



Summary of Studies Supporting USDA Product Licensure

Establishment Name	Zoetis Inc.
USDA Vet Biologics Establishment Number	190
Product Code	9580.03
True Name	Canine Allergic Dermatitis Immunotherapeutic
Tradename(s) / Distributor or Subsidiary (if different from manufacturer)	Cytopoint - No distributor specified
Date of Compilation Summary	October 04, 2021

Disclaimer: Do not use the following studies to compare one product to another. Slight differences in study design and execution can render the comparisons meaningless.

Study Type	Efficacy																																																					
Pertaining to	Pruritus associated with allergic dermatitis																																																					
Study Purpose	To demonstrate efficacy against pruritus caused by allergic dermatitis																																																					
Product Administration	Single dose, administered subcutaneously.																																																					
Study Animals	Forty laboratory beagles, approximately 17-19 months old in treatment groups: <ul style="list-style-type: none"> • Negative control - 20 dogs • Product - 20 dogs 																																																					
Challenge Description	Purified recombinant canine IL-31 administered on Days (Study Days) -7, 1, and 28.																																																					
Interval observed after challenge	On Days -7, 1 and 28 dogs were monitored for pruritus for 2 hours following each challenge.																																																					
Results	<p>The number of minutes (0-120) in the 2-hour post-challenge observation period during which pruritic behavior was observed was designated the pruritus score. Pruritic behavior included licking or chewing, scratching, head-shaking or body shaking, or rubbing any part of the body.</p> <p>Pruritus scores were recorded for each animal following IL-31 challenge on Days -7, 1 and 28.</p> <p>Table 1: Five number summary for pruritus scores by treatment group and day of IL-31 challenge.</p> <table border="1"> <thead> <tr> <th>Study Day</th> <th>Treatment</th> <th>n</th> <th>Minimum</th> <th>Q₁</th> <th>Median</th> <th>Q₃</th> <th>Maximum</th> </tr> </thead> <tbody> <tr> <td rowspan="2">-7</td> <td>negative control</td> <td>20</td> <td>46</td> <td>75</td> <td>94</td> <td>106</td> <td>120</td> </tr> <tr> <td>product</td> <td>20</td> <td>40</td> <td>78</td> <td>91</td> <td>102</td> <td>117</td> </tr> <tr> <td rowspan="2">1</td> <td>negative control</td> <td>20</td> <td>55</td> <td>100</td> <td>105</td> <td>116</td> <td>120</td> </tr> <tr> <td>product</td> <td>20</td> <td>1</td> <td>7</td> <td>10</td> <td>13</td> <td>35</td> </tr> <tr> <td rowspan="2">28</td> <td>negative control</td> <td>20</td> <td>48</td> <td>68</td> <td>98</td> <td>106</td> <td>119</td> </tr> <tr> <td>product</td> <td>20</td> <td>5</td> <td>8</td> <td>10</td> <td>18</td> <td>117</td> </tr> </tbody> </table> <p>N = number of animals; Q₁ = 25th percentile; Q₃ = 75th percentile</p> <p>The raw data are displayed in the tables below.</p>	Study Day	Treatment	n	Minimum	Q ₁	Median	Q ₃	Maximum	-7	negative control	20	46	75	94	106	120	product	20	40	78	91	102	117	1	negative control	20	55	100	105	116	120	product	20	1	7	10	13	35	28	negative control	20	48	68	98	106	119	product	20	5	8	10	18	117
Study Day	Treatment	n	Minimum	Q ₁	Median	Q ₃	Maximum																																															
-7	negative control	20	46	75	94	106	120																																															
	product	20	40	78	91	102	117																																															
1	negative control	20	55	100	105	116	120																																															
	product	20	1	7	10	13	35																																															
28	negative control	20	48	68	98	106	119																																															
	product	20	5	8	10	18	117																																															
USDA Approval Date	June 06, 2018																																																					

Table 2: Raw data

		Pruritus Score (number of minutes of pruritic behavior)		
Treatment	Animal ID	Day -7 (Baseline)	Day 1	Day 28
negative control	3148743	96	92	70
negative control	3150624	82	107	67
negative control	3156568	87	110	98
negative control	3165231	46	69	67
negative control	3172563	111	116	115
negative control	3179282	114	119	116
negative control	3180256	101	113	105
negative control	3185631	79	103	102
negative control	3188184	98	98	68
negative control	3192637	106	101	110
negative control	3195326	77	101	104
negative control	3195709	111	117	102
negative control	3205925	47	55	62
negative control	3207618	120	118	119
negative control	3211747	61	67	48
negative control	3212000	68	100	73
negative control	3212166	69	103	98
negative control	3212336	100	117	57
negative control	3212492	108	115	115
negative control	3213626	92	120	95
product	3148735	86	7	10
product	3153852	50	1	7
product	3160972	100	24	6
product	3162291	48	5	10
product	3188648	87	28	32
product	3191827	102	2	117
product	3195679	67	12	9
product	3198198	104	11	15
product	3202110	110	20	5
product	3203612	115	10	17
product	3204767	115	13	10
product	3206158	40	10	5

		Pruritus Score (number of minutes of pruritic behavior)		
Treatment	Animal ID	Day -7 (Baseline)	Day 1	Day 28
product	3207090	40	10	8
product	3207936	95	7	23
product	3208843	82	13	16
product	3216358	117	35	29
product	3216668	83	6	8
product	3217249	101	10	27
product	3218831	96	9	5
product	6534571	84	4	11

IL-31 challenge was conducted on Days (Study Day) -7, 1 and 28. Pruritus was assessed for all animals following IL-31 challenge on Day -7, and on Days 1 and 28 following administration of product on Day 0.

Study Type	Efficacy																				
Pertaining to	ALL																				
Study Purpose	Demonstrate efficacy against clinical signs due to Canine Atopic Dermatitis (CAD)																				
Product Administration	Single dose, product or placebo, administered subcutaneously																				
Study Animals	Client-owned dogs 1.5 – 12 years old, weighing 2.2 – 76.5 kg, with a documented history of non-seasonal atopic dermatitis for at least 1 year, at least “mild itching” described by the owner, and a minimum total Canine Atopic Dermatitis Extent and Severity Index (CADESI-03) score of 30 assigned by the veterinarian. Dogs (diagnosed with atopic dermatitis) at 14 veterinary practices were split into treatment groups: 50 dogs – Placebo (control group) 47 dogs – Product - 2.0 mg/kg																				
Challenge Description	Not applicable																				
Interval observed after challenge	Dogs were evaluated for clinical signs of atopic dermatitis for 56 days following product or placebo administration. Veterinarians assessed the dog’s skin using CADESI-03 weekly for the first 2 weeks, and every other week thereafter: Days 0, 7, 14, 28, 42 and 56.																				
Results	<p>The CADESI-03 skin grading system for skin condition includes four clinical signs: erythema (redness), alopecia (hair loss), excoriation (skin damage), and lichenification (skin thickening). The clinical signs were assessed at each of 62 sites on the body and graded by severity from 0 to 5.</p> <p>Table 1: Dogs withdrawn from the study</p> <table border="1"> <thead> <tr> <th rowspan="2">Study Day</th> <th colspan="2">Number of Cumulative Withdrawals/ Number of Efficacy Assessment</th> </tr> <tr> <th>Placebo</th> <th>Product</th> </tr> </thead> <tbody> <tr> <td>0-7</td> <td>7/50 (14%)</td> <td>0/47 (0%)</td> </tr> <tr> <td>8-14</td> <td>12/50 (24%)</td> <td>1/47 (2.1%)</td> </tr> <tr> <td>15-28</td> <td>21/50 (42%)</td> <td>6/47 (12.8%)</td> </tr> <tr> <td>29-42</td> <td>25/50 (50%)</td> <td>11/47 (23.4%)</td> </tr> <tr> <td>43-56</td> <td>26/50 (52%)</td> <td>12/47 (25.5%)</td> </tr> </tbody> </table> <p>Twenty-six dogs in the control group were withdrawn prior to Study Day 56 for worsening of clinical signs of CAD. Eleven dogs in the product group were withdrawn prior to Study day 56 for worsening of clinical signs of CAD. One dog was withdrawn prior to Study Day 56 for other reasons.</p> <p>The data displayed in Table 2 (placebo group) and Table 3 (product group) provide the frequencies at each severity score level for each clinical sign for study Days 0, 7, 14, 28, 42 and 56 for each animal (maximum frequency = 62).</p>	Study Day	Number of Cumulative Withdrawals/ Number of Efficacy Assessment		Placebo	Product	0-7	7/50 (14%)	0/47 (0%)	8-14	12/50 (24%)	1/47 (2.1%)	15-28	21/50 (42%)	6/47 (12.8%)	29-42	25/50 (50%)	11/47 (23.4%)	43-56	26/50 (52%)	12/47 (25.5%)
Study Day	Number of Cumulative Withdrawals/ Number of Efficacy Assessment																				
	Placebo	Product																			
0-7	7/50 (14%)	0/47 (0%)																			
8-14	12/50 (24%)	1/47 (2.1%)																			
15-28	21/50 (42%)	6/47 (12.8%)																			
29-42	25/50 (50%)	11/47 (23.4%)																			
43-56	26/50 (52%)	12/47 (25.5%)																			
USDA Approval Date	March 16, 2015																				

Table 2. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

Placebo Group																									
		Clinical Sign*																							
		Alopecia						Erythema						Excoriation						Lichenification					
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5
Animal	Study Day																								
1003	0	52	0	6	4	0	0	38	0	15	9	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	7	52	0	9	1	0	0	42	0	6	14	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	14	54	0	7	1	0	0	40	0	12	10	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1008	0	57	0	1	4	0	0	47	0	5	10	0	0	58	0	4	0	0	0	62	0	0	0	0	0
	7	62	0	0	0	0	0	49	4	9	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	14	62	0	0	0	0	0	46	6	10	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	28	62	0	0	0	0	0	55	3	4	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	42	62	0	0	0	0	0	55	7	0	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	56	62	0	0	0	0	0	52	10	0	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
1104	0	34	4	6	18	0	0	10	0	31	21	0	0	31	0	10	21	0	0	35	0	6	21	0	0
	7	43	13	4	2	0	0	4	9	37	12	0	0	27	10	15	10	0	0	30	9	13	10	0	0
	14	39	14	6	3	0	0	2	1	45	14	0	0	37	3	17	5	0	0	37	3	20	2	0	0
	28	26	14	22	0	0	0	0	23	39	0	0	0	21	17	24	0	0	0	30	10	22	0	0	0
	42	41	21	0	0	0	0	10	25	27	0	0	0	39	22	1	0	0	0	46	16	0	0	0	0
	56	33	11	17	1	0	0	0	3	42	17	0	0	28	4	27	3	0	0	30	7	23	2	0	0
1108	0	10	28	5	18	1	0	4	0	18	35	5	0	10	22	7	20	3	0	18	16	7	18	3	0
	7	29	5	11	16	1	0	0	0	41	20	1	0	34	5	6	16	1	0	38	5	2	16	1	0
	14	22	24	3	13	0	0	8	0	25	28	1	0	22	23	3	14	0	0	36	11	0	15	0	0
	28	4	46	6	6	0	0	0	2	42	18	0	0	18	10	24	10	0	0	23	18	16	5	0	0
	42	19	18	19	6	0	0	0	0	23	38	1	0	22	12	20	8	0	0	27	12	20	3	0	0
	56	11	12	25	14	0	0	0	0	12	47	3	0	18	11	18	15	0	0	27	10	11	14	0	0
1202	0	10	38	7	6	1	0	17	19	16	7	3	0	56	4	2	0	0	0	27	13	12	6	4	0
	7	15	28	7	10	2	0	19	26	11	6	0	0	59	2	1	0	0	0	36	6	11	9	0	0
	14	24	31	2	5	0	0	17	24	11	9	1	0	50	6	4	1	1	0	38	15	5	2	2	0
	28	24	21	12	5	0	0	25	22	13	2	0	0	58	2	2	0	0	0	37	8	13	4	0	0
	42	18	31	8	4	1	0	31	22	5	4	0	0	54	6	0	2	0	0	42	7	9	3	1	0
	56	25	25	9	3	0	0	25	10	18	7	2	0	57	3	2	0	0	0	24	13	15	10	0	0
1207	0	33	21	7	1	0	0	19	23	15	3	2	0	54	7	1	0	0	0	44	7	9	2	0	0
	7	25	32	4	1	0	0	19	34	8	1	0	0	57	4	0	1	0	0	37	12	12	1	0	0
	14	39	21	2	0	0	0	19	25	14	4	0	0	59	2	1	0	0	0	44	10	6	2	0	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 2. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

Placebo Group																									
		Clinical Sign*																							
		Alopecia						Erythema						Excoriation						Lichenification					
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5
Animal	Study Day																								
1207	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1301	0	60	0	2	0	0	0	33	15	4	4	6	0	53	6	3	0	0	0	50	3	5	4	0	0
	7	60	0	2	0	0	0	35	15	12	0	0	0	60	2	0	0	0	0	54	2	6	0	0	0
	14	61	0	1	0	0	0	32	21	7	2	0	0	60	2	0	0	0	0	56	1	5	0	0	0
	28	57	5	0	0	0	0	33	22	7	0	0	0	60	2	0	0	0	0	54	4	3	1	0	0
	42	62	0	0	0	0	0	41	15	6	0	0	0	62	0	0	0	0	0	56	1	5	0	0	0
	56	59	3	0	0	0	0	46	10	4	2	0	0	62	0	0	0	0	0	56	1	5	0	0	0
1308	0	42	9	10	1	0	0	11	6	27	16	2	0	50	9	3	0	0	0	46	10	6	0	0	0
	7	48	7	7	0	0	0	28	12	15	7	0	0	56	6	0	0	0	0	49	9	3	1	0	0
	14	42	10	7	3	0	0	24	13	13	9	3	0	54	5	0	3	0	0	47	8	6	1	0	0
	28	44	11	5	2	0	0	26	19	9	6	2	0	56	4	1	1	0	0	52	5	4	1	0	0
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1311	0	35	10	9	1	2	5	10	19	13	16	4	0	56	3	1	2	0	0	40	10	9	2	0	1
	7	39	9	8	3	2	1	6	23	17	13	3	0	56	4	1	1	0	0	33	18	6	4	1	0
	14	34	8	12	5	2	1	24	14	13	11	0	0	53	8	1	0	0	0	34	20	4	3	0	1
	28	36	10	7	6	2	1	20	14	14	11	3	0	59	3	0	0	0	0	34	19	6	2	1	0
	42	44	9	3	1	1	4	20	8	16	15	3	0	48	8	5	1	0	0	33	15	8	5	1	0
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1315	0	53	3	2	3	1	0	17	23	12	9	1	0	60	2	0	0	0	0	51	6	4	1	0	0
	7	54	3	2	3	0	0	18	23	16	5	0	0	59	3	0	0	0	0	49	9	4	0	0	0
	14	57	0	2	3	0	0	10	29	15	8	0	0	60	1	0	1	0	0	52	8	1	1	0	0
	28	50	4	6	2	0	0	13	16	26	7	0	0	59	1	2	0	0	0	53	4	2	3	0	0
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1318	0	42	3	7	10	0	0	25	7	15	15	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	7	48	3	9	2	0	0	32	21	5	4	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	14	58	2	2	0	0	0	38	22	2	0	0	0	62	0	0	0	0	0	61	1	0	0	0	0
	28	55	5	2	0	0	0	46	12	4	0	0	0	62	0	0	0	0	0	61	1	0	0	0	0
	42	58	4	0	0	0	0	44	18	0	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	56	62	0	0	0	0	0	50	12	0	0	0	0	62	0	0	0	0	0	61	1	0	0	0	0
1403	0	31	7	10	9	5	0	9	7	21	19	6	0	35	4	7	12	4	0	13	14	15	14	6	0

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 2. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

Placebo Group																									
		Clinical Sign*																							
		Alopecia						Erythema						Excoriation						Lichenification					
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5
Animal	Study Day																								
1403	7	32	4	14	8	4	0	16	6	31	9	0	0	50	4	7	0	1	0	21	10	22	7	2	0
	14	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1407	0	34	1	12	10	5	0	34	15	6	7	0	0	62	0	0	0	0	0	37	14	10	1	0	0
	7	34	7	13	7	1	0	39	6	12	5	0	0	62	0	0	0	0	0	38	11	12	1	0	0
	14	40	3	10	9	0	0	34	15	7	5	1	0	62	0	0	0	0	0	47	10	5	0	0	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1410	0	54	3	3	2	0	0	26	10	17	9	0	0	60	1	1	0	0	0	46	4	7	5	0	0
	7	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	14	49	2	3	6	2	0	12	9	19	19	3	0	54	0	2	5	1	0	37	7	4	8	6	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1414	0	59	0	0	2	1	0	38	1	14	8	1	0	60	0	0	1	1	0	54	5	1	2	0	0
	7	50	0	6	6	0	0	19	2	20	18	3	0	57	0	3	1	1	0	48	5	5	4	0	0
	14	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1417	0	50	5	3	4	0	0	10	20	16	15	1	0	60	1	1	0	0	0	29	14	13	6	0	0
	7	60	1	1	0	0	0	25	15	19	3	0	0	62	0	0	0	0	0	46	4	10	2	0	0
	14	54	2	5	1	0	0	25	11	20	6	0	0	59	0	3	0	0	0	46	5	6	4	1	0
	28	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	42	60	0	2	0	0	0	20	12	24	6	0	0	60	1	1	0	0	0	43	12	7	0	0	0
	56	54	3	5	0	0	0	17	16	17	9	3	0	60	1	1	0	0	0	41	13	7	1	0	0
1423	0	48	2	6	5	1	0	35	11	10	6	0	0	61	0	1	0	0	0	44	6	11	1	0	0
	7	43	3	6	10	0	0	32	15	11	4	0	0	59	1	1	1	0	0	38	7	15	2	0	0
	14	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 2. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

Placebo Group																									
		Clinical Sign*																							
		Alopecia						Erythema						Excoriation						Lichenification					
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5
Animal	Study Day																								
1423	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1425	0	37	8	11	2	4	0	14	12	27	9	0	0	55	1	4	1	1	0	47	4	10	1	0	0
	7	47	5	6	3	1	0	14	20	20	8	0	0	57	1	3	1	0	0	47	9	6	0	0	0
	14	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1432	0	53	0	6	1	2	0	31	5	12	11	3	0	55	1	2	3	1	0	51	5	3	3	0	0
	7	49	2	6	5	0	0	21	4	16	17	4	0	51	0	7	3	1	0	44	7	9	2	0	0
	14	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1435	0	60	1	0	1	0	0	31	6	16	6	3	0	56	0	3	3	0	0	47	1	1	10	3	0
	7	56	0	2	4	0	0	37	1	10	10	4	0	50	2	6	4	0	0	44	3	6	5	4	0
	14	50	1	6	5	0	0	28	2	22	7	3	0	49	2	3	7	1	0	43	2	6	7	4	0
	28	56	2	3	1	0	0	36	6	15	5	0	0	60	0	0	2	0	0	45	2	8	6	1	0
	42	49	0	4	7	2	0	35	4	11	9	3	0	55	0	5	2	0	0	49	1	1	8	3	0
	56	49	2	5	6	0	0	31	7	12	8	4	0	49	0	2	7	4	0	43	1	5	5	8	0
1439	0	51	2	5	3	1	0	32	4	14	8	4	0	56	1	0	2	3	0	42	5	4	6	4	1
	7	51	5	3	3	0	0	40	5	10	4	3	0	59	0	0	3	0	0	46	4	5	3	4	0
	14	49	3	8	1	1	0	39	4	12	6	1	0	56	0	4	2	0	0	47	2	5	4	4	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1442	0	37	1	10	9	3	2	19	7	9	18	9	0	52	0	4	4	2	0	42	7	6	7	0	0
	7	33	1	10	8	8	2	7	8	19	18	10	0	46	1	8	4	3	0	44	3	11	4	0	0
	14	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1446	0	50	3	6	3	0	0	32	9	12	7	2	0	60	0	1	1	0	0	50	4	5	2	1	0
	7	48	5	7	2	0	0	21	13	22	4	2	0	57	1	2	2	0	0	44	3	10	4	1	0

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 2. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

Placebo Group																									
		Clinical Sign*																							
		Alopecia						Erythema						Excoriation						Lichenification					
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5
Animal	Study Day																								
1446	14	59	1	0	2	0	0	35	11	11	4	1	0	60	0	1	1	0	0	48	2	7	5	0	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1703	0	37	10	15	0	0	0	32	14	12	4	0	0	61	0	1	0	0	0	60	2	0	0	0	0
	7	36	18	5	3	0	0	32	18	7	5	0	0	60	2	0	0	0	0	62	0	0	0	0	0
	14	38	18	5	1	0	0	32	19	8	3	0	0	61	1	0	0	0	0	62	0	0	0	0	0
	28	32	20	9	1	0	0	41	11	9	1	0	0	54	8	0	0	0	0	61	1	0	0	0	0
	42	35	14	10	3	0	0	39	13	9	1	0	0	62	0	0	0	0	0	61	1	0	0	0	0
	56	32	16	11	3	0	0	32	16	6	8	0	0	57	5	0	0	0	0	61	1	0	0	0	0
1706	0	34	12	6	4	5	1	6	16	19	17	4	0	50	9	1	2	0	0	54	6	1	1	0	0
	7	32	13	6	4	5	2	12	6	24	14	5	1	54	4	3	0	1	0	53	6	1	1	1	0
	14	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
1712	0	17	15	10	11	7	2	28	16	12	5	1	0	57	5	0	0	0	0	51	6	1	1	3	0
	7	16	18	11	9	7	1	27	11	12	9	3	0	55	6	1	0	0	0	54	3	1	3	1	0
	14	22	11	12	8	8	1	30	20	7	4	1	0	55	5	2	0	0	0	48	7	2	2	3	0
	28	18	9	17	10	7	1	29	11	16	5	1	0	51	9	2	0	0	0	53	4	2	1	2	0
	42	18	18	14	7	4	1	30	11	9	10	2	0	53	7	0	2	0	0	52	3	2	3	2	0
	56	20	13	12	13	2	2	27	10	16	6	3	0	59	1	2	0	0	0	46	6	5	3	2	0
1714	0	36	12	9	4	1	0	46	14	2	0	0	0	58	3	0	1	0	0	62	0	0	0	0	0
	7	39	8	12	3	0	0	44	14	3	1	0	0	59	2	0	1	0	0	62	0	0	0	0	0
	14	34	13	8	5	2	0	41	14	7	0	0	0	56	4	2	0	0	0	62	0	0	0	0	0
	28	34	10	13	5	0	0	41	13	7	1	0	0	58	2	1	1	0	0	62	0	0	0	0	0
	42	37	9	9	7	0	0	51	7	3	1	0	0	59	2	0	1	0	0	62	0	0	0	0	0
	56	43	6	9	4	0	0	48	11	3	0	0	0	61	0	1	0	0	0	62	0	0	0	0	0
1806	0	55	2	3	1	0	1	24	25	9	3	0	1	61	1	0	0	0	0	59	1	1	0	0	1
	7	55	5	1	0	1	0	21	29	12	0	0	0	62	0	0	0	0	0	61	1	0	0	0	0
	14	60	1	1	0	0	0	34	22	6	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	28	58	3	1	0	0	0	22	28	12	0	0	0	61	0	1	0	0	0	62	0	0	0	0	0
	42	61	1	0	0	0	0	31	13	15	3	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	56	60	2	0	0	0	0	18	28	13	3	0	0	62	0	0	0	0	0	62	0	0	0	0	0

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 2. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

Placebo Group																									
		Clinical Sign*																							
		Alopecia						Erythema						Excoriation						Lichenification					
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5
Animal	Study Day																								
1904	0	54	4	2	2	0	0	30	8	16	8	0	0	61	1	0	0	0	0	49	10	3	0	0	0
	7	55	5	0	2	0	0	39	17	5	1	0	0	62	0	0	0	0	0	53	9	0	0	0	0
	14	43	14	3	1	1	0	27	19	13	3	0	0	61	1	0	0	0	0	51	9	2	0	0	0
	28	41	15	3	2	1	0	29	13	16	3	1	0	62	0	0	0	0	0	50	10	1	1	0	0
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
2001	0	52	1	4	3	1	1	49	1	5	4	1	2	59	1	2	0	0	0	60	0	0	1	1	0
	7	50	3	1	4	1	3	45	6	2	6	2	1	62	0	0	0	0	0	60	0	0	1	1	0
	14	45	4	1	5	4	3	36	4	8	3	5	6	57	0	5	0	0	0	52	0	6	0	4	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
2008	0	39	14	7	2	0	0	28	9	16	9	0	0	61	1	0	0	0	0	62	0	0	0	0	0
	7	33	13	12	4	0	0	12	20	16	12	2	0	62	0	0	0	0	0	62	0	0	0	0	0
	14	35	14	6	3	2	2	17	12	24	6	1	2	59	1	1	0	1	0	62	0	0	0	0	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
2012	0	50	6	4	1	1	0	39	5	8	9	1	0	57	1	3	0	1	0	62	0	0	0	0	0
	7	58	2	2	0	0	0	51	3	6	2	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	14	60	0	0	0	1	1	48	9	3	0	1	1	58	2	1	1	0	0	60	0	2	0	0	0
	28	54	5	2	0	1	0	44	5	7	3	2	1	56	3	2	1	0	0	61	1	0	0	0	0
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
2016	0	24	15	14	6	1	2	15	9	13	16	7	2	62	0	0	0	0	0	62	0	0	0	0	0
	7	27	17	7	7	1	3	16	20	10	5	8	3	62	0	0	0	0	0	59	3	0	0	0	0
	14	19	12	13	11	3	4	30	19	8	2	3	0	61	0	1	0	0	0	57	0	4	1	0	0
	28	21	15	10	11	5	0	29	14	6	8	4	1	62	0	0	0	0	0	62	0	0	0	0	0
	42	16	10	17	11	8	0	28	16	17	1	0	0	62	0	0	0	0	0	58	0	4	0	0	0
	56	25	13	14	4	6	0	24	5	20	12	1	0	62	0	0	0	0	0	59	0	1	2	0	0
2019	0	40	4	13	3	2	0	31	8	17	6	0	0	61	1	0	0	0	0	62	0	0	0	0	0
	7	50	2	8	2	0	0	47	2	12	1	0	0	59	1	1	1	0	0	60	1	1	0	0	0
	14	30	1	13	11	7	0	24	9	15	11	2	1	57	0	2	2	1	0	62	0	0	0	0	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 2. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

Placebo Group																									
		Clinical Sign*																							
		Alopecia						Erythema						Excoriation						Lichenification					
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5
Animal	Study Day																								
2019	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
2021	0	37	8	11	2	4	0	25	5	18	11	2	1	60	0	2	0	0	0	60	1	1	0	0	0
	7	24	6	21	7	4	0	25	4	20	10	3	0	50	1	5	6	0	0	47	2	6	7	0	0
	14	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
2102	0	62	0	0	0	0	0	20	29	11	2	0	0	60	2	0	0	0	0	62	0	0	0	0	0
	7	62	0	0	0	0	0	21	28	11	2	0	0	61	0	1	0	0	0	62	0	0	0	0	0
	14	62	0	0	0	0	0	23	32	7	0	0	0	59	1	1	1	0	0	62	0	0	0	0	0
	28	62	0	0	0	0	0	30	27	5	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0
	42	62	0	0	0	0	0	27	32	3	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	56	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
2108	0	54	4	2	2	0	0	2	37	20	3	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	7	58	3	1	0	0	0	0	40	17	4	1	0	58	2	2	0	0	0	62	0	0	0	0	0
	14	53	5	4	0	0	0	0	32	23	4	2	1	59	1	1	0	1	0	62	0	0	0	0	0
	28	50	0	10	2	0	0	0	36	20	4	2	0	56	4	1	1	0	0	62	0	0	0	0	0
	42	46	3	6	7	0	0	0	31	24	5	2	0	56	0	3	0	1	2	62	0	0	0	0	0
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
2111	0	62	0	0	0	0	0	6	17	35	4	0	0	61	1	0	0	0	0	62	0	0	0	0	0
	7	62	0	0	0	0	0	6	18	31	7	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	14	62	0	0	0	0	0	8	10	27	15	2	0	62	0	0	0	0	0	61	1	0	0	0	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
2113	0	61	1	0	0	0	0	14	39	9	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	7	62	0	0	0	0	0	13	36	11	2	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	14	62	0	0	0	0	0	17	39	6	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	28	62	0	0	0	0	0	22	29	11	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	42	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	56	62	0	0	0	0	0	12	31	18	1	0	0	62	0	0	0	0	0	62	0	0	0	0	0
2202	0	61	0	1	0	0	0	25	23	11	2	1	0	61	0	0	1	0	0	58	1	3	0	0	0

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 2. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

Placebo Group																									
		Clinical Sign*																							
		Alopecia						Erythema						Excoriation						Lichenification					
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5
Animal	Study Day																								
2202	7	58	2	2	0	0	0	26	15	15	6	0	0	60	1	1	0	0	0	62	0	0	0	0	0
	14	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	28	59	2	1	0	0	0	38	12	12	0	0	0	59	2	1	0	0	0	58	2	0	2	0	0
	42	59	1	1	1	0	0	34	18	9	1	0	0	61	1	0	0	0	0	59	1	2	0	0	0
	56	56	6	0	0	0	0	43	17	2	0	0	0	62	0	0	0	0	0	60	2	0	0	0	0
2207	0	58	3	1	0	0	0	47	11	4	0	0	0	58	4	0	0	0	0	59	0	3	0	0	0
	7	52	5	5	0	0	0	37	19	6	0	0	0	61	0	1	0	0	0	62	0	0	0	0	0
	14	55	6	1	0	0	0	49	7	4	2	0	0	60	1	1	0	0	0	62	0	0	0	0	0
	28	36	14	11	0	0	1	41	16	3	2	0	0	58	1	2	1	0	0	59	3	0	0	0	0
	42	45	13	2	2	0	0	56	5	1	0	0	0	61	0	1	0	0	0	62	0	0	0	0	0
	56	56	4	1	1	0	0	56	4	2	0	0	0	59	1	2	0	0	0	62	0	0	0	0	0
2301	0	57	1	4	0	0	0	19	36	6	1	0	0	62	0	0	0	0	0	61	1	0	0	0	0
	7	48	14	0	0	0	0	28	34	0	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0
	14	62	0	0	0	0	0	39	23	0	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0
	28	62	0	0	0	0	0	47	15	0	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0
	42	62	0	0	0	0	0	41	19	2	0	0	0	60	1	1	0	0	0	62	0	0	0	0	0
	56	62	0	0	0	0	0	31	30	1	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0
2306	0	40	3	7	4	8	0	31	14	2	7	8	0	60	1	1	0	0	0	61	0	1	0	0	0
	7	46	6	7	3	0	0	38	16	5	3	0	0	62	0	0	0	0	0	62	0	0	0	0	0
	14	42	11	2	0	7	0	35	15	4	7	1	0	62	0	0	0	0	0	62	0	0	0	0	0
	28	43	9	2	8	0	0	32	9	9	4	8	0	60	2	0	0	0	0	62	0	0	0	0	0
	42	39	7	3	5	8	0	23	16	6	7	10	0	61	1	0	0	0	0	61	0	1	0	0	0
	56	37	7	6	4	8	0	27	10	9	10	6	0	62	0	0	0	0	0	60	0	2	0	0	0
2404	0	15	15	8	10	7	7	12	37	12	1	0	0	47	11	3	1	0	0	22	28	4	6	2	0
	7	8	21	8	10	6	9	10	41	8	2	1	0	42	18	1	1	0	0	9	29	13	4	4	3
	14	8	27	12	3	11	1	26	32	3	1	0	0	51	11	0	0	0	0	26	23	8	4	0	1
	28	9	18	12	9	11	3	20	27	12	1	0	2	47	14	1	0	0	0	16	26	13	5	1	1
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
2406	0	21	28	9	4	0	0	36	14	11	0	1	0	58	3	0	1	0	0	16	32	12	2	0	0
	7	25	29	7	1	0	0	43	14	3	1	1	0	59	1	0	2	0	0	18	36	7	1	0	0
	14	44	18	0	0	0	0	53	6	3	0	0	0	62	0	0	0	0	0	30	31	1	0	0	0
	28	40	20	2	0	0	0	58	3	1	0	0	0	62	0	0	0	0	0	41	21	0	0	0	0
	42	38	22	2	0	0	0	58	4	0	0	0	0	62	0	0	0	0	0	37	22	3	0	0	0

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 2. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

Placebo Group																									
		Clinical Sign*																							
		Alopecia						Erythema						Excoriation						Lichenification					
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5
Animal	Study Day																								
2406	56	24	30	6	2	0	0	48	8	4	1	1	0	59	1	0	0	1	1	26	27	8	1	0	0
2411	0	6	27	8	8	10	3	36	23	2	1	0	0	58	4	0	0	0	0	14	38	9	1	0	0
	7	21	26	7	3	4	1	52	7	0	3	0	0	61	1	0	0	0	0	33	25	3	1	0	0
	14	43	15	3	0	1	0	60	2	0	0	0	0	61	1	0	0	0	0	51	11	0	0	0	0
	28	35	21	1	4	0	1	54	6	1	1	0	0	59	3	0	0	0	0	49	9	3	1	0	0
	42	29	21	10	2	0	0	56	2	2	2	0	0	55	7	0	0	0	0	40	18	4	0	0	0
	56	41	12	7	0	2	0	56	3	1	2	0	0	58	2	2	0	0	0	43	14	3	2	0	0
2414	0	23	32	6	1	0	0	30	27	5	0	0	0	58	4	0	0	0	0	38	20	4	0	0	0
	7	42	20	0	0	0	0	49	11	2	0	0	0	60	2	0	0	0	0	53	9	0	0	0	0
	14	35	22	4	1	0	0	45	14	3	0	0	0	57	5	0	0	0	0	51	8	3	0	0	0
	28	46	16	0	0	0	0	47	14	1	0	0	0	62	0	0	0	0	0	56	6	0	0	0	0
	42	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA
	56	44	18	0	0	0	0	44	18	0	0	0	0	61	1	0	0	0	0	57	4	1	0	0	0
2419	0	23	31	8	0	0	0	52	6	4	0	0	0	61	1	0	0	0	0	34	26	2	0	0	0
	7	23	39	0	0	0	0	40	17	5	0	0	0	62	0	0	0	0	0	47	15	0	0	0	0
	14	44	18	0	0	0	0	59	3	0	0	0	0	61	1	0	0	0	0	53	9	0	0	0	0
	28	48	12	2	0	0	0	58	4	0	0	0	0	62	0	0	0	0	0	55	7	0	0	0	0
	42	42	20	0	0	0	0	60	2	0	0	0	0	62	0	0	0	0	0	57	5	0	0	0	0
	56	52	10	0	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	57	5	0	0	0	0
2421	0	37	19	5	1	0	0	41	18	2	1	0	0	61	1	0	0	0	0	46	16	0	0	0	0
	7	47	14	1	0	0	0	59	3	0	0	0	0	61	1	0	0	0	0	60	2	0	0	0	0
	14	53	9	0	0	0	0	56	5	1	0	0	0	62	0	0	0	0	0	55	7	0	0	0	0
	28	53	9	0	0	0	0	60	2	0	0	0	0	62	0	0	0	0	0	59	3	0	0	0	0
	42	54	8	0	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0	61	1	0	0	0	0
	56	58	4	0	0	0	0	60	2	0	0	0	0	62	0	0	0	0	0	61	1	0	0	0	0
2426	0	26	26	10	0	0	0	36	23	2	1	0	0	54	4	2	2	0	0	42	16	4	0	0	0
	7	49	13	0	0	0	0	56	6	0	0	0	0	59	2	1	0	0	0	50	11	1	0	0	0
	14	34	25	2	1	0	0	46	13	3	0	0	0	52	7	3	0	0	0	46	11	5	0	0	0
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
1002	0	49	0	9	4	0	0	44	0	9	9	0	0	62	0	0	0	0	0	53	0	8	1	0	0	
	7	60	0	2	0	0	0	45	0	13	4	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	14	53	8	1	0	0	0	47	6	9	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	28	59	0	3	0	0	0	49	0	9	4	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	42	54	8	0	0	0	0	48	14	0	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	56	62	0	0	0	0	0	47	9	5	1	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
1006	0	60	0	2	0	0	0	43	1	11	3	4	0	62	0	0	0	0	0	62	0	0	0	0	0	
	7	61	0	1	0	0	0	46	4	3	9	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	14	61	0	1	0	0	0	48	2	12	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	28	62	0	0	0	0	0	45	9	8	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	42	62	0	0	0	0	0	50	0	12	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	56	62	0	0	0	0	0	44	7	8	3	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
1103	0	39	3	8	12	0	0	31	3	11	17	0	0	36	4	8	14	0	0	36	4	8	14	0	0	
	7	62	0	0	0	0	0	39	13	10	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	14	62	0	0	0	0	0	39	23	0	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	28	62	0	0	0	0	0	32	28	2	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	42	62	0	0	0	0	0	19	41	2	0	0	0	62	0	0	0	0	0	60	2	0	0	0	0	
	56	58	4	0	0	0	0	17	42	3	0	0	0	56	6	0	0	0	0	60	2	0	0	0	0	
1107	0	7	1	20	7	24	3	0	0	6	12	32	12	2	0	22	9	25	4	2	0	22	9	25	4	
	7	17	42	3	0	0	0	2	4	56	0	0	0	27	35	0	0	0	0	38	24	0	0	0	0	
	14	21	37	4	0	0	0	3	49	9	1	0	0	41	18	3	0	0	0	49	10	3	0	0	0	
	28	2	25	35	0	0	0	0	0	51	11	0	0	12	12	35	3	0	0	21	13	27	1	0	0	
	42	4	42	16	0	0	0	0	5	36	21	0	0	11	25	23	3	0	0	20	19	22	1	0	0	
	56	3	18	14	24	3	0	0	0	22	36	4	0	8	15	19	19	1	0	16	12	20	14	0	0	
1112	0	24	20	17	1	0	0	0	0	16	46	0	0	32	5	24	1	0	0	34	8	20	0	0	0	
	7	36	26	0	0	0	0	10	28	24	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	14	54	6	2	0	0	0	15	39	7	1	0	0	59	3	0	0	0	0	59	3	0	0	0	0	
	28	38	21	2	1	0	0	15	1	3	43	0	0	48	11	2	1	0	0	60	2	0	0	0	0	
	42	60	2	0	0	0	0	36	0	23	3	0	0	60	1	1	0	0	0	62	0	0	0	0	0	
	56	62	0	0	0	0	0	37	16	8	1	0	0	62	0	0	0	0	0	62	0	0	0	0	0	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
1204	0	27	28	7	0	0	0	1	10	33	17	1	0	56	6	0	0	0	0	34	23	5	0	0	0	
	7	47	13	2	0	0	0	3	25	27	7	0	0	58	4	0	0	0	0	42	15	5	0	0	0	
	14	50	10	2	0	0	0	10	21	28	3	0	0	60	2	0	0	0	0	36	24	2	0	0	0	
	28	51	11	0	0	0	0	18	31	13	0	0	0	62	0	0	0	0	0	43	17	2	0	0	0	
	42	54	7	1	0	0	0	25	27	9	1	0	0	60	2	0	0	0	0	44	16	2	0	0	0	
	56	51	11	0	0	0	0	22	35	4	1	0	0	60	2	0	0	0	0	50	11	1	0	0	0	
1205	0	45	14	3	0	0	0	6	31	22	3	0	0	60	2	0	0	0	0	36	15	11	0	0	0	
	7	47	12	3	0	0	0	13	40	8	1	0	0	61	1	0	0	0	0	25	30	7	0	0	0	
	14	51	10	1	0	0	0	18	36	8	0	0	0	61	1	0	0	0	0	31	22	9	0	0	0	
	28	48	12	2	0	0	0	29	28	5	0	0	0	60	2	0	0	0	0	41	17	3	1	0	0	
	42	53	6	3	0	0	0	26	33	2	1	0	0	62	0	0	0	0	0	45	15	2	0	0	0	
	56	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
1210	0	14	20	14	7	7	0	19	20	12	10	1	0	52	8	2	0	0	0	20	16	19	5	2	0	
	7	23	19	11	9	0	0	32	16	11	3	0	0	62	0	0	0	0	0	26	17	15	3	1	0	
	14	25	19	13	5	0	0	26	18	13	5	0	0	62	0	0	0	0	0	30	17	10	5	0	0	
	28	31	15	12	4	0	0	27	20	10	5	0	0	58	4	0	0	0	0	28	17	16	1	0	0	
	42	30	22	8	2	0	0	26	9	15	10	2	0	56	4	2	0	0	0	23	19	14	6	0	0	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
1304	0	35	9	7	6	3	2	9	21	18	12	2	0	44	15	2	1	0	0	42	6	5	5	4	0	
	7	20	16	11	12	3	0	4	32	18	6	2	0	55	6	1	0	0	0	36	10	8	7	1	0	
	14	36	14	8	4	0	0	16	23	16	7	0	0	62	0	0	0	0	0	48	7	4	3	0	0	
	28	25	15	8	12	2	0	17	22	18	5	0	0	59	3	0	0	0	0	49	4	5	4	0	0	
	42	25	17	9	10	1	0	15	19	14	14	0	0	58	4	0	0	0	0	40	5	8	9	0	0	
	56	19	14	14	9	6	0	15	11	17	19	0	0	49	10	3	0	0	0	34	7	11	10	0	0	
1306	0	52	7	3	0	0	0	27	22	7	4	2	0	59	3	0	0	0	0	53	5	3	1	0	0	
	7	49	10	3	0	0	0	35	20	5	2	0	0	61	1	0	0	0	0	51	10	1	0	0	0	
	14	53	8	1	0	0	0	44	13	2	3	0	0	62	0	0	0	0	0	59	2	1	0	0	0	
	28	55	6	1	0	0	0	34	11	12	5	0	0	57	2	3	0	0	0	57	3	2	0	0	0	
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
1312	0	26	6	21	6	2	1	5	15	19	17	6	0	62	0	0	0	0	0	36	13	8	3	2	0	
	7	40	10	8	3	0	1	22	20	13	7	0	0	61	1	0	0	0	0	42	11	6	3	0	0	
	14	30	5	16	4	7	0	10	19	9	15	9	0	59	2	1	0	0	0	28	13	10	7	4	0	
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
1314	0	20	9	18	11	4	0	4	10	17	31	0	0	41	6	12	3	0	0	54	4	3	1	0	0	
	7	31	6	20	5	0	0	12	20	18	12	0	0	57	4	1	0	0	0	48	9	5	0	0	0	
	14	39	7	11	5	0	0	17	18	19	8	0	0	61	1	0	0	0	0	56	4	2	0	0	0	
	28	60	2	0	0	0	0	22	19	19	2	0	0	62	0	0	0	0	0	56	4	2	0	0	0	
	42	61	1	0	0	0	0	38	21	3	0	0	0	62	0	0	0	0	0	59	3	0	0	0	0	
	56	61	1	0	0	0	0	38	15	9	0	0	0	62	0	0	0	0	0	56	5	1	0	0	0	
1317	0	59	3	0	0	0	0	27	11	17	7	0	0	62	0	0	0	0	0	57	3	2	0	0	0	
	7	53	7	1	1	0	0	30	15	16	1	0	0	62	0	0	0	0	0	58	4	0	0	0	0	
	14	57	1	3	1	0	0	32	23	7	0	0	0	62	0	0	0	0	0	58	4	0	0	0	0	
	28	55	5	2	0	0	0	32	24	6	0	0	0	61	1	0	0	0	0	58	3	1	0	0	0	
	42	55	5	2	0	0	0	33	22	7	0	0	0	62	0	0	0	0	0	57	4	1	0	0	0	
	56	54	6	2	0	0	0	33	17	12	0	0	0	62	0	0	0	0	0	60	2	0	0	0	0	
1402	0	55	3	3	1	0	0	21	2	22	17	0	0	56	1	4	1	0	0	40	8	10	4	0	0	
	7	57	1	3	1	0	0	34	5	17	6	0	0	61	0	1	0	0	0	47	7	6	2	0	0	
	14	58	2	2	0	0	0	31	11	19	1	0	0	62	0	0	0	0	0	52	8	2	0	0	0	
	28	58	3	1	0	0	0	41	8	12	1	0	0	61	0	0	1	0	0	55	4	2	1	0	0	
	42	59	0	3	0	0	0	27	19	10	5	1	0	61	1	0	0	0	0	50	7	4	1	0	0	
	56	58	1	1	2	0	0	21	16	11	14	0	0	60	0	0	2	0	0	50	3	7	1	1	0	
1406	0	46	1	7	8	0	0	34	6	10	12	0	0	58	1	2	1	0	0	43	8	8	3	0	0	
	7	52	1	5	4	0	0	39	7	10	5	1	0	58	1	3	0	0	0	50	3	4	3	2	0	
	14	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
	28	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
	42	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
	56	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
1412	0	45	7	7	2	1	0	25	7	19	11	0	0	60	0	1	1	0	0	35	7	11	8	1	0	
	7	55	3	3	0	1	0	32	3	12	15	0	0	58	1	1	2	0	0	38	13	6	5	0	0	
	14	57	2	2	0	1	0	35	6	18	3	0	0	62	0	0	0	0	0	45	8	8	1	0	0	
	28	53	4	4	1	0	0	36	4	10	12	0	0	62	0	0	0	0	0	42	9	9	2	0	0	
	42	57	1	1	2	1	0	35	6	8	13	0	0	60	0	2	0	0	0	42	8	11	1	0	0	
	56	59	0	0	2	1	0	37	6	9	10	0	0	58	2	1	0	1	0	48	2	8	3	1	0	
1413	0	58	2	2	0	0	0	9	18	22	13	0	0	62	0	0	0	0	0	45	9	6	2	0	0	
	7	55	6	1	0	0	0	15	25	20	2	0	0	60	0	2	0	0	0	49	4	7	2	0	0	
	14	53	4	3	2	0	0	15	15	26	6	0	0	60	0	2	0	0	0	44	4	9	5	0	0	
	28	53	4	4	1	0	0	21	5	24	9	3	0	54	0	2	4	2	0	44	6	5	2	5	0	
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
1420	0	58	1	3	0	0	0	39	5	11	6	1	0	58	0	2	2	0	0	53	4	5	0	0	0	
	7	59	2	1	0	0	0	45	5	6	6	0	0	62	0	0	0	0	0	55	7	0	0	0	0	
	14	59	1	2	0	0	0	48	0	5	8	1	0	62	0	0	0	0	0	55	5	2	0	0	0	
	28	61	1	0	0	0	0	43	6	9	3	1	0	62	0	0	0	0	0	55	6	1	0	0	0	
	42	59	2	0	1	0	0	47	3	8	2	2	0	61	0	1	0	0	0	51	4	6	1	0	0	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
1424	0	57	1	3	1	0	0	41	10	6	5	0	0	58	1	2	1	0	0	50	4	4	2	2	0	
	7	57	2	2	1	0	0	43	7	6	6	0	0	61	0	1	0	0	0	50	5	4	1	2	0	
	14	59	2	1	0	0	0	42	5	10	5	0	0	59	0	1	1	1	0	51	1	5	4	1	0	
	28	61	0	0	0	1	0	45	4	12	1	0	0	54	1	4	2	1	0	54	1	2	3	2	0	
	42	52	0	2	2	5	1	37	7	8	8	2	0	54	0	2	1	5	0	45	3	6	1	5	2	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
1427	0	52	2	7	1	0	0	42	4	5	9	2	0	59	0	0	2	1	0	44	6	10	2	0	0	
	7	61	0	1	0	0	0	46	1	12	3	0	0	58	0	4	0	0	0	54	0	7	1	0	0	
	14	57	1	0	4	0	0	49	5	5	3	0	0	60	0	2	0	0	0	51	3	4	4	0	0	
	28	54	1	7	0	0	0	45	4	8	5	0	0	60	0	2	0	0	0	46	2	8	5	1	0	
	42	57	0	4	1	0	0	49	4	6	3	0	0	62	0	0	0	0	0	53	3	5	1	0	0	
	56	58	0	4	0	0	0	52	2	4	3	1	0	62	0	0	0	0	0	54	1	4	3	0	0	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
1430	0	59	2	1	0	0	0	34	12	11	5	0	0	58	1	2	1	0	0	51	4	5	2	0	0	
	7	57	1	3	1	0	0	39	6	13	4	0	0	60	0	2	0	0	0	53	3	6	0	0	0	
	14	59	1	2	0	0	0	32	6	17	6	1	0	61	0	1	0	0	0	52	4	3	3	0	0	
	28	52	4	6	0	0	0	27	0	22	10	3	0	61	1	0	0	0	0	52	1	7	2	0	0	
	42	57	1	3	1	0	0	39	3	15	5	0	0	61	1	0	0	0	0	58	0	2	2	0	0	
	56	61	0	1	0	0	0	37	10	9	6	0	0	62	0	0	0	0	0	53	4	5	0	0	0	
1434	0	45	1	6	9	1	0	13	11	23	14	1	0	45	1	4	12	0	0	36	5	11	10	0	0	
	7	35	2	15	9	1	0	15	11	25	11	0	0	54	1	5	2	0	0	38	7	11	5	1	0	
	14	41	3	13	4	1	0	18	12	24	7	1	0	53	1	4	4	0	0	46	1	12	3	0	0	
	28	38	2	15	7	0	0	24	6	25	7	0	0	58	0	3	1	0	0	43	2	8	9	0	0	
	42	41	5	14	2	0	0	26	8	16	12	0	0	60	0	1	1	0	0	43	9	6	3	1	0	
	56	53	3	5	1	0	0	35	7	11	9	0	0	59	1	0	2	0	0	50	4	6	2	0	0	
1438	0	49	6	4	3	0	0	14	9	20	16	3	0	60	0	0	2	0	0	50	7	3	2	0	0	
	7	55	1	2	4	0	0	26	8	14	14	0	0	62	0	0	0	0	0	53	4	4	1	0	0	
	14	52	2	8	0	0	0	32	10	14	6	0	0	62	0	0	0	0	0	56	3	3	0	0	0	
	28	55	1	6	0	0	0	27	2	19	14	0	0	62	0	0	0	0	0	56	0	6	0	0	0	
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
1443	0	46	4	3	5	4	0	26	4	17	13	2	0	55	1	3	3	0	0	46	2	9	4	1	0	
	7	44	0	8	7	3	0	20	6	17	16	3	0	54	1	5	2	0	0	39	1	18	4	0	0	
	14	47	2	8	2	3	0	31	5	18	6	2	0	59	0	1	1	1	0	48	2	8	4	0	0	
	28	51	3	0	6	2	0	32	3	19	8	0	0	57	1	2	2	0	0	43	4	14	1	0	0	
	42	42	2	7	9	2	0	25	7	20	9	1	0	57	1	3	1	0	0	41	3	13	4	1	0	
	56	55	0	4	3	0	0	40	3	14	5	0	0	59	1	2	0	0	0	54	3	4	1	0	0	
1447	0	55	3	3	1	0	0	23	12	17	10	0	0	59	0	3	0	0	0	44	9	7	2	0	0	
	7	58	2	2	0	0	0	32	8	17	5	0	0	60	1	1	0	0	0	46	7	8	1	0	0	
	14	59	1	2	0	0	0	28	7	22	5	0	0	61	0	1	0	0	0	50	9	3	0	0	0	
	28	60	0	2	0	0	0	26	15	19	2	0	0	62	0	0	0	0	0	49	3	10	0	0	0	
	42	59	2	1	0	0	0	39	8	13	2	0	0	62	0	0	0	0	0	53	4	5	0	0	0	
	56	57	2	3	0	0	0	34	5	18	5	0	0	60	0	2	0	0	0	54	0	8	0	0	0	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
1702	0	53	7	0	2	0	0	33	16	11	2	0	0	60	2	0	0	0	0	62	0	0	0	0	0	
	7	59	2	1	0	0	0	30	17	10	5	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	14	61	1	0	0	0	0	35	13	14	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0	
	28	54	8	0	0	0	0	35	12	11	4	0	0	59	3	0	0	0	0	62	0	0	0	0	0	
	42	56	6	0	0	0	0	34	11	12	5	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	56	61	1	0	0	0	0	34	18	10	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
1707	0	22	13	16	10	1	0	10	15	22	13	2	0	55	4	2	1	0	0	60	0	0	2	0	0	
	7	32	9	17	4	0	0	24	22	10	6	0	0	55	7	0	0	0	0	60	1	1	0	0	0	
	14	30	13	19	0	0	0	32	22	7	1	0	0	60	2	0	0	0	0	60	1	1	0	0	0	
	28	40	13	6	3	0	0	28	23	9	2	0	0	58	4	0	0	0	0	60	1	1	0	0	0	
	42	41	12	8	1	0	0	30	15	15	2	0	0	57	5	0	0	0	0	60	0	2	0	0	0	
	56	36	15	10	1	0	0	32	20	9	1	0	0	60	2	0	0	0	0	61	1	0	0	0	0	
1711	0	37	10	3	5	3	4	25	12	15	8	2	0	52	3	3	3	1	0	51	6	4	0	1	0	
	7	35	9	8	4	5	1	23	20	12	6	1	0	54	3	3	2	0	0	53	8	0	1	0	0	
	14	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
	28	40	8	5	5	4	0	32	17	9	4	0	0	60	2	0	0	0	0	53	7	2	0	0	0	
	42	41	9	3	3	4	2	28	19	8	7	0	0	59	3	0	0	0	0	53	5	3	1	0	0	
	56	40	12	5	2	3	0	24	23	11	3	1	0	62	0	0	0	0	0	56	4	2	0	0	0	
1801	0	57	2	0	3	0	0	29	16	10	4	3	0	55	2	4	0	1	0	51	6	3	2	0	0	
	7	57	1	4	0	0	0	35	11	7	6	3	0	60	0	2	0	0	0	54	3	3	2	0	0	
	14	60	1	1	0	0	0	43	7	4	7	1	0	59	0	3	0	0	0	54	3	4	1	0	0	
	28	60	0	2	0	0	0	39	11	10	2	0	0	61	0	1	0	0	0	53	8	1	0	0	0	
	42	54	4	4	0	0	0	34	11	8	9	0	0	58	2	2	0	0	0	47	5	5	5	0	0	
	56	52	0	9	1	0	0	32	12	4	9	5	0	55	1	5	0	1	0	50	0	5	7	0	0	
1808	0	56	1	4	1	0	0	24	16	16	6	0	0	57	3	1	1	0	0	50	7	3	2	0	0	
	7	59	2	1	0	0	0	38	12	9	3	0	0	60	1	1	0	0	0	52	3	7	0	0	0	
	14	60	1	1	0	0	0	31	11	17	3	0	0	58	1	3	0	0	0	53	2	7	0	0	0	
	28	55	0	6	1	0	0	18	14	19	11	0	0	55	0	6	1	0	0	42	3	16	1	0	0	
	42	62	0	0	0	0	0	45	2	11	4	0	0	61	0	1	0	0	0	60	0	2	0	0	0	
	56	61	0	1	0	0	0	28	8	16	9	1	0	58	0	4	0	0	0	54	2	4	2	0	0	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions,
 AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
1810	0	55	3	4	0	0	0	21	9	10	16	5	1	54	0	5	3	0	0	48	2	7	4	1	0	
	7	56	2	4	0	0	0	26	8	10	14	3	1	61	0	0	1	0	0	53	0	7	2	0	0	
	14	56	0	5	1	0	0	32	0	9	17	4	0	59	0	3	0	0	0	50	0	6	6	0	0	
	28	59	0	3	0	0	0	27	3	19	10	1	2	56	0	6	0	0	0	54	0	6	1	1	0	
	42	61	0	1	0	0	0	37	0	14	7	1	3	60	0	1	1	0	0	52	0	4	6	0	0	
	56	59	0	2	1	0	0	38	0	8	12	1	3	58	0	3	1	0	0	52	0	5	3	2	0	
1903	0	40	2	5	12	3	0	20	7	20	13	2	0	55	1	5	1	0	0	41	3	6	11	1	0	
	7	42	2	3	10	5	0	29	13	14	6	0	0	60	1	1	0	0	0	39	6	10	7	0	0	
	14	36	6	5	5	10	0	17	9	23	13	0	0	61	0	1	0	0	0	35	9	11	6	1	0	
	28	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
1905	0	35	2	4	13	6	2	26	17	17	2	0	0	46	6	6	4	0	0	41	17	4	0	0	0	
	7	34	3	10	8	7	0	35	26	1	0	0	0	59	2	1	0	0	0	49	13	0	0	0	0	
	14	34	6	13	4	5	0	35	26	1	0	0	0	61	1	0	0	0	0	54	8	0	0	0	0	
	28	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	NA	
	42	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
2009	0	43	7	9	2	1	0	27	10	19	6	0	0	59	2	1	0	0	0	60	0	0	0	0	2	
	7	59	0	3	0	0	0	56	3	1	1	1	0	62	0	0	0	0	0	60	0	1	1	0	0	
	14	50	11	1	0	0	0	57	4	1	0	0	0	62	0	0	0	0	0	60	0	1	1	0	0	
	28	59	2	1	0	0	0	60	0	0	2	0	0	62	0	0	0	0	0	60	0	0	2	0	0	
	42	55	2	5	0	0	0	39	12	9	1	0	1	59	1	0	2	0	0	60	0	0	1	1	0	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
2013	0	52	7	1	2	0	0	48	13	0	1	0	0	61	0	0	1	0	0	62	0	0	0	0	0	
	7	58	2	0	2	0	0	58	0	4	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	14	57	2	3	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	28	60	0	2	0	0	0	62	0	0	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0	
	42	60	1	1	0	0	0	60	1	1	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	56	59	3	0	0	0	0	61	0	0	0	1	0	62	0	0	0	0	0	62	0	0	0	0	0	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions,
AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
2020	0	47	9	2	4	0	0	36	11	6	9	0	0	62	0	0	0	0	0	59	3	0	0	0	0	
	7	62	0	0	0	0	0	53	4	5	0	0	62	0	0	0	0	0	62	0	0	0	0	0		
	14	57	5	0	0	0	0	57	3	2	0	0	62	0	0	0	0	0	62	0	0	0	0	0		
	28	62	0	0	0	0	0	56	6	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0		
	42	62	0	0	0	0	0	57	5	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0		
	56	62	0	0	0	0	0	47	3	12	0	0	62	0	0	0	0	0	62	0	0	0	0	0		
2104	0	58	3	0	1	0	0	0	18	33	11	0	0	56	5	0	0	1	0	60	1	1	0	0	0	
	7	58	2	1	1	0	0	0	37	20	5	0	0	62	0	0	0	0	0	59	2	1	0	0	0	
	14	57	5	0	0	0	0	0	46	15	1	0	0	62	0	0	0	0	0	60	2	0	0	0	0	
	28	62	0	0	0	0	0	1	30	30	1	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	42	61	1	0	0	0	0	0	33	25	4	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	56	61	1	0	0	0	0	0	10	31	19	2	0	61	1	0	0	0	0	62	0	0	0	0	0	
2107	0	62	0	0	0	0	0	1	43	16	2	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	7	62	0	0	0	0	0	0	30	32	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	14	62	0	0	0	0	0	2	32	26	2	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	28	62	0	0	0	0	0	1	34	27		0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	42	62	0	0	0	0	0	0	11	39	12	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	56	62	0	0	0	0	0	0	28	31	3	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
2109	0	60	0	2	0	0	0	24	29	4	4	1	0	60	2	0	0	0	0	62	0	0	0	0	0	
	7	60	1	1	0	0	0	29	28	3	2	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	14	59	2	1	0	0	0	34	22	4	2	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	28	61	1	0	0	0	0	34	22	6	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	42	62	0	0	0	0	0	35	19	8	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	56	61	1	0	0	0	0	42	13	5	2	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
2203	0	58	2	1	1	0	0	47	7	6	2	0	0	60	0	1	0	1	0	61	1	0	0	0	0	
	7	58	3	1	0	0	0	49	9	3	1	0	0	58	0	3	1	0	0	62	0	0	0	0	0	
	14	59	3	0	0	0	0	55	7	0	0	0	0	61	0	1	0	0	0	62	0	0	0	0	0	
	28	59	1	2	0	0	0	58	3	1	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0	
	42	58	3	1	0	0	0	53	9	0	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	
	56	61	1	0	0	0	0	59	3	0	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions, AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
2206	0	50	5	4	3	0	0	31	19	8	4	0	0	62	0	0	0	0	0	52	3	1	1	5	0	
	7	54	4	2	0	2	0	44	12	2	3	1	0	62	0	0	0	0	0	56	0	4	1	1	0	
	14	53	3	5	1	0	0	43	14	3	1	1	0	61	1	0	0	0	0	56	1	2	3	0	0	
	28	56	2	2	1	1	0	45	13	4	0	0	0	62	0	0	0	0	0	57	0	4	1	0	0	
	42	53	6	2	1	0	0	43	10	6	3	0	0	60	1	1	0	0	0	55	2	1	3	1	0	
	56	59	1	1	0	0	1	47	9	3	3	0	0	59	3	0	0	0	0	57	0	3	2	0	0	
2304	0	23	26	11	2	0	0	24	19	10	8	1	0	54	6	2	0	0	0	56	1	2	3	0	0	
	7	50	11	1	0	0	0	46	9	7	0	0	0	61	1	0	0	0	0	60	0	2	0	0	0	
	14	48	14	0	0	0	0	39	13	9	1	0	0	62	0	0	0	0	0	60	2	0	0	0	0	
	28	49	13	0	0	0	0	35	25	2	0	0	0	62	0	0	0	0	0	60	0	2	0	0	0	
	42	44	13	3	2	0	0	44	8	9	1	0	0	62	0	0	0	0	0	61	1	0	0	0	0	
	56	55	7	0	0	0	0	44	14	2	2	0	0	61	1	0	0	0	0	60	2	0	0	0	0	
2401	0	18	18	6	10	8	2	15	28	11	1	6	1	58	4	0	0	0	0	27	22	11	2	0	0	
	7	23	19	10	8	1	1	24	25	7	4	1	1	56	4	1	0	1	0	36	20	6	0	0	0	
	14	22	21	9	7	3	0	20	29	9	4	0	0	60	1	0	0	0	1	40	12	9	0	1	0	
	28	32	19	9	2	0	0	41	15	5	0	1	0	61	0	0	1	0	0	43	15	4	0	0	0	
	42	36	21	5	0	0	0	44	16	1	1	0	0	61	1	0	0	0	0	50	11	1	0	0	0	
	56	36	20	5	1	0	0	49	10	2	1	0	0	61	0	0	1	0	0	52	10	0	0	0	0	
2405	0	9	19	21	8	3	2	3	34	14	6	4	1	51	11	0	0	0	0	14	36	11	1	0	0	
	7	8	35	13	3	3	0	22	23	10	6	1	0	59	3	0	0	0	0	19	34	8	1	0	0	
	14	1	26	12	18	5	0	15	23	9	3	8	4	53	6	3	0	0	0	17	39	5	1	0	0	
	28	36	25	1	0	0	0	60	2	0	0	0	0	62	0	0	0	0	0	47	15	0	0	0	0	
	42	40	20	2	0	0	0	60	2	0	0	0	0	62	0	0	0	0	0	39	22	1	0	0	0	
	56	29	27	5	1	0	0	53	8	1	0	0	0	61	0	1	0	0	0	46	15	1	0	0	0	
2410	0	29	21	11	1	0	0	37	16	8	1	0	0	58	4	0	0	0	0	39	22	1	0	0	0	
	7	32	23	6	1	0	0	54	6	2	0	0	0	61	1	0	0	0	0	50	12	0	0	0	0	
	14	50	12	0	0	0	0	59	3	0	0	0	0	62	0	0	0	0	0	56	6	0	0	0	0	
	28	53	9	0	0	0	0	57	5	0	0	0	0	62	0	0	0	0	0	57	5	0	0	0	0	
	42	52	10	0	0	0	0	53	8	0	0	1	0	59	3	0	0	0	0	57	4	1	0	0	0	
	56	55	7	0	0	0	0	54	8	0	0	0	0	62	0	0	0	0	0	60	2	0	0	0	0	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions,
 AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Table 3. Frequency at each severity score level for each clinical sign for each animal at study Days 0, 7, 14, 28, 42 and 56.

		Product Group																								
		Clinical Sign*																								
		Alopecia					Erythema					Excoriation					Lichenification									
		0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	0	1	2	3	4	5	
Animal	Study Day																									
2416	0	19	35	6	1	1	0	37	14	6	4	1	0	50	6	4	1	1	0	24	29	8	1	0	0	
	7	23	30	6	2	1	0	34	20	4	2	0	2	58	4	0	0	0	0	34	20	6	1	1	0	
	14	34	23	4	1	0	0	42	16	2	1	1	0	59	3	0	0	0	0	43	15	2	1	1	0	
	28	30	24	6	2	0	0	40	20	0	1	1	0	58	2	0	2	0	0	39	20	1	1	0	1	
	42	34	18	9	1	0	0	36	13	3	8	2	0	55	6	1	0	0	0	44	13	4	1	0	0	
	56	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	AD	
2420	0	21	31	8	2	0	0	39	22	1	0	0	0	61	1	0	0	0	0	34	26	2	0	0	0	
	7	49	13	0	0	0	0	61	1	0	0	0	0	62	0	0	0	0	0	47	15	0	0	0	0	
	14	56	6	0	0	0	0	58	4	0	0	0	0	62	0	0	0	0	0	47	15	0	0	0	0	
	28	56	6	0	0	0	0	60	2	0	0	0	0	61	1	0	0	0	0	49	13	0	0	0	0	
	42	47	15	0	0	0	0	60	2	0	0	0	0	62	0	0	0	0	0	48	14	0	0	0	0	
	56	55	6	1	0	0	0	62	0	0	0	0	0	62	0	0	0	0	0	56	6	0	0	0	0	

* 0 = None (no lesions, normal skin), 1 = Mild lesions, 2 or 3 = Moderate lesions, 4 or 5 = Severe lesions,
AD = Withdrawn due to worsening of clinical signs of AD, NA = not available.

Study Type	Safety																																																																																																																																																																																																																																																	
Pertaining to	ALL																																																																																																																																																																																																																																																	
Study Purpose	Demonstrate safety of product under typical use conditions																																																																																																																																																																																																																																																	
Product Administration	2 doses administered one month apart by subcutaneous route																																																																																																																																																																																																																																																	
Study Animals	245 dogs diagnosed with atopic dermatitis at 14 veterinary practices. 162 of the dogs were administered the product. The remaining 83 were administered a placebo (control group). Product dosing was administered according to a set of 4 bodyweight bands (1.0-3.3 mg/kg body weight).																																																																																																																																																																																																																																																	
Challenge Description	Not applicable																																																																																																																																																																																																																																																	
Interval observed after challenge	All dogs were observed for a minimum 30-minute period after each injection. Owners were contacted by telephone on day 14. Dog observations also were made by the attending veterinarians on days 28 and 42 of the study.																																																																																																																																																																																																																																																	
Results	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="text-align: center;">Frequency of adverse events</th> <th style="text-align: center;">Placebo (Control)</th> <th style="text-align: center;">1.0-3.3 mg/kg dose (Product)</th> </tr> </thead> <tbody> <tr> <td style="text-align: center;">Injection Site Itching</td> <td style="text-align: center;">0 (0.0%)</td> <td style="text-align: center;">1 (0.6%)</td> </tr> <tr> <td style="text-align: center;">Injection Site Discomfort – 1st injection</td> <td style="text-align: center;">4 (4.8%)</td> <td style="text-align: center;">10 (6.2%)</td> </tr> <tr> <td style="text-align: center;">Injection Site Discomfort – 2nd injection</td> <td style="text-align: center;">6 (7.2%)</td> <td style="text-align: center;">5 (3.1%)</td> </tr> <tr> <td style="text-align: center;">Immediate Hypersensitivity Reaction</td> <td style="text-align: center;">0 (0.0%)</td> <td style="text-align: center;">0 (0.0%)</td> </tr> <tr> <td style="text-align: center;">No Adverse Events</td> <td style="text-align: center;">73 (88.0%)</td> <td style="text-align: center;">146 (90.1%)</td> </tr> <tr> <td style="text-align: center;">Total</td> <td style="text-align: center;">83 (100%)</td> <td style="text-align: center;">162 (100%)</td> </tr> </tbody> </table> <p>A wide variety of concomitant medications were safely used, including parasiticides, antibiotics, antifungals, corticosteroids, vaccines, allergic-specific immunotherapy, antihistamines and other antipruritics, such as oclacitinib and cyclosporine.</p> <p>There was no clinically important difference in pathology changes between groups following either dose as determined by licensee.</p> <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 10px;"> <thead> <tr> <th colspan="13" style="text-align: center;">Hematology Shift Table: % of Animals with a Shift from Below/Within the Reference Range at Day 0 to Above (Increase) or From Within/Above Reference Range at Day 0 to Below (Decrease)</th> </tr> <tr> <th colspan="13" style="text-align: center;">Hematology Variables (reference range)</th> </tr> <tr> <th rowspan="2">Visit</th> <th colspan="2">Red Blood Cells (5.5-8.5x10⁶ cells/uL)</th> <th colspan="2">Hemoglobin (12-18 g/dL)</th> <th colspan="2">Hematocrit (37-55%)</th> <th colspan="2">MCV (60-72 fl)</th> <th colspan="2">MCH (19.5-24.5 pg)</th> <th colspan="2">MCHC (34-38 g/dL)</th> </tr> <tr> <th>T01</th> <th>T02</th> <th>T01</th> <th>T02</th> <th>T01</th> <th>T02</th> <th>T01</th> <th>T02</th> <th>T01</th> <th>T02</th> <th>T01</th> <th>T02</th> </tr> </thead> <tbody> <tr> <td>Day 0</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>N</td> <td>82</td><td>160</td> <td>82</td><td>160</td> <td>82</td><td>160</td> <td>82</td><td>160</td> <td>82</td><td>160</td> <td>82</td><td>160</td> </tr> <tr> <td>Mean</td> <td>6.77</td><td>6.69</td> <td>16.50</td><td>16.15</td> <td>45.39</td><td>44.52</td> <td>67.08</td><td>66.64</td> <td>24.40</td><td>24.18</td> <td>36.40</td><td>36.30</td> </tr> <tr> <td>Day 28</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>N</td> <td>81</td><td>160</td> <td>81</td><td>160</td> <td>81</td><td>160</td> <td>81</td><td>160</td> <td>81</td><td>160</td> <td>81</td><td>160</td> </tr> <tr> <td>Mean</td> <td>6.74</td><td>6.82</td> <td>16.56</td><td>16.39</td> <td>45.25</td><td>45.16</td> <td>67.24</td><td>66.23</td> <td>24.59</td><td>24.04</td> <td>36.57</td><td>36.30</td> </tr> <tr> <td>Increase</td> <td>0.0</td><td>1.3</td> <td>7.4</td><td>10.1</td> <td>0.0</td><td>0.6</td> <td>1.2</td><td>0.0</td> <td>7.4</td><td>7.5</td> <td>3.7</td><td>3.1</td> </tr> <tr> <td>Decrease</td> <td>4.9</td><td>0.6</td> <td>1.2</td><td>0.6</td> <td>3.7</td><td>1.3</td> <td>0.0</td><td>1.9</td> <td>0.0</td><td>0.0</td> <td>0.0</td><td>0.0</td> </tr> <tr> <td>Day 42</td> <td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td><td></td> </tr> <tr> <td>N</td> <td>81</td><td>159</td> <td>81</td><td>159</td> <td>81</td><td>159</td> <td>81</td><td>159</td> <td>81</td><td>159</td> <td>81</td><td>159</td> </tr> <tr> <td>Mean</td> <td>6.75</td><td>6.80</td> <td>16.55</td><td>16.30</td> <td>45.34</td><td>44.99</td> <td>67.27</td><td>66.25</td> <td>24.54</td><td>24.01</td> <td>36.48</td><td>36.24</td> </tr> <tr> <td>Increase</td> <td>0.0</td><td>0.0</td> <td>4.9</td><td>8.9</td> <td>0.0</td><td>0.6</td> <td>0.0</td><td>0.6</td> <td>12.3</td><td>5.7</td> <td>1.2</td><td>2.5</td> </tr> <tr> <td>Decrease</td> <td>3.7</td><td>2.5</td> <td>2.5</td><td>1.3</td> <td>2.5</td><td>3.8</td> <td>0.0</td><td>1.3</td> <td>0.0</td><td>0.0</td> <td>1.2</td><td>0.6</td> </tr> </tbody> </table>	Frequency of adverse events	Placebo (Control)	1.0-3.3 mg/kg dose (Product)	Injection Site Itching	0 (0.0%)	1 (0.6%)	Injection Site Discomfort – 1 st injection	4 (4.8%)	10 (6.2%)	Injection Site Discomfort – 2 nd injection	6 (7.2%)	5 (3.1%)	Immediate Hypersensitivity Reaction	0 (0.0%)	0 (0.0%)	No Adverse Events	73 (88.0%)	146 (90.1%)	Total	83 (100%)	162 (100%)	Hematology Shift Table: % of Animals with a Shift from Below/Within the Reference Range at Day 0 to Above (Increase) or From Within/Above Reference Range at Day 0 to Below (Decrease)													Hematology Variables (reference range)													Visit	Red Blood Cells (5.5-8.5x10 ⁶ cells/uL)		Hemoglobin (12-18 g/dL)		Hematocrit (37-55%)		MCV (60-72 fl)		MCH (19.5-24.5 pg)		MCHC (34-38 g/dL)		T01	T02	T01	T02	T01	T02	T01	T02	T01	T02	T01	T02	Day 0													N	82	160	82	160	82	160	82	160	82	160	82	160	Mean	6.77	6.69	16.50	16.15	45.39	44.52	67.08	66.64	24.40	24.18	36.40	36.30	Day 28													N	81	160	81	160	81	160	81	160	81	160	81	160	Mean	6.74	6.82	16.56	16.39	45.25	45.16	67.24	66.23	24.59	24.04	36.57	36.30	Increase	0.0	1.3	7.4	10.1	0.0	0.6	1.2	0.0	7.4	7.5	3.7	3.1	Decrease	4.9	0.6	1.2	0.6	3.7	1.3	0.0	1.9	0.0	0.0	0.0	0.0	Day 42													N	81	159	81	159	81	159	81	159	81	159	81	159	Mean	6.75	6.80	16.55	16.30	45.34	44.99	67.27	66.25	24.54	24.01	36.48	36.24	Increase	0.0	0.0	4.9	8.9	0.0	0.6	0.0	0.6	12.3	5.7	1.2	2.5	Decrease	3.7	2.5	2.5	1.3	2.5	3.8	0.0	1.3	0.0	0.0	1.2	0.6
Frequency of adverse events	Placebo (Control)	1.0-3.3 mg/kg dose (Product)																																																																																																																																																																																																																																																
Injection Site Itching	0 (0.0%)	1 (0.6%)																																																																																																																																																																																																																																																
Injection Site Discomfort – 1 st injection	4 (4.8%)	10 (6.2%)																																																																																																																																																																																																																																																
Injection Site Discomfort – 2 nd injection	6 (7.2%)	5 (3.1%)																																																																																																																																																																																																																																																
Immediate Hypersensitivity Reaction	0 (0.0%)	0 (0.0%)																																																																																																																																																																																																																																																
No Adverse Events	73 (88.0%)	146 (90.1%)																																																																																																																																																																																																																																																
Total	83 (100%)	162 (100%)																																																																																																																																																																																																																																																
Hematology Shift Table: % of Animals with a Shift from Below/Within the Reference Range at Day 0 to Above (Increase) or From Within/Above Reference Range at Day 0 to Below (Decrease)																																																																																																																																																																																																																																																		
Hematology Variables (reference range)																																																																																																																																																																																																																																																		
Visit	Red Blood Cells (5.5-8.5x10 ⁶ cells/uL)		Hemoglobin (12-18 g/dL)		Hematocrit (37-55%)		MCV (60-72 fl)		MCH (19.5-24.5 pg)		MCHC (34-38 g/dL)																																																																																																																																																																																																																																							
	T01	T02	T01	T02	T01	T02	T01	T02	T01	T02	T01	T02																																																																																																																																																																																																																																						
Day 0																																																																																																																																																																																																																																																		
N	82	160	82	160	82	160	82	160	82	160	82	160																																																																																																																																																																																																																																						
Mean	6.77	6.69	16.50	16.15	45.39	44.52	67.08	66.64	24.40	24.18	36.40	36.30																																																																																																																																																																																																																																						
Day 28																																																																																																																																																																																																																																																		
N	81	160	81	160	81	160	81	160	81	160	81	160																																																																																																																																																																																																																																						
Mean	6.74	6.82	16.56	16.39	45.25	45.16	67.24	66.23	24.59	24.04	36.57	36.30																																																																																																																																																																																																																																						
Increase	0.0	1.3	7.4	10.1	0.0	0.6	1.2	0.0	7.4	7.5	3.7	3.1																																																																																																																																																																																																																																						
Decrease	4.9	0.6	1.2	0.6	3.7	1.3	0.0	1.9	0.0	0.0	0.0	0.0																																																																																																																																																																																																																																						
Day 42																																																																																																																																																																																																																																																		
N	81	159	81	159	81	159	81	159	81	159	81	159																																																																																																																																																																																																																																						
Mean	6.75	6.80	16.55	16.30	45.34	44.99	67.27	66.25	24.54	24.01	36.48	36.24																																																																																																																																																																																																																																						
Increase	0.0	0.0	4.9	8.9	0.0	0.6	0.0	0.6	12.3	5.7	1.2	2.5																																																																																																																																																																																																																																						
Decrease	3.7	2.5	2.5	1.3	2.5	3.8	0.0	1.3	0.0	0.0	1.2	0.6																																																																																																																																																																																																																																						

Hematology Variables (reference range)												
Visit	Platelets* (200-500x10 ³ /uL)		White Blood Cells (6-17x10 ³ cells/uL)		Neutrophils (3-11.5x10 ³ cells/uL)		Eosinophils (0.1-1.2x10 ³ cells/uL)		Lymphocytes (1-4.8x10 ³ cells/uL)		Monocytes (0.2-1.4x10 ³ cells/uL)	
	T01	T02	T01	T02	T01	T02	T01	T02	T01	T02	T01	T02
Day 0												
N	67	125	82	160	82	160	71	147	82	160	79	158
Mean	284	288	9.01	9.16	6.79	6.83	0.33	0.43	1.44	1.36	0.49	0.49
Day 28												
N	60	110	81	160	81	160	67	146	81	160	81	159
Mean	303	290	8.75	8.70	6.46	6.18	0.39	0.49	1.44	1.58	0.48	0.47
Increase	3.3	0.9	0.0	1.3	4.9	3.1	0.0	4.8	0.0	0.6	1.2	0.6
Decrease	5.0	0.9	3.7	10.1	1.2	4.4	9.0	2.8	18.5	9.4	6.2	12.0
Day 42												
N	53	113	81	159	81	159	68	150	81	159	80	157
Mean	306	294	8.98	8.99	6.83	6.55	0.35	0.45	1.34	1.50	0.51	0.50
Increase	1.9	2.7	1.2	1.3	8.6	6.3	0.0	2.0	0.0	0.6	1.3	3.8
Decrease	1.9	3.6	7.4	5.7	2.5	1.9	2.9	4.0	18.5	8.9	8.8	9.6

T01, placebo; T02, Product; N=Number of dogs with a result from a sample collected at a planned visit. Mean values are truncated such that “*” no decimal places are shown.

Clinical Chemistry Shift Table: % Of Animals With Shift From Below/Within Reference Range At Day 0 To Above (Increase) or From Within/Above Reference Range At Day 0 To Below (Decrease)

Clinical Chemistry Variable (Reference Range)												
	(ALT) Alanine Aminotransferase* (10-120 U/L)		(ALP) Alkaline Phosphatase* (18-141 U/L)		Albumin (2.7-4.5 grams/dL)		Globulin† (1.9-3.4 grams/dL)		Total Protein† (5.4-7.4 grams/dL)		Cholesterol* (130-300 mg/dL)	
	T01	T02	T01	T02	T01	T02	T01	T02	T01	T02	T01	T02
Day 0												
N	83	161	83	161	83	161	83	161	83	161	83	161
Mean	53	47	183	129	3.68	3.65	2.7	2.8	6.4	6.4	218	220
Day 28												
N	82	161	82	161	82	161	82	161	82	161	82	161
Mean	46	44	175	92	3.65	3.61	2.6	2.8	6.3	6.3	228	223
Increase	0.0	0.6	0.0	1.3	0.0	0.0	2.4	4.4	1.2	1.9	8.5	3.1
Decrease	0.0	0.0	1.2	0.6	0.0	1.9	0.0	0.0	1.2	0.0	1.2	2.5
Day 42												
N	81	158	81	158	81	158	81	158	81	158	81	158
Mean	54	44	187	95	3.69	3.59	2.7	2.8	6.3	6.3	236	219
Increase	2.5	1.3	3.7	1.9	0.0	0.0	1.2	3.8	1.2	3.2	11.1	4.5
Decrease	0.0	0.0	2.5	3.8	0.0	1.3	0.0	0.0	1.2	0.6	0.0	1.3

	BUN (Urea Nitrogen) (7-28 mg/dL)		Creatinine (0.6-1.5 mg/dL)		Amylase* (50-1250 U/L)		Lipase* (0-230 U/L)		(CK) Creatine Kinase* (50-250 U/L)	
	T01	T02	T01	T02	T01	T02	T01	T02	T01	T02
Day 0										
N	83	161	83	161	83	161	83	161	83	161
Mean	16.34	17.50	0.82	0.89	645	690	89	91	190	153
Day 28										
N	82	161	82	161	82	161	82	161	82	161
Mean	16.65	17.68	0.85	0.91	672	742	85	109	156	156
Increase	3.7	1.9	2.4	1.9	2.4	4.4	1.2	6.3	8.5	8.1
Decrease	1.2	1.3	3.7	2.5	0.0	0.0	0.0	0.0	2.4	1.3
Day 42										
N	81	158	81	158	81	158	81	158	81	158
Mean	16.64	18.11	0.79	0.91	667	754	100	112	160	174
Increase	3.7	3.8	0.0	2.5	3.7	5.1	3.7	5.1	6.2	12.7
Decrease	0.0	1.3	4.9	2.5	0.0	0.0	0.0	0.0	0.0	0.0

T01, placebo; T02, Product; N=number of dogs with a result from a sample collected at a planned visit. Mean values are truncated such that “*” no decimal places are shown or “†” 1 decimal place is shown.

**USDA
Approval Date**

February 13, 2015