seven children who presented with diaper rash received Desitin Original and the other fifty-five received Desitin Creamy. Children received applications of the investigational product following a gentle cleansing of the diaper zone at every diaper change and following bathing of the child. Assessments by the trained evaluator were performed at baseline and after 12 and 24 hours of treatment. Assessments by the parents/guardians were performed at 12 and 24 hours after the initial product treatment.

Digital photographs were taken from approximately 30 subjects for documenting response to treatment at all visits except for the screening visit.

Subjects were randomized and stratified by sex to receive one of the two investigational products. Subjects received applications of the investigational products following a gentle cleansing of the diaper zone at every diaper change and following bathing of the child during a 24-hour period.

**Number of Subjects (planned and analyzed):** Fifty-seven children who presented with diaper rash received Desitin Original and the other fifty-five received Desitin Creamy.
### Name of Sponsor/Company
Pfizer, Inc.

### Name of Finished Product:
- Desitin® Zinc Oxide Diaper Rash Ointment, Desitin
- Creamy® Zinc Oxide Diaper Rash Ointment

### Name of Active Ingredient:

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#### Diagnosis and Main Criteria for Inclusion:
To be eligible for study participation, subjects must have been healthy male and female children between 2 and 36 months of age, wear diapers 24 hours a day, presented to the test facility with a baseline diaper rash “Overall Severity Score” \(\geq 1.5\), and not have met any of the exclusion criteria.

#### Test Product, Dose and Mode of Administration, Batch Number:
- Desitin® Zinc Oxide Diaper Rash Ointment (Desitin Original); formula number 311-2, topical
- Desitin Creamy® Zinc Oxide Diaper Rash Ointment (Desitin Creamy), formula number 316-1, topical

The investigational products were supplied by the sponsor in individually sealed packages. The commercial identities of the investigational products were covered so that the subjects were not aware of the brand names of the products used.

The evaluator was blinded to randomization of the investigational products. A recorder was present at each evaluation session to record the skin reactions observed by the trained evaluator.

Investigational products were weighed prior to dispensing, following initial product application, and at the 12 and 24 hour visits.

#### Duration of Treatment:
24 hours from the time of first product application

#### Reference Therapy, Dose and Mode of Administration, Batch Number:

#### Criteria for Evaluation:

**Efficacy:** Efficacy was assessed during this study through the documentation of the severity of diaper rash as assessed by the trained evaluator and with the documentation of response to treatment as assessed by the parent/guardian. The trained evaluator performed
assessments at baseline, and at 12 and 24 hours post-baseline treatment. The parent/guardian performed assessments at 12 and 24 hours post-baseline assessment.

**Safety:** Safety was assessed through documentation of adverse events reported during the course of the study. Parents/guardians were asked at each visit if their child had any changes in health or medication and the responses were recorded. Adverse events were followed to completion where possible.

**Statistical Methods:** The data from this trial was managed by Hill Top Research, Inc. and analyzed by the Statistics and Data Management Department of Pfizer Consumer Healthcare.

The analysis population was the Intent-To-Treat (ITT) population which consisted of all randomized subjects. All efficacy and safety analysis were based on ITT population. One primary efficacy measurement was the average diaper rash severity score of five anatomic areas within the diaper zone by the evaluator. The scoring system was a 7-point scale, from 0 (None) to 3 (Severe) with half point allowed. Change from baseline at 12 hours was the primary efficacy endpoint. Within treatment comparison was performed using paired t-test.

The co-primary efficacy measurement was the diaper rash improvement assessed by the parent/guardian at 12 and 24 hours post-baseline by comparing to the baseline condition. The scoring system was a 5-point scale.

All efficacy measurements were analyzed within each treatment, and no between treatment comparison was performed.

For diaper rash score assessed by the evaluator, paired t-test was performed at 12 and 24 hours post-baseline separately. For diaper rash improvement assessed by parent/guardian, one sample t-test was performed at 12 and 24 hours post-baseline separately.
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Name of Active Ingredient:

Change of diaper rash score from baseline by evaluator at 12 hours and diaper rash improvement assessed by parent/guardian at 12 hours post-baseline were primary efficacy endpoints.

The secondary endpoints included change of diaper rash score from baseline by evaluator at 24 hours, diaper rash improvement assessed by parent/guardian at 24 hours post-baseline, and the change of overall severity score from baseline by evaluator at both 12 and 24 hours post-baseline.

The number and percentage of subjects who experienced at least one adverse event was summarized by treatment and body system. The number and percentage of subjects who experienced at least one serious adverse event was summarized by treatment and body system. The number and percentage of subjects who experienced at least one drug related adverse event was summarized by treatment and body system. The number and percentage of subjects who discontinued the trial due to adverse event was summarized by treatment and body system.

**SUMMARY - CONCLUSIONS**

**Efficacy Results:** Two hundred fifty-one subjects were screened and signed the Informed Consent Form. One hundred twelve subjects (112) were enrolled on the study and 111 subjects (48 male, 63 female) completed all phases of the study. One subject, No. 10011233, did not complete the study due to withdrawal of consent to participate. A summary of subject disposition can be found in Table 13.1.1.

Results of the five anatomic areas and overall severity score by the evaluator’s assessments, and parent/guardian’s assessments all indicated that both products were significantly effective (P < 0.05) in relieving diaper dermatitis after 12 and 24 hours of treatment.
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**Safety Results:** There were no adverse events reported or observed during the course of the study. Overall, the reporting of no adverse events under the conditions of the protocol indicate that the investigational products would appear to be safe for their intended use.

**Conclusions:** Overall, the results of the study show that both Desitin® Zinc Oxide Diaper Rash Ointment (Desitin Original) and Desitin Creamy® Zinc Oxide Diaper Rash Ointment (Desitin Creamy) provide fast (in 12 and 24 hours) and effective treatment of diaper rash.

**Date of the Report:** Study completed in October 2005.