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OPP OFFICIAL RECORD
HEALTH EFFECTS DIVISION
SCIENTIFIC DATA REVIEWS
EPA SERIES 361

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DATA EVALUATION RECORD

Study Type: Teratology - Developmental Toxicity
Species: Rat Guideline: 83-3 a 030702

EPA ID No.s: EPA MRID No. 00106320
EPA Pesticide Chemical Code 030703
Toxicology Chemical Code 780A (Na salt), 592 (acid)

Test Material: Alanap S Technical (Na Salt)

Synonyms: Naptalam, C465

Title of Report: Teratologic Evaluation of Alanap S Technical in Sprague-Dawley Rats

Sponsor: Uniroyal Chemical, Bethany Conn 06526

Testing Facility: Food and Drug Research Laboratories, Inc. (FDRL)

Study Number(s): 5888a

Author(s): Michael Knickerbocker, Thomas A. Re, Ph.D.

Report Issued: December 22, 1978

Executive Summary: In a developmental toxicity (teratology) study (MRID# 00106320), sexually mature Sprague-Dawley rats of the BLU: (SD) BR strain from Blue Spruce Farms, Inc., Altamont, NY received either 0, 15, 115, or 500 mg/kg/day Alanap S Technical (Na Salt; unknown purity) by oral gavage in corn oil. The study originally had a high dose of 900 mg/kg/day of which all animals died after the first few doses; a new group was substituted using 500 mg/kg/day.

Maternal toxicity was noted at 115 mg/kg/day and above in the form of reduced body weight gain during the dosing period (gestation days 6-15), the post dosing period (gestation days 15-20), for the combined dosing plus post dosing period (gestation days 6-20) and for the entire gestation period (except 115 mg/kg/day). The 900 mg/kg/day dose group had complete deaths and there was increased maternal wastage at 500 mg/kg/day. **The Maternal Toxicity LOEL is 115 mg/kg/day and the Maternal Toxicity NOEL is 15 mg/kg/day based on reduced body weight gain.**

Developmental toxicity was noted in the 500 mg/kg/day dose

group as lower mean fetal weight compared to the control group and there was an increased incidence of unspecified missing sternebrae, incomplete ossification of unspecified vertebrae, unspecified skull bones, unspecified extremities and increased missing or reduced hyoid bone in the 500 mg/kg/day dose group. **The Developmental Toxicity LOEL is 500 mg/kg/day and the Developmental Toxicity NOEL is 115 mg/kg/day based on reduced mean fetal weight and increased skeletal observations.**

The study is classified as Core Supplementary Data and does not satisfy the guideline requirement for a developmental toxicity (teratology) study (§ 83-3a) in the rat. The study may be upgraded if the deficiencies listed below are addressed to the Agency's satisfaction.

Study Deficiencies:

The percent active ingredient of the test compound was not provided.

No analysis of dosing solutions was performed (however, toxicity was noted so the animals did receive compound).

Bones that were affected in the fetuses were not identified.

Limited data were provided for maternal effects; however, this study was conducted prior to the 1984 Guidelines.

A. Materials and Methods: A copy of the "materials and methods" section from the investigators report is appended.

Test Compound: Alanap S
Purity: not provided
Density: not provided
Description: light brown powder
Batch No. B19062, CC4035
Receipt date: April 22, 1980
Contaminants: none provided

Vehicle(s): corn oil

Test Animal(s): Species: sexually mature Sprague-Dawley rats
Strain: BLU: (SD) BR
Source: Blue Spruce Farms, Inc., Altamont, NY
Age: not provided
Body Weight: females - 248.6-269.1 g - day 0
Males - same strain

B. Study Design

This study was designed to assess the developmental toxicity potential of Alanap S when administered by oral gavage (intragastric intubation) to Sprague-Dawley rats on gestation days 6 through 15, inclusive.

Mating Procedure

Natural mating was used, the females were mated with males at a 1:1 ratio (female:male). *Observation of the vaginal sperm plug was considered day 0 of gestation.*

Animal Husbandry

Animals were kept under standard animal care conditions and there was no indication as to the time period the animals were acclimated to the laboratory conditions. They received ground Charles River Rat/Mouse/Hamster Formula (Agway) and tap water *ad libitum.*

Group Arrangement:

Test Group	Dose Level (mg/kg)	Number Assigned
Control	Corn Oil	40
Positive Control	Aspirin: 250 mg/kg/day)	45
Low Dose	15	30
Mid Dose	115	25
High Dose	900/500*	34

** = Level terminated after two weeks due to excessive deaths of dams. New level of 500 mg/kg/day Alanap added to study 8/7/78.*

No indication was given as to how doses were chosen.

Dose Administration:

All doses were administered in a volume of 10 ml/kg of body weight/day prepared weekly during the dosing period. The dosing solutions were not analyzed for concentration and stability. Dosing was based on gestation day 6 body weight.

Observations

The animals were checked daily for mortality or abnormal condition and body weights were taken on gestation days 0, 6, 11, 15, and 20. Dams were sacrificed on day 20 of gestation. Examinations at sacrifice consisted of the following (from the investigators report):

> **At the time of sacrifice on day 20 (or if the animal died [redacted] sacrificed moribund) the following observations were recorded for each female: numbers of corpora lutea, implantation sites, resorption sites, live and dead fetuses; sex of fetuses; and body weights of fetuses.**

The fetuses were examined in the following manner (from the investigators report):

> **At the time of uterine examination, all fetuses were examined grossly for the presence of external congential abnormalities. One-third of the fetuses from each litter were randomly selected and placed in Bouin's solution of detailed visceral examination employing the Wilson free-hand slicing technique. Any fetus showing external abnormalities was selected for examination by this technique.**
>
> **The remaining fetuses were eviscerated, fixed in 70% isopropyl alcohol, macerated in a 2% potassium hydroxide solution, stained with Alizarin-Red S dye, cleared in glycerine, and examined under low power magnification for skeletal anomalies and ossification variations. Each fetus was processed, examined and stored for possible further examination in a manner retaining the identity of both dam number and uterine position.**

Historical control data were not provided to allow comparison with concurrent controls.

Statistical analysis

The following statistical analysis methods were employed (from the investigators report):

> **Incidences of occurence were expressed as percent, and comparisons between the control and test groups were made using 95% confidence intervals for proportions or by computation of exact probabilities. Continuous data were analyzed using a one-way completely random classification analysis of variance for fixed effects. Differences were deemed significant when the probability of rejecting the null hypothesis when true was less than 0.05. The least significant difference test was then employed to determine which test group(s) differed from the control.**
>
> **Continuous data from both test materials were evaluated simultaneously to increase the degree of freedom and better indicate differences.**

Compliance

A signed and dated statement of no data confidentiality claims **was not** provided.

A signed and dated good laboratory practices statement of compliance **was not** provided.

A signed and dated review by the quality assurance unit **was not** provided.

A Flagging Criteria statement **was not** provided.

C. Results

Analysis of Dosing Solutions

No analysis was presented in the report.

1. Maternal Toxicity:

Mortality

All animals died at the 900 mg/kg/day dose group after 3 or 4 doses; therefore an additional dose level of 500 mg/kg/day was added. No data were provided for the 900 mg/kg/day dose group animals.

Clinical Observations

No clinical signs related to treatment were reported.

Body Weight

The investigators provided group mean, and individual animal data. The following table presents body weight gain data calculated by the reviewer from the supplied mean body weight data (except for 0-20):

Table I: Body Weight Gains (grams)[a]

Group:	0-6	6-15	15-20	6-20	0-20
Control	19.4	32.1	62.8	94.9	114.3
Aspirin	19.1	15.6[48.6][1]	38.9[61.9]	54.5[57.4]	73.6*[64.4]
LDT	19.2	31.6	63.0	94.6	113.6
MDT	17.4	28.4[88.5]	57.0[90.8]	85.4[90.0]	102.8[89.9]
HDT	18.2	9.8[30.5]	55.7[88.7]	65.5[69.0]	83.7*[73.2]

* = 0.05 as compared to control [only data analyzed statistically]
[1] = percent of control
[a] = Data extracted from Laboratory No. 5888a, Table 2.

From the provided data it is apparent that the mid and high dose groups gained less weight than the control during the dosing period (gestation days 6-15), the post dosing period (gestation days 15-20), the combined dosing plus post dosing period (gestation days 6-20) and for the entire gestation period.

Food Consumption

Food consumption was not measured and Food Efficiency could not be calculated.

Gross Pathological Observations

No data were provided.

Cesarean Section Observations

Table II: Cesarean Section Observations[a]

Dose:	Control	LDT	MDT	HDT	Pos.Control
#Animals Assigned	40	30	25	34	45
#Animals Mated/Inseminated	40	30	25	34	45
#Animals Pregnant	36	23	23	30	42
Pregnancy Rate (%) 90	77	92	88	93	
Maternal Wastage - dead or abortions	0	0	2*	6*	4*
Total litters available	36	23	21	24	38
Total Corpora Lutea	data not available				
Corpora Lutea/dam					
Total Implantations	418	276	233	274	428
Implantations/Dam	11.6	12.0	11.1	11.4	11.3
Total Live Fetuses	407	266	216	253	212
Live Fetuses/Dam	11.3	11.6	10.3	10.5	5.6*
Total Resorptions	11	7	17	21	215
Dams affected	8	5	5	7	30*
Total litter resorptions	0	0	0	0	11
Mean Fetal Weight (gm)	3.50	3.48	3.51	3.17*	2.21*
Preimplantation Loss(%)	could not be calculated - no corpora lutea data				
Postimplantation Loss(%)[1]	2.63	3.62	7.30	7.66	50.47
Sex Ratio (% Male)	data not available				

* = p < 0.05 compared to control; [1] = calculated by reviewer
[a] = Data extracted from Laboratory No. 5888a, Table 1.

There was reduced mean fetal weight in the high dose group (statistically significant) along with increased maternal wastage. There was a slightly increased number of resorptions and postimplantation loss in the mid and high dose group along with slightly reduced litter sizes.

2. Developmental Toxicity

The following *Table 3* from the investigators report presents the fetal observations for skeletal examinations.

Table 3

Summary of Skeletal Findings in Fetuses[1]

Findings	Corn Oil Control[2] (10ml/kg)	Aspirin 250	Alanap 15 mg/kg	Alanap 115 mg/kg	Alanap 500 mg/kg
Live Fetuses Examined (at term)	285/36	146/27	183/23	148/21	175/24
Sternebrae					
Incomplete oss.	184/33	116/25	110/21	76/19	123/22
Bipartite		4/2			
Missing	5/4	113/26*	4/3	3/2	20/8*
Ribs					
Incomplete oss.					1/1
Fused/split		14/8*			
Wavy		1/1			2/1
Less than 12		5/2			
More than 13:					
Rudimentary	45/22	34/14	19/9	23/11	17/8
Extra		80/21*		2/1	
Vertebrae					
Incomplete oss.	22/14	105/25*	15/9	16/9	25/14*
Skull					
Incomplete oss.	1/1	54/18*		1/1	14/5*
Extremities					
Incomplete oss.		64/18*	1/1	2/2*	2/2*
Miscellaneous					
Hyoid; missing	1/1	27/11*			5/2
Hyoid; reduced	5/4	66/19*	3/3	2/2	7/6*

1 Numerator = number of fetuses affected; Denominator = number of litters affected.
2 All materials administered by gavage days 6-15 of gestation.
* Significantly different from control ($p<.05$)

From the data provided there is an indication that the high dose had increased incidence of missing sternebrae (slight; which not specified), incomplete ossification of the vertebrae (which not specified), skull (which bones not specified), extremities (which not specified) and increased missing or reduced hyoid bone.

The following *Table 4* from the investigators report presents the observations for visceral observations.

Table 4

Summary of Soft Tissue Abnormalities of Fetuses

(Wilson Sections)

Treatment[1]/Findings	Fetus (No. affected/No. observed)	Litter (No. affected/No. observed)
Control: Corn Oil 10 ml/kg		
Gastroschisis	1/122	1/36
Hemorrhagic thorax	3/122	1/36
Hemorrhagic abdomen	10/122	8/36
Positive Control: Aspirin 250 mg/kg		
Spina bifida	10/66	7*/25
Encephalomeningocele	15/66	12*/25
Exophthalmas	1/66	1/25
Gastroschisis	3/66	2/25
Hemorrhagic abdomen	5/66	4/25
Pup(s) small	2/66	2/25
Fluid under skin	1/66	1/25
Alanap: 15 mg/kg		
Gastroschisis	2/83	2/23
Hemorrhagic abdomen	8/83	5/23
Alanap: 115 mg/kg		
Hemorrhagic abdomen	3/68	3/21
Pup small	1/68	1/21
Alanap: 500 mg/kg		
Hemorrhagic abdomen	2/78	2/24
Pup(s) small	7/78	4*/24

1 All materials administered by gavage days 6-15 of gestation.
* Significantly different from control ($p<.05$).

No specific treatment related effects were noted.

D. Discussion/Conclusions

a. Maternal Toxicity:

Maternal toxicity was noted at 115 mg/kg/day and above in the form of reduced body weight gain during the dosing period (gestation days 6-15), the post dosing period (gestation days 15-20) and for the combined dosing plus post dosing period (gestation days 6-20) and for the entire gestation period. The 900 mg/kg/day dose group had complete deaths and there was increased maternal wastage at 500 mg/kg/day.

b. Developmental Toxicity:

i. Deaths/Resorptions:
There was a slightly increased number of resorptions and postimplantation loss in the 115 and 500 mg/kg/day dose groups along with slightly reduced litter sizes.

ii. Altered Growth:
There was reduced mean fetal weight in the 500 mg/kg/day dose group (statistically significantly different).

iii. Developmental Anomalies:
There was increased incidence of missing sternebrae (slight; which not specified), incomplete ossification of the vertebrae (which not specified), skull (which bones not specified), extremities (which not specified) and increased missing or reduced hyoid bone in the 500 mg/kg/day dose group.

iv. Malformations:
No treatment related effects were noted.

E. Study Deficiencies:

The percent active ingredient of the test compound was not provided.

No analysis of dosing solutions was performed (however, toxicity was noted so the animals did receive compound).

Bones that were affected in the fetuses were not identified.

Limited data were provided for maternal effects; however, this study was conducted prior to the 1984 Guidelines.

F. Core Classification: Core Supplementary Data.
Maternal Toxicity NOEL = 15 mg/kg/day
Maternal Toxicity LOEL = 115 mg/kg/day
Developmental Toxicity NOEL = 115 mg/kg/day
Developmental Toxicity LOEL = 500 mg/kg/day

FDRL

Introduction

This report describes the results of a study designed to evaluate the teratogenic potential of Alanap Technical following oral intubation in pregnant Sprague-Dawley rats during organogenesis. The study as outlined in Food and Drug Research Laboratories, Inc. (FDRL) Proposal No. 78005-A was authorized by Mr. Rene' Dupre', Product Specialist, Uniroyal Chemical in a letter dated April 26, 1978. Procedures used were defined in an FDRL Working Protocol prepared July 21, 1978 and ammended August 22, 1978.

Supplied by the sponsor, the test material was received at the Waverly Research Center of FDRL on June 1, 1978. A light brown powdered material contained in a glass pint jar, the label identified the contents as: ALANAP S TECHNICAL; C465; Na Salt; 200 grams; BL9062; CC 4035. Additional material from the same lot/batch was received August 10, 1978.

In conjunction with this study, another test chemical was evaluated in the same manner using common control groups for both materials. The evaluation of the other material (H719 Technical) is reported separately.

Procedures

Animals and Husbandry

All animals used in this study were sexually mature Sprague-Dawley rats -- BLU: (SD) BR. All rats were purchased from Blue Spruce Farms, Inc., Altamont, NY. All animals were

individually housed in wire-mesh bottom cages in temperature controlled (70 ± 3°F) quarters. Fresh tap water and ground Charles River Rat/Mouse/Hamster Formula (Agway) were provided ad libitum throughout the study.

Treatment

Females were mated 1:1 with males in sufficient numbers to produce 120 pregnancies at termination. Observation of the vaginal sperm plug was considered day 0 of gestation. The pregnant rats were then distributed into five treatment groups using a random number assignment sheet. One male was not allowed to impregnate more than one female per group. Three test groups each consisting of at least 20 pregnant females were established. In addition, a vehicle (negative) control group and a positive control group each consisting of at least 30 pregnant females were established. Extra females were assigned to each group to allow for false pregnancies and maternal deaths.

Beginning on day 6 of gestation and continuing daily through day 15 of gestation, the appropriate materials were administered by oral intubation to the pregnant females. The test material was prepared fresh weekly and administered as a suspension in corn oil on a 10 ml/kg basis. The positive control compound (aspirin) was given as an aqueous suspension. The amount of material administered to each animal was determined by the body weight on day 6 of gestation and maintained throughout the treatment period. The dosage regimen was as follows:

Group	Minimum No. Pregnant Females	Treatment/Level
A	30	Corn Oil: 10 ml/kg/day
B	30	Aspirin: 250 mg/kg/day
C	20	Alanap: 15 mg/kg/day
D	20	Alanap: 115 mg/kg/day
E*	20	Alanap: 900 mg/kg/day

* Level terminated after two weeks due to excessive deaths of dams. New level of 500 mg/kg/day Alanap added to study 8/7/78.

On day 20 of gestation, all females were killed by a 5-10 minute exposure to chloroform vapors. The uterine contents of each were removed and the reproductive performance recorded. The urogenital tract of each female was examined for anatomical normality. All females that died or were sacrificed moribund during the course of the study were weighed; the weights were recorded; and all were subjected to a thorough uterine examination.

Observations

Body weights of all females were recorded on days 0, 6, 11, 15 and 20 of gestation. All animals were observed daily for signs of toxicity and a record maintained.

At the time of sacrifice on day 20 (or if the animal died or was sacrificed moribund) the following observations were recorded for each female: numbers of corpora lutea, implantation sites, resorption sites, live and dead fetuses; sex of fetuses; and body weights of fetuses.

At the time of uterine examination, all fetuses were examined grossly for the presence of external congential abnormalities. One-third of the fetuses from each litter were randomly selected and placed in Bouin's solution of detailed visceral examination employing the Wilson free-hand slicing technique. Any fetus showing external abnormalities was selected for examination by this technique.

The remaining fetuses were eviscerated, fixed in 70% isopropyl alcohol, macerated in a 2% potassium hydroxide solution, stained with Alizarin-Red S dye, cleared in glycerine, and examined under low power magnification for skeletal anomalies and ossification variations. Each fetus was processed, examined and stored for possible further examination in a manner retaining the identity of both dam number and uterine position.

Statistical Evaluation

Incidences of occurence were expressed as percent, and comparisons between the control and test groups were made using 95% confidence intervals for proportions or by computation of exact probabilities. Continuous data were analyzed using a one-way completely random classification analysis of variance for fi[redacted]fects. Differences were deemed significant when the probability of rejecting the null hypothesis when true was less than 0.05. The least significant difference test was then employed to determine which test group(s) differed from the control.

FOIL

Continuous data from both test materials were evaluated simulta... to increase the degree of freedom and better indicate differences.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

DATE: August 10, 1979

SUBJECT: Alanap S. (Sodium N-1 naphthylphthalamate) - Addition of Data to Files
EPA Reg. Nos. 400-49, 75, 86. CASWELL#780A

FROM: Carlos A. Rodriguez Carlos A. Rodriguez
Toxicology Branch (TS-769)

TO: Robert Taylor
Product Manager #25
Registration Division, (TS-767)

Registrant: Uniroyal Chemical
74 Amity Road
Bethany, Connecticut 06525

Product Name: Alanap^{R} -L

Recommendation(s):

1. The toxicity studies submitted (Teratology and Mutagenicity) are designated Core-Minimum Data. These studies are made part of the files for your product.

2. Reasons for or against the acceptability for the Mutagenicity Study are presented under conclusions in the review.

Review of Submitted Toxicity Studies:

1. Teratologic Evaluation of Alanap S Technical in Sprague-Dawley Rats, (Food and Drugy Research Labs., Inc., Dec. 22, 1978, Laboratory No. 5888$_a$, submitted by Uniroyal Chemical

Protocol: 60 pregnant, sexually mature Sprague-Dawley rats were dosed with 15, 115 and 900 mg/kg/day of Alanap during days 6-15 of gestation. In addition a vehicle (negative) control group and a positive control group each consisting of at least 30 pregnant females were used. The test material was administered as a suspension in corn oil in a 10 ml/kg basis. The positive control compound (aspirin) was given as an aqueous suspension. On day 20 of gestation, all females were killed by chloroform exposure, the uterine contents removed and reproductive performance recorded. Observations included fetal viability, live and dead pups, numbers of corpora lutea, implantation sites, resorption site sex and body weight of fetuses, visceral and skeletal examination.

Dams dosed at the high level (900 mg/kg/day) died after three or four doses. A new "high" level of 500 mg/kg/day was established and the 900 mg/kg/day was terminated.

Results; There were no significant differences in pregnancy, implantation, number of live and dead fetuses per dam between any test level and the vehicle control.

At 115 and 500 mg/kg/day - increased maternal mortality.

At 500 mg/kg/day retardation in maturation, decreased dam body weight during gestation, fetuses showed lower mean body weight than controls. Skeletal examinations revealed a significant increase in missing sternebrae, incomplete vertebrae, incomplete skull closure, incomplete ossification of extremities, and a reduction in thyoid size.

Conclusion - Alanap maternal toxicity was demonstrated at 500 mg/kg/day and to a lesser degree at 115 mg/kg/day. At 500 mg/kg/day resulted in underdeveloped fetuses. At 15 and 115 mg/kg/day resulted in fetuses no different than the vehicle control.

Evaluation: The maternal fetotoxicity of Alanap was demostrated at 500 mg/kg/day and to a lesser degree at 115 mg/kg/day. Therefore NOEL for fetotoxicity is 15 mg/kg/day.

Rat Teratology: Negative at 500 mg/kg/day (highest dose tested).

Classification: Core-Minimum Study

2. Acute Intraperitioneal LD50 with Alanap Technical, BL8658, (Product Safety Labs., Report#T-281 - December 22, 1978, submitted by Uniroyal)

50 Sprague Dawley albino rats were distributed into 5 groups, each composed of 5 male and five female animals weighing 200-300 grams. The dosage administered by intraperitioneal injection for males were 300, 450, 600, 1,050 and 1,050 mg/kg and for females 600, 700, 800, 900 and 1000 mg/kg. The animals were observed for mortality or other signs of gross toxicity for 14 days.

Results:

Intraperitoneal LD50 (rats, males) = 530 mg/kg
95% Confidence Interval: 260 - 1050 mg/kg

Intraperitoneal LD50 (rats, females) = 750 mg/kg
95% Confidence Interval: 590 - 925 mg/kg

Autopsies: Internal hemorrhage in almost all the dead animals. Hemorrhage most evident in lungs and to a lesser extent in the abdominal area. Discoloration of liver and stomach distension.

Classification: Core-Minimum Study

Toxicity Category: III

3. Mutagenicity Evaluation of Alanap Technical in the Ames Salmonella/ Microsome Plate Test, (Litton Bionetics, Inc., LBT, Project #2098, October 1978, submitted by Uniroyal Chemical)

The test compound was tested for mutagenic activity in a series of in vitro microbial assays employing the following indicator microorganism:

Salmonella typhimurium - TA-1535
TA-1537
TA-1538
TA-98
TA-100

Saccharomyces cerevisiae - D_4

Activation and non-activation tests were done concurrently in the presence or absence of mammalian metabolic activation preparations. Enzymic preparations were obtained from the 9,000 X g supernatant fraction of liver homogenate obtained from adult male Sprague-Dawley rats pretested for 5 consecutive days with Aroclor 1254. The reaction mixture for activation tests included TPN (sodium salt) glucose-6-phosphate, sodium phosphate (dibasic), $MgCl_2$, KCl, homogenate S 9 fraction, and 9,000 X g supernatant.

Approximately 10 cells of each microbial strain were cultured in molten agar supplemental with biotin and histidien. Activation and nonactivation tests were done concurrently. For nonactivation tests, 4 dose levels of the test compound were added over the surfaces of selective agar plates, and in the activation tests, at least 4 dose levels of the test chemical were added to the appropriate tubes with cells. Just prior to pouring, the liver homogenate was added to each of the activation tubes, mixed, and the contents poured over the surface of a minimal agar plates were incubated for 48 hours at 37°C. The D_4 yeasts plates were incubated at 30C for 3-5 days and scored for the number of colonies growing on each of the plates Positive control chemicals included in the activation were N-methyl, N-Nitro nitrosoguanidine, 2-aminocridine, 2-nitrofluorene, 2-anthramine. The solven control was DMSO. Mutagenic effects were based on the number of revertants per plate.

Results:

The number of revertants/plate was enhanced markedly in all bacterial strain exposed to the positive control chemicals. The tests conducted with the test compound were all negative. TA-1537 and TA-100 were repeated because of increased revertants observed at higher doses in the initial test. The repeated test performed at 100, 500, 1,000 and 2,000 µg with these two strains were negative.

Conclusion

The test compound, Alanap Technical, is non-mutagenic by the Ames and yeast tests.

Classification: Core-Minimum - unless mutagenicity guidelines be modified consequently.

per
W. M. Butler

13544

R058676

Chemical:	**Benzoic acid, 2-((1-naphthalenylamino)ca**
PC Code:	**030702**
HED File Code	**13000 Tox Reviews**
Memo Date:	**06/22/94 12:00:00 AM**
File ID:	**00000000**
Accession Number:	**412-04-0046**

HED Records Reference Center
03/25/2004