



**SYN524464**

**SYN524464 FS (A16148F) – Potential Genotoxicity – Prokaryotic –  
The *Salmonella*/Microsome Mutagenicity Assay (Ames)**

**Final Report**

**DATA REQUIREMENT(S):** Not Applicable

**AUTHOR(S):** Helena Campos Rolla

**STUDY COMPLETION DATE:** March 26, 2010

**PERFORMING LABORATORY:** Bioensaios Análises e Consultoria Ambiental Ltda.  
Palermo Street, 257 – Santa Isabel  
94480-775 – Viamão – RS - Brazil

**LABORATORY PROJECT ID:** Report Number: 2077-AMES-080-09  
Study Number: 2077-AMES-080-09  
Task Number: TK0008605

**SUBMITTER/SPONSOR:** Syngenta Crop Protection, Inc.  
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Post Office Box 18300  
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**VOLUME 1 OF 1 OF STUDY**

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**RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS**

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Company  
Syngenta Crop Protection, Inc.

Company Agent: Adora Clark, Ph.D.

*Adora Clark*  
U. S. Product Registration Manager

*April 9, 2010*  
Date

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## GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

The study in this volume was conducted in compliance with OECD Principles of Good Laboratory Practice adopted November 26, 1997.

See Page 5 of this volume for the Good Laboratory Practice Compliance Statement signed by the Study Director.



Richard C. Pepper, Ph.D., DABT  
Representative of Submitter/Sponsor

9 April 2010

Date

Submitter/Sponsor: Syngenta Crop Protection, Inc.  
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**SYN524464**  
**SYN524464 FS (A16148F) - Potential Genotoxicity – Prokaryotic**  
**The *Salmonella*/Microsome Mutagenicity Assay (Ames)**  
**Final Report**

**DATA REQUIREMENT (S):** OECD Method 471 “Bacterial Reverse Mutation Test” (Adopted: 21<sup>st</sup> July 1997)

**AUTHOR (S):** Helena Campos Rolla

**STUDY COMPLETION DATE:** 26 Mar 2010

**PERFORMING LABORATORY:** Bioensaio Análises e Consultoria Ambiental Ltda.  
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## GOOD LABORATORY PRACTICE COMPLIANCE STATEMENT

Study: Potential genotoxicity - prokaryotic  
The *Salmonella*/microsome mutagenicity assay (Ames) – SYN524464 FS  
(A16148F)  
Study Number: 2077-AMES-080-09

I declare that Study Plan objectives were successfully reached and concluded. I declare that Raw Data are valid and that Final Report reflects the methods used and obtained raw data.

I declare that the study was conducted in accordance to the Good Laboratory Practice - GLP guideline INMETRO-NIT-DICLA-035 to 041 (Jul/09), based on OECD-Principles on Good Laboratory Practice (1997).

I declare that the GLP principles were completely complied.

Viamão, 26 / Mar / 2010.



Helena Campos Rolla  
Study Director

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório – BPL  
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## QUALITY ASSURANCE STATEMENT

Study: Potential genotoxicity - prokaryotic  
The *Salmonella*/microsome mutagenicity assay (Ames) – SYN524464 FS  
(A16148F)  
Study Number: 2077-AMES-080-09

I declare that this study was conducted according to the GLP principles and I declare that the final report was revised and it reflects the raw data.

I declare that the Study Director signed the declaration that the Study was conducted according to principles GLP in 26 Mar 2010.

I declare below that audits had been carried through, as specified in the table, protocol deviations were not observed or non-conformities that could affect the quality of the results.

Object of the Audit	Audit date	Report date to the Study Director	Report date to the Manager
SOP *	29 Jul. 2008	06 Aug. 2008	06 Aug. 2008
<i>Study phase *</i>			
Strains check (genetic integrity)	31 Jul. 2008	06 Aug. 2008	06 Aug. 2008
Assay and exposition	31 Jul. 2008	06 Aug. 2008	06 Aug. 2008
Counting of plates	04 Aug. 2008	06 Aug. 2008	06 Aug. 2008
Raw Dates	26 Mar. 2010	26 Mar 2010	26 Mar 2010
Final Report	26 Mar. 2010	26 Mar 2010	26 Mar 2010

SOP: Standard Operating Procedure.

\* Process audits based in the study 1973-AMES-180-08 audit.

Viamão, 26 / Mar / 2010.

*Aline Garcia dos Santos*  
Aline Garcia dos Santos  
Quality Assurance Sector  
Rua Palermo, 257 - Viamão - RS - Brazil

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## GENERAL INFORMATION

### Contributors

The following contributed to this report in the capacities indicated:

Name	Title
Helena Campos Rolla	Study Director
Alexandre Brandelli	Test facility manager
Aline Garcia dos Santos	Quality assurance manager

### Study dates

Study initiation date: 27 Apr 09  
Experimental start date: 26 May 09  
Experimental termination date: 12 Mar 10

### Deviations from the guidelines

None

### Retention of samples

The Study Plan, Raw Data and Final Report were archived for, at least, the next five years and the test substance for, at least, 60 days after the conclusion of all studies at Bioensaios Análises e Consultoria Ambiental Ltda dependencies.

### Performing Laboratory Test Substance Reference Number

Substance number: 2077  
Batch number: GP080609

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## 1.0 EXECUTIVE SUMMARY

The test substance SYN524464 FS (A16148F), an agricultural formulation containing the active ingredient sedaxane (SYN524464), was tested for reverse induction of mutation at locus *his* in five strains of *Salmonella typhimurium* (TA97a, TA98, TA100, TA102 and TA1535) with the preincubation method in presence and absence of the metabolic activation using the post-mitochondrial fraction from the livers of rodents treated with Aroclor 1254 (S9).

The dose levels tested were 800, 1250, 2000, 3200 and 5000 µg of the test substance per plate.

In all experiments negative (solvent) and positive controls for each strain were included. The mean number of revertant colonies in the plates of negative control were within the range of literature cited spontaneous mutations and confirmed the sensitivity and specificity of the strains in the positive control plates.

For the strains TA97a, TA98, TA100 and TA102, the test substance did not induce a statistically significant increase in reverse mutations at the *His*<sup>+</sup> locus, and the frequency of the revertant colonies at all test concentrations was less than twice the frequency of the revertant colonies in the negative controls.

A weak statistical correlation for increased revertant colony counts in strain TA1535 was observed in certain of the four experiments, but only in the absence of a metabolic activation. However, the fold increase in mutant colonies (mutagenic index) did not meet the pre-established criteria for a positive response, and therefore was not considered biologically significant. A substance is mutagenic for strain TA1535 when the mutagenic index is  $\geq 3$ . In the original four experiments with this strain, and in seven supplemental experiments, the mutagenic index was less than three. These results confirmed the lack of reproducibility of the observed effect, and further confirmed the lack of treatment related effect. There was no indication of an increase in TA1535 revertant colonies in the presence of metabolic activation.

Therefore, the test substance is considered non-mutagenic under the conditions of this assay.

## SUMÁRIO EXECUTIVO

A substância teste SYN524464 FS (A16148F), uma formulação agrícola contendo o ingrediente ativo sedaxane (SYN524464), foi testada para indução de mutação reversa para o locus *his* em cinco linhagens de *Salmonella typhimurium* (TA97a, TA98, TA100, TA102 e TA1535) pelo método de pré-incubação em presença e em ausência de ativação metabólica de fração pós-mitocondrial de fígado de ratos induzido por Aroclor 1254 (S9).

As doses testadas foram 800, 1250, 2000, 3200 e 5000 µg de substância teste por placa.

Em todos experimentos foram incluídos o controle negativo (solvente) e o controle positivo indicado para cada linhagem. O número médio de colônias revertentes nas placas de controle negativo esteve dentro da faixa de frequência de mutação espontânea citada na literatura e confirmam a sensibilidade e especificidade das linhagens nas placas de controle positivo.

Para as linhagens TA97a, TA98, TA100 e TA102, a substância teste não induziu um aumento estatisticamente significativo de mutações reversas no locus *His*<sup>+</sup>, e a frequência de colônias revertentes em todas as concentrações testadas foram inferior ao dobro da frequência de colônias revertentes do controle negativo.

Foi observada uma correlação estatisticamente fraca devido ao aumento na contagem de colônias revertentes, em alguns dos quatro testes com a linhagem TA1535, mas somente na ausência de ativação metabólica. Entretanto, o número de vezes mais colônias mutantes (índice mutagênico) não satisfaz os critérios pré-estabelecidos para uma resposta positiva, e, portanto, não foi considerado biologicamente significativo. A substância é mutagênica para a linhagem TA1535 quando o índice mutagênico é  $\geq 3$ . Nos quatro testes originais com esta linhagem, e nos sete testes adicionais, o índice mutagênico foi menor que três. Estes resultados confirmam a perda de reprodutibilidade do efeito observado, e, além disto, confirmam a perda do efeito relacionado ao tratamento. Não existe indicação de um aumento de colônias revertentes na linhagem TA1535 na presença de ativação metabólica.

Portanto, a substância teste não foi considerada mutagênica sobre as condições do teste.

## 2.0 INTRODUCTION

The *Salmonella*/microsome test is commonly employed as an initial screen for genotoxic activity and, in particular, for point mutation-inducing activity, which involves substitution, addition or deletion of one or a few DNA base pairs.

An extensive data base has demonstrated that many chemicals that are positive in this test also exhibit mutagenic activity in other tests. It is a rapid test, inexpensive and relatively easy to perform.

The test uses *Salmonella typhimurium* bacteria strains that produce different mutations in the histidine operon, each of which is designed to be responsive to mutagens that act via different mechanisms.

Besides the mutations in the histidine operon, the strains present other mutations that increase the capacity to detect mutagenic substances, such as the expansion of the DNA sequences responsible for reversion sites, increased cell permeability to large molecules and elimination of DNA repair systems or enhancement of error-prone DNA repair processes.

The principle of this bacterial reverse mutation test is that it detects mutations present in the tester strains that restore the functional capability of the bacteria to synthesize an essential amino acid (histidine). The revertant bacteria are detected by their ability to grow in the absence of the amino acid (histidine) required by the parent tester strain.

### 2.1 Study dates

Study plan	: 27 Apr 2009
Experiment start	: 26 May 2009
Experiment end	: 12 Mar 2010
Final report	: 26 Mar 2010

## 3.0 MATERIALS AND METHODS

### 3.1 Test substance

Test substance name	: SYN524464 FS (A16148F)
Alias	: A16148F
Chemical name of a.i.	: Mixture of 2 cis-isomers 2'-[(1RS,2RS)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide and 2 trans-isomers 2'-[(1RS,2SR)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide
Common name of a.i.	: Sedaxane
Sponsor's Code for a.i.	: SYN524464
Activity	: Fungicide
CAS Number of a.i.	: 874967-67-6

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Form physical : Liquid  
Batch number : GP080609  
Test substance number : 2077  
Expiration date : 31 Jul 2010  
Packing opening date : 28 Apr 2009  
Stability : Stable for two years at room temperature  
Homogeneity : Visually homogeneous  
Declared a.i. content : 500 g/L  
Measured a. i. content : 498.8 g/L

The analysis of the active ingredient content was conducted by Bioensaios Análises e Consultoria Ambiental Ltda and results are presented in Appedix 1

### 3.2 Reference substances

Chemical name : 4- nitroquinoline-N-oxide (4-NQO)  
CAS number : 56-57-5  
Mark : Sigma-Aldrich  
Batch number : 067K1267  
Expiration date : 30 Apr 2010  
Purity : 100%

Chemical name : Sodium azide (NaZ)  
CAS number : 26628-22-8  
Mark : Labsynth  
Batch number : 1043043401  
Expiration date : August/2010  
Purity : 99%

Chemical name : 2-aminofluorene (2-AF)  
CAS number : 153-78-6  
Mark : Acros  
Batch number : A011750701  
Expiration date : 20 Mar 2008\*  
Purity : 98%

\* The response of diagnostic positive strain (mutagenicity index values inside the frequency ranges expected from the laboratory's historical control data and within the range reported in the literature) assured the validity of references substances, to the assay performed after expiration date.

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### 3.3 Procedures

Mutagenicity was assayed by the preincubation procedure modified in the absence and in the presence of 8% of a metabolic activation mixture (S-9 *mix*).

Triplicate sterile test tubes, protected against light, each containing different sample concentrations and controls, were incubated with 100  $\mu\text{L}$  ( $1-2 \times 10^9$  cells. $\text{mL}^{-1}$ ) of tester strain cultures and 2 mL of molten top agar supplemented with 0.5 mM histidine and biotin. Five hundred  $\mu\text{L}$  of the S9-mix was added to the tubes in the tests with metabolic activation.

The contents of the tubes was mixed and poured onto the surface of minimal agar plates.

After the top agar hardened the plates are inverted and incubated at  $37 \pm 1$  °C for 48h, at which time histidine-revertant colonies are counted on all plates.

#### 3.3.1 Test system (strains)

Five *Salmonella typhimurium* strains were used in this study, some of them producing revertants by frameshift mutations, through the addition or deletion of nucleotides within the DNA molecule (TA97a, TA98); others, by base-pair substitutions, transitions and transversions (TA100, TA102, TA1535).

The strains originated from master plates, or from cryogenic tubes containing cultures in glycerol or DMSO maintained in liquid nitrogen and incubated in nutrient broth with no antibiotics for the TA1535 strain, or containing ampicillin for the TA97a, TA98 and TA100 strains, and containing tetracycline for the TA102 strain. The incubation was carried out in an water bath at  $37 \pm 1$  °C, protected against light and under an aeration system.

The tester strains were analyzed for their genetic integrity (*his*, *rfa*, *uvrB-bio*), spontaneous mutation rate, and for the presence of plasmids pKM101 and pAQ1 whenever an experiment was performed.

#### Genotypes of the strains used for mutagenesis testing

strain	mutation	reversion event	LPS defect	deletion	mutation	Plasmid	spontaneous revertant
TA97a	<i>hisD6610</i>	frameshift mutations	<i>rfa</i>	$\Delta\text{uvrB}$	bio	pKM101	70-200
TA98	<i>hisD3052</i>	frameshift mutations	<i>rfa</i>	$\Delta\text{uvrB}$	bio	pKM101	20-50
TA100	<i>hisG46</i>	base-pair substitutions	<i>rfa</i>	$\Delta\text{uvrB}$	bio	pKM101	75-225
TA102	<i>hisG428</i>	base-pair substitutions	<i>rfa</i>	wild type	wild type	pKM101 pAQ1	100-300
TA1535	<i>hisG46</i>	base-pair substitutions	<i>rfa</i>	$\Delta\text{uvrB}$	bio	No plasmid	10-30

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*his*: mutation in the histidine operon; *ΔuvrB-bio*: deletion that affects the accurate DNA repair pathway and which makes the cells biotin dependent; *rfa*: mutation leads to a defective lipopolysaccharide (LPS) layer.

pKM101: enhances chemical and UV-induced mutagenesis via an increase in the error-prone recombination DNA repair pathway, confers ampicillin resistance.

pAQ1: multicopy plasmid which carries the *hisG428* mutation with the aim of amplifying the number of target sites and a tetracycline resistance gene.

### 3.3.2 Solutions and dose preparation

Test solution: test substance was weighed (about 100 mg) and suspended to a 1 mL volumetric flasks make up to H<sub>2</sub>O on each day of experimentation.

The test was performed with five concentrations of test substance with intervals selected on a log basis. The tested doses were 8, 12.5, 20; 32 and 50 µL per plate of the test solution that corresponded 800, 1250, 2000, 3200 and 5000 µg of the test substance per plate.

The test substance solution was homogeneous. The vehicle was chosen due to its solvent properties and known lack of toxicity to the bacteria.

### 3.3.3 Metabolic activation system (S-9 mix)

The test was carried out in the presence and absence of an exogenous metabolization system, which allows detection of substances with direct action on the cell's genetic material, as well as monitoring the positive or negative activity of the metabolites generated by biotransformation, to mimic what may occur in the liver.

The microsomal fraction employed in the metabolic activation system was acquired from Molecular Toxicology Inc (Moltox™), batch 2401, and prepared from livers of Sprague-Dawleys rats treated with Aroclor 1254 (mixture biphenyl polychlorinated - PCB), which induces a set of enzymes of the hepatic microsomal system. The S-9 *mix* is prepared according to the following table:

Ingredients	Quantity to prepare 50 mL S-9mix
Sterile bideionized H <sub>2</sub> O	17.75 mL
0.2 M Sodium phosphate buffer (pH 7.4)	25.00mL
0.1 M NADP	2.00mL
1 M glucose-6-phosphate	0.25mL
MgCl <sub>2</sub> / KCl salts	1.00mL
Rat liver S9 (suspended in 2.0 mL of sterile bideionized water)	4.0mL

### 3.3.4 Controls

Each experiment included a negative control (sterile bideionized water) and positive control to confirm the response and specificity of each tester strain and the efficiency of the metabolic activation system.

The following table lists the positive control chemicals with their respective concentration/plate that has been routinely used in the laboratory.

Chemical	Final concentration (µg/plate)	Strains	S-9 mix
4-nitroquinoline-N-oxide (4-NQO)	0.5	TA97a, TA98, TA102	-
Sodium azide (NaZ)	1	TA100, TA 1535	-
2-Aminofluorene (2-AF)	10	All strains	+

### 3.3.5 Analysis of Results

After the plates were removed from the incubator, the colonies were counted and the results were expressed as the mean number of revertant colonies per plate with standard deviation for the test substance and the controls. The number of control revertants was compared to the normal ranges for the revertant colonies mean number in this laboratory and in cited literature. The dose-response curves were statistically evaluated with the SALANAL program developed by the Environmental Monitoring Systems Laboratory, EPA – Software version 1.0 - 1993. This software predicts the dose-response relationship of these assays and can fit at least four regression models: CONSTANTE  $y = b$ ; LINEAR  $y = bx+a$ ; LINTOX 1 (linear attenuated by simple exponential toxicity)  $y = (bx+a)^{-T1x}$ ; LINTOX 2 (linear attenuated by exponential toxicity elevated to the second power)  $y = (bx+a)^{-T2x^2}$ .

The software also considers the BERNSTEIN model which consists of removing one or more doses from the analysis, using only results compatible with the linear model.

Through this analysis we obtained the statistical significance of:

- analysis of variance between the mean revertant number in the tested doses (test F), where the P values below or equal to 5% indicate significant differences;
- adjustment to the acceptable model: P values indicate the probability of adjustment to the most appropriate model. When these values are below 5% the program only calculates the variance;
- calculation of the positive trend of the dose-response curve: P values below or equal to 5% indicate that there is positive tendency in the curve.

When there is significant difference between the different doses and positive trend at the origin of the dose-response curve other parameters calculated by the program may be taken into account. The inclination of the straight line in the linear part of the dose-response curve provides an estimate of the number of induced revertants per tested sample unit (His<sup>+</sup>/µg of product). The program also sets the standard error and the 90% reliability interval of this determination.

### 3.3.5.1 Criteria for assay validation

The assays were considered valid if the following criteria are achieved:

- the mean number of negative control (solvent) revertants should be within the normal range (historical range of spontaneous revertants in this laboratory (mean  $\pm$ s.d.) and mentioned in the literature);
- the positive control must clearly induce an increase in the number of revertants, confirming the discrimination between different strains in the presence or absence of metabolic activation;
- the contamination rate must be below 5% of total plates used.

### 3.3.5.2 Results evaluation criteria

The test substance was deemed mutagenic if it reproducibly met the following criteria:

the increase in the mean number of revertants in the test plates was at least twice that found in the negative control plates (Mutagenic Index value, IM=2) for strains TA97a, TA98, TA100 or TA102 and at least three times that found in negative control (IM=3) for strains TA1535. A substance is mutagenic for strain TA1535 when the mutagenic index is  $\geq 3$ , due to the lower spontaneous mutation frequency and therefore more susceptibility to change in the reading of revertants.

AND

the results showed a statistically significant difference from control by ANOVA ( $P \leq 0.05$ ) or a significant dose-effect correlation ( $p \leq 0.05$ ).

## 4.0 RESULTS AND DISCUSSION

The test substance SYN524464 FS (A16148F) was tested for induction of reverse mutations in the *locus his* in five *Salmonella typhimurium* strains (TA97a, TA98, TA100, TA102 and TA1535) by the pre-incubation method, in the presence and absence of an exogenous metabolic activation system.

A preliminary toxicity test was performed under the same conditions as the final test, to determine an appropriate dose range, without inducing toxicity. The test substance did not show toxicity up to the recommended maximum test concentration by OECD 471 – 5000  $\mu\text{g}$  per plate (Table 1 - Tables Section).

The dose levels tested were; 800, 1250, 2000, 3200 and 5000  $\mu\text{g}$  of the test substance per plate (prepared according to item 3.3.2.). In one experiment, experiment 2 with strain TA1535 in the absence of metabolic activation, a higher dose level of 8000  $\mu\text{g}/\text{plate}$  was used. No test substance precipitation was observed in any experiments.

The quantity of active ingredient (Sedaxane or SYN524464) per plate was calculated using the test substance mass and the content of a.i. in the formulation given in the Certificate of Analysis (Appendix 1).

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response was observed in TA1535 in the presence of a metabolic activation system, or in any of the other tester strains in the presence or absence of metabolic activation.

## 5.0 CONCLUSION

The test substance SYN524464 FS (A16148F) is considered non-mutagenic under the conditions of this assay.

## 6.0 REFERENCES

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Viamão, 26 / Mar / 2010 .

  
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TABLES SECTION

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**TABLE 1** Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA100 after Treatment with the Test Substance in the Absence and Presence of Metabolic Activation (preliminary test).

26/05/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate -S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	170	179	182	177.00 ± 6.24	-
ST	8	167	139	139	148.33 ± 16.17	0.84
ST	40	180	193	167	180.00 ± 13.00	1.02
ST	200	154	178	200	177.33 ± 23.01	1.00
ST	1000	202	200	196	199.33 ± 3.06	1.13
ST	5000	175	154	200	176.33 ± 23.03	1.00
CP (NaZ)	1	1288	1512	-	1400.00 ± 158.39	7.91

CN: negative control; CP: positive control; ST: test substance.

28/05/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	171	167	165	167.67 ± 3.06	-
ST	8	156	163	172	163.67 ± 8.02	0.98
ST	40	166	148	152	155.33 ± 9.45	0.93
ST	200	149	155	167	157.00 ± 9.17	0.94
ST	1000	153	161	168	160.67 ± 7.51	0.96
ST	5000	150	153	144	149.00 ± 4.58	0.89
CP (2-AF)	10	1106	1002	-	1054.00 ± 73.54	6.29

CN: negative control; CP: positive control; ST: test substance.



**Continued TABLE 2 Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA97a after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

09/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	130	160	156	148.67 ± 16.29	-
ST	800	158	130	163	150.33 ± 17.79	1,01
ST	1250	143	130	158	143.67 ± 14.01	0.97
ST	2000	128	135	177	146.67 ± 26.50	0.99
ST	3200	123	132	121	125.33 ± 5.86	0.84
ST	5000	166	145	161	157.33 ± 10.97	1.06
CP (2-AF)	10	952	896	-	924.00 ± 39.60	6.22

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.266

Acceptable model (P): Linear 0.186

P dose response: 0.589

Results: negative

Revertants/mL: -

Confidence limits: -

20/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	127	119	143	129.67 ± 12.22	-
ST	800	132	126	129	129.00 ± 3.00	0.99
ST	1250	120	121	118	119.67 ± 1.53	0.92
ST	2000	114	137	125	125.33 ± 11.50	0.97
ST	3200	134	144	110	129.33 ± 17.47	1.00
ST	5000	121	125	119	121.67 ± 3.06	0.94
CP (2-AF)	10	1090	987	-	1038.50 ± 72.83	8.01

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.717

Acceptable model (P): Linear 0.658

P dose response: 0.734

Results: negative

Revertants/mL: -

Confidence limits: -

**TABLE 3 Reverse Mutation His<sup>+</sup> Frequency in Salmonella typhimurium TA98 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

30/06/09

Substance	Dose (µg/plate)	Revertants His <sup>+</sup> /plate -S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	28	22	22	24.00 ± 3.46	-
ST	800	25	27	30	27.33 ± 2.52	1.14
ST	1250	21	28	21	23.33 ± 4.04	0.97
ST	2000	25	24	26	25.00 ± 1.00	1.04
ST	3200	28	32	24	28.00 ± 4.00	1.17
ST	5000	25	22	30	25.67 ± 4.04	1.07
CP(4-NQO)	0.5	870	540	-	705.00 ± 233.35	29.38

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.531

Acceptable model (P): Linear 0.480

P dose response: 0.223

Results: negative

Revertants/mL: -

Confidence limits: -

08/07/09

Substance	Dose (µg/plate)	Revertants His <sup>+</sup> /plate -S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	20	25	18	21.00 ± 3.61	-
ST	800	19	21	21	20.33 ± 1.15	0.97
ST	1250	22	28	26	25.33 ± 3.06	1.21
ST	2000	16	19	18	17.67 ± 1.53	0.84
ST	3200	19	23	21	21.00 ± 2.00	1.00
ST	5000	13	21	20	18.00 ± 4.36	0.86
CP(4-NQO)	0.5	538	630	-	584.00 ± 65.05	27.81

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.095

Acceptable model (P): Linear 0.109

P dose response: 0.935

Results: negative

Revertants/mL: -

Confidence limits: -

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**Continued TABLE 3 Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA98 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

16/06/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard		Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3			
CN	0	31	32	28	30.33	± 2.08	-
ST	800	29	27	23	26.33	± 3.06	0.87
ST	1250	22	28	31	27.00	± 4.58	0.89
ST	2000	19	34	26	26.33	± 7.51	0.87
ST	3200	28	33	22	27.67	± 5.51	0.91
ST	5000	25	31	31	29.00	± 3.46	0.96
CP (2-AF)	10	870	982	-	926.00	± 79.20	30.53

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.893

Acceptable model (P): Linear 0.810

P dose response: 0.453

Results: negative

Revertants/mL: -

Confidence limits: -

09/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard		Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3			
CN	0	28	21	26	25.00	± 3.61	-
ST	800	20	26	29	25.00	± 4.58	1.00
ST	1250	20	24	21	21.67	± 2.08	0.87
ST	2000	21	25	27	24.33	± 3.06	0.97
ST	3200	24	30	31	28.33	± 3.79	1.13
ST	5000	22	21	26	23.00	± 2.65	0.92
CP (2-AF)	10	1120	1288	-	1204.00	± 118.79	48.16

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.325

Acceptable model (P): Linear 0.230

P dose response: 0.510

Results: negative

Revertants/mL: -

Confidence limits: -

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**TABLE 4 Reverse Mutation *His<sup>+</sup>* Frequency in *Salmonella typhimurium* TA100 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

16/06/09

Substance	Dose (µg/plate)	Revertants <i>His<sup>+</sup></i> /plate --S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	158	140	162	153.33 ± 11.72	-
ST	800	141	136	176	151.00 ± 21.79	0.98
ST	1250	152	170	166	162.67 ± 9.45	1.06
ST	2000	149	108	139	132.00 ± 21.38	0.86
ST	3200	141	169	129	146.33 ± 20.53	0.95
ST	5000	153	171	157	160.33 ± 9.45	1.05
CP (NaZ)	1	1680	1456	-	1568.00 ± 158.39	10.23

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.310

Acceptable model (P): Linear 0.220

P dose response: 0.425

Results: negative

Revertants/mL: -

Confidence limits: -

10/09/09

Substance	Dose (µg/plate)	Revertants <i>His<sup>+</sup></i> /plate --S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	191	178	169	179.33 ± 11.06	-
ST	800	141	171	152	154.67 ± 15.18	0.86
ST	1250	135	187	167	163.00 ± 26.23	0.91
ST	2000	158	138	184	160.00 ± 23.07	0.89
ST	3200	161	159	188	169.33 ± 16.20	0.94
ST	5000	141	136	133	136.67 ± 4.04	0.76
CP (NaZ)	1	1456	1232	-	1344.00 ± 158.39	7.49

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.120

Acceptable model (P): Linear 0.344

P dose response: 0.985

Results: negative

Revertants/mL: -

Confidence limits: -

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**Continued TABLE 4 Reverse Mutation His<sup>+</sup> Frequency in Salmonella typhimurium TA100 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

22/09/09

Substance	Dose (µg/plate)	Revertants His <sup>+</sup> /plate -S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	165	186	208	186.33 ± 21.50	-
ST	1250	227	183	165	191.67 ± 31.90	1.03
ST	2000	170	201	203	191.33 ± 18.50	1.03
ST	3200	214	110	144	156.00 ± 53.03	0.84
ST	5000	211	164	165	180.00 ± 26.85	0.97
ST	8000	162	165	164	163.67 ± 1.53	0.88
CP (NaZ)	1	1176	896	-	1036.00 ± 197.99	5.56

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.602

Acceptable model (P): Linear 0.662

P dose response: 0.861

Results: negative

Revertants/mL: -

Confidence limits: -

25/09/09

Substance	Dose (µg/plate)	Revertants His <sup>+</sup> /plate -S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	111	100	118	109.67 ± 9.07	-
ST	800	159	112	110	127.00 ± 27.73	1.16
ST	1250	131	120	134	128.33 ± 7.37	1.17
ST	2000	113	105	104	107.33 ± 4.93	0.98
ST	3200	110	96	108	104.67 ± 7.57	0.95
ST	5000	124	128	98	116.67 ± 16.29	1.06
CP (NaZ)	1	1344	872	-	1108.00 ± 333.75	10.10

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.247

Acceptable model (P): Linear 0.183

P dose response: 0.712

Results: negative

Revertants/mL: -

Confidence limits: -

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**Continued TABLE 4 Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA100 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

07/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	159	137	160	152.00 ± 13.00	-
ST	800	190	181	190	187.00 ± 5.20	1.23
ST	1250	161	190	159	170.00 ± 17.35	1.12
ST	2000	177	158	148	161.00 ± 14.73	1.06
ST	3200	185	189	140	171.33 ± 27.21	1.13
ST	5000	176	151	138	155.00 ± 19.31	1.02
CP (2-AF)	10	1456	1512	-	1484.00 ± 39.60	9.76

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.252

Acceptable model (P): Linear 0.185

P dose response: 0.692

Results: negative

Revertants/mL: -

Confidence limits: -

01/09/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	122	124	171	139.00 ± 27.73	-
ST	800	80	93	110	94.33 ± 15.04	0.68
ST	1250	130	152	117	133.00 ± 17.69	0.96
ST	2000	148	163	140	150.33 ± 11.68	1.08
ST	3200	133	130	176	146.33 ± 25.74	1.05
ST	5000	105	125	86	105.33 ± 19.50	0.76
CP (2-AF)	10	896	786	-	841.00 ± 77.78	6.05

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.016

Acceptable model (P): Linear 0.100

P dose response: 0.802

Results: negative

Revertants/mL: -

Confidence limits: -

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**Continued TABLE 4 Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA100 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

09/09/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	116	118	148	127.33 ± 17.93	-
ST	800	105	159	104	122.67 ± 31.47	0.96
ST	1250	139	119	124	127.33 ± 10.41	1.00
ST	2000	155	113	145	137.67 ± 21.94	1.08
ST	3200	125	133	122	126.67 ± 5.69	0.99
ST	5000	102	100	89	97.00 ± 7.00	0.76
CP (2-AF)	10	1288	1568	-	1428.00 ± 197.99	11.21

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.122

Acceptable model (P): Linear 0.372

P dose response: 0.986

Results: negative

Revertants/mL: -

Confidence limits: -

13/10/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	153	195	131	159.67 ± 32.52	-
ST	1250	158	174	130	154.00 ± 22.27	0.96
ST	2000	120	160	125	135.00 ± 21.79	0.85
ST	3200	109	132	159	133.33 ± 25.03	0.84
ST	5000	166	179	125	156.67 ± 28.18	0.98
ST	8000	150	123	186	153.00 ± 31.61	0.96
CP (2-AF)	10	1680	1288	-	1484.00 ± 277.19	9.29

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.722

Acceptable model (P): Linear 0.601

P dose response: 0.452

Results: negative

Revertants/mL: -

Confidence limits: -

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**RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS**  
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**TABLE 5** Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA102 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation

20/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate –S9			Mean ± Deviation standard			Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3				
CN	0	202	205	230	212.33	±	15.37	-
ST	800	201	180	180	187.00	±	12.12	0.88
ST	1250	176	228	182	195.33	±	28.45	0.92
ST	2000	187	184	180	183.67	±	3.51	0.86
ST	3200	185	180	184	183.00	±	2.65	0.86
ST	5000	190	184	188	187.33	±	3.06	0.88
CP(4-NQO)	0.5	1176	1232		1204.00	±	39.60	5.67

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.202

Acceptable model (P): Linear 0.286

P dose response: 0.945

Results: negative

Revertants/mL: -

Confidence limits: -

09/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate –S9			Mean ± Deviation standard			Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3				
CN	0	212	221	227	220.00	±	7.55	-
ST	800	200	237	213	216.67	±	18.77	0.98
ST	1250	214	235	210	219.67	±	13.43	1.00
ST	2000	236	219	199	218.00	±	18.52	0.99
ST	3200	135	198	196	176.33	±	35.81	0.80
ST	5000	218	231	201	216.67	±	15.04	0.98
CP(4-NQO)	0.5	807	803		805.00	±	2.83	3.66

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.106

Acceptable model (P): Linear 0.100

P dose response: 0.896

Results: negative

Revertants/mL: -

Confidence limits: -

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**Continued TABLE 5 Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA102 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

21/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard		Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3			
CN	0	236	247	251	244.67	± 7.77	-
ST	800	233	230	265	242.67	± 19.40	0.99
ST	1250	258	257	219	244.67	± 22.23	1.00
ST	2000	239	243	238	240.00	± 2.65	0.98
ST	3200	239	261	256	252.00	± 11.53	1.03
ST	5000	243	118	231	197.33	± 68.97	0.81
CP (2-AF)	10	903	1012		957.50	± 77.07	3.91

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.374

Acceptable model (P): Linear 0.678

P dose response: 0.958

Results: negative

Revertants/mL: -

Confidence limits: -

30/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard		Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3			
CN	0	220	263	233	238.67	± 22.05	-
ST	800	255	248	274	259.00	± 13.45	1.09
ST	1250	235	220	220	225.00	± 8.66	0.94
ST	2000	243	239	200	227.33	± 23.76	0.95
ST	3200	282	299	273	284.67	± 13.20	1.19
ST	5000	200	243	245	229.33	± 25.42	0.96
CP (2-AF)	10	1904	1806	-	1855.00	± 69.30	7.77

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.023

Acceptable model (P): Bernstein 0.408

P dose response: 0.871

Results: negative

Revertants/mL: -

Confidence limits: -

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**TABLE 6** Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA1535 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation

21/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate -S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	20	26	25	23.67 ± 3.21	-
ST	800	38	32	28	32.67 ± 5.03	1.38
ST	1250	47	28	27	34.00 ± 11.27	1.44
ST	2000	38	31	26	31.67 ± 6.03	1.34
ST	3200	48	44	45	45.67 ± 2.08	1.93
ST	5000	50	49	43	47.33 ± 3.79	2.00
CP (NaZ)	1	1400	1120	-	1260.00 ± 197.99	53.24

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.005

Results: significant ANOVA and trend test.

Acceptable model (P): Linear 0.402%

Revertants/mL: <0.003147, 0.006500>.

P dose response: < 0.001

Confidence limits: -

09/09/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate -S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	17	18	12	15.67 ± 3.21	-
ST	800	17	23	30	23.33 ± 6.51	1.49
ST	1250	18	19	30	22.33 ± 6.66	1.43
ST	2000	18	28	26	24.00 ± 5.29	1.53
ST	3200	36	28	31	31.67 ± 4.04	2.02
ST	5000	28	18	32	26.00 ± 7.21	1.66
CP (NaZ)	1	780	940	-	860.00 ± 113.14	54.89

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.063

Results: significant trend test

Acceptable model (P): Linear 0.284

Revertants/mL: <0.000905, 0.003712>

P dose response: 0.006

Confidence limits: -

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório, BPL

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**Continued TABLE 6 Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA1535 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

10/09/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate –S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	30	28	26	28.00 ± 2.00	-
ST	800	37	28	23	29.33 ± 7.09	1.05
ST	1250	30	43	30	34.33 ± 7.51	1.23
ST	2000	34	36	29	33.00 ± 3.61	1.18
ST	3200	37	43	30	36.67 ± 6.51	1.31
ST	5000	36	33	28	32.33 ± 4.04	1.15
CP (NaZ)	1	728	915	-	821.50 ± 132.23	29.34

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.434

Acceptable model (P): Linear 0.515

P dose response: 0.102

Results: negative

Revertants/mL: -

Confidence limits: -

13/10/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate –S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	20	20	19	19.67 ± 0.58	-
ST	1250	29	27	25	27.00 ± 2.00	1.37
ST	2000	25	30	38	31.00 ± 6.56	1.58
ST	3200	32	25	27	28.00 ± 3.61	1.42
ST	5000	44	28	44	38.67 ± 9.24	1.97
ST	8000	24	37	48	36.33 ± 12.01	1.85
CP (NaZ)	1	1344	1008	-	1176.00 ± 237.59	59.80

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.018

Acceptable model (P): Linear 0.335

P dose response: <0.001

Results: significant ANOVA and trend test

Revertants/mL: <0.001990, 0.005129>

Confidence limits: -

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Este informe contém os resultados de testes e outros dados não divulgados  
Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório - BPL da SYNGENTA PROTEÇÃO DE CULTIVOS LTDA., protegidos na forma da Lei 10.603/02 e do artigo 195, XIV da Lei 9.279/96

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**Continued TABLE 6 Reverse Mutation *His*<sup>+</sup> Frequency in *Salmonella typhimurium* TA1535 after Treatment with the Test Substance, Pre-incubation Method in the Absence or Presence of Metabolic Activation**

21/07/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	26	24	21	23.67 ± 2.52	-
ST	800	24	28	28	26.67 ± 2.31	1.13
ST	1250	29	26	26	27.00 ± 1.73	1.14
ST	2000	29	30	24	27.67 ± 3.21	1.17
ST	3200	34	24	22	26.67 ± 6.43	1.13
ST	5000	21	27	28	25.33 ± 3.79	1.07
CP (2-AF)	10	870	930	-	900.00 ± 42.43	38.03

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.770

Results: negative

Acceptable model (P): Linear 0.667

Revertants/mL: -

P dose response: 0.386

Confidence limits: -

09/09/09

Substance	Dose (µg/plate)	Revertants <i>His</i> <sup>+</sup> /plate +S9			Mean ± Deviation standard	Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3		
CN	0	21	28	26	25,00 ± 3,61	-
ST	800	29	32	35	32,00 ± 3,00	1,28
ST	1250	11	34	45	30,00 ± 17,35	1,20
ST	2000	19	11	18	16,00 ± 4,36	0,64
ST	3200	27	33	35	31,67 ± 4,16	1,27
ST	5000	18	27	21	22,00 ± 4,58	0,88
CP (2-AF)	10	1456	1120	-	1288,00 ± 237,59	51,52

CN: negative control; CP: positive control; ST: test substance.

P ANOVA: 0.073

Results: negative

Acceptable model (P): Bernstein 0.050

Revertants/mL: -

P dose response: 0.700

Confidence limits: -

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## APPENDIX 2 Quality Control Statement of Microsomal Fraction

**MICROTOX POST MITOCHONDRIAL SUPERNATANT (S-9)**  
**QUALITY CONTROL STATEMENT**

LOT NO.: 1401	SPECIES: Rat	PREPARATION DATE: April 16, 2009
PART NO.: 11-01L	STRAIN: Sprague Dawley	EXPIRATION DATE: April 16, 2011
VOLUME: 2.1 ml	SEX: Male	BUFFER: 0.154 M KCl Trisphosphate buffer
STORAGE: At or below -20°C	TISSUE: Liver	INDUCING AGENT(s): Aroclor 1254 Monazine Lot No. KL613

**BIOCHEMISTRY:**

**- PROTEIN:**

37.9 mg/ml

Assayed according to the method of Lowry et al. JBC 193:265, 1951 using bovine serum albumin as the standard

**- ALKOXYRESORUFIN-O-DEALKYLASE ACTIVITIES**

Activity	SA <sub>50</sub>	Fold - Induction	Assays for ethoxyresorufin-O-deethylase (EROD), pentoxy-, methoxy- and benzyloxyresorufin-O-dealkylases
EROD	1A1, 1A2	34.2	MROD & BROD) were conducted
PROD.	PROD	1B1, 3B2	105.7 inductions calculated as the
using a modification of the			control specific activities (SA). Control
Shore 34: 3337, 1981. Fold-		MROD	1A2
ratio of the sample vs. uninduced			
SA's (pmoles/min/mg		BROD	3A, 2B
EROD PROD.			27.0
			8.6 for
			MROD & BROD, respectively.

**BIOASSAY:**

**- TEST FOR THE PRESENCE OF ADVENTITIOUS AGENTS**

Samples of S-9 were assayed for the presence of contaminating microfungi by plating 1.0 ml volumes on Nutrient Agar and Minimal Glucose (Vogel-Bounar E, supplemented with 0.05 mM L-threonine and D-biotin) media. Duplicate plates were read after 24 - 48 h incubation at 35 ± 2°C. The tested samples met acceptance criteria.

**- PROMUTAGEN ACTIVATION**

No. His <sup>+</sup> Revertants	TA98	TA1535
	467.6	918

The ability of the sample to activate ethidium bromide (EtBr), EtBr CPA and cyclophosphamide (CPA) to intermediates mutagenic to TA98 and TA1535, respectively, was determined according to Leica et al. *Mutation Res* 129:299, 1984. Data were expressed as revertants per µg EtBr or per mg CPA.

Dilutions of the sample S-9, ranging from 0.1 - 10%, in S-9 mix, were tested for their ability to activate benzo(a)pyrene (BP) and 2-aminofluorene (2-AA) to intermediates mutagenic to TA100. Assays were conducted using duplicate plates as described by Maron & Ames (*Mutat Res* 113:173, 1983).

µl S-9 per plate number his<sup>+</sup> revertants per plate

Promutagen	0	1	5	10	20	50
BP (5 µg)	107	107	525	929	1155	936
2-AA (2.5 µg)	109	583	2093	2440	2499	1385

**MOLECULAR TOXICOLOGY, INC.**

151 Industrial Park Dr.  
Boone, NC 28607  
(828) 284-0100  
www.mto.com

Approved: [Signature] 4/20/09

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**RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS**

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APPENDICES SECTION

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Lei 9.279/96

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## APPENDIX 1 Analytical determination of Active Ingredient

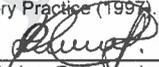
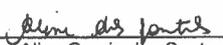
### CERTIFICATE OF ANALYSIS (SUMMARY OF THE REPORT - 2077-CRO-078-09-Rev01)

Test substance name	: SYN524464 FS (A16148F)
Alias	: A16148F
Chemical name of a.i.	: Mixture of 2 cis-isomers 2'-[(1RS,2RS)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide and 2 trans-isomers 2'-[(1RS,2SR)-1,1'-bicycloprop-2-yl]-3-(difluoromethyl)-1-methylpyrazole-4-carboxanilide
Common name of a.i.	: Sedaxane
Batch of test substance	: GP080609
Test substance number	: 2077
Expiration date	: 31 Jul 2010
Packing opening date	: 28 Apr 2009
Stability	: Stable for 2 years at room temperature
Homogeneity	: Visually homogeneous
Declared a.i. content	: 500 g/L

Sponsor	: Syngenta Proteção de Cultivos Ltda Av. das Nações Unidas, 18001 – 2 <sup>nd</sup> floor 04795-900 - São Paulo - SP - Brazil
Testing facility	: Bioensaios Análises e Consultoria Ambiental Ltda. Palermo Street, 257 - CEP 94480-775 - Viamão - RS - Brazil

### ANALYTICAL RESULTS

<u>Chemical Analysis</u>	
Active ingredient content:	498.8 g/L of Sedaxane
<u>Analytical Method</u>	
Liquid chromatography with external standardization.	

GLP COMPLIANCE STATEMENT	QUALITY ASSURANCE STATEMENT
I declare that the Certificate of Analysis reflects the Raw Data obtained. I declare that preparation for the Study of the Certificate was conducted in accordance with the principles of Good Laboratory Practice for - GLP, standards INMETRO-NIT-DICLA-035 to 041 (Jul/2009), Based on OECD-Principles on Good Laboratory Practice (1997).	I declare that the Certificate of Analysis has been reviewed and that reflects the Raw Data, not observed deviations or nonconformance that could affect the quality of results.
 Shana Feiner Robaina dos Santos Study Director	 Aline Garcia dos Santos Quality Assurance Sector
22/Mar/2010 Date	22/Mar/2010 Date

The test substance in this study is a formulation, SYN524464 FS (A16148F). The active ingredient (SYN524464 or sedaxane) is present at a nominal concentration of 500 g/L.

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## APPENDIX 2 Quality Control Statement of Microsomal Fraction

MOLTOX POST MITOCHONDRIAL SUPERNATANT (S-9) QUALITY CONTROL STATEMENT		
LOT NO.: 1401	SPECIES: Rat	PREPARATION DATE: April 16, 2009
PART NO.: 11-01L	STRAIN: Sprague Dawley	EXPIRATION DATE: April 16, 2011
VOLUME: 2.1 ml	SEX: Male	BUFFER: 0.154 M KCl Trisphosphate buffer
STORAGE: At or below -20°C	TISSUE: Liver	INDUCING AGENT(s): Aroclor 1254 Monazine Lot No. KL613

### BIOCHEMISTRY:

#### - PROTEIN:

37.9 mg/ml

Assayed according to the method of Lowry et al. JBC 193:265, 1951 using bovine serum albumin as the standard

#### - ALKOXYRESORUFIN-O-DEALKYLASE ACTIVITIES

Activity	Substrate	Fold-Induction	Assays for ethoxyresorufin-O-deethylase (EROD), pentoxy-, methoxy- and benzyloxyresorufin-O-dealkylases (MROD, & BROD) were conducted using a modification of the Shuster 34: 3337, 1981. Fold-ratio of the sample vs. uninduced SA's (pmoles/min/mg EROD PROD.
EROD	1A1, 1A2	34.2	
PROD	PROD	1B1, 3B2	33.4
	MROD	1A2	105.7
	BROD	3A, 2B	27.0

### BIOASSAY:

#### - TEST FOR THE PRESENCE OF ADVENTITIOUS AGENTS

Samples of S-9 were assayed for the presence of contaminating microfungi by plating 1.0 ml volumes on Nutrient Agar and Minimal Glucose (Vogel-Bounar E, supplemented with 0.05 mM L-threonine and D-biotin) media. Duplicate plates were read after 24 - 48 h incubation at 35 ± 2°C. The tested samples met acceptance criteria.

#### - PROMUTAGEN ACTIVATION

No. His<sup>+</sup> Revertants: The ability of the sample to activate ethidium bromide (EtBr) EtBr CPA and cyclophosphamide (CPA) to intermediates mutagenic to TASS and TA1538, respectively, was determined according to Leica et al. *Mutation Res* 129:299, 1984. Data were expressed as revertants per µg EtBr or per mg CPA.

TASS	TA1538
467.6	918

Dilutions of the sample S-9, ranging from 0.1 - 10%, in S9 mix, were tested for their ability to activate benzo(a)pyrene (BP) and 2-aminofluorene (2-AA) to intermediates mutagenic to TA100. Assays were conducted using duplicate plates as described by Maron & Ames (*Mutat. Res.* 113:173, 1983).

µl S9 per plate number his<sup>+</sup> revertants per plate

Promutagen	0	1	5	10	20	50
BP (5 µg)	107	107	525	929	1155	936
2-AA (2.5 µg)	109	583	2093	2440	2499	1385

### MOLECULAR TOXICOLOGY, INC.

157 Industrial Park Dr.  
Boone, NC 28607  
(828) 284-0100  
www.moltox.com

Approved: [Signature] 4/20/09

Best available copy.

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#### RESULTADOS DE TESTES E OUTROS DADOS NÃO DIVULGADOS

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### APPENDIX 3 Statistical analysis (Program SALANAL)

\*\*\*\*\* SALANAL: record 1 \*\*\*\*\*

Test Sample Name: Sedaxane  
 Source/Batch/Lot: GP080609  
 Solvent: Agua bideionizada  
 Exp. Date: 30/06/2009  
 Exp. No.: 2077  
 Technician:  
 Assay Type: Preincubation - Time [20min ] Temp [37C ]  
 Strain: TA97a

Metabolic activation: None

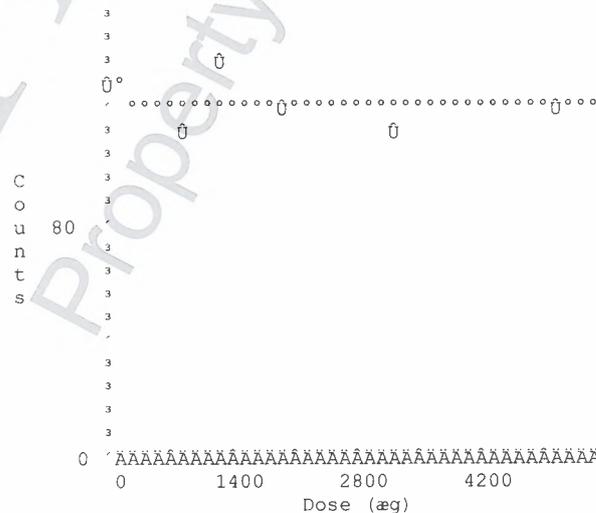
Data File Name: C:\DOCUME-1\TEMP\DESKTOP\SALANA-1\2077C

Code	Dose	counts	Mean	S.D.	Predicted Linear
0.00	133	129 121	127.67	6.11	124.25
800.00	129	119 99	115.67	15.28	123.20
1250.00	142	135 137	138.00	3.61	122.60
2000.00	138	90 125	117.67	24.83	121.61
3200.00	114	108 113	111.67	3.21	120.03
5000.00	138	122 111	123.67	13.58	117.66
p	0.50	1100p 1002p			

P-value for ANOVA test of dose response is 0.308  
 ANOVA test is not significant. Other significant results should be viewed with caution.  
 An acceptable model is Linear with pval = 0.242

Estimate of the slope is = -0.001318 .  
 Standard error of the slope is = 0.001980 .  
 90% confidence limits for the slope are <-0.004847, 0.002210>.

P-value for the test of the positive dose response (slope at origin) is 0.741  
 Note: Smaller P-value means more positive dose response



û = Observed; ° = Predicted.  
 The predicted values are based on Linear model.

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\*\*\*\*\* SALANAL: record 1 \*\*\*\*\*

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 08/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA97a

Metabolic activation: None

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077

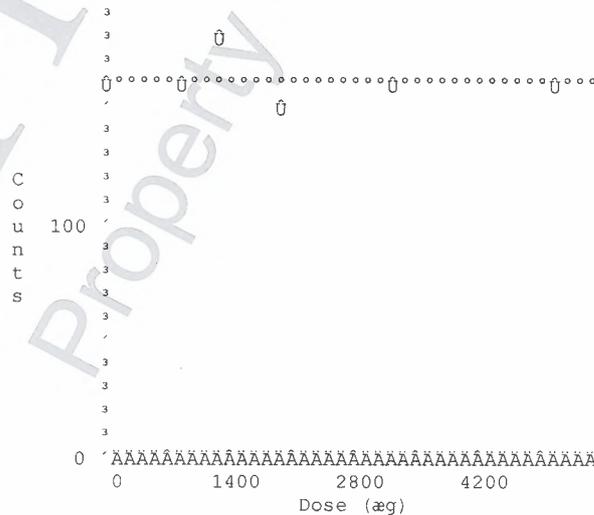
Code	Dose	counts	Mean	S.D.	Predicted Linear
0.00	160	158 164	160.67	3.06	161.78
800.00	136	158 185	159.67	24.54	161.56
1250.00	187	168 172	175.67	10.02	161.44
2000.00	162	134 161	152.33	15.89	161.24
3200.00	156	156 164	158.67	4.62	160.91
5000.00	167	183 139	163.00	22.27	160.43
p	0.50	980p 960p			

P-value for ANOVA test of dose response is 0.647  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Linear with pval = 0.522

Estimate of the slope is = -0.000271 .  
Standard error of the slope is = 0.002257 .  
90% confidence limits for the slope are <-0.004293, 0.003751>.

P-value for the test of the positive dose response (slope at origin) is 0.547  
Note: Smaller P-value means more positive dose response



û = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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\*\*\*\*\* SALANAL: record 2 \*\*\*\*\*

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 20/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA97a

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor  
S9 concentration ... 0.50

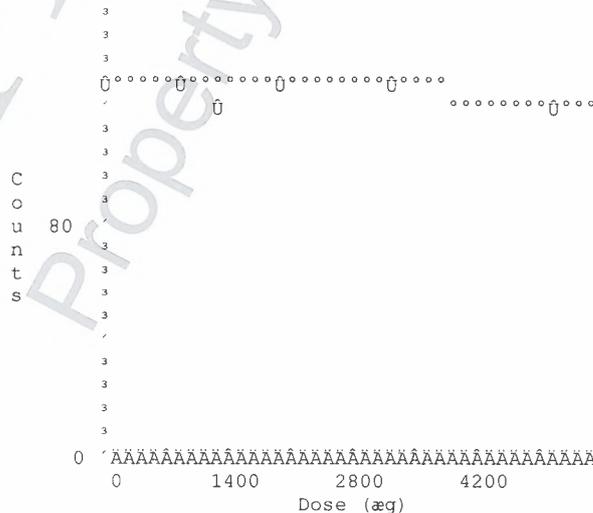
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077C

Code	Dose	--	counts	--	Mean	S.D.	Predicted Linear
	0.00	127	119	143	129.67	12.22	127.46
	800.00	132	126	129	129.00	3.00	126.74
	1250.00	120	121	118	119.67	1.53	126.33
	2000.00	114	137	125	125.33	11.50	125.66
	3200.00	134	144	110	129.33	17.47	124.57
	5000.00	121	125	119	121.67	3.06	122.95
p	10.00	1090p	987p				

P-value for ANOVA test of dose response is 0.717  
ANOVA test is not significant. Other significant results  
should be viewed with caution.  
An acceptable model is Linear with pval = 0.658

Estimate of the slope is = -0.000903 .  
Standard error of the slope is = 0.001404 .  
90% confidence limits for the slope are <-0.003404, 0.001599>.

P-value for the test of the positive dose response  
(slope at origin) is 0.734  
Note: Smaller P-value means more positive dose response



U = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Lei 9.279/96

+++++ SALANAL: record 2 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 09/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA97a

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor 1254  
S9 concentration ... 0.50

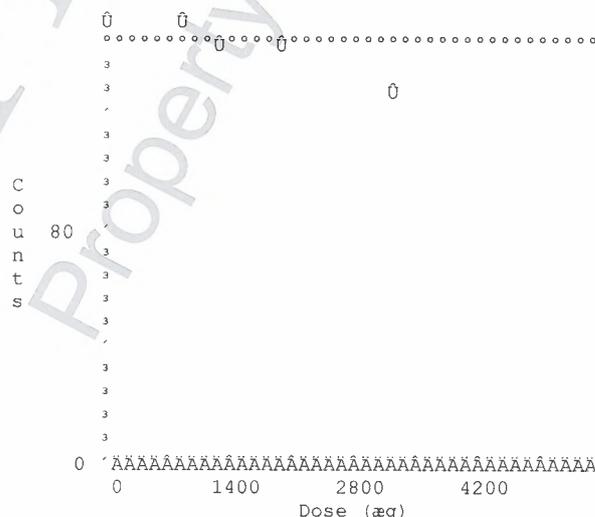
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077

Code	Dose	counts	Mean	S.D.	Predicted Linear
0.00	130	160 156	148.67	16.29	145.35
800.00	158	130 163	150.33	17.79	144.91
1250.00	143	130 158	143.67	14.01	144.66
2000.00	128	135 177	146.67	26.50	144.25
3200.00	123	132 121	125.33	5.86	143.60
5000.00	166	145 161	157.33	10.97	142.61
p	10.00	952p 896p			

P-value for ANOVA test of dose response is 0.266  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.186

Estimate of the slope is = -0.000547 .  
Standard error of the slope is = 0.002388 .  
90% confidence limits for the slope are <-0.004804, 0.003710>.

P-value for the test of the positive dose response (slope at origin) is 0.589  
Note: Smaller P-value means more positive dose response



û = Observed; ° = Predicted.  
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+++++ SALANAL: record 3 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 30/06/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA98

Metabolic activation: None

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	28 22 22	24.00	3.46	24.64
	800.00	25 27 30	27.33	2.52	24.95
	1250.00	21 28 21	23.33	4.04	25.12
	2000.00	25 24 26	25.00	1.00	25.40
	3200.00	28 32 24	28.00	4.00	25.86
	5000.00	25 22 30	25.67	4.04	26.54
p	0.50	870p 540p			

P-value for ANOVA test of dose response is 0.531  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.480

Estimate of the slope is = 0.000379 .  
Standard error of the slope is = 0.000481 .  
90% confidence limits for the slope are <-0.000478, 0.001236>.

P-value for the test of the positive dose response (slope at origin) is 0.223  
Note: Smaller P-value means more positive dose response



û = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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\*\*\*\*\* SALANAL: record 3 \*\*\*\*\*

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 08/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA98

Metabolic activation: None

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077C

Code	Dose	--	counts	--	Mean	S.D.	Predicted Linear
	0.00	20	25	18	21.00	3.61	21.54
	800.00	19	21	21	20.33	1.15	21.02
	1250.00	22	28	26	25.33	3.06	20.73
	2000.00	16	19	18	17.67	1.53	20.25
	3200.00	19	23	21	21.00	2.00	19.47
	5000.00	13	21	20	18.00	4.36	18.31
p	0.50	538p	630p				

P-value for ANOVA test of dose response is 0.095  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.109

Estimate of the slope is = -0.000646 .  
Standard error of the slope is = 0.000397 .  
90% confidence limits for the slope are <-0.001353, 0.000061>.

P-value for the test of the positive dose response (slope at origin) is 0.935  
Note: Smaller P-value means more positive dose response



Ū = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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\*\*\*\*\* SALANAL: record 4 \*\*\*\*\*

Test Sample Name: Sedaxane  
 Source/Batch/Lot: GP080609  
 Solvent: Agua bideionizada  
 Exp. Date: 16/06/2009  
 Exp. No.: 2077  
 Technician:  
 Assay Type: Preincubation - Time [20min ] Temp [37C ]  
 Strain: TA98

Metabolic activation species..... rat  
 organ ..... liver  
 inducer ..... Aroclor 1254  
 S9 concentration ... 0.50

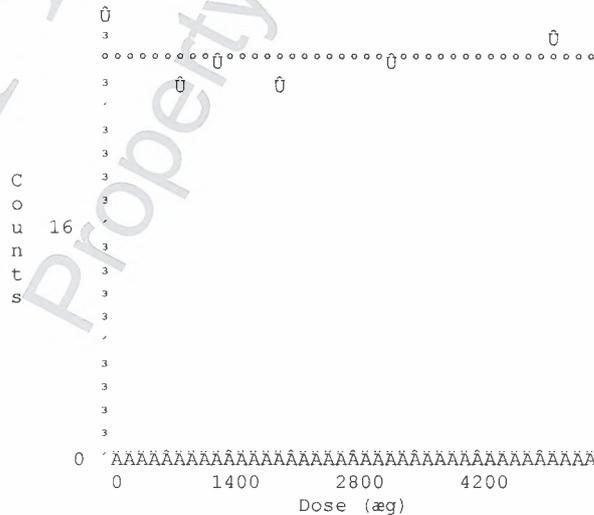
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077C

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	31 32 28	30.33	2.08	27.49
	800.00	29 27 23	26.33	3.06	27.56
	1250.00	22 28 31	27.00	4.58	27.60
	2000.00	19 34 26	26.33	7.51	27.66
	3200.00	28 33 22	27.67	5.51	27.77
	5000.00	25 31 31	29.00	3.46	27.92
p	10.00	870p 982p			

P-value for ANOVA test of dose response is 0.893  
 ANOVA test is not significant. Other significant results should be viewed with caution.  
 An acceptable model is Linear with pval = 0.810

Estimate of the slope is = 0.000086 .  
 Standard error of the slope is = 0.000704 .  
 90% confidence limits for the slope are <-0.001169, 0.001341>.

P-value for the test of the positive dose response (slope at origin) is 0.453  
 Note: Smaller P-value means more positive dose response



Ū = Observed; ° = Predicted.  
 The predicted values are based on Linear model.

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 Fone: (51) 3493-6888 Fax: (51) 3493-6885 / e-mail: [bioensaios@bioensaios.com.br](mailto:bioensaios@bioensaios.com.br)

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+++++ SALANAL: record 4 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 09/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA98

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor 1254  
S9 concentration ... 0.50

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	28 21 26	25.00	3.61	24.33
	800.00	20 26 29	25.00	4.58	24.32
	1250.00	20 24 21	21.67	2.08	24.32
	2000.00	21 25 27	24.33	3.06	24.31
	3200.00	24 30 31	28.33	3.79	24.29
	5000.00	22 21 26	23.00	2.65	24.27
p	10.00	1120p 1288p			

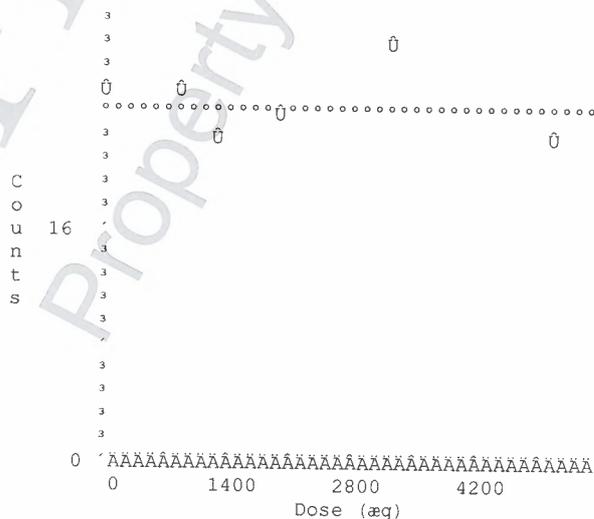
P-value for ANOVA test of dose response is 0.325  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Linear with pval = 0.230

Estimate of the slope is = -0.000012 .  
Standard error of the slope is = 0.000467 .  
90% confidence limits for the slope are <-0.000845, 0.000822>.

P-value for the test of the positive dose response (slope at origin) is 0.510

Note: Smaller P-value means more positive dose response



Ū = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório BPL  
Lei 9.279/96

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Todos os infratores poderão ser processados civil e criminalmente

+++++ SALANAL: record 5 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 16/06/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA100

Metabolic activation: None

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077

Code	Dose	counts			Mean	S.D.	Predicted Linear
	0.00	158	140	162	153.33	11.72	148.88
	800.00	141	136	176	151.00	21.79	149.27
	1250.00	152	170	166	162.67	9.45	149.49
	2000.00	149	108	139	132.00	21.38	149.85
	3200.00	141	169	129	146.33	20.53	150.43
	5000.00	153	171	157	160.33	9.45	151.30
p	1.00	1680p	1456p				

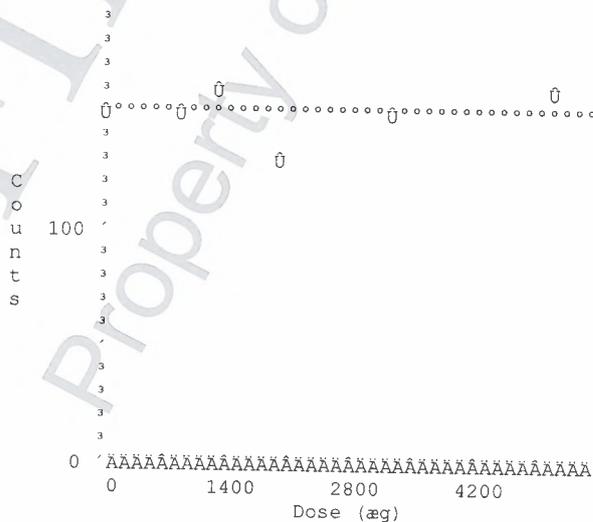
P-value for ANOVA test of dose response is 0.310  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Linear with pval = 0.220

Estimate of the slope is = 0.000483 .  
Standard error of the slope is = 0.002513 .  
90% confidence limits for the slope are <-0.003996, 0.004963>.

P-value for the test of the positive dose response (slope at origin) is 0.425

Note: Smaller P-value means more positive dose response



Ū = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório - BPL  
SYNGENTA PROTEÇÃO DE CULTIVOS LTDA., protegidos na forma da Lei nº 9.397/96 e do artigo 15, XIV da

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Todos os infratores poderão ser processados civil e criminalmente

+++++ SALANAL: record 1 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 10/09/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA100

Metabolic activation: None

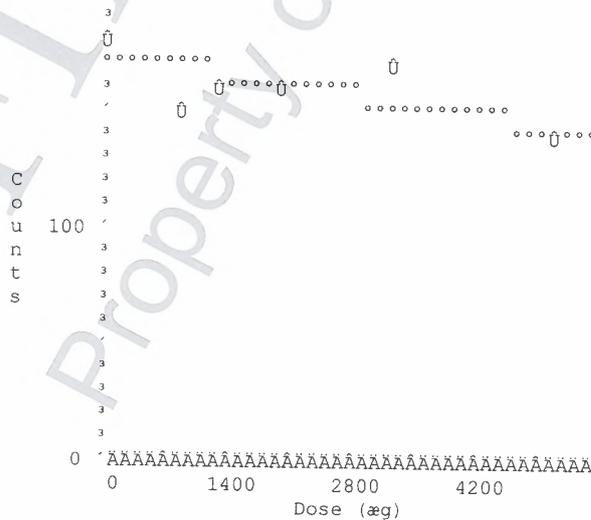
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077B

Code	Dose	counts	Mean	S.D.	Predicted Linear	
0.00	191	178	169	179.33	11.06	171.68
800.00	141	171	152	154.67	15.18	167.00
1250.00	135	187	167	163.00	26.23	164.36
2000.00	158	138	184	160.00	23.07	159.97
3200.00	161	159	188	169.33	16.20	152.93
5000.00	141	136	133	136.67	4.04	142.39
p	1.00	1456p	1232p			

P-value for ANOVA test of dose response is 0.120  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.344

Estimate of the slope is = -0.005859 .  
Standard error of the slope is = 0.002368 .  
90% confidence limits for the slope are <-0.010081, -0.001638>.

P-value for the test of the positive dose response (slope at origin) is 0.985  
Note: Smaller P-value means more positive dose response



o = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório - BPL  
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Report Number: 2077-AMES-080-09

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Todos os infratores poderão ser processados civil e criminalmente

+++++ SALANAL: record 2 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 22/09/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA100

Metabolic activation: None

Data File Name: C:\DOCUME-1\TEMP\DESKTOP\SALANA-1\2077B

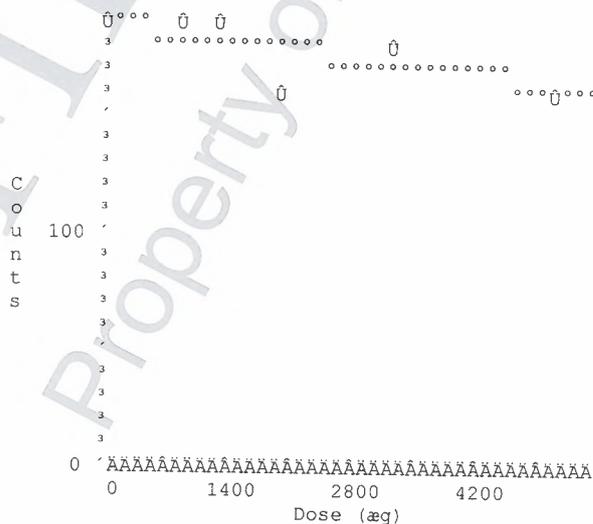
Code	Dose	counts		Mean	S.D.	Predicted Linear	
	0.00	165	186	208	186.33	21.50	187.19
	1250.00	227	183	165	191.67	31.90	183.23
	2000.00	170	201	203	191.33	18.50	181.00
	3200.00	214	110	144	156.00	53.03	177.29
	5000.00	211	164	165	180.00	26.85	171.34
	8000.00	162	165	164	163.67	1.53	162.43
p	1.00	1176p	896p				

P-value for ANOVA test of dose response is 0.602  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Linear with pval = 0.662

Estimate of the slope is = -0.004952 .  
Standard error of the slope is = 0.004350 .  
90% confidence limits for the slope are <-0.012704, 0.002801>.

P-value for the test of the positive dose response (slope at origin) is 0.861  
Note: Smaller P-value means more positive dose response



Ū = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório - BPL  
Estas informações, resultados de testes e outros dados não divulgados

+++++ SALANAL: record 3 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 25/09/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA100

Metabolic activation: None

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA-1\2077B

Code	Dose	counts	Mean	S.D.	Predicted Linear	
0.00	111	100	118	109.67	9.07	116.88
800.00	159	112	110	127.00	27.73	115.98
1250.00	131	120	134	128.33	7.37	115.47
2000.00	113	105	104	107.33	4.93	114.62
3200.00	110	96	108	104.67	7.57	113.26
5000.00	124	128	98	116.67	16.29	111.23
p	1.00	1344p	872p			

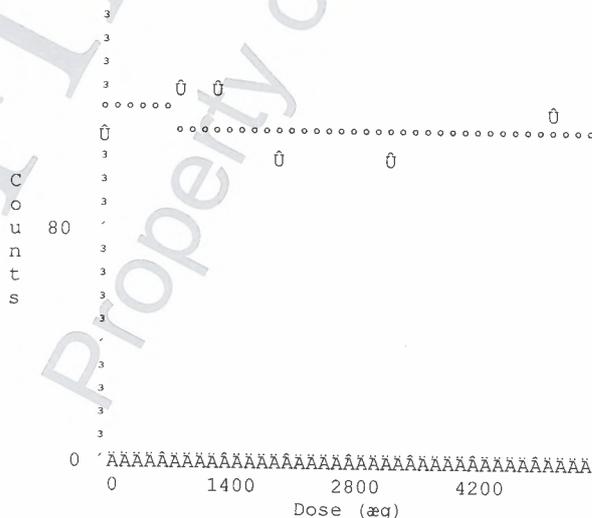
P-value for ANOVA test of dose response is 0.247  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Linear with pval = 0.183

Estimate of the slope is = -0.001131 .  
Standard error of the slope is = 0.001971 .  
90% confidence limits for the slope are <-0.004644, 0.002383>.

P-value for the test of the positive dose response (slope at origin) is 0.712

Note: Smaller P-value means more positive dose response



o = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório BPL  
Lei 9.279/96

+++++ SALANAL: record 6 +++++

Test Sample Name: Sedaxane  
 Source/Batch/Lot: GP080609  
 Solvent: Agua bideionizada  
 Exp. Date: 07/07/2009  
 Exp. No.: 2077  
 Technician:  
 Assay Type: Preincubation - Time [20min ] Temp [37C ]  
 Strain: TA100

Metabolic activation species..... rat  
 organ ..... liver  
 inducer ..... Aroclor 1254  
 S9 concentration ... 0.50

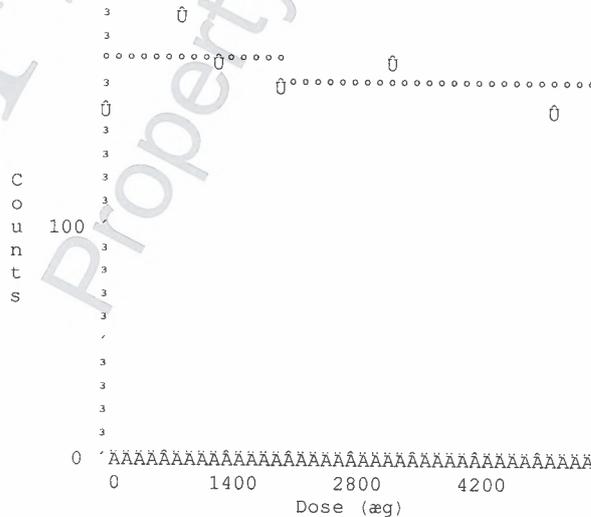
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	159 137 160	152.00	13.00	167.45
	800.00	190 181 190	187.00	5.20*	166.45
	1250.00	161 190 159	170.00	17.35	165.89
	2000.00	177 158 148	161.00	14.73	164.96
	3200.00	185 189 140	171.33	27.21	163.46
	5000.00	176 151 138	155.00	19.31	161.22
p	10.00	1456p 1512p			

Note: \*\* = significant at 1%; \*significant at 5%  
 P-value for ANOVA test of dose response is 0.252  
 ANOVA test is not significant. Other significant results  
 should be viewed with caution.  
 An acceptable model is Linear with pval = 0.185

Estimate of the slope is = -0.001246 .  
 Standard error of the slope is = 0.002416 .  
 90% confidence limits for the slope are <-0.005553, 0.003061>.

P-value for the test of the positive dose response  
 (slope at origin) is 0.692  
 Note: Smaller P-value means more positive dose response



° = Observed; ° = Predicted.  
 The predicted values are based on Linear model.

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Estes informes são resultados de testes e outros dados não divulgados são confidenciais e de propriedade da SYNGENTA PROTEÇÃO DE CULTIVOS LTDA., protegidos na forma da Lei 10.693/02 e do artigo 133, XIV da Lei 9.279/96

++++ SALANAL: record 5 +++++

Test Sample Name: Sedaxane  
 Source/Batch/Lot: GP080609  
 Solvent: Agua bideionizada  
 Exp. Date: 01/09/2009  
 Exp. No.: 2077  
 Technician:  
 Assay Type: Preincubation - Time [20min ] Temp [37C ]  
 Strain: TA100

Metabolic activation species..... rat  
 organ ..... liver  
 inducer ..... Aroclor 1254  
 S9 concentration ... 0.50

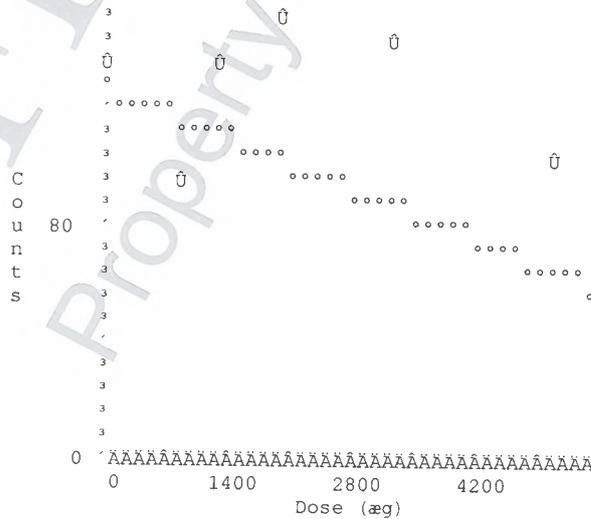
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077B

Code	Dose	counts	Mean	S.D.	Predicted Bernstein
	0.00	122 124 171	139.00	27.73	125.29
	800.00	80 93 110	94.33	15.04	115.62
	1250.00	130 152 117	133.00	17.69	110.19
	2000.00	148 163 140	150.33	11.68	
	3200.00	133 130 176	146.33	25.74	
	5000.00	105 125 86	105.33	19.50	
p	1.00	896p 786p			

P-value for ANOVA test of dose response is 0.016  
 An acceptable model is Bernstein with pval = 0.100  
 Bernstein model used the first 3 doses

Estimate of the slope is = -0.012082 .  
 Standard error of the slope is = 0.013737 .  
 90% confidence limits for the slope are <-0.036567, 0.012403>.

P-value for the test of the positive dose response  
 (slope at origin) is 0.802  
 Note: Smaller P-value means more positive dose response



o = Observed; ° = Predicted.  
 The predicted values are based on Bernstein model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório - BPL  
 Lei 9.279/96

+++++ SALANAL: record 4 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 09/09/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA100

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor 1254  
S9 concentration ... 0.50

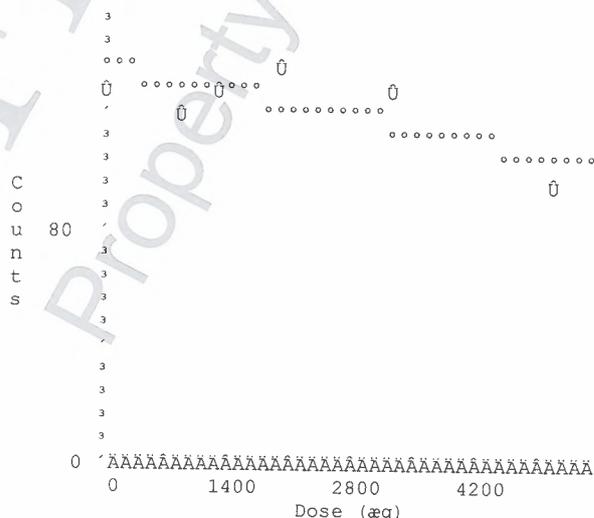
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077B

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	116 118 148	127.33	17.93	134.07
	800.00	105 159 104	122.67	31.47	129.39
	1250.00	139 119 124	127.33	10.41	126.76
	2000.00	155 113 145	137.67	21.94	122.37
	3200.00	125 133 122	126.67	5.69	115.35
	5000.00	102 100 89	97.00	7.00	104.81
p	10.00	1288p 1568p			

P-value for ANOVA test of dose response is 0.122  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.372

Estimate of the slope is = -0.005851 .  
Standard error of the slope is = 0.002328 .  
90% confidence limits for the slope are <-0.010000, -0.001702>.

P-value for the test of the positive dose response (slope at origin) is 0.986  
Note: Smaller P-value means more positive dose response



Ū = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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\*\*\*\*\* SALANAL: record 6 \*\*\*\*\*

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 13/10/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA100

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor 1254  
S9 concentration ... 0.50

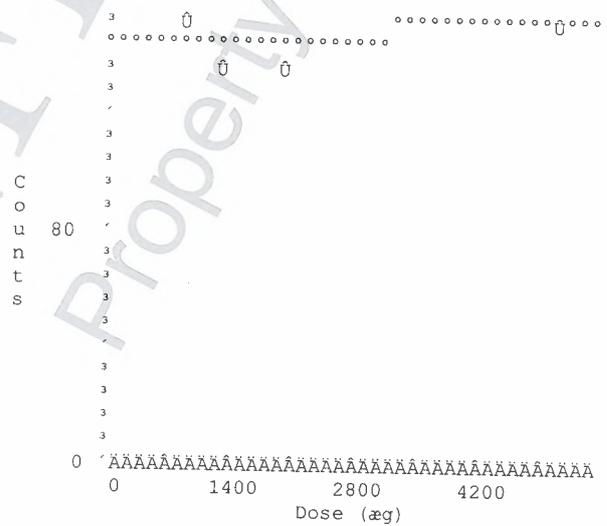
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077B

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	153 195 131	159.67	32.52	146.47
	1250.00	158 174 130	154.00	22.27	146.86
	2000.00	120 160 125	135.00	21.79	147.07
	3200.00	109 132 159	133.33	25.03	147.44
	5000.00	166 179 125	156.67	28.18	148.02
	8000.00	150 123 186	153.00	31.61	148.90
p	10.00	1680p 1288p			

P-value for ANOVA test of dose response is 0.722  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.601

Estimate of the slope is = 0.000486 .  
Standard error of the slope is = 0.003963 .  
90% confidence limits for the slope are <-0.006578, 0.007549>.

P-value for the test of the positive dose response (slope at origin) is 0.452  
Note: Smaller P-value means more positive dose response



o = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Todos os infratores poderão ser processados civil e criminalmente

\*\*\*\*\* SALANAL: record 7 \*\*\*\*\*

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 20/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA102

Metabolic activation: None

Data File Name: C:\DOCUME~1\HELENA\DESKTOP\SALANA~1\2077B

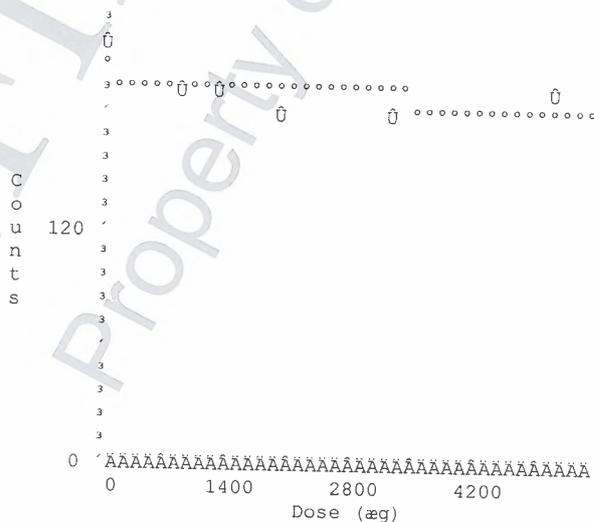
Code	Dose	counts			Mean	S.D.	Predicted Linear
	0.00	202	205	230	212.33	15.37	198.02
	800.00	201	180	180	187.00	12.12	195.25
	1250.00	176	228	182	195.33	28.45	193.69
	2000.00	187	184	180	183.67	3.51	191.10
	3200.00	185	180	184	183.00	2.65	186.95
	5000.00	190	184	188	187.33	3.06	180.72
p	0.50	1176p	1232p				

P-value for ANOVA test of dose response is 0.202  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Linear with pval = 0.286

Estimate of the slope is = -0.003461 .  
Standard error of the slope is = 0.002002 .  
90% confidence limits for the slope are <-0.007029, 0.000107>.

P-value for the test of the positive dose response (slope at origin) is 0.945  
Note: Smaller P-value means more positive dose response



o = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório - BPL  
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Todos os infratores poderão ser processados civil e criminalmente

+++++ SALANAL: record 9 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 09/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA102

Metabolic activation: None

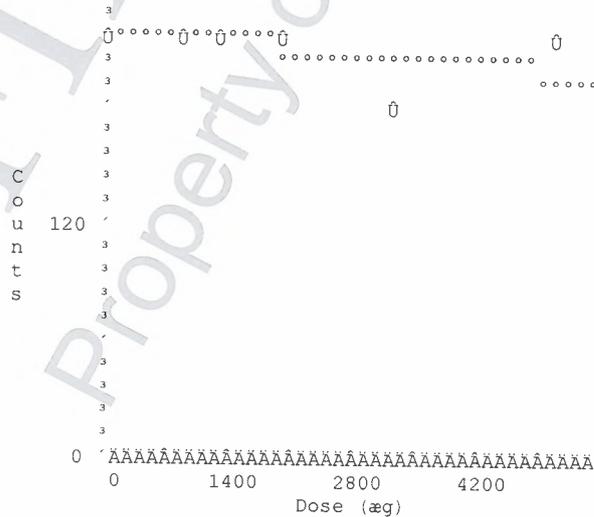
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA-1\2077B

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	212 221 227	220.00	7.55	217.87
	800.00	200 237 213	216.67	18.77	214.58
	1250.00	214 235 210	219.67	13.43	212.72
	2000.00	236 219 199	218.00	18.52	209.64
	3200.00	135 198 196	176.33	35.81	204.70
	5000.00	218 231 201	216.67	15.04	197.29
p	0.50	807p 803p			

P-value for ANOVA test of dose response is 0.106  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.100

Estimate of the slope is = -0.004116 .  
Standard error of the slope is = 0.003098 .  
90% confidence limits for the slope are <-0.009638, 0.001405>.

P-value for the test of the positive dose response (slope at origin) is 0.896  
Note: Smaller P-value means more positive dose response



o = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório BPL  
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Todos os infratores poderão ser processados civil e criminalmente

++++ SALANAL: record 8 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 21/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA102

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor 1254  
S9 concentration ... 0.50

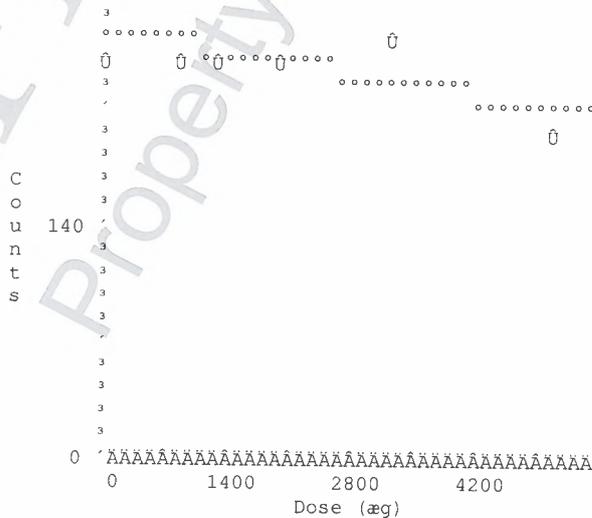
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077B

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	236 247 251	244.67	7.77	253.84
	800.00	233 230 265	242.67	19.40	246.81
	1250.00	258 257 219	244.67	22.23	242.86
	2000.00	239 243 238	240.00	2.65	236.28
	3200.00	239 261 256	252.00	11.53	225.74
	5000.00	243 118 231	197.33	68.97	209.93
p	10.00	903p 1012p			

P-value for ANOVA test of dose response is 0.374  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.678

Estimate of the slope is = -0.008781 .  
Standard error of the slope is = 0.004659 .  
90% confidence limits for the slope are <-0.017085, -0.000478>.

P-value for the test of the positive dose response (slope at origin) is 0.958  
Note: Smaller P-value means more positive dose response



û = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório - BPL  
Lei 9.279/96

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Todos os infratores poderão ser processados civil e criminalmente

++++ SALANAL: record 10 +++++

Test Sample Name: Sedaxane  
 Source/Batch/Lot: GP080609  
 Solvent: Agua bideionizada  
 Exp. Date: 30/07/2009  
 Exp. No.: 2077  
 Technician:  
 Assay Type: Preincubation - Time [20min ] Temp [37C ]  
 Strain: TA102

Metabolic activation species..... rat  
 organ ..... liver  
 inducer ..... Aroclor 1254  
 S9 concentration ... 0.50

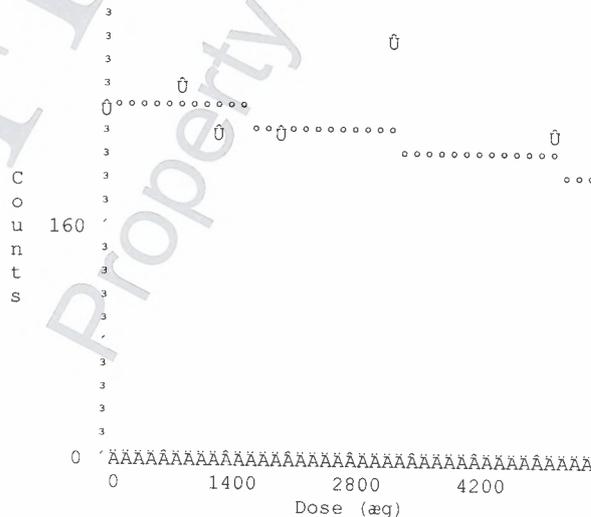
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077B

Code	Dose	counts	Mean	S.D.	Predicted Bernstein
	0.00	220 263 233	238.67	22.05	245.60
	800.00	255 248 274	259.00	13.45	238.55
	1250.00	235 220 220	225.00	8.66	234.58
	2000.00	243 239 200	227.33	23.76	227.98
	3200.00	282 299 273	284.67	13.20	
	5000.00	200 243 245	229.33	25.42	
p	10.00	1904p 1806p			

P-value for ANOVA test of dose response is 0.023  
 An acceptable model is Bernstein with pval = 0.408  
 Bernstein model used the first 4 doses

Estimate of the slope is = -0.008809 .  
 Standard error of the slope is = 0.007425 .  
 90% confidence limits for the slope are <-0.022043, 0.004425>.

P-value for the test of the positive dose response  
 (slope at origin) is 0.871  
 Note: Smaller P-value means more positive dose response



û = Observed; ° = Predicted.  
 The predicted values are based on Bernstein model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório BPL  
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+++++ SALANAL: record 9 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 21/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA1535

Metabolic activation: None

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077

Code	Dose	counts	Mean	S.D.	Predicted Linear
0.00	20	26 25	23.67	3.21	25.60
800.00	38	32 28	32.67	5.03	29.46
1250.00	47	28 27	34.00	11.27	31.63
2000.00	38	31 26	31.67	6.03	35.25
3200.00	48	44 45	45.67	2.08**	41.03
5000.00	50	49 43	47.33	3.79**	49.72
p	1.00	1400p 1120p			

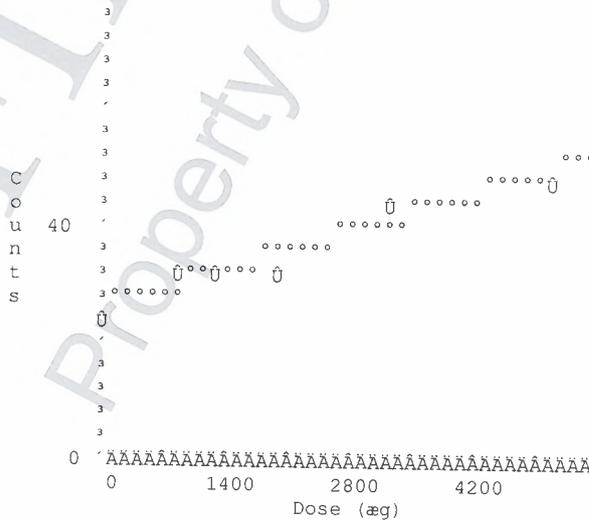
Note: \*\* = significant at 1%; \*significant at 5%

P-value for ANOVA test of dose response is 0.005  
An acceptable model is Linear with pval = 0.402

Estimate of the slope is = 0.004824 .  
Standard error of the slope is = 0.000941 .  
90% confidence limits for the slope are <0.003147, 0.006500>.

P-value for the test of the positive dose response  
(slope at origin) is < .001

Note: Smaller P-value means more positive dose response



Ū = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório - BPL  
SYNGENTA PROTEÇÃO RECONHECIDA EM CONFORMIDADE AOS PRINCÍPIOS DAS BOAS PRÁTICAS DE LABORATÓRIO - BPL

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Todos os infratores poderão ser processados civil e criminalmente

+++++ SALANAL: record 5 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 09/09/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA1535

Metabolic activation: None

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077C

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	17 18 12	15.67	3.21	18.49
	800.00	17 23 30	23.33	6.51	20.33
	1250.00	18 19 30	22.33	6.66	21.37
	2000.00	18 28 26	24.00	5.29	23.10
	3200.00	36 28 31	31.67	4.04*	25.87
	5000.00	28 18 32	26.00	7.21	30.03
p	1.00	780p 940p			

Note: \*\* = significant at 1%; \*significant at 5%

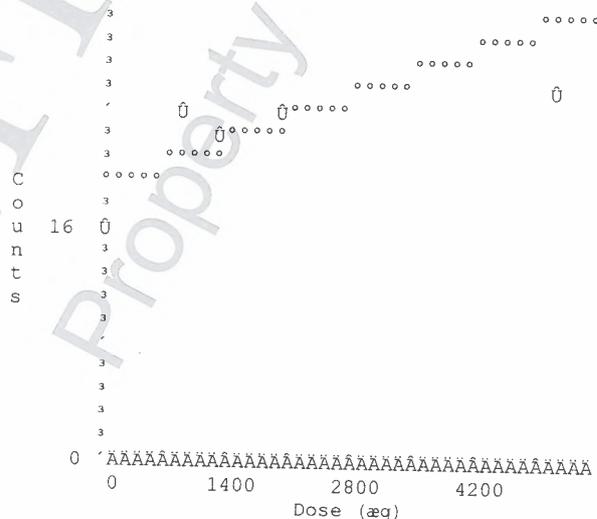
P-value for ANOVA test of dose response is 0.063  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Linear with pval = 0.284

Estimate of the slope is = 0.002309 .  
Standard error of the slope is = 0.000787 .  
90% confidence limits for the slope are <0.000905, 0.003712>.

P-value for the test of the positive dose response (slope at origin) is 0.006

Note: Smaller P-value means more positive dose response



û = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Instalação de Teste Reconhecida em Conformidade aos Princípios das Boas Práticas de Laboratório - BPL  
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Todos os infratores poderão ser processados civil e criminalmente

+++++ SALANAL: record 7 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 10/09/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA1535

Metabolic activation: None

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077C

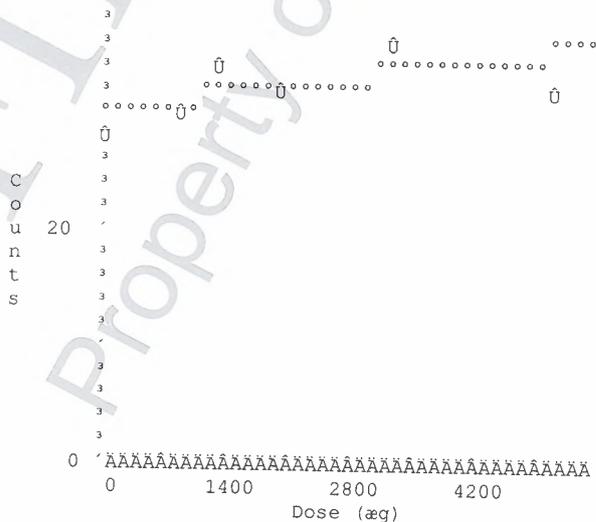
Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	30 28 26	28.00	2.00	29.93
	800.00	37 28 23	29.33	7.09	30.75
	1250.00	30 43 30	34.33	7.51	31.21
	2000.00	34 36 29	33.00	3.61	31.97
	3200.00	37 43 30	36.67	6.51	33.19
	5000.00	36 33 28	32.33	4.04	35.03
p	1.00	728p 915p			

P-value for ANOVA test of dose response is 0.434  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Linear with pval = 0.515

Estimate of the slope is = 0.001018 .  
Standard error of the slope is = 0.000758 .  
90% confidence limits for the slope are <-0.000333, 0.002369>.

P-value for the test of the positive dose response (slope at origin) is 0.102  
Note: Smaller P-value means more positive dose response



û = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Todos os infratores poderão ser processados civil e criminalmente

+++++ SALANAL: record 9 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 13/10/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA1535

Metabolic activation: None

Data File Name: C:\DOCUME-1\TEMP\DESKTOP\SALANA~1\2077C

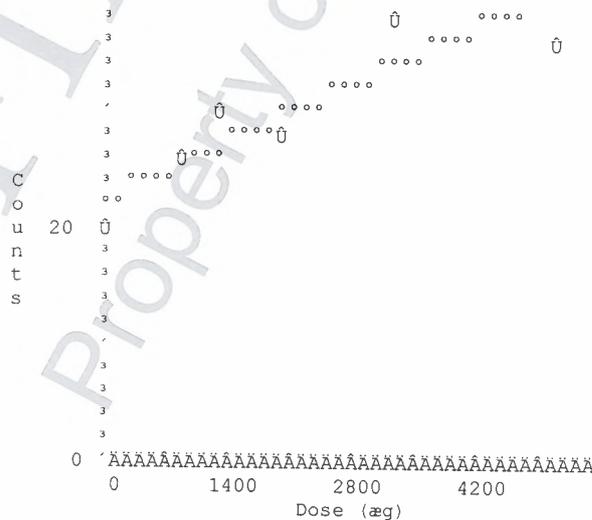
Code	Dose	counts	Mean	S.D.	Predicted Linear	
0.00	20	20	19	19.67	0.58	22.34
1250.00	29	27	25	27.00	2.00*	25.19
2000.00	25	30	38	31.00	6.56	26.79
3200.00	32	25	27	28.00	3.61*	29.46
5000.00	44	28	44	38.67	9.24	33.73
8000.00	24	37	48	36.33	12.01	40.14
p	1.00	1344p	1008p			

Note: \*\* = significant at 1%; \*significant at 5%

P-value for ANOVA test of dose response is 0.018  
An acceptable model is Linear with pval = 0.335

Estimate of the slope is = 0.003560 .  
Standard error of the slope is = 0.000881 .  
90% confidence limits for the slope are <0.001990, 0.005129>.

P-value for the test of the positive dose response  
(slope at origin) is < .001  
Note: Smaller P-value means more positive dose response



° = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Todos os infratores poderão ser processados civil e criminalmente

++++ SALANAL: record 10 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 21/07/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA1535

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor 1254  
S9 concentration ... 0.50

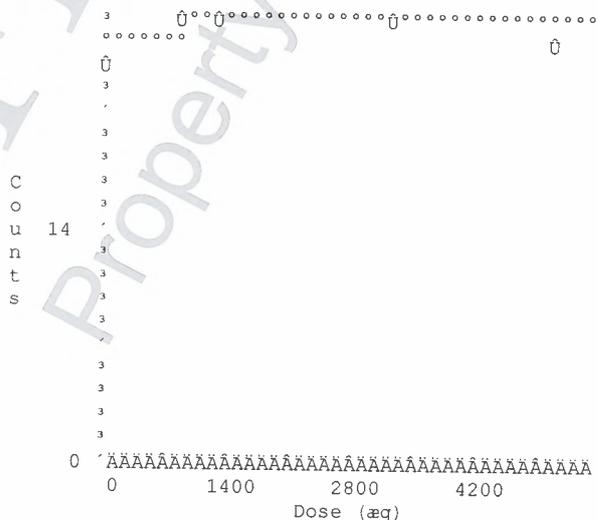
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	26 24 21	23.67	2.52	25.76
	800.00	24 28 28	26.67	2.31	25.88
	1250.00	29 26 26	27.00	1.73	25.95
	2000.00	29 30 24	27.67	3.21	26.06
	3200.00	34 24 22	26.67	6.43	26.24
	5000.00	21 27 28	25.33	3.79	26.51
p	10.00	870p 930p			

P-value for ANOVA test of dose response is 0.770  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.667

Estimate of the slope is = 0.000149 .  
Standard error of the slope is = 0.000505 .  
90% confidence limits for the slope are <-0.000751, 0.001050>.

P-value for the test of the positive dose response (slope at origin) is 0.386  
Note: Smaller P-value means more positive dose response



° = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Todos os infratores poderão ser processados civil e criminalmente

\*\*\*\*\* SALANAL: record 6 \*\*\*\*\*

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 09/09/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA1535

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor 1254  
S9 concentration ... 0.50

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077C

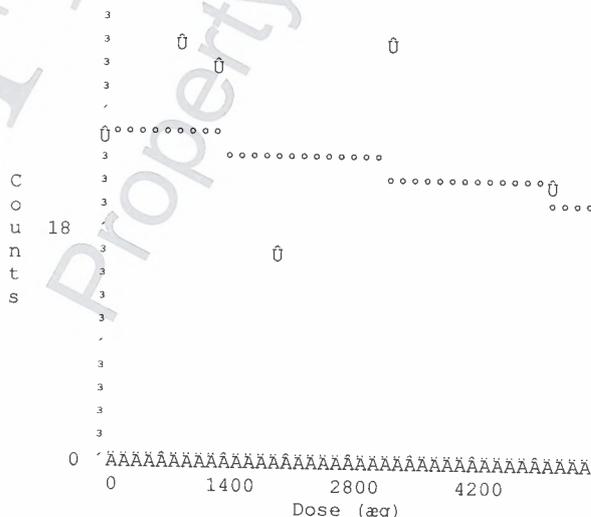
Code	Dose	counts	Mean	S.D.	Predicted Bernstein
	0.00	21 28 26	25.00	3.61	25.67
	800.00	29 32 35	32.00	3.00	24.87
	1250.00	11 34 45	30.00	17.35	24.42
	2000.00	19 11 18	16.00	4.36	23.66
	3200.00	27 33 35	31.67	4.16	22.46
	5000.00	18 27 21	22.00	4.58	
p	.1.00	1456p 1120p			

P-value for ANOVA test of dose response is 0.073  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Bernstein with pval = 0.050  
Bernstein model used the first 5 doses

Estimate of the slope is = -0.001005 .  
Standard error of the slope is = 0.001866 .  
90% confidence limits for the slope are <-0.004331, 0.002321>.

P-value for the test of the positive dose response (slope at origin) is 0.700  
Note: Smaller P-value means more positive dose response



Ū = Observed; ° = Predicted.  
The predicted values are based on Bernstein model.

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SYNGENTA PROTEÇÃO DE CULTIVOS LTDA., protegidos na forma da Lei 10.803/02 e do artigo 15, XIV da Lei 9.279/96

\*\*\*\*\* SALANAL: record 8 \*\*\*\*\*

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 10/09/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA1535

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor 1254  
S9 concentration ... 0.50

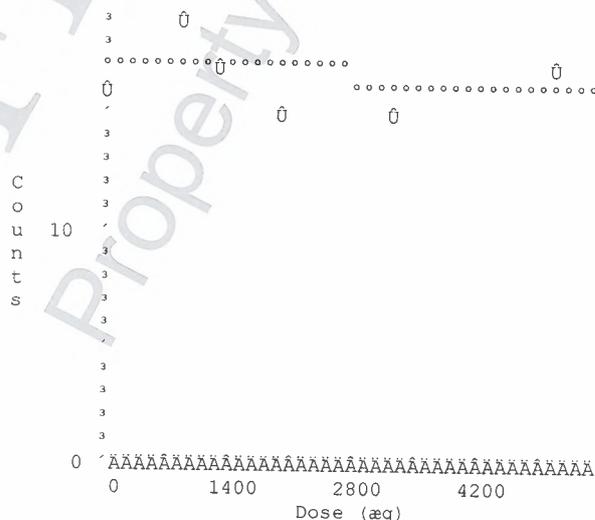
Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA~1\2077C

Code	Dose	counts	Mean	S.D.	Predicted Linear
	0.00	16 15 18	16.33	1.53	16.89
	800.00	20 18 20	19.33	1.15	16.78
	1250.00	16 17 19	17.33	1.53	16.71
	2000.00	18 17 10	15.00	4.36	16.61
	3200.00	13 14 19	15.33	3.21	16.44
	5000.00	16 16 20	17.33	2.31	16.19
p	10.00	630p 750p			

P-value for ANOVA test of dose response is 0.480  
ANOVA test is not significant. Other significant results should be viewed with caution.  
An acceptable model is Linear with pval = 0.374

Estimate of the slope is = -0.000141 .  
Standard error of the slope is = 0.000395 .  
90% confidence limits for the slope are <-0.000845, 0.000563>.

P-value for the test of the positive dose response (slope at origin) is 0.636  
Note: Smaller P-value means more positive dose response



Ō = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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Todos os infratores poderão ser processados civil e criminalmente

+++++ SALANAL: record 10 +++++

Test Sample Name: Sedaxane  
Source/Batch/Lot: GP080609  
Solvent: Agua bideionizada  
Exp. Date: 13/10/2009  
Exp. No.: 2077  
Technician:  
Assay Type: Preincubation - Time [20min ] Temp [37C ]  
Strain: TA1535

Metabolic activation species..... rat  
organ ..... liver  
inducer ..... Aroclor 1254  
S9 concentration ... 0.50

Data File Name: C:\DOCUME~1\TEMP\DESKTOP\SALANA-1\2077C

Code Dose	--	counts	--	Mean	S.D.	Predicted Linear
0.00	14	15	16	15.00	1.00	15.96
1250.00	13	13	20	15.33	4.04	15.78
2000.00	24	14	16	18.00	5.29	15.68
3200.00	15	15	14	14.67	0.58	15.52
5000.00	20	13	18	17.00	3.61	15.25
8000.00	10	17	15	14.00	3.61	14.86
p 10.00	1560p	1008p				

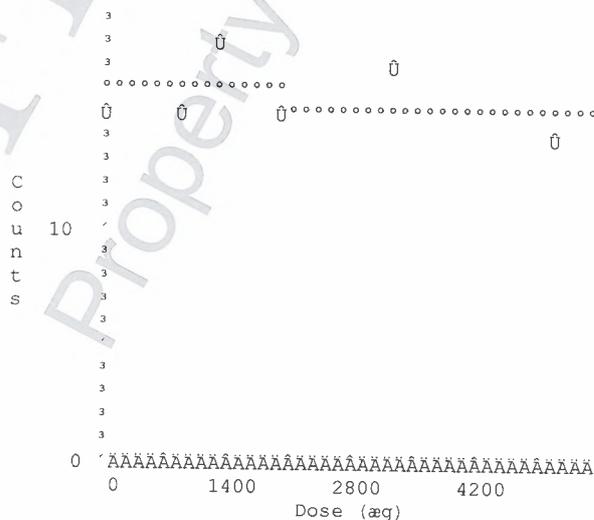
P-value for ANOVA test of dose response is 0.721  
ANOVA test is not significant. Other significant results should be viewed with caution.

An acceptable model is Linear with pval = 0.633

Estimate of the slope is = -0.000220 .  
Standard error of the slope is = 0.000457 .  
90% confidence limits for the slope are <-0.001034, 0.000594>.

P-value for the test of the positive dose response (slope at origin) is 0.681

Note: Smaller P-value means more positive dose response



° = Observed; ° = Predicted.  
The predicted values are based on Linear model.

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**APPENDIX 4 Supplemental Experiments: Reverse Mutation His<sup>+</sup> Frequency in Salmonella typhimurium TA1535 after Treatment with the Test Substance, Pre-incubation Method in the Absence of Metabolic Activation**

Substance	Dose (µg/plate)	Revertants His <sup>+</sup> /plate -S9			Mean ± Deviation standard		Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3			
24/02/2010							
CN	0	17	21	26	21.33	4.51	-
ST	800	42	36	40	39.33	3.06	1.84
ST	1250	55	43	35	44.33	10.07	2.08
ST	2000	31	58	51	46.67	14.01	2.19
ST	3200	49	48	46	47.67	1.53	2.23
ST	5000	56	43	64	54.33	10.60	255
CP (NaZ)	1	896	1008	-	952.00	79.20	44.63
02/03/2010							
CN	0	45	45	38	42.67	4.04	-
ST	800	66	68	50	61.33	9.87	1.44
ST	1250	42	64	52	52.67	11.02	1.23
ST	2000	75	64	58	65.67	8.62	1.54
ST	3200	63	65	60	62.67	2.52	1.47
ST	5000	40	46	68	51.33	14.74	1.20
CP (NaZ)	1	1120	1288	-	1204.00	118.79	28.22
05/03/2010							
CN	0	47	43	50	46.67	3.51	-
ST	800	47	38	46	43.67	4.93	0.94
ST	1250	41	43	49	44.33	4.16	0.95
ST	2000	56	44	44	48.00	6.93	1.03
ST	3200	42	48	39	43.00	4.58	0.92
ST	5000	39	50	41	43.33	586	0.93
ST	8000	45	47	49	47.00	2,00	1.01
CP (NaZ)	1	1213	1319	-	1266.00	74.95	27.13
10/03/2010							
CN	0	24	28	23	25.00	2.65	-
ST	800	48	36	32	38.67	8.33	1.55
ST	1250	36	49	46	43.67	6.81	1.75
ST	2000	42	32	32	35.33	5.77	1.41
ST	3200	30	28	29	29.00	1.00	1.16
ST	5000	46	47	43	45.33	2.08	1.81
ST	8000	41	44	54	46.33	6.81	1.85
CP (NaZ)	1	1344	728	-	1036.00	435.58	41.44

CN: negative control; CP: positive control; ST: test substance.

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**Continued APPENDIX 4:**

Substance	Dose (µg/plate)	Revertants His <sup>+</sup> /plate -S9			Mean ± Deviation standard		Index Mutagenic
		Replicate 1	Replicate 2	Replicate 3			
10/03/2010							
CN	0	16	13	18	15.67	2.52	-
ST	500	36	43	34	37.67	4.73	2.40
ST	800	35	38	41	38.00	3.00	2.43
ST	1250	42	47	33	40.67	7.09	2.60
ST	2000	37	59	34	43.33	13.65	2.77
ST	3200	52	35	47	44.67	8.74	2.85
ST	5000	32	38	32	34.00	3.46	2.17
CP (NaZ)	1	728	784	-	756.00	39.60	48.26
10/03/2010							
CN	0	15	21	27	21.00	6.00	-
ST	800	43	46	36	41.67	5.13	1.98
ST	1250	37	38	57	44.00	11.27	2.10
ST	2000	53	54	66	57.67	7.23	2.75
ST	3200	47	36	72	51.67	18.45	2.46
ST	5000	51	39	49	46.33	6.43	2.21
ST	8000	30	37	48	38.33	9.07	1.83
CP (NaZ)	1	840	840	-	840.00	0.00	40.00
10/03/2010							
CN	0	38	41	49	42.67	5.69	-
ST	800	57	38	41	45.33	10.21	1.06
ST	1250	57	46	51	51.33	5.51	1.20
ST	2000	38	63	52	51.00	12.53	1.20
ST	3200	46	53	47	48.67	3.79	1.14
ST	5000	55	55	cont	55.00	0.00	1.29
ST	8000	56	68	56	60.00	6.93	1.41
CP (NaZ)	1	784	808	-	796.00	16.97	18.66

CN: negative control; CP: positive control; ST: test substance; Cont: contamination.

Supplementary experimental results were not evaluated statistically, since the main purpose was to examine reproducibility and whether a mutagenic index of >3 was achieved.

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**APPENDIX 5 Laboratory's historical control values (Test period: August/2003 to March/2010)**

	Without S9		With S9	
<b>TA97a</b>	Solvent Controls	0.5 µg 4-NQO	Solvent Controls	10 µg 2-AF
Mean ± SD	140.72± 29.55	1086.40± 274.16	142.65 ± 25.88	1108.74 ± 226.92
N	81	81	81	81
Minimum	58	399	13	441
Maximum	200	3808	200	1988
	Without S9		With S9	
<b>TA98</b>	Solvent Controls	0.5 µg 4-NQO	Solvent Controls	10 µg 2-AF
Mean ± SD	27.40 ± 6.06	785.67 ± 170.30	28.52 ± 4.86	1138.56 ± 287.49
N	278	278	278	278
Minimum	17	119	17	139
Maximum	54	1764	46	2390
	Without S9		With S9	
<b>TA100</b>	Solvent Controls s	1 µg AZS	Solvent Controls	10 µg 2-AF
Mean ± SD	159.67 ± 21.97	1985.09 ± 612.62	163.48 ± 18.66	1344.19 ± 268.27
N	343	343	185	185
Minimum	97	501	101	608
Maximum	235	6636	211	4148
	Without S9		With S9	
<b>TA102</b>	Solvent Controls	0.5 µg 4-NQO	Solvent Controls	10 µg 2-AF
Mean ± SD	223.55 ± 44.04	1351.17 ± 281.32	283.57± 53.52	1430.06 ± 350.26
N	87	87	82	82
Minimum	114	511	117	504
Maximum	371	2660	463	2436
	Without S9		With S9	
<b>TA1535</b>	Solvent Controls	1 µg AZS	Solvent Controls	10 µg 2-AF
Mean ± SD	20.16 ± 4.48	1188.79 ± 243.61	18.78 ± 3.61	728.07 ± 325.86
N	81	81	76	76
Minimum	7	326	8	121
Maximum	35	2716	30	130

Key to Positive Controls

NaZ: Sodium Azide; 2-AF: 2 Aminofluorene; 4NQO: 4 nitroquinoline 1-oxide

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