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CERTIFICATION OF GOOD LABORATORY PRACTICE AND VERIFICATION OF A COMPLETE AND UNALTERED COPY OF THE REPORT BY THE STUDY SPONSOR

The Statement of Compliance with Good Laboratory Practice found on page 4 of this report, and signed by the Study Director is truthful and accurate, and this report as provided by the testing facility is complete and unaltered.

Signature of the Sponsor: _____ Date: August 27, 1994

5.1.2.eWoo

Address of the Sponsor: CIBA-GEIGY Limited
Crop Protection Division
Basle, Switzerland

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STATEMENT OF COMPLIANCE WITH GOOD LABORATORY PRACTICE

This study has been performed in compliance with "Verfahren und Grundsätze der Guten Laborpraxis (GLP) in der Schweiz" (Good Laboratory Practice (GLP) in Switzerland, Procedures and Principles, March 1986), issued by the Swiss Federal Department of the Interior which recognize the OECD Principles of Good Laboratory Practice (Council Decision 81/30, adopted on May 12th 1981, and the OECD Recommendation 83/95 concerning the 'Mutual Recognition of Compliance with Good Laboratory Practice', adopted on July 26th 1983).

The competent Swiss Federal Authorities have signed Memoranda of Understanding concerning the mutual recognition of compliance with Good Laboratory Practice with the following agencies:

- the US Food and Drug Administration (April 29, 1985)
- the US Environmental Protection Agency (June 22, 1988)

The testing procedure is also in compliance with the Good Laboratory Practice Standards for Toxicological Studies on Agricultural Chemicals of the Japan Ministry of Agriculture, Forestry and Fisheries, (59 NohSan Notification No. 3850, Director General of Agricultural Production Bureau, August 10, 1984)

Study Director: 5.1.2.e Woo

Date: August 17, 1994

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QUALITY ASSURANCE STATEMENT

Project	943012
Test Substance	CGA 329351 tech.
Study Title	SALMONELLA AND ESCHERICHIA/MAMMALIAN-MICROSOME MUTAGENICITY TEST
Study Director	5.1.2.e Woo
QA-Inspector	

I hereby certify that the following Quality Assurance activities were performed:

Activity	Performed	Reported
Facility Inspection	October 20, 1993	December 20, 1993
Protocol Audit	March 10, 1994	March 10, 1994
Study Related Inspection	April 14, 1994	April 18, 1994
Final Report Audit	August 11, 1994	August 11, 1994

August 19, 1994

Date

5.1.2.e Woo

Inspector Quality Assurance

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COMPOUND INFORMATION

Test material:	CGA 329351 tech.
Chemical name/type:	Methyl-N-(2-methoxyacetyl)
Application:	Fungicide
Batch No.:	KGL 4634/6
Purity:	97.3%
Stability (in the vehicle used, under the conditions of the test):	Stable
Appearance:	Liquid
Reanalysis date:	February 1996
Material submitted by:	CIBA-GEIGY Limited Crop Protection Division Basle, Switzerland

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GENERAL

Type of study: Salmonella and Escherichia/Mammalian-Microsome Mutagenicity Test. According to SOP No. 30 50 03, CIBA-GEIGY Limited, Basle, Switzerland.

The test procedure is based on:

- OECD guideline [1]
- EEC guideline [2]
- MHW guideline [3]
- EPA guideline [4]

Purpose: To evaluate the test compound for mutagenic activity in bacterial test systems in the presence and absence of a rat liver metabolic activation system

Test organisms: Strains of Salmonella typhimurium: TA 98, TA 100, TA 102, TA 1535, TA 1537

Except for strain TA 100 all strains from Prof. 5.1.2.e Woo Berkeley, USA. Strain TA 100 from Dr. 5.1.2.e Woo, Hoffmann-La Roche Limited, Basle, Switzerland.

Strain of Escherichia coli: E. coli WP2 uvrA

Origin: National Collection of Industrial Bacteria, Aberdeen, Scotland.

Testing facility: CIBA-GEIGY Limited
Basle, Switzerland
Genetic Toxicology

Archives: Archives of Genetic Toxicology
CIBA-GEIGY Limited
Basle, Switzerland

Personnel: Technical conduct:

5.1.2.e Woo

Study Director:	5.1.2.e Woo
Responsible for analytical study	
	CIBA-GEIGY Limited Basle, Switzerland Laboratories of Ecotoxicology Analytical Services
Sponsor:	CIBA-GEIGY Limited Basle, Switzerland
Division:	Crop Protection Division
Sponsor monitoring scientist:	5.1.2.e Woo
Test number:	943012
Vehicle:	Dimethylsulfoxide
Concentration range in the range finding test:	20.6 to 5000.0 µg/plate
Concentration ranges in the mutagenicity tests:	*Original experiment* 312.5 to 5000.0 µg/plate
	Confirmatory experiment 312.5 to 5000.0 µg/plate
	2nd confirmatory experiment 312.5 to 5000.0 µg/plate
Study initiation date:	February 28, 1994
Experimental start date:	April 07, 1994
Experimental termination date:	June 27, 1994
Study termination date:	August 17, 1994

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ABSTRACT

The fungicide CGA 329351 tech., identified as liquid, purity 97.3%, batch no. KGL4634/6, was tested for mutagenic effects in vitro in histidine-requiring strains of Salmonella typhimurium and in a tryptophan-requiring strain of Escherichia coli. The following strains were used: S. typhimurium TA 98, TA 100, TA 102, TA 1535, TA 1537 and E. coli WP2 uvrA. The test was performed with and without the addition of rat-liver post mitochondrial supernatant (S9 fraction) as an extrinsic metabolic activation system. The compound was dissolved in DMSO and tested at five concentrations in the range of 312.5 to 5000.0 µg/plate in the presence and absence of a metabolic activation system. In order to confirm the results, the experiments were repeated with and without metabolic activation at five concentrations in the range of 312.5 to 5000.0 µg/plate. A third experiment was performed with strain TA 102 in the absence of metabolic activation using the same concentrations. Each strain was additionally tested in the presence and in the absence of a metabolic activation system with a suitable, known mutagen as positive control.

In the experiments, performed with and without metabolic activation, none of the tested concentrations of CGA 329351 tech. led to a meaningful increase in the incidence of either histidine- or tryptophan-prototrophic mutants by comparison with the negative control.

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CONCLUSION

Based on the results of these experiments and on standard evaluation criteria, it is concluded that CGA 329351 tech. and its metabolites did not induce gene mutations in the strains of S. typhimurium and E. coli used.

The test was performed under Good Laboratory Practice conditions and was subjected to a periodical quality assurance evaluation.

No circumstances, which may have affected the quality or integrity of the data, have been noted.

Study Director: 5.1.2.e Woo

Date: August 17, 1994

Report reviewed and approved by: 5.1.2.e Woo

Head of Genetic Toxicology

Date: August 17, 1994

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RATIONALE

This test permits the detection of gene mutations induced by the test material or its metabolites in histidine-requiring strains of Salmonella typhimurium and in a tryptophan-requiring strain of Escherichia coli [5-11].

When the Salmonella strains are exposed to a mutagen, some of the bacteria in the treated population, through chemical interaction with the compound or its metabolites, undergo genetic changes which cause them to revert to a non-histidine-requiring state and thus to grow in the absence of exogenous histidine . Similarly, after mutation, the Escherichia coli bacteria are able to grow in tryptophan-free medium. Mutagenic effects of the test substance are demonstrable on comparison of the number of bacteria in the treated and control cultures that have undergone reverse-mutation to histidine prototrophism or tryptophan prototrophism, respectively. Different tester strains are used because of differing sensitivities to known mutagens. The following bacterial strains have been used in this study:

Strain	Type of Mutation
S. typhimurium TA 100	base-pair substitution
S. typhimurium TA 1535	base-pair substitution
E. coli WP2 uvrA	base-pair substitution
S. typhimurium TA 102	base-pair substitution
S. typhimurium TA 98	frame-shift
S. typhimurium TA 1537	frame-shift

PROCEDURE

Source of strains

The histidine-auxotrophic strains of Salmonella typhimurium (TA 98, TA 102, TA 1535, TA 1537) were obtained from Prof. 5.1.2.e Woo Berkeley, USA. Strain TA 100 was obtained from Dr. 5.1.2.e Woo 5.1.2.e Woo Hoffmann-La Roche Limited, Basel, Switzerland. The tryptophan-auxotrophic strain of Escherichia coli (WP2 uvrA) was obtained from the National Collection of Industrial Bacteria, Aberdeen, Scotland.

Source of chemicals

Chemical	Quality	Purity	Supplier
2-Aminoanthracene	practicum	*	Sigma, USA
2-Nitrofluorene	p.a.	>98.0%	Merck, Germany
4-Nitroquinoline	purum	>97.0%	Fluka, Switzerland
9-Aminoacridine	purum	98.5%	Fluka, Switzerland
Aroclor 1254	*	*	Analabs, USA
Cyclophosphamide	purum	*	Koch-Light, England
Sodium azide	purum	>99.0%	Fluka, Switzerland
Mitomycin-C	*	*	Syntex Pharm AG, Switzerland
Dimethylsulfoxide	puriss	99.5%	Merck, Germany

* No data available

Preparation of the bacterial cultures

Inoculates from frozen master copies were set up monthly. They were grown in liquid nutrient broth medium (NB-medium) overnight and then plated on NB-agar. After incubation, single colonies were taken from the plates, grown overnight in liquid NB-medium and then used for the experiment.

Control of the genotype of the strains

The characteristics of the strains were checked monthly. Histidine-auxotrophy of the Salmonella strains was demonstrated by the requirement for L-histidine. The presence of the rfa character was assayed by the sensitivity for crystal-violet. The deletion of the uvrB gene was demonstrated by the sensitivity for UV-light. The Salmonella strains containing the R-factor (TA 98 and TA 100) were additionally checked for ampicillin resistance. The tryptophan-auxotrophy of E. coli WP2 uvrA was demonstrated by the requirement for tryptophan. The absence of the uvrA gene was demonstrated by the sensitivity of the strain for UV-light. Furthermore, all strains were checked for their characteristic reversion properties with known mutagens (positive controls).

Preparation of the metabolic activation mixture

Rat-liver post mitochondrial supernatant (S9 fraction) was prepared in advance from male RAI rats (Tif: RAIf [SPF]), reared at the Animal Farm of CIBA-GEIGY Limited, Sisseln, Switzerland. The animals were treated with Aroclor 1254 (500 mg/kg, i.p.) 5 days prior to sacrifice. The livers were homogenized with 3 volumes of 150 mM KCl. The homogenate was centrifuged for 15 minutes at 9000x g and the resulting supernatant (S9 fraction) was stored at approximately -80°C for no longer than one year. The protein content of the S9 fraction was 40.63,38.60 and 32.22 mg/ml.

The activation mixture contained:

Rat liver S9 fraction	100.0 µl/ml
NADP	4.0 µmol/ml
$MgCl_2$	8.0 µmol/ml
KCl	33.0 µmol/ml
Na-phosphate-buffer, pH 7.4	100.0 µmol/ml
Glucose-6-phosphate	5.0 µmol/ml

Solubilisation of the test substance

CGA 329351 tech. was dissolved in DMSO at room temperature. The test substance CGA 329351 tech. was soluble up to the concentration of 50 mg/ml. Lower concentrations of the test substance were obtained by appropriate dilution of the stock solution with DMSO. No precipitates or aggregates were noted.

Analytical control

To demonstrate that the test system was exposed to the intended concentrations of the test substance in the mutagenicity tests, the concentration of the substance in solution has been determined by the analytical unit. The analysis was performed with the lowest concentration, which was obtained by serial dilution of the highest concentration used.

Setting up of the test plates

0.1 ml of the overnight cultures were mixed with 2 ml of top agar, either 0.5 ml of 100 mM sodium phosphate buffer (experiments without activation) or 0.5 ml of the activation mixture (experiments with activation) and 0.1 ml of a solution of the test substance, the positive control or the solvent as a negative control and poured on minimal agar in Petri dishes. Each Petri dish contained about 20.0 ml of minimal agar (1.5% agar supplemented with 2% salts of the Vogel-Bonner Medium E and 2% glucose). The top agar was composed of 0.6% agar and 0.6% NaCl. In the experiment with Salmonella the top agar was supplemented with 10% of 0.5 mM L-histidine and 0.5 mM (+)biotin dissolved in water. In the experiment with E. coli it was supplemented with 10% of 0.5 mM L-tryptophan dissolved in water.

Preliminary range finding test

A range finding test was carried out with strains S. typhimurium TA 100 and E. coli WP2 uvrA with and without metabolic activation at six concentrations of the test substance and one negative control according to a Standard Operating Procedure of Genetic Toxicology. The highest concentration applied was 5000 µg/plate. The five lower concentrations decreased by a factor of three. The plates were inverted and incubated for about 48 hours at 37±1.5°C in darkness. Thereafter, they were

evaluated by counting the colonies and determining the background lawn. One plate per test substance concentration and negative control was used.

Mutagenicity test

The mutagenicity test was performed with the Salmonella typhimurium strains TA 98, TA 100, TA 102, TA 1535, TA 1537 and with the Escherichia coli strain WP2 uvrA with and without metabolic activation according to Standard Operating Procedures of Genetic Toxicology. Each of the five concentrations of the test substance, a negative and a positive control were tested, using three plates per test substance concentration and controls. The highest concentration applied was determined in the preliminary range finding test and the four lower concentrations decreased by a factor of two. The plates were inverted and incubated for about 48 hours at 37±1.5°C in darkness. Thereafter, they were evaluated by counting the number of colonies and determining the background lawn.

Negative and positive controls

The solvent alone was used as the negative control. The positive controls were the following reference mutagens:

Experiment with metabolic activation			
Strain	**Mutagen**	**Solvent**	**Concentration**
TA 100	2-Aminoanthracene	DMSO	2.5 µg/plate
TA 1535	Cyclophosphamide	Bidistilled water	400.0 µg/plate
WP2 uvrA	2-Aminoanthracene	DMSO	50.0 µg/plate
TA 102	2-Aminoanthracene	DMSO	20.0 µg/plate
TA 98	2-Aminoanthracene	DMSO	2.5 µg/plate
TA 1537	2-Aminoanthracene	DMSO	2.5 µg/plate

Experiment without metabolic activation			
Strain	**Mutagen**	**Solvent**	**Concentration**
TA 100	Sodium azide	Bidistilled water	5.0 µg/plate
TA 1535	Sodium azide	Bidistilled water	5.0 µg/plate
WP2 uvrA	4-Nitroquinoline (4-NQO)	DMSO	2.0 µg/plate
TA 102	Mitomycin-C	Bidistilled water	2.0 µg/plate
TA 98	2-Nitrofluorene	DMSO	20.0 µg/plate
TA 1537	9-Aminoacridine	DMSO	150.0 µg/plate

Colony counting and scoring of the plates

Colonies were counted electronically using an Artek Colony Counter (Fisher Scientific), or manually where minor agar damage or test chemical precipitates or strong coloration of the agar plates might have interfered with automating counting. The results were sent on line to a computer. They were

checked on a random basis by the operator. Observations indicating precipitates of the test substance in the top agar or a reduced or absent bacterial background lawn were registered additionally. Means for all mutagenicity assays were calculated and included in the Results section.

Assay acceptance criteria

A test is considered acceptable if the mean colony counts of the negative control values of all strains are within the acceptable ranges and if the results of the positive controls meet the criteria for a positive response. In either case the final decision is based on the scientific judgement of the Study Director.

Criteria for a positive response

The test substance will be considered to be positive in the test system if one or both of the following conditions are met:

- At least a reproducible doubling of the mean number of revertants per plate above that of the negative control at any concentration for one or more of the following strains: TA 98, TA 1535, TA 1537, E. coli WP2 uvrA.
- A reproducible increase of the mean number of revertants per plate for any concentration above that of the negative control by at least a factor of 1.5 for strains TA 100 or TA 102.

Generally a concentration-related effect should be demonstrable.

Statistics

A statistical analysis was not performed. At present the use of statistical methods concerning this particular test system is not generally recommended [8].

Negative and positive historical control data and acceptable ranges for negative controls

Arithmetic Mean and Standard Deviation (SD) of colony counts obtained in 75* separate experiments over the period of January 01, 1993 to December 31, 1993 and acceptable ranges for mean colony counts of spontaneous revertants.

With metabolic activation					
Strain	**Substance**	**µg/plate**	**Mean**	**SD**	**Acceptable range**
TA 100	Negative control		140.07	23.38	70-220
	2-Aminoanthracene	2.5	1834.51	455.72	
TA 1535	Negative control		14.21	2.98	7-35
	Cyclophosphamide	400.0	418.92	68.15	
WP2 uvrA	Negative control		20.99	6.71	8-50
	2-Aminoanthracene	50.0	1033.06	308.96	
TA 102	Negative control		266.51	60.21	180-360
	2-Aminoanthracene	20.0	1956.71	576.93	
TA 98	Negative control		37.76	7.12	20-70
	2-Aminoanthracene	2.5	1918.43	399.61	
TA 1537	Negative control		9.41	2.58	5-30
	2-Aminoanthracene	2.5	244.55	95.51	

Without metabolic activation					
Strain	**Substance**	**µg/plate**	**Mean**	**SD**	**Acceptable range**
TA 100	Negative control		130.94	23.24	80-220
	Sodium azide	5.0	1230.86	218.37	
TA 1535	Negative control		13.38	2.83	7-30
	Sodium azide	5.0	1038.50	195.49	
WP2 uvrA	Negative control		19.56	6.58	8-40
	4-Nitroquinoline	2.0	700.02	256.72	
TA 102	Negative control		277.17	89.12	180-360
	Mitomycin-C	2.0	1440.24	365.13	
TA 98	Negative control		21.34	5.69	12-50
	2-Nitrofluorene	20.0	1742.71	267.01	
TA 1537	Negative control		8.61	2.71	3-20
	9-Aminoacridine	150.0	2068.69	483.99	

* 39 of 75 experiments were performed with E.coli WP2 uvrA

RESULTS

Range finding test

Six concentrations of CGA 329351 tech. ranging from 20.6 to 5000.0 µg/plate were tested with strain Salmonella typhimurium TA 100 and strain Escherichia coli WP2 uvrA to determine the highest concentration to be used in the mutagenicity assay. The experiments were performed with and without metabolic activation. Normal background growth was observed with both strains. The numbers of revertant colonies were not reduced except with E. coli in the absence of activation at the highest concentration. From the results obtained (Tables 1-4), the highest concentration suitable for the mutagenicity test was selected to be 5000.0 µg/plate with and 5000.0 µg/plate without metabolic activation.

Mutagenicity test, original experiment

In the experiments performed with and without metabolic activation, treatment of strains TA 98, TA 100, TA 102, TA 1535, TA 1537 and WP2 uvrA with CGA 329351 tech. did not lead to an increase in the incidence of either histidine- or tryptophan-prototrophic mutants in comparison with the negative control (Tables 5, 6 and 10-21).

Mutagenicity test, confirmatory experiment

In the experiments performed with and without metabolic activation, again after treatment of strains TA 98, TA 100, TA 1535, TA 1537 and WP2 uvrA with CGA 329351 tech. no increase in the incidence of either histidine- or tryptophan-prototrophic mutants was observed in comparison with the negative control. Strain TA 102, showed a slight increase at the concentration of 2500 µg/plate in the absence of metabolic activation (Tables 7, 8 and 22-33).

Mutagenicity test, 2nd confirmatory experiment

Due to the slight increase observed with strain TA 102 in the confirmatory experiment without metabolic activation, an additional experiment was performed with this strain. No increase in the incidence of histidine-prototrophic mutants was observed in comparison with the negative control (Tables 9 and 34).
The slight effect observed with strain TA 102 in one out of three experiments is therefore considered purely fortuitous and not related to treatment with the test compound.

In the mutagenicity tests normal background growth was observed with all strains at all concentrations. The numbers of revertant colonies were not reduced with increasing concentration. Therefore, the test substance exerted no toxic effect on the growth of the bacteria.

Analytical control

To confirm that the cells were actually exposed to the intended test concentrations and to confirm the stability of the test substance in the vehicle used, determination of the concentration of the test substance in solution was performed by HPLC with UV-detection. The values found by analysis of the different samples were in agreement with the intended concentrations (92.4, 93.4, and 85.0%), thus demonstrating a sufficient stability of the test substance in the vehicle.

There were no known circumstances or occurrences in this study that were considered to have affected the quality or integrity of the test data.

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LITERATURE

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LEGEND TO TABLES 1 TO 34

P	**Precipitates**
B	**Background reduced**
I	**Background invisible**
E	**Error**
M	**Manual counting**
-	**No remarks**

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TABLE 1 : RANGE FINDING TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 100

Treatment	Colony counts	Mean
Negative control	93	
CGA 329351 tech.:		
20.58 µg/plate	90	
61.73 µg/plate	88	
185.19 µg/plate	113	
555.56 µg/plate	86	
1666.67 µg/plate	113	
5000.00 µg/plate	80	

Treatment	Remarks	Factor
Negative control	-	1.00
CGA 329351 tech.:		
20.58 µg/plate	-	0.97
61.73 µg/plate	-	0.95
185.19 µg/plate	-	1.22
555.56 µg/plate	-	0.92
1666.67 µg/plate	-	1.22
5000.00 µg/plate	-	0.86

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TABLE 2 : RANGE FINDING TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 100

Treatment	Colony counts	Mean
Negative control	104	
CGA 329351 tech.:		
20.58 µg/plate	109	
61.73 µg/plate	101	
185.19 µg/plate	108	
555.56 µg/plate	132	
1666.67 µg/plate	123	
5000.00 µg/plate	81	

Treatment	Remarks	Factor
Negative control	-	1.00
CGA 329351 tech.:		
20.58 µg/plate	-	1.05
61.73 µg/plate	-	0.97
185.19 µg/plate	-	1.04
555.56 µg/plate	-	1.27
1666.67 µg/plate	-	1.18
5000.00 µg/plate	-	0.78

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TABLE 3 : RANGE FINDING TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : WP2 uvrA

Treatment	Colony counts	Mean
Negative control	21	
CGA 329351 tech.:		
20.58 µg/plate	26	
61.73 µg/plate	30	
185.19 µg/plate	24	
555.56 µg/plate	17	
1666.67 µg/plate	29	
5000.00 µg/plate	20	

Treatment	Remarks	Factor
Negative control	-	1.00
CGA 329351 tech.:		
20.58 µg/plate	-	1.24
61.73 µg/plate	-	1.43
185.19 µg/plate	-	1.14
555.56 µg/plate	-	0.81
1666.67 µg/plate	-	1.38
5000.00 µg/plate	-	0.95

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TABLE 4 : RANGE FINDING TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : WP2 uvrA

Treatment	Colony counts	Mean
Negative control	22	
CGA 329351 tech.:		
20.58 µg/plate	19	
61.73 µg/plate	14	
185.19 µg/plate	13	
555.56 µg/plate	28	
1666.67 µg/plate	15	
5000.00 µg/plate	5	

Treatment	Remarks	Factor
Negative control	-	1.00
CGA 329351 tech.:		
20.58 µg/plate	-	0.86
61.73 µg/plate	-	0.64
185.19 µg/plate	-	0.59
555.56 µg/plate	-	1.27
1666.67 µg/plate	-	0.68
5000.00 µg/plate	-	0.23

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TABLE 5 : SUMMARY OF THE MUTAGENICITY EXPERIMENTS
Experiments with metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.

Strain	Treatment	Mean Counts	Strain	Treatment	Mean Counts
TA 100	Negative control	97.00	TA 1535	Negative control	12.00
	312.50 µg/plate	101.67		312.50 µg/plate	11.67
	625.00 µg/plate	103.33		625.00 µg/plate	11.00
	1250.00 µg/plate	82.00		1250.00 µg/plate	13.67
	2500.00 µg/plate	96.67		2500.00 µg/plate	10.00
	5000.00 µg/plate	80.33		5000.00 µg/plate	12.67
	Positive control	1841.67		Positive control	408.00
WP2 uvrA	Negative control	17.67	TA 98	Negative control	33.67
	312.50 µg/plate	17.67		312.50 µg/plate	35.00
	625.00 µg/plate	22.33		625.00 µg/plate	32.67
	1250.00 µg/plate	22.00		1250.00 µg/plate	31.67
	2500.00 µg/plate	19.67		2500.00 µg/plate	29.33
	5000.00 µg/plate	18.33		5000.00 µg/plate	28.67
	Positive control	807.67		Positive control	1788.00
TA 1537	Negative control	6.33	TA 102	Negative control	218.67
	312.50 µg/plate	4.00		312.50 µg/plate	248.67
	625.00 µg/plate	3.33		625.00 µg/plate	246.67
	1250.00 µg/plate	6.00		1250.00 µg/plate	237.67
	2500.00 µg/plate	5.67		2500.00 µg/plate	137.67
	5000.00 µg/plate	5.33		5000.00 µg/plate	150.00
	Positive control	189.33		Positive control	1395.33

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TABLE 6 : SUMMARY OF THE MUTAGENICITY EXPERIMENTS
Experiments without metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.

Strain	Treatment	Mean Counts	Strain	Treatment	Mean Counts
TA 100	Negative control	99.00	TA 1535	Negative control	13.67
	312.50 µg/plate	100.33		312.50 µg/plate	16.67
	625.00 µg/plate	78.33		625.00 µg/plate	9.67
	1250.00 µg/plate	81.67		1250.00 µg/plate	12.33
	2500.00 µg/plate	86.67		2500.00 µg/plate	10.67
	5000.00 µg/plate	86.00		5000.00 µg/plate	9.33
	Positive control	1609.67		Positive control	877.00
WP2 uvrA	Negative control	17.67	TA 98	Negative control	42.33
	312.50 µg/plate	20.00		312.50 µg/plate	46.00
	625.00 µg/plate	17.33		625.00 µg/plate	40.33
	1250.00 µg/plate	19.67		1250.00 µg/plate	45.00
	2500.00 µg/plate	22.33		2500.00 µg/plate	39.67
	5000.00 µg/plate	19.67		5000.00 µg/plate	44.33
	Positive control	678.67		Positive control	1617.00
TA 1537	Negative control	7.00	TA 102	Negative control	226.67
	312.50 µg/plate	5.67		312.50 µg/plate	241.00
	625.00 µg/plate	8.67		625.00 µg/plate	204.33
	1250.00 µg/plate	9.33		1250.00 µg/plate	189.00
	2500.00 µg/plate	7.67		2500.00 µg/plate	131.33
	5000.00 µg/plate	7.00		5000.00 µg/plate	117.00
	Positive control	2956.00		Positive control	1320.33

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TABLE 7 : SUMMARY OF THE MUTAGENICITY EXPERIMENTS
Experiments with metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.

Strain	Treatment	Mean Counts	Strain	Treatment	Mean Counts
TA 100	Negative control	139.33	TA 1535	Negative control	17.67
	312.50 µg/plate	121.33		312.50 µg/plate	19.33
	625.00 µg/plate	142.00		625.00 µg/plate	18.67
	1250.00 µg/plate	113.00		1250.00 µg/plate	19.00
	2500.00 µg/plate	137.33		2500.00 µg/plate	26.33
	5000.00 µg/plate	115.33		5000.00 µg/plate	19.00
	Positive control	2338.00		Positive control	541.33
WP2 uvrA	Negative control	27.67	TA 98	Negative control	53.67
	312.50 µg/plate	30.67		312.50 µg/plate	37.33
	625.00 µg/plate	30.00		625.00 µg/plate	41.00
	1250.00 µg/plate	31.00		1250.00 µg/plate	43.33
	2500.00 µg/plate	24.00		2500.00 µg/plate	50.00
	5000.00 µg/plate	27.33		5000.00 µg/plate	40.67
	Positive control	799.67		Positive control	1851.67
TA 1537	Negative control	11.00	TA 102	Negative control	281.33
	312.50 µg/plate	12.00		312.50 µg/plate	268.00
	625.00 µg/plate	9.00		625.00 µg/plate	385.00
	1250.00 µg/plate	9.00		1250.00 µg/plate	376.00
	2500.00 µg/plate	8.33		2500.00 µg/plate	298.00
	5000.00 µg/plate	10.33		5000.00 µg/plate	218.33
	Positive control	292.00		Positive control	2247.67

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TABLE 8 : SUMMARY OF THE MUTAGENICITY EXPERIMENTS
Experiments without metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.

Strain	Treatment	Mean Counts	Strain	Treatment	Mean Counts
TA 100	Negative control	136.67	TA 1535	Negative control	26.67
	312.50 µg/plate	122.00		312.50 µg/plate	26.33
	625.00 µg/plate	128.67		625.00 µg/plate	19.67
	1250.00 µg/plate	120.67		1250.00 µg/plate	21.67
	2500.00 µg/plate	131.67		2500.00 µg/plate	20.00
	5000.00 µg/plate	139.67		5000.00 µg/plate	15.67
	Positive control	1504.67		Positive control	1219.33
WP2 uvrA	Negative control	24.33	TA 98	Negative control	30.33
	312.50 µg/plate	21.33		312.50 µg/plate	32.33
	625.00 µg/plate	27.33		625.00 µg/plate	27.33
	1250.00 µg/plate	23.67		1250.00 µg/plate	27.00
	2500.00 µg/plate	20.67		2500.00 µg/plate	35.33
	5000.00 µg/plate	19.67		5000.00 µg/plate	28.33
	Positive control	545.67		Positive control	2030.67
TA 1537	Negative control	7.33	TA 102	Negative control	191.00
	312.50 µg/plate	10.00		312.50 µg/plate	174.00
	625.00 µg/plate	8.67		625.00 µg/plate	210.00
	1250.00 µg/plate	12.67		1250.00 µg/plate	170.33
	2500.00 µg/plate	8.00		2500.00 µg/plate	316.00
	5000.00 µg/plate	9.00		5000.00 µg/plate	223.33
	Positive control	2912.00		Positive control	977.00

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TABLE 9 : SUMMARY OF THE MUTAGENICITY EXPERIMENTS
Experiments without metabolic activation

Test number : 943012
Experiment : 2nd Confirmatory
Test substance : CGA 329351 tech.

Strain	Treatment	Mean Counts	Strain	Treatment	Mean Counts
			TA 102	Negative control	252.33
				312.50 µg/plate	240.00
				625.00 µg/plate	216.67
				1250.00 µg/plate	229.33
				2500.00 µg/plate	235.33
				5000.00 µg/plate	196.67
				Positive control	1697.33

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TABLE 10 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 100

Treatment	Colony counts			Mean
Negative control	90	92	109	97.00
CGA 329351 tech.:				
312.50 µg/plate	110	97	98	101.67
625.00 µg/plate	110	98	102	103.33
1250.00 µg/plate	96	76	74	82.00
2500.00 µg/plate	108	92	90	96.67
5000.00 µg/plate	77	80	84	80.33
2-Aminoanthracene 2.50 µg/plate	1740	1748	2037	1841.67

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.05
625.00 µg/plate	-	-	-	1.07
1250.00 µg/plate	-	-	-	0.85
2500.00 µg/plate	-	-	-	1.00
5000.00 µg/plate	-	-	-	0.83
2-Aminoanthracene	-	-	-	18.99

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TABLE 11 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 1535

Treatment	Colony counts			Mean
Negative control	9	12	15	12.00
CGA 329351 tech.:				
312.50 µg/plate	14	11	10	11.67
625.00 µg/plate	16	13	4	11.00
1250.00 µg/plate	14	15	12	13.67
2500.00 µg/plate	15	3	12	10.00
5000.00 µg/plate	6	17	15	12.67
Cyclophosphamide 400.00 µg/plate	414	323	487	408.00

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.97
625.00 µg/plate	-	-	-	0.92
1250.00 µg/plate	-	-	-	1.14
2500.00 µg/plate	-	-	-	0.83
5000.00 µg/plate	-	-	-	1.06
Cyclophosphamide	-	-	-	34.00

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TABLE 12 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : WP2 uvrA

Treatment	Colony counts			Mean
Negative control	17	24	12	17.67
CGA 329351 tech.:				
312.50 µg/plate	13	16	24	17.67
625.00 µg/plate	28	15	24	22.33
1250.00 µg/plate	28	18	20	22.00
2500.00 µg/plate	19	25	15	19.67
5000.00 µg/plate	14	24	17	18.33
2-Aminoanthracene 50.00 µg/plate	861	717	845	807.67

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.00
625.00 µg/plate	-	-	-	1.26
1250.00 µg/plate	-	-	-	1.25
2500.00 µg/plate	-	-	-	1.11
5000.00 µg/plate	-	-	-	1.04
2-Aminoanthracene	-	-	-	45.72

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TABLE 13 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number	:	**943012**
Experiment	:	**Original**
Test substance	:	**CGA 329351 tech.**
Batch	:	**KGL4634/6**
Strain	:	**TA 102**

Treatment	Colony counts			Mean
Negative control	219	206	231	218.67
CGA 329351 tech.:				
312.50 µg/plate	246	282	218	248.67
625.00 µg/plate	222	233	285	246.67
1250.00 µg/plate	207	258	248	237.67
2500.00 µg/plate	125	139	149	137.67
5000.00 µg/plate	111	192	147	150.00
2-Aminoanthracene 20.00 µg/plate	1425	1377	1384	1395.33

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.14
625.00 µg/plate	-	-	-	1.13
1250.00 µg/plate	-	-	-	1.09
2500.00 µg/plate	-	-	-	0.63
5000.00 µg/plate	-	-	-	0.69
2-Aminoanthracene	-	-	-	6.38

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TABLE 14 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 98

Treatment	Colony counts			Mean
Negative control	41	33	27	33.67
CGA 329351 tech.:				
312.50 µg/plate	37	36	32	35.00
625.00 µg/plate	29	27	42	32.67
1250.00 µg/plate	33	24	38	31.67
2500.00 µg/plate	38	26	24	29.33
5000.00 µg/plate	28	31	27	28.67
2-Aminoanthracene 2.50 µg/plate	1400	1880	2084	1788.00

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.04
625.00 µg/plate	-	-	-	0.97
1250.00 µg/plate	-	-	-	0.94
2500.00 µg/plate	-	-	-	0.87
5000.00 µg/plate	-	-	-	0.85
2-Aminoanthracene	-	-	-	53.11

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TABLE 15 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 1537

Treatment	Colony counts			Mean
Negative control	8	4	7	6.33
CGA 329351 tech.:				
312.50 µg/plate	4	3	5	4.00
625.00 µg/plate	3	5	2	3.33
1250.00 µg/plate	3	9	6	6.00
2500.00 µg/plate	6	4	7	5.67
5000.00 µg/plate	7	5	4	5.33
2-Aminoanthracene 2.50 µg/plate	124	198	246	189.33

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.63
625.00 µg/plate	-	-	-	0.53
1250.00 µg/plate	-	-	-	0.95
2500.00 µg/plate	-	-	-	0.89
5000.00 µg/plate	-	-	-	0.84
2-Aminoanthracene	-	-	-	29.89

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TABLE 16 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 100

Treatment	Colony counts			Mean
Negative control	113	80	104	99.00
CGA 329351 tech.:				
312.50 µg/plate	99	101	101	100.33
625.00 µg/plate	87	82	66	78.33
1250.00 µg/plate	81	84	80	81.67
2500.00 µg/plate	92	88	80	86.67
5000.00 µg/plate	89	75	94	86.00
Sodium azide 5.00 µg/plate	1612	1671	1546	1609.67

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.01
625.00 µg/plate	-	-	-	0.79
1250.00 µg/plate	-	-	-	0.82
2500.00 µg/plate	-	-	-	0.88
5000.00 µg/plate	-	-	-	0.87
Sodium azide	-	-	-	16.26

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TABLE 17 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 1535

Treatment	Colony counts			Mean
Negative control	14	14	13	13.67
CGA 329351 tech.:				
312.50 µg/plate	21	12	17	16.67
625.00 µg/plate	6	16	7	9.67
1250.00 µg/plate	17	13	7	12.33
2500.00 µg/plate	13	5	14	10.67
5000.00 µg/plate	14	8	6	9.33
Sodium azide 5.00 µg/plate	868	856	907	877.00

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.22
625.00 µg/plate	-	-	-	0.71
1250.00 µg/plate	-	-	-	0.90
2500.00 µg/plate	-	-	-	0.78
5000.00 µg/plate	-	-	-	0.68
Sodium azide	-	-	-	64.17

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TABLE 18 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number	:	**943012**
Experiment	:	**Original**
Test substance	:	**CGA 329351 tech.**
Batch	:	**KGL4634/6**
Strain	:	**WP2 uvrA**

Treatment	**Colony counts**			**Mean**
Negative control	19	21	13	17.67
CGA 329351 tech.:				
312.50 µg/plate	21	24	15	20.00
625.00 µg/plate	16	24	12	17.33
1250.00 µg/plate	18	24	17	19.67
2500.00 µg/plate	16	25	26	22.33
5000.00 µg/plate	20	14	25	19.67
4-NQO 2.00 µg/plate	699	708	629	678.67

Treatment	**Remarks**			**Factor**
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.13
625.00 µg/plate	-	-	-	0.98
1250.00 µg/plate	-	-	-	1.11
2500.00 µg/plate	-	-	-	1.26
5000.00 µg/plate	-	-	-	1.11
4-NQO	-	-	-	38.42

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TABLE 19 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 102

Treatment	Colony counts			Mean
Negative control	210	254	216	226.67
CGA 329351 tech.:				
312.50 µg/plate	265	205	253	241.00
625.00 µg/plate	157	227	229	204.33
1250.00 µg/plate	197	164	206	189.00
2500.00 µg/plate	114	145	135	131.33
5000.00 µg/plate	100	151	100	117.00
Mitomycin-C 2.00 µg/plate	1344	1325	1292	1320.33

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.06
625.00 µg/plate	-	-	-	0.90
1250.00 µg/plate	-	-	-	0.83
2500.00 µg/plate	-	-	-	0.58
5000.00 µg/plate	-	-	-	0.52
Mitomycin-C	-	-	-	5.83

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TABLE 20 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 98

Treatment	Colony counts			Mean
Negative control	40	42	45	42.33
CGA 329351 tech.:				
312.50 µg/plate	48	42	48	46.00
625.00 µg/plate	42	39	40	40.33
1250.00 µg/plate	39	47	49	45.00
2500.00 µg/plate	42	36	41	39.67
5000.00 µg/plate	49	40	44	44.33
2-Nitrofluorene 20.00 µg/plate	1707	1492	1652	1617.00

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.09
625.00 µg/plate	-	-	-	0.95
1250.00 µg/plate	-	-	-	1.06
2500.00 µg/plate	-	-	-	0.94
5000.00 µg/plate	-	-	-	1.05
2-Nitrofluorene	-	-	-	38.20

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TABLE 21 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Original
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 1537

Treatment	Colony counts			Mean
Negative control	6	6	9	7.00
CGA 329351 tech.:				
312.50 µg/plate	8	5	4	5.67
625.00 µg/plate	8	6	12	8.67
1250.00 µg/plate	11	5	12	9.33
2500.00 µg/plate	9	5	9	7.67
5000.00 µg/plate	6	7	8	7.00
9-Aminoacridine 150.00 µg/plate	3067	2837	2964	2956.00

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.81
625.00 µg/plate	-	-	-	1.24
1250.00 µg/plate	-	-	-	1.33
2500.00 µg/plate	-	-	-	1.10
5000.00 µg/plate	-	-	-	1.00
9-Aminoacridine	-	-	-	422.29

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TABLE 22 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 100

Treatment	Colony counts			Mean
Negative control	136	168	114	139.33
CGA 329351 tech.:				
312.50 µg/plate	136	108	120	121.33
625.00 µg/plate	115	163	148	142.00
1250.00 µg/plate	111	117	111	113.00
2500.00 µg/plate	139	133	140	137.33
5000.00 µg/plate	103	103	140	115.33
2-Aminoanthracene 2.50 µg/plate	2523	2245	2246	2338.00

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.87
625.00 µg/plate	-	-	-	1.02
1250.00 µg/plate	-	-	-	0.81
2500.00 µg/plate	-	-	-	0.99
5000.00 µg/plate	-	-	-	0.83
2-Aminoanthracene	-	-	-	16.78

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TABLE 23 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number	: 943012
Experiment	: Confirmatory
Test substance	: CGA 329351 tech.
Batch	: KGL4634/6
Strain	: TA 1535

Treatment	Colony counts			Mean
Negative control	20	16	17	17.67
CGA 329351 tech.:				
312.50 µg/plate	19	21	18	19.33
625.00 µg/plate	16	15	25	18.67
1250.00 µg/plate	18	19	20	19.00
2500.00 µg/plate	28	32	19	26.33
5000.00 µg/plate	21	16	20	19.00
Cyclophosphamide 400.00 µg/plate	508	561	555	541.33

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.09
625.00 µg/plate	-	-	-	1.06
1250.00 µg/plate	-	-	-	1.08
2500.00 µg/plate	-	-	-	1.49
5000.00 µg/plate	-	-	-	1.08
Cyclophosphamide	-	-	-	30.64

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TABLE 24 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : WP2 uvrA

Treatment	Colony counts			Mean
Negative control	21	26	36	27.67
CGA 329351 tech.:				
312.50 µg/plate	27	38	27	30.67
625.00 µg/plate	31	32	27	30.00
1250.00 µg/plate	26	41	26	31.00
2500.00 µg/plate	26	26	20	24.00
5000.00 µg/plate	31	25	26	27.33
2-Aminoanthracene 50.00 µg/plate	589	884	926	799.67

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.11
625.00 µg/plate	-	-	-	1.08
1250.00 µg/plate	-	-	-	1.12
2500.00 µg/plate	-	-	-	0.87
5000.00 µg/plate	-	-	-	0.99
2-Aminoanthracene	-	-	-	28.90

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TABLE 25 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 102

Treatment	Colony counts			Mean
Negative control	269	290	285	281.33
CGA 329351 tech.:				
312.50 µg/plate	230	290	284	268.00
625.00 µg/plate	396	362	397	385.00
1250.00 µg/plate	339	389	400	376.00
2500.00 µg/plate	277	309	308	298.00
5000.00 µg/plate	210	186	259	218.33
2-Aminoanthracene 20.00 µg/plate	2258	2251	2234	2247.67

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.95
625.00 µg/plate	-	-	-	1.37
1250.00 µg/plate	-	-	-	1.34
2500.00 µg/plate	-	-	-	1.06
5000.00 µg/plate	-	-	-	0.78
2-Aminoanthracene	-	-	-	7.99

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TABLE 26 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 98

Treatment	Colony counts			Mean
Negative control	50	51	60	53.67
CGA 329351 tech.:				
312.50 µg/plate	45	38	29	37.33
625.00 µg/plate	32	36	55	41.00
1250.00 µg/plate	31	51	48	43.33
2500.00 µg/plate	55	62	33	50.00
5000.00 µg/plate	42	42	38	40.67
2-Aminoanthracene 2.50 µg/plate	1365	2168	2022	1851.67

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.70
625.00 µg/plate	-	-	-	0.76
1250.00 µg/plate	-	-	-	0.81
2500.00 µg/plate	-	-	-	0.93
5000.00 µg/plate	-	-	-	0.76
2-Aminoanthracene	-	-	-	34.50

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TABLE 27 : MUTAGENICITY TEST
Experiment with metabolic activation

Test number	:	**943012**
Experiment	:	**Confirmatory**
Test substance	:	**CGA 329351 tech.**
Batch	:	**KGL4634/6**
Strain	:	**TA 1537**

Treatment	Colony counts			Mean
Negative control	8	12	13	11.00
CGA 329351 tech.:				
312.50 µg/plate	15	7	14	12.00
625.00 µg/plate	6	6	15	9.00
1250.00 µg/plate	6	16	5	9.00
2500.00 µg/plate	8	8	9	8.33
5000.00 µg/plate	14	12	5	10.33
2-Aminoanthracene 2.50 µg/plate	245	326	305	292.00

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.09
625.00 µg/plate	-	-	-	0.82
1250.00 µg/plate	-	-	-	0.82
2500.00 µg/plate	-	-	-	0.76
5000.00 µg/plate	-	-	-	0.94
2-Aminoanthracene	-	-	-	26.55

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TABLE 28 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 100

Treatment	Colony counts			Mean
Negative control	147	129	134	136.67
CGA 329351 tech.:				
312.50 µg/plate	111	141	114	122.00
625.00 µg/plate	124	129	133	128.67
1250.00 µg/plate	116	141	105	120.67
2500.00 µg/plate	134	138	123	131.67
5000.00 µg/plate	133	140	146	139.67
Sodium azide 5.00 µg/plate	1449	1404	1661	1504.67

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.89
625.00 µg/plate	-	-	-	0.94
1250.00 µg/plate	-	-	-	0.88
2500.00 µg/plate	-	-	-	0.96
5000.00 µg/plate	-	-	-	1.02
Sodium azide	-	-	-	11.01

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TABLE 29 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 1535

Treatment	Colony counts			Mean
Negative control	29	27	24	26.67
CGA 329351 tech.:				
312.50 µg/plate	28	24	27	26.33
625.00 µg/plate	18	20	21	19.67
1250.00 µg/plate	21	20	24	21.67
2500.00 µg/plate	18	25	17	20.00
5000.00 µg/plate	17	15	15	15.67
Sodium azide 5.00 µg/plate	1230	1256	1172	1219.33

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.99
625.00 µg/plate	-	-	-	0.74
1250.00 µg/plate	-	-	-	0.81
2500.00 µg/plate	-	-	-	0.75
5000.00 µg/plate	-	-	-	0.59
Sodium azide	-	-	-	45.73

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TABLE 30 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : WP2 uvrA

Treatment	Colony counts			Mean
Negative control	21	26	26	24.33
CGA 329351 tech.:				
312.50 µg/plate	26	20	18	21.33
625.00 µg/plate	31	25	26	27.33
1250.00 µg/plate	25	27	19	23.67
2500.00 µg/plate	20	18	24	20.67
5000.00 µg/plate	25	14	20	19.67
4-NQO 2.00 µg/plate	590	560	487	545.67

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.88
625.00 µg/plate	-	-	-	1.12
1250.00 µg/plate	-	-	-	0.97
2500.00 µg/plate	-	-	-	0.85
5000.00 µg/plate	-	-	-	0.81
4-NQO	-	-	-	22.42

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TABLE 31 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 102

Treatment	Colony counts			Mean
Negative control	168	184	221	191.00
CGA 329351 tech.:				
312.50 µg/plate	136	170	216	174.00
625.00 µg/plate	208	241	181	210.00
1250.00 µg/plate	148	180	183	170.33
2500.00 µg/plate	290	331	327	316.00
5000.00 µg/plate	195	211	264	223.33
Mitomycin-C 2.00 µg/plate	784	1096	1051	977.00

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.91
625.00 µg/plate	-	-	-	1.10
1250.00 µg/plate	-	-	-	0.89
2500.00 µg/plate	-	-	-	1.65
5000.00 µg/plate	-	-	-	1.17
Mitomycin-C	-	-	-	5.12

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TABLE 32 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 98

Treatment	Colony counts			Mean
Negative control	28	31	32	30.33
CGA 329351 tech.:				
312.50 µg/plate	29	31	37	32.33
625.00 µg/plate	32	24	26	27.33
1250.00 µg/plate	30	25	26	27.00
2500.00 µg/plate	26	44	36	35.33
5000.00 µg/plate	17	40	28	28.33
2-Nitrofluorene 20.00 µg/plate	1965	1972	2155	2030.67

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.07
625.00 µg/plate	-	-	-	0.90
1250.00 µg/plate	-	-	-	0.89
2500.00 µg/plate	-	-	-	1.16
5000.00 µg/plate	-	-	-	0.93
2-Nitrofluorene	-	-	-	66.95

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TABLE 33 : MUTAGENICITY TEST
Experiment without metabolic activation

Test number : 943012
Experiment : Confirmatory
Test substance : CGA 329351 tech.
Batch : KGL4634/6
Strain : TA 1537

Treatment	Colony counts			Mean
Negative control	7	7	8	7.33
CGA 329351 tech.:				
312.50 µg/plate	8	14	8	10.00
625.00 µg/plate	12	6	8	8.67
1250.00 µg/plate	14	12	12	12.67
2500.00 µg/plate	7	8	9	8.00
5000.00 µg/plate	6	7	14	9.00
9-Aminoacridine 150.00 µg/plate	2814	2910	3012	2912.00

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	1.36
625.00 µg/plate	-	-	-	1.18
1250.00 µg/plate	-	-	-	1.73
2500.00 µg/plate	-	-	-	1.09
5000.00 µg/plate	-	-	-	1.23
9-Aminoacridine	-	-	-	397.09

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TABLE 34	:	MUTAGENICITY TEST Experiment without metabolic activation
Test number	:	943012
Experiment	:	2nd Confirmatory
Test substance	:	CGA 329351 tech.
Batch	:	KGL4634/6
Strain	:	TA 102

Treatment	Colony counts			Mean
Negative control	269	240	248	252.33
CGA 329351 tech.:				
312.50 µg/plate	222	255	243	240.00
625.00 µg/plate	230	211	209	216.67
1250.00 µg/plate	234	212	242	229.33
2500.00 µg/plate	261	240	205	235.33
5000.00 µg/plate	165	229	196	196.67
Mitomycin-C 2.00 µg/plate	1746	1694	1652	1697.33

Treatment	Remarks			Factor
Negative control	-	-	-	1.00
CGA 329351 tech.:				
312.50 µg/plate	-	-	-	0.95
625.00 µg/plate	-	-	-	0.86
1250.00 µg/plate	-	-	-	0.91
2500.00 µg/plate	-	-	-	0.93
5000.00 µg/plate	-	-	-	0.78
Mitomycin-C	-	-	-	6.73

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SALMONELLA AND ESCHERICHIA/MAMMALIAN-MICROSOME MUTAGENICITY TEST

SUMMARIZED REPORT TO 943012

CGA 329351 tech.

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Report of Result of Mutagenicity Test using Microorganisms

1. General Item

Name of the new chemical substance (IUPAC nomenclature)			
Other name	CGA 329351 tech.		
Structural formula or rational formula (or outline of manu-facturing method, in case both are unknown)			
Purity of the new chemical substance tested	97.3%	**Lot of the chemical substance tested**	KGL4634/6
Name and concentration of impurities			
CAS number		**Vapor pressure**	
Molecular weight		**Partition coefficient**	
Melting point		**Appearance at ordinary temperature**	Liquid
Boiling point			
Stability			

Solubility in solvent	**Solvent**	**Solubility**	**Solvent**	**Solubility**
	Water		DMSO	>50mg/ml
	Acetone			

2. Tester Strains

(1) Procurement

Strains	Obtained from	Date obtained	Date of confirming genotypes of the stored lot used in the experiment
TA 98	Prof. [redacted]	January 1983	March 01, April 04 and June 08, 1994
TA 100	Dr. [redacted] (Hoffmann-La Roche)	June 1986	March 01, April 04 and June 08, 1994
TA 102	Prof. [redacted]	January 1983	March 01, April 04 and June 08, 1994
TA 1535	Prof. [redacted]	January 1983	March 01, April 04 and June 08, 1994
TA 1537	Prof. [redacted]	January 1983	March 01, April 04 and June 08, 1994
E. coli WP2 uvrA	National Collection of Industrial Bacteria, Aberdeen, Scotland	April 1977	March 01, April 04 and June 08, 1994

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(2) Storage (The applicable number is darkly marked)

Method of storage	1. Frozen in small volume	2. Frozen in large volume	3. Others
Storage temperature	-80°C		
Composition	Bacterial suspension: 9.25 ml DMSO: 0.75 ml		

3. S9 Mix

(1) Source of S9 (The applicable number is darkly marked)

Made in-house or purchased	1. Made in-house	2. Purchased
Prepared on -	January 27,February 03 and March 16, 1994	
Lot No. (if purchased)		
Storage temperature	-80°C	

(2) Preparation of S9

Animal used		Inducing substance	
Species, Strain	Rat, Tif:RAIF [SPF]	Name	Aroclor 1254
Sex	Male	Administration method	i.p.
Age (in weeks)	Approx. 7 weeks	Administration period and amount (g/kg body weight)	Single application 5 days prior sacrifice 0.5 g/kg in sesame oil
Weight	178 to 201, 195 to 207 and 177 to 197 g		

(3) Composition of S9 Mix

Constituents	Amount in 1 ml S9 mix	Constituents	Amount in 1 ml S9 mix
S9	0.1 ml		
$MgCl_2$	8.0 µmol	NADP	4.0 µmol
KCl	33.0 µmol	Na-phosphate buffer (pH 7.4)	100.0 µmol
Glucose-6-phosphate	5.0 µmol		
Glucose-6-phosphate dehydrogenase			

4. Positive Control and its Solvent (The applicable number is darkly marked)

Substance		Supplier	Lot No.	Grade	Purity %	Solvent
Positive control	9-Aminoacridine	Fluka Switzerland	266691 688	purum	98.5	DMSO
	2-Aminoanthracene	Sigma USA	58 F 3463	practicum	*	DMSO
	Cyclophosphamide	Koch-Light England	86649	purum	*	Bidistilled water
	Sodium azide	Fluka Switzerland	202476 978	purum	>99.0	Bidistilled water
	4-Nitroquinoline (4-NQO)	Fluka Switzerland	219741 889	purum	>97.0	DMSO
	2-Nitrofluorene	Merck Germany	8249156	p.a.	>98.0	DMSO
	Mitomycin-C	Syntex Pharm Switzerland	922122	*	*	Bidistilled water
Preparation and storage etc. of the solution of the positive control		1. Prepared in use				
		2. Distributed and stored (storage temperature -20°C)				
		3. Numbers 1&2 §				

* No data available
§ Cyclophosphamide prepared in use. From all other controls stored samples were used

5. Preparation of the Solution of the Test Substance (The applicable number is darkly marked)

Solvent used	Name	Supplier	Lot No.	Grade	Purity %
	Dimethylsulfoxide	Merck	17817352	puriss	99.5%
Stability of the test substance in the solvent					
Rationale for selection of the solvent	Solubility				
Method of suspension etc. when test substance is difficult to dissolve					
Storage period and temperature of the solution from preparation until use	About half an hour In case aqueous solutions are used they are stored on ice at 4°C All other solutions are stored at room temperature in the dark				
Correction of purity	Yes				
	No				

6. Conditions of Pre-culture, etc.

(1) Condition

Nutrient broth	Name	Manufacture	Lot No.
	Nutrient broth No. 2	Oxoid Ltd., Basingstoke, England	CM67
Period of pre-culture	About 16 hours		
Storage period/temperature from inoculation of the tester strains until initiation of incubation with shaking	About 5 minutes at room temperature		
Storage period/temperature from completion of incubation until use	2-3 hours at 4°C		
Model and manufacturer of shaking incubator	Horizontal shaker INFORS AG, Basle, Switzerland		
Method of shaking (Procedure, times of shaking, etc.)	Horizontal shaking at 37°C, 130-140 rounds per minute		
Container for incubation (shape, volume)	250 ml glass bottles		
Volume of medium	100 ml	Volume of the tester strain inoculated	3-8 colonies from a master plate

(2) Density of Tester Strain Cultures at the Termination of Pre-culture (The applicable number is darkly marked)

		Base-pair substitution type				Frameshift type	
		TA 100	TA 1535	WP2 uvrA	TA 102	TA 98	TA 1537
Density $x10^9$/ml	Range finding study	0.80		0.71			
	Main study Orig./Conf.	0.58/0.92	0.69/1.16	0.58/1.51	0.39/0.034/ 1.18	0.72/1.36	0.09/0.13
Method of determination		1. Conversion from O.D. value					
		2. Dilution method					
		3. Others					

7. Agar Medium, etc.

(1) Top Agar

Agar	Name	Agar, bacteriological grade
	Manufacturer	GIBCO Ltd., Paisley, Scotland
	Lot No.	20H0240B

(2) Minimum Glucose Agar Plate Medium (The applicable number is darkly marked)

Made in-house or purchased	**1. Made in-house**
	2. Purchased
Prepared on	2-10 days before start of the experiment
Lot No. (if purchased)	
Name/Manufacturer/Lot No. of agar used	GIBCO Ltd., Paisley, Scotland 20H0240B

8. Sterility Test

	Bacterial growth other than those used for test	
Test substance solution	Yes	**No**
S9 Mix	Yes	**No**

9. Test Method

		Plate method	Pre-incubation method
Composition	**Bacterial suspension**	0.1 ml	
	Test substance solution	0.1 ml	
	Na-phosphate buffer	0.5 ml	
	S9 Mix (in case of metabolic activation method)	0.5 ml	
	Top agar solution	2.0 ml	
Pre-incubation	**Temperature**		
	Time		
Incubation	**Temperature**	about 37°C	
	Time	about 48 hours	

10. Method of Counting the Number of Colonies (The applicable number is darkly marked)

Method of counting	1. Manual
	2. With colony counter
Rationale for using the methods of nos. 1 and 2	Method is exact, efficient and economic
Name, model and manufacturer of colony counter	Artek Colony Counter, Model 880 Artek Systems Corporation, USA
Method for correction	1. Not corrected
	2. Correction with area
	3. Correction for numbers counted out
	4. Nos. 2 & 3

11. Test results

(1) Test results should be reported on the attached form
(2) Judgement of the result

Judgement	Positive
	Negative
Reason for judgement and referential matters: There was no increase in the number of back-mutant colonies in comparison with the negative control at any tested concentration of CGA 329351 tech.	

12. Others

Testing Institution	**Name**	CIBA-GEIGY Ltd., Genetic Toxicology		
	Address	CH-4002 Basle, Switzerland, Tel.: 41 61/697 11 11		
Administrator	**Name**	Dr. [redacted]	**Signature**	[redacted]
			Final education career and specialized field	[redacted] Zoology University of Basle
Individual Responsible for Archive Storage	**Name**	Mrs. [redacted]	**Signature**	[redacted]
Individual Responsible for Quality Assurance	**Name**	Mr. [redacted]	**Signature**	[redacted]
Study Director	**Name**	Dr. [redacted]	**Signature**	[redacted]
	Years of experience	4 years	**Final education career and specialized field**	Dr. [redacted], Cell Biology Zürich
Personnel engaged in study	**Name**	Mr. [redacted]	**Signature**	[redacted]
	Years of experience	3 years	**Final education career and specialized field**	See Appendix
Personnel engaged in study	**Name**	Mrs. [redacted]	**Signature**	[redacted]
	Years of experience	8 years	**Final education career and specialized field**	See Appendix
Personnel engaged in study	**Name**	Mrs. [redacted]	**Signature**	[redacted]
	Years of experience	1 year	**Final education career and specialized field**	See Appendix
Test dates	February 28 to June 27, 1994			
Test number	943012			

Remarks
1. "Stability". Fill in the stability for water, other solvents, heat, light, etc.
2. "Vapor pressure". Fill in the vapor pressure of the test substance at 25°C.
3. "Solubility". Fill in such information as water-soluble, soluble in oil.
4. "Degree of solubility". Fill in the solubility at 25°C for each solvent.
5. "Partition coefficient": Fill in the value at 37°C and the name of the solvent used for the measurement.
6. "Years of experience". Fill in the years of experience performing mutagenicity test.
7. "Reason for judgement and referential matters". Fill in the opinion of the Study Director of the test results.
8. "Administrator", "Study Director" and "Personnel engaged in a study" are defined in paragraph 2 of Annex 3, "Standards to be observed, Mutagenicity Testing Institutions".

Table of Test Results

(Original experiment)

Name of Test Substance: CGA 329351 tech.

With(+) or without(-) S9 Mix	Test substance concentration (µg/plate)	Number of revertants (number of colonies/plate)					
		Base-pair substitution type				Frameshift type	
		TA 100	TA 1535	WP2 uvrA	TA 102	TA 98	TA 1537
S9 Mix (+)	Solvent control	90 92 109 (97)	9 12 15 (12)	17 24 12 (18)	219 206 231 (219)	41 33 27 (34)	8 4 7 (6)
	312.50	110 97 98 (102)	14 11 10 (12)	13 16 24 (18)	246 282 218 (249)	37 36 32 (35)	4 3 5 (4)
	625.00	110 98 102 (103)	16 13 4 (11)	28 15 24 (22)	222 233 285 (247)	29 27 42 (33)	3 5 2 (3)
	1250.00	96 76 74 (82)	14 15 12 (14)	28 18 20 (22)	207 258 248 (238)	33 24 38 (32)	3 9 6 (6)
	≥2500.00	108 92 90 (97)	15 3 12 (10)	19 25 15 (20)	125 139 149 (138)	38 26 24 (29)	6 4 7 (6)
	5000.00	77 80 84 (80)	6 17 15 (13)	14 24 17 (18)	111 192 147 (150)	28 31 27 (29)	7 5 4 (5)
S9 Mix (-)	Solvent control	113 80 104 (99)	14 14 13 (14)	19 21 13 (18)	210 254 216 (227)	40 42 45 (42)	6 6 9 (7)
	312.50	99 101 101 (100)	21 12 17 (17)	21 24 15 (20)	265 205 253 (241)	48 42 48 (46)	8 5 4 (6)
	625.00	87 82 66 (78)	6 16 7 (10)	16 24 12 (17)	157 227 229 (204)	42 39 40 (40)	8 6 12 (9)
	1250.00	81 84 80 (82)	17 13 7 (12)	18 24 17 (20)	197 164 206 (189)	39 47 49 (45)	11 5 12 (9)
	2500.00	92 88 80 (87)	13 5 14 (11)	16 25 26 (22)	114 145 135 (131)	42 36 41 (40)	9 5 9 (8)
	5000.00	89 75 94 (86)	14 8 6 (9)	20 14 25 (20)	100 151 100 (117)	49 40 44 (44)	6 7 8 (7)
Positive control requiring S9 Mix	Name	2-Amino-anthracene	Cyclo-phosphamide	2-Amino-anthracene	2-Amino-anthracene	2-Amino-anthracene	2-Amino-anthracene
	Concentration (µg/plate)	2.50	400.00	50.00	20.00	2.50	2.50
	Number of colonies/plate	1740 1748 2037 (1842)	414 323 487 (408)	861 717 845 (808)	1425 1377 1384 (1395)	1400 1880 2084 (1788)	124 198 246 (189)
Positive control not requiring S9 Mix	Name	Sodium azide	Sodium azide	4-NQO	Mitomycin-C	2-Nitro-fluorene	9-Amino-acridine
	Concentration (µg/plate)	5.00	5.00	2.00	2.00	20.00	150.00
	Number of colonies/plate	1612 1671 1546 (1610)	868 856 907 (877)	699 708 629 (679)	1344 1325 1292 (1320)	1707 1492 1652 (1617)	3067 2837 2964 (2956)

Notes:
1. When inhibition is found against growth of the bacteria, mark the applicable value with an asterix
2. Fill the average number of colonies in each concentration in the ( )
3. "Number of revertants"-Fill in the observed value and average value in order beginning with low concentration of the test substance

Table of Test Results

(Confirmatory experiment)

Name of Test Substance: CGA 329351 tech.

With(+) or without(-) S9 Mix	Test substance concentration (μg/plate)	Number of revertants (number of colonies/plate)					
		Base-pair substitution type				Frameshift type	
		TA 100	TA 1535	WP2 uvrA	TA 102	TA 98	TA 1537
S9 Mix (+)	Solvent control	136 168 114 (139)	20 16 17 (18)	21 26 36 (28)	269 290 285 (281)	50 51 60 (54)	8 12 13 (11)
	312.50	136 108 120 (121)	19 21 18 (19)	27 38 27 (31)	230 290 284 (268)	45 38 29 (37)	15 7 14 (12)
	625.00	115 163 148 (142)	16 15 25 (19)	31 32 27 (30)	396 362 397 (385)	32 36 55 (41)	6 6 15 (9)
	1250.00	111 117 111 (113)	18 19 20 (19)	26 41 26 (31)	339 389 400 (376)	31 51 48 (43)	6 16 5 (9)
	2500.00	139 133 140 (137)	28 32 19 (26)	26 26 20 (24)	277 309 308 (298)	55 62 33 (50)	8 8 9 (8)
	5000.00	103 103 140 (115)	21 16 20 (19)	31 25 26 (27)	210 186 259 (218)	42 42 38 (41)	14 12 5 (10)
S9 Mix (-)	Solvent control	147 129 134 (137)	29 27 24 (27)	21 26 26 (24)	168 184 221 (191)	28 31 32 (30)	7 7 8 (7)
	312.50	111 141 114 (122)	28 24 27 (26)	26 20 18 (21)	136 170 216 (174)	29 31 37 (32)	8 14 8 (10)
	625.00	124 129 133 (129)	18 20 21 (20)	31 25 26 (27)	208 241 181 (210)	32 24 26 (27)	12 6 8 (9)
	1250.00	116 141 105 (121)	21 20 24 (22)	25 27 19 (24)	148 180 183 (170)	30 25 26 (27)	14 12 12 (13)
	2500.00	134 138 123 (132)	18 25 17 (20)	20 18 24 (21)	290 331 327 (316)	26 44 36 (35)	7 8 9 (8)
	5000.00	133 140 146 (140)	17 15 15 (16)	25 14 20 (20)	195 211 264 (223)	17 40 28 (28)	6 7 14 (9)
Positive control requiring S9 Mix	Name	2-Amino-anthracene	Cyclo-phosphamide	2-Amino-anthracene	2-Amino-anthracene	2-Amino-anthracene	2-Amino-anthracene
	Concentration (μg/plate)	2.50	400.00	50.00	20.00	2.50	2.50
	Number of colonies/plate	2523 2245 2246 (2338)	508 561 555 (541)	589 884 926 (800)	2258 2251 2234 (2248)	1365 2168 2022 (1852)	245 326 305 (292)
Positive control not requiring S9 Mix	Name	Sodium azide	Sodium azide	4-NQO	Mitomycin-C	2-Nitro-fluorene	9-Amino-acridine
	Concentration (μg/plate)	5.00	5.00	2.00	2.00	20.00	150.00
	Number of colonies/plate	1449 1404 1661 (1505)	1230 1256 1172 (1219)	590 560 487 (546)	784 1096 1051 (977)	1965 1972 2155 (2031)	2814 2910 3012 (2912)

Notes:
1. When inhibition is found against growth of the bacteria, mark the applicable value with an asterix
2. Fill the average number of colonies in each concentration in the ( )
3. "Number of revertants"-Fill in the observed value and average value in order beginning with low concentration of the test substance

Table of Test Results

(Confirmatory experiment)

Name of Test Substance: CGA 329351 tech.

With(+) or without(-) S9 Mix	Test substance concentration (µg/plate)	Number of revertants (number of colonies/plate)					
		Base-pair substitution type				Frameshift type	
					TA 102		
S9 Mix (+)	Solvent control						
S9 Mix (-)	Solvent control				269 240 248 (252)		
	312.50				222 255 243 (240)		
	625.00				230 211 209 (217)		
	1250.00				234 212 242 (229)		
	2500.00				261 240 205 (235)		
	5000.00				165 229 196 (197)		
Positive control requiring S9 Mix	Name						
	Concentration (µg/plate)						
	Number of colonies/plate						
Positive control not requiring S9 Mix	Name				Mitomycin-C		
	Concentration (µg/plate)				2.00		
	Number of colonies/plate				1746 1694 1652 (1697)		

Notes:
1. When inhibition is found against growth of the bacteria, mark the applicable value with an asterix
2. Fill the average number of colonies in each concentration in the ( )
3. "Number of revertants"-Fill in the observed value and average value in order beginning with low concentration of the test substance

SALMONELLA AND ESCHERICHIA/MAMMALIAN-MICROSOME MUTAGENICITY TEST

CGA 329351 tech.

APPENDIX TO THE SUMMARIZED REPORT 943012

PERSONAL RECORDS OF PERSONNEL

(6 pages)

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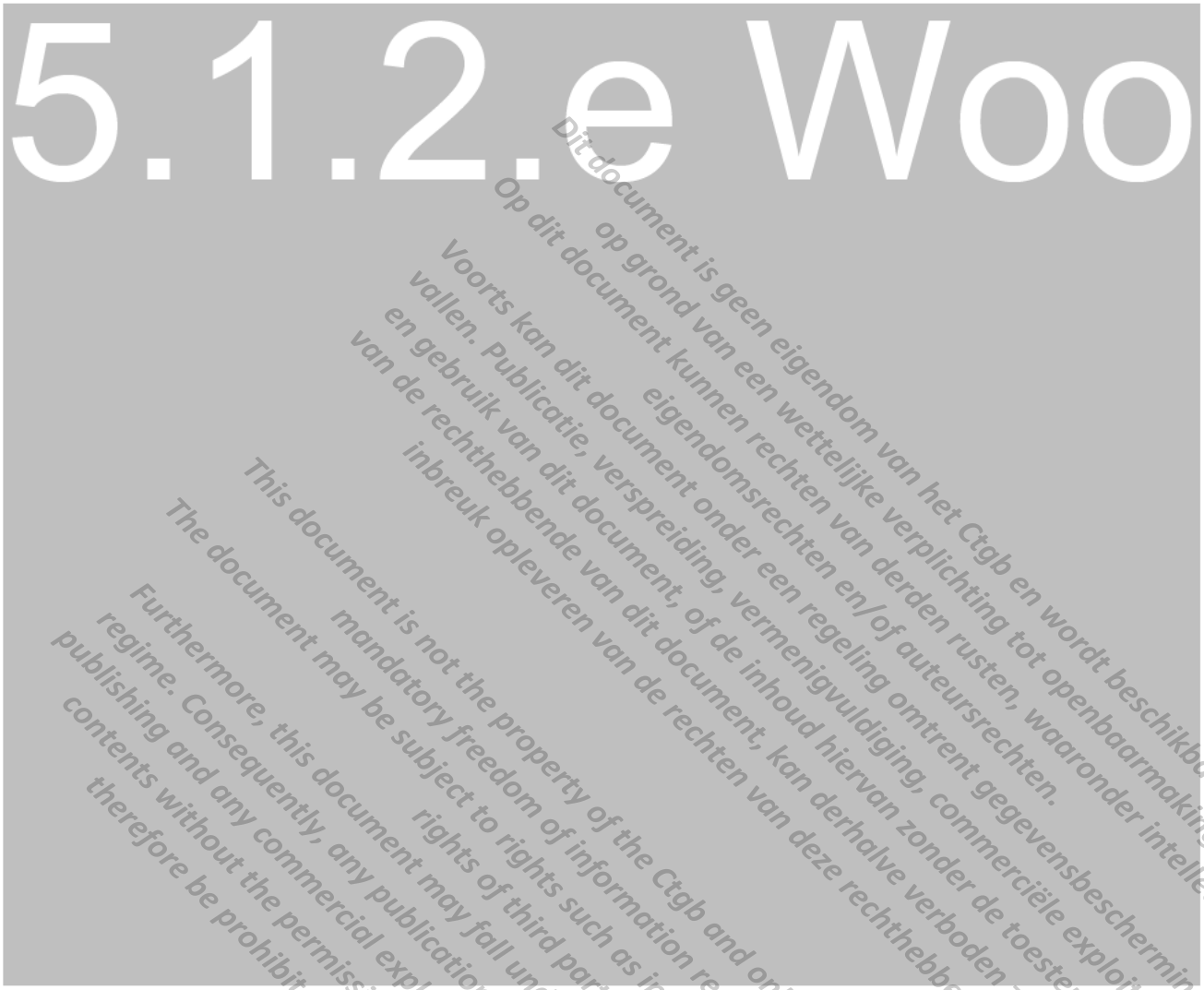

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