



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

s22

Wild Child Laboratories Pty Ltd  
16 Howe Street,  
Osborne Park, WA 6017

Dear s22

**Subject: Onsite TGA GMP Inspection Announcement of Wild Child Laboratories Pty Ltd - MI-2024-LI-09302-1**

I am writing to confirm our email correspondence to announce the onsite GMP inspection of your 16 Howe Street, Osborne Park, WA 6017 facility on (1<sup>st</sup>, 2<sup>nd</sup> and 3<sup>rd</sup>) of September 2025, commencing at approximately 9am.

The purpose of the inspection is to establish compliance with the standard determined under the Therapeutic Goods Act 1989: the PIC/S Guide to Good Manufacturing Practice for medicinal products – PE009-16.

Additional information on the inspection process is available from our website at [Manufacturer inspections: an overview | Therapeutic Goods Administration \(TGA\)](#)

On this occasion, the inspection team will consist of 1 inspector: s22

This inspection is now part of a firm schedule and will only be cancelled in exceptional circumstances.

To assist in preparation for the inspection please note the following requests and information:

- Please provide any documents requested in a searchable electronic format, e.g., PDF.
- The TGA website includes information on the inspection procedures and reporting processes that will apply to this inspection. Please refer to the information available at: [Australian manufacturing licences and overseas GMP certification | Therapeutic Goods Administration \(TGA\)](#)
- As per Australian Government requirements, inspectors cannot accept any gifts in relation to the inspection.

The final compliance rating following this inspection will be determined after review of your response/s to the Post Inspection Letter. Information on the TGA's system to determine manufacturer compliance can be found on the TGA web site at:

[Manufacturer GMP compliance history | Therapeutic Goods Administration \(TGA\)](#)

Once the inspection is closed out, a report will be sent to you to confirm close out, which will also advise on the final compliance rating. Subsequently, the compliance rating will be used as input to determine re-inspection frequency. Information on how this is done can be found on the TGA web site at:

[Manufacturer inspections - a risk-based approach to frequency | Therapeutic Goods Administration \(TGA\)](#)

If there are any updates to the Site Master File previously forwarded, it would be appreciated if you could send them to me as soon as possible and prior to the inspection date. A request for documents to be provided prior to and during the inspection is attached in the email accompanying this letter. It would be appreciated if you could send them to me as soon as possible and at least one week prior to the inspection date.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

*(Signed electronically; contains no visible signature)*

s22  
GMP Inspector  
Manufacturing Quality Branch  
25 August 2025

Tel: s22  
E-mail: s22@health.gov.au

**From:** s22  
**To:** s22  
**Subject:** Closing Meeting Summary [SEC=OFFICIAL]  
**Date:** Thursday, 4 September 2025 7:30:00 PM  
**Attachments:** [Closing meeting summary - Wild Child Laboratories Pty Ltd - MI-2024-LI-09302-1.pdf](#)  
[image001.png](#)

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Dear s22

Please find attached closing meeting summary for our close out meeting.

Kind regards, s22

s22  
GMP Inspector  
Inspection Section  
Manufacturing Quality Branch

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Medical Device and Product Quality Division | Health Products Regulation Group  
Therapeutic Goods Administration (TGA) | Australian Government, Department of Health, Disability  
and Ageing  
Telephone: s22 or Mobile: s22 E-mail: s22@health.gov.au  
Location: Level 15, 595 Collins St Melbourne VIC 3000  
PO Box 100, Woden ACT 2606, Australia

*The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*  
*This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.*



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

Manufacturing Quality Branch

## Inspection closing Meeting Summary

<b>Manufacturer name:</b>	Wild Child Laboratories Pty Ltd
<b>Manufacturer address:</b>	16 Howe Street Osborne Park WA 6017
<b>Inspection type:</b>	Special Inspection
<b>Inspection date/s:</b>	(2 <sup>nd</sup> , 3 <sup>rd</sup> and 4 <sup>th</sup> ) of Sept 2025
<b>Inspector/s:</b>	s22 (Lead Inspector) & s22 (Laboratory Specialist)
<b>Inspection standard:</b>	PIC/S Guide to GMP for Medicinal Products PE009-16 + applicable Annexes

The following is a reflection of deficiencies against the requirements of the standard that were identified during the inspection. They may have also been discussed at a debrief meeting at the end of each day.

The deficiencies are not yet classified or referenced to the standard. Following further consideration and internal review, they may be reworded or grouped to accurately reference the applicable clause/s of the standard. The manufacturer is not required to respond to this interim document, but only to the list of deficiencies in the inspection report.

### Note:

- This special inspection focused on the above listed manufacturer's Pharmaceutical Quality System (PQS) & s47G Light Mineral Sunscreen base formulation.

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#### 40 Conditions of licences

(4) In addition to any conditions imposed under subsection (1) or (2), each licence is, except as otherwise specified in the licence, subject to the conditions that the holder of the licence will:

(ab) as soon as the holder of the licence becomes aware of information of a kind mentioned in subsection (5), give the information to the Secretary in writing; and

(5) The information with which paragraph (4)(ab) is concerned is information of the following kinds:

(a) information that indicates that the use of the goods in accordance with the recommendations for their use may have an unintended harmful effect;

(b) information that indicates that the goods, when used in accordance with the recommendations for their use, may not be as effective as was suggested by:

(i) the application for registration or listing of the goods; or

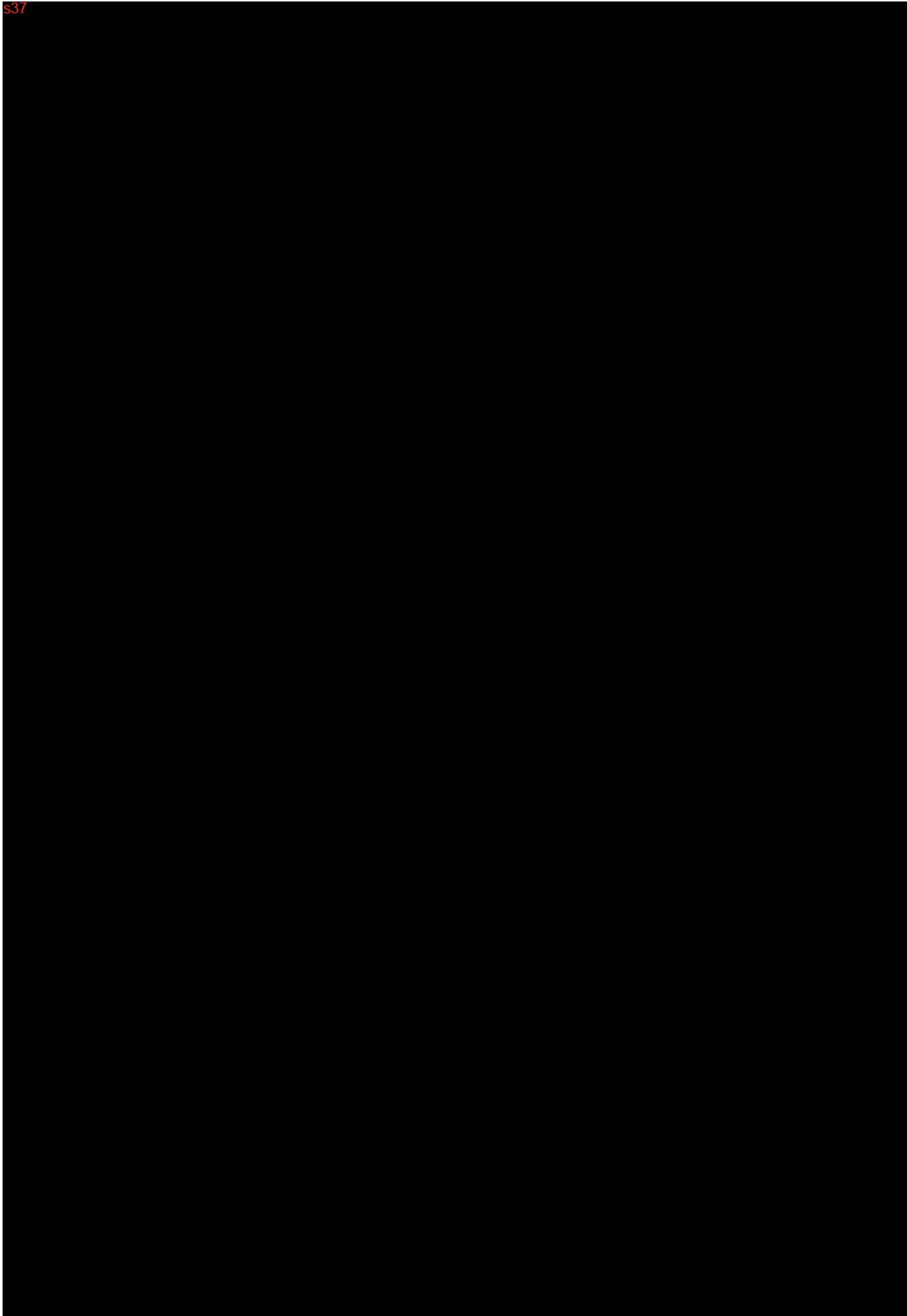
(ii) information already furnished by the holder of the licence under this Act; or

(iii) if the holder of the licence is not the sponsor of the goods—information already furnished by the sponsor of the goods under this Act;

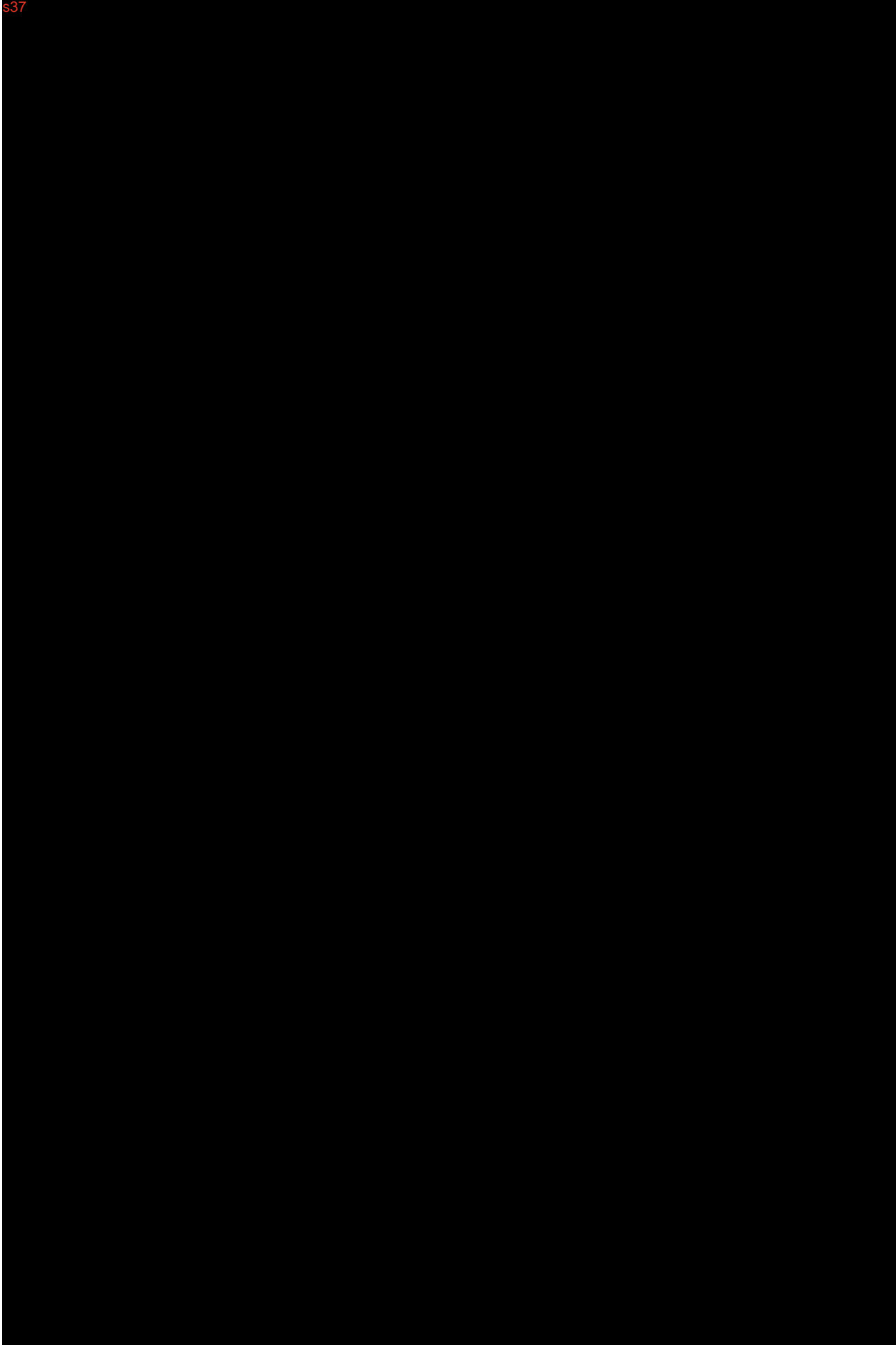
(c) information that indicates that the quality, safety or efficacy of the goods is unacceptable.

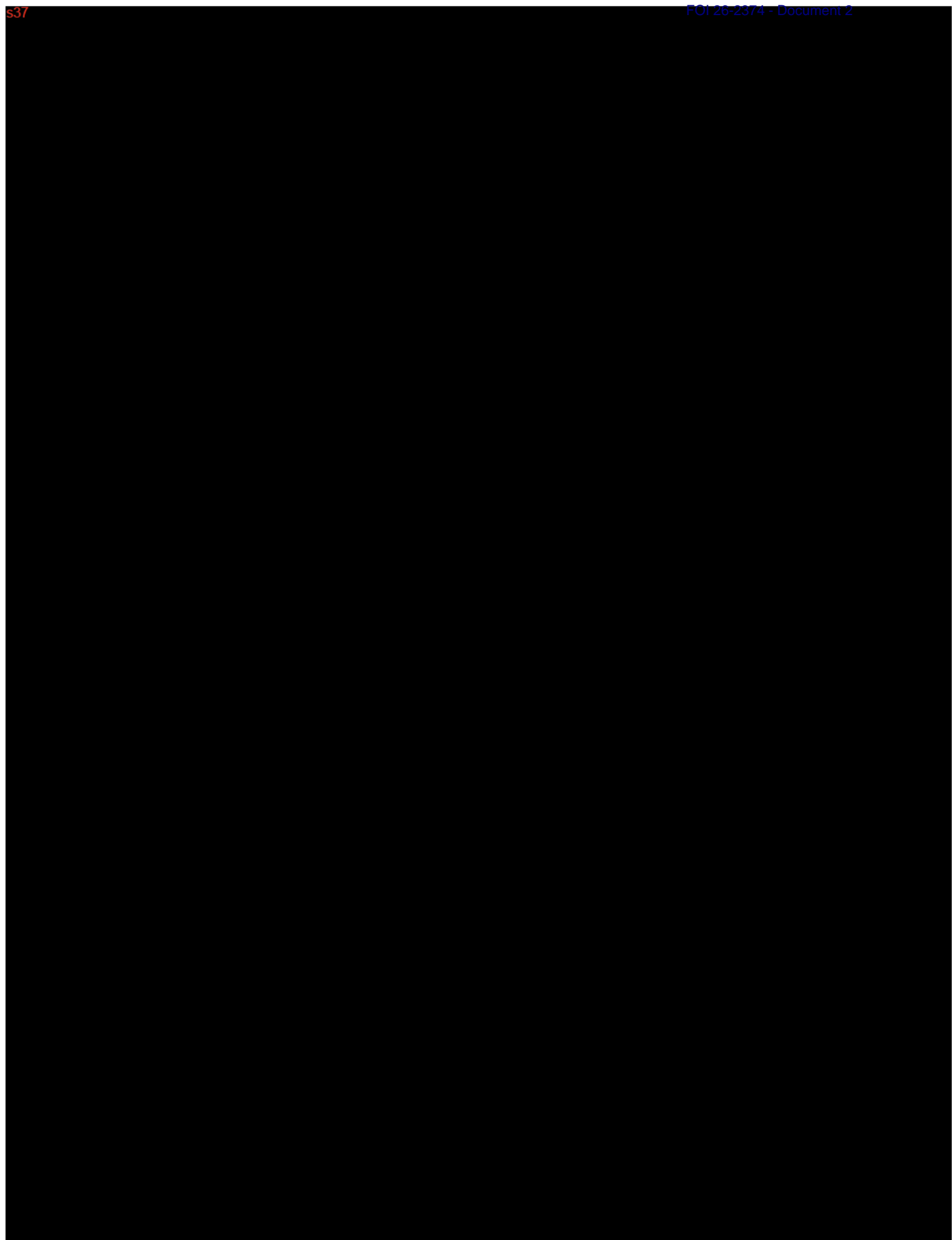
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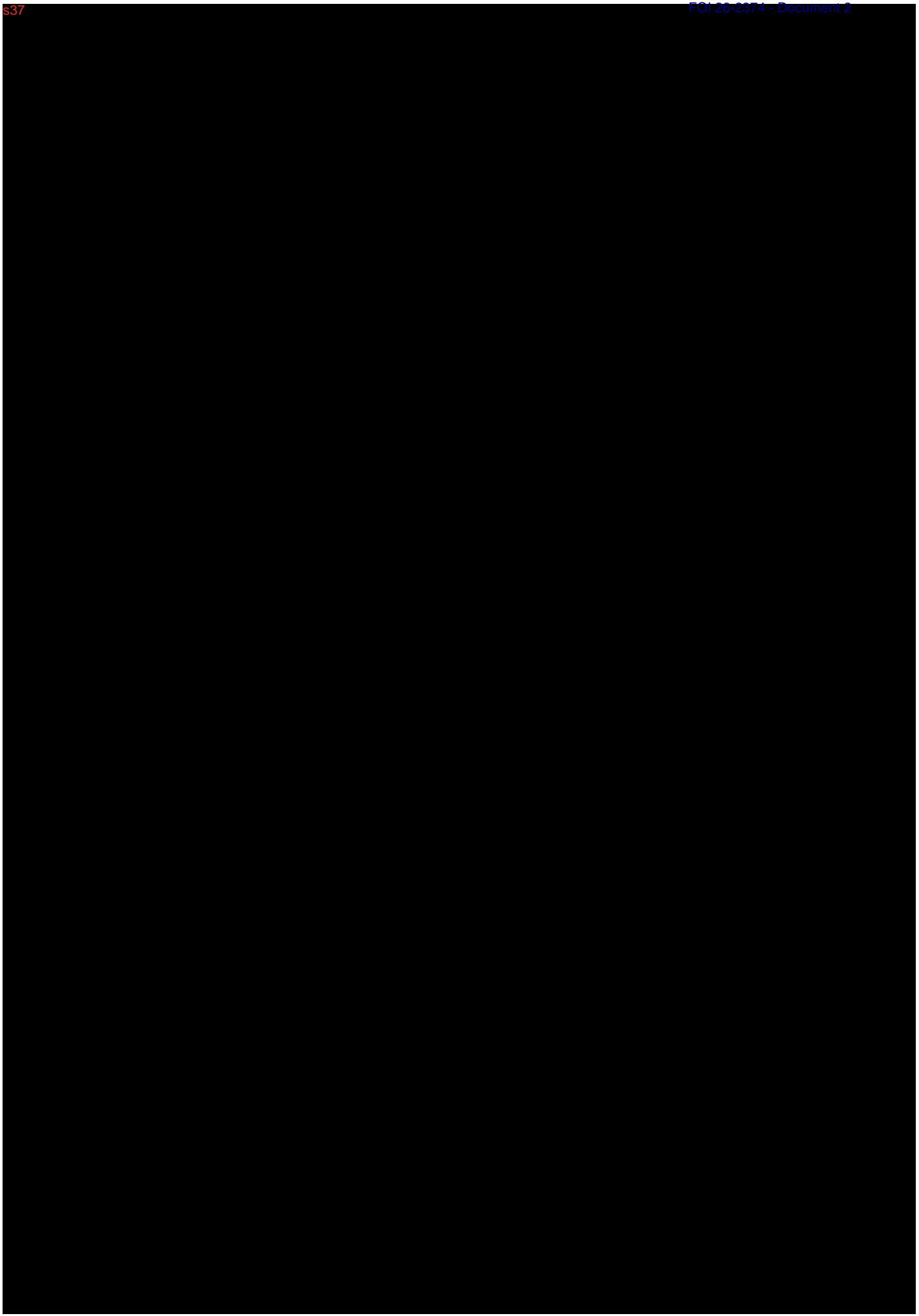
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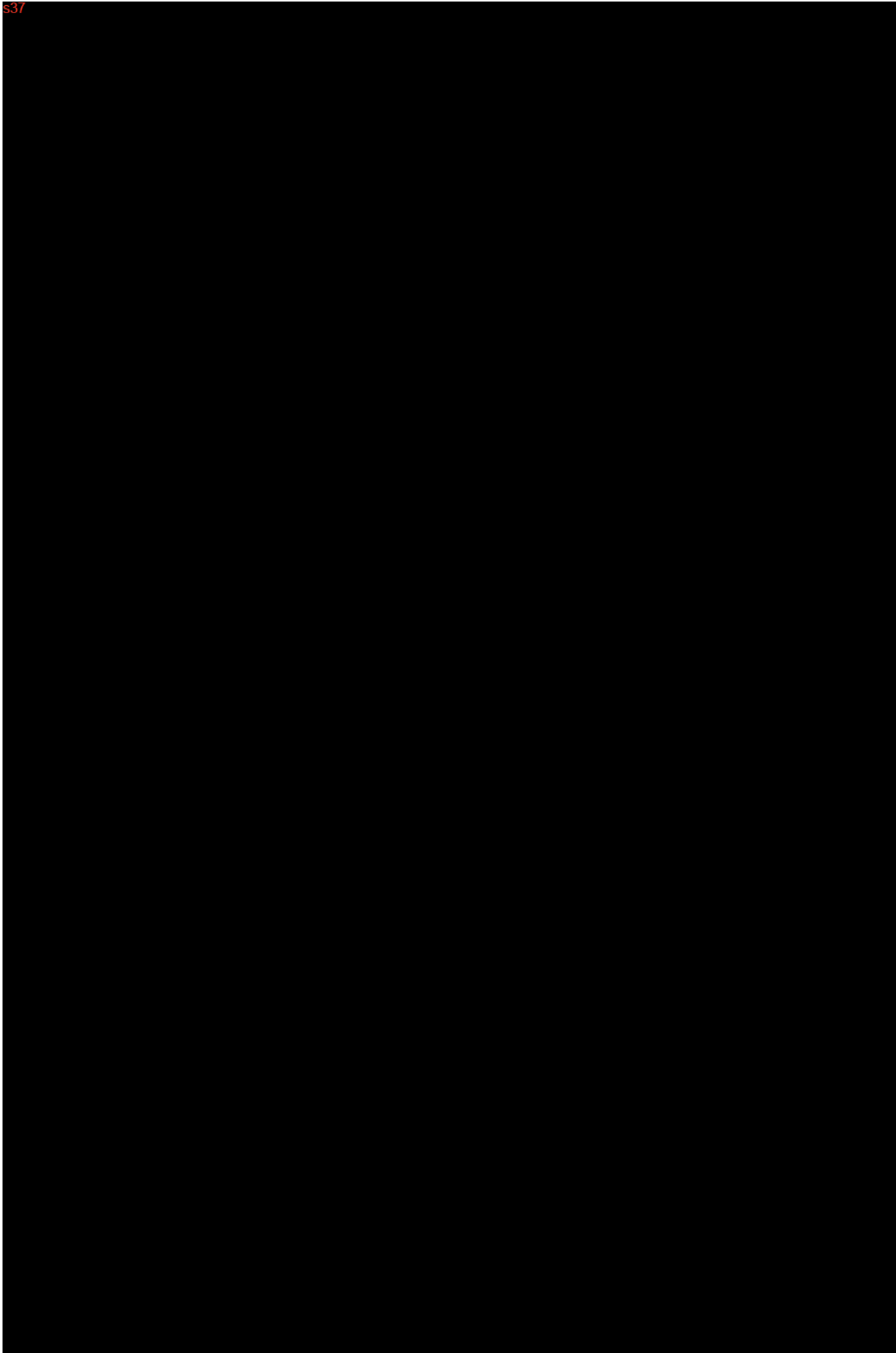
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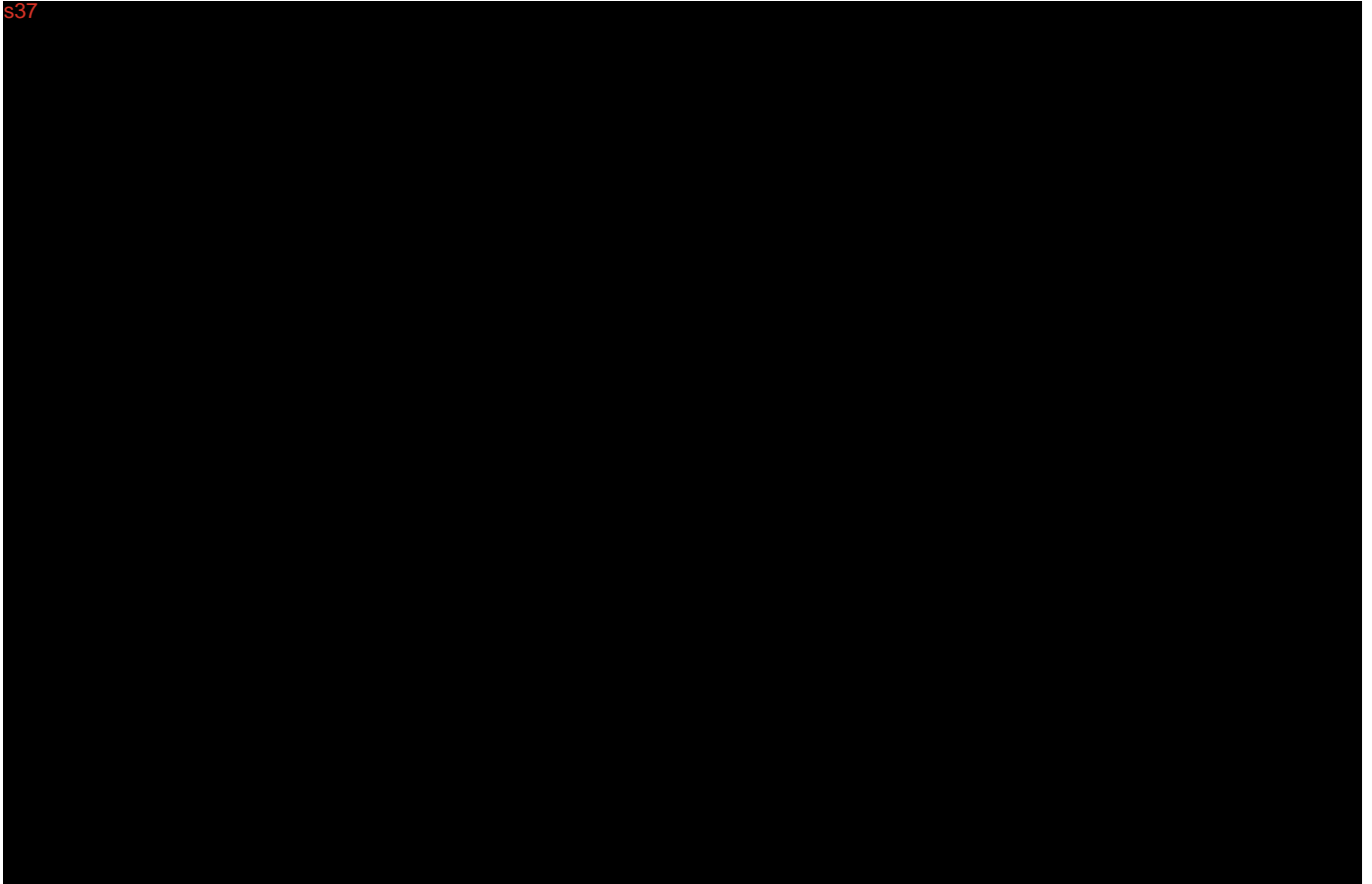




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Please note:

- The Manufacturing Quality Branch (MQB) is actively seeking manufacturers' feedback following TGA inspections. The feedback will be used to improve inspection procedures and training. The MQB ensures that feedback provided will not have any negative impact on the manufacturer, the inspection and its outcome. The manufacturer is requested to complete and submit the relevant form. All relevant information can be found on the TGA website at: <http://www.tga.gov.au/industry/manuf-forms-audit-feedback.htm>



**COPY**  
040 03 Sep 25

PCR CORP REPORT NO: s47G

13<sup>th</sup> January 2021

**A STEPWISE IN VIVO STUDY TO DETERMINE THE SUN PROTECTION FACTOR OF ONE PRODUCT FOLLOWING ISO:24444 COSMETICS – SUN PROTECTION TEST METHODS (IN VIVO DETERMINATION OF SUN PROTECTION FACTOR (SPF) BASED ON THE ISO:24444 SPF TEST METHODS (AUSTRALIAN/NEW ZEALAND STANDARD METHOD AS/NZS 2604:2012).**

Prepared for:

Wild Child Laboratories  
2 Action Road  
Malaga  
WA, 6090  
Australia

Prepared by:

PCR Corp  
8 Richmond Road  
Dukes Park  
Chelmsford  
Essex  
CM2 6UA  
United Kingdom

Draft Report v1: 17<sup>th</sup> December 2020  
Final Report: 13<sup>th</sup> January 2021

PCR CORP REPORT NO: s47G

13<sup>th</sup> January 2021

**A STEPWISE IN VIVO STUDY TO DETERMINE THE SUN PROTECTION FACTOR OF ONE PRODUCT FOLLOWING ISO:24444 COSMETICS – SUN PROTECTION TEST METHODS (IN VIVO DETERMINATION OF SUN PROTECTION FACTOR (SPF) BASED ON THE ISO:24444 SPF TEST METHODS (AUSTRALIAN/NEW ZEALAND STANDARD METHOD AS/NZS 2604:2012).**

**PCR CORP REPORT NO: s47G**

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study. The aspects of the study conducted by PCR Corp were performed, where relevant, in accordance with the principles of Good Clinical Research Practice.

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14 / 01 / 2021

Date.....

s22

14 / 01 / 2021

Date.....

**QUALITY ASSURANCE STATEMENT**

This report has been audited and is considered to be an accurate description of the methods used and an accurate presentation of the data obtained during the conduct of the study.

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s22

14 / 01 / 2021

Date.....

**CONTENTS**

<b>INTRODUCTION AND OBJECTIVE .....</b>	<b>5</b>
<b>MATERIALS AND METHODS.....</b>	<b>6</b>
<b>1. Study design.....</b>	<b>6</b>
<b>2. Selection of subjects .....</b>	<b>6</b>
2.1. Screening.....	6
2.2. Inclusion Criteria.....	6
2.3. Exclusion Criteria .....	7
2.4. Prohibitions and Restrictions.....	7
<b>3. Materials.....</b>	<b>7</b>
3.1. Test Articles .....	7
<b>4. Method .....</b>	<b>9</b>
4.1. ARTIFICIAL LIGHT SOURCE .....	9
4.3.1 MED (MINIMAL ERYTHEMAL DOSE) DETERMINATIONS .....	9
4.3.2 MED ASSESSMENT.....	10
4.3.3 DAY 1 - TEST ARTICLE SPF DETERMINATION.....	10
4.3.4 DAY 2 –SPF DETERMINATION .....	11
4.3.5 SPF ASSESSMENT AND CALCULATION .....	12
<b>5. Study ethics.....</b>	<b>15</b>
5.1 DECLARATION OF HELSINKI.....	15
<b>6. Quality assurance.....</b>	<b>15</b>
<b>7. Retention of data .....</b>	<b>16</b>
<b>8. References .....</b>	<b>16</b>
<b>RESULTS.....</b>	<b>17</b>
<b>1 LOCATION AND DATES OF THE STUDY .....</b>	<b>17</b>
<b>2 SUBJECTS .....</b>	<b>17</b>
<b>3 ADVERSE EVENTS, ADVERSE REACTIONS AND SUBJECTS NOT COMPLETING THE STUDY .....</b>	<b>17</b>
<b>4 QUALITY OF UV IRRADIATION .....</b>	<b>17</b>
<b>5 ASSESSMENTS.....</b>	<b>17</b>

## SUMMARY

1. This was a stepwise single blind study in healthy volunteers to determine the sun protection factor (SPF) of one sun protection product when compared to unprotected skin after the sites were exposed to an artificial "sun" light source based on the ISO 24444:2019" (Australian/New Zealand standard method AS/NZS 2604:2012) Cosmetics – Sun protection test methods – In vivo determination of the sun protection factor (SPF)" and the AS/NZS 2604:2012.
2. Each subject was treated with a series of five light exposures in order to determine the MED for unprotected skin. Subsites were graded 20 ± 4 (16 to 24) hours after the MED exposure. The MED was assessed as being the lowest dose that elicited minimally perceptible erythema at a subsite.
3. Following MED determination, three test areas were outlined on the back, above the MED test area. The P8 standard preparation (SPF range of 43.9 - 82.3) was applied to one test area, one area remained untreated to re-determine the MED and the test preparations were applied to the remaining areas. UV exposures commenced 15 – 30 minutes after product application. Length of exposure was determined by reference to the individual subject's MED. The exposure time for the control article was 1.25 times greater than the previous one. The exposure time for the test article was 1.12 times greater than the previous one for each test article with an expected SPF ≥ SPF25.
4. The erythema level of the test and control subsites was assessed 20 ± 4 (16 to 24) hours after exposure and the MED for "protected" skin were determined. Individual and mean SPF values were then calculated.
5. The mean SPF value for the P8 standard preparation was s47G. Since the expected SPF for this preparation was between s47G and s47G the study can be considered valid.
6. Mean Static SPF results (N=10) for the test article:

Test article s47G achieved a mean SPF value of s47G

**KEY STUDY PERSONNEL AND RESPONSIBILITIES**

Key personnel	General responsibilities
<p>s22 s22 PCR Corp Baypoint Commerce Center 9600 Koger Blvd N. St. Petersburg, Florida 33702 USA</p> <p>Tel: s22</p>	<p>The PI will be responsible for ensuring sufficient resources are available to conduct the study according to Good Clinical Practice (GCP), for reporting any serious adverse events to the Sponsor, the study design, compiling the results and writing the clinical report.</p>
<p>s22 s22 PCR Corp 8 Richmond Road Dukes Park Chelmsford Essex CM2 6UA United Kingdom</p>	<p>The Project Manager (PM) will be involved with the study design, compiling the results and writing the clinical report.</p>
<p>s22 s22 s22 PCR Corp 667A Stockport Road Ardwick Manchester M12 4QE United Kingdom</p> <p>Tel: s22</p>	<p>The PS will be responsible for the conduct of the study on a daily basis.</p>
<p>s22 s22 Wild Child Laboratories 2 Action Road Malaga WA 6090 Australia</p> <p>Email: s22</p>	<p>The PC will be the primary point of contact on behalf of the Sponsor of this project and will represent the Sponsor of this study.</p>

## INTRODUCTION AND OBJECTIVE

A stepwise study in healthy volunteers to determine the sun protection factor (SPF) of one Sun Protection product when compared to unprotected skin after the sites were exposed to an artificial "sun" light source (based on the ISO 24444:2019 SPF test methods (Australian/New Zealand standard method AS/NZS 2604:2012) - In vivo determination of Sun Protection Factor (SPF).

## MATERIALS AND METHODS

### 1. STUDY DESIGN

The study was conducted single blind, in a single centre.

A total of 10 subjects were dosed with the test article (the study followed the stepwise approach, testing 5 subjects in the first phase, and 5 subjects in the second phase).

### 2. SELECTION OF SUBJECTS

#### 2.1. SCREENING

A total of ten subjects were recruited into the study that satisfied the following inclusion and exclusion criteria, and who were prepared to accept the prohibitions and restrictions and who gave written informed consent (Appendices 1 and 2).

The suitability of each potential subject was confirmed before their acceptance by review of a study specific pre-treatment questionnaire (Appendix 3).

#### 2.2. INCLUSION CRITERIA

- a. Healthy male and female volunteers aged 18 to 70 years.
- b. Subject shall be selected using the colourimetric ITA° value. The skin of the subject shall have a colourimetric ITA° value of  $\geq 28^\circ$  (Intermediate  $>28^\circ$  to  $41^\circ$ ; Light  $>41^\circ$  to  $55^\circ$ ; Very light  $>55^\circ$ ).
- c. Completed written informed consent.

### 2.3. EXCLUSION CRITERIA

- a. Pregnancy or lactation.
- b. Inadequate precautions/procedures to prevent pregnancy (women of childbearing potential only).
- c. A current skin disease of any type apart from mild acne
- d. Heavy alcohol consumption (i.e. more than 21 units per week or 8 units a day for men, more than 14 units per week or 4 units a day for women).
- e. Significant past medical history of hepatic, renal, cardiac, pulmonary, digestive, haematological, neurological disease.
- f. A history of multiple drug hypersensitivity.
- g. Concomitant medication associated with photosensitivity reactions or which is likely to affect the response of the test articles or confuse the results of the study.
- h. Greater than 10 naevi or other skin lesions on the back, which mean that these would be exposed to UV light.
- i. A high number of naevi (arbitrarily assigned as >100) on the body.
- j. Participation in a Sun Protection Factor test (SPF test), photoallergy test, or phototoxicity test, or follow-up work within the last 2 months.
- k. Subject has exhibited sensitisation or questionable sensitisation in an SPF test.
- l. Previous history of skin tumours.
- m. Use of tanning equipment in the past 2 months.
- n. A history of abnormal response to the sun.

### 2.4. PROHIBITIONS AND RESTRICTIONS

- a. Discontinuation of aspirin or non-steroidal anti-inflammatory medication for the duration of the study.
- b. Discontinuation of sun bed or sun lamp use, and avoidance of exposure of the test sites to natural sunlight for the duration of the study.
- c. Prevention of test areas from getting wet for the duration of the study.

## 3. MATERIALS

### 3.1. TEST ARTICLES

The Sponsor provided the ingredient listing (Appendix 4) and certified that the product supplied to PCR Corp for the clinical trial had been manufactured/formulated with ingredients that are safe and suitable for the product's stated purpose.

The Sponsor confirms that:

The test articles do not contain antibiotics, antiseptics, steroids, hormones, or any other substances at levels of concentration requiring label declaration by the relevant regulatory authorities.

The following sunscreen preparation was tested:

1. s47G
2. s47G

The s47G standard preparation (supplied by PCR Corp) with an expected mean SPF value of s47G (SPF range of s47G) was included in the study.

**Amount of Product Applied/Area:**

The amount of test product and reference standard was s47G. The minimum total area for a test site for product application was s47G the maximum was s47G.

**Mode of Delivery/Application:**

Products were applied by use of a finger cot unless it interfered with even application. A new finger cot was used for each new application of product and was not pre-saturated with the test product. If a naked finger was used for spreading, it would have been cleaned between test products.

Liquid products (e.g. lotions, liquids, milks, creams, sprays and sticks): were pipetted onto the surface of the skin in small droplets and then spread over the site test site using light pressure. Spreading time was in the range of s47G seconds.

It was the responsibility of the Sponsor to determine, for each batch of test article, the identity, strength, purity, composition, and other characteristics which appropriately defined the test article before its use in the study. The determination of its stability and documentation of methods of synthesis and derivation were also the Sponsor's responsibility.

It was the responsibility of the Sponsor that the test articles met all necessary transport regulations, particularly those regulations involving the carriage of hazardous goods and the import/export of goods, and that any costs including tax/duty are fully met by the Sponsor prior to receipt of the test article at PCR Corp. No liability with regard to safe receipt or costs involved in carriage of goods to any PCR Corp site would have been accepted.

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PCR CORP. REPORT NO: s47G [REDACTED]

13<sup>th</sup> January 2021

On study completion any remaining unused test articles were disposed of, unless otherwise requested by the Sponsor, after issuance of the Final Report or 28 days after study completion, whichever came first. Sponsors requesting the return of products were liable for any costs incurred.

#### 4. METHOD

##### 4.1. ARTIFICIAL LIGHT SOURCE

s47G [REDACTED]

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PCR CORP REPORT NO: s47G

13<sup>th</sup> January 2021

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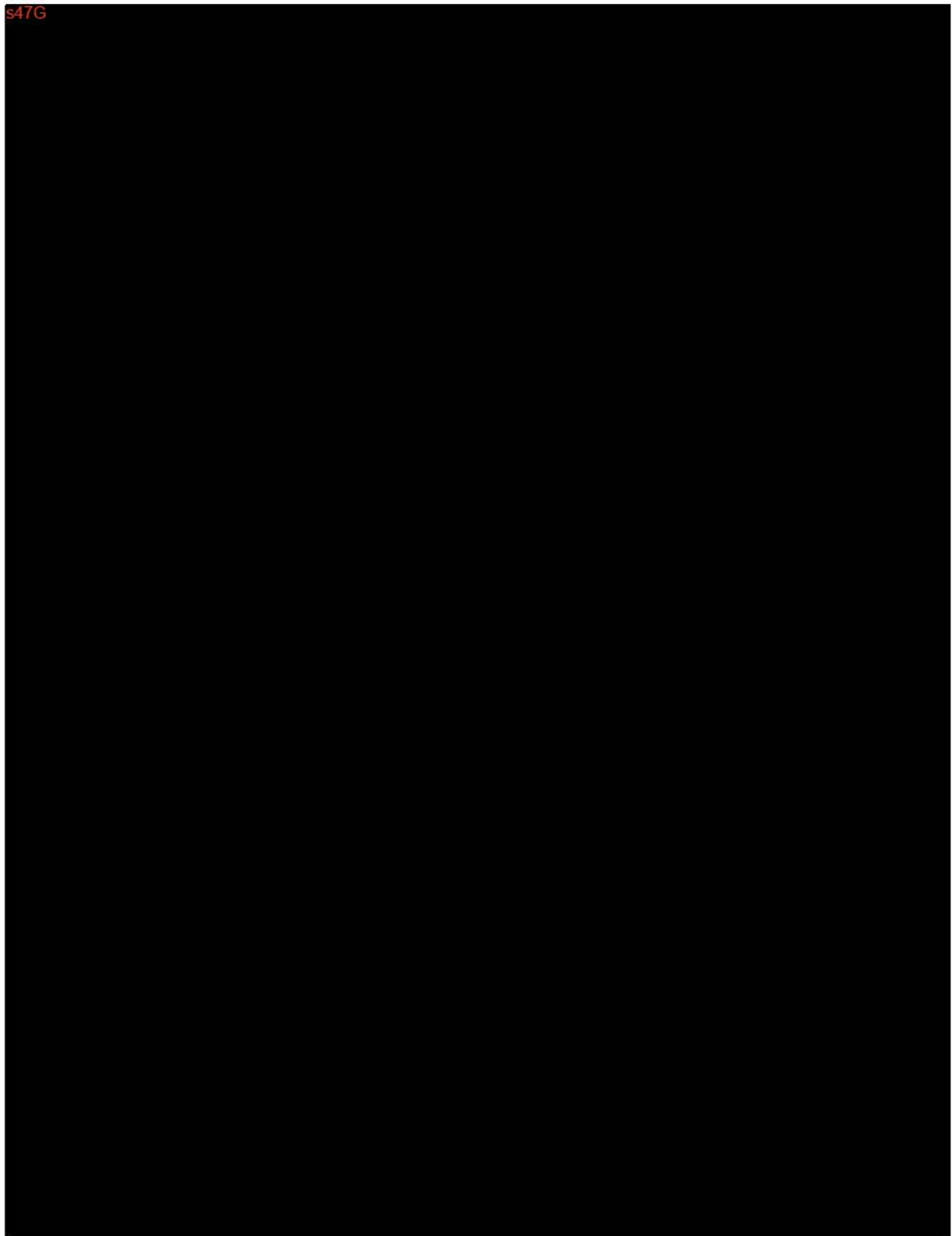
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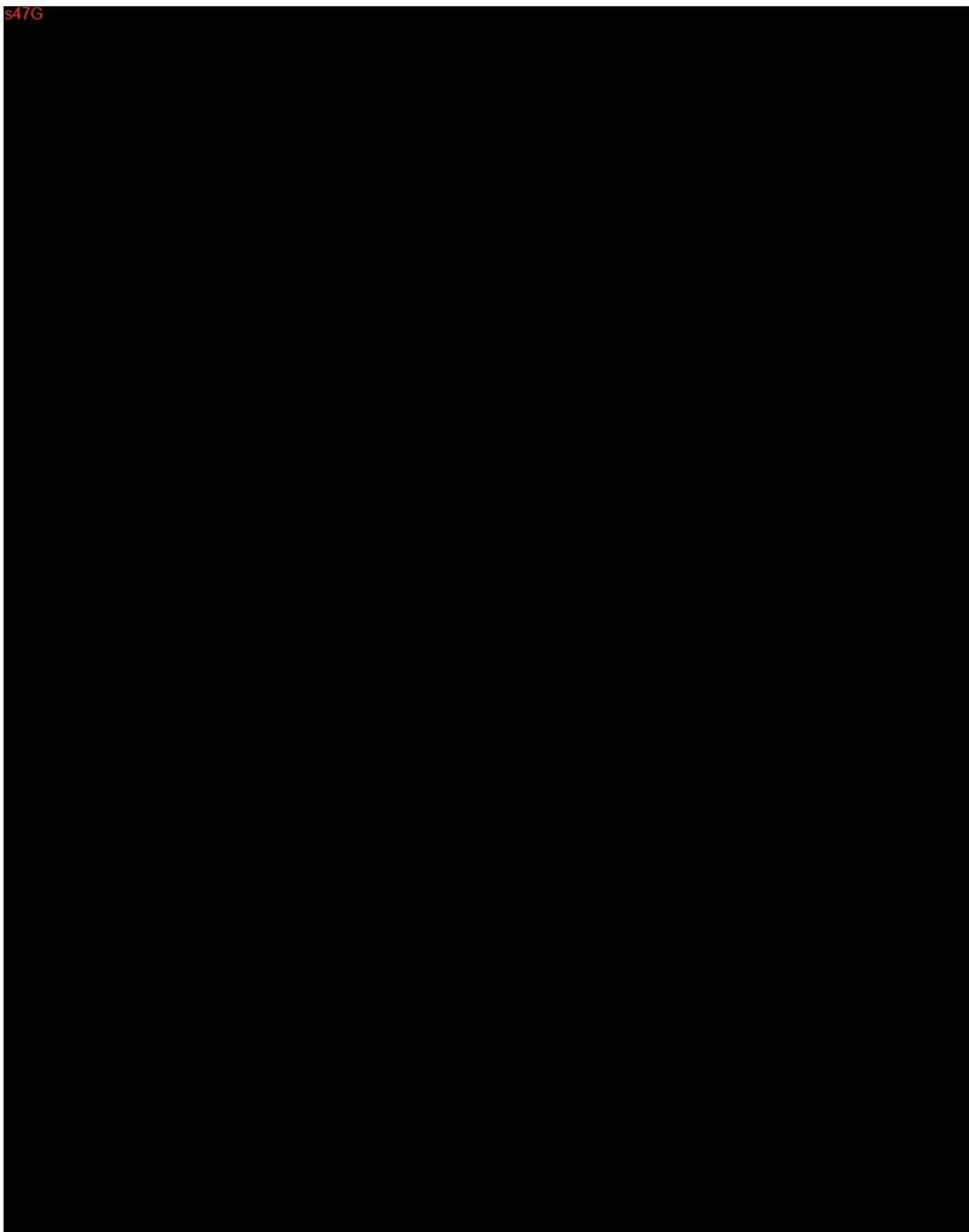
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PCR CORP REPORT NO: s47G

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## RESULTS

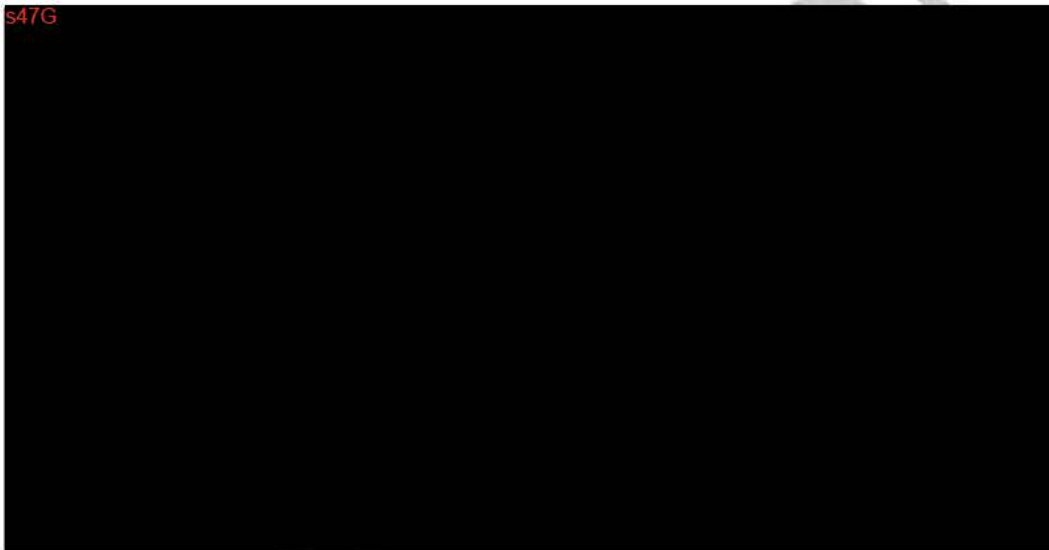
### **1 LOCATION AND DATES OF THE STUDY**

The study was performed at PCR Corp, between w/c 26<sup>th</sup> October 2020 and w/e 27<sup>th</sup> November 2020.

### **2 SUBJECTS**

10 subjects of both sexes were recruited into and completed the study.

s47G



### **3 ADVERSE EVENTS, ADVERSE REACTIONS AND SUBJECTS NOT COMPLETING THE STUDY**

No adverse events or reactions were reported, no subjects withdrew. The study was completed by all 10 subjects.

### **4 QUALITY OF UV IRRADIATION**

The percentage RCEE (relative cumulative erythema effectiveness) for the solar simulator used in this study was within the acceptable lower and upper limits directed by the ISO 24444:2019 SPF test methods (Australian/New Zealand standard method AS/NZS 2604:2012) - In vivo determination of Sun Protection Factor (SPF).

### **5 ASSESSMENTS**

Individual and mean SPF values, their standard deviations and confidence intervals for all 10 subjects are presented in Tables 1 and 2.

s47G

PCR CORP REPORT NO: s47G

13<sup>th</sup> January 2021

The mean SPF value for the s47G standard preparation was s47G. Since the expected SPF for this preparation was between s47G, the study can be considered valid.

Mean Static SPF results (N=10) for the test article:

Test article s47G

PCR CORP



s47G

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APPENDIX 1: CONSENT FORM

Study Code: s47G

Subject #: \_\_\_\_\_

**INTRODUCTION**

You are being asked to participate in a research study. Prior to giving your consent to be a subject, it is important that you take the time to read and understand what your participation would involve. This consent form may contain technical language which you may not understand. If you do not understand any of this consent form, please ask the clinical staff any questions you may have.

You will be provided with a signed copy of this consent form and any other necessary written information prior to the start of the study.

**OBJECTIVE**

The objective of this research study is to determine the sun protection factor (SPF) of four test articles. A control will also be tested to validate the study.

**TEST ARTICLES**

The test articles will be applied on the back by study staff and may include cosmetics, personal care products, toiletries, sunscreens, etc.

**STUDY PROCEDURES**

You will be one of approximately 10 subjects enrolled onto this study. Your participation in this study will last approximately five days and will include three visits to the testing facility.

**Visit 1** (Study day 1): Prior to acceptance on the study, you will be consented and screened for eligibility to participate on the study. We will mark out six areas, 5 cm x 6 cm on your back while you are sitting upright on a backless chair. We will expose this site to UV light from a sunlamp. The site will be exposed with five different intensities of UV light so that we can find out the dose needed to produce an area of faint pinkness.

**Visit 2** (Study day 2): We will assess the degree of pinkness at the sites. If we do not see the expected pinkness needed, we may perform an additional exposure of a new area of your back to UV light to determine the more exact dose to produce this faint pinkness.

**If not needed:** We will then mark out six 5 cm x 6 cm areas on your back. On these different areas we will apply the four test products, a control and one area will remain untreated. We will then expose each test area to UV light at 5 different strengths based on the sensitivity of your skin and the SPF of the test product.

**Visit 3** (Study day 3): We will assess your back on this day. Once all procedures are complete, your participation will be considered complete and compensation will be provided.

**RISKS**

Exposure to UV rays (simulated sunlight) will result in redness (slight sunburn) to the areas exposed to the UV light. This redness is expected to fade over the next 3-7 days. The UV exposed sites may also tan, and the tan sites may persist for up to six (6) months or longer.

To the best of our knowledge, these products are not expected to induce an allergic reaction. While the potential for irritation or other reactions during this study are minimal, it is possible for a reaction to occur. Expected reactions for these test articles categories are mild in nature and may include the following: redness, itching, peeling or blistering. In addition to the risks described, there may be other risks that are currently unforeseeable.

No significant adverse reactions are expected to occur. However, if you develop an adverse reaction or complication as a result of your participation in this study, medical treatment will be provided by clinical staff at PCR Corp or you will be referred for appropriate treatment at no cost to you, as long as you have followed the study instructions. Provisions of such medical care is not an admission of legal responsibility. You will be followed by PCR Corp until the adverse reaction has resolved. No additional compensation will be available to you. Neither the sponsoring company nor the investigating company will be held responsible for any future medical expenses.

#### **BENEFITS**

While it is likely that you will not receive any direct benefit from your participation in the study, the study results may have the potential to increase scientific knowledge about skincare products and may allow for new and improved products to be marketed.

#### **CONFIDENTIALITY**

Information concerning you that is obtained in connection with this study will be kept confidential by PCR Corp, except that the sponsoring company whose products are being tested will receive a copy of the study records. The data will be uniquely coded to protect your identity. In addition, the study investigator, third party regulatory authorities, including the U.S. Food and Drug Administration (FDA), IRB/IEC or the sponsor (including monitors and auditors), may inspect the records of the study. Therefore, total privacy cannot be guaranteed.

Your signature on the Informed Consent provides your permission for these agencies to view your personal information and the study data.

#### **IN CASE OF STUDY RELATED INJURY**

If you are injured while participating in this study, PCR Corp will provide you with treatment. If your illness or injury is the result of the study products or any procedure required by the study that you would not have undergone were it not for your participation in the study, the sponsor will pay usual and customary medical fees for reasonable and necessary treatment, provided you have not already otherwise been properly reimbursed by your insurance, a government program, or other third party coverage for such medical expenses. The sponsor is not responsible for expenses that are due to pre-existing medical conditions, underlying disease, procedures which would have been performed even if you were not participating in the study, your negligence or wilful misconduct, or the negligence or wilful misconduct of institution, principal investigators, or third parties. No funds have been set aside by the sponsor to compensate you for lost wages, disability, or discomfort due to your participation in this study. You do not give up any legal rights as a research participant by signing this consent form.

#### **COMPENSATION FOR INJURY**

No significant adverse reactions are expected to occur. However, if you develop an adverse reaction or complication as a result of your participation in this study, medical treatment will be provided by clinical study staff at PCR Corp or you will be referred for appropriate treatment at no cost to you. Provisions of such medical care are not an admission of legal responsibility. You will be followed by PCR Corp until the adverse reaction has resolved. No additional compensation will be available to you. Neither the sponsoring company nor the investigating company will be held responsible for any future medical expenses.

In no way does signing this consent form waive your legal rights nor does it relieve the investigators, Sponsor or involved institutions from their legal and professional responsibilities.

To pay these medical expenses, the sponsor will need to know some information about you like your name, date of birth, and social security number or Medicare Health Insurance Claim Number. We will get this information from you in the event this becomes necessary. This is because the sponsor has to check to see if you receive Medicare and if you do, report the payment it makes to Medicare. The sponsor will not use this information for any other purpose.

#### **FEMALES OF CHILDBEARING POTENTIAL**

Pregnant and/or nursing women may not take part in this study. Signing and dating this consent form means that you are stating that you are not pregnant, planning a pregnancy, or nursing at the start of the study.

The test products may involve unknown risks to you, your nursing infant, or your unborn child if you become pregnant while on the study. By signing this form, you agree to practice an acceptable method of birth control for the duration of the study.

#### **NEW FINDINGS**

Any new information that is discovered during the study and which may influence your willingness to continue in the study will be made available to you.

#### **MEDICAL TREATMENT**

In the event of an emergency, dial 999. If you receive any medical care during the course of the study, inform medical personnel that you are participating in a research study. Please contact PCR Corp staff as soon as possible to inform them of your condition.

#### **CONTACT**

If you have any questions about this study or in the case of an emergency, contact §22 §22 or §22 during normal business hours.

#### **VOLUNTARY PARTICIPATION/WITHDRAWAL**

Your participation in this research study is strictly voluntary. You may refuse to participate or may discontinue participation at any time during the study without penalty or loss of benefits to which you are otherwise entitled. However, you must contact the test facility and inform a clinical staff member of your decision to withdraw from the study.

If you agree to participate in the study, you are also agreeing to provide PCR Corp with accurate information and to follow study instructions as given to you. If you fail to follow study instructions, you may be asked to discontinue participation.

Your participation in the study may be discontinued at any time without your consent by PCR Corp, regulatory agencies, or the sponsoring company for reasons of but not limited to a severe side effect and accompanying illness, or if you do not follow study instructions.

#### **NON-DISCLOSURE**

As a condition to your participation in the study you are asked not to discuss any information regarding the products that you are testing, your experiences with the products, or your opinion of the products with anyone outside of the testing facility. By your signature on the Consent you are agreeing to abide by this condition of participation.

#### **PHOTOGRAPHY AUTHORISATION**

As an additional part of this study, study staff may take photographs or videotape during the study. These photos or videos may be used for the following purposes: training of PCR staff, PCR advertising, documentation of study procedures/results or upon request of the sponsor. By signing this consent form, you are giving your authorisation for PCR to take, use, reproduce, and distribute these photographs/videotapes taken during your participation in this study.



APPENDIX 2: SUBJECT INFORMATION SHEET

Study Code: §47G

You have agreed to participate in a research study. By agreeing to participate, you are also agreeing to the following prohibitions and restrictions:

- Discontinuation of aspirin or non-steroidal anti-inflammatory medication for the duration of the study.
- Discontinuation of sun bed or sun lamp use, and avoidance of exposure of the test sites to natural sunlight for the duration of the study.
- Prevention of test areas from getting wet for the duration of the study.

You will be assigned to the following study schedule:

Monday	Tuesday	Wednesday	Thursday	Friday
26 <sup>th</sup> October	27 <sup>th</sup> October	28 <sup>th</sup> October	29 <sup>th</sup> October	30 <sup>th</sup> October
<b>Visit 1</b>	<b>Visit 2</b>			<b>Visit 3</b>
<i>Baseline measure.</i>	<i>Assessment of the degree of pinkness to the skin where necessary.</i>			<i>Assessment of the degree of pinkness to the skin.</i>
<i>Area of the back to be exposed to UV light for different lengths of time to produce a faint pinkness to the skin.</i>	<i>Six new test areas will be marked out on your back, the test articles applied and then exposed to UV light for different times depending on your skin sensitivity.</i>			<i>Compensation</i>

\*You must come in for all visits; no misses will be allowed. If you are unable to come in for a visit, your participation will be discontinued.

Upon completion of this study on 30<sup>th</sup> October 2020, you will receive £XX for your participation.

If you have any questions about this study or in the case of a suspected allergic reaction, call §22 on §22 during normal business hours.

APPENDIX 3: PRE-TREATMENT QUESTIONNAIRE

Study Code: s47G

FOR OFFICE USE ONLY		
Subject's Initials:		
Subject No		
Subject's DOB: _____		
Subject's Age: _____		
Fitz: _____	ITA: _____	
MALE/FEMALE		

STRICTLY CONFIDENTIAL

Inclusion Criteria		Yes	No
1.	Subject is a healthy male or female, aged 18 years to 70 years.	<input type="checkbox"/>	<input type="checkbox"/>
2.	The skin of the subject shall have a colourimetric ITA <sup>6</sup> value of $\geq 28^\circ$ (Intermediate $>28^\circ$ to $41^\circ$ ; Light $>41^\circ$ to $55^\circ$ ; Very light $>55^\circ$ ).	<input type="checkbox"/>	<input type="checkbox"/>
3.	Subject has completed written informed consent.	<input type="checkbox"/>	<input type="checkbox"/>
Exclusion Criteria		Yes	No
1.	Subject is pregnant, nursing, or planning to become pregnant. Male N/A <input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.	Subject reports inadequate precaution/procedures to prevent pregnancy (women of childbearing potential only).	<input type="checkbox"/>	<input type="checkbox"/>
3.	Subject reports a current skin disease of any type apart from mild facial acne.	<input type="checkbox"/>	<input type="checkbox"/>
4.	Subject has heavy alcohol consumption (i.e. more than 21 units/week or 8 units/day for men, more than 14 units/week or 4 units/day for women)	<input type="checkbox"/>	<input type="checkbox"/>
5.	Subject has a significant past medical history of hepatic, renal, cardiac, pulmonary, digestive, haematological or neurological disease	<input type="checkbox"/>	<input type="checkbox"/>
6.	Subject has a history of multiple drug hypersensitivity	<input type="checkbox"/>	<input type="checkbox"/>
7.	Subject is taking concomitant medication associated with photosensitivity reactions which is likely to affect the response of the test articles or confuse the results of the study	<input type="checkbox"/>	<input type="checkbox"/>
8.	Subject has greater than 10 naevi or other skin lesions on the back, which mean that these would be exposed to UV light.	<input type="checkbox"/>	<input type="checkbox"/>
9.	Subject has a high number of naevi (arbitrary assigned a $>100$ ) on the body.	<input type="checkbox"/>	<input type="checkbox"/>
10.	Subject has participated in a Sun Protection Factor test (SPF test) or follow-up work within the last 21 days.	<input type="checkbox"/>	<input type="checkbox"/>
11.	Subject has exhibited sensitization or questionable sensitization in an SPF test.	<input type="checkbox"/>	<input type="checkbox"/>
12.	Subject has a history of skin cancer.	<input type="checkbox"/>	<input type="checkbox"/>
13.	Subject is a regular sunbed user.	<input type="checkbox"/>	<input type="checkbox"/>
14.	Subject has a history of abnormal response to the sun.	<input type="checkbox"/>	<input type="checkbox"/>
Prohibitions and Restrictions		Yes	No
1.	Subject agrees to discontinue use of aspirin or non-steroidal anti-inflammatory medication for the duration of the study.	<input type="checkbox"/>	<input type="checkbox"/>
2.	Subject agrees to discontinue use of sun beds or sun lamps, and to avoid exposure of the test sites to natural sunlight for the duration of the study.	<input type="checkbox"/>	<input type="checkbox"/>

3.	Subject agrees to prevent test areas from getting wet for the duration of the study.	<input type="checkbox"/>	<input type="checkbox"/>
----	--	--------------------------	--------------------------

Have you ever had any skin problems related to the use of any of the following types of material?

Material	Yes	No	When? – Which products? – What happens?
Sun Protection oils/lotions/creams			
Other Personal Care Products – please specify			

Questionnaire checked and confirmed by:

\_\_\_\_\_  
Signature                      Date

PCR CORP

APPENDIX 4: TEST ARTICLE INGREDIENT LISTING

s47 [REDACTED]

PCR CORP



Audit trail

TITLE s47G Signed Report  
 FILE NAME s47G Final Report 13Jan21.pdf  
 DOCUMENT ID s47G  
 AUDIT TRAIL DATE FORMAT DD / MM / YYYY  
 STATUS ● Completed

Document history



14 / 01 / 2021  
09:34:28 UTC

Sent for signature s22  
s22  
IP: 213.31.148.24



14 / 01 / 2021  
13:17:15 UTC

Viewed by s22  
IP: 159.250.124.33



14 / 01 / 2021  
13:17:27 UTC

Signed by s22  
IP: 159.250.124.33



14 / 01 / 2021  
22:04:28 UTC

Viewed by s22  
IP: 47.197.134.168



14 / 01 / 2021  
22:04:51 UTC

Signed by s22  
IP: 47.197.134.168



14 / 01 / 2021  
22:04:51 UTC

The document has been completed.

PCR CORP STUDY NO: s47G

8<sup>th</sup> November 2022

## EXECUTIVE SUMMARY REPORT

PCR Corp Study No: s47G

Title:

An in-vitro test to determine the UVA protection Factor (UVA-PF) of one test article based on the ISO 24443:2012 UVA method for the EU, SA, Japan, Aus & NZ.

Sponsor:

Wild Child Laboratories  
2 Action Road  
Malaga  
WA 6090  
Australia

Study Centre:

PCR Corp  
8 Richmond Road  
Dukes Park  
Chelmsford  
Essex  
CM2 6UA  
United Kingdom

Date:

8<sup>th</sup> November 2022

Conclusions:

It can be concluded that the test article met the Broad-Spectrum criteria.

References:

ISO 24443 SUN PROTECTION TEST METHODS  
DETERMINATION OF SUNSCREEN UVA  
PHOTOPROTECTION IN VITRO (ISO  
24443:2012)

PCR CORP STUDY NO: s47G [REDACTED]

8<sup>th</sup> November 2022

**PCR Corp Report No:** s47G [REDACTED]

I declare that the following report constitutes a true and faithful account of the procedures adopted and the results obtained in the performance of this study.

s22 [REDACTED]  
(Principal Investigator)

s22 [REDACTED]

Date 08 / 11 / 2022

s22 [REDACTED]  
(Project Manager)

s22 [REDACTED]

Date 08 / 11 / 2022

PCR CORP STUDY NO: s47G [REDACTED]

8<sup>th</sup> November 2022

**TEST ARTICLE 1 – Light Mineral Sunscreen** s47G [REDACTED]

ISO 24443:2012  
Results Report

Product: Light Mineral Sunscreen

Description: s47G [REDACTED]

Operator: s22 [REDACTED]

s47G [REDACTED]

Date: 04/10/2022 13:53:51

Product Results

s47G [REDACTED]

Reference Sunscreen S2 Validation

Validation Date	29/06/2022 16:37:05
UVAPF	14.49

s47G



s47G



s47G



PCR CORP STUDY NO: s47G

8<sup>th</sup> November 2022

TEST ARTICLE INGREDIENT LISTINGS

s47G

s47

PCR CORP



**COPY**  
CE 04SEP25

<b>CONFIDENTIAL</b>	Title	<b>COMPLAINTS AND ADVERSE EVENT FORM</b>		
WILD CHILD	Document number	s47G	Document version	6

Complaint log number	s47G *
----------------------	--------

Product name	s47G		
Product code	s47G		
Batch number	s47G		
Date of complaint	21 Jul 2025		
# of Units Impacted	batch		
Who received the complaint	Public article s22		
Format of complaint	Choice Article		
Complaint attached by	s22		
Complainant contact details	N/A		
Reason for complaint	SPF testing performed on marketed product returned results below labelled SPF		
Additional Information Requested	YES/NO (circle)	Sign/Date	s22 21 Jul 25

Complaint categories	<b>Product Defect</b> <input type="checkbox"/> Colour <input type="checkbox"/> Texture <input type="checkbox"/> Odour <input type="checkbox"/> Foreign contamination <input type="checkbox"/> Other physical property	<b>Packaging Defect</b> <input type="checkbox"/> Leaking <input type="checkbox"/> Print <input type="checkbox"/> Deformation <input type="checkbox"/> Other packaging defect	<input type="checkbox"/> Safety <input type="checkbox"/> Lack of Efficacy <input type="checkbox"/> Counterfeit <input type="checkbox"/> Adverse Event <input checked="" type="checkbox"/> Other:

Form completed by	Sign	s22	Date	21 Jul 25
QA review	Sign	s22	Date	21 Jul 25

Responsible department:	Quality/R&D
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\* Investigation is ongoing and still in progress

s22  
04 Sep 25

COPY

<b>CONFIDENTIAL</b>	<b>Title</b>	<b>COMPLAINTS AND ADVERSE EVENT FORM</b>		
	<b>Document number</b>	s47G	<b>Document version</b>	6

<b>Immediate actions</b>	<p><b>Retention samples viewed:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A</p> <p><b>Comments:</b>                  Retentions inspected and confirmed there is no evidence of emulsion splitting, graininess or aggregation. ROI and Zinc Oxide tested as per NRT 111. Results met expiry specification. Retention samples sent for external SPF testing using Florida laboratories</p>
	<p><b>Batch document reviewed:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p><b>Comments:</b>                  Batch documents of both s47G have been reviewed with no issues identified that would result in the reduced SPF result</p> <p><b>List of Manufacturing/Filling Equipment:</b>                  s47G</p>
	<p><b>Testing results reviewed:</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p><b>Comments:</b>                  Both batches at release met internal release limits and release specifications. Zinc oxide dispersion batches s47G used in s47G were reviewed and confirmed to have met release specifications with no reported issues during manufacture.</p>
	<p><b>Review of returned of defective product:</b> <input type="checkbox"/> Yes <input type="checkbox"/> No <input checked="" type="checkbox"/> N/A</p> <p><b>Comments:</b>                  Sample tested externally is not available for return. Retention samples will be used for any further testing to be performed.</p>
	<p><b>Immediate action comments:</b></p> <ul style="list-style-type: none"> <li>- Retention samples inspected and retested for s47G content</li> <li>- Retention sample sent for SPF testing to s47G</li> </ul>

COPY

CONFIDENTIAL	Title	COMPLAINTS AND ADVERSE EVENT FORM		
 WILD CHILD	Document number	s47G	Document version	6

Investigation	<p>Has a complaint been logged for this product previously? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A                  If yes, complaint log number(s):                  Comments: <i>consider the number of complaints for this issue and the proportion of the product impacted</i></p> <p>This is the first complaint for this product and Base Formula s47G</p>
	<p>Is the issue apparent in other batches? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A                  If yes, batch number(s):                  Comments: <i>consider the number of complaints for this issue and the number of impacted batches with respect to the total number of batches manufactured.</i></p> <p>This is the first complaint for this product and Base Formula s47G</p> <p>Is there an assignable root cause? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N/A                  Comments:</p> <p>Further testing and investigation is required to determine root cause.</p>

COPY

<b>CONFIDENTIAL</b>	Title	<b>COMPLAINTS AND ADVERSE EVENT FORM</b>		
 <b>WILD CHILD</b>	Document number	s47G [REDACTED]	Document version	6

<b>Quality Risk Assessment</b>	<p><b>How does the defect impact the end user?</b></p> <p>Due to the low SPF result the end user is at risk of not having adequate sun protection when using the product.</p>
	<p><b>Does the defect present any risk to the end users health or safety?</b> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p> <p>If yes, describe the risk in detail, including the severity and likelihood of occurrence</p> <p>Original product SPF testing was confirmed to meet stated claim, however additional testing performed in market does not align with original results. This is a medium severity as there is a large variability in the SPF results obtained for this product.</p> <p>There have been no complaints for lack of effect or adverse event reported for this product therefore there is no evidence that the product does not provide adequate sun protection. Therefore there is a low occurrence rate of risk to the end user.</p> <p>Preliminary risk is considered medium. Further assessment will be performed upon further investigation.</p> <p>If further risk assessment is required, refer to s47G [REDACTED]</p>

<b>Actions</b>	<p><b>Based on the above, what actions will be taken?</b></p> <p>Additional SPF testing is being performed using a different laboratory to that of the original SPF testing performed.</p> <p>Further investigation ongoing to determine root cause of the low SPF result obtained.</p>
----------------	---

<b>Complaint verified:</b>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
<b>Further investigation required:</b>	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

COMPANY INTRODUCTION

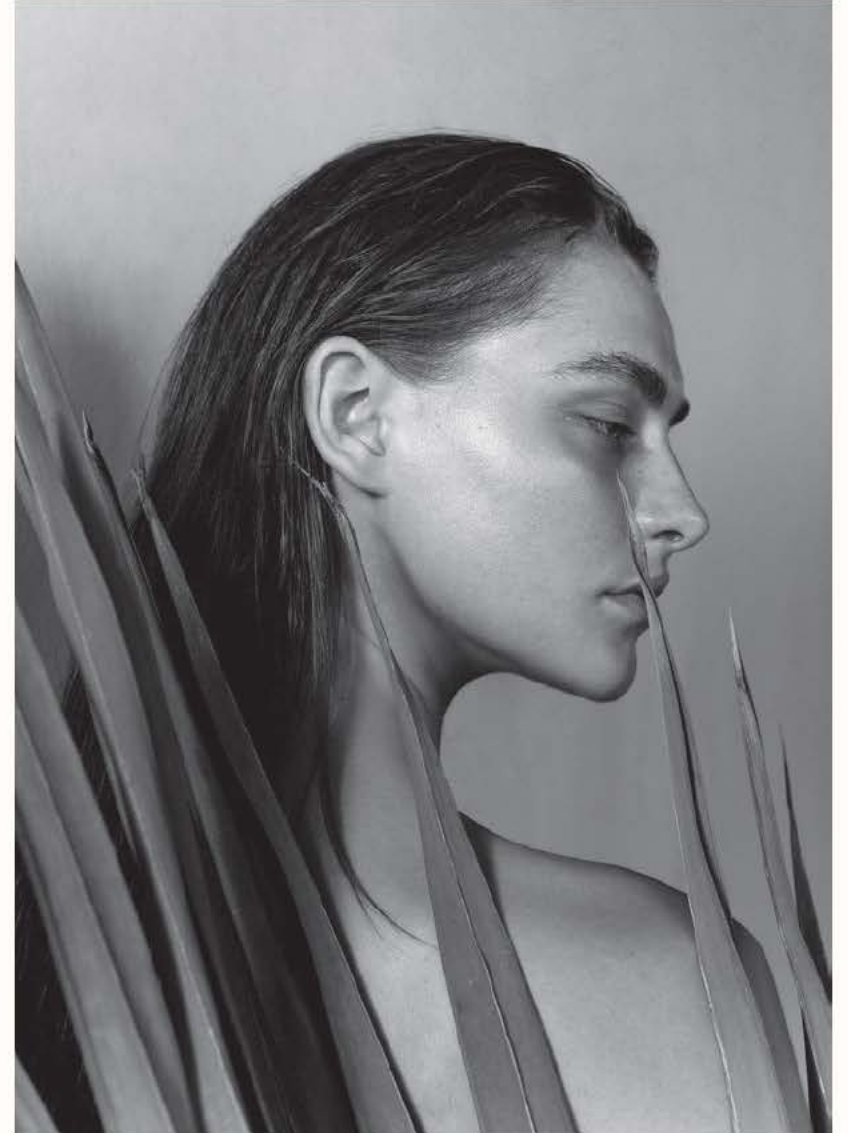
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TGA SITE INSPECTION, SEPT 2025

# WILD CHILD

WILDCHILD

2025





# CONTENTS

- 3. OUR PURPOSE
- 4. OUR VALUES
- 5. OUR JOURNEY
- 6. OUR LEADERS
- 7. OUR ORGANISATION
- 8. OUR SERVICES
- 10. GMP INSPECTION HISTORY
- 11. OUR FACILITY
- 12. OUR NEW HOME
- 16. OUR QUALITY PLEDGE
- 17. OUR COMMITMENT TO SAFETY

CONTENTS

WILD CHILD

COMPANY INTRODUCTION



# OUR PURPOSE

Wild Child is in business to develop and produce **innovative**, **high-performing** and **sustainable** products that enhance the health and beauty of **everyone** on this planet.

Wild Child is more than a manufacturing supplier to leading SPF, skincare and cosmetic brands from around the world, we are a **strategic innovation partner** for ambitious brands that want to seize more of the market with new product development.



# OUR VALUES



## INTEGRITY

We are honest, transparent and committed to doing what's best for our Clients, our Company and the community we operate in. We openly collaborate in pursuit of trusted partnerships and the creation of the highest-quality products in the world. Because, in our business, if we don't, we're no longer in business.

## CURIOSITY

We're really interested in our Client's businesses and how we can add value to them. We have the courage to actively seek new insights and knowledge to build deeper connections, create new ideas and improve our expertise.

## INCLUSIVITY

We never forget who our products are made by and who they're for - human beings - not their gender, age, skin tone, skin type, religion, or race. We celebrate our diversity and are committed to building a caring and supportive workplace. We nurture and support the unique talents of every team member to guarantee individual growth and amplify our collective impact.



## AGILITY

We are nimble and ready to respond to the ever-changing needs of our Clients and the world. We live by our entrepreneurial heritage, acting on opportunities for growth and challenging conventions. Momentum is everything. If we're not progressing, we're dead.

## FUN

It's important to every single person who works at Wild Child. If you're not enjoying the process of making great products, then you're not making great products. Passion, enthusiasm and pride in what we do are key to the success of our business. And we want our clients to enjoy working with us too.

# OUR JOURNEY



1997

Development of QuitNits portfolio and creation of Wild Child Laboratories.

2013

Established manufacturing facility in Malaga, Western Australia and commenced the manufacture of Class 1 Medical Devices, Skincare & Cosmetics.

2016

Received TGA Licence at Malaga facility **and commenced** manufacture of listed and complementary medicines.

2019

First FDA site inspection of Facility in Malaga, Western Australia.

2023

Move to new purpose-built facility in Osborne Park, Western Australia.

2021

Change in company ownership and establishment of new leadership team.

BRAND MANAGER

CONTRACT MANUFACTURER

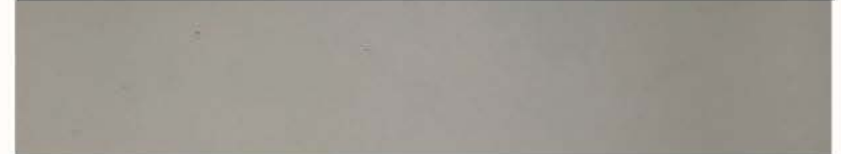
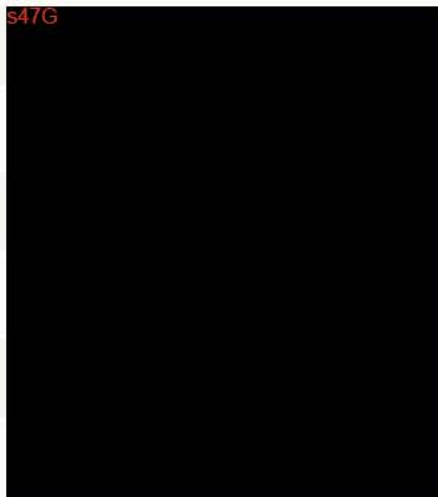
# OUR LEADERS

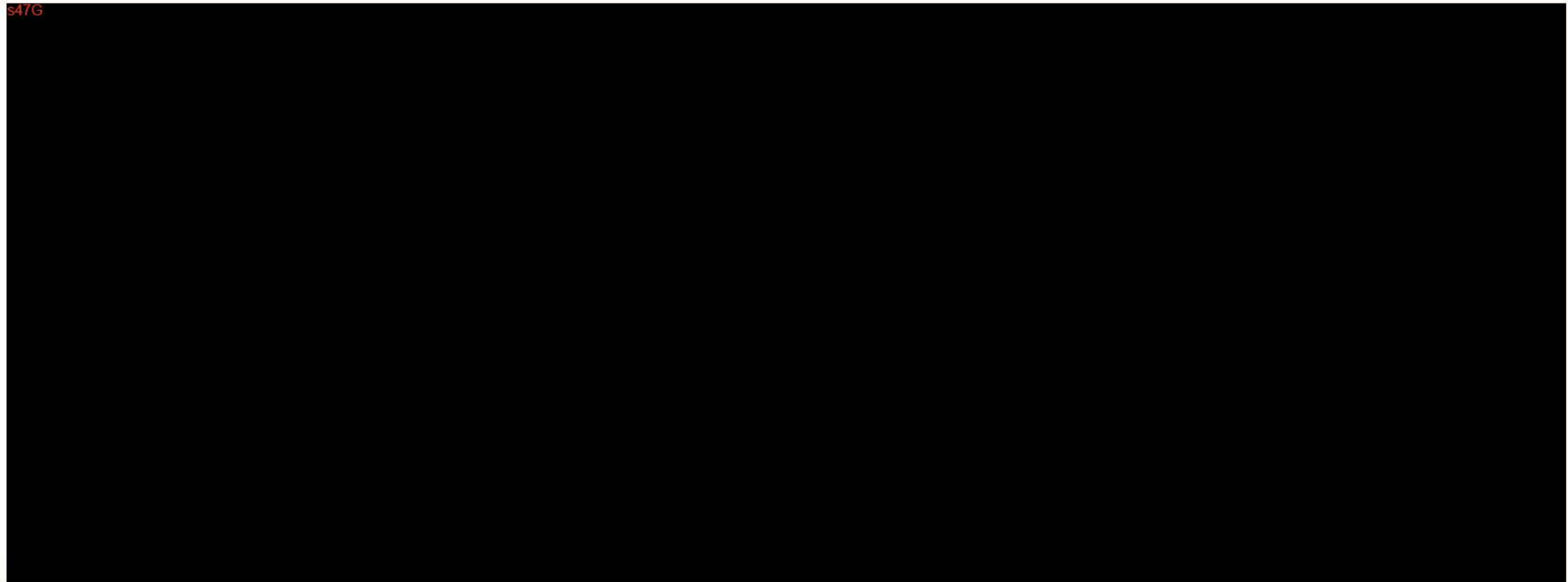
Experienced leadership team delivering highest quality full-service contract manufacturing solutions to support the growth and success of our Clients.

s22



s47G







# OUR SERVICES



WILD CHILD PROVIDES FULL-SERVICE CONTRACT MANUFACTURING SERVICES TO LOCAL AND INTERNATIONAL BRANDS THAT SUCCESSFULLY MARKET THEIR PRODUCTS AROUND THE WORLD

Wild Child develops and produces non-sterile topical products, including:

- Sunscreen
- Skincare
- Cosmetics

These products are produced in the following formats:

- Liquids
- Lotions
- Gels
- Creams
- Solutions
- Balms



WILD CHILD

COMPANY INTRODUCTION

s47G



s47G



b47G



b47G



s47G



S47G



Having a high standard  
Safety  
+ Reputation

SAFE  
EFFECTIVE  
😊

TO LOVE  
SAFE

Happy

EYE  
for  
detail

The pride in  
my work  
- think about  
experience of  
end user

JOY

EXCITED

With  
the  
\$

Joy  
Luxury  
Good results  
FUN

TO WANT  
TO BUY  
AGAIN

PRODUCT  
EXCEEDING  
EXPECTATION

Product safety  
Produce efficiency  
Happy customer  
follow procedures  
High standard  
Compliant product  
TESTING

SAME  
EVERYTIME

SAFE

RECOMMEND  
TO  
OTHERS

Safe

**We take pride in  
making products  
that customers love  
and can't live  
without**

s22 CHILD



# OUR COMMITMENT TO SAFETY

Wild Child is committed to doing everything to **keep our employees, clients and the users of our products safe.**

Wild Child will **train, encourage and provide** the tools for its employees to record and report safety incidents, hazards and near-misses.

Wild Child will remind its employees that there is always time to complete our work safely and when in doubt, stop and ask someone with the right knowledge and expertise before proceeding.



CONFIDENTIAL

| 2025

15

## OVERVIEW OF WILD CHILD SAFETY SYSTEM

- Company Safety Manual and Site Evacuation Plan
- s47G ( ) which details the requirement of accident and injury management on site
- Site Safety Representative and First Aider elected
- Daily safety shares implemented at all daily huddles to discuss safety incidents, hazards and near-misses
- Risk assessments completed for high-risk tasks
- Monthly safety meetings with representation from all functions
- Introduction of PPE (safety boots, glasses , high-vis and hearing protection)
- All safety management activities supported by external safety consultant to ensure best practice is implemented





**From:** s22  
**To:** s22  
**Subject:** FW: Follow up on special inspection: MI-2024-LI-09302-1 [SEC=OFFICIAL]  
**Date:** Friday, 12 September 2025 11:47:00 AM  
**Attachments:** [image001.png](#)

---

FYI

---

**From:** s22  
**Sent:** Thursday, 11 September 2025 11:27 PM  
**To:** s22 @wildchild.com.au  
**Subject:** Follow up on special inspection: MI-2024-LI-09302-1 [SEC=OFFICIAL]

Dear s22

Firstly, thank you for hosting the special inspection last week.

I sincerely understood the pressure and I came to your site open minded and will continue to be open minded.

Having said this - would you be ok if I organise a meeting for us this coming Monday, 15<sup>th</sup> September 2025 and potentially couple of meetings before I finalise the post inspection letter, my intention is to go through your complaint investigation (CAE129) findings so far?

I feel we had a good chat and I know this may appear as an out of box approach but I would like to work with you and your team to make sure I get your investigation findings correct and go with nothing but factual information and data, step by step so that I can make a correct interpretation of your final findings.

Please let me know your thoughts on what I'm proposing.

Please don't hesitate to contact me if you have any questions.

Once again, thank you & I look forward to hearing back from you.

Kind regards, s22

s22  
GMP Inspector  
Inspection Section  
Manufacturing Quality Branch

---

Medical Device and Product Quality Division | Health Products Regulation Group  
Therapeutic Goods Administration (TGA) | Australian Government, Department of Health, Disability and Ageing

Telephone: s22 or Mobile: s22 ; E-mail: s22 @health.gov.au

Location: Level 15, 595 Collins St Melbourne VIC 3000

PO Box 100, Woden ACT 2606, Australia

*The Department of Health, Disability and Ageing acknowledges First Nations peoples as the*

*Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

*This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.*

**From:** s22  
**To:** s22  
**Cc:** s22  
**Subject:** RE: Follow up on special inspection: MI-2024-LI-09302-1 [SEC=OFFICIAL]  
**Date:** Monday, 15 September 2025 1:51:14 PM  
**Attachments:** [image001.png](#)

---

Dear s22

Thanks for the update.

We will look forward to hearing from you in the coming weeks if you would like to discuss anything further.

Kind regards, s22

---

**From:** s22 @Health.gov.au>  
**Sent:** Monday, 15 September 2025 9:40 AM  
**To:** s22 @wildchild.com.au>  
**Cc:** s22 @wildchild.com.au>; s22 @wildchild.com.au>; s22 @wildchild.com.au>  
**Subject:** RE: Follow up on special inspection: MI-2024-LI-09302-1 [SEC=OFFICIAL]

Dear s22

Thank you for the below. I understand that my colleagues in the Complementary and OTC Medicines Branch are in the process of arranging a meeting with s22 tomorrow to discuss the Florida Suncare testing report.

To avoid any confusion, I propose that we hold off any further discussions until those conversations have concluded.

I will be in touch in the coming weeks.

Kind regards, s22

s22  
GMP Inspector  
Inspection Section  
Manufacturing Quality Branch

---

Medical Device and Product Quality Division | Health Products Regulation Group  
Therapeutic Goods Administration (TGA) | Australian Government, Department of Health, Disability and Ageing  
Telephone: s22 or Mobile: s22; E-mail: s22 @health.gov.au  
Location: Level 15, 595 Collins St Melbourne VIC 3000  
PO Box 100, Woden ACT 2606, Australia

*The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and*

*community. We pay our respects to them and their cultures, and to all Elders both past and present. This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.*

---

**From:** s22 [REDACTED]@wildchild.com.au>  
**Sent:** Friday, 12 September 2025 7:41 PM  
**To:** s22 [REDACTED]@Health.gov.au>  
**Cc:** s22 [REDACTED]@wildchild.com.au>; s22 [REDACTED]@wildchild.com.au>; s22 [REDACTED]@wildchild.com.au>  
**Subject:** RE: Follow up on special inspection: MI-2024-LI-09302-1 [SEC=OFFICIAL]

OFFICIAL

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22 [REDACTED]

Thank you, and thanks again for your time on site last week. I really appreciated your collaborative approach and support of our open investigation (CAE129).

We're happy to meet on Monday. s22 [REDACTED] s22 [REDACTED] s22 [REDACTED]  
s22 [REDACTED] s22 [REDACTED] s22 [REDACTED] s22 [REDACTED] and I will attend. Please let us know your availability and we will try to accommodate it.

One additional note, we have engaged life-sciences counsel to support our interactions with the TGA and would like to invite s22 [REDACTED] s22 [REDACTED] to join the meeting so she can be across the factual record and provide technical/legal support where needed.

We remain committed to full cooperation and to working constructively with you to ensure the investigation and any subsequent reporting are accurate and evidence-based.

Best, s22 [REDACTED]

OFFICIAL

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**From:** s22 [REDACTED]@Health.gov.au>  
**Sent:** Thursday, 11 September 2025 9:27 PM  
**To:** s22 [REDACTED]@wildchild.com.au>  
**Subject:** Follow up on special inspection: MI-2024-LI-09302-1 [SEC=OFFICIAL]

Dear s22 [REDACTED]

Firstly, thank you for hosting the special inspection last week.

I sincerely understood the pressure and I came to your site open minded and will continue to be open minded.

Having said this - would you be ok if I organise a meeting for us this coming Monday, 15<sup>th</sup> September 2025 and potentially couple of meetings before I finalise the post inspection letter, my intention is to go through your complaint investigation (CAE129) findings so far?

I feel we had a good chat and I know this may appear as an out of box approach but I would like to work with you and your team to make sure I get your investigation findings correct and go with nothing but factual information and data, step by step so that I can make a correct interpretation of your final findings.

Please let me know your thoughts on what I'm proposing.

Please don't hesitate to contact me if you have any questions.

Once again, thank you & I look forward to hearing back from you.

Kind regards, s22

s22

GMP Inspector  
Inspection Section  
Manufacturing Quality Branch

---

Medical Device and Product Quality Division | Health Products Regulation Group  
Therapeutic Goods Administration (TGA) | Australian Government, Department of Health, Disability and Ageing

Telephone: s22 or Mobile s22 ; E-mail: s22 @health.gov.au

Location: Level 15, 595 Collins St Melbourne VIC 3000  
PO Box 100, Woden ACT 2606, Australia

*The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

*This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.*

"Important: This transmission is intended only for the use of the addressee and may contain confidential or legally privileged information. If you are not the intended recipient, you are notified that any use or dissemination of this communication is strictly prohibited. If you receive this transmission in error please notify the author immediately and delete all copies of this transmission."

**From:** s22  
**To:** s22  
**Subject:** Images from facility walk through  
**Date:** Wednesday, 3 September 2025 6:30:50 PM  
**Attachments:** s47G

---

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hello s22

Please find images attached from todays walk through the Wildchild facility

Thank you

s22

s22



---

**Wild Child Laboratories Pty Ltd**  
A 16 Howe St, Osborne Park, WA 6017  
P s22  
E s22@wildchild.com.au W wildchild.com.au



















**From:** s22  
**To:** s22  
**Cc:** s22  
**Subject:** Fw: Section 41AB Notice - Wild Child Laboratories Pty Ltd - TRIM: E25-381806 [SEC=OFFICIAL]  
**Date:** Thursday, 4 September 2025 1:03:13 PM  
**Attachments:** [image001.png](#)  
[image002.png](#)  
[image003.png](#)  
[image004.png](#)  
[image005.png](#)  
[image006.png](#)  
[image007.png](#)  
[Outlook-1zsh0tal.png](#)  
[image.png](#)  
[image.png](#)  
[image.png](#)  
[image.png](#)

---

OFFICIAL

Hi s22

Please find below the email sent to s22 to correct the list of current market formulation of AUST L 332788 which is supplied to sponsors other than Grace & Fire Pty Ltd for use as a sunscreen.

Please let me know if you require any further information

Thank you

s22

s22



---

**Wild Child Laboratories Pty Ltd**  
A 16 Howe St, Osborne Park, WA 6017  
P s22  
E s22 [@wildchild.com.au](mailto:s22@wildchild.com.au) W [wildchild.com.au](http://wildchild.com.au)

OFFICIAL

---

**From:** s22 <s22@wildchild.com.au>  
**Sent:** Wednesday, 3 September 2025 2:04 PM  
**To:** s22 <s22@health.gov.au>  
**Subject:** Re: Section 41AB Notice - Wild Child Laboratories Pty Ltd - TRIM: E25-381806 [SEC=OFFICIAL]

Dear s22

We are currently undergoing a TGA inspection and it has been identified that the list of current market formulation of AUST L 332788 which is supplied to sponsors other than Grace & Fire Pty Ltd for use as a sunscreen, contains an error.

The following two batches have not been manufactured or released to market.



The following product has been included in error and is not the same formulation as AUST L 332788 supplied to sponsors other than Grace & Fire Pty



Please let me know if you require any further information.

Thank you

s22

s22



Wild Child Laboratories Pty Ltd  
 A 16 Howe St, Osborne Park, WA 6017  
 P s22  
 E s22 @wildchild.com.au W wildchild.com.au

---

**From:** s22 @wildchild.com.au>  
**Sent:** Friday, 1 August 2025 2:50 PM  
**To:** s22 @health.gov.au>  
**Subject:** Re: Section 41AB Notice - Wild Child Laboratories Pty Ltd - TRIM: E25-381806 [SEC=OFFICIAL]

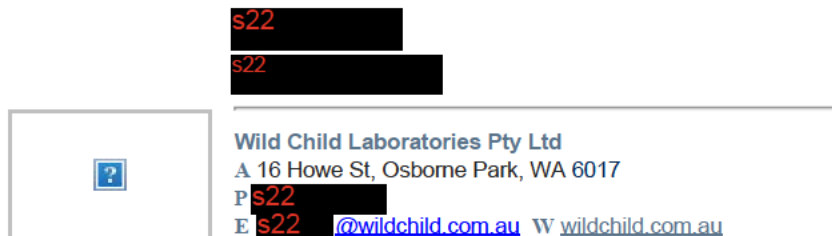
Dear s22

**RE: Ultra Violette Lean Screen SPF50+ (AUST L 332788) sponsored Grace & Fire Pty Ltd**

Please find attached our response to your request for information (TGA Reference: LMP-SP-2025-00775) containing a list of the sunscreen name(s) and corresponding AUST L number(s) for:

1. the current market formulation of AUST L 332788 which is used in other sunscreen products sponsored by Grace & Fire Pty Ltd.
2. the current market formulation of AUST L 332788 which is supplied to sponsors other than Grace & Fire Pty Ltd for use as a sunscreen.

If you require further information or details please do not hesitate to contact me.




---

**From:** s22 @health.gov.au  
**Sent:** Wednesday, 23 July 2025 1:42 PM  
**To:** s22 @wildchild.com.au  
**Cc:** s22 @wildchild.com.au  
**Subject:** RE: Section 41AB Notice - Wild Child Laboratories Pty Ltd - TRIM: E25-381806  
 [SEC=OFFICIAL]

Dear s22

We do not provide comments on individual matters including whether they may be subject to investigation or compliance and enforcement activities, due to privacy and legal restrictions under the *Therapeutic Goods Act 1989* (the **Act**). However, should the TGA find a breach of the therapeutic goods legislation, the appropriate regulatory action will be taken in accordance with our [risk-based compliance framework](#). The TGA does, from time to time, publish [compliance actions and outcomes](#) taken under the Act.

In relation to your request for an extension, I am happy to grant an extension until **COB 1 August 2025**.

In relation to your additional questions:

- As you know, in Australia therapeutic sunscreens are required to be included in the [Australian Register of Therapeutic Goods](#) (ARTG) before they can legally be marketed in Australia. These sunscreens are required to be manufactured in accordance with the principles of [Good Manufacturing Practice \(GMP\)](#) and must comply with the requirements specified in the Australian and New Zealand Sunscreen Standard. The Australian Sunscreen Standard specifies the tests for determination of UVA protection and of the sun protection factor (SPF).
- Currently, the internationally accepted ISO method of sunscreen SPF testing [(ISO 24444:2019, *Cosmetics — Sun protection test methods — In vivo determination of the sun protection factor (SPF)*)] uses human subjects. It is a known issue that there is variability in SPF testing results across laboratories because testing on humans can be highly subjective and the response to a test can differ dramatically from one individual to another. While

progress is being made internationally toward *in-vitro* sunscreen testing (e.g. not on human subjects), which will improve consistency of results, these methods are not yet in place.

- The TGA does not accredit laboratories for SPF testing. Laboratories conducting SPF testing are typically recognised through other forms of quality certification or operate under a manufacturer's GMP licence.

Kind regards

s22

### Listing Compliance Section

Complementary and OTC Medicines Branch  
Australian Government, Department of Health, Disability and Ageing  
Therapeutic Goods Administration

Phone: s22

Email: s22@health.gov.au

PO Box 100, Woden ACT 2606

[../../../../th0022/AppData/Local/Hewlett-Packard/HP%20TRIM/TEMP/HPTRIM.18288/www.tga.gov.au]www.tga.gov.au



***This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.***

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---

**From:** s22@wildchild.com.au>

**Sent:** Tuesday, 22 July 2025 5:42 PM

**To:** s22@health.gov.au>

**Cc:** s22@wildchild.com.au>

**Subject:** Re: Section 41AB Notice - Wild Child Laboratories Pty Ltd - TRIM: E25-381806  
[SEC=OFFICIAL]

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Dear s22

Thank you for your email.

Are you able to share any further information on the regulatory issues that you are investigating in relation to Ultra Violette Lean Screen SPF50+ (AUST L 332788) sponsored Grace & Fire Pty Ltd? We have on file all the requisite supporting information and would be happy to share any information with you that would support your investigation. We are confident that this product has been made in compliance with your guidelines.

We are happy to respond directly to your two questions below. Respectfully, I would like to request an extension to our deadline until the end of next week (1 August). This will give us the time to compile a list of products and sponsors that are within expiry.

Due to the nature and timing of your request, are you able to assist us with the following questions:

1. Is this information request in direct response to the CHOICE investigation into SPF products that was published on 12 June 2025?
2. Assuming the above answer is yes, does the TGA still accept ISO 24444 & AS/NZ testing reports from Princeton Consumer Research?
3. If not, what is the timeframe the TGA will give brands to get re-tested / amend formulas where needed?
4. What is the list of approved labs going forwards?
5. Can the TGA confirm that one 10 subject study is what is required? Or does the TGA require more than one laboratory test result?
6. If more than one SPF study has been completed with the same or multiple laboratories, what is the TGA's protocol in determining the label claim if expected interlaboratory variability is observed?

Regards

s22

s22



---

**Wild Child Laboratories Pty Ltd**  
A 16 Howe St, Osborne Park, WA 6017  
P s22  
E s22@wildchild.com.au W wildchild.com.au

---

**From:** s22 [REDACTED]@health.gov.au>  
**Sent:** Thursday, 17 July 2025 2:19 PM  
**To:** s22 [REDACTED]@wildchild.com.au>  
**Subject:** Section 41AB Notice - Wild Child Laboratories Pty Ltd - TRIM: E25-381806  
[SEC=OFFICIAL]

TGA Reference: LMP-SP-2025-00775

Dear Sir/Madam

**RE: Ultra Violette Lean Screen SPF50+ (AUST L 332788) sponsored Grace & Fire Pty Ltd**

The Therapeutic Goods Administration (TGA) has become aware of potential regulatory issues regarding the abovementioned medicine manufactured Wild Child Laboratories Pty Ltd (**you**) and an investigation has therefore been initiated.

Pursuant to section 41AB of the *Therapeutic Goods Act 1989* (the **Act**), I (in my capacity as a delegate of the Secretary of Health, Disability and Ageing) require you to provide the following information:

1. Please confirm whether the current market formulation of AUST L 332788 has been used in any other sunscreen products sponsored by Grace & Fire Pty Ltd. If so, please provide the sunscreen name(s) and corresponding AUST L number(s).
2. Please confirm whether the current market formulation of AUST L 332788 has been supplied to sponsors other than Grace & Fire Pty Ltd for use as a sunscreen. If so, please provide the sponsor name, the sunscreen name(s) and corresponding AUST L number(s).

Please ensure that you provide your response to [nonprescriptionmedicines@health.gov.au](mailto:nonprescriptionmedicines@health.gov.au) by **COB 24 July 2025**.

If you do not comply with this further request for information notice by the due date or provide false or misleading information, we may take further regulatory action, which may include civil or criminal penalty (in accordance with, for example, sections 31 or 31AAA of the Act).

The Complementary & OTC Medicines Branch understands that you have included this email address in eBS as a contact point. The TGA will only be sending this notice via email so it is important that you keep your details up-to-date. If you wish to update your contact details with the TGA, please login to your account through TGA Business Services or contact the eBS Helpdesk on 1800 010 624 or [ebs@tga.gov.au](mailto:ebs@tga.gov.au).

Please note that under the *Electronic Transaction Act 1999*, any notice sent via email is assumed to have been received once it is delivered to the email address; not when it is opened.

If you have any questions about this notice, please do not hesitate to contact me.

Kind regards

s22

### Listing Compliance Section

Complementary and OTC Medicines Branch  
 Australian Government, Department of Health, Disability and Ageing  
 Therapeutic Goods Administration

Phone: s22

Email: s22@health.gov.au

PO Box 100, Woden ACT 2606

[../../../.././th0022/AppData/Local/Hewlett-  
 Packard/HP%20TRIM/TEMP/HPTRIM.18288/www.tga.gov.au]www.tga.gov.au



***This information is given to you without prejudice and is not binding on the TGA. It is the responsibility of the sponsor to ensure that all of the legislative requirements are met.***

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**From:** s22  
**To:** s22  
**Cc:** s22  
**Subject:** Open Howe St Change requests  
**Date:** Thursday, 4 September 2025 1:37:31 PM  
**Attachments:** [image.png](#)  
s47G

---

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

Please find attached the list of CC records and action in progress from the move from Malaga to Osborne Park.

Thank you

s22  
s22



---

**Wild Child Laboratories Pty Ltd**  
A 16 Howe St, Osborne Park, WA 6017  
P s22  
E s22@wildchild.com.au W [wildchild.com.au](http://wildchild.com.au)

s47G



**From:** s22  
**To:** s22  
**Cc:** s22  
**Subject:** list of products and first batches of s47G  
**Date:** Thursday, 4 September 2025 2:01:18 PM  
**Attachments:** [image.png](#)  
[list of first batch manufactured.xlsx](#)

---

**REMINDER:** Think before you click! This email originated from outside our organisation. Only click links or open attachments if you recognise the sender and know the content is safe.

Hi s22

Please find attached requested document

Thanks

s22  
s22



---

**Wild Child Laboratories Pty Ltd**  
A 16 Howe St, Osborne Park, WA 6017  
P s22  
E s22 [@wildchild.com.au](mailto:s22@wildchild.com.au) W [wildchild.com.au](http://wildchild.com.au)

Brand	Product Name	ARTG	Batch	DOM
Naked Sundays	Collagen Glow Mineral Sunscreen	356754	A1089	6-May-21
Ethical Zinc	Daily Wear Light Sunscreen	333136	A0907	28-Jul-20
Ethical Zinc	Daily Wear Tinted Facial Sunscreen (Dark)	384897	A1424	12-Jul-22
Ethical Zinc	Daily Wear Tinted Facial Sunscreen (Light)	384897	A1423	7-Jul-22
Endota	Mineral Protect SPF50 Sunscreen	333138	A0984	24-Nov-20
McoBeauty	SPF50+ Mineral Mattifying Sunscreen	420373	A1334	3-Mar-22
We Are Feel Good Inc	Mineral Sunscreen SPF50+	409094	A1854	20-Sep-23
Aesthetics Rx	Aesthetics Rx Ultra Protection Sunscreen Cream	364858	A1133	21-Jul-21
New Day Skin	Good Vibes Sunscreen SPF50+	339406	A0989	3-Dec-20
New Day Skin	Happy Days Sunscreen SPF50+	339819	A0988	3-Dec-20
Aspect Sun	Aspect Sun SPF50+ Physical Sun Protection	365276	A1184	1-Oct-21
Aspect Sun	Aspect Sun SPF50+ Tinted Physical Sun Protection	389983	A1629	21-Feb-23
Beauti-FLTR	Beauti-FLTR Lustre Mineral SPF50+	383583	A1404	23-Jun-22
Found My Skin	Found My Skin SPF 50+ Tinted Face/Body Cream	408261	A1325	11-Mar-22
GlindaWand	The Fountain of Youth Environmental Defence Cream SPF50+	392832	A1592	3-Feb-23
Outside Beauty & Skincare	SPF 50+ Mineral Primer	411860	A1902	24-Oct-23
Salus	SPF50+ Daily Facial Sunscreen Broad Spectrum	401588	A1707	13-Jul-23
People4Ocean	SPF 50+ Mineral Bioactive Shield Lightly Tinted Cream	412979	A1915	5-Dec-23
Allganics	Allganics Light Sunscreen SPF50+	346159	A1039	12-Feb-21
Ultra Violette	Ultra Violette Lean Screen SPF50+	332788	A0901	16-Jul-20
Salt and Stone	Daily Lightweight Sunscreen SPF40	338974	A1043	19-Feb-21

**From:** s22  
**To:** s22  
**Subject:** Post Inspection Letter & Close Out Record for Wild Child Laboratories Pty Ltd - MI-2024-LI-09302-1 [SEC=OFFICIAL]  
**Date:** Thursday, 16 October 2025 3:19:00 PM  
**Attachments:** [image001.png](#)  
[Post Inspection Letter - Wild Child Laboratories Pty Ltd - MI-2024-LI-09302-1.pdf](#)  
[Close-Out-Record - Wild Child Laboratories Pty Ltd - MI-2024-LI-09302-1.docx](#)  
**Importance:** High

---

Dear s22

**RE:** Post Inspection Letter & Close Out Record for Wild Child Laboratories Pty Ltd - MI-2024-LI-09302-1

Please find attached to this email the following documents:

- Post Inspection Letter
- Close Out Record for your use to provide response for each listed deficiency.

Please do not hesitate to contact me if you have any questions and kindly acknowledge the receipt of this email and the two attachments.

Kind regards, s22

s22

GMP Inspector  
Inspection Section  
Manufacturing Quality Branch

---

Medical Device and Product Quality Division | Health Products Regulation Group  
Therapeutic Goods Administration (TGA) | Australian Government, Department of Health, Disability and Ageing  
Telephone: s22 or Mobile: s22 E-mail: s22@health.gov.au  
Location: Level 15, 595 Collins St Melbourne VIC 3000  
PO Box 100, Woden ACT 2606, Australia

*The Department of Health, Disability and Ageing acknowledges First Nations peoples as the Traditional Owners of Country throughout Australia, and their continuing connection to land, sea and community. We pay our respects to them and their cultures, and to all Elders both past and present.*

*This response is general information given to you without prejudice; it is not binding on the TGA and you should get your own independent legal advice to ensure that all of the legislative requirements are met.*



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

s22

Wild Child Laboratories Pty Ltd  
16 Howe Street,  
Osborne Park, WA 6017

Ref: PH24/3927

RE: **The Therapeutic Goods Act 1989**  
**On-site Special Inspection of Wild Child Laboratories Pty Ltd**  
**Inspection Tracking Numbers: MI-2024-LI-09302-1**

Dear s22

I would like to thank you and the management and staff for the courtesy and attention extended during the on-site special inspection of your 16 Howe Street, Osborne Park, WA 6017 facility on (2<sup>nd</sup>, 3<sup>rd</sup> and 4<sup>th</sup>) of September 2025.

During the inspection, a number of inspection findings, listed as deficiencies in the appendix to this letter, have been identified, that indicate a departure from acceptable GMP standards, and these items require prompt resolution.

You are requested to respond to the deficiencies recorded below within four (4) weeks from the date of this letter. A standard form (in Word) to prepare the response has been issued with this letter. The preferable format for your response is:

- For the response form (Close out record): as a Word document that is not marked as final.
- For all other documents: in any searchable electronic format, e.g., PDF.
- For all deficiencies categorised as 'critical' or 'major' a CAPA plan should be submitted that includes root cause analysis, corrective action/s to the root cause, preventative action/s to the root cause, corrections to observed examples, and due date for completion of actions.
- For the deficiencies categorised as 'other', a CAPA plan is not required; however, the response date, the correction and due date for completion are required to be provided.

All correspondence regarding the inspection should be addressed to me at the email address below.

Yours sincerely  
(Signed electronically; contains no visible signature)

s22

Lead GMP Inspector  
Manufacturing Quality Branch  
Date: 16 October 2025  
Tel: s22  
E-mail: s22@health.gov.au



































**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

s22

s22

Wild Child Laboratories Pty Ltd  
16 Howe Street,  
Osborne Park- WA 6017

Ref: E23-517357

Dear s22

**RE: GMP INSPECTION of Inspection of Wild Child Laboratories Pty Ltd**

Please find attached the inspection report for the inspection that took place at your Osborne Park WA site on 17-19 July 2023.

Your response(s) to the deficiencies reported in the post inspection letter have been evaluated and have been accepted. Effective implementation will be reviewed at the next GMP inspection.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

Signed and authorised by Lead Inspector  
Manufacturing Quality Branch

Date: 17/11/2023

Tel: s22

E-mail: s22@health.gov.au



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

## Inspection Report

<b>Manufacturer:</b>	Wild Child Laboratories Pty Ltd
<b>Inspected site/s:</b>	16 Howe Street, Osborne Park WA 6017
<b>Activities carried out by manufacturer:</b>	<input checked="" type="checkbox"/> Manufacture of finished medicinal product <input type="checkbox"/> Manufacture of intermediate or bulk <input type="checkbox"/> Packaging <input type="checkbox"/> Laboratory testing <input type="checkbox"/> Release for supply <input type="checkbox"/> Other:
<b>Type of inspection:</b>	<input checked="" type="checkbox"/> Initial inspection <input type="checkbox"/> Re-inspection <input checked="" type="checkbox"/> Full inspection <input type="checkbox"/> Special inspection <input type="checkbox"/> Reduced scope inspection Applicable sections of the <i>Therapeutic Goods Act 1989</i> : <input checked="" type="checkbox"/> section 37(2)(b) (licence application) <input type="checkbox"/> section 40B(10)(a) (licence variation) <input type="checkbox"/> section 40(4)(b) (re-inspection of licensed site) <input type="checkbox"/> section 25(1)(g) (overseas in relation to registration) <input type="checkbox"/> sections 26(1)(g), 26A(3) (overseas in relation to listing)
<b>Scope of Inspection</b>	Finished Product Manufacture of listed medicines- Dosage Forms: Liquids-Solutions, Lotion, Cream and Topical Sunscreen, and gel. API packaging and labelling
<b>Inspection date/s:</b>	17-19 July 2023 <sup>s47G</sup> [REDACTED]
<b>Inspector/s:</b>	s22 [REDACTED]
<b>Manufacturing Standard used:</b>	PIC/S Guide to Good Manufacturing Practice for Medicinal Products - 1 May 2021
<b>References:</b>	Manufacturing Licence number: MI-2023-LI-02284-1 File reference number/s: PH23/20806

## **Introduction**

Wild Child Laboratories Pty Ltd herein known as 'Wild Child' is a wholly owned subsidiary of Wild Child Pty Ltd. The company has held a TGA licence for the manufacture and packaging of sunscreen products, complimentary and listed OTC medicines along with the repackaging of APIs and finished product since October 2016. s47G

s47G

s47G

Date of previous inspection: Not applicable

Names of inspectors involved in previous inspection: Not applicable

## **Brief report of the inspection activities undertaken**

### **Scope of inspection**

The inspection was performed to assess manufacturer compliance with the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 May 2021 for the following manufacturing steps, dosage forms and conditions:

<b><u>Manufacturing Type</u></b>	<b><u>Sterility</u></b>	<b><u>Dosage Form</u></b>	<b><u>Product Code</u></b>	<b><u>Manufacturing Step</u></b>
Medicine Manufacture	Non-Sterile	API – Not Defined	Raw Materials	Packaging and Labelling
Medicine Manufacture	Non-Sterile	Liquids - Solutions	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine Manufacture	Non-Sterile	Cream	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine Manufacture	Non-Sterile	Lotion	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine Manufacture	Non-Sterile	Topical Sunscreen Forms	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicine Manufacture	Non-Sterile	Liquids - Emulsion	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
Medicines Manufacture	Non-Sterile	Gel	Listed Therapeutic Goods	Full Product Manufacture - excluding Microbiological Testing

### **Inspected areas**

Onsite inspection to verify site qualification and suitability of design, this included facility design and qualification, including warehouse, manufacturing, packaging, utilities and equipment qualifications. In addition, assessment of some CAPA completions from the previous inspection of

the Malaga site, as required by previous Malaga inspector; those deficiencies that would potentially impact this new site.

### **Personnel met during the inspection**

Refer to attached attendance sheet.

### **Inspection findings and observations**

Major changes since the previous inspection: New site

Future Planned Changes:

Transfer of manufacturing and testing operations to this new facility and completion of validations.

### **Overview of inspection findings from last inspection and the corrective action taken**

The inspector reviewed the effectiveness of selected corrective actions from the previous TGA inspection of Malaga site, these that would potentially impact the operation of this new sites. Some of the CAPAs were still in progress.

### **Quality Management**

Wild Child had established a Quality management system to meet the requirements of the PICS Guide to GMP. There were deficiencies against elements of the Guide noted; these have been recorded in the relevant sections of this report.

Inspection of the quality system was not conducted as this was the same in operation at Malaga that was closed out a week before this inspection. The inspector could not review examples of incidents as there were none generated from this new site (not in operation as yet).

The quality system covered elements of the Guide including risk management, deviations, CAPA, change control, release for supply, annual product review and others. Details of those systems were recorded in the Malaga inspection.

s47

### **Personnel**

Wild Child had established position descriptions for key personnel and company organisation charts provided clear reporting and authority flows. The inspector confirmed that the newly appointed heads of production and quality were independent from each other.

There was a training programme in place that covered induction, GMP and on going training with a training matrix. A deficiency was raised at the Malaga inspection that was still not completely corrected (Deficiency 8).

The gowning procedure defined the different gowning requirements and washing and sanitisation that were found to be generally appropriate, it was noted however that there was s47G [REDACTED] Deficiency 3a).

The company had implemented appropriate systems to ensure that staff with infectious diseases, or other relevant health issues could not adversely affect product quality. Medical checks were requested upon recruitment.

## Premises and Equipment

<sup>s47</sup> [REDACTED]. The design for personnel and material flows were generally appropriate for the activities to be undertaken on site. <sup>s47</sup> [REDACTED]

. However, the inspector noted the site was <sup>s47</sup> [REDACTED]

[REDACTED] (Deficiency 2). The inspector noted that the design of doors was acceptable with a combination of conventional doors and rapid roller doors (RRD) for equipment entry/exit to establish air locks.

<sup>s47</sup> [REDACTED]

<sup>s47</sup> [REDACTED] (Deficiency 1d).

The site did not require any storage for any temperature sensitive products.

The company had established a manual status control system with physical locations and status control labels. However will transfer to <sup>s47</sup> [REDACTED]

The sampling room was located <sup>s47</sup> [REDACTED] with <sup>s47</sup> [REDACTED] at the door. <sup>s47</sup> [REDACTED]

(Deficiency 3a).

<sup>s47</sup> [REDACTED]

<sup>s47</sup> [REDACTED]

The inspector noted potential cross contamination issues with current air flow set up (Deficiency 3c).

<sup>s47</sup> [REDACTED]

However, the company had not completed full qualification and transfer of equipment from Malaga at the time of inspection (Deficiencies 1,2 and 4).

The company had a calibration and maintenance program at the Malaga site that was compliant as noted at the Malaga inspection, however, the

program <sup>s47</sup> [REDACTED]  
[REDACTED] (Deficiency 5).

<sup>s47</sup> [REDACTED]  
<sup>s47</sup> [REDACTED] (Deficiencies 1e,1i and 3b). The company intended to finalise system qualification and ensure that the system maintained a minimum of <sup>s47</sup> pressure differential for <sup>s47</sup> areas to minimise potential cross contamination. The system would be monitored via the <sup>s47</sup>.

The water system generated purified water by <sup>s47</sup> [REDACTED]. The system was equipped with <sup>s47</sup> [REDACTED]. The system was <sup>s47</sup> as required by procedure and intended to be weekly monitored chemically and microbiologically. However, the system had not been fully qualified to date of inspections (Deficiency 1a).

<sup>s47</sup> [REDACTED] The system was equipped with <sup>s47</sup> [REDACTED] and was qualified.

The site does not have a <sup>s47</sup> [REDACTED]

The manufacturer had not yet established a pest control system with relevant documents, though pest control was service contracted with bait plans (Deficiency 2b).

Secure waste disposal <sup>s47</sup> [REDACTED]

## Documentation

Wild Child had an established documentation system that would be transferred to <sup>s47</sup> [REDACTED] <sup>s47</sup> [REDACTED]  
[REDACTED]

Master documents are printed on coloured paper with any photocopies on white paper.

Master Work Orders (batch records) were generated in word. These were also saved as master PDF documents. <sup>s47</sup> [REDACTED]  
[REDACTED]

There was a document design issue that was identified at the current site last inspection that had not been fully corrected (Deficiency 6).

Specifications documents were in place transferred from the old site for raw materials, and products.

No batch records were reviewed at this site.

## Production

There was no production at the site. Production processes would be recorded in <sup>s47</sup> [REDACTED].

<sup>s47</sup> [REDACTED] was inspected at the last inspection of current operating site with issues that were not fully corrected (Deficiency 7).

The inspector briefly verified that all production systems would be transferred to current site.

The company had a validation master plan (VMP) that detailed the company's approach to validation. <sup>s47</sup>

<sup>s47</sup> The inspector reviewed a number of validation and qualification documents and noted a number of gaps in the documents; also <sup>s47</sup>

(Deficiency 1).

<sup>s47</sup>

### Quality Control

There was <sup>s47</sup> and the <sup>s47</sup> was in the process of being set up. The inspector verified that the <sup>s47</sup> was well designed with required services for <sup>s47</sup>. As the <sup>s47</sup> was still in operation at the current site, none of the equipment were transferred at the date of inspection (Deficiencies 1e and 2a).

The inspector verified that the FTIR audit trail deficiency from the previous inspection was still open and required correction (Deficiency 10).

The inspector did not cover any laboratory procedures and systems at the inspection, as these would be the same as for the Malaga site that was in operation.

### Outsourced Activities

<sup>s47</sup>

### Complaints and Product Recall

There was a complaint management system in operation and a recall procedure at Malaga, which would be transferred to this site. Deficiencies against the system were corrected and accepted by previous inspector at Malaga.

### Self-Inspection

The company had a generally compliant system for self-inspection. The inspector verified the presence of an <sup>s47</sup> inspection schedule.

### Compliance with Marketing Authorisations

Compliance with market authorisation aspects for products were inspected at the Malaga site. Not reviewed at this new site.

### Specific Annexes

The Annexes of the Standard applicable to the inspection were Annexes 8, 9, 11, 15, 19 & 20)

### Other specific issues identified

- The manufacturer was not fully ready for the inspection, the <sup>s47</sup> on the proviso that a close out inspection will take place to verify facility readiness with qualification finalisation of equipment and areas.
- The inspection of the Malaga facility was closed a week before this inspection of new site at Osborne Park. A decision NOT to cover certain aspects of the routine inspection as these were

reviewed and closed at the Malaga inspection. The focus of this inspections was on the new facility and related new systems, as the quality system will be transferred from Malaga.

**Site Master File**

The company provided a copy of their §47 version 1 dated 31 March 2023, which covered the company's site and activities undertaken.

**Miscellaneous**

**Samples taken:**

None.

**Distribution of Report:**

Wild Child Laboratories and filed in TGA Trim file: E23-517357

**Attachments:**

Attendance record

**List of Deficiencies observed during the inspection**

**Critical deficiencies:**

None observed

**Major deficiencies:**

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Other deficiencies:**

S47 [REDACTED]

s47

**Comments**

No further comments

**Summary and conclusions****Assessment of manufacturer's responses**

A response to the deficiencies reported to the manufacturer was received on 19/08/23. This inspection will be closed after the close out inspection conducted on 9 November 2023, if all corrections are finalised and/or had suitable effective completion date.

The manufacturer's corrective actions have been evaluated and accepted, based on the agreement that all corrective actions will be carried out as described in the inspection close out correspondence.

**Final evaluation and recommendations:**

1. The manufacturer operates in accordance with the relevant GMP requirements.
2. TGA records have been updated to show a final compliance rating of your facility of <sup>s47G</sup> [REDACTED] with the manufacturing standard established under the *Therapeutic Goods Act 1989*.
3. There will be a scheduled re-inspection within <sup>s47G</sup> [REDACTED].

Signed and authorised by Lead Inspector  
Manufacturing Quality Branch  
Date: 17/11/2023

Tel: <sup>s22</sup> [REDACTED]  
E-mail: <sup>s22</sup> [REDACTED]@[health.gov.au](mailto:health.gov.au)

## DEFINITIONS

### Marketing Authorisation

Compliance with regulatory requirements specified in the ARTG and any other requirements imposed by a relevant Delegate of the Secretary, upon product listing or registration.

Examples of regulatory requirements include but not limited to the following: compliance with registered formulations, special storage and transportation conditions, shelf life, labelling, batch release testing requirements etc.

### Critical Deficiency

A deficiency in a practice or process that has produced, or may result in, a significant risk of producing a product that is harmful to the user. Also occurs when it is observed that the manufacturer has engaged in fraud, misrepresentation or falsification of products or data.

### Major Deficiency

A non-critical deficiency that:

- has produced or may produce a product which does not comply with its marketing authorisation; and/or
- indicates a major deviation from the Good Manufacturing Practice; and/or
- indicates a major deviation from the terms of the manufacturing licence or GMP approval (overseas manufacturers); and/or
- indicates a failure to carry out satisfactory procedures for release of batches; and/or
- indicates a failure of the person responsible for QA/QC to fulfil his/her duties; and/or
- consists of several other deficiencies, none of which on its own may be major, but which may together represent a major deficiency and should be explained and reported as such.

### Other Deficiency

A deficiency that cannot be classified as either critical or major, but indicates a departure from good manufacturing practice.

A deficiency may be “other” either because it is judged as minor, or because there is insufficient information to classify it as major or critical.

One-off minor lapses or less significant issues are usually not formally reported, but are brought to the attention of the manufacturer.

### Note:

1. Classification of a deficiency is based on the assessed risk level and may vary depending on the nature of products manufactured, e.g. in some circumstances an example of major deficiency may be categorised as critical.
2. A deficiency that was reported at a previous inspection and not corrected may be reported in a higher classification.

**FOR OFFICIAL USE ONLY**



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

Manufacturing Quality Branch

**Inspection attendance sheet**

<b>Manufacturer name:</b>	Wild Child
<b>Manufacturer address:</b>	16 Howe Street Osborne Park WA 6017
<b>Inspection type:</b>	Initial inspection (site transfer)
<b>Inspection date/s:</b>	17, 18 and 20 July 2023 (20 July is a remote inspection day)
<b>Inspector/s:</b>	s22
<b>Inspection standard:</b>	PIC Guide to GMP for medicinal products- PE-009 -15, May 2021

<b>Opening meeting starting time:</b> 11:45			
<b>Closing meeting starting time:</b> 4pm			
<b>Name</b> <i>(please print)</i>	<b>Position</b> <i>(please print)</i>	<b>Opening meeting</b> <i>(initials)</i>	<b>Closing meeting</b> <i>(initials)</i>
s22	s22	s22	



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

s22

s22

Wild Child Laboratories Pty Ltd  
2 Action Road, Malaga,  
Western Australia 6090

Ref: E19-609003

Dear s22

**RE: GMP Inspection of Wild Child Laboratories Pty Ltd**

Please find attached the inspection report for the inspection that took place at your Malaga, WA site on 9, 10, 11 & 12 (Part Day) of June 2020.

Your response(s) to the deficiencies reported in the post inspection letter have been evaluated and have been accepted. Effective implementation will be reviewed at the next GMP inspection.

Should you have any questions regarding the inspection, please do not hesitate to contact me.

Yours sincerely

Signed and authorised by Lead Inspector

s22

Manufacturing Quality Branch

Date: 07 November 2020

Tel: s22

E-mail: s22@tga.gov.au

**Inspection Report**



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

<b>Manufacturer:</b>	Wild Child Laboratories Pty Ltd
<b>Inspected site/s:</b>	2 Action Road, Malaga, WA 6090
<b>Activities carried out by manufacturer:</b>	<input checked="" type="checkbox"/> Manufacture of finished medicinal product <input checked="" type="checkbox"/> Manufacture of intermediate or bulk <input checked="" type="checkbox"/> Packaging <input checked="" type="checkbox"/> Laboratory testing <input checked="" type="checkbox"/> Release for supply <input type="checkbox"/> Other:
<b>Type of inspection:</b>	<input type="checkbox"/> Initial inspection <input checked="" type="checkbox"/> Re-inspection <input type="checkbox"/> Full inspection <input type="checkbox"/> Special inspection <input type="checkbox"/> Reduced scope inspection Applicable sections of the <i>Therapeutic Goods Act 1989</i> : <input type="checkbox"/> section 37(2)(b) (licence application) <input checked="" type="checkbox"/> section 40B(10)(a) (licence variation) <input checked="" type="checkbox"/> section 40(4)(b) (re-inspection of licensed site) <input type="checkbox"/> section 25(1)(g) (overseas in relation to registration) <input type="checkbox"/> sections 26(1)(g), 26A(3) (overseas in relation to listing)
<b>Scope of Inspection</b>	Finished Product Manufacture - Dosage Forms: Gels, Liquids-Solutions, Lotion, Cream and Topical Sunscreen Forms. Packaging and Labelling - API Not defined
<b>Inspection dates:</b>	9, 10,11 & 12 <sup>th</sup> (Part Day) June 2020
<b>Inspector:</b>	s22
<b>Manufacturing Standard used:</b>	PIC/S Guide to Good Manufacturing Practice for Medicinal Products - 1 July 2018
<b>References:</b>	Manufacturing Licence number: M1-2013-L1- 0560-I Tracking Number: MI-2019-LI-08519-1 File reference numbers: E19-591017 & 2016/001072

## **Introduction**

Wild Child Laboratories Pty Ltd herein known as Wild Child is a wholly owned subsidiary of Wild Child Pty Ltd. The company has held a TGA licence for the manufacture and packaging of sunscreen products, complimentary and listed OTC medicines along with the repackaging of APIs and finished product since October 2016.

Date of previous inspection: 26 – 28 September 2017

Names of inspectors involved in previous inspection: s22

## **Brief report of the inspection activities undertaken**

### **Scope of inspection**

The inspection was performed to assess manufacturer compliance with the PIC/S Guide to Good Manufacturing Practice for Medicinal Products – 1 July 2018 for the manufacture as covered in the previous table (reinspection Tracking Number – MI-2019-LI-08519-1).

The inspection also reviewed QC related activities in line with Variation Application Number: LI-2020-LI-08519-1) to include physical and chemical testing of dosage forms manufactured in site. The revised manufacturing table is included at the end of this report for information.

**This Inspection was performed Remotely/virtually due to COVID 19 limitations with no presence on site at all.**

### **Inspected areas**

General areas covered at the main site included receipt, sampling, dispensing, powder blending, hard shell encapsulation, primary & secondary packaging, warehousing, Quality Control (QC) chemistry laboratory, some utilities for the site. In addition, the quality system and associated records for compliance to the GMP code were reviewed. This inspection also included an assessment of corrective and preventative actions that were implemented to address the deficiencies identified in the 2017 TGA inspection.

### **Personnel met during the inspection**

Please refer to the Inspection Attendance Sheet

### **Inspection findings and observations**

Major changes since the previous inspection:

- Since the last inspection the following changes were made:
  - An additional clean room (ungraded)
  - Some equipment
  - Regulatory changes
- New QC testing equipment/procedures/methods and the intention to move some QC testing in house following approval of the variation application.

Future Planned Changes:

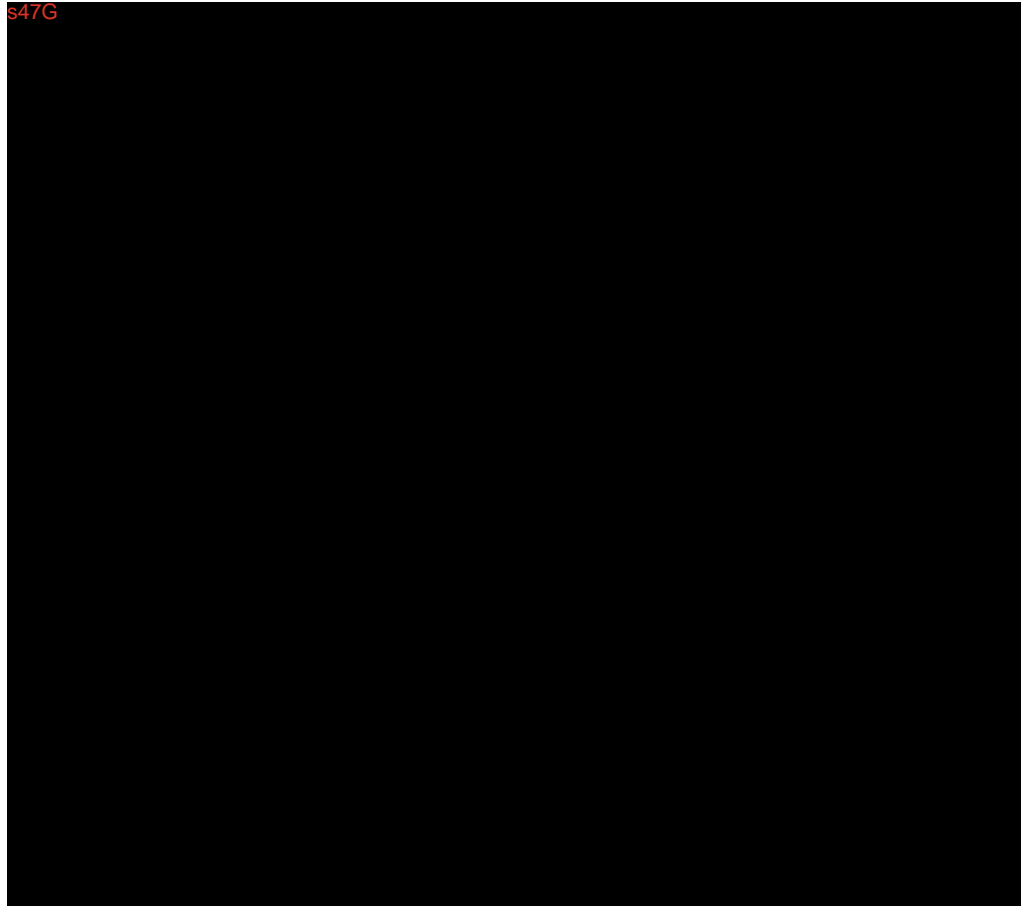
No future changes were advised during the inspection.

**Overview of inspection findings from last inspection and the corrective action taken**

The inspector reviewed the effectiveness of selected corrective actions from the previous TGA inspection. The Close Out Report with the stated actions was consistent with evidence examined on site and found to be acceptable.

**Quality Management**





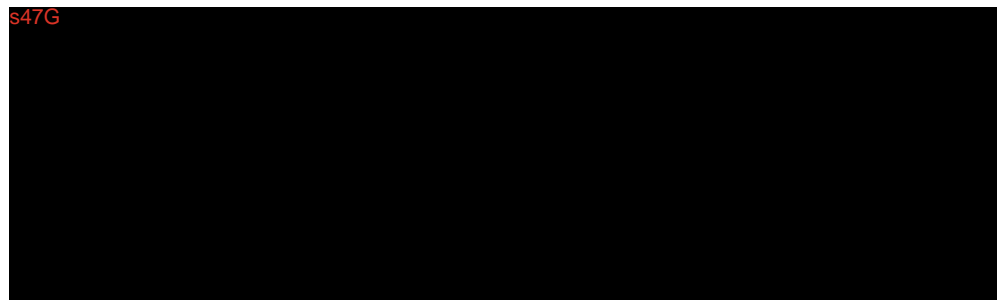
**Personnel**

The organisational chart within the site master file, defined key personnel and position descriptions with separation of production and quality assurance responsibilities. s47G

[Redacted] (Deficiency 3)

A training program was in place for 2020 that included an induction training program. Full-time employees attended GMP refresher training courses biannually; s47G

[Redacted] (Deficiency 4b) The training courses were recorded on a training record and placed into personnel training files. Employees training included procedural reading for new changes. Personnel training requirements stemmed from a spreadsheet matrix with links to a job function. Specific procedures were assigned for completion and readily identifiable by the use of different colours.



**Premises and Equipment**



b47G



b47G

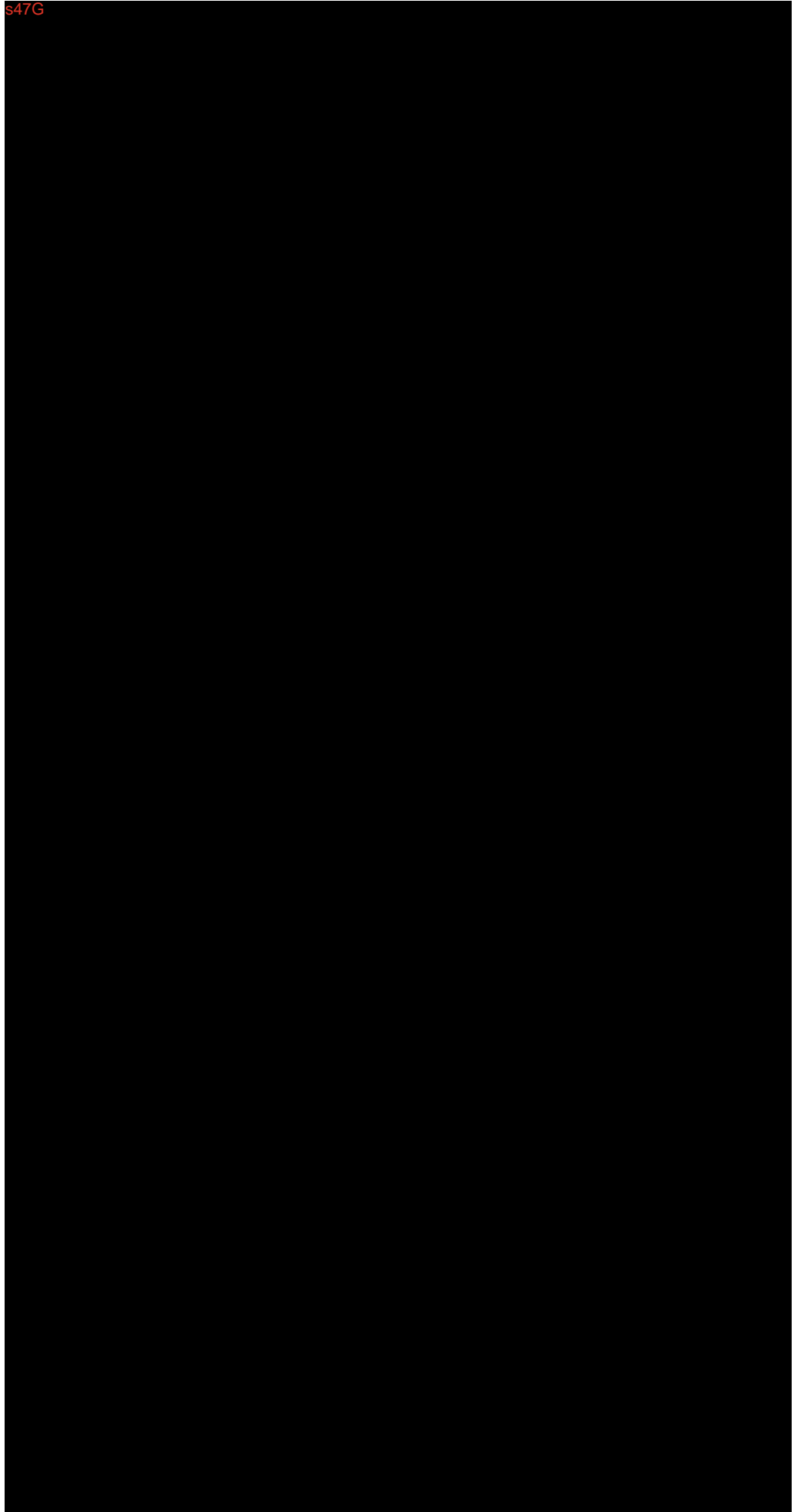
**Documentation**

**Production**

b47G



s47G



**Quality Control**

s47G



s47G



**Outsourced Activities**

GMP contracts were not reviewed due to time constraints; however, this area was reviewed at the last TGA inspection conducted in September 2017.

**Complaints and Product Recall**

An SOP, form and a Compliant/Adverse Events log were in place for the recording of customer complaints. s47G

Complaints were classified based on complaint types with statically review and Pareto chart used for trend analysis. The company forwarded complaints onto the product sponsor and provided input where necessary.

**Self Inspection**

There was an internal audit procedure and an audit plan was in place for 2020. Audits were generally conducted on an annual basis. The audit process covered all relevant areas applicable to GMP requirements and a checklist was used. The QA/Production Managers performed the internal audits and observations were recorded on a controlled form. Where observations were noted, Wild Child raised deviations and/or CAPAs as required with close out by the QA manager.

**Compliance with Marketing Authorisations**

Wild Child had established an appropriate process to ensure that market authorisation aspects for products were adequately covered

**Specific Annexes**

The Annexes of the Standard applicable to the inspection were Annexes 8, 9, 15, 19 and 20.

**Other specific issues identified**

Licence Variation MI-2020-LI-05659-1 was submitted by the Manufacturer to have a scope change included in the Inspection with an additional half day added. The variation was to add chemical and physical testing to the current licence authorisations.

**Site Master File**

The company provided a copy of their SMF (POL 001 version 4 dated May 2019), which appropriately covered the company's activities.

**Miscellaneous**

**Samples taken:**

N/A

**Distribution of Report:**

Copy to the company and filed in TRIM E19-591017 & 2016/001072

**Attachments:**

Inspection attendance sheet.

**List of Deficiencies observed during the inspection**

**Critical deficiencies:**

None observed

**Major deficiencies:**

s47G



**Other deficiencies:**

s47G



b47G



s47G



**Comments**

None.

**Summary and conclusions**

**Assessment of manufacturer's responses**

A suitable response to the deficiencies reported to the manufacturer was received on 21/08/2020. No further responses were requested.

The manufacturer's corrective actions have been evaluated and accepted, based on the agreement that all corrective actions will be carried out as described in the inspection close out correspondence.

### Final evaluation and recommendations:

1. The manufacturer operates in accordance with the relevant GMP requirements.
2. As discussed during the inspection and throughout the close out process, the following variations to your Licence for approved steps in manufacture, known as authorisations under section 40A of the *Therapeutic Goods Act 1989*, or variations to conditions under section 40 of the *Therapeutic Goods Act 1989*, have been submitted to the delegate for approval: If approved, the Licence will be re-issued with these amendments. (see table below)

No	Manufacturing Type	Sterility	Manufacturing Class	Dosage Form	Product Code	Manufacturing Step
1	Active Pharmaceutical Ingredient manufacture	Non Sterile	Not Applicable	API - Not Defined	Raw material	Packaging and labelling
2	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Gel	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
3	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Liquids - Solutions	Registered Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
4	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Cream	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
5	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Gel	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
6	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Lotion	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
7	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Topical Sunscreen Forms	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing
8	Medicine manufacture	Non Sterile	Multiple manufacturing steps/Multiple products	Liquids - Solutions	Listed Therapeutic Good	Full Product Manufacture - excluding Microbiological Testing

3. TGA records have been updated to show a final compliance rating of your facility of A2: satisfactory compliance with the manufacturing standard established under the *Therapeutic Goods Act 1989*.

4. The next re inspection is expected to be performed within 20 months.
5. The duration of the next inspection is estimated at this time to be 3.5 days.

Signed and authorised by:

s22 [REDACTED]

Inspector

Manufacturing Quality Branch

Date: XX November 2020

Tel: s22 [REDACTED]

E-mail: s22 [REDACTED]@tga.gov.au

## DEFINITIONS

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