

**RCC PROJECT 651475**

DETERMINATION OF PHOTOTOXICITY WITH

**CGF-C-1607**

IN ALBINO GUINEA PIGS

**Second Amendment to Report**

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Date: 09-JUN-1998

## QUALITY ASSURANCE STATEMENT

RCC, Research & Consulting Company Ltd., CH-4452 Itingen / Switzerland

PROJECT NUMBER : 651475  
TEST ARTICLE : CGF-C-1607  
STUDY DIRECTOR : G. Arcelin  
TITLE : Determination of Phototoxicity with CGF-C-1607 in Albino Guinea Pigs.

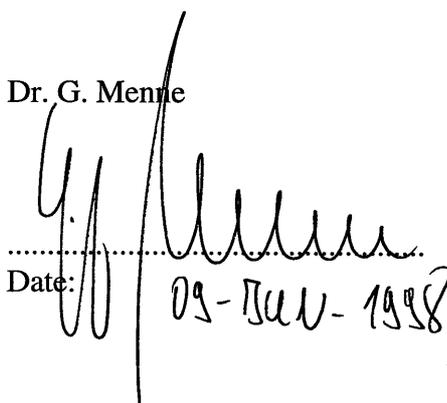
This Second Amendment to Report was audited by the RCC Quality Assurance Unit.  
The dates are given below.

Dates of QAU Inspections / Audits	Dates of Reports to the Study Director and to Management
08-JUN-1998	08-JUN-1998

Manager, Quality Assurance Unit:

Dr. G. Menne

Date:

  
09-JUN-1998

The following supplements to this report were requested by the Sponsor.

CONCERNING:	TEST PROCEDURE / INDUCTION PHASE
PAGE:	14
PRESENT:	To the test areas of 2 cm <sup>2</sup> of the different test article concentrations were applied with a spatula to the left flank in order to saturate the test sites.
NEW:	The test article concentrations of 30, 25, 15 and 10 % were applied to the left flank with a spatula. The test article at the described concentrations was considered to be too thick to be applied with a push button fixed volume pipet. A thin layer of the test article was applied to the test sites of 2 cm <sup>2</sup> . The test article volume was not determined.
REASON FOR THE ALTERATION:	Completion of the protocol and correction of the formulation.
CONCERNING:	FIRST AMENDMENT TO REPORT / STUDY TITLE
PAGE:	1 and 2
PRESENT:	Determination of Photoallergenicity with CGF-C-1607 in Albino Guinea Pigs
NEW:	Determination of Phototoxicity with CGF-C-1607 in Albino Guinea Pigs
REASON FOR THE ALTERATION:	Typing error.

Study Director:

G. Arcelin

A handwritten signature in black ink, appearing to read "G. Arcelin", written over a dotted horizontal line.

Date: 09-JUN-1988

Distribution:

Original: Study Director

Copy: Sponsor