

Study Number: C20302B-01
Test Type: TOX
Route: Whole-Body Inhalation
Species/Strain: Mouse/B6C3F1/N

I05: Clinical Observations Summary
Test Compound: alpha-Pinene
CAS Number: 80-56-8

Date Report Requested: 11/08/2023
Time Report Requested: 11:14:29
Lab: Battelle with EPL

Study Number: C20302B-01
Study Sex: Both
PWG Approval Date: See web page for date of PWG Approval
Version: v1.6.0

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Date Report Requested: 11/08/2023
Time Report Requested: 11:14:29
Lab: Battelle with EPL

Male: Interim Males					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Coat Ruffled	0 / 10	0 / 10	1 / 10 SD 10	0 / 10

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CAS Number: 80-56-8

Date Report Requested: 11/08/2023
Time Report Requested: 11:14:29
Lab: Battelle with EPL

Male: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Alopecia Abdomen; Bilateral	0 / 50	0 / 50	4 / 50 SD 311	1 / 50 SD 423
SD	Alopecia Abdomen; Right	0 / 50	0 / 50	0 / 50	1 / 50 SD 423
SD	Alopecia Head; Left	0 / 50	0 / 50	0 / 50	1 / 50 SD 256
SD	Alopecia Head	0 / 50	2 / 50 SD 451	0 / 50	0 / 50
SD	Alopecia Thorax	0 / 50	0 / 50	4 / 50 SD 256	0 / 50
SD	Break Fore Limb; Left	0 / 50	1 / 50 SD 367	0 / 50	0 / 50
SD	Breathing, labored	1 / 50 SD 369	2 / 50 SD 540	0 / 50	1 / 50 SD 603
SD	Breathing, rapid	0 / 50	1 / 50 SD 599	0 / 50	0 / 50
SD	Bulging Eye; Left	0 / 50	0 / 50	1 / 50 SD 731	1 / 50 SD 451
SD	Bulging Eye; Right	0 / 50	0 / 50	1 / 50 SD 479	2 / 50 SD 451

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Lab: Battelle with EPL

Male: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Coat Ruffled	6 / 50 SD 143	4 / 50 SD 256	5 / 50 SD 311	4 / 50 SD 311
SD	Coat Unkempt	0 / 50	1 / 50 SD 600	1 / 50 SD 558	0 / 50
SD	Cold To Touch	0 / 50	1 / 50 SD 554	0 / 50	0 / 50
SD	Damaged Tail	2 / 50 SD 420	2 / 50 SD 395	2 / 50 SD 199	6 / 50 SD 227
SD	Dehydrated	1 / 50 SD 311	3 / 50 SD 367	0 / 50	0 / 50
SD	Discharge Eye; Clear	0 / 50	0 / 50	0 / 50	2 / 50 SD 507
SD	Discharge Eye; Left, Red	0 / 50	0 / 50	0 / 50	1 / 50 SD 731
SD	Discharge Nose/Snout; Red	0 / 50	0 / 50	0 / 50	1 / 50 SD 667
SD	Discharge Penis; Brown	0 / 50	0 / 50	1 / 50 SD 681	0 / 50
SD	Discolored Urogenital; Red	1 / 50 SD 507	0 / 50	1 / 50 SD 619	1 / 50 SD 619

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Lab: Battelle with EPL

Male: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Edema	1 / 50 SD 507	0 / 50	0 / 50	0 / 50
SD	Eye Abnormality Left	1 / 50 SD 395	0 / 50	2 / 50 SD 619	3 / 50 SD 507
SD	Eye Abnormality Right	0 / 50	1 / 50 SD 563	0 / 50	1 / 50 SD 507
SD	Eye Shut Bilateral	1 / 50 SD 621	0 / 50	0 / 50	0 / 50
SD	Eye Shut Right	0 / 50	0 / 50	0 / 50	1 / 50 SD 479
SD	Gait Abnormal	0 / 50	1 / 50 SD 600	0 / 50	0 / 50
SD	Hunched	3 / 50 SD 369	6 / 50 SD 507	3 / 50 SD 624	3 / 50 SD 603
SD	Lethargic	2 / 50 SD 369	1 / 50 SD 599	4 / 50 SD 624	4 / 50 SD 603
SD	Limping Hind Limb; Severe	0 / 50	1 / 50 SD 599	0 / 50	0 / 50
SD	Maloccluded/Broken Teeth	0 / 50	0 / 50	0 / 50	1 / 50 SD 542

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Lab: Battelle with EPL

Male: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Mass Abdomen; 1, Bilateral, Medium (6-15mm)	0 / 50	0 / 50	1 / 50 SD 729	0 / 50
SD	Mass Abdomen; 1, Large (>15mm)	0 / 50	0 / 50	0 / 50	1 / 50 SD 667
SD	Mass Abdomen; 1, Large (>15mm), Left	0 / 50	0 / 50	1 / 50 SD 675	0 / 50
SD	Mass Abdomen; 1, Left, Medium (6-15mm)	0 / 50	0 / 50	0 / 50	1 / 50 SD 619
SD	Mass Abdomen; 1, Medium (6-15mm), Right	0 / 50	0 / 50	0 / 50	1 / 50 SD 647
SD	Mass Abdomen; Right	0 / 50	0 / 50	0 / 50	1 / 50 SD 507
SD	Mass Ear; Left	0 / 50	0 / 50	0 / 50	1 / 50 SD 479
SD	Mass Ear; Small (1-5mm)	0 / 50	0 / 50	0 / 50	1 / 50 SD 591
SD	Mass Fore Limb; Left	1 / 50 SD 507	0 / 50	0 / 50	0 / 50
SD	Mass Head; 1, Left, Medium (6-15mm)	2 / 50 SD 675	0 / 50	0 / 50	1 / 50 SD 731

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Male: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Mass Head; 1, Left, Small (1-5mm)	0 / 50	0 / 50	0 / 50	1 / 50 SD 708
SD	Mass Head; 1, Right, Small (1-5mm)	0 / 50	1 / 50 SD 703	1 / 50 SD 729	0 / 50
SD	Mass Testis; 1, Bilateral, Medium (6-15mm)	0 / 50	0 / 50	0 / 50	1 / 50 SD 730
SD	Paralysis Hind Limb; Bilateral	1 / 50 SD 621	0 / 50	0 / 50	0 / 50
SD	Paralysis Hind Limb	0 / 50	0 / 50	1 / 50 SD 194	0 / 50
SD	Prolapse Urogenital	2 / 50 SD 600	2 / 50 SD 600	2 / 50 SD 716	0 / 50
SD	Scab Dorsum; Bilateral	0 / 50	1 / 50 SD 535	0 / 50	0 / 50
SD	Sore Abdomen; Bilateral	0 / 50	0 / 50	0 / 50	1 / 50 SD 507
SD	Sore Head; Bilateral	0 / 50	1 / 50 SD 554	1 / 50 SD 555	0 / 50
SD	Stained Anus; Yellow	1 / 50 SD 621	0 / 50	0 / 50	0 / 50

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Male: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Swelling Hind Limb; Bilateral	1 / 50 SD 507	0 / 50	0 / 50	0 / 50
SD	Swelling Nose/Snout; Left	1 / 50 SD 619	0 / 50	0 / 50	0 / 50
SD	Thin	3 / 50 SD 367	3 / 50 SD 507	3 / 50 SD 185	1 / 50 SD 680
SD	Tremors Mild	0 / 50	0 / 50	1 / 50 SD 638	0 / 50
SD	Wet Urogenital	0 / 50	1 / 50 SD 600	1 / 50 SD 638	1 / 50 SD 680
SD	Wound Abdomen; Left	0 / 50	0 / 50	1 / 50 SD 675	0 / 50
SD	Wound Dorsum; Left	0 / 50	0 / 50	1 / 50 SD 729	0 / 50
SD	Wound Ear; Right	0 / 50	0 / 50	1 / 50 SD 722	0 / 50
SD	Wound Head; Bilateral	0 / 50	0 / 50	1 / 50 SD 576	0 / 50
SD	Wound Head; Left	0 / 50	1 / 50 SD 609	0 / 50	0 / 50

Male: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Wound Hind Limb; Right	0 / 50	0 / 50	1 / 50 SD 667	0 / 50
SD	Wound Multiple Sites (>3); Bilateral	0 / 50	0 / 50	1 / 50 SD 558	0 / 50
SD	Wound Nose/Snout; Right	0 / 50	0 / 50	1 / 50 SD 563	0 / 50
SD	Wound Penis; Bilateral	0 / 50	1 / 50 SD 367	0 / 50	0 / 50
SD	Wound Scrotum; Bilateral	0 / 50	1 / 50 SD 729	0 / 50	1 / 50 SD 395
SD	Wound Urogenital; Bilateral	0 / 50	0 / 50	1 / 50 SD 716	0 / 50

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Female: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Alopecia Abdomen; Bilateral	0 / 50	0 / 50	8 / 40 SD 367	9 / 50 SD 283
SD	Alopecia Abdomen; Left	2 / 50 SD 283	2 / 50 SD 451	0 / 40	0 / 50
SD	Alopecia Abdomen; Right	1 / 50 SD 423	1 / 50 SD 451	0 / 40	0 / 50
SD	Alopecia Abdomen	0 / 50	1 / 50 SD 256	0 / 40	0 / 50
SD	Alopecia Dorsum; Bilateral	0 / 50	1 / 50 SD 339	0 / 40	0 / 50
SD	Alopecia Dorsum; Left	1 / 50 SD 283	1 / 50 SD 423	0 / 40	1 / 50 SD 423
SD	Alopecia Dorsum; Right	0 / 50	0 / 50	0 / 40	1 / 50 SD 423
SD	Alopecia Dorsum	1 / 50 SD 59	4 / 50 SD 283	0 / 40	0 / 50
SD	Alopecia Fore Limb; Left	1 / 50 SD 451	2 / 50 SD 367	0 / 40	0 / 50
SD	Alopecia Fore Limb; Right	0 / 50	0 / 50	0 / 40	1 / 50 SD 423

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Female: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Alopecia Head; Bilateral	1 / 50 SD 339	0 / 50	0 / 40	0 / 50
SD	Alopecia Head; Left	1 / 50 SD 451	0 / 50	0 / 40	0 / 50
SD	Alopecia Head; Right	1 / 50 SD 451	0 / 50	0 / 40	0 / 50
SD	Alopecia Head	1 / 50 SD 311	0 / 50	0 / 40	0 / 50
SD	Alopecia Hind Limb; Bilateral	0 / 50	0 / 50	1 / 40 SD 256	1 / 50 SD 256
SD	Alopecia Hind Limb; Left	1 / 50 SD 451	1 / 50 SD 367	0 / 40	2 / 50 SD 423
SD	Alopecia Hind Limb; Right	0 / 50	0 / 50	0 / 40	1 / 50 SD 423
SD	Alopecia Thorax	0 / 50	1 / 50 SD 283	6 / 40 SD 94	1 / 50 SD 227
SD	Ataxia Moderate	1 / 50 SD 507	0 / 50	0 / 40	0 / 50
SD	Breathing, gasping	0 / 50	0 / 50	2 / 40 SD 669	1 / 50 SD 722

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Female: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Breathing, labored	1 / 50 SD 479	4 / 50 SD 306	1 / 40 SD 563	4 / 50 SD 227
SD	Breathing, rapid	1 / 50 SD 685	0 / 50	0 / 40	0 / 50
SD	Bulging Eye; Left	0 / 50	0 / 50	1 / 40 SD 732	2 / 50 SD 675
SD	Bulging Eye	0 / 50	0 / 50	0 / 40	1 / 50 SD 451
SD	Circling	1 / 50 SD 508	0 / 50	0 / 40	0 / 50
SD	Coat Ruffled	1 / 50 SD 508	5 / 50 SD 283	3 / 40 SD 311	4 / 50 SD 311
SD	Coat Soiled Multiple Sites (>3)	0 / 50	0 / 50	0 / 40	1 / 50 SD 367
SD	Cold To Touch	0 / 50	2 / 50 SD 502	0 / 40	0 / 50
SD	Damaged Tail	1 / 50 SD 675	1 / 50 SD 562	2 / 40 SD 256	3 / 50 SD 256
SD	Dehydrated	1 / 50 SD 450	0 / 50	0 / 40	2 / 50 SD 311

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Female: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Discharge Urogenital; Brown	0 / 50	0 / 50	1 / 40 SD 697	0 / 50
SD	Discolored Hind Paw; Bluish	1 / 50 SD 515	0 / 50	0 / 40	0 / 50
SD	Edema	1 / 50 SD 507	0 / 50	0 / 40	0 / 50
SD	Eye Abnormality Left	1 / 50 SD 395	0 / 50	0 / 40	2 / 50 SD 484
SD	Eye Abnormality Right	0 / 50	1 / 50 SD 733	0 / 40	0 / 50
SD	Eye Shut Right	0 / 50	0 / 50	0 / 40	1 / 50 SD 619
SD	Head Tilt	1 / 50 SD 508	0 / 50	0 / 40	0 / 50
SD	Hunched	2 / 50 SD 394	4 / 50 SD 306	2 / 40 SD 563	7 / 50 SD 227
SD	Hypoactivity	0 / 50	1 / 50 SD 502	0 / 40	0 / 50
SD	Lethargic	2 / 50 SD 685	5 / 50 SD 689	1 / 40 SD 669	5 / 50 SD 459

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Female: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Limping Hind Limb; Severe	1 / 50 SD 515	0 / 50	0 / 40	0 / 50
SD	Limping	1 / 50 SD 515	0 / 50	0 / 40	0 / 50
SD	Mass Abdomen; 1, Large (>15mm)	0 / 50	1 / 50 SD 657	0 / 40	0 / 50
SD	Mass Abdomen; 1, Large (>15mm), Left, Ulcerated	0 / 50	1 / 50 SD 675	0 / 40	0 / 50
SD	Mass Abdomen; 1, Large (>15mm), Right	0 / 50	1 / 50 SD 675	0 / 40	2 / 50 SD 591
SD	Mass Abdomen; 1, Large (>15mm), Right, Ulcerated	1 / 50 SD 719	0 / 50	0 / 40	0 / 50
SD	Mass Abdomen; 1, Left, Medium (6-15mm)	0 / 50	1 / 50 SD 647	0 / 40	0 / 50
SD	Mass Abdomen; 1, Left, Small (1-5mm)	0 / 50	1 / 50 SD 647	0 / 40	0 / 50
SD	Mass Abdomen; 1, Right, Small (1-5mm)	1 / 50 SD 703	0 / 50	0 / 40	0 / 50

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Female: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Mass Abdomen; 2, Bilateral, Large (>15mm)	0 / 50	1 / 50 SD 675	0 / 40	0 / 50
SD	Mass Abdomen; 2, Bilateral, Medium (6-15mm)	0 / 50	1 / 50 SD 703	0 / 40	0 / 50
SD	Mass Abdomen; 2, Large (>15mm), Right, Ulcerated	0 / 50	0 / 50	0 / 40	1 / 50 SD 703
SD	Mass Abdomen; 2, Medium (6-15mm), Right	0 / 50	0 / 50	0 / 40	1 / 50 SD 697
SD	Mass Abdomen; Right	0 / 50	0 / 50	1 / 40 SD 479	1 / 50 SD 451
SD	Mass Dorsum; 1, Bilateral, Large (>15mm)	0 / 50	1 / 50 SD 726	1 / 40 SD 619	1 / 50 SD 731
SD	Mass Dorsum; 1, Large (>15mm), Right	0 / 50	1 / 50 SD 731	0 / 40	0 / 50
SD	Mass Dorsum; 1, Left, Medium (6-15mm)	1 / 50 SD 733	0 / 50	0 / 40	0 / 50
SD	Mass Dorsum; Medium (6-15mm)	0 / 50	0 / 50	1 / 40 SD 725	0 / 50
SD	Mass Ear; 1, Large (>15mm), Left, Ulcerated	1 / 50 SD 619	0 / 50	0 / 40	0 / 50

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Female: Core Animals					
Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Mass Fore Limb; 1, Medium (6-15mm), Right	0 / 50	0 / 50	0 / 40	2 / 50 SD 683
SD	Mass Head; 1, Bilateral, Large (>15mm)	1 / 50 SD 733	0 / 50	0 / 40	0 / 50
SD	Mass Head; 1, Large (>15mm), Right	0 / 50	1 / 50 SD 732	0 / 40	0 / 50
SD	Mass Head; 1, Left, Medium (6-15mm)	0 / 50	1 / 50 SD 675	0 / 40	0 / 50
SD	Mass Head; 1, Medium (6-15mm), Right	0 / 50	1 / 50 SD 675	1 / 40 SD 619	0 / 50
SD	Mass Head; 1, Right, Small (1-5mm)	0 / 50	0 / 50	0 / 40	1 / 50 SD 645
SD	Mass Hind Limb; 1, Large (>15mm), Right	0 / 50	0 / 50	0 / 40	1 / 50 SD 732
SD	Mass Hind Limb; 1, Large (>15mm), Right, Scabbed	0 / 50	1 / 50 SD 668	0 / 40	0 / 50
SD	Mass Hind Limb; 1, Large (>15mm), Right, Soft	0 / 50	0 / 50	0 / 40	1 / 50 SD 722
SD	Mass Hind Limb; 1, Left, Small (1-5mm)	1 / 50 SD 675	0 / 50	0 / 40	0 / 50

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Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Mass Hind Paw; 1, Large (>15mm), Right, Scabbed	0 / 50	1 / 50 SD 647	0 / 40	0 / 50
SD	Mass Thorax; 1, Bilateral, Large (>15mm)	0 / 50	0 / 50	0 / 40	1 / 50 SD 591
SD	Mass Thorax; 1, Bilateral, Large (>15mm), Ulcerated	0 / 50	0 / 50	0 / 40	1 / 50 SD 619
SD	Mass Thorax; 1, Firm, Right, Small (1-5mm)	0 / 50	0 / 50	0 / 40	1 / 50 SD 704
SD	Mass Thorax; 1, Large (>15mm), Left	0 / 50	1 / 50 SD 731	0 / 40	2 / 50 SD 647
SD	Mass Thorax; 1, Large (>15mm), Right, Ulcerated	1 / 50 SD 731	0 / 50	0 / 40	0 / 50
SD	Missing Eye; Right	0 / 50	0 / 50	0 / 40	1 / 50 SD 587
SD	Missing Fore Limb; Right	0 / 50	0 / 50	1 / 40 SD 716	0 / 50
SD	Missing Hind Paw; Right	0 / 50	0 / 50	0 / 40	1 / 50 SD 227

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		0	100	200	400
SD	Pale	0 / 50	0 / 50	0 / 40	1 / 50 SD 283
SD	Scab Abdomen; Bilateral	0 / 50	0 / 50	1 / 40 SD 703	0 / 50
SD	Scab Dorsum; Bilateral	0 / 50	0 / 50	1 / 40 SD 716	0 / 50
SD	Scab Face; Right	0 / 50	1 / 50 SD 591	0 / 40	0 / 50
SD	Scab Head; Bilateral	0 / 50	0 / 50	0 / 40	1 / 50 SD 703
SD	Sore Abdomen; Right	1 / 50 SD 423	1 / 50 SD 535	0 / 40	0 / 50
SD	Sore Face; Bilateral	0 / 50	1 / 50 SD 380	0 / 40	0 / 50
SD	Splay Hind Limb; Bilateral	1 / 50 SD 394	0 / 50	0 / 40	0 / 50
SD	Swelling Hind Paw; Right	1 / 50 SD 515	0 / 50	0 / 40	0 / 50
SD	Thin	4 / 50 SD 227	6 / 50 SD 256	2 / 40 SD 581	10 / 50 SD 227

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Phase	Observation	Treatment Groups (ppm)			
		0	100	200	400
SD	Weakness Fore Limb; Right	1 / 50 SD 688	0 / 50	0 / 40	0 / 50
SD	Weakness Hind Limb; Bilateral	0 / 50	0 / 50	0 / 40	1 / 50 SD 680
SD	Wet Urogenital	0 / 50	0 / 50	0 / 40	1 / 50 SD 680
SD	Wound Abdomen; Left	1 / 50 SD 673	0 / 50	0 / 40	0 / 50
SD	Wound Abdomen; Right	1 / 50 SD 731	0 / 50	0 / 40	0 / 50
SD	Wound Head; Right	0 / 50	0 / 50	0 / 40	1 / 50 SD 587
SD	Wound Nose/Snout; Bilateral	0 / 50	1 / 50 SD 518	0 / 40	0 / 50
SD	Wound Tail; Bilateral	0 / 50	0 / 50	1 / 40 SD 581	0 / 50

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LEGEND

Animals exhibiting clinical observations "within normal limits" were recorded as scheduled but are omitted from the table for clarity.

Upper row displays cumulative number of animals with observation / total animals started on study for SD days, total number of pregnant animals for GD days, or total number of littered females for LD days.

Lower row displays day of observation onset

SD – Study Day

**** END OF REPORT ****