Scale for Scoring Ocular Lesions

CORNEA	
A. Opacity - Degree of Density (area most dense taken for reading)	
No ulceration or opacity	0
Scattered or diffuse areas of opacity (other than slight dulling of normal luster), details of iris clearly visible	**1
Easily discernible translucent areas, details of iris slightly obscured	2
Opalescent areas, no details of iris visible, size of pupil barely discernible	3
Opaque, iris invisible	4
B. Area of Cornea Involved	
One quarter (or less), but not zero	1
Greater than one quarter, but less than half	2
Greater than half, but less than three quarters	3
Greater than three quarter, up to whole area	4
Score = A x B x 5	**Total Maximum = 80**
IRIS	
A. Values	
Normal	0
Markedly deepened rugae, congestion, swelling, moderate circumcorneal hyperemia or injection, .or any combinations thereof; iris still reacting to light (sluggish reaction is positive)	**1
No reaction to light, hemorrhage, gross destruction (any or all of these)	2
Score = A x 5	**Total Maximum = 10**
CONJUNCTIVAE	
A. Redness (refers to palpebral and bulbar conjunctivae excluding cornea and iris)	
Vessels Normal	0
Vessels definitely injected above normal	1
More diffuse, deeper crimson red, individual vessels not easily discernible	**2
Diffuse beefy red	3
B. Chemosis	
No swelling	0
Any swelling above normal (includes nictitating membrane)	1
Obvious swelling with partial eversion of lids	**2
Swelling with lids about half closed	3
Swelling with lids about half closed to completely closed	4
C. Discharge	
No discharge	0
Any amount different from normal (does not include small amounts observed in inner canthus of normal animals)	1
Discharge with moistening of the lids and hairs just adjacent to lids	2
Discharge with moistening of the lids and hairs and considerable area around the eyes	3
Score = (A + B + C) x 2	**Total Maximum = 20**
Cornea + Iris + Conjunctivae Scores	**Total Maximum Score Possible = 110**

**Figures indicate lowest grades considered positive under the U.S. Health Effects Test Guideline (1998). OPPTS 870.2400

FIGURE 1

Ocular Observations/Post Treatment - Test Article Treated

Animal #/Sex		Pre-Dose	1 Hour	24 Hour	48 Hour	72 Hour
2671	**Cornea**					
Male	A. Opacity-Degree	0	0	0	0	0
	B. Area Involved	0	0	0	0	0
	A x B x 5 =	0	0	0	0	0
	Iris					
	A. Values	0	0	0	0	0
	A x 5 =	0	0	0	0	0
	Conjunctivae					
	A. Redness	0	1	0	0	0
	B. Chemosis	0	1	0	0	0
	C. Discharge	0	1	0	0	0
	(A + B + C) x 2 =	0	6	0	0	0
	TOTAL SCORE	0	6	0	0	0
Animal #/Sex		**Pre-Dose**	**1 Hour**	**24 Hour**	**48 Hour**	**72 Hour**
2672	**Cornea**					
Male	A. Opacity-Degree	0	0	0	0	0
	B. Area Involved	0	0	0	0	0
	A x B x 5 =	0	0	0	0	0
	Iris					
	A. Values	0	0	0	0	0
	A x 5 =	0	0	0	0	0
	Conjunctivae					
	A. Redness	0	1	0	0	0
	B. Chemosis	0	0	0	0	0
	C. Discharge	0	1	0	0	0
	(A + B + C) x 2 =	0	4	0	0	0
	TOTAL SCORE	0	4	0	0	0
Animal #/Sex		**Pre-Dose**	**1 Hour**	**24 Hour**	**48 Hour**	**72 Hour**
2673	**Cornea**					
Male	A. Opacity-Degree	0	0	0	0	0
	B. Area Involved	0	0	0	0	0
	A x B x 5 =	0	0	0	0	0
	Iris					
	A. Values	0	0	0	0	0
	A x 5 =	0	0	0	0	0
	Conjunctivae					
	A. Redness	0	1	0	0	0
	B. Chemosis	0	0	0	0	0
	C. Discharge	0	1	0	0	0
	(A + B + C) x 2 =	0	4	0	0	0
	TOTAL SCORE	0	4	0	0	0

FIGURE 2

Ocular Observations/Post Treatment - Untreated

Animal #/Sex		Pre-Dose	1 Hour	24 Hour	48 Hour	72 Hour
2671	**Cornea**					
Male	A. Opacity-Degree	0	0	0	0	0
	B. Area Involved	0	0	0	0	0
	A x B x 5 =	0	0	0	0	0
	Iris					
	A. Values	0	0	0	0	0
	A x 5 =	0	0	0	0	0
	Conjunctivae					
	A. Redness	0	0	0	0	0
	B. Chemosis	0	0	0	0	0
	C. Discharge	0	0	0	0	0
	(A + B + C) x 2 =	0	0	0	0	0
	TOTAL SCORE	0	0	0	0	0
Animal #/Sex		**Pre-Dose**	**1 Hour**	**24 Hour**	**48 Hour**	**72 Hour**
2672	**Cornea**					
Male	A. Opacity-Degree	0	0	0	0	0
	B. Area Involved	0	0	0	0	0
	A x B x 5 =	0	0	0	0	0
	Iris					
	A. Values	0	0	0	0	0
	A x 5 =	0	0	0	0	0
	Conjunctivae					
	A. Redness	0	0	0	0	0
	B. Chemosis	0	0	0	0	0
	C. Discharge	0	0	0	0	0
	(A + B + C) x 2 =	0	0	0	0	0
	TOTAL SCORE	0	0	0	0	0
Animal #/Sex		**Pre-Dose**	**1 Hour**	**24 Hour**	**48 Hour**	**72 Hour**
2673	**Cornea**					
Male	A. Opacity-Degree	0	0	0	0	0
	B. Area Involved	0	0	0	0	0
	A x B x 5 =	0	0	0	0	0
	Iris					
	A. Values	0	0	0	0	0
	A x 5 =	0	0	0	0	0
	Conjunctivae					
	A. Redness	0	0	0	0	0
	B. Chemosis	0	0	0	0	0
	C. Discharge	0	0	0	0	0
	(A + B + C) x 2 =	0	0	0	0	0
	TOTAL SCORE	0	0	0	0	0

FIGURE 3

EEC Ocular Evaluation Criteria

Scoring Parameter	EEC Risk Phrase	Mean Ocular Irritation Score (6 animals) or Individual Mean Ocular Irritation Scores in 2/3 animals (3 animals)	Irritation Rating
Corneal Opacity	-	0.00 - 1.99	Nonirritant
	Irritating to eyes	2.00 - 2.99	Irritant
	Risk of serious damage to eyes	≥3.00	Serious Damage
Iris Lesion	-	0.00 - 0.99	Nonirritant
	Irritating to eyes	1.00 - 1.99*	Irritant
	Risk of serious damage to eyes	≥2.00**	Serious Damage
Conjunctival Redness	-	0.00 - 2.49	Nonirritant
	Irritating to eyes	≥2.50	Irritant
Conjunctival Edema	-	0.00 - 1.99	Nonirritant
	Irritating to eyes	≥2.00	Irritant

* 1.5 for 6 animals rather than 1.99 for 3 animals.
** >1.50 for 6 animals rather than ≥ 2.00 for 3 animals.

FIGURE 4