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TNO Report

V6420/06 |

**Formulation R-BIX (A9409AL): Measurement of
excreted paraquat in workers following three
consecutive days use in bananas with PPE
according to label recommendation**

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Statement of GLP compliance

I, the undersigned, hereby declare that this report constitutes a complete, true and accurate representation of the study and its results. All study activities performed by TNO Quality of Life and by Staphyt Residue were carried out in compliance with the current OECD Principles of Good Laboratory Practice¹. TNO makes no GLP compliance claim for characterisation and verification of the test substance identity and properties.

Study director

D.H. Brouwer

Name

Signature

Date (dd-mm-yyyy)

06/09/2007

Approval by management

J. C.M. Mossink

Name

Signature

Date (dd-mm-yyyy)

6 sept 2007

¹ The OECD principles of Good Laboratory Practice are accepted by Regulatory Authorities throughout the European Community, USA and Japan. The most recent endorsement of compliance of the test facility and the test site with these principles is attached to the report as Annex 2

Quality assurance statement

Report Title : Formulation R-BIX (A940AL): Measurement of excreted paraquat in workers following three consecutive days use in bananas with PPE according to label recommendation
Report number : V6420/06
Report date : September 2007

The study plan was audited as follows:

Date of audit	Date of report
27 March 2007 (protocol, amendments 1, 2 and 3)	27 March 2007
6 July 2007 (amendment 4)	6 July 2007

The experimental phase was audited as follows:

Date of audit	Date of report
17 April 2007 (sample pre-treatment and chromatography)	17 April 2007
16 Mai 2007 (PQ analysis)	16 Mai 2007

This report was audited as follows:

Start date of audit	Date of report
29 August 2007 (draft)	29 August 2007
6 September 2007 (final)	6 September 2007

All audits were reported to the Study Director and to laboratory management on the dates indicated.

This field phase was audited by the Quality Assurance Unit of Staphyt Residue as follows:

Date of audit	Date of report to Prin. Invest.
19 March 2007 (field- and laboratory activities)	11 July 2007
25 June - 11 July 2007 (field trial notebook)	23 July 2007

I, the undersigned, hereby declare that this report provides an accurate record of the procedures employed and the results obtained in this study.



M.T.A. Wolters, B.Sc.
Quality Assurance Auditor

Date: 6 September 2007

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Annex 2	Endorsement of GLP
Annex 3	Certificate of Analysis

Abbreviations

CCPPRB	Comité Consultatif de Protection des Personnes participant à la Recherche Biomédicale
CoA	Certificate of Analysis
HPLC	High Performance Liquid Chromatography
ID	Internal Diameter
LLOQ	Lower Limit of Quantification
OECD	Organisation for Economic Co-operation and Development
PI	Principal Investigator (Field Phase)
PIN	Personal Identification Number (of study subjects)
PPE	Personal Protective Equipment
PQ	Paraquat
PS	Polystyrene
RPE	Respiratory protective equipment
QAU	Quality Assurance Unit
QC	Quality Control
SD	Study Director
TNO QoL	TNO Quality of Life

Summary

A field study was conducted to provide representative data on exposure of agricultural workers to paraquat resulting from mixing, loading and application of the test product, R-BIX (A9409AL), according to their habitual work practices.

Excreted paraquat was measured for 15 operators who used R-BIX (A9409AL) during three consecutive days of backpack spray application according to their habitual work patterns in bananas, using a selected set of PPE.

The field phase of the study was conducted in the Isle of Martinique (West Indies) in March 2007. Operators collected 24 h-urines starting at the day prior to the first day of application, and ended the morning of the sixth day following the last day of application.

All operators mixed, loaded and applied the test product, however, for some operators the volume they mixed was more or less than they actually applied, as they worked together at the same location. Some operators mixed the product for two or more operators to subsequently apply.

In total over the period of application the area treated varied from approximately 4430 to 25500 m², using 5.36 to 13.33 kg of the test product as spray dilution.

The PPE comprised a final prototype of a specifically designed PVC poncho, long trouser with PVC coating, a long sleeved shirt and a hat with PVC protective neck guard. In addition protective gloves and rubber boots were provided. For respiratory protection during mixing, loading and application a P3 disposable mask was used. A face shield was used only during mixing and loading.

Five operators showed no quantifiable concentration of paraquat in all urine samples. With the exception of one sample from each of two different operators (PIN 235 and PIN 238) collected during the days of application, all quantifiable paraquat concentrations were below 3 µg/L. The highest concentration observed was approximately 13 µg/L. Operators PIN 235 and PIN 238 also showed the highest 24 h paraquat excretion (up to about 8 µg/24 h); all others had no levels of paraquat excretion exceeding 2 µg/24 h.

The recoveries of the field QC samples were within the range 70% to 120% and therefore considered to be acceptable and no corrections of field sample results were required.