A 6-Week, Randomized Study to Evaluate the Potential of MC2-01 cream to Induce a Photoallergic Skin Reaction in Healthy Subjects, Using a Controlled Photopatch Test Design

Statistical Analysis Plan

Sponsor Protocol No. MC2-01-C10
TKL Study No. PB710518

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1. STUDY PROTOCOL AND AMENDMENTS

This Statistical Analysis Plan is based on the Final Protocol dated 10 January 2019.

2. OBJECTIVES

The primary objective of this study will be to determine the photoallergic potential of MC2-01 cream when topical application to healthy skin is followed by light exposure. In addition, safety will be assessed by evaluation of any AEs reported during the study.

3. STUDY DESIGN

This will be a randomized, double-blind, single-center, controlled, within-subject comparison study of the investigational products (IPs), MC2-01 cream, MC2-01 vehicle, and an untreated irradiated control site in healthy volunteer subjects. A total of 8 application sites (2 cm x 2 cm each) will be marked on the subject's back and distributed so that 4 sites are on one side of the back for induction, and 4 sites are on the other side for challenge patches. The IPs will be applied in two sets. One set of patches on the back will be designated for irradiation after approximately 24 hours (± 4 hours) of study product application and the other set will remain non-irradiated. An additional site will be marked on the back during Challenge. The site will receive no treatment but will be irradiated at Challenge to serve as an untreated irradiated control.

A defined area (approximately 50 cm^2) on the infrascapular region of each subject's back will be irradiated to determine the minimal erythemal dose (MED) of ultraviolet (UV) light.

During the 3-week Induction Phase of the study, 0.2 g of each study product will be applied to 2 sites twice each week (Monday and Thursday) for approximately 24 hours (± 4 hours) under semi-occlusive patch conditions (6 applications). After patch removal, all application sites will be evaluated, and one application site of each study product will be irradiated with 2 times the subject's MED using the full Xenon lamp spectrum. The sites will be evaluated by a trained evaluator. All sites will be reevaluated post irradiation, at approximately 48 hours later when irradiated on Tuesdays and at approximately 72 hours later when irradiated on Fridays except when irradiated on the last Friday of the Induction Phase or after the last make-up visit (if required), the sites will not be evaluated because these readings are not used for determination of photosensitization and any response will have subsided by Monday. These procedures will be performed each week for 3 weeks of the Induction Phase. Dermal reactions at the application sites will be evaluated using a visual scale that rates the degree of erythema, edema, and other signs of cutaneous irritation.

At the end of the Induction Phase, the subjects will enter a Rest Period of 10-17 days and then a Challenge Phase. One application/irradiation session may be missed during the Induction Phase. If a subject misses an irradiation session during the Induction Phase, an additional application/irradiation session will be scheduled the Monday of rest period (week 4).

At Challenge, each study product will be applied in an amount of 0.2 g to 2 naive sites once for approximately 24 hours (±4 hours) under semi-occlusive patches. After 24 hours (±4 hours) of product application, all sites will be evaluated, and one application site of each product and the additional untreated site will be irradiated. The sites will be examined for dermal reactions at approximately 24 hours (±4 hours), 48 hours (±4 hours), and 72 hours (±4 hours) post-irradiation. A Rechallenge should be performed if a cutaneous response observed during the Challenge Phase indicates possible photosensitization or at the discretion of the Investigator.

The safety endpoints for this study are irritation responses during the Induction Phase, positive responses at Challenge (ie, reactions indicative of a sensitization response) and AEs.

4. DATA SETS

The study database will be constructed and maintained by TKL Data Management in accordance with its standard operating procedures (SOPs) and the Sponsor's specifications. A data management plan (DMP), including database/screen design specifications, CRF review guidelines, coding instructions, and edit check specifications will be submitted to the Sponsor for review prior to data entry. When the database has been declared to be complete and accurate as per the DMP, the database will be locked (i.e., the database software will not allow any further additions to, removals from, or other edits of the database). All changes to the database after that time must be authorized by the Sponsor in writing and a database unlock form and then the re-lock form will be signed by both TKL and Sponsor. Study Data Tabulation Model (SDTM) datasets will be constructed from the raw data sets. Analysis datasets (ADaM) that are necessary for table analyses will be generated from SDTM.

The study SDTM and ADaM datasets will be taken as input to validated SAS programs which generate the report-ready tables and listings. Each output display will show the names of the data sets and SAS program used to produce it. Upon completion of the study report, the data sets will be provided to the sponsor as SAS XPT transport files. Data sets will be CDISC compliant. A CDISC compliant define.xml and annotated CRF for SDTM datasets will also be provided to the sponsor.

5. HARDWARE AND SOFTWARE

Statistical analysis will be performed following TKL SOP 03-02-04 Preparation of Tables and Listings for Statistical Reporting. All statistical analysis will be performed using SAS Version 9.2 or higher with program code prepared specifically for the project by qualified TKL statisticians and SAS programmers.

The SAS programs will generate rich-text-formatted (RTF) output with the "RTF" extension using the SAS Output Delivery System (ODS). The summary tables and listings will be formatted using the Courier New 9-point font. The RTF output is included in report documents prepared with Microsoft Word and converted to PDF format without typographical change.

6. CODING

The Medical Dictionary for Regulatory Activities (MedDRA, Version 22.0 2019) coding dictionary will be used for the assignment of system organ class and preferred terms to AEs. The WHO Drug Dictionary Enhanced (WHO DDE Version B 1Q19) will be used for assignment of preferred terms and drug classifications (i.e., Anatomic-Therapeutic-Chemical [ATC] subgroups) to concomitant medications, as described in the Data Management Plan (DMP).

7. STATISTICAL DATA REVIEW

Data verification activities to be performed prior to delivery of the SAS datasets to the project statistician are described in the approved DMP. After completion of the data verification activities, the SAS datasets will be delivered to the project statistician along with documentation of any unresolved queries and data conventions applied that are not fully explained in the data or the DMP. After delivery of the SAS datasets and prior to unblinding of the study data, the project statistician will perform completeness and self-consistency checks of the study data. Queries will be issued to the Data Manager and resolved before closure of the database.

8. HANDLING OF MISSING DATA

Missing values will not be imputed.

9. DATABASE CLOSURE

After completion of all data review procedures, validation of the project database, and approval of the final database in writing by the Sponsor, the database will be closed ("locked"). After the closure of the clinical database and authorization to unblind the study, the treatment codes will be merged to the analysis data sets. Any changes to data, coding, populations, or analysis plan after database closure must be approved by the Sponsor, in writing, and TKL management, and documented in the study archive with a detailed explanation of changes and reasons for changes.

10.INTERIM AND SUBGROUP ANALYSES

No interim or subgroup analyses are planned.

11.STATISTICAL EVALUATION

11.1 General Considerations for Data Analyses

The focus of the statistical analysis will be the comparison with controls of the photoallergic response to the investigational product. The parameter for photoallergy will be the mean numerical

equivalent score. The diagnosis of a reaction indicative of photosensitivity will be made by the Principal Investigator according to working criteria described in detail in the study protocol. Photosensitivity is not to be determined by statistical methods. However, a supportive statistical analysis of numerical photoirritation scores during the Induction Phase will be performed.

All statistical processing will be performed using the SAS® system (version 9.2).

11.2 Subject Populations for Analysis

Three analysis populations will be defined. All subjects who receive treatment will be evaluable for AEs (Population III). The evaluation of photosensitization will be based on all subjects who complete the challenge phase of the study (Population I). The analysis of local tolerability will be based off all subjects who complete the induction phase of the study (Population II).

11.2.1. Population I

Photosensitization potential for each test product site will be assessed only among subjects completing the Induction and Challenge Phases for that product. To be considered a complete case for a particular test product, a subject must have 6 applications/irradiation and no less than 11 **subsequent** readings during Induction, 10-17 days rest, and 1 application and at 3 post-irradiation evaluations during Challenge for that product. However, those subjects who demonstrate photosensitization, even though they have not completed all visits, will also be included in this population and will be evaluated. If subject's patch sites were discontinued because they were considered by the Investigator to be pre-photosensitized during Induction, this subject will not be included in this population for that test product.

11.2.2. Population II

Photoirritation potential for each test product will be assessed only among subjects completing the Induction Phase. To be considered a complete case for each test product, a subject must have 6 applications/irradiation as scheduled in the Induction Phase and no less than 11 **subsequent** readings as scheduled during the Induction Phase for that product.

11.2.3. Population III

This population will include all subjects who received the study products. This will also be the population used for adverse events analyses.

11.3 Subject Disposition

The number of subjects screened, randomized, completing the Induction phase, completing the Challenge phase, included in the analysis of photosensitization (Population I), included in the

analysis of photoirritation (Population II), included in the analysis of adverse events (Population III) and discontinued (by reason for discontinuation) will be summarized using descriptive statistics.

11.4 Background and Demographic Characteristics

Descriptive statistics will be used to summarize demographic characteristics (i.e., age, gender, ethnicity, and race) and background characteristics (i.e. Fitzpatrick skin type and MED) for the randomized subject population. Past/coexistent medical history information for all randomized subjects will be presented in a by-subject listing. Urine pregnancy test results will be presented in a by-subject listing.

11.5 Study Products/Visit Compliance

Descriptive statistics will be used to summarize study product compliance for the randomized subject population.

11.6 Prior and Concomitant Therapy

Prior and concomitant medication information for all randomized subjects will be presented in a by-subject listing.

11.7 Dermal Response Evaluation

The following scoring grades and notations will be used for the evaluation of dermal response at each application and control site throughout the Induction and Challenge Phases of the study. Tape related irritation will not be graded as an irritant response at the patch site.

Grading of Responses

Response	Symbol	Numerical Equivalent Score
Erythema		
No reaction	-	0
Mild, but definite erythema	+	1.0
Moderate erythema	++	2.0
Marked/severe erythema	+++	3.0
Edema		
No reaction	0	0
Mild, but definite edema	**	1.0
Definite edema with erosion/vesiculation	***	2.0

Response Notations

Response/Comment	Notation
Hyperpigmentation	Hr
Hypopigmentation	Ho
Vesiculation	V
Papular response	p
Papulovesicular response	pv
Damage to epidermis: oozing, crusting and/or superficial erosions	D
Itching	I
Spreading of reaction beyond patch study site (i.e., reaction where material did not contact skin)	S
Follicular irritation with or without pustule formation (folliculitis)	f
Subject absent	X
Patch dislodged	PD
Not patched	NP
No reaction	0

Note: The numerical score for edema is to be added to the numerical score for erythema. The literal notations in the second part of the table are not associated with additional numerical value.

All assigned scores during the study will be summarized using frequency counts by treatment at each time point. Erythema and edema scores will be summarized separately. All pairwise comparisons will be performed on the mean of the Induction Phase response scores using Fisher's least significant differences in the analysis of variance (ANOVA) with effects of subjects and treatment. The response score for each subject will be calculated by summing the erythema and edema score and then the mean of the response scores at each reading during the Induction Phase will be calculated for the subject. Pairwise differences will be tested only if the null hypothesis of a common mean score for all products is rejected at the 5% level.

In case of gross violations of the model assumptions (normality, homoscedasticity), non-parametric analysis will be performed. All assigned scores during Induction for each product will be ranked within subject and compared pairwise using Wilcoxon signed-rank test. Pairs to be compared include each test sample irradiated versus non-irradiated and all pairwise comparisons on each side.

11.8 Safety Evaluation

Assessment of Photosensitization Response

The determination of dermal photosensitization potential will be based on specific scoring criteria derived from observations in the Challenge Phase of the study and confirmed in the Rechallenge Phase, if necessary. Criteria specified in the study protocol may cause the continuation of a subject into the Rechallenge Phase of the study. The diagnosis of a photosensitization response will be made by the Investigator based on review of the observed skin responses after Challenge. Photosensitivity will not be determined by statistical methods. All assigned scores during induction and challenge will be summarized by frequency counts by time point and treatment. The incidence of photosensitization reactions will be summarized by frequency counts for each treatment.

Local Tolerability Assessments

The mean numerical equivalent score by subject and treatment, including all scores assigned during induction, will be analyzed in the analysis of variance (ANOVA) with factors subject and treatment. Selected pairwise comparisons will be performed in the context of the ANOVA. Pairs to be compared are: each test sample irradiated versus non-irradiated (MC2-01 cream irradiated versus non-irradiated; vehicle irradiated versus non-irradiated, and untreated control irradiated versus non-irradiated) and all pairwise comparisons on each side (MC2-01 cream versus vehicle; MC2-01 cream versus untreated control; and vehicle versus untreated control; all on both the irradiated and non-irradiated sides).

Adverse Events

Adverse events will be summarized as an overall incidence of at least one event, incidence within body systems only, and incidence by body system and preferred term. Each subject will contribute only once (e.g., the first occurrence) to each of the rates, regardless of the number of occurrences (events) the subject experiences. Treatment-emergent AEs will be summarized and tabulated by the system organ class and preferred term, by severity (mild, moderate, severe) and by relationship to study product (none, possible, probable, or definite). Treatment-emergent will be defined as any AE with an onset date on or after the first study product administration date. Any event with a missing onset date will be included as a treatment-emergent AE. Deaths and SAEs will be listed by subject.

11.9 Rationale for Selection of Sample Size

The sample size of 50 evaluable subjects conforms to industry and regulatory standards for determination of irritation when topical application to skin is followed by light exposure.

12.CHANGES FROM THE PROTOCOL AND PLANNED ANALYSES

There are no changes from the planned analyses in the protocol.

13.HEADINGS

Each page of the analysis will show the Sponsor's name and study number. Report tables will be embedded in the MS Word report document from SAS program output without change. The footer of each table will show the name of the SAS program module which generated it, the names of all data sets providing input data in the program and the date and time the table was generated.

14.ARCHIVING

After finalization of the analysis, the following will be archived at TKL Research, Inc. and/or with the Sponsor:

- Randomization list
- Statistical Analysis Plan
- Data Management Plan
- Annotated CRF
- All SAS code used in the project for statistical analysis
- Final delivered tables and listings as included in the clinical study report
- Final SAS datasets, with full audit trail from initial data entry through final accepted version
- SDTM and ADaM data sets
- Define.xml
- Study data and analysis data reviewer guides for any unavoidable CDISC-checker errors or warnings
- Relevant Correspondence

15.OUTLINE OF PROPOSED TABLES, FIGURES, AND LISTINGS

Summary Tables

Table Number	Title
14.1.1	Summary of Subject Enrollment and Disposition
14.1.2	Summary of Subject Demographics and Baseline Characteristics
14.1.3	Summary of Study Product and Visit Compliance
14.2.1.1	Summary of Dermal Responses by Response Scores and Notations during Induction
14.2.1.2	Summary of Dermal Responses by Response Scores during Induction
14.2.1.3	Summary of Dermal Responses by Response Scores and Notations during Challenge
14.2.1.4	Summary of Dermal Responses by Response Scores during Challenge
14.3.1.1	Overall Summary of Adverse Events
14.3.1.2*	Summary of Treatment-Emergent Adverse Events by Maximum Severity
14.3.1.3*	Summary of Treatment-Emergent Adverse Events by Maximum Relationship

*Tables 14.3.1.2 and 14.3.1.3 will only be included if there are a sufficient number of Treatment-Emergent AEs for multiple classified AE tables.

Data Listings

Listing Number	Title
16.1.7	Subject Randomization
16.2.1	Subject Disposition and Population Inclusion
16.2.2	Protocol Deviations
16.2.4.1	Subject Demographics and Baseline Characteristics
16.2.4.2	Medical History
16.2.4.3	Prior and Concomitant Medications
16.2.5	MED Determination
16.2.6.1	Assessment of Dermal Responses during Induction
16.2.6.2	Assessment of Residual Dermal Responses at Relocated Sites
16.2.6.3	Assessment of Dermal Responses during Challenge
16.2.7.1	Adverse Events
16.2.7.2	Serious Adverse Events and Deaths
16.2.8	Urine Pregnancy Test Results
16.2.9	Comments

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Table 14.1.1: Summary of Subject Enrollment and Disposition

Number of Subjects Screened	XX
Screen Failures, n (%) [1]	XX (XX.X)
Reason Not Randomized, n (%)	
Inclusion X: XXXXXXXXXXXXXXXXXXXXXXX	XX (XX.X)
Exclusion X: XXXXXXXXXXXXXXXXXXXXXXX	XX (XX.X)
Other	XX (XX.X)
Etc.	
Number of Subjects Randomized	XX
Number of Subjects Completing Induction, n (%)	XX (XX.X)
Number of Subjects Completing Challenge, n (%)	XX (XX.X)
Subjects Included in Analysis of Photosensitization (Population I), n (%)	XXX (XX.X)
Subjects Included in Analysis of Photoirritation (Population II), n (%)	XXX (XX.X)
Subjects Included in Analysis of Adverse Events (Population III), n (%)	XXX (XX.X)
Number of Subjects Discontinued, n (%)	XX (XX.X)
Reason for Discontinuation, n (%)	
Protocol Violation	X (XX.X)
Withdrawal of informed consent	X (XX.X)
Etc.	

Note: Percentages are relative to the number of randomized subjects except where otherwise specified.

[1] Percentage is relative to total number screened.

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Table 14.1.2: Summary of Subject Demographics and Baseline Characteristics
All Randomized Subjects

Age (years)	Mean (SD)	XX.XX (X.XX)
	Median	XX.X
	Minimum, Maximum	XX.X, XX.X
Gender, n (%)	Male	XX (XX.X)
	Female	XX (XX.X)
Race, n (%)	White	XX (XX.X)
	Black or African American	XX (XX.X)
	Asian	XX (XX.X)
	American Indian or Alaskan Native	XX (XX.X)
	Native Hawaiian or Pacific Islander	XX (XX.X)
	Multiple: XXXX and XXXX	XX (XX.X)
Ethnicity, n (%)	Hispanic or Latino	XX (XX.X)
	Non-Hispanic or Latino	XX (XX.X)
Fitzpatrick Skin Type, n (%) [1]	I	XX (XX.X)
	II	XX (XX.X)
	III	XX (XX.X)
MED	Mean (SD)	X.XX (X.XX)
	Minimum, Maximum	X.XX, X.XX

[1] I = Always burns easily, never tans; II = Always burns easily, tans minimally; III = Burns moderately, tans gradually

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Table 14.1.3: Summary of Study Product and Visit Compliance
All Randomized Subjects

	Number of Subjects Applied with Study Product or Evaluated, n(%)		
Number of Subjects Attending, n(%)	**MC2-01 cream**	**MC2-01 vehicle**	**Untreated**
Screening/Day 1	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 1/Study Day 1 Application	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 1/Study Day 2 Evaluation	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 1/Study Day 4 Evaluation/Application	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 1/Study Day 5 Evaluation	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 2/Study Day 8 Evaluation/Application	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 2/Study Day 9 Evaluation	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 2/Study Day 11 Evaluation/Application	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 2/Study Day 12 Evaluation	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 3/Study Day 15 Evaluation/Application	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 3/Study Day 16 Evaluation	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 3/Study Day 18 Evaluation/Application	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Induction Week 3/Study Day 19 Evaluation	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Challenge Week 6/Patch Application	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Challenge Week 6/Evaluation and Irradiation	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Challenge Week 6/24 Hour Post-Irradiation Evaluation	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Challenge Week 6/48 Hour Post-Irradiation Evaluation	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)
Challenge Week 6/72 Hour Post-Irradiation Evaluation/End of Study	xx (XX.XX)	xx (XX.XX)	xx (XX.XX)

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Table 14.2.1.1: Summary of Dermal Responses by Response Scores and Notations During Induction
Population II

	MC2-01 cream		MC2-01 vehicle		Untreated
Response	**Irradiated**	**Non-Irradiated**	**Irradiated**	**Non-Irradiated**	**Irradiated**
Reading 1, n (%) Response Score (Sum of Erythema and Edema)					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 Hr	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Reading 2, n (%)] to [Reading 11, n (%)] Response Score					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Scores:
Erythema: 0 = No reaction; 1 = Mild, but definite erythema; 2 = Moderate erythema; 3 = Marked/severe erythema;
Edema: 0 = No reaction; 1 = Mild, but definite edema; 2 = Definite edema with erosion/vesiculation

Notations:
Hr = hyperpigmentation; Ho = hypopigmentation; V = vesiculation; p= Papular response; pv= Papulovesicular response; D= Damage to epidermis; oozing, crusting, and/or superficial erosions; I=Itching; S= Spreading of reaction beyond patch study site (i.e., reaction where material did not contact skin); f= Follicular irritation with or without pustule formation (folliculitis).; X=Subject absent; PD=Patch dislodged; NP = Not Patched ; 0=No Reaction

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Table 14.2.1.2: Summary of Dermal Responses by Response Scores During Induction (Part I)
Population II

	MC2-01 cream		MC2-01 vehicle		Untreated
Response	**Irradiated**	**Non-Irradiated**	**Irradiated**	**Non-Irradiated**	**Irradiated**
Reading 1, n (%) Response Score (Sum of Erythema and Edema)					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[Reading 2, n (%)] to [Reading 11, n (%)] Response Score					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

Scores:
Erythema: 0 = No reaction; 1 = Mild, but definite erythema; 2 = Moderate erythema; 3 = Marked/severe erythema;
Edema: 0 = No reaction; 1 = Mild, but definite edema; 2 = Definite edema with erosion/vesiculation

Note: *P* values are from an analysis of variance of the average numerical score over all Induction Phase readings, with effects of subject and treatment, using Fisher's least significant differences.

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Table 14.2.1.2: Summary of Dermal Responses by Response Scores During Induction (Part II)
Population II

	MC2-01 cream		MC2-01 vehicle		Untreated
	Irradiated	**Non-Irradiated**	**Irradiated**	**Non-Irradiated**	**Irradiated**
N	xx	xx	xx	xx	xx
Mean (SD)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)	x.xx (x.xx)
***P* values**					
vs MC2-01 cream Irr	--	x.xxx	x.xxx	x.xxx	x.xxx
vs MC2-01 cream Non-Irr		--	x.xxx	x.xxx	x.xxx
vs MC2-01 vehicle Irr			--	x.xxx	x.xxx
vs MC2-01 vehicle Non-Irr				--	x.xxx
vs Untreated Irr					--

Mean: The mean is the average of the response scores, where the response scores are calculated by summing the erythema and edema scores for each subject.

Scores:
Erythema: 0 = No reaction; 1 = Mild, but definite erythema; 2 = Moderate erythema; 3 = Marked/severe erythema;
Edema: 0 = No reaction; 1 = Mild, but definite edema; 2 = Definite edema with erosion/vesiculation

Note: *P* values are from an analysis of variance of the average numerical score (sum of erythema and edema) over all Induction Phase readings, with effects of subject and treatment, using Fisher's least significant differences.

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Table 14.2.1.3: Summary of Dermal Responses by Response Scores and Notations During Challenge
Population I
(N=XXX)

	MC2-01 cream		MC2-01 vehicle		Untreated
Time Post-Irradiation	**Irradiated**	**Non-Irradiated**	**Irradiated**	**Non-Irradiated**	**Irradiated**
N Sensitized [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
0 hours, n (%)					
-0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[24 hours, n (%)] to [72 hours, n (%)]					
Response Score (Sum of Erythema and Edema)					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1 Hr	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Sensitization classification made by the PI based on Challenge and Re-challenge

Scores:

Erythema: 0 = No reaction; 1 = Mild, but definite erythema; 2 = Moderate erythema; 3 = Marked/severe erythema;
Edema: 0 = No reaction; 1 = Mild, but definite edema; 2 = Definite edema with erosion/vesiculation

Notations:

Hr = hyperpigmentation; Ho = hypopigmentation; V = vesiculation; p= Papular response; pv= Papulovesicular response; D= Damage to epidermis; oozing, crusting, and/or superficial erosions; I=Itching; S= Spreading of reaction beyond patch study site (i.e., reaction where material did not contact skin); f= Follicular irritation with or without pustule formation (folliculitis).; X=Subject absent; PD=Patch dislodged; NP = Not Patched ; 0=No Reaction

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Table 14.2.1.4: Summary of Dermal Responses by Response Scores During Challenge
Population I
(N=XXX)

	MC2-01 cream		MC2-01 vehicle		Untreated
Time Post-Irradiation	**Irradiated**	**Non-Irradiated**	**Irradiated**	**Non-Irradiated**	**Irradiated**
N Sensitized [1]	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
0 hours, n (%)					
-0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
[24 hours, n (%)] to [72 hours, n (%)]					
Response Score (Sum of Erythema and Edema)					
0	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
1	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
2	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
3	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
4	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)
etc.	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)	xx (xx.x)

[1] Sensitization classification made by the PI based on Challenge and Re-challenge

Scores:
Erythema: 0 = No reaction; 1 = Mild, but definite erythema; 2 = Moderate erythema; 3 = Marked/severe erythema;
Edema: 0 = No reaction; 1 = Mild, but definite edema; 2 = Definite edema with erosion/vesiculation

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Table 14.3.1.1: Overall Summary of Adverse Events
Population III

	(N = XX)
Subjects with Any AE, n (%)	XX (XX.X)
Number of AEs	XX
Subjects with Any Treatment-emergent AE (TEAE), n (%)	XX (XX.X)
Number of Treatment-emergent AEs	XX
Subjects with Any Treatment-related TEAE, n (%) [1]	XX (XX.X)
Number of Treatment-related TEAEs	XX
Subjects with Any Serious TEAE, n (%)	XX (XX.X)
Number of Serious TEAEs	XX
Subjects with Any Severe TEAE, n (%)	XX (XX.X)
Number of Severe TEAEs	XX
Subjects with Any Moderate TEAE, n (%)	XX (XX.X)
Number of Moderate TEAEs	XX
Subjects with Any Mild TEAE, n (%)	XX (XX.X)
Number of Mild TEAEs	XX
Subjects with Any TEAE Leading to Discontinuation of Study Medication, n (%)	XX (XX.X)
Number of TEAEs Leading to Discontinuation of Study Medication	XX

[1] Treatment-related AEs include definitely related, probably related and possibly related.

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Table 14.3.1.2: Summary of Treatment-Emergent Adverse Events
By Severity
Population III

	All (n=x)	
Severity	**No. Events**	**No. Subjects (%)**
Mild	xx	xx (xx.x)
Moderate	xx	xx (xx.x)
Severe	xx	xx (xx.x)

<Programming note: sort AE tables by number of subjects.>

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Table 14.3.1.3: Summary of Treatment-Emergent Adverse Events
By Relationship
Population III

	All (n=x)	
Relationship	**No. Events**	**No. Subjects (%)**
Definitely Related	xx	xx (xx.x)
Probably Related	xx	xx (xx.x)
Possibly Related	xx	xx (xx.x)
Not Related	xx	xx (xx.x)

<Programming note: sort AE tables by number of subjects.>

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Listing 16.1.7: Subject Randomization
All Randomized Subjects

Subject Number	Informed Consent Date	Met all Inclusion/Exclusion Criteria?	Randomization Date	Randomization Number	Randomization [1]	
					Site 1	Site 2
XX	XXXX-XX-XX	Yes	XXXX-XX-XX	XX	A	B
XX	XXXX-XX-XX	Yes	XXXX-XX-XX	XX	B	A
XX	XXXX-XX-XX	Yes	XXXX-XX-XX	XX	A	B
XX	XXXX-XX-XX	Yes	XXXX-XX-XX	XX	B	A
XX	XXXX-XX-XX	Yes	XXXX-XX-XX	XX	B	A

[1] A = MC2-01 cream; B = MC2-01 vehicle

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Listing 16.2.1: Subject Disposition and Population Inclusion
All Randomized Subjects

	Date (Day [1]) of						Analysis Population		
Subject Number	**Screening**	**Day 1**	**Last Visit**	**Last Contact**	**End of Study Status**	**Number of Days in Study [2]**	**Population I – Photosensitization/ Completed Challenge**	**Population II – Local Tolerability / Completed Induction but not Challenge**	**Population III – AE Safety/All Subjects who Received Treatment**
XX	XXXX-XX-XX	XXXX-XX-XX	XXXX-XX-XX (X)		COMPLETED	xx	Y	Y	Y
XX	XXXX-XX-XX	XXXX-XX-XX	XXXX-XX-XX (X)		COMPLETED	xx	Y	Y	Y
XX	XXXX-XX-XX	XXXX-XX-XX	XXXX-XX-XX (X)	XXXX-XX-XX (X)	SUBJECT IS LOST TO FOLLOW-UP	xx	Y	Y	Y
XX	XXXX-XX-XX	XXXX-XX-XX	XXXX-XX-XX (X)	XXXX-XX-XX (X)	COMPLETED	xx	Y	Y	Y
XX	XXXX-XX-XX	XXXX-XX-XX	XXXX-XX-XX (X)		INVESTIGATOR'S JUDGEMENT	xx	Y	Y	Y

[1] Study day is relative to Day 1.
[2] Number of Days in Study is calculated as Date of Last Visit minus Date of Day 1 plus 1.

Population I: Photosensitization potential for each test product site will be assessed only among subjects completing the Induction and Challenge Phases for that product.
Population II: Photoirritation potential for each test product will be assessed only among subjects completing the Induction Phase.
Population III: This population will include all subjects who received the study products.

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Listing 16.2.2: Protocol Deviations
All Randomized Subjects

Subject Number	Protocol Deviation Description	Type	Action Taken
xx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxx
xx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxx
xx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxxxxxxxx	xxxxx

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Listing 16.2.4.1: Demographics and Baseline Characteristics
All Randomized Subjects

Subject Number	Date of Birth	Age (Years) [1]	Gender	Race	Ethnicity	Fitzpatrick Skin Type [2]
xx	xxxx-xx-xx	xx	xxxxxx	xxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxx	I
xx	xxxx-xx-xx	xx	xxxxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxx	III
xx	xxxx-xx-xx	xx	xxxxxx	Multiple: xxxxxxxxxxxx	xxxxxxxxxxxxxxxxxxxxx	II
xx	xxxx-xx-xx	xx	xxxxxx	xxxxxx	xxxxxxxxxxxxxxxxxxxxxxx	I

[1] Age is relative to Day 1.
[2] I = Always burns easily, never tans; II = Always burns easily, tans minimally; III = Burns moderately, tans gradually

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Listing 16.2.4.2: Medical History
All Randomized Subjects

Subject Number	Diagnosis and/or Procedure	Onset Date	Resolution Date
xx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	XXXX	XXXX-XX-XX
	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	XXXX-XX-XX	Ongoing
xx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	XXXX-XX-XX	XXXX-XX-XX
xx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	XXXX-XX	Ongoing

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Listing 16.2.4.3: Prior and Concomitant Medications
All Randomized Subjects

Subject Number	WHO Preferred Term (Verbatim Term)/ ATC Classification	Indication / Dose / Unit / Route / Frequency	Start Date (Day) – Stop Date (Day)
XX	XXXXXXXX (XXXXXXXXXXXXXXXXXXXX)/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX XXXXX / XX / XXXX/ XXXX	XXXX-XX-XX (XX) – XXXX-XX-XX (XX)
	XXXXXXXX (XXXXXXXXXXXXXXXXXXXX)/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX XXXXX / XX / XXXX/ XXXX	XXXX – Ongoing
XX	XXXXXXXX (XXXXXXXXXXXXXXXXXXXX)/ XXXXXXXXXXXXXXXXXXXXXXXXXXXXXX	XXXXXXXXXXXXXXX XXXXX / XX / XXXX/ XXXX	XXXX – XXXX-XX-XX (XX)

Note: Study day is calculated relative to Baseline (Day 1).

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Listing 16.2.5: MED Determination
All Randomized Subjects

Subject Number	Date-Time of Irradiation	Time Point Post-Irradiation	Date-Time of Reading		Subsite 1	2	3	4	5	6	MED
xx	xxxx-xx-xxTxx:xx			UVB/UVA Intensity ($\mu W/cm^2$)	xx	xx	xx	xx	xx	xx	
				Exposure (seconds)	xx	xx	xx	xx	xx	xx	
		Immediate	xxxx-xx-xxTxx:xx	Reading	xx	xx	xx	xx	xx	xx	
		16 – 24 Hours	xxxx-xx-xxTxx:xx	Reading	xx	xx	xx	xx	xx	xx	x.xx
xx	xxxx-xx-xxTxx:xx			UVB/UVA Intensity ($\mu W/cm^2$)	xx	xx	xx	xx	xx	xx	
				Exposure (seconds)	xx	xx	xx	xx	xx	xx	
		Immediate	xxxx-xx-xxTxx:xx	Reading	xx	xx	xx	xx	xx	xx	
		16 – 24 Hours	xxxx-xx-xxTxx:xx	Reading	xx	xx	xx	xx	xx	xx	x.xx

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Listing 16.2.6.1: Assessment of Dermal Responses During Induction
Population II

Subject Number	Date-Time of Application	UVB/UVA ($\mu W/cm^2$)	2xMED (seconds)	Time Point	Date-Time of Reading	MC2-01 cream		MC2-01 vehicle		Untreated
						Irradiated	Non-Irradiated	Irradiated	Non-Irradiated	Irradiated
						ER/ED (Sum)	ER/ED (Sum)	ER/ED (Sum)	ER/ED (Sum)	ER/ED (Sum)
xx	xxxx-xx-xxTxx:xx	x.xx	x.xx	Day 2	xxxx-xx-xxTxx:xx	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)
				Day 4	xxxx-xx-xxTxx:xx	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)
				Day 5	xxxx-xx-xxTxx:xx	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)
				Day 8	xxxx-xx-xxTxx:xx	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)
				Day 9	xxxx-xx-xxTxx:xx	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)
				etc.						
			Mean Patch Response Score			xx	xx	xx	xx	xx
				etc						

Scores:
Erythema: 0 = No reaction; 1 = Mild, but definite erythema; 2 = Moderate erythema; 3 = Marked/severe erythema;
Edema: 0 = No reaction; 1 = Mild, but definite edema; 2 = Definite edema with erosion/vesiculation

Notations:
Hr = hyperpigmentation; Ho = hypopigmentation; V = vesiculation; p= Papular response; pv= Papulovesicular response; D= Damage to epidermis; oozing, crusting, and/or superficial erosions; I=Itching; S= Spreading of reaction beyond patch study site (i.e., reaction where material did not contact skin); f= Follicular irritation with or without pustule formation (folliculitis).; X=Subject absent; PD=Patch dislodged; NP = Not Patched ; 0=No Reaction

[Programming Note: Present Notation if applicable after erythema and edema scores, in the format: ER/ED/NOTATION (Sum).]

Generated on XX/XX/XX:XXXX by XXXXXXX / Uses: XXXX, XXXX

[A similar listing will be produced for Residual Dermal Responses at Relocated Treatment Sites if Necessary (Listing 16.2.6.2)]

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Listing 16.2.6.3: Assessment of Dermal Responses During Challenge
All Randomized Subjects

Subject Number	Date-Time of Application	UVB /UVA (µW/ cm²)	UVA (mW/ cm²)	½ MED UVB/UVA (sec)	6 J/cm² UVA (sec)	Time Point Post-Irradiation	Date-Time of Reading	MC2-01 cream		MC2-01 vehicle		Untreated
								Irradiated	Non-Irradiated	Irradiated	Non-Irradiated	Irradiated
								ER/ED (Sum)	ER/ED (Sum)	ER/ED (Sum)	ER/ED (Sum)	ER/ED (Sum)
xx	xxxx-xx-xxTxx:xx	x.xx	xx.xx	xx.xx	xx.xx	0 hrs	xxxx-xx-xx Txx:xx	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)
						24 hrs	xxxx-xx-xx Txx:xx	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)
						48 hrs	xxxx-xx-xx Txx:xx	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)
						72 hrs	xxxx-xx-xx Txx:xx	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)	x/y (Sum)
						Photosensitized (Yes/No) [1]		No	No	No	No	No

[1] Sensitization classification made by the PI based on Challenge and Re-challenge

Scores:
Erythema: 0 = No reaction; 1 = Mild, but definite erythema; 2 = Moderate erythema; 3 = Marked/severe erythema;
Edema: 0 = No reaction; 1 = Mild, but definite edema; 2 = Definite edema with erosion/vesiculation

Notations:
Hr = hyperpigmentation; Ho = hypopigmentation; V = vesiculation; p= Papular response; pv= Papulovesicular response; D= Damage to epidermis; oozing, crusting, and/or superficial erosions; I=Itching; S= Spreading of reaction beyond patch study site (i.e., reaction where material did not contact skin); f= Follicular irritation with or without pustule formation (folliculitis).; X=Subject absent; PD=Patch dislodged; NP = Not Patched ; 0=No Reaction

[Programming Note: Present Notation if applicable after erythema and edema scores, in the format: ER/ED/NOTATION (Sum).]

Generated on XX/XX/XX:XXXX by XXXXXXX / Uses: XXXX, XXXX

[Note: A similar listing will be produced for any Rechallenge Phase assessments as needed.]

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Listing 16.2.7.1: Adverse Events
Population III

Subject Number	MedDRA Term (Verbatim Term) / MedDRA SOC Term	Treatment-emergent? / Date (Day) of Onset – Date of Resolution (Day)	Intensity / Relationship / Outcome	Action Taken with Study Drug / Action Taken to Treat the Event? / Serious Adverse Event (SAE)?
xx	xxxxxxxxx (xxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	Yes / xxxx-xx-xx (xx) – xxxx-xx-xx (xx)	Severe / Possibly Related / Recovering	Dose reduced / Yes / Yes
	xxxxxxxxx (xxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	No / xxxx-xx-xx (xx) – Ongoing	Mild / Not related / Recovered	Dose not changed / No / No
xx	xxxxxxxxx (xxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	Yes / xxxx-xx-xx (xx) – xxxx-xx-xx (xx)	Moderate / Probably Related / Recovered	Dose not changed / No / No

Note: A treatment-emergent AE is an AE with an onset date on or after the first study product administration date. Study day is relative to Day 1.

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Listing 16.2.7.2: Serious Adverse Events and Deaths
All Randomized Subjects

Subject Number	MedDRA Term (Verbatim Term) / MedDRA SOC Term	Treatment-emergent? / Date (Day) of Onset – Date of Resolution (Day)	Intensity / Relationship / Outcome	Action Taken with Study Drug / Action Taken to Treat the Event?/ Which Serious Criteria Met?
xx	xxxxxxxxx (xxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	Yes / xxxx-xx-xx (xx) – xxxx-xx-xx (xx)	Severe / Possibly Related / Recovering	Dose reduced / Yes / Life Threatening
	xxxxxxxxx (xxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	No / xxxx-xx-xx (xx) – Ongoing	Severe / Not related / Recovering	Drug withdrawn / Yes / Hospitalization
xx	xxxxxxxxx (xxxxxxxxxxxxxxxxxxxxx) / xxxxxxxxxxxxxxxxxxxxxxxxx	Yes / xxxx-xx-xx (xx) – xxxx-xx-xx (xx)	Moderate / Probably related / Recovered	Drug withdrawn / Yes / Other Medically Serious Event

Note: A treatment-emergent AE is an AE with an onset date on or after the first study product administration date. Study day is relative to Day 1.

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Listing 16.2.8: Urine Pregnancy Test Results
All Randomized Subjects

Subject Number	Childbearing Potential	Urine Pregnancy Test			
		Day 1		End of Study	
		Date	Result	Date	Result
xx	xxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxxx	xxxx-xx-xx	Negative	xxxx-xx-xx	Negative
xx	Postmenopausal	--	N/A	--	N/A
xx	N/A (Male Subject)	--	N/A	--	N/A

Note: NA for males/females of non-childbearing potential.

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Listing 16.2.9: Comments
All Randomized Subjects

Subject Number	Reference	Comment
xx	GENERAL COMMENTS	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
	END OF STUDY	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX
xx	GENERAL COMMENTS	XXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXXX

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