

TABLE 1: Desirable characteristics of a dosing formulation and its preparation^{2,3}

Preparation of the formulation should not involve heating of the test material to a point anywhere near altering its chemical or physical characteristics, or so as to harm test animals receiving the formulation
If the material is a solid and is to be assessed for dermal effects, its shape and particle size should be preserved. If intended for use in man, topical studies should be conducted with the closest possible formulation to that to be used on humans.
Multicomponent test materials (mixtures) should be formulated so that the administered form accurately represents the original mixture (i.e., components should not be selectively suspended or taken into solution).
Formulation should preserve the chemical stability and identity of the test material.
The formulation should be such as to minimize total administered test volumes. Use just enough solvent or vehicle unless there is reason to dilute the active ingredient.
The formulation should be as easy as possible to accurately administer. Highly viscous solutions or suspensions should be avoided.
The pH of dosing formulation should be between 5 and 9, if possible.
Acids or bases should not be used to dilute or solubilize the test material (for both humane reasons and to avoid pH partitioning or stability issues in either the gut or the renal tubule).
If a parenteral route is to be employed, final solutions should be as nearly isotonic as possible. Do not assume a solution will remain such upon injection into the blood stream. It is usually a good idea to verify that the drug stays in solution upon injection by placing some drops into plasma.
Formulations for use by parenteral routes should be as endotoxin free as possible. Particularly if the test material (or formulation component) is biologically derived or produced, they should be evaluated for acceptable endotoxin content before actual formulation preparation to preclude problems.
Particularly if use is to be more than a single injection, steps (such as filtration) should be taken to ensure suitable sterility.

TABLE 2: Route Specific Considerations²

Route	Points of Consideration	Possible Adjustments to Regimen to Improve Tolerance	References
Oral (PO)	1) Stomach of some species (dog, rabbit) easily irritated 2) Stomach presents acid environment which may compromise stability of active drug 3) Most absorption actually occurs in the intestines 4) Species specific volume considerations	1) Split Dose over course of day 2) Use of capsules in dogs and mini-pigs to limit stomach irritation/emesis and to avoid acid stability of drug issues 3) Dose with food to improve absorption and tolerance in stomach 4) Intubation an option	Strickley ^{10, 11}
Intra-Articular (IA) <i>Injection into knee joints</i>	1) Species specific volume considerations 2) Administration in pigs is limited as they only have such joints in their front limbs		
Intra-Dermal (ID)	1) Care must be taken to confirm that drug will stay in solution in blood stream 2) Need to ensure sterility of formulation 3) Vascular irritation, thrombosis and hemolysis are concerns. Need to perform hemolysis and flocculation studies in advance 4) Species specific volume considerations	1) Infusion better tolerated than bolus 2) Decrease rate of infusion to decrease systemic/local Cmax of drug 3) Need to ensure sterility of formulation 4) 50 Distal to site of injection vascular damage is now a field of significant concern. May not always be due to IV administered drug 5) For repeated injections need to move site around	Lee et.al ¹²
Intramuscular (IM)	1) Injection site irritation and infection is a concern 2) Species specific volume considerations	1) Adjust injection volume to multiple sites 2) For repeated injections need to move site around	
Intraperitoneal (IP)	1) Scarring and inflammation responses at injection sites 2) Species specific volume considerations 3) Need to make sure injection is into the peritoneal space		
Subcutaneous (SC)	1) Nonpolar organic vehicles “defat” tissues if injected 2) Species specific volume considerations	1) Non-polar organic vehicles all “defat” tissues if injected 2) May need to do multiple sites 3) Adjust volume	
Dermal (Topical)	1) Irritation and sensitization 2) Selection of correct model species essential to be relevant to humans 3) Need to consider formulation viscosity and changes with temperature 4) Need to consider solvents used in formulation, as choices can affect mechanism of absorption	1) May need to wrap 2) May need to do multiple sites 3) May need to collar animals	Zesch ¹³
Periocular	1) Ocular irritation – tissue very sensitive to acid and base 2) Intraocular avoids local immune responses 3) Always keep in mind that anything injected in and around the eye is not going away quickly, so one is stuck with side effects. Be very concerned with pharmacology and half-life before injection 4) Length of needle changes with species 5) Angle of injection changes with species		Ubels et al ¹⁴
Inhalation	1) Delivery mode/particle size dictate where in respiration tree delivery of drug occurs 2) Consider insufflation as alternative		Warheit et al ¹⁵

TABLE 3: Volume Guidelines for Administration of Compounds to Laboratory Animals²

Species	Intranasal mL/nostril	Gavage mL/kg*		IV Bolus** mL/kg*		IP*** mL/kg*		SC**** mL/kg*		IM mL/kg*		ID mL/site*		IV Infusion** mL/kg		Continuous Infusion		Intra Vaginal mL	Intra Vitreal µL/eye	Intra Articular mL/joint		Perivenous / Periarterial mL/ear
	Vol.	Ideal	Max	Ideal	Max	Ideal	Max	Ideal	Max	Ideal	Max	Vol.	Rate mL/min	Max ^p mL/kg/hr	Cath. Maint. Rate mL/hr	Max	Vol.	Joint	Vol.	Max		
Mouse	25 µl	10	40 ^a	5	25	5-10	50	1-5	20 ^h	0.1	1 ^{i,j}	0.1	0.1	50	1			2				
Rat	50 µl	10	20 ^b	1	20	5-10	20	1	20 ^h	0.1	10 ^m	0.1	0.1	50	1	5	0.1-0.5	0.35	10	Stifle 0.1 Tarsal 0.05		
Guinea Pig	100 µl	10	30	1	5	1-5	20	1-5	10 ^h	0.1	0.5-1	0.1	0.1	10	1							
Rabbit	200 µl	1	20 ^c	1 ^d	10 ^d	3	5 ^e	1-2.5	10 ^h	0.1-0.5	1	0.1	0.1	20	1			2.0	100 ^o	Stifle 0.5	0.5	
Dog	500 µl	5	20	1	10	3	5	0.5	2 ^h	0.1-0.25	1 ^{k,n}	0.1	0.1	20	5	5	1-2	2.0	100	Stifle 1		
Non-human Primate	200 µl	5	10	1	10	3	5	0.5	2 ^h	0.1-0.5	1 ^{k,n}	0.1	0.1	20	1	5	1-2		50			
Mini-Swine				1	10	1	5	1	3 ^h	0.25	0.5 ^f	0.1	0.1	10	1	5	1-2					

* Single dose per day except where noted otherwise

** Solution properties such as tonicity, pH, etc. need to be taken into account when approaching the volume limits or determining the volume to be infused IV. The recommended working range for pH is 4.5-8.0. The order of degree of tolerance of pH for different dosing routes is: Oral>intravenous>intramuscular>subcutaneous>intraperitoneal.

Animal health must also be taken into consideration, such as kidney function and cardiovascular function. These systems must be normal to handle increased fluid volumes.

*** When administering a solution IP, the viscosity, concentration, tonicity and pH of the solution need to be taken into account.

**** When administering a solution SC, the concentration, tonicity, and pH of the solution must be taken into account.

a To accommodate a larger volume, the dose may be divided over time (e.g. 20mL/kg administered four times per day to reach a total of 80mL/kg in a 24 hour period).

b To accommodate a larger volume, the dose may be divided over time (e.g. 10mL/kg administered four times per day to reach a total of 40 mL/kg in a 24-hour period).

c Rabbits should not be fed prior to administration. Rabbits should be fed after the completion of dose administration.

d These volumes may also be used for intraarterial injection.

g Not often used.

h If volumes greater than those cited above are used, the volume must be divided over multiple sites.

i May be used if divided over multiple sites and alternating legs, maximum of 5 sites per leg. Final volume not to exceed 0.10mL.

j 0.05mL total volume limit per site

k 3mL total volume limit per site

l 5mL total volume limit per site

m Up to 20mL/kg if divided over multiple sites.

n 3 mL total volume limit

o Repeat dose 67µl in the rabbit.

p Solution properties such as tonicity, pH, etc., need to be taken into account when determining the volume that may be infused i.v. Animal health must also be taken into consideration, such as kidney function and cardiovascular function. These systems need to be normal to handle increased fluid volumes.

TABLE 4: Gavage Needle/Tube Size Recommendations²

Species	
Mouse	The most commonly used gavage needle is a stainless steel curved 18 gauge needle with a 2.25mm ball, but any other gauge needle that facilitates dose administration is acceptable
Rat	The most commonly used gavage needle is a stainless steel curved 16 gauge needle with a 3mm ball, but any other gauge needle that facilitates dose administration is acceptable
Guinea Pig	The most commonly used gavage needle is a stainless steel curved 16 gauge needle with a 3mm ball, but any other gauge needle that facilitates dose administration is acceptable
Rabbit	Either a flexible feeding tube or a stainless steel gavage needle may be used for oral gavage. A 10 or 12 French flexible feeding tube is most commonly used for larger rabbits and an 8 French feeding tube is recommended for smaller rabbits, but any other size flexible feeding tube that facilitates dose administration may be used. The most commonly used stainless steel gavage needle is a curved 12 gauge needle that is 6 inches in length with a 3.5 mm ball but any other gauge needle that facilitates dose administration is acceptable.
Dog	A 30 French, 30 inch long, rubber tube is most commonly used but any other size feeding tube that facilitates dose administration may be used.
Non-human Primate	A pediatric feeding tube (8-12 French) is most commonly used.
Gottingen mini-swine	An 18 French, 16 inch long, rubber tube is most commonly used but any other size feeding tube that facilitates dose administration may be used. Additional required equipment: Dosing bench and bite bar.

TABLE 5: Acacia

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-human Primate	PO	Efficacity	100 mg/kg/day	Well tolerated; Some weight loss, reduction in food intake	Arabic gum; 3% solution in water	Gad et al. ¹
Rat	PO	1 month	500 mg/kg	Well tolerated		Gad et al. ¹
	PO	90 days	10 ml/kg	Well Tolerated	20% solution	Gad et al. ¹

TABLE 6: Acetic Acid

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	PO	1 month	5 ml/kg	Not toxic	15% solution	Gad et al. ¹
	PO (gavage)	90 days	5 ml/kg	Well tolerated	3% solution	Gad et al. ¹
Rat	PO	Acute	5 ml/kg	Not toxic	10% solution	Gad et al. ¹
	PO	1 month	10 ml/kg	Not toxic	20% solution	Gad et al. ¹
	PO (gavage)	90 days	5 ml/kg/day	Well tolerated	3% in purified water (92/8)	Gad et al. ¹

TABLE 7: Acetone

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Guinea Pig	Dermal	1 month	1 ml	Well tolerated		Gad et al. ¹
Mouse	Dermal	2 year	0.5 ml	Well tolerated		Gad et al. ¹
	PO	2 weeks	3 ml/kg	Higher doses cause acidosis; Transitory neurobehavioral effects at this dose.		Gad et al. ¹
Rabbit	Dermal	90 days	1 ml	Defatting of application site		Gad et al. ¹
Rat	Dermal	30 days	5 ml/kg	Well tolerated		Gad et al. ¹
	Dermal	90 days	1.5 ml/kg 6 hours daily, 5 d/wk	Well tolerated	Sham treatment group included, vehicle similar to sham treatment; 100% Acetone; Age 60 days; ♂/♀	New contributed data
	PO	2 weeks	5 ml/kg	Higher doses cause acidosis; Transitory neurobehavioral effects at this dose.		Gad et al. ¹

TABLE 8: Acetylmethylamide						
Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-human Primate	PO	One month (ADME)		Well tolerated	In water	Contributed data, 2006

TABLE 9: Alginic Acid						
Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	IP	1 month	100 mg/kg	Not toxic		Gad et al. ¹

TABLE 10: Anecortave Acetate						
Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	SC (bolus)	4 doses	2 ml/kg	Not toxic		Gad et al. ¹

TABLE 11: Avicel CL-611						
Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (gavage)	Single dose	1 ml/kg	Soft feces	2.4% in sterile water; Age 5 months; ♂/♀	New contributed data

TABLE 12: Balanced Salt Saline						
Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	Intravitreal	43 days	50 mL/eye q14d	None	Non-GLP; Age 5 months; 2♂/2♀	New contributed data

TABLE 13: Basal Salt Solution						
Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	Subretinal Injection	SD for 9 months	2.0 µL	None	Non-GLP; Age 5-7 weeks; 44♂	New contributed data

TABLE 14: Benzoic Acid

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	PO	Acute	100 mg/kg	Not toxic		Gad et al. ¹

TABLE 15: Beta-cyclodextrin

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IP	1 month	50 mg/kg	Not toxic		Contributed data, 2006
	IV	1 month	100 mg/kg	Not toxic		Contributed data, 2006
	PO	1 month	200 mg/kg	Not toxic		Contributed data, 2006
Mouse	IP	1 month	10 mg/kg	Not toxic		Contributed data, 2006
Non-human Primate	PO	12 months		Tubular hypertrophy at doses above 100 mg/kg/day at 3 months or longer		Gad et al. ¹
Rat	IV			Tubular hypertrophy at doses above 100 mg/kg/day at 3 months or longer		Gad et al. ¹
	PO	12 month	500 g/kg	Hepatitis, nephrosis, acute tubular necrosis at dose levels above 20 g/kg.		Gad et al. ¹

Table 16: Bicarbonate Buffer, pH 9.5

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	PO (gavage)	QD for 2 months	10 ml/kg	None	Age 8-10 weeks; ♂/♀	New contributed data

TABLE 17: Calcium Chloride

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	IV	1x/wk for 4 weeks	1.61 ml/kg	None	0.5M; Age 5 weeks; ♂/♀	New contributed data
	SC	1x/wk for 4 weeks	1.61 ml/kg	None	0.5M; Age 5 weeks; ♂/♀	New contributed data

TABLE 18: Canola Oil

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	1 month	2 ml/kg	Not toxic		Gad et al. ¹

TABLE 19: Capryol 90

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	28 days	1000 mg/kg	Non-toxic		Gad et al. ¹
	PO	28 days	2500 mg/kg	Non-toxic		Gad et al. ¹
Rabbit	Dermal	Acute	No dilution	Mildly irritant		Gad et al. ¹
	Ocular	Acute	No dilution	Moderately irritant		Gad et al. ¹
Rat	PO	Acute		Non-toxic LD50> 5g/kg		Gad et al. ¹
	PO	7 days	300, 1000, 2500 mg/kg	Well tolerated		Gad et al. ¹
	PO	28 days	500, 1500, 2500 mg/kg	NOAEL of 2500 mg/kg		Gad et al. ¹

TABLE 20: Captisol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (gavage)	2x/wk for 28 days	5 ml/kg	None	15% in DI water; Age 5-6 months; ♂/♀	New contributed data
	IV (bolus)		1 ml/kg	Well tolerated	12% solution in water pH 3-11	Strickley ¹¹
	IV (infusion)		2 ml/kg	Well tolerated	12% solution in water pH 3-11	Strickley ¹¹
Mouse	PO	1 month	500 mg/kg	Well tolerated	10% solution	Gad et al. ¹
	SC	90 days	1200 mg/kg	NOEL		Gad et al. ¹
	SC	6 month	1200 mg/kg	NOAEL		Gad et al. ¹
Non-human Primate	PO	9 months	1 g/kg	Well tolerated	10% solution	Gad et al. ¹
	SC	3x/wk for 12 months	120 mg/kg	Well tolerated		Gad et al. ¹
Rat	IV	1 month	4 ml/kg	Not toxic	12% in water	Gad et al. ¹
	IV (bolus)		2 ml/kg	Well tolerated	12% solution in water pH 3-11	Strickley ¹¹
	IV (infusion)		5 ml/kg	Well tolerated	12% solution in water pH 3-11	Strickley ¹¹
	PO	1 month	10 ml/kg	Not toxic	12% in water	Gad et al. ¹
	PO (gavage)	2x/wk for 28 days	10 ml/kg	None	15% in DI water; Age 7-8 weeks; ♂/♀	New contributed data

TABLE 21: Carboxymethylcellulose

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Minipig	PO	14 days	8.0 ml/kg SD	None	0.5% CMC in water; GLP; Age 3 months; 1♂/1♀	New contributed data
	PO	28 days	8.0 ml/kg QD	None	0.5% CMC in water; GLP; Age 3-4 months; 4♂/4♀	New contributed data
Non-human Primate	PO	30 days		Well tolerated	5% in water	Gad et al. ¹
	SC	Acute	10 ml/kg	Well tolerated		Gad et al. ¹
Rat	PO		20 mg/kg	NOEL	5 % in water	Gad et al. ¹
	PO	14 days	8.0 ml/kg SD	None	0.5% CMC in water; GLP; Age 8 weeks; 5♂/5♀	New contributed data
	PO	28 days	8.0 ml/kg QD	None	0.5% CMC in water; GLP; Age 8 weeks; 10♂/10♀	New contributed data
	PO (gavage)	93 weeks	10 ml/kg QD	None	1% CMC (Medium Viscosity) in DI water; Age 6 weeks; ♂/♀	New contributed data

TABLE 22: Carboxymethylcellulose Calcium

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	90 days	1 ml/kg	Not toxic	1% solution	Gad et al. ¹

TABLE 23: Carboxymethylcellulose Sodium

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	PO	1 month	0.5 ml/kg	Not toxic	1% solution	Gad et al. ¹

TABLE 24: Cetyl Alcohol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	IP	1 month	100 mg/kg	Well tolerated		Gad et al. ¹

TABLE 25: Citrate Buffer

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV infusion	8 doses	30 ml/kg/day	Not toxic	0.1 M, Aqueous	Gad et al. ¹
	SC	30 days	10 ml/kg QD	Well tolerated		Gad et al. ¹
Rat	IV	4 weeks	nd	Hypoactivity, pains at injection site	100 mM at pH 5	Contributed data, 2006
	PO	2 weeks	10 ml/kg	Well tolerated	50 mM	Gad et al. ¹
	PO	2 weeks	15 ml/kg	Well tolerated	50 mM	Gad et al. ¹

TABLE 26: Citric Acid Buffer

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	PO (gavage)	182 days	2 ml/kg QD	None	0.015 M at pH 4.50; Age 6-7 weeks; ♂/♀	New contributed data
Non-Human Primate	PO (gavage)	39 weeks	7.5 ml/kg QD	None	10 mM; Age 3-3.5 years; ♂/♀	New contributed data
Rat	PO	2 weeks	10 ml/kg QD	Not toxic	50 mM	Gad et al. ¹
	PO	2 weeks	15 ml/kg QD	Not toxic	50 mM	Gad et al. ¹

TABLE 27: Collagen Matrix

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-human Primate	Implantation in humerus bone	6 months	10 ml/kg/day	Well tolerated	Bovine type I and hydroxyapatite	Gad et al. ¹
Rabbit	Implantation	6 months	Single application, 5 ml/kg	Well tolerated		Gad et al. ¹

TABLE 28: Corn Oil

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Chicken Embryo	Injection into egg	Single dose	0.1 mL/g egg	Less mortality than 1.0 mL/g egg		Gad et al. ¹
	Injection into egg	Single dose	1.0 mL/g egg	Increased mortality, decreased activity during righting reflex, running time, visual discrimination, and olfactory aversion test.		Gad et al. ¹
Dog	PO	1 month	3.0 ml/kg	Not toxic		Gad et al. ¹
Mouse	PO	1 month	2.5 ml/kg	Not toxic		Gad et al. ¹
Non-human Primate	PO	1 month	1 ml/kg	Not toxic		Contributed data, 2006
Rabbit	PO	1 month	1 ml/kg	Not toxic		Gad et al. ¹
Rat	PO (gavage)	Single dose	10 ml/kg	Not toxic		Gad et al. ¹
	PO (gavage)	20 doses	5 ml/kg	Not toxic		Gad et al. ¹
	PO (gavage)	90 days	5 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data

TABLE 29: Cottonseen Oil

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	SC	Single dose	1 ml	Well tolerated; No evidence of irritation macroscopically or histologically.	100% solution	New contributed data

TABLE 30: Cyclohexane

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	PO	30 days	0.5 ml/kg/day	Well tolerated		Gad et al. ¹
Rat	Dermal	30 days	1 ml/kg/day	Well tolerated		Gad et al. ¹
	PO (gavage)	4 weeks	5 ml/kg/day	Intermittent convulsive after dosing, piloerection round back and emaciated appearance		Gad et al. ¹

TABLE 31: Dextrose

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Cat	Oral mucosa	24 hours	0.6 ml SD	None	5%; Non-GLP; Age >6 months; 3♂/3♀	New contributed data
Dog	IV	Single dose	150 ml/hour	Not toxic	5%, USP	Contributed data, 2006
	IV/ PO	ADME	2/10 ml/kg/day	Well tolerated	5% solution	Gad et al. ¹
Non-Human Primate	PO (gavage)	13 weeks	0.78-9.3 ml/kg/day	Well tolerated	10% solution (w/w)	Gad et al. ¹
	PO (gavage)	ADME	5 ml/kg/day	Well tolerated	5% solution	Gad et al. ¹
	PO (gavage)	Card. Vas.	5 ml/kg/day	Well tolerated	5% solution	Gad et al. ¹
Rabbit	IV (slow bolus)	12 doses		Not toxic	5%, USP	Contributed data, 2006
Rat	IV	Single dose	1.4 ml/animal	Not toxic	5%, USP	Gad et al. ¹
	IV	7 days	5 ml/kg SD	None	5%; Non-GLP; Age 7-10 weeks; 2♂/2♀	New contributed data
	PO (gavage)	26 weeks	0.71-8.6 ml/kg/day	Well tolerated	10% solution (w/w)	Gad et al. ¹
	PO (gavage)	Prelim	5 ml/kg/day	Well tolerated	5% solution	Gad et al. ¹
	SC	2 weeks	0.75 ml/kg/day	Well tolerated	5% solution	Gad et al. ¹

TABLE 32: Dichlorvos

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-Human Primate	IV Infusion	2 weeks	2 ml/kg 10 Minutes 3x /week	Well tolerated	10 mg/ml Dichlorvos; Age 3-6.5 years; ♀	New contributed data

TABLE 33: Diethylacetamide

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Cat	IV		1 g/kg (1000 mg/kg)	LD _{LO}	Behavioral: altered sleep time (including change in righting reflex)	Budden et al ¹⁶
Chicken	IV		3900 mg/kg	LD _{LO}		Caujolle et al ¹⁷
Dog	IV		1 gm/kg (1000 mg/kg)	LD _{LO}	Behavioral: altered sleep time (including change in righting reflex)	Budden et al ¹⁶
Mouse	IP		1600 mg/kg	LD ₅₀	Sense organs and special senses: mydriasis (pupillary dilation)	ChemIDplus ¹⁸
	IV	Range finding	MTD: 1.4 g/kg; NOEL: 468 mg/kg		Published LD ₅₀ = 2.3-3.2 g/kg	Sambrone ⁵
Rabbit	IV		1920 mg/kg	LD _{LO}		Caujolle et al ¹⁷
Rat	IP		1840 mg/kg	LD ₅₀		Caujolle et al ¹⁷
	IV		1 g/kg (1000 mg/kg)	LD ₅₀	Behavioral: altered sleep time (including change in righting reflex)	Budden et al ¹⁶

TABLE 34: Diethyleneglycol-monoethylether

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-Human Primate	IV	1 month (ADME)	.355 ml/kg Single injection	Well tolerated	Into saphena vein	Gad et al. ¹

TABLE 35: Dimethylacetamide

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Chicken	IV	Acute	12000 mg/kg	LDLo	Lowest published lethal dose	Leadscope Data Portal ¹⁹
Dog	Dermal	6 weeks	2690.476 mg/kg QD	TDLo; Fatty liver degeneration; chronic death (nutritional and gross metabolic); reproductive		Leadscope Data Portal ¹⁹
Mouse	IP	Acute	2800 mg/kg	LD50		Leadscope Data Portal ¹⁹
	IV	Acute	3020 mg/kg	LD50		Leadscope Data Portal ¹⁹
	IV (into tail vein)	Acute	469 mg/kg (dose vol 5 ml/kg)	NOEL	10% solution	Thackaberry ²⁰
	IV (into tail vein)	Acute	1405 mg/kg (dose vol 5 ml/kg)	MTD	30% solution; Mild to moderate hypoactivity for up to 6 minutes is typical	Thackaberry ²⁰
	PO	Acute	4620 mg/kg	LD50	Intragastric feeding or introduction with drinking water	Leadscope Data Portal ¹⁹
Rabbit	Dermal	Acute	2240 mg/kg	LD50	Application directly onto the skin, either intact or abraded	Leadscope Data Portal ¹⁹
	IV	Acute	8340 mg/kg	LDLo	Lowest published lethal dose	Leadscope Data Portal ¹⁹
	PO		3900 mg/kg	TDLo; Specific developmental abnormalities (eye, ear, craniofacial including nose and tongue, musculoskeletal system); post-implantation mortality; fetotoxicity (except death, e.g., stunted fetus)	Intragastric feeding or introduction with drinking water; 6-18 days preg.	Leadscope Data Portal ¹⁹
Rat	Inhalation	6 hours	281 ppm	TDLo	Inhalation in chamber by cannulation or through mask; 6-15 days preg.	Leadscope Data Portal ¹⁹
	IP		2 mg/kg	TDLo; post-implantation mortality; fetotoxicity (except death, e.g. stunted fetus)	1 day preg.	Leadscope Data Portal ¹⁹
	IP	Acute	2750	LD50		Leadscope Data

		mg/kg			Portal ¹⁹
IV	Acute	2640 mg/kg	LD50		Leadslope Data Portal ¹⁹
PO		5600 mg/kg	TDLo; effects on fertility, post-implantation mortality; fetal death; specific developmental abnormalities (craniofacial, including nose and tongue, musculoskeletal system, cardiovascular system, homeostasis); fetotoxicity (except death, e.g. stunted fetus)	Intragastric feeding or introduction with drinking water; 6-19 days preg.	Leadslope Data Portal ¹⁹
PO		2240 mg/kg	TDLo	Intragastric feeding or introduction with drinking water; 6-19 days preg.	Leadslope Data Portal ¹⁹
PO	Acute	4300 mg/kg	LD50	Intragastric feeding or introduction with drinking water	Leadslope Data Portal ¹⁹
PO	10 days	1500 mg/kg QD	TDLo; Findings in Digestive system and liver; Chronic	Intragastric feeding or introduction with drinking water; Lowest published toxic dose	Leadslope Data Portal ¹⁹
PO	26 weeks	2 mg/kg QD	TDLo; Enzyme inhibition, induction, or change in blood or tissue levels; Liver	Intragastric feeding or introduction with drinking water; Lowest published toxic dose	Leadslope Data Portal ¹⁹
PO	90 days	50 mg/kg QD	TDLo; Changes in erythrocyte (RBC) and leucocyte (WBC) counts	Intragastric feeding or introduction with drinking water; Lowest published toxic dose	Leadslope Data Portal ¹⁹

TABLE 36: Dimethylsulfoxide

Species	Route	28 doses		Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV	Single dose @ 0.2ml/minute for 18.5 minutes	0.43 - 0.46 ml/kg	During dose administration excessive salivation and labored respiration were noted. At 1 and 4 hours post dose AN	MUST use IV catheter; 100% solution	New contributed data
	IV		2 mg/kg			New contributed data
	IV		2.5 g/kg	LD ₅₀	MUST use IV catheter; 100% solution	New contributed data
	IV	Intermittent for 4 weeks	57,600 mg/kg	LD ₅₀ ; Lowest published toxic dose, hematuria, normocytic anemia, death	MUST use IV catheter	New contributed data
	IV		2,500 mg/kg	LD ₅₀ ; Cardiac changes, hematuria		New contributed data
		Single dose	1 ml/kg	Not toxic	10% solution	New contributed data
	IV		0.1 ml/kg		MUST use IV catheter; 100% solution	New contributed data
	IV	1 month	1.25 ml/(0.112)x(BW)	Not toxic		Gad et al. ¹
Guinea Pig	IV	1 month	0.1 ml/kg	Not toxic		Gad et al. ¹
	IP		6.5 g/kg	LD ₅₀	100% solution	New contributed data
Mouse	IP	1 month	2.5 g/kg	LD ₅₀	100% solution	New contributed data
	IP		3.82-10.73 g/kg	LD ₅₀	100% solution	New contributed data
	IP		8.2 g/kg	LD ₅₀	100% solution	New contributed data
	IP		20.06 g/kg	LD 50	100% solution	New contributed data
	IP	1 month	100 mg/kg	Not toxic		Gad et al. ¹
	IP	3 days	10 ml/kg	Not toxic	15% solution	Gad et al. ¹
	IV (into tail vein)	Acute	1650 mg/kg (dose vol 5 ml/kg)	NOEL	30% solution	Thackaberry ²⁰

	IV (into tail vein)	Acute	2200 mg/kg (dose vol 5 ml/kg)	MTD; Rapid breathing, ataxia and muscle contractions, with full recovery by 1 min is typical	40% solution	Thackaberry ²⁰
	IV	Range finding	MTD: 2.2 g/kg; NOEL: 1.6 g/kg		Published LD ₅₀ = 3.8-7.6 g/kg	Sambrone ⁵
	IV		3,100 mg/kg	LD50; Eye hemorrhage, conjuctiva irritation		New contributed data
	IV		240 gm/kg	Lowest published toxic dose. Post implantation mortality	Age Day 1-20 presumed pregnant	New contributed data
	PO (gavage)		15.0-22 g/kg	LD50	100% solution	New contributed data
	PO (gavage)		7.9 g/kg	LD50	100% solution	New contributed data
	PO		5 ml/kg			Gad et al. ¹
	SC		13.9-20.5 g/kg	LD50	100% solution	New contributed data
Non-human Primate	PO (gavage)	Efficacy	3 ml/kg/day	Well tolerated		Gad et al. ¹
Rabbit	SC	1 month	1 ml/kg	Erytheme, inflammation		Gad et al. ¹
Rat	IV		4 to 5 mg/kg			New contributed data
	IV		5.25-5.36 g/kg	LD50	100% solution	New contributed data
	IV		5.3 g/kg	LD50	100% solution	New contributed data
	IV	Single dose	200 mg/kg	In serum, slightly and transiently changed metabolic parameters including glucose, lactate, triglycerides, free fatty acids, or creatinine as well as electrolytes (Na, Cl, Mg) and osmolality, increased ALT, impeded clinical chemistry measurements of various parameters at 4hr post dose, kidney function - induced loss of protein and albumin	2% solution	New contributed data

IV		5,360 mg/kg	LD50; Tremors, muscle weakness, dyspnea		New contributed data
IV	1 month	200 mg/kg	Not toxic		Gad et al. ¹
SC		12 g/kg	LD50	100% solution	New contributed data
PO (gavage)	7 days	5 ml/kg/day	Well tolerated		Gad et al. ¹
PO (gavage)	4 weeks	5 ml/kg/day	Well tolerated		Gad et al. ¹
PO (gavage)		16.0-28.3 g/kg	LD50	100% solution	New contributed data
PO (gavage)		14.5 g/kg	LD50	100% solution	New contributed data
PO (gavage)	Single dose	200 mg/kg	Did not affect stomach emptying, did not reduce intestinal transit time	2% solution	New contributed data
PO (gavage)	Single dose	1000 mg/kg	Did not affect stomach emptying, did not reduce intestinal transit time	10% solution	New contributed data
IP	28 doses	5 ml/kg	Not toxic	15% solution	Gad et al. ¹
IP		6.5-13.621 g/kg	LD50	100% solution	New contributed data
IP		8.2 g/kg	LD50	100% solution	New contributed data

TABLE 37: Dulbecco's Modified PBS

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	IV (into tail vein)	1 month	1 ml/kg/day	Well tolerated		Gad et al. ¹

TABLE 38: Dulbecco's PBS

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	PO (gavage)	1 month	0.1, 0.8 and 1.2 mg/kg/day	Well tolerated		Gad et al. ¹

TABLE 39: Ethanol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV		5ml/kg at a rate of 0.3ml/kg	Hemolysis <i>in vitro</i> dog blood	30% solution	New contributed data
	IV		5ml/kg at a rate of 0.3ml/kg	Hemolysis <i>in vitro</i> dog blood	40% solution	New contributed data
	IV	Single dose	1 ml/kg	Not toxic	10% solution	New contributed data
	IV	Single dose	1 ml/kg	CNS depression, ataxia	30% solution	Gad et al. ¹
	IV	5 Days	1 ml/k at 2ml/minute	Excessive salivation	30% solution; MUST use winged infusion set	New contributed data
	IV	At 3, 7, 14, and 24 hours after ingestion of ethylene glycol	1584 mg/kg	Remained recumbent or severely ataxic for 36, depressed for 72	20% solution	New contributed data
	IV	Every 4 hours for 5 treatments then every 6 hours for 4 treatments	5.5 ml/kg		20% solution	New contributed data
	PO	1 month	5 ml/kg	Not toxic	7.5% solution	Gad et al. ¹
	PO	6 months	400 ml/kg	Hepatopathy, myopathy; CNS changes		Gad et al. ¹
	PO	90 days	5 ml/kg	Not toxic	5% solution	Gad et al. ¹
Minipig	Dermal	ADME	nd (5 mg/cm ²)	Well tolerated	60/40: Purified water/ethyl alcohol absolute: v/v	Contributed data, 2006
Mouse	Dermal	13 weeks	100 mL/animal/day	Well tolerated	70% (62% m/m)	Gad et al. ¹
	Dermal	7 days	0.5 ml (fixed vol) QD	Well tolerated	80% solution; Age 6 weeks; ♂/♀	New contributed data
	IP	Acute	5 ml/kg	Well tolerated	5% solution	Gad et al. ¹
	IV	Range finding	MTD: 986 mg/kg; NOEL: 1 97 mg/kg		Published LD ₅₀ = 1.6-4.3 g/kg	Sambrone ⁵
	IV (into tail vein)	Acute	197 mg/kg (dose vol 5 ml/kg)	NOEL	5% solution	Thackaberry ²⁰
	IV (into tail vein)	Acute	986 mg/kg (dose vol 5 ml/kg)	MTD: Ventral recumbancy and "swimming" behavior immediately post-dose, ataxia for up to 6 mins is typical	25% solution	Thackaberry ²⁰
	PO	1 month	2.5 ml/kg	Well tolerated	5% solution	Gad et al. ¹
	PO	6 month	2500	Well tolerated		Gad et al. ¹

			gm/kg			
Non-Human Primate	PO	9 months	250 gm/kg	Behavioral changes		Gad et al. ¹
Rat	Dermal	ADME	nd (5 mg/cm2)	Well tolerated	60/40: Purified water/ethyl alcohol absolute: v/v	Contributed data, 2006
	Dermal	91 days	0.5 ml (fixed vol) QD	Well tolerated	80% solution; Age 6 weeks; ♂/♀	New contributed data
	IP		3.75 g/kg	LD50		New contributed data
	IV		1.44 g/kg	LD50		New contributed data
	IV		5 ml/kg at a rate of 0.3 ml/kg	Hematuria	30% solution	New contributed data
	IV	9 days	5 ml/kg at 2ml/minute	Ataxia, respiratory depression and death is dosed faster than 2ml/minute	30% solution	New contributed data
	IV	12 months	250 g/kg	Nephrosis, ATN, bladder changes, weight loss		Gad et al. ¹
	PO		7.06 g/kg	LD50		New contributed data
	PO (gavage)	7 days	0.8, 2 and 5 ml/kg/day	Well tolerated	70% (62% m/m)	Contributed data, 2006
	PO	7 days	10 ml/kg	Not toxic	10% solution	Gad et al. ¹
	PO	Acute	5 ml/kg	Depression		Gad et al. ¹
	PO (gavage)	4 weeks	2 ml/kg QD	Hypokinesia, dyspnea regurgitation, distended lungs/ileum and swollen abdomen	70% (62% m/m)	Gad et al. ¹
	PO	28 doses	175 g/kg	Depression, decreased RBC		Gad et al. ¹
	PO	90 day	8 ml/kg	Not toxic	10% solution	Gad et al. ¹
	PO	12 month	1000 mg/kg	Fatty liver		Gad et al. ¹

TABLE 40: Gelatin Capsules

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	5 days	QD	Well tolerated		Contributed data, 2006
	PO	6 days	QD	Well tolerated		Contributed data, 2006
	PO	8 days	QD	Well tolerated		Contributed data, 2006
	PO	14 days	QD	Well tolerated		Contributed data, 2006
	PO	16 days	QD	Well tolerated		Contributed data, 2006

TABLE 41: Gelatin Phosphate Buffer

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Minipig	Topical	28 days	10 ml q14d x 2 doses	None	GLP; Age 4-6 months; 5♂/5♀	New contributed data

TABLE 42: Gelucire 44/14

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	3 months	400, 1000, 2500 mg/kg/day	NOAEL: >2500 mg/kg/day		Gad et al. ¹
	PO	14 days	400, 1000, 2500 mg/kg/day	NOAEL: >2500 mg/kg/day		Gad et al. ¹
Rabbit	Dermal	Acute	0.5 ml	Not irritant		Gad et al. ¹
	Ocular	Acute	0.1 ml	Slight irritant		Gad et al. ¹
Rat	PO	28 day	600, 1500, 2400 mg/kg/day	NOEL: 2400 mg/kg/day		Gad et al. ¹
	PO	7 day	600, 1500, 2400 mg/kg/day	NOEL: 2400 mg/kg/day		Gad et al. ¹
	PO	Acute	No dilution	LD50: >2004 mg/kg/day		Gad et al. ¹

TABLE 43: Gelucire 50/13

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	PO	Acute		Not toxic	No dilution; $LD_0 \geq 20,000$ mg/kg/day	Gattefossé Technical Document ²¹

TABLE 44: Gluconic Acid

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (gavage)	14 days	2 ml/kg QD	Well tolerated	0.3M gluconic acid pH 3.0; Age 11 months; ♂/♀	New contributed data
Rat	PO (gavage)	14 days	10 ml/kg QD	Well tolerated	0.3M gluconic acid pH 3.0; Age 10 weeks; ♂/♀	New contributed data

TABLE 45: Glycerol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	SC	28 days	20 ml/day (fixed volume)	None	2% solution in sterile water; Age 5-6 months; ♂/♀	New contributed data
Guinea Pig	PO	1 month	500 mg/kg	Not toxic		Gad et al. ¹
Mouse	IV	1 month	100 mg/kg	Well tolerated		Gad et al. ¹
	IP	1 month	250 mg/kg	Well tolerated		Gad et al. ¹
	PO	90 day	500 mg/kg	Depression and reduced respiration		Gad et al. ¹
	SC	Acute	10 mg/kg	Not toxic		Gad et al. ¹
	Rabbit	IV	Acute	10 mg/kg	Not toxic	Gad et al. ¹
Rat	PO	Acute	1000 mg/kg	Not toxic		Gad et al. ¹
	PO	1 month	15 g/kg	Reduced adrenal weights		Gad et al. ¹
	PO	1 month	1000 mg/kg	Not toxic		Gad et al. ¹
	SC	Acute	10 mg/kg	Not toxic		Gad et al. ¹

TABLE 46: Glycofurool

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV	Single dose	1 ml/kg	Not toxic	50% solution	New contributed data

TABLE 47: Gum Tragacanth

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	PO (gavage)	2 weeks	10 ml/kg QD	Not toxic	In distilled water, 0.5%	Gad et al. ¹

TABLE 48: Gum Xanthane

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	PO (gavage)	Tolerance	3 ml/kg/day	Well tolerated	0.4% aqueous solution	Contributed data, 2006
	PO (gavage)	Segmt. II	3 ml/kg/day	Well tolerated	0.4% aqueous solution	Contributed data, 2006

TABLE 49: Hydrochloric Acid

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (gavage)	4 weeks	4 ml/kg QD	None	0.1 N; Age 5-6 Months; ♂/♀	New contributed data
	PO (gavage)	Daily	10 ml/kg	None	0.1%-10% in Water; Beagles Age 5 months; ♂/♀	New contributed data
Rat	PO (gavage)	26 weeks	10 ml/kg QD	None	0.05 M HCl; Age 6 weeks; ♂/♀	New contributed data
	PO (gavage)	Daily	10 ml/kg	None	0.1%-10% in Water; Age 6-8 weeks; ♂/♀	New contributed data

TABLE 50: Hydroxyethyl Cellulose

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	PO	Single dose	20 mg/kg	Intestinal transit was slightly enhanced, not dose dependent.	0.5%	New contributed data
	PO	Single dose	100 mg/kg	Intestinal transit was slightly enhanced, not dose dependent.	1%	New contributed data
	PO	28 days	50 mg/kg	Easiest and most tolerable formulation for PO administration		New contributed data

TABLE 51: Hydroxypropyl - β -Cyclodextrin

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV	1 dose	1 ml/kg	Not toxic	40% solution	New contributed data
	IV (slow bolus)	1 dose	1.2 ml/kg	Not toxic	6% solution	Contributed data, 2006
	IV (2 hour infusion)	1 month	10 ml/kg	Not toxic	40% solution	Gad et al. ¹
	Intranasal	14 days	1 ml/nostril TID 2 hours apart	Well tolerated	45%; Beagle dogs (Marshall) age ~ 6 months; ♂/♀	New contributed data
	PO (gavage)	1 dose	10 ml/kg	Not toxic	6% solution	Contributed data, 2006
	PO (gavage)	90 days	Dose Vol 5 ml/kg; Daily dose 500, 1000 mg/kg	Loose/soft stools in high dose group	Dose concentration 100, 200 mg/ml (respectively)	Thackaberry ²²
	PO (Gelatin capsules)	28 doses		emesis, fecal changes	6% solution	Contributed data, 2006
	SC	91 days	0.86 ml/kg QD	None	10% solution in sterile water; Age 5.5-6 months; ♂/♀	New contributed data
Mouse	IV	Acute	5000 mg/kg	LD	Administartion directly into the vein by hypodermic needle; >5 gm/kg	Leadscope Data Portal ²³
	PO (gavage)	90 days	Dose Vol 10 ml/kg; Daily dose 500, 1000 mg/kg	Produced elevated transaminase (aspartate and alanine aminotransferase) levels; Use with caution	Dose concentrations 50, 100 mg/ml (respectively)	Thackaberry ²²
Non-human Primate	PO (gavage)	13 doses	5 ml/kg	None	11% solution	Contributed data, 2006
	PO (gavage)	90 days	Dose Vol 5 ml/kg; Daily dose 500, 1000 mg/kg	Loose/soft stools in high dose group	Dose concentration 100, 200 mg/ml (respectively)	Thackaberry ²²
Rabbit	PO (gavage)	12 doses	2 ml/kg	Not toxic	11% solution	Contributed data, 2006
Rat	Intranasal	14 days	50 ml/nostril TID 2 hours apart	Well tolerated	45%; Sprague Dawley (Harlan) age ~8-10 weeks at initiation; ♂/♀ ; Histopath limited to Purulent exudates (minimal to mild) involving the nasal turbinates	New contributed data

IP injection	Single dose	1000 mg/kg	Increased glucose levels at 4hrs., minor transient changes for triglycerides and BUN, no functional changes were observed, only slight enhancement of ALT and AST.	10% solution	New contributed data
IV	Single dose	1 ml/kg	Not toxic	20% solution	Contributed data, 2006
IV	Single dose	10 ml/kg	Death occurred within a few minute of receiving a bolus dose of the vehicle. The rate of administration was slowed to ~2min, which was tolerated and clinical observations limited to red urine	45%; Sprague Dawley (harlan); Age ~8 weeks of age; ♂/♀	New contributed data
IV (slow bolus)	10 doses	4 ml/kg	Not toxic	12.5% solution	Contributed data, 2006
IV (1 hour infusion)	1 month	10 ml/kg	Not toxic	40% solution	New contributed data
IV (slow bolus)		2 ml/kg	Not toxic	12.5% solution	Contributed data, 2006
PO	Single dose	up to 2000 mg/kg	No effect on gastric emptying, modestly inhibited intestinal transit.	20% solution	New contributed data
PO (gavage)	Single dose	10 ml/kg	Not toxic	6% solution	Contributed data, 2006
PO (gavage)	10 doses	10 ml/kg	Not toxic	11% solution	Contributed data, 2006
PO (gavage)	4 weeks	10 ml/kg QD	None	20%; Age 6 weeks; ♂/♀	New contributed data
PO (gavage)	90 days	Dose Vol 5 ml/kg; Daily dose 500, 1000 mg/kg	Produced elevated transaminase (aspartate and alanine aminotransferase) levels; Use with caution	Dose concentrations 100, 200 mg/ml (respectively)	Thackaberry ²²
SC	91 days	1.14 ml/kg QD	None	10% solution in sterile water; Age 7 weeks; ♂/♀	New contributed data

TABLE 52: Hydroxypropyl Cellulose

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	PO	90 day	1000 gm/kg	Not toxic		Gad et al. ¹

TABLE 53: Hydroxypropyl methylcellulose

Species	Routes	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IP	Acute	200 mg/kg	Not toxic		Gad et al. ¹
	PO (gavage)		5 ml/kg	None	1% (methocel E5 premium LV, 5cp) in DI water; Age 6.5-7 months; ♂/♀	New contributed data
	PO (gavage)	90 days	Dose Vol 5 ml/kg, Daily dose 20 mg/kg (0.4% wt/vol)	Well tolerated		Thackaberry ²²
Minipig	PO (gavage)	7 days	5 ml/kg QD	None	0.5% in distilled water: Age 6.5-11.5 months; ♂/♀	New contributed data
Mouse	IP	Single dose	5 ml/kg	Not toxic	0.5%	Gad et al. ¹
	IP	Acute	50 mg/kg	Not toxic		Gad et al. ¹
	PO	5 days	20 ml/kg BID	None	0.5%; Non-GLP; Age 9 weeks; 6♀	New contributed data
	PO (gavage)	Single dose	10 ml/kg	Not toxic	0.5%	Gad et al. ¹
	PO (gavage)	10 doses	10 ml/kg	Not toxic	0.2%	Gad et al. ¹
	PO (gavage)	90 days	Dose Vol 10 ml/kg, Daily dose 20 mg/kg (0.4% wt/vol)	Well tolerated		Thackaberry ²²
Non-human Primate	PO (gavage)	28 days	2 ml/kg QD	None	0.5% in distilled water; Age 2-3 years; ♂/♀	New contributed data
	PO (gavage)	28 days	5 ml/kg QD	Soft feces (non-adverse)	1% (Methocel E5 premium LV, 5cp) in DI water; Age 2.5-3.5 years; ♂/♀	New contributed data
	PO (gavage)	90 days	Dose Vol 5 ml/kg, Daily dose 20 mg/kg (0.4% wt/vol)	Well tolerated		Thackaberry ²²
	PO (gavage)	91 days	5 ml/kg QD	None	0.2% in distilled water; Cynomolgulous Monkeys age 2 years; ♂/♀	New contributed data

	IP	Single dose	5 ml/kg	Not toxic	0.5%	Gad et al. ¹
	PO (gavage)	Single dose	10 ml/kg	Not toxic	0.2%	Gad et al. ¹
	PO (gavage)	Single dose	10 ml/kg	Not toxic	0.5%	Gad et al. ¹
	PO (gavage)	90 days	Dose Vol 5 ml/kg, Daily dose 20 mg/kg (0.4% wt/vol)	Well tolerated		Thackaberry ²²
Rat	PO (gavage)	91 days	5 ml/kg QD	None	1% (Methocel E5 premium LV, 5cp) in DI water; Age 6 weeks; ♂/♀	New contributed data
	PO (gavage)	up to 104 weeks	10 ml/kg QD	None	0.2% in distilled water; Age 6-11 weeks; ♂/♀	New contributed data
	PO (gavage)	182 days	10 ml/kg QD	None	0.5% in distilled water; Age 6 weeks; ♂/♀	New contributed data

TABLE 54: Hypotonic PBS

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV	2 days	2 ml/kg SD	None	GLP; Age 6 months; 5♂/5♀	New contributed data
Rat	IV	2 days	2 ml/kg SD	None	GLP; Age ≥8 weeks; 10♂/10♀	New contributed data

TABLE 55: Isopropyl Alcohol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	Dermal	1 month	1000 gm/kg	Not toxic		Gad et al. ¹

TABLE 56: Isopropyl Myristate

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	Dermal	1 month	500 mg/kg	Not toxic		Gad et al. ¹

TABLE 57: Kolliphor EL

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV	1 month	2 mL/kg	Well tolerated		Gad et al. ¹
Rat	PO	1 month	100 mg/kg	Not toxic		Gad et al. ¹

TABLE 58: Kolliphor ELP

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog					Up to 50%; Never use for dog studies! Anaphylaxis!	Access Biosciences ²⁴

TABLE 59: Kolliphor RH40

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV	1 month	2 ml/kg	Not toxic		Gad et al. ¹

TABLE 60: Labrafil M1944

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	1 month	2 mg/kg	Not toxic		Gad et al. ¹
Rabbit	Dermal	Acute		Non irritant	No dilution; 0.38 dermal irritation index	Gattefossé technical document ²⁵
Rat	PO	Acute		Not toxic	No dilution; $LD_0 \geq 20,000$ mg/kg/day	Gattefossé technical document ²⁵

TABLE 61: Labrasol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	14 day	100, 300, 1000 and 3000 mg/kg/day	In high dose group, moderate suppurative inflammation of the lungs. No adverse affects on survival and clinical observations.		Gad et al. ¹
	PO	13 week	0, 300, 1000 and 3000 mg/kg/day	NOEL: 1000 mg/kg/day; NOAEL: 3000 mg/kg/day		Gad et al. ¹
Rabbit	Dermal	Patch test	0.5 ml	Well tolerated		Gad et al. ¹
	Ocular	Acute	0.1 ml	Slight irritant		Gad et al. ¹
Rat	Dermal	Acute		Very well tolerated		Gad et al. ¹
	Dermal	Patch test	0.02 ml/animal	Well tolerated		Gad et al. ¹
	IV	ADME	10 mg/kg/day			Gad et al. ¹
	Ocular			Slight irritant		Gad et al. ¹
	PO	Acute	20, 22.4, 25.1, 28.21 and 31.60 g/kg	LD ₅₀ > 22 g/kg; Non toxic		Gad et al. ¹
	PO	ADME	10, 150 mg/kg/day	Well tolerated		Gad et al. ¹
	PO	Segment II: Embryofetal development	1000, 2000 or 3000 mg/kg/day	NOEL: 3000 mg/kg/day with no indication of a teratogenicity		Gad et al. ¹
	PO	14 day	100, 300, 1000, 3000 mg/kg/day	NOAEL: 3000 mg/kg/day		Gad et al. ¹
	PO	6 months	300, 1000 and 3000 mg/kg/day	NOEL: 300 mg/kg/day; NOAEL: 3000 mg/kg/day		Gad et al. ¹

TABLE 62: Lactose

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-human Primate	Inhalation	2 weeks	1 L/min/animal	Well tolerated	Lactose 200 M; anhy	Gad et al. ¹

TABLE 63: Lanolin

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	Dermal	90 days	1000 mg/kg	Not toxic		Gad et al. ¹

TABLE 64: Lauroglycol 90

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	Dermal	Acute	No dilution	Moderately irritant		Gad et al. ¹
	Ocular	Acute	No dilution	Slightly irritant		Gad et al. ¹
Rat	PO	Acute		LD50: >2003 mg/kg/day		Gad et al. ¹

TABLE 65: Maltitol Solution

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	IP	1 month	500 mg/kg	Not toxic		Gad et al. ¹

TABLE 66: Maltol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Guinea Pig	PO	1 month	75 mg/kg	No toxic		Gad et al. ¹
Rabbit	PO	1 month	100 mg/kg	Not toxic		Gad et al. ¹

TABLE 67: Mannitol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Minipig	SC	Tolerance	0.2 ml/kg/day	Well tolerated	5% solution	Contributed data, 2006
Non-human Primate	PO (gavage)	2 sem	10 ml/kg/day	Well tolerated		Gad et al. ¹
Rabbit	IV	ADME	0.8 ml/kg	Well tolerated		Contributed data, 2006
	PO	ADME	1.6 ml/kg	Well tolerated		Contributed data, 2006

TABLE 68: Methylcellulose

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV		40 ml	Anemia, decreased WBC, increased sedimentation rate in 24 hours	0.7-2.8% solution	New contributed data
	PO	14 days	5.0 ml/kg QD	None	GLP; Age 6 months; 6♂/6♀	New contributed data
	PO (dietary)	90 days	6%	Not toxic		Thackaberry ²²
	PO (gavage)	14 doses	10 ml/kg/dose	Not toxic	0.5%	Gad et al. ¹
	PO (gavage)	39 weeks	5 ml/kg QD	Soft/mucoid feces	0.5% solution (400cps) in DI water; Age 6-10.5 months; ♂/♀	New contributed data
Guinea Pig	PO	12 doses	4 ml/kg	Not toxic	0.5%	Gad et al. ¹
	Topical	3 weeks	0.4 ml Once/week	None	0.5% solution (400cps) in DI water; Age 2-3 months; ♂/♀	New contributed data
Mouse	PO	90 days	10 ml/kg	Not toxic	0.5%	Gad et al. ¹
Non-human Primate	IV	30 minute infusion in a single dose	1 ml/kg	None	0.5% solution (400cps) in DIwater: ♂/♀	New contributed data
	PO (gavage)	14 doses	5 ml/kg	Not toxic	0.5%	Gad et al. ¹
	PO	1 month	10 ml/kg/dose	Not toxic	0.5%	Gad et al. ¹
	PO (gavage)	28 doses	5 ml/kg/dose	Not toxic	1%	Gad et al. ¹
	PO (gavage)	28 doses	10 ml/kg	Not toxic	0.1%	Gad et al. ¹
Rabbit	PO (gavage)	12 doses	4 ml/kg	Not toxic	0.5%	Gad et al. ¹
Rat	PO (dietary)	90 days	10%	Not toxic		Thackaberry ²²
	PO (gavage)		1020 mg/kg	NOAEL		Thackaberry ²²
	PO (gavage)	Single dose	10 ml/kg	None	1%	Contributed data, 2006
	PO (gavage)	Single dose	10 ml/kg	None	0.5%	Contributed data, 2006
	PO	Single dose	10 ml/kg	Not toxic	2%	Gad et al. ¹

PO	3 days	10 ml/kg QD	None	1% solution in water; Non-GLP; Age 11 weeks; 5♀	New contributed data
PO (gavage)	5 doses	10 ml/kg	None	0.5%	Contributed data, 2006
PO (gavage)	9 doses	10 ml/kg/day	None	0.5%	Contributed data, 2006
PO (gavage)	14 days	10 ml/kg QD	Not toxic	1%	Gad et al. ¹
PO	1 month	10 ml/kg	Not toxic	0.5%	Gad et al. ¹
PO	1 month	5 ml/kg	Not toxic	0.5%	Gad et al. ¹
PO (gavage)	28 doses	5 ml/kg/dose	None	1%	Contributed data, 2006
	2 year	120 mg/kg	Not toxic	1%	Contributed data, 2006
PO (gavage)	182 days	10 ml/kg BID	None	0.5% solution (400cps) in DI water; Age 6 weeks; ♂/♀	New contributed data

TABLE 69: Methylpyrrolidone

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV	Single dose	0.25 ml/kg	Not toxic	50% solution	New contributed data
Mouse	IV	Range finding	MTD: 1.3 g/kg; NOEL: 257 mg/kg		Published LD ₅₀ = 54-36000 mg/kg	Sambrone ⁵
	IV (into tail vein)	Acute	257 mg/kg (dose vol 5 ml/kg)	NOEL	5% solution	Thackaberry ²⁰
	IV (into tail vein)	Acute	1285 mg/kg (dose vol 5 ml/kg)	MTD; Struggling and vocalization at dosing, rapid breathing, stiff tail and splayed limbs immediately post dose. Hypoactivity for up to 15 mins is typical.	25% solution	Thackaberry ²⁰

TABLE 70: Mineral Oil

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Cat	Topical	2x/wk x 2 doses for 28 days	1.15 ml total: 0.35 ml, then 0.4 ml every 60 min after initial application for 2 doses	None	GLP; Age 54-57 days; 6♂/6♀	New contributed data
	Topical	q14d for 56 days	2.1 ml total: 0.5 ml, then 0.4 ml every 30 min after initial application for four applications	None	GLP; Age 9 weeks; 6♂/6♀	New contributed data
Dog	PO	1 month	2.5 ml/kg	Not toxic		Gad et al. ¹
Guinea Pig	Topical	28 days	0.4 ml q7d	None	GLP; Age 6 weeks; 11♀	New contributed data
Mouse	PO	1 month	250 mg/kg	Not toxic		Gad et al. ¹
Rat	PO	1 month	5 ml/kg	Not toxic		Gad et al. ¹

TABLE 71: Olive Oil

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	PO (gavage)	28 days	10 ml/kg QD	Well tolerated	Age 6 weeks; ♂/♀	New contributed data

TABLE 72: Peanut Oil

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	PO	1 month	10 g/kg	Not toxic		Gad et al. ¹
	PO	12 month	10 g/kg	Not toxic		Gad et al. ¹
	PO	90 day	10 g/kg	Not toxic		Gad et al. ¹
	PO (gavage)		5 ml/kg/day	Well tolerated		Contributed data, 2006
	SC		2 ml/kg/day	Well tolerated		Contributed data, 2006

TABLE 73: PEG 200

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-human Primate	PO (gavage)	14 days	5 ml/kg QD	Soft/watery feces (non-adverse)	Age 2-3.5 years; ♂/♀	New contributed data
Rabbit	IV		>10 g/kg bw	LD ₅₀		Smyth et al ²⁶
Rat	IP		8-9 g/kg bw	LD ₅₀		Quadbeck ²⁷
	PO (dietary)	90 days	20, 40, 80, 160, 240 g/kg diet QD (1.5, 3. 6. 12. 18 g/kg bw QD)	NOAEL = 6 g/kg bw QD	At 12, 18 g/kg bw liver and liver/kidney weights increased (respectively); 5♂/5♀	Smyth et al ²⁸
	PO (drinking water)	90 days	4.8 g/kg bw QD	NOAEL	5♂	Smyth et al ²⁹
	PO (drinking water)	90 days	10.9 g/kg bw QD	66% mortality; Decreased body weight gain	5♂	Smyth et al ²⁹

TABLE 74: PEG 300

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (gavage)	28 days	1 ml/kg BID	None	Age 5.5-6 Months; ♂/♀	New contributed data
Guinea Pig	IV	1 month	1 ml/kg	Not toxic		Gad et al. ¹
Mouse	PO (gavage)	ADME	10 ml/kg/day	Well tolerated		Gad et al. ¹
Rabbit	PO	1 month	500 gm/kg	Not toxic		Gad et al. ¹
	IV		>10 g/kg bw	LD ₅₀		Smyth et al ²⁶
	IP		16-18 g/kg bw	LD ₅₀		Quadbeck ²⁷
	IP		17 g/kg bw	LD ₅₀		Smyth et al ²⁶
	IV		8 g/kg bw	LD ₅₀		Carpenter & Shaffer ³⁰
	IV		7.1 g/kg bw	LD ₅₀		Rowe & Wolf ³¹
Rat	PO (dietary)	90 days	20, 40, 80, 160, 240 g/kg diet QD (1.5, 3, 6, 12, 18 g/kg bw QD)	NOAEL = 3 g/kg bw QD	At 6, 12, 18 g/kg bw decreased body weight gain, liver and kidney weight increase, and both decreased body weight gain and increased liver weight (respectively); 5♂/5♀	Smyth et al ²⁸
	PO (drinking water)	90 days	5.4 g/kg bw QD	NOAEL	5♂	Smyth et al ²⁹
	PO (drinking water)	90 days	20.5 g/kg bw QD	66% mortality; Decreased body weight gain; Liver and kidney changes	5♂	Smyth et al ²⁹
	PO (gavage)	2 weeks	7.5 ml/kg once, or 2.5 ml/kg TID	Well tolerated	50%	Contributed data, 2006
	PO (gavage)	4 weeks	5 ml/kg/day	Well tolerated	50%	Contributed data, 2006
	PO (gavage)	28 days	2 ml/kg BID	None	Age 8 weeks; ♂/♀	New contributed data

TABLE 75: PEG 400

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV	Single dose	Total Dose <2g/kg		100%	New contributed data
	IV	28 days	2-3 g/kg	Decreased blood pressure and reversible depression in respiration. These symptoms increased at doses of 3g/kg or greater and eventually resulted in complete respiratory arrest. At necropsy dogs were found to have pulmonary edema and small infarcts in the lungs, but no changes in the heart or kidneys.	100%	New contributed data
	IV				NS solution; Hemolysis occurs > 33% (v/v) concentration	Li et al ³²
	IV	Single dose	1 ml/kg	Not toxic	30%	New contributed data
	IV	30 days, + 21 day recovery	8.45 g/kg QD	Dry mouth and dry nasal mucous membrane; histopathological change in kidney; reversible cloudy swelling of kidney cells and increased glomerular volume	NS solution 25% (v/v)	Li et al ³²
	IV	30 days, + 21 day recovery	5 ml/kg/day	Dry mouth and dry nasal mucous membrane	NS solution 25% (v/v)	Li et al ³²
	IV	30 days, + 21 day recovery	4.23 g/kg QD	Increased values of electrolytes (Na ⁺ and Cl ⁻)	NS solution 25% (v/v)	Li et al ³²
	IV (bolus)		1 ml/kg	Well tolerated	60% solution in water pH 3-11	Strickley ¹¹
	IV (infusion)		2 ml/kg	Well tolerated	60% solution in water pH 3-11	Strickley ¹¹
	IV (infusion)		0.5 ml/kg	Well tolerated	80% solution in water pH 3-11	Strickley ¹¹
Guinea Pig	PO (dietary)	1 year	20 g/kg diet QD (0.5 g/kg bw QD)	NOAEL = 0.5 g/kg bw QD	3♂/1♀	Smyth et al ²⁸
	PO (gavage)	28 days	0.25 ml/kg QD	Soft/watery feces (non adverse)	Age 5-5.5 Months; ♂/♀	New contributed data
Minipig	Dermal	2 weeks	2.5 ml/kg	Well tolerated		Gad et al. ¹

	Topical	90 days	2 ml/kg QD	Mild dose-site inflammation after >30 days of administration	GLP; Age 4-6 months; 6♂/6♀	New contributed data
Mouse	IP	3 days	10 ml/kg	Not toxic	35%	Gad et al. ¹
	IP	1 month	2.5 ml/kg	Not toxic	40% solution	Gad et al. ¹
	IP	28 doses	500 mg/kg	Not toxic		Gad et al. ¹
	IP		14.5 g/kg bw	LD ₅₀		Bartsch et al ³³
	IP		9.2 g/kg bw	LD ₅₀		Shideman & Procita ³⁴
	IV		8.6 g/kg bw	LD ₅₀		Bartsch et al ³³
	IV	Range finding	MTD: 4.5 g/kg; NOEL: 1.7 g/kg		Published LD ₅₀ = 8.6-9.7 g/kg	Sambrone ⁵
	IV (into tail vein)	Acute	1692 mg/kg (dose vol 5 ml/kg)	NOEL	30% solution	Thackaberry ²⁰
	IV (into tail vein)	Acute	4512 mg/kg (dose vol 5 ml/kg)	MTD; Tremors, ventral recumbancy and splayed limbs shortly after dosing, hypoactivity for up to 12 minutes is typical	80% solution	Thackaberry ²⁰
	PO (gavage)	4 weeks	10 ml/kg/day	Well tolerated		Gad et al. ¹
	PO	13 weeks	5 ml/kg BID	Well tolerated	100%; CD-1 (Harlan); Age ~7 weeks at study initiation; ♂/♀	New contributed data
Non-Human Primate	PO (gavage)	28 days	1 ml/kg QD	Soft/watery feces (non adverse)	In DI water; Age 1-2 years; ♂/♀	New contributed data
	PO (gavage)	28 days	5 ml/kg QD	Soft/watery feces (non adverse)	In DI water; Age 1-2 years; ♂/♀	New contributed data
Rabbit	IV		>10 g/kg bw	LD ₅₀		Smyth et al ²⁶
Rat	Dermal	13 weeks	2.5 ml/kg/day	Well tolerated		Gad et al. ¹
	Dermal	104 weeks	2.5 ml/kg/day	Well tolerated		Gad et al. ¹
	IP		14.7 g/kg bw	LD ₅₀		Bartsch et al ³³

IP		12.3 g/kg bw	LD ₅₀		Rowe & Wolf ³¹
IP	1 month	5 ml/kg	Not toxic	35%	Gad et al. ¹
IV		4.7 g/kg bw	LD ₅₀		Rowe & Wolf ³¹
IV	Single dose	0.5 ml/kg	Not toxic		Gad et al. ¹
IV (bolus)		2 ml/kg	Well tolerated	60% solution in water pH 3-11	Strickley ¹¹
IV (infusion)		5 ml/kg	Well tolerated	60% solution in water pH 3-11	Strickley ¹¹
PO (gavage)		2 ml/kg	Not toxic		Gad et al. ¹
PO (gavage)	Single dose	5 ml/kg	Not toxic		Gad et al. ¹
PO (gavage)	10 doses	1.67 mg/kg	Not toxic		Gad et al. ¹
PO	1 month	5 ml/kg	Not toxic		Gad et al. ¹
PO (gavage)	4 weeks	5 ml/kg/day	Well tolerated		Gad et al. ¹
PO (gavage)	28 days	3 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
PO (gavage)	28 days	10 ml/kg QD	None	In DI water; Age 6 weeks; ♂/♀	New contributed data
PO	13 weeks	10 ml/kg/day	Loose feces and decreased food consumption; increased water consumption; increases in relative kidney weights; reversible renal toxicity		Li et al ³²
PO	26 weeks	5 ml/kg BID	Well tolerated	100%; Sprague Dawley (Harlan) age ~8 weeks at initiation; ♂/♀	New contributed data
PO (dietary)	90 days	20, 40, 80, 160, 240 g/kg diet QD (1.5, 3, 6, 12, 18 g/kg bw QD)	NOAEL = 6 g/kg bw QD	At 12, 18 g/kg bw Decreased body weight gain and liver and kidney weight increase (respectively); 5♂/5♀	Smyth et al ²⁸
PO (dietary)	2 years	10, 20, 40, 80 g/kg diet QD (0.75, 1.5, 3, 6 g/kg bw QD)	NOAEL = 1.5 g/kg bw QD	From 3 g/kg bw decreased body weight gain (male); 20♂/20♀	Smyth et al ²⁸
PO (drinking)	90 days	4.8 g/kg bw	NOAEL	5♂	Smyth et al ²⁹

water)		QD				
PO (drinking water)	90 days	16.4 g/kg bw QD	66% mortality, decreased body weight gain		5♂	Smyth et al ²⁹

TABLE 76: PEG 600

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	IP		14.1 g/kg bw	LD ₅₀		Rowe & Wolf ³¹
	IV		7.7 g/kg bw	LD ₅₀		Pfordte ³⁵
	PO (dietary)	90 days	20, 40, 80, 160, 240 g/kg diet QD (1.5, 3, 6, 12, 18 g/kg bw QD)	NOAEL = 6 g/kg bw QD	From 12 g/kg bw decreased body weight gain and increased kidney weights; 5♂/5♀	Smyth et al ²⁸

TABLE 77: PEG 810

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	IV		13 g/kg bw	LD ₅₀		Käber ³⁶
	SC		16 g/kg bw	LD ₅₀		Käber ³⁶

TABLE 78: PEG 1000

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	IP		2 g/kg bw	LD ₅₀		Shideman & Procita ³⁴
Rabbit	IV		>10 g/kg bw	LD ₅₀		Smyth et al ²⁶
Rat	IP		15.6 g/kg bw	LD ₅₀		Smyth et al ²⁶
	PO (dietary)	90 days	20, 40, 80, 160, 240 g/kg diet QD (1.5, 3, 6, 12, 18 g/kg bw QD)	NOAEL = 6 g/kg bw QD	From 12 g/kg bw decreased body weight gain; 5♂/5♀	Smyth et al ²⁶

TABLE 79: PEG 1500

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rat	IP		17.7 g/kg bw	LD ₅₀		Smyth et al ²⁶
	IV		8.5 g/kg bw	LD ₅₀		Rowe & Wolf ³¹
	PO (dietary)	90 days	0.88, 4.05, 8.1, 22.9 g/kg bw QD	NOAEL = 2 g/kg bw QD	From 4.05 g/kg bw kidney damage	Smyth et al ³⁷
	PO (drinking water)	90 days	20, 40, 80, 160, 240 g/kg diet QD (1.5, 3, 6, 12, 18 g/kg bw QD)	NOAEL = 3 g/kg bw QD	From 6 g/kg decreased body weight gain; at 18 g/kg bw increased kidney weights; 5♂/5♀	Smyth et al ²⁸
	PO (drinking water)	2 years	0.2, 0.8, 4, 20 g/l QD (0.015, 0.059, 0.27, 1.69 g/kg bw QD)	1.69 g/kg bw QD: No effects on fertility, survival, haematology or histopathology	8♂/8♀	Smyth et al ³⁸ , Smyth et al ²⁶

TABLE 80: PEG 1540

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (dietary)	1 year	20 g/kg diet QD (0.5 g/kg bw QD)	NOAEL = 0.5 g/kg bw QD		Smyth et al ²⁸
Rabbit	IV		>10 g/kg bw	LD ₅₀		Smyth et al ²⁶
Rat	IP		15.4 g/kg bw	LD ₅₀		Smyth et al ²⁶
	PO (dietary)	90 days	20, 40, 80, 160, 240 g/kg diet QD (1.5, 3, 6, 12, 18 g/kg bw QD)	NOAEL = 3 g/kg bw QD	From 6 g/kg bw decreased body weight gain; From 18 g/kg bw increased kidney weights; 5♂/5♀	Smyth et al ²⁸
	PO (dietary)	2 years	0.2, 0.8, 4, 20, 40, 80 g/kg diet QD (0.015, 0.06, 0.3, 1.5, 3, 6 g/kg bw QD)	NOAEL = 3 g/kg bw QD	From 6 g/kg QD cloudy swelling in the liver; 35♂/35♀	Smyth et al ²⁸

TABLE 81: PEG 4000

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (dietary)	1 year	20 g/kg diet QD (0.5 g/kg bw QD)	NOAEL = 0.5 g/kg bw QD		Smyth et al ²⁸
Mouse	IP		8.0 g/kg bw	LD ₅₀		Shideman & Procita ³⁴
Rabbit	IV		>10 g/kg bw	LD ₅₀		Smyth et al ²⁶
	PO (gavage)	5 weeks (6 days/wk)	5, 10, 20 g/kg bw QD	From 5 g/kg bw decreased body weight gain, decreased glycogen storage; From 20 g/kg bw decreased body weights		Smyth et al ³⁷
Rat	IP		11.6-13 g/kg bw	LD ₅₀		Smyth et al ²⁶
	IP		9.7 g/kg bw	LD ₅₀		Rowe & Wolf ³¹
	IV		7.5 g/kg bw	LD ₅₀		Rowe & Wolf ³¹
	PO (dietary)	90 days	20, 40, 80, 160, 240 g/kg diet QD (1.5, 3, 6, 12, 18 g/kg bw QD)	NOAEL = 3 g/kg bw QD	From 6 g/kg bw decreased body weight gain; From 12 g/kg bw increased kidney weights; 5♂/5♀	Smyth et al ²⁸
	PO (dietary)	90 days	1.6 g/kg bw QD	NOAEL = 1.6 g/kg bw QD		Smyth et al ²⁶
	PO (dietary)	2 years	0.375, 0.75, 1.5, 3, 6 g/kg bw QD	NOAEL = 3 g/kg bw QD	At 6 g/kg bw decreased body weight gain; 20♂/20♀	Smyth et al ²⁸
	PO (drinking water)	90 days	0.04-19 g/kg bw QD	NOAEL = 0.8 g/kg bw QD	At 0.23 g/kg bw degeneration of the testis tubules, degenerated sperm; From 7 g/kg bw decreased body weight gain; At 19 g/kg bw kidney damage; 5♂	Smyth et al ³⁷
	PO (drinking water)	2 years	0.00085, 0.0036, 0.017, 0.062 g/kg bw QD	NOAEL = 0.062 g/kg bw QD	8♂/8♀	Smyth et al ³⁸ Smyth et al ²⁶

TABLE 82: PEG 6000

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	IV		>10 g/kg bw	LD ₅₀		Smyth et al ²⁶
	IP		6.8 g/kg bw	LD ₅₀		Smyth et al ²⁶
Rat	PO (dietary)	90 days	20, 40, 80, 160, 240 g/kg diet QD (1.5, 3, 6, 12, 18 g/kg bw QD)	NOAEL = 12 g/kg bw QD	At 18 g/kg bw kidney weights increased, decreased body weight gain; 5♂/5♀	Smyth et al ²⁸

TABLE 83: PEG 10000

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
	IP		12.6 g/kg bw	LD ₅₀		Smyth et al ²⁶
Rat	PO (dietary)	90 days	1.6 g/kg bw QD	NOAEL		Smyth et al ²⁶

TABLE 84: PEG 4000000

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
	IV		>10 g/kg bw	LD ₅₀		Smyth et al ²⁶
Rat	PO (dietary)	90 days	8.0, 18.4 g/kg bw QD	From 8 g/kg bw cloudy swelling in the renal tubules; At 18.4 g/kg bw decreased body weight gain (males), decreased relative liver weights	10♂/10♀	Smyth et al ³⁹
	PO (dietary)	2 years	Up to 2.76 g/kg bw QD	NOAEL = 2.76 g/kg bw QD	36♂/36♀	Smyth et al ³⁹
	PO (dietary)	2 years	Up to 0.56 g/kg bw QD	NOAEL = 0.56 g/kg bw QD	4♂/2♀	Smyth et al ³⁹

TABLE 85: Petrolatum

Species	Route	Duration	Dose	Adverse	Notes	Data Source
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				Reactions/Toxicity		
Rabbit	Dermal	1 month	1 gm/kg	Not toxic		Gad et al. ¹

TABLE 86: Phosphate Buffered Saline

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV (Slow bolus)	28 days	2.5 ml/kg/dose (5 ml/kg/day) BID	Well tolerated	pH 7.2; Age 5-6 months; ♂/♀	New contributed data
	1 hr infusion	1 hr infusion single dose	10 ml/kg	Well tolerated	0.01 M PBS (powder) in sterile water for injection; 0.02 Beagle dog; 0.03 Age 5 months; ♂/♀	New contributed data
	PO (gavage)	28 days	5 ml/kg QD	Well tolerated	pH 7.2; Age 5-6 months; ♂/♀	New contributed data
	Topical	q7d x2 doses for 7 weeks	1.4 ml/kg divided into 3 doses 60 minutes apart	Well tolerated	Non-GLP; Age 7 weeks; 2♂/2♀	New contributed data
Minipig	IV	14 days	5 ml/kg QD	Well tolerated	GLP; pH 6.0; Age 17-21 days; 5♂/5♀	New contributed data
	IV	14 days	1 ml/kg QD	Well tolerated	GLP; pH 6.0; Age 5-8 months; 5♂/5♀	New contributed data
	PO	7 days	5 ml/kg BID	Well tolerated	GLP; Age 4 days; 4♂/4♀	New contributed data
	PO	28 days	5 ml/kg BID	Well tolerated	GLP; pH 6.0; Age 4-5 days; 10♂/10♀	New contributed data
Mouse	SC (infusion)	Continuous (24 hrs/day) infusion for 7 days	1.0 ml/hr (+0.15ml/hr)	Well tolerated	pH 7.2; Age 10 weeks; ♂/♀	New contributed data
	SC (bolus)	Every 2 days for 1 week then weekly for 26 weeks	10-11.83 ml/kg	Well tolerated	pH 7.2; Age 6 weeks; ♂/♀	New contributed data
	SC	6 month	10 ml/kg	Not toxic		Gad et al. ¹
Non-human Primate	IV (Slow bolus)	28 days	10 ml/kg	Well tolerated	pH 7.2; Age 2-3 years; ♂/♀	New contributed data

			QD			
	PO (gavage)	2 weeks	10 ml/kg/dose	Not toxic		Gad et al. ¹
	PO (gavage)	2 weeks	1.6 ml/kg	Not toxic		Gad et al. ¹
	SC	1 week	0.2 ml/kg	Not toxic		Gad et al. ¹
	SC	9 months	1 ml/kg	Not toxic		Gad et al. ¹
Rabbit	IV	12 weeks	1.0 ml/kg q7d	Well tolerated	Non-GLP; pH 6.5; Age 7-8 months; 9♂	New contributed data
Rat	IV	Single dose	1 ml/kg	Not toxic		Gad et al. ¹
	IV (Slow bolus)	28 days	5 ml/kg Once weekly	Well tolerated	pH 7.2; Age 6 weeks; ♂/♀	New contributed data
	PO (gavage)	5 doses	10 ml/kg	Well tolerated		Contributed data, 2006
	PO	28 doses	10 ml/kg	Not toxic		Gad et al. ¹
	PO (gavage)	28 days	10 ml/kg/dose QD	Well tolerated	pH 7.2; Age 6 weeks; ♂/♀	New contributed data
	SC	1 month	1 ml/kg QD	Not toxic		Gad et al. ¹
	Slow bolus injection	11 doses	1 ml/kg	Not toxic		Gad et al. ¹

TABLE 87: Poloxamer 188

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	SC	4 weeks	5 ml/kg QD	Dog vehicle changed following a single administration due to animal distress in response to the injections. The distress was attributed to the vehicle.	2% in DI water; pH 5 ±0.2; Age 5-6 months; ♂/♀	New contributed data
Mouse	PO	1 month	10 ml/kg	Not toxic	5% Solution	Gad et al. ¹
Rat	PO	1 month	10 ml/kg	Not toxic	7.5% Solution	Gad et al. ¹
	SC	4 weeks	5 ml/kg QD	None	2% in DI water; pH 5 ±0.2; Age 6 weeks; ♂/♀	New contributed data

TABLE 88: Poly(glycolide-co-DL-lactide) microspheres

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	Into periodontal pockets	28 days	3.5 mg/pocket SD	Well tolerated	GLP; Age 6-10 years	New contributed data

TABLE 89: Polyglycerol Oleate

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	Dermal	Acute		Moderately irritant (Irritation and corrosion test)	No dilution	Gattefossé Technical Document ⁴⁰
	Ocular	Acute		Slightly irritant (irritation and corrosion test)	No dilution	Gattefossé Technical Document ⁴⁰
Rat	PO	Acute	LD ₅₀ ≥ 2005 mg/kg/day		No dilution	Gattefossé Technical Document ⁴⁰

TABLE 90: Polyvinylpyrrolidone

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	Acute		Causes histamine release in dogs. The reaction is highly variable ranging from no discernible effect to reddening of extremities to total collapse.		New contributed data
Rat	IM	Single dose	1 ml	Not toxic	1%	Gad et al. ¹

TABLE 91: Propylene Glycol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV	Single dose	1 ml/kg	NOAEL; Some vomitous & diarrhea.	30%	New contributed data
	IV	14 days	5 ml/kg at a rate of 0.3 ml/kg	Hemolysis <i>in vitro</i> dog blood	60% solution in water	New contributed data
	IV (bolus)		1 ml/kg	Well tolerated	40% solution in water pH 3-11; 50% PG causes hemolysis	Strickley ¹¹
	IV (infusion)		2 ml/kg	Well tolerated	40% solution in water pH 3-11; 50% PG causes hemolysis	Strickley ¹¹
	PO	28 days	1.5 ml/kg	Not toxic	100%	New contributed data
	PO	1 month	2.5 ml/kg	Not toxic		Gad et al. ¹
	PO (gavage)	Up to 7 days	2 ml/kg/day	Well tolerated		Gad et al. ¹
	PO (gavage)	90 days	Dose Vol 5 ml/kg, Daily dose 1000 mg/kg (20% wt/vol)	Well tolerated	Dose concentration 200 mg/ml	Thackaberry ²²
Minipig	Dermal	26 weeks	2.5 ml/kg	Well tolerated		Gad et al. ¹
Non-human Primate	PO (gavage)	90 days	Dose Vol 5 ml/kg, Daily dose 1000 mg/kg (20% wt/vol)	Well tolerated	Dose concentration 200 mg/ml	Thackaberry ²²
Mouse	IP	1 month	2.5 ml/kg	Not toxic	40% solution	Gad et al. ¹
	IV	Range finding	MTD: 1.5 g/kg; NOEL: 1 g/kg		Published LD ₅₀ = 5.0-8.6 g/kg	Sambrone ⁵
	IV (into tail vein)	Acute	1036 mg/kg (dose vol 5 ml/kg)	NOEL	20% solution	Thackaberry ²⁰
	IV (into tail vein)	Acute	1554 mg/kg (dose vol 5 ml/kg)	MTD; Tremors and hind limb ataxia, full recovery by 1 min is typical	30% solution	Thackaberry ²⁰
	PO	1 month	10 ml/kg	Not toxic	50% solution	Gad et al. ¹
	PO (gavage)	90 days	Dose Vol 10 ml/kg, Daily dose 1000 mg/kg (20% wt/vol)	Well tolerated	Dose concentration 100 mg/ml	Thackaberry ²²
Rat	IV (bolus)		2 ml/kg	Well tolerated	40% solution in water pH 3-11; 50% PG causes hemolysis	Strickley ¹¹
	IV (infusion)		5 ml/kg	Well tolerated	40% solution in water pH 3-11; 50% PG causes hemolysis	Strickley ¹¹

PO	1 month	2.5 ml/kg	Not toxic		Gad et al. ¹
PO (gavage)	Prelim./ Segment II	5 ml/kg/day	Well tolerated	60/40: Purified water/ Propylene glycol: W/W	Contributed data, 2006
PO (gavage)	2 weeks	5 ml/kg/day	Well tolerated	60/40: Purified water/ Propylene glycol: W/W	Contributed data, 2006
PO (gavage)	Segment II	5 ml/kg/day	Well tolerated	60/40: Purified water/ Propylene glycol: W/W	Contributed data, 2006
PO (gavage)	2 weeks	2 ml/kg/day	Well tolerated		Gad et al. ¹
PO (gavage)	90 days	Dose Vol 5 ml/kg, Daily dose 1000 mg/kg (20% wt/vol)	Well tolerated	Dose concentration 200 mg/ml	Thackaberry ²²
SC	4 weeks	2.5 ml/kg/day	Well tolerated		Gad et al. ¹

TABLE 92: RAMEB

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-human Primate	Intranasal	1 month	82.8 mg/ml (with treatment) 74.7 mg/ml (placebo) TID	Well tolerated	7.5%	Gad et al. ¹

TABLE 93: Safflower Oil

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	SC	Single dose	1 ml	Well tolerated, No evidence of irritation macroscopically or histologically.	100%	New contributed data

TABLE 94: Saline (pH Adj.)

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	IM	14 days	4 ml/kg SD	None	(pH 4.5); Non-GLP; Age 6 weeks; 8♂/8♀	New contributed data

TABLE 95: Sesame Oil

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	1 month	5 ml/kg	Not toxic		Gad et al. ¹
	PO (gavage)	28 days	5 ml/kg QD	None	Age 7-8 months; ♂/♀	New contributed data
	PO (gavage)	9 months	1 ml/kg QD	None	Age 7-8 months; ♂/♀	New contributed data
Mouse	PO	1 month	0.25 ml/kg	Not toxic		Gad et al. ¹
Rabbit	PO	1 month	0.5 ml/kg	Not toxic		Gad et al. ¹
Rat	PO	1 month	1 ml/kg	Not toxic		Gad et al. ¹
	PO (gavage)	26 weeks	1 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data

TABLE 96: Sodium Acetate Trihydrate buffer

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-human Primate	IV		1 ml/kg	Well tolerated		Gad et al. ¹

TABLE 97: Sodium Chloride

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Cat	SC	9 days	0.1 ml/kg QD	None	0.9% Saline; Non-GLP; Age 4 Months; 2♂/2♀	New contributed data
	SC	9 days	0.1 ml/kg QD	None	Non-GLP; 2♂/2♀	New contributed data
	IV	8 days	1.9 ml/kg SD	None	0.9% Saline; Non-GLP; Age 8-9 months; 2♂/2♀	New contributed data
	IV	19 days	1.32 ml/kg 3x/wk x2wk	None	0.9% Saline; Non-GLP; Age 8-9 months; 2♂/2♀	New contributed data
Dog	IV	Single dose	10 ml/kg	Not toxic	0.9%	Gad et al. ¹

	IV	Single dose	2 ml/kg	Not toxic	0.9%	Gad et al. ¹
	IV	2 weeks	5 ml/kg/day	Not toxic	0.9%	Gad et al. ¹
	IV (bolus)	Single dose	0.3 ml/kg	Not toxic	0.9%	Gad et al. ¹
	IV	14 days	2.5 ml/kg QD	None	0.9% Saline and water to make 0.8% Saline; GLP; Age 8 weeks; 10♂/10♀	New contributed data
	IV	14 days	2 ml/kg QD	None	0.9% Saline and water to make 0.8% Saline; GLP; Age 10-11 months; 12♂/12♀	New contributed data
	IV (infusion)	8 weeks	1 ml/kg 30 min infusion 3x/wk	None	Non-GLP; Age 8-15 months; 2♀	New contributed data
	IV (infusion)	48 hours	2 ml/kg 20 min infusion SD	None	0.9% Saline; Non-GLP; Age 8-13 Months; 2♂/2♀	New contributed data
	IV (infusion)	4 hours	2 ml/kg 20 min infusion SD	None	0.9% Saline; Non-GLP; Age 8-9 months; 1♀	New contributed data
	Ocular	6 months	1 drop/eye TID	None	0.9% Saline; GLP; Age 6-7 months; 4♂/4♀	New contributed data
	PO	Single dose	0.282 ml/kg	Not toxic	0.9%	Gad et al. ¹
	SC	1 month	0.025 ml	NOEL	0.9%	Gad et al. ¹
	SC	6 months	0.5 ml/kg total: 0.1 ml/kg at 5 separate locations q21d	Occasional transient injection-site erythema	0.9% Saline; GLP; Age 5-6 months; 4♂/4♀	New contributed data
Minipig	SC	28 days	0.0225 ml/kg QD	None	0.9% Saline; GLP; Age 3 months; 4♂/4♀	New contributed data
	IM	49 days	0.5 ml q28d x 2 doses	None	0.9% Saline; Non-GLP; Age 4 months; 3♂	New contributed data
	ID	49 days	0.5 ml q28d x 2 doses	None	0.9% Saline; Non-GLP; Age 4 months; 3♂	New contributed data
Mouse	IM	30 doses		Not toxic	0.9%	Contributed data, 2006
	IV	Single dose	10 ml/kg	Not toxic	0.9%	Gad et al. ¹

	IV	2 days	10 ml/kg SD	None	0.9% Saline and water to make 0.8% Saline; GLP; Age 4-7 weeks; 11♂/11♀	New contributed data
	SC	Single dose	10 ml/kg	Not toxic	0.9%	Gad et al. ¹
	Topical	7 days	0.10 ml QD	None	0.9% Saline; Non-GLP; Age 8 weeks; 28♂	New contributed data
Non-human Primate	SC	28 doses	0.67 ml/kg	Not toxic	0.9%	Gad et al. ¹
	SC	56 doses	0.5 ml/kg/dose	Not toxic	0.9%	Gad et al. ¹
	Slow Bolus	9 doses	10 ml/kg/dose	None	0.9%	Contributed data, 2006
Rabbit	IM	33 days	0.2 ml q14d x 3 doses	None	0.9% Saline; GLP; Age 6 months; 6♀	New contributed data
	IV	Single dose	0.1 ml/kg	Not toxic	0.9%	Gad et al. ¹
	Perivascular	Single dose	0.1 ml/kg	Not toxic	0.9%	Contributed data, 2006
	SC	Single dose	0.5 ml/kg	Not toxic	0.9%	Contributed data, 2006
Rat	IP	90 days	10 ml/kg QD	None	0.9% Saline; GLP; Age 9 weeks; 10♂/10♀	New contributed data
	IV	6 hours	4 μL/g SD	None	0.9% Saline; Non-GLP; Age 8-9 weeks; 2♂/2♀	New contributed data
	IV	Single dose	1 ml/kg	Not toxic	0.9%	Gad et al. ¹
	IV	Single dose	2 ml/kg	None	0.9%	Contributed data, 2006
	IV	Single dose	10 ml/kg	Not toxic	0.9%	Contributed data, 2006
	IV	3 doses	4 ml/kg	Not toxic	0.9%	Gad et al. ¹
	IV	3 days	0.376 ml/kg QD	None	0.9% Saline; GLP; Age 4 months; 5♂	New contributed data
	IV	7 doses	1 ml/kg	None	0.9%	Contributed data, 2006
	IV	2 weeks	10 ml/kg/day	Not toxic	0.9%	Gad et al. ¹
	IV infusion	13 weeks	10 ml/kg 30 min infusion	None	0.9% Saline; GLP; Age 11 weeks; 20♂/20♀	New contributed data

		q7d			
SC	Single dose	0.1-0.4 ml	Not toxic	0.9%	Contributed data, 2006
SC	14 days	0.5 ml/kg QD	None	0.9% Saline; GLP; Age 71-72 days; 15♂/15♀	New contributed data
SC	28 doses	4 ml/kg	Not toxic	0.9%	Gad et al. ¹
SC	56 doses	2 ml/kg/dose	Not toxic	0.9%	Gad et al. ¹
Slow Bolus	Single dose	1 ml/kg	Not toxic	0.9%	Gad et al. ¹
Slow Bolus	Single dose	5 ml/kg	Not toxic	0.9%	Contributed data, 2006
Slow Bolus	Single dose	10 ml/kg	Not toxic	0.9%	Gad et al. ¹
Slow bolus	3 doses	2 ml/dose	Not toxic	0.9%	Contributed data, 2006

TABLE 98: Sodium Dihydrogen Phosphate Dihydrate

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	PO (gavage)	91 days	10 ml/kg QD	None	0.5M SDPD in DI water; Age 5 weeks; ♂/♀	New contributed data
Non-Human Primate	PO (gavage)	91 days	10 ml/kg QD	None	0.5M SDPD in DI water; Age 2.5-3.5 years; ♂/♀	New contributed data

TABLE 99: Sodium Metabisulfite

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	PO (gavage)	91 days	20 ml/kg QD	Well tolerated	10% in distilled water; Age 6 weeks; ♂/♀	New contributed data
Non-Human Primate	PO (gavage)	91 days	10 ml/kg QD	Well tolerated	10% in distilled water; Age 2-4.5 years; ♂/♀	New contributed data
Rat	PO (gavage)	91 days	10 ml/kg QD	Well tolerated	10% in distilled water; Age 6 weeks; ♂/♀	New contributed data

TABLE 100: Sodium Phosphate Buffer

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO	14 doses	10 ml/kg/dose	Not toxic	70 mM	Gad et al. ¹
Mouse	PO (gavage)	90 days	10 ml/kg QD	Well tolerated	0.1 M; pH 7.0; 0.2 Age 6 weeks; ♂/♀	New contributed data
Non-Human Primate	PO (gavage)	90 days	5 ml/kg QD	Well tolerated	0.1 M; pH 7.0; 0.2 Age 2-3 years; ♂/♀	New contributed data
	PO (gavage)	91 days	5 ml/kg QD	Well tolerated	0.1 M; pH 7.0; 0.2 Age 2-3 years; ♂/♀	New contributed data
Rat	PO	2 weeks	10 ml/kg QD	Not toxic	70 mM	Gad et al. ¹
	PO (gavage)	90 days	10 ml/kg QD	None	0.1 M; pH 7.0; Age 6 weeks; ♂/♀	New contributed data
	PO (gavage)	91 days	10 ml/kg QD	None	0.1 M; pH 7.0; Age 6 weeks; ♂/♀	New contributed data

TABLE 101: Sodium Sulfite

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	Ocular (Topical)	28 days	50 ml/dose QID	None	10% in reverse osmosis DI water; Age 7 months; ♂/♀	New contributed data

TABLE 102: Solutol HS15

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	Any	1 dose	Varies	Poorly tolerated in significant amounts	Solutol® HS15/purified water	New contributed data
Mouse	IP	2 weeks	10 ml/kg 3x/wk	None	10% Solutol; Non-GLP; Age 4-5 weeks; 5♂/5♀	New contributed data
	IV	2 weeks	10 ml/kg 3x/wk	None	10% Solutol; Non-GLP; Age 4-5 weeks; 5♂/5♀	New contributed data
Rat	PO (gavage)	Two months	10 ml/kg/day	Well tolerated	10% Solutol HS15 in purified water; Sprague Dawley rats	Contributed data, 2006

TABLE 103: Sulfolbutylether- β -cyclodextrin

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Mouse	PO	7 days	10 ml/kg BID	None	10%; Non-GLP; Age 7 weeks; 3♂/3♀	New contributed data

TABLE 104: Tartaric Acid

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Rabbit	PO (gavage)	Prelim. Segmt. II	3 ml/kg/day	Well tolerated		Gad et al. ¹
	PO (gavage)	Segmt. II	3 ml/kg/day	Well tolerated		Gad et al. ¹
Rat	PO (gavage)	39 week	0.5 ml/kg	Well tolerated		Gad et al. ¹
	PO (gavage)	Sys.nerv	3 ml/kg/day	Well tolerated		Gad et al. ¹

TABLE 105: Terbafine HCL Placebo Nail Lacquer

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Pig	Dermal	1 month	600 mL/kg	Erythema, peeling or flaking skin		Contributed data, 2006

TABLE 106: Transcutol ®

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Cat	IV	1 month	2 ml/kg Single dose	Well tolerated	No evidence of hemolysis or hematotoxicity	Gad et al. ¹
	IV	Acute		LD ₅₀ = 1000 mg/kg		Sullivan et al ⁴¹
Dog	IV	Acute		LD ₅₀ = 3000 mg/kg		Sullivan et al ⁴¹
	PO	90 days	1500 mg/kg/day	NOAEL		Sullivan et al ⁴¹
	PO (gavage)	Acute (dose escalating)	500, 1000, 1500, 2000 mg/kg	MTD > 2000 mg/kg	Undiluted	Sullivan et al ⁴¹
	PO (gavage)	Subacute (7 day DRF)	0, 500, 1000, 2000 mg/kg/day	MTD > 2000 mg/kg/day		Sullivan et al ⁴¹
	PO (gavage)	Subchronic 13-weeks	0, 400, 1000, 2000/1500 mg/kg/day	NOAEL = 1000 mg/kg/day		Sullivan et al ⁴¹
Guinea Pig	PO	Acute		LD ₅₀ = 300 mg/kg		Sullivan et al ⁴¹

Minipig	PO	90 days	0, 167, 500, 1500 mg/kg/day	NOAEL = 167 mg/kg/day	Uremia, death at 1500 mg/kg/day; High dose reduced to 1000 mg/kg/day after 21 days; Histopath in doses > 500 mg/kg/day include hydropic degeneration of liver and proximal kidney tubules; at > 1000 mg/kg/day increased relative kidney weight and decreased RBC (males)	Sullivan et al ⁴¹
Mouse	IP	Acute		LD ₅₀ = 3900 mg/kg		Sullivan et al ⁴¹
	IV	Acute		LD ₅₀ = 4300 mg/kg		Sullivan et al ⁴¹
	IV (bolus, tail vein)	Acute (dose escalating)	25, 50, 100, 200, 400, 800, 1600, 6400, 3200 and 4800 mg/kg	MTD (IV): 3200 mg/kg	Males; physiological saline solution;	Sullivan et al ⁴¹
	IV (bolus, tail vein)	Acute (dose escalating)	25, 50, 100, 200, 400, 800, 1600, 8000, 6400, 4800 and 3200 mg/kg	MTD (IV): 3200 mg/kg	Females; physiological saline solution;	Sullivan et al ⁴¹
	PO	Acute	6.6 g/kg	Tested toxic		Sullivan et al ⁴¹
	PO	Acute		LD ₅₀ = 7250 mg/kg		Sullivan et al ⁴¹
	PO (gavage)	Developmental (Dosed GD 7-14, Littered and reared to PND 3)	5500 mg/kg/day	No developmental toxicity	>99% pure; 50 Mated CD1 mice; 14% maternal mortality, maternal weight gain decreased, no external malformations on pups.	Sullivan et al ⁴¹
	PO	90 days	300, 900, 2700, and 8100 mg/kg bw (0%, 0.2%, 0.6%, 1.8% 5.4% in diet respectively)	NOAEL = 850-1000 mg/kg bw (0.6% in diet)	At 8100 mg/kg bw intracellular edema of the kidney, increased organ weights, decreased RBC (males), liver cell enlargement, protein inclusions in bladder lumen (males), tubular degeneration and atrophy. At 2700 mg/kg bw increased relative kidney weights in males was seen.	Sullivan et al ⁴¹
	PO	Chronic (12 months)	850-1000 mg/kg	NOEL		Sullivan et al ⁴¹
	SC	Acute		LD ₅₀ = 5500 mg/kg		Sullivan et al ⁴¹

Rabbit	Dermal	Skin irritation	0.5 ml over 2 cm ² area	Non-irritant	50%	Gad et al. ¹
	Dermal	28 days	0, 300, 1000, 3000 mg/kg/day	NOEL >1000 mg/kg/day	Undiluted	Gad et al. ¹
	IM	14 days	0, 0.62, 0.82, 1.6 ml/kg/day	NOAEL = 1.6 ml/kg/day	No treatment-related effects	Sullivan et al ⁴¹
	Ocular	Eye irritation	0.1 ml	Slight irritation	30%	Gad et al. ¹
	Ocular	Eye irritation	0.1 ml	Slight irritation	Undiluted	Gad et al. ¹
	PO	Acute		LD ₅₀ = 3620 mg/kg		Sullivan et al ⁴¹
	SC	Acute		LD ₅₀ = 2000 mg/kg		Sullivan et al ⁴¹
Rat	Inhalation (nasal)	28 days (6 h/day, 5 days/wk)	0, 16, 49, 200 ppm (0, 90, 270, 1100 mg/m ³ respectively)	NOAEL = 1100 mg/m ³	No systemic effects; Mild local irritation; Focal necrosis in larynx (males); 1100mg/m ³ was higher than max concentration at which only vapor present	Sullivan et al ⁴¹
	Inhalation (whole body)	Developmental (7 h/day from GD 7-15)	0, 102 ppm	No maternal or fetal toxicity	98-99.5% pure; Sprague Dawley rats	Sullivan et al ⁴¹
	IP	Acute		LD ₅₀ = 6300 mg/kg		Sullivan et al ⁴¹
	IV	Acute		LD ₅₀ = 4000 mg/kg		Sullivan et al ⁴¹
	PO	Acute		LD ₅₀ = 7500 mg/kg		Sullivan et al ⁴¹
	PO	Acute	5.0 g/kg	LD 50> 5000 mg/kg	Undiluted	Gad et al. ¹
	PO	90 days	0%, 0.25%, 1% and 5%	NOEL = 1%		Gad et al. ¹
	PO (gavage)	90 days	250, 2500 mg/kg bw (0.5% and 5.0% in diet respectively)	NOAEL = 250 mg/kg bw	High dose group saw reduction in growth rate and food consumption, decreased hemoglobin, rbc decreased (females), oxalate crystals in urine (females), increased organ weights, calcification of renal cortex; CFE rats	Sullivan et al ⁴¹
	PO (gavage)	Fertility (Segment I)	0, 300, 1000, 2000 mg/kg/day	NOAEL (oral) = 2000 mg/kg/day	In sterile water	Sullivan et al ⁴¹
	PO (gavage)	6 weeks	1340, 2680, 5360 mg/kg/day	NOAEL = 1340 mg/kg/day	Death, hematological/clinical signs in intermediate and high dose groups; Lethargy during first week; 10♂; Sprague Dawley rats	Sullivan et al ⁴¹

PO (gavage)	Embryo/fetal development study (Segment II)	0, 300, 1000, 2000 mg/kg/day	NOAEL(dev, mat) 1000 mg/kg/day	In sterile water	Sullivan et al ⁴¹
PO	Fertility and embryotoxicity range-finding study	500, 1000, 2000, 4000 mg/kg/day	NOEL > 500 mg/kg/day		Gad et al. ¹
SC	Acute		LD ₅₀ = 6000 mg/kg		Sullivan et al ⁴¹

TABLE 107: Trisodium Citrate Dihydrate

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (gavage)	52 week	10 ml/kg/day	Well tolerated	2.65% aqueous (pH 6.4)	Gad et al. ¹
Hamster	PO (gavage)	13 week	10 ml/kg/day	Well tolerated	2.65% aqueous (pH 6.4)	Contributed data, 2006
Mouse	PO (gavage)	13 week	10 ml/kg/day	Well tolerated	2.65% aqueous (pH 6.4)	Gad et al. ¹
Rat	PO (gavage)	4 week	10 ml/kg/day	Well tolerated	2.65% aqueous (pH 6.4)	Gad et al. ¹
	PO (gavage)	Segm. III	10 ml/kg/day	Well tolerated	2.65% aqueous (pH 6.4)	Gad et al. ¹
	PO (gavage)	39 week	10 ml/kg/day	Well tolerated	2.65% aqueous (pH 6.4)	Gad et al. ¹

TABLE 108: Tween 20

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV, SC, IP	Single dose		Not tolerated in any significant amount		New contributed data
	PO	Single dose		Poorly tolerated in significant amounts		New contributed data
Mouse	PO	Acute	10 g/kg	Not toxic		Contributed data, 2006
	PO		10 g/kg	Not toxic		Gad et al. ¹
Non-Human Primate	IV (slow bolus)	28 days	10 ml/kg 3x/wk	Red/back discoloration of the skin (anogenital region, and hindlimbs and forelimbs)	1.01% in sterile water for injection, USP; Age 2-3 years; ♂/♀	New contributed data
Rat	PO	1 month	250 mg/kg	Not toxic		Gad et al. ¹
	PO	90 day	500 g/kg	Diarrhea		Gad et al. ¹
	IV (slow bolus)	6 months	10 ml/kg 3x/wk	None	1.01% in sterile water for injection, USP; Age 7-8 weeks; ♂/♀	New contributed data

TABLE 109: Tween 80

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	IV, SC, IP	Single dose	Varies	Not tolerated in any significant amount; Hypersensitivity		New contributed data; Thackaberry ²²
	PO	Single dose	Varies	Poorly tolerated in significant amounts		New contributed data
	PO (gavage)	ADME	5 ml/kg/day	Well tolerated	0.1%	Gad et al. ¹
	PO (gavage)	90 days	Dose Vol 5 ml/kg, Daily dose 10 mg/kg (0.2% wt/vol)	Well tolerated	Dose concentration 2 mg/ml	Thackaberry ¹²²
Mouse	Intranasal	3 days	10 mL/nostril	Not toxic	0.2%	Gad et al. ¹
	IP	1 month	10 ml/kg	Not toxic	2% solution	Gad et al. ¹
	PO (gavage)	35 days	10 ml/kg BID	Distended abdomen, skin cold to the touch, feces few/absent, limb function impaired, head tilt, swollen abdomen, death; Vehicle was not tolerated following 35 days of daily administration	10% in distilled water; Age 6 weeks; ♂/♀	New contributed data
	PO (gavage)	90 days	Dose Vol 10 ml/kg, Daily dose 10 mg/kg (0.2% wt/vol)	Well tolerated	Dose concentration 1 mg/ml	Thackaberry ²²
Non-human Primate	PO (gavage)	Efficac.	5 ml/kg/day	Well tolerated	0.1%	Gad et al. ¹
	PO (gavage)	90 days	Dose Vol 5 ml/kg, Daily dose 10 mg/kg (0.2% wt/vol)	Well tolerated	Dose concentration 2 mg/ml	Thackaberry ¹⁷
Rat	IP	Efficac.	10 ml/kg/day	Well tolerated	0.2%	Contributed data, 2006
	IV	Acute	100 mg/kg	Not toxic		Gad et al. ¹
	PO	Acute	350 mg/kg	Not toxic		Gad et al. ¹
	PO	7 days	10 ml/kg	Not toxic	1% solution	Gad et al. ¹
	PO (dietary)		2% (1 g/kg)	NOAEL		Thackaberry ²²
	PO (gavage)	4 week	5 ml/kg/day	Well tolerated	0.1%	Gad et al. ¹

	PO (gavage)	90 days	Dose Vol 5 ml/kg, Daily dose 10 mg/kg (0.2% wt/vol)	Well tolerated	Dose concentration 2 mg/ml	Thackaberry ²²
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TABLE 110: Vitamin E TPGS

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (gavage)	32 days	5 ml/kg QD	None	20% in DI water; Age 5-5.5 months; ♂/♀	New contributed data
Rat	PO (gavage)	QD for 4 days then off for 4 days (x 5 cycles) for total of 32 days	10 ml/kg	None	20% in DI water; Age 6 Weeks; ♂/♀	New contributed data
	PO (gavage)	Single dose	10 ml/kg	None	10% Vitamin E TPGS in DI water; Age 6 weeks; ♂	New contributed data

TABLE 111: Water

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Dog	PO (gavage)	14 doses	10 ml/kg/dose	None	Distilled	Contributed data, 2006
	PO (gavage)	28 doses	5 ml/kg/day	None	Distilled	Contributed data, 2006
	PO (gavage)	30 doses	10 ml/kg	None	Distilled	Contributed data, 2006
	PO	9 months	0.052 ml/kg TID	None	GLP; Age 5-6 months; 6♂/6♀	New contributed data
Minipig	SC & IA	q7d x 3 wks for 90 days	12 ml total: 2 ml/site	None	GLP; Age 5-6 months; 4♂/4♀	New contributed data
Mouse	PO (gavage)	2 doses	20 ml/kg/day	None	Distilled	Contributed data, 2006
	PO (gavage)	28 doses	10 ml/kg	None	Deionized	Contributed data, 2006
Non-human Primate	PO (gavage)	14 doses	10 ml/kg	None	Sterile, USP	Contributed data, 2006
	PO (gavage)	28 doses	10 ml/kg	None	Deionized	Contributed data, 2006
Pig	Dermal	9 doses	10	None	Deionized	Contributed data, 2006

			ml/animal/day			
Rat	IV	11 doses	5 ml/kg	None	Sterile, USP	Contributed data, 2006
	IV (slow bolus)	4 doses	4 ml/kg	None	Sterile, USP	Contributed data, 2006
	PO (gavage)	Single dose	5 ml/kg	None	Sterile, USP	Contributed data, 2006
	PO (gavage)	Single dose	5 ml/kg	None	Deionized	Contributed data, 2006
	PO (gavage)	Single dose	10 ml/kg	None	Distilled	Contributed data, 2006
	PO (gavage)	Single dose	10 ml/kg	None	Deionized	Contributed data, 2006
	PO (gavage)	Single dose	10 ml/kg	None	Sterile, USP	Contributed data, 2006
	PO	Single dose	20 ml/kg	None	Sterile, USP	Contributed data, 2006
	PO (gavage)	5 doses	10 ml/kg	None	Deionized	Contributed data, 2006
	PO (gavage)	14 doses	5 ml/kg	None	Sterile, USP	Contributed data, 2006
	PO (gavage)	14 doses	10 ml/kg	None	Distilled	Contributed data, 2006
	PO (gavage)	14 doses	10 ml/kg	None	Sterile, USP	Contributed data, 2006
	PO	26 weeks	5 ml/kg TID	None	GLP; Age 6 weeks; 25♂/25♀	New contributed data
	PO (gavage)	28 doses	5 ml/kg	None	Deionized	Contributed data, 2006
	PO (gavage)	28 doses	10 ml/kg	None	Deionized	Contributed data, 2006
	PO (gavage)	30 doses	10 ml/kg	None	Distilled	Contributed data, 2006

TABLE 112: Xylitol

Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
Non-human Primate	Intranasal	1 month	Control and high dose of 1200 mL/day ; Intermediate dose of 400 mL/day ; Low dose of 200 mL/day	Well tolerated at 1200 mL/day	3.3% in water (w/v)	Gad et al. ¹

TABLE 113: Excipient Information

Excipient/Vehicle	Data in Table #(s)	CAS#	Synonyms	Formula	Key Toxicity Review Articles / Sources	Animal species evaluated	Administration routes evaluated
Acacia	5; 114	9000-01-5	Acaciae gummi	Natural product	Anderson DM ⁴² ; Bachmann ⁴³ ; TOXNET ⁴⁴	Non-Human Primate, Rat	PO
Acetate Buffer	114 (Comb. Only)	71-50-1	Acetate ion	C2-H3-O2	TOXNET ⁴⁵	Non-human Primate, Minipig, Mouse, Rat	IM, IV, PO
Acetic Acid	6; 114	64-19-7	Ethanoic Acid	C2H4O2	Schonwald ⁴⁶ ; Szilagyi ⁴⁷ ; TOXNET ⁴⁸	Dog, Mouse, Rat	IV, PO
Acetone	7; 114	67-64-1	2-Propanone	C3-H6-O	TOXNET ⁴⁹	Guinea Pig, Mouse, Rabbit, Rat	Dermal, PO
Acetonitrile	114 (Comb. Only)	75-05-8		C2-H3-N	TOXNET ⁵⁰	Dog	PO
Acetylated Lanolin Alcohol	114 (Comb. Only)	61788-49-6		N/A	TOXNET ⁵¹	Minipig	Topical
Acetyl methylamide	8	79-16-3	n-methylacetamide	C3H7NO	TOXNET ⁵²	Non-human primate	PO
Alcohol Denatured SDA	114 (Comb. Only)					Minipig	Topical
Alginic Acid	9	9005-32-7	Norgine		JECFA ⁵³ ; TOXNET ⁵⁴	Rat	IP
Anecortave Acetate	10	7753-60-8		C23H30OS	Jockovich et al ⁵⁵ ; Talsma ⁵⁶ ; TOXNET ⁵⁷	Rat	SC
Antifoam 1510-US	114 (Comb. Only)		Silicone emulsion		Dow Corning ⁵⁸	Rat	PO
Avicel CL-611	11		microcrystalline cellulose and carboxymethylcellulose sodium, NF, Ph. Eur		TOXNET ⁵⁹	Dog	PO
Balanced Salt Saline	12					Rabbit	Intravitreal

Basal Salt Solution	13					Mouse	Subretinal Injection
Benzoic Acid	14	65-85-0	Benzoic Acid	C7H6O2	David et al ⁶⁰ ; Nair ⁶¹ ; TOXNET ⁶²	Rat	PO
Benzyl Alcohol	114 (Comb. Only)	100-51-6		C7-H8-O	Nair ⁶¹ ; TOXNET ⁶³	Cat, Dog, Non-Human Primate, Rat	IV, PO, Topical
Beta-Cyclodextrin	15	7585-39-9	Beta-Dextrin; Betadex	C42H70O35	Albers & Muller ⁶⁴ ; Challa et al ⁶⁵ ; Marttin et al ⁶⁶ ; Rajewski et al ⁶⁷ ; TOXNET ⁶⁸ ; Toyoda et al ⁶⁹ ; Waner et al ⁷⁰	Dog, Mouse, Non-Human Primate, Rat	IP, IV, PO
BHA	114 (Comb. Only)	25013-16-5	Butylated hydroxyanisole	C11-H16-O2	TOXNET ⁷¹	Minipig	Topical
BHT	114 (Comb. Only)	128-37-0	Butylated Hydroxytoluene	C15H24O	Briggs et al ⁷² ; Lanigan & Yamarik ⁷³ ; Nakagawa et al ⁷⁴ ; TOXNET ⁷⁵	Cat, Dog, Minipig, Mouse, Rat	IV, PO, Topical
Bicarbonate Buffer	16	71-52-3	Bicarbonate ion	C-H-O3	TOXNET ⁷⁶	Mouse	PO
Calcium Chloride	17	10035-04-8		Ca-Cl2.2H2-O	TOXNET ⁷⁷	Mouse	IV, SC
Canola Oil	18	120962-03-0	Canbra oil	Natural product	Evangelista et al ⁷⁸ ; TOXNET ⁷⁹	Dog	PO
Capmul MCM	114 (Comb. Only)	26402-22-2, 26402-26-6	Medium Chain Mono- and Diglycerides	N/A	Susananta et al ⁸⁰	Non-human Primate	PO
Capmul MCM NF	114 (Comb. Only)	91744-32-0, 26402-22-2, 26402-26-6	Glyceryl Caprylate/Caprate	N/A		Dog, Rat	PO
Capryol 90	19	31565-12-5	Propylene glycol monocaprylate (type II) NF; Capmul PG-8	C11H22O3	Li et al ⁸¹ ; Cho et al ⁸²	Dog, Rabbit, Rat	Dermal, Ocular, PO
Captisol	20; 114	182410-00-0	Beta-cyclodextrin sulfobutyl ether, sodium salt (CDSBE)	C42H70-nO35 * (C4H8SO3Na)n	Albers & Muller ⁶⁴ ; Challa et al ⁶⁵ ; Marttin et al ⁶⁶ ; TOXNET ⁸³	Dog, Mouse, Non-human Primate, Rat,	IV, PO, SC
Carbomer 974P	114 (Comb. Only)	151687-96-6	Carbomer homopolymer type B (allyl pentaerythritol crosslinked)	N/A	TOXNET ⁸⁴	Minipig, Mouse	Topical
Carbopol Ultrez 10	114 (Comb. Only)	195739-91-4		N/A	TOXNET ⁸⁵	Minipig	Topical

Carboxymethylcellulose	21; 114	9000-11-7	CMC; acetic acid; 2,3,4,5,6-pentahydroxyhexanal	N/A	Gupta et al ⁸⁶ ; Mehlman ⁸⁷ ; TOXNET ⁸⁸	Dog, Minipig, Mouse, Non-Human Primate, Rabbit, Rat	IA, PO, SC
Carboxymethylcellulose Calcium	22	9050_04_8	Calcium CMC; Carmellose Calcium	N/A	TOXNET ⁸⁹	Dog	PO
Carboxymethylcellulose Sodium	23; 114	9004-32-4	Sodium CMC; Carmellose Sodium	N/A	Bachmann et al ⁴³ ; Bar et al ⁹⁰ ; Cavender ⁹¹ ; Freeman et al ⁹² ; TOXNET ⁹³	Mouse, Rabbit, Rat	PO
Cetostearyl Alcohol	114 (Comb. Only)	67762-27-0		N/A	TOXNET ⁹⁴	Minipig	Topical
Cetyl Acetate	114 (Comb. Only)	629-70-9		C18-H36-O2	TOXNET ⁹⁵	Minipig	Topical
Cetyl Alcohol	24; 114	36653-82-4	Hexadecan-1-ol; 1-Hexadecanol	C16H34O1	Bevan ⁹⁶ ; TOXNET ⁹⁷	Minipig, Mouse	IP, Topical
Citrate Buffer	25; 114	77-92-9	Sodium citrate-citric acid buffer	C6-H8-O7	Schonwald ⁹⁸	Dog, Non-human Primate, Rat	IV, PO, SC
Citric Acid Buffer	26	77-92-9		C6H8O7*H2O	Szilagy ⁹⁹	Mouse, Non-human Primate, Rat	PO
Coconut Oil	114 (Comb. Only)	8001-31-8		Natural product	National Toxicology Program ¹⁰⁰ ; Shadnia et al ¹⁰¹ ; TOXNET ¹⁰²	Minipig	Topical
Collagen Matrix	27	9007-34-5	Collagen Human	Natural product	McCarthy et al ¹⁰³ ; Clark et al ¹⁰⁴	Non-Human Primate, Rabbit	Implantation in humerus bone, Implantation
Corn oil	28; 114	8001-30-7	corn germ oil, glyceridic	Natural product	DeWitt et al ¹⁰⁵ ; Dupont et al ¹⁰⁶ ; TOXNET ¹⁰⁷ ; Wu et al ¹⁰⁸	Chicken Embryo, Dog, Mouse, Non-human Primate, Rabbit, Rat	injection into egg, PO
Cottonseed Oil	29	8001-29-4		Natural product	TOXNET ¹⁰⁹	Dog	SC
Cyclodextrin	114 (Comb. Only)	12619-70-4			TOXNET ¹¹⁰	Rat	PO
Cyclohexane	30; 114	110-82-7	Hexahydrobenzene; hexamethylene; Hexanaphthene	C6H12	Gad ¹¹¹ ; Kreckmann et al ¹¹² ; Malley et al ¹¹³ ; TOXNET ¹¹⁴	Rabbit, Rat	PO, Dermal

Cyclomethicone NF	114 (Comb. Only)	69430-24-6		N/A	TOXNET ¹¹⁵	Minipig	Topical
DAM	114 (Comb. Only)	57-71-6	Diacyetylmonoxime; 2,3-Butanedione 2-oxime	C4-H7-N-O2	TOXNET ¹¹⁶	Dog, Rat	IV
Dextrose	31; 114	50-99-7	Glucose; D-glucose, anhydrous; dextrosol	C6H12O6	Buard et al ¹¹⁷ , Robertson et al ¹¹⁸ , TOXNET ¹¹⁹	Cat, Dog, Minipig, Non-Human Primate, Rabbit, Rat	IV, IV/PO, Perivascular, PO, SC
Dichlorvos	32	62-73-7	DDVP; Dichlorophos; Dichlorphos; Divipan; 2,2-dichloroethyl methyl phosphate	C4H7Cl2O4P	TOXNET ¹²⁰	Non-human Primate	IV
Diethylacetamide	33; 114	685-91-6	N,N-Diethylacetamide	C6-H13-N-O	Budden et al ¹⁶ , Caujolle et al ¹⁷ , TOXNET ¹²¹	Cat, Chicken, Dog, Mouse, Rabbit, Rat	IP, IV
Diethyleneglycol-monoethyl ether	34	111-90-0	2-(2-Ethoxyethoxy)ethanol; Carbitol	C6-H14-O3	Hardin ¹²² , Hardin et al ¹²³ , TOXNET ¹²⁴	Non-Human Primate	IV
Dimethicone	114 (Comb. Only)	9006-65-9		N/A	TOXNET ¹²⁵	Rabbit	PO
Dimethiconol Blend 20	114 (Comb. Only)	70131-67-8 and 63148-62-9	Dimethicone and Dimethiconol		Dow Corning ¹²⁶	Minipig	Topical
Dimethyl acetamide	35; 114	127-19-5	DMA; N,N-Dimethylacetamide; Acetdimethylamide	C4-H9-N-O	TOXNET ¹²⁷	Chicken, Dog, Mouse, Rabbit, Rat	Dermal, Inhalation, IP, IV, PO
Dimethylsulfoxide	36; 114	67-68-5	DMSO	C2H6OS	Ali ¹²⁸ , Augustine et al ¹²⁹ , Bartsch et al ³³ , Pestel et al ¹³⁰ , PharmPK ¹³¹ , RTECS ¹³² , Ruble et al ¹³³ , Schonwald ⁴⁶ , Sodicoff et al ¹³⁴ , TOXNET ¹³⁵ , White et al ¹³⁶ , Wood et al ¹³⁷	Dog, Guinea Pig, Minipig, Mouse, Non-Human Primate, Rabbit, Rat	IP, IV, PO, SC
Di-sodium hydrogen phosphate dihydrate	114 (Comb. Only)	10140-65-5	Sodium phosphate, dibasic	H3-O4-P.x-H2-O.2Na	TOXNET ¹³⁸	Non-human Primate	SC
Docosanol	114 (Comb. Only)	661-19-8	1-Docosanol	C22-H46-O	TOXNET ¹³⁹	Minipig	Topical

Dulbecco's modified PBS	37					Rat	IV (tail vein)
Dulbecco's PBS	38					Rat	PO
EDTA	114 (Comb. Only)	60-00-4	Ethylenediamineetraacetic acid; Edetic Acid	C10-H16-N2-O8	Cavender ¹⁴⁰ , Heimbach et al ¹⁴¹ , Lanigan & Yamarik ¹⁴² , TOXNET ¹⁴³	Minipig, Non-human Primate, Rat	IV, Topical
Ethanol	39; 114	64-17-5	Ethyl Alcohol	C2H6O	Bartsch et al ³³ , Bevan ¹⁴⁴ , Church & Witting ¹⁴⁵ , Fort et al ¹⁴⁶ , Moorman et al ¹⁴⁷ , Rowe et al ¹⁴⁸ , Ruble et al ¹³³ , Sivilotti ¹⁴⁹ , TOXNET ¹⁵⁰	Dog, Minipig, Mouse, Non-Human Primate, Rat	Dermal, IP, IV, PO, SC, Topical
Fumaric Acid	114 (Comb. Only)	110-17-8	2-Butenedioic acid	C4-H4-O4	TOXNET ¹⁵¹	Dog	PO
Gelatin	40; 114	9000-70-8			TOXNET ¹⁵²	Dog, Non-human Primate	PO
Gelatin Phosphate Buffer	41					Minipig	Topical
Gelucire 44/14	42; 114	121548-04-7	PEG-32 glyceryl laurate		Cavender ¹⁵³ , Dordunoos et al ¹⁵⁴ , Kawakami et al ¹⁵⁵ , Ratsimbazafy et al ¹⁵⁶ , TOXNET ¹⁵⁷ , Working et al ¹⁵⁸	Dog, Minipig, Mouse Rabbit, Rat	Dermal, Ocular, PO
Gelucire 50/13	43	121548-05-8	G-50-13		Fini et al ¹⁵⁹ , Passerini et al ¹⁶⁰ , Ratsimbazafy et al ¹⁵⁶ , Sharma ¹⁶¹ , TOXNET ¹⁶²	Rat	PO
Gluconic Acid	44	133-42-6		C6-H12-O7	TOXNET ¹⁶³	Dog, Rat	PO
Glycerol	45; 114	56-81-5	Glycerine; Glycerin	C3H8O3	Anderson et al ¹⁶⁴ , Bartsch et al ³³ , Cosmetic Ingredient Review ¹⁶⁵ , TOXNET ¹⁶⁶	Dog, Guinea Pig, Mouse, Non-human Primate, Rabbit, Rat	IP, IV, PO, SC, Topical

Glyceryl Stearate SE	114 (Comb. Only)	11099-07-3		C18-H36-O2.x-C3-H8-O3	Cosmetic Ingredient Review ¹⁶⁵	Minipig	Topical
Glycofurol	46	31692-85-0		(C2-H4-O)mult-C5-H10-O2	Ruble et al ¹³³ , TOXNET ¹⁶⁷	Dog	IV
Glycol Dimethacrylate Cross Polymer	114 (Comb. Only)					Rat	Topical
Gum Tragacanth	47	9000-65-1		Natural product	Anderson DM ¹⁶⁸ , Bachmann et al ⁴³ , Hagiwara et al ¹⁶⁹ , TOXNET ¹⁷⁰	Mouse	PO
Gum Xanthane	48; 114	11138-66-2	Keltrol	(C ₃₅ H ₄₉ O ₂₉) _n	TOXNET ¹⁷¹	Minipig, Rabbit, Rat	PO, Topical
Hexylene Glycol	114 (Comb. Only)	107-41-5		C6-H14-O2		Minipig	Topical
Histidine	114 (Comb. Only)	71-00-1		C6-H9-N3-O2	TOXNET ¹⁷²	Dog, Rat	IV, SC
Hydrochloric Acid	49	7647-01-0	Hydrogen chloride; Muriatic acid; Chlorohydric acid; Chlorane	HCl	TOXNET ¹⁷³	Dog, Rat	PO
Hydrogenated Castor Oil	114 (Comb. Only)	8001-78-3			TOXNET ¹⁷⁴	Minipig	Topical
Hydroxyethylcellulose	50; 114	9004-62-0	Natrosol; 2-Hydroxyethyl Ether Cellulose		Pestel et al ¹³⁰ , TOXNET ¹⁷⁵	Rat	PO
Hydroxypropyl Beta-Cyclodextrin	51; 114	128446-35-5	2-hydroxypropyl Beta-Cyclodextrin, HPβCD; Hydroxypropyl Betadex; Cavasol W7 HP	C54H102O39	Albers & Muller ⁶⁴ , Challa et al ⁶⁵ , Coussement et al ¹⁷⁶ , Gerloczy et al ¹⁷⁷ , Gould & Scott ¹⁷⁸ , Marttin et.al ⁶⁶ , Pestel et al ¹³⁰ , Ruble et al ¹³³ , Thackaberry et al ²² , TOXNET ¹⁷⁹	Dog, Mouse, Non-human Primate, Rabbit, Rat,	Intra-nasal, IP, IV, PO, SC

Hydroxypropyl Cellulose	52; 114	9004-64-2	Hyprolose (INN), 2-Hydroxypropyl Cellulose	N/A	Cavender ¹⁸⁰ ; TOXNET ¹⁸¹	Minipig, Rat	PO, Topical
Hydroxypropyl methylcellulose	53; 114	9004-65-3	Benecel MHPG, Hypromellose, HPMC; Methocel E50 Premium LV	N/A	Feitoza et al ¹⁸² ; Geerling et al ¹⁸³ ; Maki et al ¹⁸⁴ ; Mehlman ¹⁸⁵ ; Obara et al ¹⁸⁶ ; Rosen et al ¹⁸⁷ ; Thackaberry et al ²² ; TOXNET ¹⁸⁸	Dog, Minipig, Mouse, Non-human Primate, Rat	IP, PO
Hydroxypropyl Methylcellulose Acetate Succinate	114 (Comb. Only)	71138-97-1	Hypromellose Acetate Succinate; HPMC AS	N/A	TOXNET ¹⁸⁹	Dog, Minipig, Mouse, Rabbit, Rat	PO
Hymetellose	114 (Comb. Only)	9032-42-2	Methyl hydroxyethylcellulose; Tylose MH50	N/A	TOXNET ¹⁹⁰	Rabbit	PO
Hypotonic PBS	54					Dog, Rat	IV
Imwitor 742	114 (Comb. Only)		Caprylic / Capric Glycerides; Glyceryl Monocaprylocaprate, Type 1		Susananta et al ⁸⁰	Hamster, Non-human Primate, Rat	PO
Isopropyl Alcohol	55	67-63-0	2-propanol; Isopropanol; sec-propyl Alcohol	C3H8O	Allen et al ¹⁹¹ ; Bevan C ¹⁹² ; Burleigh-Flayer H ¹⁹³ ; Church and Witting ¹⁴⁵ ; Sivilotti ¹⁴⁹ ; TOXNET ¹⁹⁴ ; Tyl et.al ¹⁹⁵	Rabbit	Dermal
Isopropyl Myristate	56; 114	110-27-0	1-Methylethyl tetradecanoate; Crodamol IPM	C17H34O2	Campbell & Bruce ¹⁹⁶ ; Komatsu et al ¹⁹⁷ ; TOXNET ¹⁹⁸	Minipig, Rabbit	Dermal, Topical
Isotonic Saline	114 (Comb. Only)					Rat	PO
Kolliphor	114 (Comb. Only)		Cremophor; Polyoxyn castor oil			Non-human Primate	IV, PO

Kolliphor EL	57; 114	61791-12-6	Cremophor EL; Polyoxyal castor oil; Polyoxyal 35 castor oil	n/a	Gelderblom et al ¹⁹⁹ ; Gupta et al ⁸⁶ ; Lorenz et. al ²⁰⁰ ; PharmPK ²⁰¹ ; Ramadan et al ²⁰² ; Stokes et al ²⁰³ ; TOXNET ²⁰⁴	Dog, Mouse, Non-human Primate, Rat	IV, PO
Kolliphor ELP	58	61791-12-6	Cremophor EL; Polyoxyal castor oil; Polyoxyal 35 castor oil	n/a	TOXNET ²⁰⁴	Dog	
Kolliphor RH40	59; 114	61788-85-0	Cremophor RH40; PEG-40 Hydrogenated Castor Oil; Polyoxyal 40 Hydrogenated Castor Oil; Macrogolglycerol Hydroxystearate	n/a	Gupta et al ⁸⁶ ; Stokes et al ²⁰³ ; TOXNET ²⁰⁵	Dog, Rat	IV, PO
Labrafil M1944	60; 114	62563-68-2	Labrafil	n/a	Beckwith-Hall et al ²⁰⁶ ; TOXNET ²⁰⁷	Dog, Rabbit, Rat	Dermal, PO
Labrasol	61; 114	85536-07-8	Polyglycolyzed Glycerides	n/a	Hu et al ²⁰⁸ ; Hu et al ²⁰⁹	Dog, Minipig, Rabbit, Rat	Dermal, IV, Ocular, PO
Lactated Ringer's	114 (Comb. Only)	8026-79-7	Sodium chloride, sodium lactate, potassium chloride and calcium chloride; Compound sodium lactate injection	C3-H6-O3.Ca-Cl2.Cl-K.Na	TOXNET ²¹⁰	Non-human Primate	IV
Lactic Acid	114 (Comb. Only)	50-21-5	2-Hydroxypropanoic acid	C3-H6-O3	TOXNET ²¹¹	Dog, Rat	IA, IV
Lactose	62; 114	63-42-3(anhy)	O-β-D-Galactopyranosyl-(1->4)-α-Dglucopyranose	C12H22O11 (anhy)	Ahmad et al ²¹² ; Baldrick and Bamford ²¹³ ; TOXNET ²¹⁴	Dog, Non-human Primate, Rat	Inhalation, IV, SC
Lanolin	63; 114	8006-54-0	Wool wax	n/a	Kligman ²¹⁵ ; TOXNET ²¹⁶	Minipig, Rabbit	Dermal, Topical
Lanolin Alcohol NF	114	8027-33-6	Eucerin	Natural product	TOXNET ²¹⁷	Minipig	Topical
L-Arginine HCl USP	114 (Comb. Only)	15595-35-4	L-Arginine Hydrochloride	C6-H14-N4-O2.x-Cl-H	TOXNET ²¹⁸	Minipig, Non-human Primate	SC, Topical
L-Ascorbic Acid	114 (Comb. Only)	50-81-7	Cevatine, Cevex, Cevital	C6H8O6	Bendich and Cohen ²¹⁹ ; Dykes & Meier ²²⁰ ; Temple ²²¹ ; TOXNET ²²²	Rat	PO
Lauroglycol 90	64	27194-74-7	Propylene glycol monolaurate; Lauric acid, monoester with propane-1,2-diol	C15-H30-O3	Bartsch et al ³³ ; Liu H et al ²²³ ; TOXNET ²²⁴	Rabbit, Rat	Dermal, Ocular, PO
Maltitol Solution	65	9053-46-7	Liquid Maltitol; Lycasin	C12H24O11 + C6H14O6	Modderman ²²⁵ ; Walker and El Harith ²²⁶ ,	Rat	IP

					TOXNET ²²⁷		
Maltool	66	118-71-8	2-Methyl pyromeconic acid; 2-Methyl-3-hydroxy-4-pyrone	C6H6O3	Hironishi et al ²²⁸ ; Murakami et al ²²⁹ ; TOXNET ²³⁰	Guinea Pig, Rabbit	PO
Mannitol	67; 114	69-65-8	D-Mannitol	C6H14O6	Horvath et al ²³¹ ; Lina et al ²³² ; TOXNET ²³³	Minipig, Non-human Primate, Rabbit	IV, PO, SC
Methane Sulfonic Acid	114 (Comb. Only)	75-75-2	Methylsulfonic acid	CH4O3S	Shertzer ²³⁴ ; TOXNET ²³⁵	Rat	PO
Methocel	114 (Comb. Only)					Non-human Primate; Rat	PO
Methyl Methacrylate	114 (Comb. Only)	80-62-6		C5-H8-O2	TOXNET ²³⁶	Rat	Topical
Methylcellulose	68; 114	9004-67-5	Cellulose Methyl Ether; Methocel; Methocel A4M Premium	n/a	Bachmann et al ⁴³ ; Gupta et al ⁸⁶ ; Mehlman ²³⁷ ; Sellers et al ²³⁸ ; TOXNET ²³⁹	Dog, Guinea Pig, Mouse, Non-Human Primate, Rabbit, Rat	IV, PO, Topical
Methylparaben	114 (Comb. Only)	99-76-3	4-Hydroxybenzoic acid, methyl ester	C8-H8-O3	TOXNET ²⁴⁰	Minipig	SC, Topical
Methylpyrrolidone	69	872-50-4	N-methyl-2-pyrrolidone, 1-methyl-2-pyrrolidone, Pharmasolv, NMP	C5H9NO	Bartsch et al ³³ ; Kennedy ²⁴¹ ; Lee KP et al ²⁴² ; Ruble et al ¹³³ ; Solomon et al ²⁴³ ; TOXNET ²⁴⁴	Dog, Mouse	IV
Miglyol 810		85409-09-2	caprylic, capric triglycerides	n/a	Sellers et al ²³⁸ ; Susananta et al ⁸⁰ ; TOXNET ²⁴⁵ ; Traul et al ²⁴⁶		
Mineral Oil	70; 114	8012-95-1	Liquid paraffin	Natural product	Carlton et al ²⁴⁷ ; Dalbey and Biles ²⁴⁸ ; Nash et al ²⁴⁹ ; TOXNET ²⁵⁰ ; Trimmer et al ²⁵¹	Cat, Dog, Guinea pig, Minipig, Mouse, Rat	PO, Topical
Myristyl Alcohol	114 (Comb. Only)	112-72-1	1-Tetradecanol	C14-H30-O	TOXNET ²⁵²	Minipig	Topical
Neobee 1053 oil	114 (Comb. Only)	73398-61-5	Medium Chain Triglycerides	n/a	Bellantone ²⁵³ ; Susananta et al ⁸⁰ ; Wieland et al ²⁵⁴	Mouse, Rat	IV, PO

Octoxynol-40	114 (Comb. Only)	9002-93-1		(C2-H4-O)mult-.C14-H22-O (C2-H4-O)mult-C14-H22-O C34-H62-O11	TOXNET ²⁵³	Dog, Rabbit	Ocular
Oleic Acid NF	114 (Comb. Only)	112-80-1	9-Octadecenoic acid	C18-H34-O2	TOXNET ²⁵⁶	Minipig	Topical
Oleyl Alcohol NF	114 (Comb. Only)	143-28-2		C18-H36-O	TOXNET ²⁵⁷	Minipig	Topical
Olive Oil	71; 114	8001-25-0		Natural product	Evangelista et al ⁷⁸ ; TOXNET ²⁵⁸	Minipig, Rat	PO, Topical
OraPlus suspension	114 (Comb. Only)		Purified water, microcrystalline cellulose, carboxymethylcellulose sodium, xanthan gum, carrageenan, calcium sulfate, trisodium phosphate, citric acid and sodium phosphate as buffers, dimethicone antifoam emulsion. Preserved with methylparaben and potassium sorbate.		Paddock ²⁵⁹	Rat	PO
Panthenol	114 (Comb. Only)	16485-10-2	Dexpanthenol	C9-H19-N-O4	TOXNET ²⁶⁰	Minipig	Topical
Peanut Oil	72; 114	8002-03-7	Arachis oil; Fletcher's	Natural product	Cosmetic Ingredient Review ²⁶¹ . Patel et al ²⁶² ; TOXNET ²⁶³	Dog, Rat	PO, SC
Peceol	114 (Comb. Only)	25496-72-4	Glyceryl monooleate NF; Monoolein	C21-H40-O4	TOXNET ²⁶⁴	Dog, Rat	PO
PEG 1000	78	25322-68-3	Polyethylene glycol 1000	(C2-H4-O)mult-H2-O	Shideman & Procita ³⁴ ; Smyth et al ²⁶ ; TOXNET ²⁶⁵	Mouse, Rabbit, Rat	IP, IV, PO
PEG 10000	83	25322-68-3	Polyethylene glycol 10000	(C2-H4-O)mult-H2-O	Smyth et al ²⁶ ; TOXNET ²⁶⁵	Rat	IP, PO

PEG 1500	79	25322-68-3	Polyethylene glycol 1500	(C ₂ -H ₄ -O)mult-H ₂ -O	Rowe & Wolf ³¹ ; Smyth et al ⁴⁸ ; Smyth et al ²⁶ ; Smyth et al ³⁷ ; Smyth et al ²⁸ ; TOXNET ²⁶⁵	Rat	IP, iV, PO
PEG 1540	80	25322-68-3	Polyethylene glycol 1540	(C ₂ -H ₄ -O)mult-H ₂ -O	Smyth et al ²⁶ ; Smyth et al ²⁸ ; TOXNET ²⁶⁵	Dog, Rabbit, Rat	IP, IV, PO
PEG 200	73; 114	25322-68-3	Polyethylene glycol 200	(C ₂ -H ₄ -O)mult-H ₂ -O	Cavender ¹⁵² ; Dordunoos et al ¹⁵⁴ ; Smyth et al ²⁹ ; Smyth et al ²⁶ ; Smyth et al ²⁸ ; Quadbeck ²⁷ ; TOXNET ²⁶⁵ ; Working et al ¹⁵⁸	Non-human Primate, Rabbit, Rat	IP, IV, PO
PEG 300	74; 114	25322-68-3	Polyethylene glycol 300	(C ₂ -H ₄ -O)mult-H ₂ -O	Carpenter & Shaffer ³⁰ ; Cavender ¹⁵³ ; Dordunoos et al ¹⁵⁴ ; Patel et al ²⁶² ; Rowe & Wolf ³¹ ; Smyth et al ²⁹ ; Smyth et al ²⁶ ; Smyth et al ²⁸ ; TOXNET ²⁶⁵ ; Working et al ¹⁵⁸	Cat, Dog, Guinea pig, Mouse, Rabbit, Rat	IP, IV, PO, PO Mucosa
PEG 400	75; 114	25322-68-3	Polyethylene glycol 400	(C ₂ -H ₄ -O)mult-H ₂ -O	Bartsch et al ³³ ; Cavender ¹⁵³ ; Dordunoos et al ¹⁵⁴ ; Fort et al ¹⁴⁶ ; Gupta et al ⁸⁶ ; Gutiérrez-Cabano ²⁶⁶ ; Hermansky et.al. ²⁶⁷ ; Li et al ³² ; Patel et al ²⁶² ; Rowe & Wolf ³¹ ; Ruble et al ¹³³ ; Shideman & Procita ³⁴ ; Smyth et al ²⁹ ;	Dog, Guinea Pig, Minipig, Mouse, Non-human Primate, Minipig, Rabbit Rat	Dermal, IP, IV, PO, Topical

					Smyth et al ²⁶ ; Smyth et al ²⁸ ; Stokes et al ²⁰³ ; Strickley ¹¹ ; Thackaberry ²⁰ ; TOXNET ²⁶⁵ ; Working et al ¹⁵⁸		
PEG 4000	81; 114	25322-68-3	Polyethylene glycol 4000	(C ₂ -H ₄ -O)mult-H ₂ -O	Rowe & Wolf ³¹ ; Shideman & Procita ³⁴ ; Smyth et al ³⁷ ; Smyth et al ³⁸ ; Smyth et al ²⁶ ; Smyth et al ²⁸ ; TOXNET ²⁶⁵	Dog, Mouse, Rabbit, Rat	IP, IV, PO
PEG 400000	84	25322-68-3	Polyethylene glycol 400000	(C ₂ -H ₄ -O)mult-H ₂ -O	Smyth et al ²⁶ ; Smyth et al ³⁹ ; TOXNET ²⁶⁵	Rat	IV, PO
PEG 600	76	25322-68-3	Polyethylene glycol 600	(C ₂ -H ₄ -O)mult-H ₂ -O	Pfordte ³⁵ ; Rowe & Wolf ³¹ ; Smyth et al ²⁸ ; TOXNET ²⁶⁵	Rat	IP, IV, PO
PEG 6000	82	25322-68-3	Polyethylene glycol 6000	(C ₂ -H ₄ -O)mult-H ₂ -O	Smyth et al ²⁶ ; Smyth et al ²⁸ ; TOXNET ²⁶⁵	Rabbit, Rat	IP, IV, PO
PEG 810	77	25322-68-3	Polyethylene glycol 810	(C ₂ -H ₄ -O)mult-H ₂ -O	Käber ³⁶ ; TOXNET ²⁶⁰	Rat	IV, SC
Petrolatum	85	8009-03-8	Yellow soft paraffin; Petroleum Jelly	n/a	TOXNET ²⁶⁸	Rabbit	Dermal
Phenoxyethanol	114 (Comb. Only)	122-99-6	2-Phenoxyethanol	C8-H10-O2	TOXNET ²⁶⁹	Minipig, Mouse	Topical
Phosal 53 MCT	114 (Comb. Only)		Lecithin in caprylic/capric triglycerides, alcohol, glyceryl stearate, oleic acid and ascorbyl palmitate		American Lecithin ²⁷⁰ ; Susananta et al ⁸⁰	Rat	PO
Phosphate	114 (Comb. Only)	14265-44-2	Phosphate ion	O4-P	TOXNET ²⁷¹	Non-human Primate, Rat	IV, SC
Phosphate Buffered Saline	86; 114		PBS			Dog, Minipig, Mouse, Non-human primate, Rabbit, Rat	IA, IV, PO, SC, Topical
Polawax	114 (Comb. Only)		Emulsifying wax		Carlton et al ²⁴⁷	Minipig, Mouse	Topical

Poloxamer	87; 114	9003-11-6	Poloxamer 188; Poloxamer 124; Poloxalene	(C3-H6-O-C2-H4-O)x-	Benita ²⁷² Curry et al ²⁷³ ; Frim et al ²⁷⁴ ; Grindel et al ²⁷⁵ ; Lemieux et al ²⁷⁶ ; Serbest et al ²⁷⁷ ; TOXNET ²⁷⁸	Dog, Minipig, Mouse, Non-human Primate, Rabbit, Rat	PO, SC
Poly(glycolide-co-dl-lactide) microspheres	88	26780-50-7				Dog	Into periodontal pockets
Polyglyceryl Oleate	89	9007-48-1	1,2,3-propanetriol, homopolymer, (Z)-9-octadecenoate; Decaglyceryl monooleate	C18-H34-O2.x-(C3H8-O3)x-	TOXNET ²⁷⁹	Rabbit, Rat	Dermal, Ocular, PO
Polyvinylpyrrolidone	90; 114	9003-39-8	Povidone; PVP; PVP K30	(C6-H9-N-O)x-	Beiji et al ²⁸⁰ ; PharmPK ²⁰¹ ; TOXNET ²⁸¹	Dog, Non-human Primate, Rabbit, Rat	IM, PO
Potassium Chloride	114 (Comb. Only)	7447-40-7	KCl	KCl	TOXNET ²⁸²	Minipig	Topical
Propylene glycol	91; 114	57-55-6	1,2-Dihydroxypropane	C3H8O2	Cavender FL ²⁸³ ; Fort et al ¹⁴⁶ ; Cosmetic Ingredient Review ²⁸⁴ ; Ruble et al ¹³³ ; Thackaberry et al ²² ; TOXNET ²²⁴	Dog, Minipig, Guinea pig, Non-human Primate, Mouse, Rabbit, Rat	Dermal, IP, IV, PO, SC, Topical
Propylene Glycol Dicaprylate/Dicaprate	114 (Comb. Only)	68583-51-7	Caprylic, capric acid, propylene glycol diester	C10-H20-O2.C8-H16-O2.C3-H8-O2	Cosmetic Ingredient Review ²⁸⁴ ; TOXNET ²⁸⁵	Rat	Topical
Propylparaben	114 (Comb. Only)	94-13-3	4-Hydroxybenzoic acid, propyl ester	C10-H12-O3	TOXNET ²⁸⁶	Minipig	SC, Topical
PVP VA 64	114 (Comb. Only)	25086-89-9	Vinylpyrrolidone-vinyl acetate copolymer; Copovidone; PVP VA	(C6-H9-N-O-C4-H6-O2)x-	TOXNET ²⁸⁷	Dog, Rat	PO
RAMEB	92		Randomly Methylated-beta-cyclodextrins		Challa et al ⁶⁵	Non-human Primate	Intranasal
Safflower Oil	93	8001-23-8	Carthamus tinctorius oil	Natural product	TOXNET ²⁸⁸	Dog	SC
Salicylic Acid	114 (Comb. Only)	69-72-7	Benzoic acid, 2-hydroxy-	C7-H6-O3	TOXNET ²⁸⁹	Minipig	Topical
Saline (pH adjusted, pH 4.5)	94					Mouse	IM
Sesame Oil	95; 114	8008-74-0	Gingilli oil	Natural product	Farber et al ²⁹⁰ ; Genovese et al ²⁹¹ ; Prasamthi et al ²⁹² ;	Dog, Mouse, Rabbit, Rat	PO

					TOXNET ²⁹³		
Shea Butter	114 (Comb. Only)	194043-92-0		Natural product	TOXNET ²⁹⁴	Minipig	Topical
Simethicone	114 (Comb. Only)	8050-81-5	Silicone antifoam agent S 184; Gas-x	N/A	TOXNET ²⁹⁵	Rat	PO
Sodium Acetate	114 (Comb. Only)	127-09-3	Acetic Acid Sodium Salt	C2H3NaO2	TOXNET ²⁹⁶	Dog, Mouse, Non-human Primate, Rat	IV, PO, SC
Sodium acetate trihydrate buffer	96; 114	6131-90-4				Mouse, Non-human Primate	IV, PO
Sodium Chloride	97; 114	7467-14-5	Salt; Saline; Halite	NaCl	Barrie et al ²⁹⁷ ; Caraccio et al ²⁹⁸ ; Meneely et al ²⁹⁹ ; Meneely et al ³⁰⁰ ; Moore et al ³⁰¹	Cat, Dog, Minipig, Mouse, Non-human Primate, Rabbit, Rat	ID, IM, IV, Ocular, Perivascular, PO, SC, Topical
Sodium Citrate	114 (Comb. Only)	994-36-5		C6-H8-O7.x-Na	TOXNET ³⁰²	Non-human Primate, Rat	IV, PO
Sodium Dihydrogen Phosphate Dihydrate	98; 114	13472-35-0	Sodium phosphate, monobasic, dihydrate	H2-O4-P.Na.2H2-O	TOXNET ³⁰³	Mouse, Non-human Primate	PO, SC
Sodium Hydroxide	114 (Comb. Only)	1310-73-2	Caustic soda	NaOH	TOXNET ³⁰⁴	Minipig, Mouse, Non-human Primate, Rat	IV, SC, Topical
Sodium lauryl sulfate	114 (Comb. Only)	151-21-3	Sodium dodecyl sulfate	C12-H26-O4-S.Na	TOXNET ³⁰⁵	Dog, Rat	PO
Sodium Metabisulfite	99	7681-57-4			TOXNET ³⁰⁶	Mouse, Non-human Primate, Rat	PO
Sodium Methylparaben	114 (Comb. Only)	5026-62-0	Benzoic acid, 4-hydroxy-, methyl ester, sodium salt	C8-H7-Na-O3	TOXNET ³⁰⁶⁷	Minipig, Mouse, Rat	PO, Topical
Sodium Phosphate Buffer	100; 114	7558-80-7			Jefferson ³⁰⁸ ; Moore et al ³⁰¹ ; TOXNET ³⁰⁹	Dog, Mouse, Non-human Primate, Rat	IV, PO
Sodium Propylparaben	114 (Comb. Only)	35285-69-9	4-Hydroxybenzoic acid, propyl ester, sodium salt	C10-H11-Na-O3	TOXNET ³¹⁰	Mouse, Rat	PO
Sodium Succinate	114 (Comb. Only)	150-90-3	Succinic Acid Sodium Salt; Succinic Acid; Disodium butanedioate	C4H4Na2O4	Szilagyi ³¹¹ ; TOXNET ³¹²	Dog, Mouse, Rat	IV, SC
Sodium Sulfite	101	7757-83-7	Sulfurous acid, disodium salt	H2-O3-S.2Na O3-S.2Na	TOXNET ³¹³	Rabbit	Ocular (Topical)
Solutol® HS15	102; 114	61909-81-7	Polyethylene glycol-15-hydroxystearate; Polyethylene glycol 660	(C2-H4-O)mult-.C18-H36-O3	Cavender ¹⁵³ ; Coon et al ³¹⁴ ; Dordunoos et al ¹⁵⁴ ,	Dog, Mouse, Rat	IV, IP, PO, Any

			hydroxy stearate		Ruchatz ³¹⁵ , Stokes et al ²⁰³ , TOXNET ³¹⁶		
Sorbitan Tristearate	114 (Comb. Only)	26658-19-5	Sorbitan, trioctadecanoate	C60-H114-O8	Lanigan & Yamarik ³¹⁷ TOXNET ³¹⁸	Minipig	Topical
Sorbitol	114 (Comb. Only)	50-70-4	D-Sorbitol	C6-H14-O6	TOXNET ³¹⁹	Dog, Non-human Primate, Rat	IV
Soybean Oil	114 (Comb. Only)	8001-22-7		Natural product	Farber et al ²⁹⁰ , TOXNET ³²⁰	Minipig	Topical
Squalene NF	114 (Comb. Only)	111-02-4		C30-H50	TOXNET ³²¹	Minipig	Topical
Stearic Acid	114 (Comb. Only)	57-11-4	n-Octadecanoic acid	C18-H36-O2	TOXNET ³²²	Minipig	Topical
Stearyl Alcohol	114 (Comb. Only)	112-92-5	1-Octadecanol	C18-H38-O	TOXNET ³²³	Minipig	Topical
Sucrose	114 (Comb. Only)	57-50-1	Sugar	C12-H22-O11	TOXNET ³²⁴	Cat, Dog, Non- human Primate, Rabbit, Rat	IV, PO mucosa, PO, SC
Sucrose Acetate Isobutyrate	114 (Comb. Only)	27216-37-1	SAIB	C40-H62-O19	TOXNET ³²⁵	Cat	PO Mucosa
Sulfobutylether β - cyclodextrin	103	182410-00-0	SBEDC	N/A	Albers and Muller ⁶⁴ , Challa et al ⁶⁵ , Kim et al ³²⁶ , Marttin et al ⁶⁶ , TOXNET ³²⁷ , Ueda et al ³²⁸	Mouse	PO
Tartaric acid	104	87-69-4	d-tartaric acid; 2,3- dihydroxybutanedioic acid	C4-H6-O6	Sourkes and Koppanyi ³²⁹ , Szilagyi ³³⁰ , TOXNET ³³¹	Rabbit, Rat	PO
Terbafine HCL Placebo Nail Lacquer	105	78628-80-5	Terbafine Hydrochloride	C21-H25-N.Cl-H	TOXNET ³³²	Pig	Dermal
Tetraglycol	114 (Comb. Only)	15826-19-4			TOXNET ³³³	Minipig, Rat	IV
Transcutol	106; 114	111-90-0	Diethylene glycol monoethyl ether; DEGEE; 2-(2- Ethoxyethoxy)ethanol	C ₆ H ₁₄ O ₃	Liu et al ³³⁴ , Sullivan et al ⁴¹ , TOXNET ¹²⁴	Cat, Dog, Guinea pig, Minipig, Mouse, Rabbit, Rat	Dermal, IM, IP, IV, Inhalation, Ocular, PO, SC

Trehalose	114 (Comb. Only)	99-20-7	alpha-D-Trehalose	C12-H22-O11	TOXNET ³³⁵	Dog, Rat	IA, IV
Tris buffer	114 (Comb. Only)	77-86-1	Tromethamine	C4-H11-N-O3	TOXNET ³³⁶	Minipig, Non-human Primate	IV, Topical
Trisodium citrate dihydrate	107	6132-04-3	Trisodium citrate; Sodium citrate	C6H5Na3O7·2H2O	TOXNET ³⁰²	Dog, Hamster, Mouse, Rat	PO
Tween 20	108; 114	9005-64-5	Polysorbate 20 NF	n/a	Bartsch et al ³³ ; TOXNET ³³⁷	Dog, Minipig, Mouse, Non-human Primate, Rat	IV/SC/IP, IV, PO, SC, Topical
Tween 80	109; 114	9005-65-6	Polysorbate 80; armotan pmo-20, Tween(R) 80; Polyoxyethylene (20) sorbitan monooleate	n/a	Daher et al ³³⁸ ; Fisherman & Cohen ³³⁹ , Gelperina et al ³⁴⁰ ; National Toxicology Program ³⁴¹ ; O'Sullivan et al ³⁴² ; Oz et al ³⁴³ ; Sellers et al ²³⁸ ; Thackaberry et al ²² ; TOXNET ³⁴⁴	Dog, Guinea Pig, Hamster, Minipig, Mouse, Non-human Primate, Rabbit, Rat	IA, IV/SC/IP, Intranasal, IV, IP, PO
Vitamin E	114 (Comb. Only)	59-02-9	Alpha-tocopherol	C29-H50-O2	TOXNET ³⁴⁵	Dog, Rabbit, Rat	Ocular, PO
Vitamin E TPGS	110; 114	9002-96-4	Tocophersolan (USAN)	(C2-H4-O)mult-C33-H54-O5 (C2-H4-O)n-C33-H54-O5	TOXNET ³⁴⁶	Dog, Mouse, Rabbit, Rat	PO
Water	111; 114	7732-18-5		H2O		Dog, Minipig, Mouse, Non-human Primate, Pig, Rat	Dermal, IA/SC, IV, PO
White Wax	114 (Comb. Only)	8012-89-3	Beeswax	Natural product	Carlton et al ²⁴⁷ ; TOXNET ³⁴⁷	Minipig	Topical
Xylitol	112	87-99-0	Xylite	C5H12O5	Takahashi et al ³⁴⁸ ; TOXNET ³⁴⁹	Non-human Primate	Intranasal

TABLE 114: Combination Formulations

This table consists of entirely as-yet-unpublished submissions gathered during the collection effort for Gad et al (2006) as well as a number of submissions collected since.

#	Formulation	Species	Route	Duration	Dose	Adverse Reactions/Toxicity	Notes	Data Source
1	Acacia (10%) / Antifoam 1510-US (0.05%) / Water (purified)	Rat	PO (gavage)	14 days	10 ml/kg QD	Well tolerated	Age 9-11 weeks; ♂/♀	New contributed data
2	Acacia gum (10%) / DMSO (1%)	Non-human Primate	PO (gavage)	2 months (ADME)	5 ml/kg	Well tolerated		Contributed data, 2006
3	Acacia gum (10%) / DMSO (1%)	Rat	PO (gavage)	1 week (ADME)	5 ml/kg	Well tolerated	Sprague-Dawley	Contributed data, 2006
4	Acacia gum (10%) / DMSO (1%)	Rat	PO (gavage)	1 month (ADME)	5 ml/kg	Well tolerated	Sprague-Dawley	Contributed data, 2006
5	Acacia gum (10%) / DMSO (1%)	Rat	PO (gavage)	1 month (ADME)	5 ml/kg	Well tolerated	Sprague-Dawley	Contributed data, 2006
6	Acacia Gum (10%) /Tween 80 (0.5%)	Rat	PO (gavage)	Prelim / Segment II	5 ml/kg/day	Well tolerated		Contributed data, 2006
7	Acacia Gum (10%) /Tween 80 (0.5%)	Rat	PO (gavage)	Segment II	5 ml/kg/day	Well tolerated		Contributed data, 2006
8	Acetate Buffer (pH 5) / Benzyl alcohol (1% pH 5.0)(acetate: 100 mM, citrate: 10 mM)	Non-human Primate	IV (into saphena vein)	2 weeks	0.92 ml/kg	Well tolerated		Contributed data, 2006
9	Acetate Buffer pH 5 with 1.0% Benzyl Alcohol (acetate: 100 mM, citrate: 10 mM). pH 5.0	Rat	IV (into tail vein)	28 days	0.92 ml/kg	Well tolerated	Sprague-Dawley	Contributed data, 2006
10	Acetic Acid (0.01 M) / DMA (95/5)	Dog	30 minute infusion	1 day	3 ml/kg in single infusion	None	99% solution; Beagles age 5 months; ♂/♀	New contributed data
11	Acetone / Cyclohexane (50/50)	Rat	Dermal	6h daily, 5d/wk over 14 days	1.5 ml/kg	None	100% soultion; No sham group; Age ~60 days; ♀	New contributed data
12	Acetonitrile / Acetic Acid (99/1)	Dog	PO (Dietary)	ad libitum over 1 year		None	Age 7-8 months; ♂/♀	New contributed data
13	Benzyl alcohol: 60.2% / Citric acid: 0.1% / BHT: 0.1%	Cat	Topical	24 hours	0.3 ml SD	None	Non-GLP; Age 1 Y ear; 1♂/1♀	New contributed data
14	BHT / Benzyl Alcohol / Isopropanol	Dog	Topical	q7d x 2 doses over 7 weeks	1.4 ml/kg divided into 3 doses 60 minutes apart	None	Non-GLP; Age 7 weeks; 4♂/4♀	New contributed data

15	Capmul MCM / Kolliphor EL (50/50)	Non-human Primate	PO (gavage)	Once weekly over 4 weeks	5 ml/kg	None	Age 3-6 years; ♂/♀	New contributed data
16	Capmul MCM NF/Propylene Glycol/Kolliphor EL in a ratio of 1:1:1 (by weight)	Rat	PO	13-weeks	3ml/kg BD	Well tolerated	Wistar Hans (CRL) Age ~7-9 weeks at study initiation; ♂/♀	New contributed data
17	Captisol (5.4%) / Dextrose (2.5%) / Water (pH 4)	Dog	IV (infusion)	3 days	2 ml/kg/hr, 24 hr/day	None	Age 7-8 months; ♂/♀	New contributed data
18	Citrate Buffer (50 mM containing 0.5% Methocel E50 Premium LV and 0.2% Tween 20, pH 4 ± 0.1)	Rat	PO (gavage)	14 days	10 ml/kg QD	None	Age 8-9 weeks; ♂/♀	New contributed data
19	Citrate Buffer (53.8-54.9 mM containing 0.5% Methocel E50 Premium LV and 0.2% Tween 20, pH 4 ± 0.1)	Non-human Primate	PO (gavage)	1 day	5 ml/kg Single dose	None	Age 3-6 years; ♂	New contributed data
20	CMC (0.5%) / Tween 80 (0.1% (w/w))	Rabbit	PO (gavage)	Prelim / Segment III	5 ml/kg/day	Well tolerated		Contributed data, 2006
21	CMC (1%) / Tween 80 (0.5%)	Dog	PO	28 days	10 ml/kg	Not toxic		Contributed data, 2006
22	CMC (1%) / Tween 80 (0.5%)	Rat	PO	28 days	20 ml/kg	Not toxic		Contributed data, 2006
23	CMC (high viscosity, 0.25%) / Tween 80 (0.2%) / Water (sterile for injection, USP)	Mouse	PO (gavage)	102 weeks	10 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
24	CMC (low viscosity, 1%) / Tween 80 (0.01%) / Water (distilled)	Rat	PO (gavage)	105 weeks	10 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
25	CMC (low viscosity, 1%) / Tween 80 (0.01%) / Water (distilled)	Non-human Primate	PO (gavage)	≤ 365 days	10 ml/kg QD	None	Age 4.5-8 years; ♂/♀	New contributed data
26	CMC (low viscosity, 1%) / Tween 80 (0.01%) / Water (distilled)	Mouse	PO (gavage)	91 weeks	10 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
27	CMC (Medium viscosity, 0.5% w/v), Tween 80 (0.1%, v/v) / Water (sterile for injection, USP)	Mouse	PO (gavage)	13 weeks	10 ml/kg QD	None	Age 5 weeks; ♂/♀	New contributed data

28	CMC: 0.5% / Tween 80: 0.05% / in PBS pH 7.4	Dog	IA	2 days	0.35 ml SD	1 day post-dosing, 1 animal had moderate hemorrhage of R stifle fat pad and mildly increased synovial fluid volume on necropsy, 2 had lameness 2 days post-injection, resolved within 24 hours	GLP; Age 8 months; 6♂/6♀	New contributed data
29	CMC: 0.5% / Tween 80: 0.05% / in PBS pH 7.4	Dog	IA	q30d over 3 months	350 µL	None	GLP; age 5-6 months; 5♂/5♀	New contributed data
30	CMC: 0.5% / Tween 80: 0.05% / in PBS pH 7.4	Dog	IA	q30d over 9 months	350 µL	None	GLP; Age 5-6 months; 5♂/5♀	New contributed data
31	Corn oil / Benzyl alcohol (99:1)	Rat	PO (gavage)	1 month	1 ml/kg/day	Well tolerated	Sprague-Dawley; during the frst 3 days of the study, the vehicle was di(ethyleneglycol)ethyl ether. From the 4th day it was replaced by corn oil/benzyl alcohol	Contributed data, 2006
32	Corn oil / ETOH 20%	Rat	PO (gavage)	1 month	2.5 ml/kg/day	Well tolerated	Sprague-Dawley	Contributed data, 2006
33	Corn oil / ETOH 20%	Rat	PO (gavage)	1 month	5 ml/kg/day	Well tolerated	Sprague-Dawley	Contributed data, 2006
34	Cyclodextrin / OraPlus suspension	Rat	PO (gavage)	28 doses	15 ml/kg	Fecal changes (soft, watery or mucoid); kidney lesions		Contributed data, 2006
35	Cyclodextrin / OraPlus suspension	Rat	PO (gavage)	Single dose	20 ml/kg	None		Contributed data, 2006
36	Cyclodextrin / OraPlus suspension	Rat	PO (gavage)	Single dose	20 ml/kg	None		Contributed data, 2006
37	Cyclodextrin / OraPlus suspension	Rat	PO (gavage)	5 doses		None		Contributed data, 2006
38	Dehydrated ETOH (200 proof): 86.249% / Hexylene Glycol: 10.000% / Dimethiconol blend 20: 2.500% / Hydroxypropylcellulose: 1.250% / Anhydrous Citric Acid: 0.001%	Minipig	Topical	28 days	5 ml QD	None	GLP; Age 3-5 months; 5♂/5♀	New contributed data
39	Dextrose / Trehalose (25%)	Rat	Bolus injection	28 doses	10 ml/kg	None	5% solution	Contributed data, 2006

40	Dextrose for Injection (USP) / ETOH (5%)	Rat	PO (gavage)	Single dose		None	5% solution	Contributed data, 2006
41	Diethylacetamide / NaCL	Mouse	IV		MTD: 1.4 g/kg; LD50: 2.3-3.2 g/kg; NOEL: 468 mg/kg		CD-1 mice; 30% of a 5 mL/kg dose volume at MTD; (%v/v) in NaCL	Sambrone ⁵
42	Di-sodium hydrogen phosphate dihydrate (8 mM) / Sodium dihydrogen phosphate dihydrate (7 mM) / NaCl (50 mM) / Sucrose (146 mM) / Poloxamer 188 (0.12 mM) / Water (for injection, pH 6.9 ± 0.4)	Non-human Primate	SC	26 weeks	2 ml/kg Once Weekly	None	Age 1-1.5 years; ♂/♀	New contributed data
43	DMSO (1.25%) /5% Mannitol (5%) / Kolliphor (1.25%)	Non-human Primate	PO (gavage)	ADME	1 ml/kg/day	Well tolerated		Contributed data, 2006
44	DMSO (2%) / PEG 400 (10%)	Non-human Primate	IV	1 month (ADME)	1.5 ml/kg	Well tolerated		Contributed data, 2006
45	DMSO (2%) / PEG 400 (10%)	Non-human Primate	IV	1 week (ADME)	1.5 ml/kg	Well tolerated		Contributed data, 2006
46	DMSO (2%) / PEG 400 (10%)	Non-human Primate	IV	2 month (ADME)	1.5 ml/kg	Well tolerated		Contributed data, 2006
47	DMSO (3.5%) / PEG 400	Non-human Primate	PO (gavage)	Prelim.	5 ml/kg/day	Soft liquid feces		Contributed data, 2006
48	DMSO (5%) / Mannitol (4.5%) / Kolliphor (5%)	Non-human Primate	IV	2 weeks	2 ml/kg/day	Well tolerated		Contributed data, 2006
49	DMSO / NaCL	Mouse	IV		MTD: 2.2 g/kg; LD50: 3.8-7.6 g/kg; NOEL: 1.6 g/kg		CD-1 mice; 40% of a 5 mL/kg dose volume at MTD; (%v/v) in NaCL	Sambrone ⁵
50	DMSO / PEG 400 (99%)	Rat	PO (gavage)	11 doses		None	1% solution	Contributed data, 2006
51	DMSO / PEG 400 (99%)	Rat	PO (gavage)	11 doses	2 ml/kg	None	1% solution	Contributed data, 2006

52	DMSO / PEG 400 / Tris Buffer	Non-human Primate	IV (bolus)	ADME	2 ml/kg	Well tolerated		Contributed data, 2006
53	DMSO / PEG 4000 / Water (DI) (15/35/50)	Rat	IP	28 days	10 ml/kg	Not toxic		Contributed data, 2006
54	DMSO / PEG 4000 / Water (DI) (15/35/50)	Mouse	IP	28 days	10 ml/kg	Not toxic		Contributed data, 2006
55	DMSO / Solutol HS15 / Water (pH 3-11) (20/5/75)	Rat	IV (bolus)		2 ml/kg	Well tolerated		Strickley ¹¹
56	DMSO / Tetraglycol (50/50)	Minipig	IV	1 day	0.4 ml/kg SD	Immediate cardiac arrest; study was cancelled after first dose	Age 3 months; 1♂	New contributed data
57	DMSO + 1% Tween80 at 0.12% in water for injection	Mouse	SC	RNA extraction, 7 days	4/10 ml/kg/injection	Well tolerated		Contributed data, 2006
58	EDTA (0.2 mg/ml) / Citric Acid Anhy (0.8 mg/ml) / NaCl (4.6 mg/ml, low iron) / Water (sterile for injection, USP, pH 3.9-4.0)	Rat	IV (slow bolus)	13 weeks	4.5 ml/kg QD	Red/blue skin discoloration and edema of the tail (non-adverse)	Age 6 weeks; ♂/♀	New contributed data
59	EDTA pH 7.3 (Phosphate 10 mM; NaCl 150 mM; EDTA 0.5 mM)	Rat	IV (into tail vein)	1 month	0.92 ml/kg	Well tolerated	Sprague-Dawley	Contributed data, 2006
60	EDTA pH 7.3 (Phosphate 10 mM; NaCl 150 mM; EDTA 0.5 mM)	Non-human Primate	IV (into saphena vein)	2 weeks	0.92 ml/kg	Well tolerated		Contributed data, 2006
61	ETOH (190 Proof): 63.37% / Glycerol: 3% / Carbopol Ultrez 10: 2.5% / Tween 20: 2% / Propylene Glycol: 2% / Panthenol: 0.15% / Salicylic Acid: 0.15% / EDTA: 0.05% / Water (DI): 26.78%	Minipig	Topical	92 days	1 g QD	None	GLP; Age 3-4 Months; 5♂/5♀	New contributed data
62	ETOH / Kolliphor EL / Water for injection (10/5/85)	Non-human Primate	IV	ADME	0.4 ml/kg	Well tolerated		Contributed data, 2006
63	ETOH / Kolliphor EL / Water for injection (10/5/85)	Rat	IV	ADME	2 ml/kg	Well tolerated		Contributed data, 2006

64	ETOH / NaCL	Mouse	IV		MTD: 986 mg/kg; LD50: 1.6-4.3 g/kg; NOEL: 197 mg/kg		CD-1 mice; 25% of a 5 mL/kg dose volume at MTD; (%v/v) in NaCL	Sambrone ⁵
65	ETOH / Propylene glycol / Water (12.5/15.5/75, v/v/v)	Rat	PO (gavage)	2 weeks	5 ml/kg/day	Well tolerated		Contributed data, 2006
66	ETOH / Propylene glycol / Water (12.5/15.5/75, v/v/v)	Rat	SC	2 weeks	2 ml/kg/day	Well tolerated		Contributed data, 2006
67	ETOH / Propylene glycol / Water (30/10/60)	Dog	IV		5 ml/kg at a rate of 0.3 ml/kg	Hemolyis <i>in vitro</i> Dog Blood.		New contributed data
68	ETOH / Propylene glycol / Water (30/20/50)	Dog	IV		5 ml/kg at a rate of 0.3 ml/kg	Hemolyis <i>in vitro</i> Dog Blood.		New contributed data
69	ETOH / Propylene glycol / Water (40/10/50)	Dog	IV		5 ml/kg at a rate of 0.3 ml/kg	Hemolyis <i>in vitro</i> Dog Blood.		New contributed data
70	ETOH / SolutolR HS15 / Water	Non-human Primate	PO (gavage)	39 weeks	1 ml/kg/day	Well tolerated		Contributed data, 2006
71	ETOH / SolutolR HS15 / Water	Non-human Primate	PO (gavage)	4 weeks	1 ml/kg/day	Well tolerated		Contributed data, 2006
72	ETOH / Water (30/70)	Rat	IV		5 ml/kg at a rate of 0.3 ml/kg	Hematuria		New contributed data
73	ETOH: 50% / Propylene glycol: 50% / with BHA: 0.05% / BHT: 0.05%	Minipig	Topical	16 weeks	1 ml TID	All males had increased AST at end of study, up to 500 IU/L (ref: 19-263 IU/L)	GLP; Age 3-4 Months; 6♂/6♀	New contributed data
74	Gelatin (0.5% m/v) / Mannitol (5% m/v) / Water for injection	Non-human Primate	PO (gavage)	Prelim.	5 ml/kg/day	Well tolerated		Contributed data, 2006
75	Gelucire / PEG 400 / NMP / Transcutol HP (50/30/10/10)	Minipig	PO	4 days	5 ml/kg QD	None	Non-GLP; Age 4-6 months; 3♀	New contributed data
76	Gelucire 44/14 / PEG 400 / NMP / Transcutol HP (50/30/10/10)	Minipig	PO	3 days	5 ml/kg QD	Mild transient diarrhea 24-30 hours post-first dose	Non-GLP; Age 7-8 Months; 3♀	New contributed data
77	Gelucire 44/14 / PEG 400 / NMP / Transcutol HP (50/30/10/10)	Mouse	PO	5 days	5 ml/kg QD	None	Non-GLP; Age 9-14 weeks; 6♂/6♀	New contributed data
78	Histidine (20 mM, pH 6.5)	Rat	IV	14 days	5 ml/kg	None	Age 6 weeks; ♂/♀	New

	/ Sucrose (8.8%)		(slow bolus)		QD			contributed data
79	Histidine (20 mM, pH 6.5) / Sucrose (8.8%)	Dog	SC	14 days	1 ml/kg 2 QD	None	Age 5-6 months; ♂/♀	New contributed data
80	Histidine Buffered Solution (10 mM, pH 6.5) / NaCl (130 mM) / Water (sterile)	Rat	IV (bolus)	1 day	7.14 ml/kg Single dose	None	Age 5 months; ♂	New contributed data
81	HPMC (0.5%) / Tween 80 (0.1%) / Water (DI)	Non-human Primate	PO (gavage)	28 days	5 ml/kg QD	Soft/watery feces	Age 2-4 years; ♂/♀	New contributed data
82	HPMC (0.5%) / Tween 80 (5%)	Rat	PO (gavage)	2 weeks	5 / 1 ml/kg/day	Well tolerated		Contributed data, 2006
83	HPMC (1%) / Poloxamer 188 (1%)	Dog	PO	2 weeks	5 ml/kg/day	Well tolerated	Beagle	Contributed data, 2006
84	HPMC (1%) / Poloxamer 188 (1%)	Dog	PO	2 weeks	10 or 20 ml/kg/day	Well tolerated	Beagle	Contributed data, 2006
85	HPMC (1%) / Poloxamer 188 (1%)	Dog	PO	2 months	10 ml/kg/day	Well tolerated	Beagle	Contributed data, 2006
86	HPMC (1%) / Tween 80 (0.25%) / Water (purified)	Rat	PO (gavage)	11 days	10 ml/kg QD	None	Age 8-10 weeks; ♀	New contributed data
87	HPMC / Sodium lauryl sulfate (2%) / Water (distilled)	Rat	PO (gavage)	Single dose	10 ml/kg	None	0.5% solution	Contributed data, 2006
88	HPMC Acetate Succinate (90 mg/ml) / Methylcellulose (0.5%)	Mouse	PO	14 days	5 ml/kg EOD	None	GLP; Age 61-63 days; 20♂/20♀	New contributed data
89	HPMC Acetate Succinate (90 mg/ml) / Methylcellulose (0.5%)	Minipig	PO	14 days	6 ml/kg EOD	None	GLP; Age 3-5 Months; 5♂/5♀	New contributed data
90	HPMC: 1% / Fumaric Acid: 0.5% / Tween 80: 0.1% / Glycerol: 0.1% / in water	Dog	PO	14 days	5 ml/kg QD	None	Non-GLP; Age 7-9 months; 1♂/1♀	New contributed data
91	HPβCD (20% solution) / DMSO (99/1)	Dog	IV	ADME	4 ml/kg/day	Well tolerated		Contributed data, 2006
92	HPβCD (20%) / Sodium Acetate (25 mM, pH 4)	Rat	PO (gavage)	28 days	5 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data

93	HP β CD (20%) / Sodium Acetate (25 mM, pH 4)	Non-human Primate	PO (gavage)	28 days	2.5 ml/kg/dose BID	None	Age 2-3.5 years; ♂/♀	New contributed data
94	HP β CD (30%) / DMSO (5%) / Water (purified) (Acidic solution, w/w)	Non-human Primate	IV	4 weeks	1 ml/kg/day	Well tolerated		Contributed data, 2006
95	HP β CD / Citric Acid Solution (0.05 M)	Dog	PO (gavage)	14 doses	3 ml/kg	None	20% solution	Contributed data, 2006
96	HP β CD / NaCL solution (0.9%)	Dog	IV	Single dose	1 ml/kg	None	10% solution	Contributed data, 2006
97	HP β CD / NaCL solution (0.9%)	Rat	IV	Single dose	1 ml/kg	None	10% solution	Contributed data, 2006
98	HP β CD: 12% / EtOH: 8% / Propylene glycol: 2% / Water for injection	Dog	IV (1 hour infusion)	q7d x 3 doses over 16 days	2 ml/kg	May cause temporary mild diarrhea	Non-GLP; Age 1-4 Years; 2♂/2♀	New contributed data
99	HP β CD: 12% / EtOH: 8% / Propylene glycol: 2% / Water for injection	Dog	IV (1 hour infusion)	q7d x 3 doses over 16 days	1.5 ml/kg	May cause diarrhea	Non-GLP; Age 1-4 years; 2♂/2♀	New contributed data
100	Hydroxyethylcellulose (1%) / Tween 80 (0.25%) / Antifoam (0.05%) / Water (purified)	Rat	PO (gavage)	1 day	10 ml/kg Single dose	None	Age 6 weeks; ♂	New contributed data
101	Hydroxyethylcellulose (1%, w/v) / Tween 80 (0.25%) / Antifoam 1510-US (0.05%) / Water (purified)	Rat	PO (gavage)	4 days	10 ml/kg QD	None	Age 8-9 weeks; ♀	New contributed data
102	Hymetellose (1%) / Poloxamer 188 (0.1%)	Rabbit	PO (gavage)	1 month	3 ml/kg/day	Well tolerated		Contributed data, 2006
103	Imwitor 742 / Tween 80 (1:1, w/w)	Rat	PO (gavage)	7 days	10 ml/kg QD	None	Age 7 weeks; ♂/♀	New contributed data
104	Imwitor 742 / Tween 80 (1:1, w/w)	Non-human Primate	PO (gavage)	7 days	5 ml/kg QD	Soft/watery feces	Age 2-3 years; ♂/♀	New contributed data
105	Imwitor 742 / Tween 80 (1:1, w/w)	Hamster	PO (gavage)	7 days	5 ml/kg QD	None	Age 5 weeks; ♂/♀	New contributed data
106	Kolliphor EL / PEG 300 / (4:1, w/w)	Mouse	PO (gavage)	104 weeks	3 ml/kg/day	Well tolerated		Contributed data, 2006
107	Kolliphor RH40: 41.5% / PEG 400: 20% / TPGS: 20% / Propylene Glycol: 10% / Tween 80: 8.5%	Rat	PO (gavage)	92 days	10 ml/kg QD	None	Age 10-23 weeks; ♂/♀	New contributed data

108	Kolliphor® EL/ 10% 190 proof ETOH/ 80% 5% dextrose in water (D5W)	Rabbit	IV	Single dose	5 ml/kg	None	10 % solution	Contributed data, 2006
109	Kolliphor® EL/ 10% 190 proof ETOH/ 80% 5% dextrose in water (D5W)	Rabbit	IV	Single dose	5 ml/kg	Local irritation, very slight to well-defined erythema	10 % solution	Contributed data, 2006
110	Kolliphor® EL/ 10% 190 proof ETOH/ 80% 5% dextrose in water (D5W)	Rabbit	Perivascular Injection	Single dose	0.5 ml/kg	None	10 % solution	Contributed data, 2006
111	Kolliphor® EL/ 10% 190 proof ETOH/ 80% 5% dextrose in water (D5W)	Rabbit	Perivascular Injection	Single dose	0.5 ml/kg	Erythema	10 % solution	Contributed data, 2006
112	Labrafil / Tween 80® (0.1%)	Rat	PO (gavage)	2 doses	2 ml/kg/dose	None		Contributed data, 2006
113	Labrasol / Kpllichor HS15 / Transcutol HP (60/30/10)	Minipig	PO (gavage)	Once weekly over 4 weeks	3.75 ml/kg	None	Age 6-7 months; ♂/♀	New contributed data
114	Labrasol / Labrafil / Transcutol ®	Rat	PO	4 weeks	0, 5, 10, or 20 ml/k/day	Tolerated at 5 ml/kg/day	Changes in appearance and behavior at 10 ml/kg/day; lethality and renal and hepatic effects at 20 ml/kg/day; Wistar rats	Sullivan et al ⁴¹
115	Labrasol / PEG-400 (60/40)	Rat	PO	7-days	5ml/kg BD	Well tolerated	Sprague-Dawley Rats (Harlan) Age ~8-10 weeks; ♂/♀	New contributed data
116	Lactated Ringer's Injection (USP)	Non-human Primate	IV	28 days	2 ml/kg QD	None		Contributed data, 2006
117	L-Ascorbic Acid / Isotonic NaCL	Rat	PO	90 days	500 g/kg	Hematologic changes, weight loss		Gad et al., 2006
118	Mannitol (47 mg/ml) / Succinic Acid (1.181 mg/ml) / Water (Sterile, USP)	Dog	SC	28 days	0.1 ml/kg QD	None	Age 5 months; ♂/♀	New contributed data
119	Mannitol (5%) / Acetate buffer pH4 (4:6)	Minipig	IM	Tolerance	0.8/1.2 ml/kg/day	Well tolerated		Contributed data, 2006
120	Mannitol (5%) / Gelatin (0.5%) / Tween 80 (0.2%) (Aqueous solution, % m/v)	Non-human Primate	PO (gavage)	2 weeks	2 ml/kg/day	Well tolerated		Contributed data, 2006
121	Mannitol: 120 mg / Na2HPO4: 12 mg / NaCl: 10.5 mg / Water: 4 ml	Dog	IV	One week (placebo) then one-day (with the test item)	0.15 ml/kg	Well tolerated	Beagle dogs	Contributed data, 2006

123	Mannitol: 250 mM / Sodium Succinate: 25 mM / Water pH 4.9	Rat	SC	28 days	4 ml/kg	Not toxic		Contributed data, 2006
124	Mannitol: 250 mM / Sodium Succinate: 25 mM / Water pH 4.9	Mouse	SC	28 days	20 ml/kg	Not toxic		Contributed data, 2006
125	Methane Sulfonic Acid (5%) / ETOH (5%) / Water	Rat	PO	28 days	10 ml/kg	Not toxic		Contributed data, 2006
126	Methocel (0.5%) / Tween 80 (0.1%) / Water (reverse osmosis)	Rat	PO (gavage)	182 days	10 ml/kg QD	None	Age 6 weeks; ♀	New contributed data
127	Methocel (A4M Premium, 0.5%) / Simethicone (0.1%) / TPGS (10%) / Citrate Buffer (17 mM, pH 4 ± 0.05)	Rat	PO (gavage)	28 days	10 ml/kg QD	None	Age 8 weeks; ♂/♀	New contributed data
128	Methyl Methacrylate/Glycol Dimethacrylate Cross polymer, Propylene Glycol Dicaprylate/Dicaprate, BHT	Rat	Topical	90 days	2.4 ml/kg x 44-46 d, then 0.75 ml/kg QD	None	GLP; Age 8 weeks; 15♂/15♀	New contributed data
129	Methyl Paraben, Propyl Paraben	Minipig	Topical	91 days	0.05 ml/cm² TID	None	Age 2-3 Months; 6♂/6♀	New contributed data
130	Methylcellulose (0.5% w/v) / Tween 80 (0.1%)	Guinea Pig	PO	28 days	10 ml/kg	Not toxc		Contributed data, 2006
131	Methylcellulose (Aqueous, 0.5% w/w) / Tween 80 (0.5% w/w)	Rat	PO (gavage)	Prelim / Segment III	5 ml/kg/day	Well tolerated		Contributed data, 2006
132	Methylcellulose / PEG 200 (5%)	Rat	PO (gavage)	Single dose	10 ml/kg	None	0.5% solution	Contributed data, 2006
133	Methylcellulose / Tween 80 (0.1% v/v)	Rat	PO (gavage)	Single dose	7.5 ml/kg	None	0.5% solution	Contributed data, 2006
134	Methylcellulose / Tween 80 (0.1% v/v)	Rat	PO (gavage)	Single dose	5 ml/kg	None	0.5% solution	Contributed data, 2006
135	Methylcellulose / Tween 80 (0.1% v/v)	Rat	PO (gavage)	28 doses	5 ml/kg/dose	None	0.5% solution	Contributed data, 2006
136	Methylcellulose / Tween 80 (0.1% v/v)	Dog	PO (gavage)	28 doses	1 ml/kg/dose	None	0.5% solution	Contributed data, 2006
137	Methylcellulose / Tween 80 (0.1% v/v)	Dog	PO (gavage)	Single dose	5 ml/kg/dose	None	0.5% solution	Contributed data, 2006
138	Methylcellulose / Tween 80 (0.1%)	Rat	PO (gavage)	Single dose	10 ml/kg	None	0.5% solution	Contributed data, 2006

139	Methylcellulose 1500 cps (0.5%) / Tween 80 (0.1%) / Acetate Buffer (10 mM) / Water (Distilled, pH 4.5 ± 0.1)	Mouse	PO (gavage)	28 days	10 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
140	Methylcellulose 1500 cps (0.5%) / Tween 80 (0.1%) / Acetate Buffer (10 mM) / Water (Distilled, pH 4.5 ± 0.1)	Mouse	PO (gavage)	13 weeks	10 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
141	Methylcellulose 1500 cps (0.5%) / Tween 80 (0.1%) / Acetate Buffer (10 mM) / Water (Distilled, pH 4.5 ± 0.1)	Non-human Primate	PO (gavage)	91 days	5 ml/kg QD	None	Age 2-4 years; ♂/♀	New contributed data
142	Methylcellulose 1500 cps (0.5%) / Tween 80 (0.1%) / Acetate Buffer (10 mM) / Water (Distilled, pH 4.5 ± 0.1)	Rat	PO (gavage)	91 days	10 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
143	Methylcellulose 400 cps (0.5%) / Sodium Lauryl Sulfate (0.5%)	Rat	PO (gavage)	26 weeks	10 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
144	Methylcellulose 400 cps (0.5%) / Sodium Lauryl Sulfate (0.5%) / Simethicone (0.01%) / Water (DI) (% w/v)	Rat	PO (gavage)	13-26 weeks	5 ml/kg QD	None	Age 8 weeks; ♂/♀	New contributed data
145	Methylcellulose 400 cps (0.5%) / Sodium Lauryl Sulfate (0.5%) / Water (DI)	Dog	PO (gavage)	26 weeks	5 ml/kg QD	Soft/watery feces (non adverse)	Age 4-5 months; ♂/♀	New contributed data
146	Methylcellulose 400 cps (0.5%) / Sodium Lauryl Sulfate (0.5%) / Water (DI)	Dog	PO (gavage)	52 weeks	5 ml/kg QD	Soft/watery feces (non adverse)	Age 4-5 months; ♂/♀	New contributed data
147	Methylcellulose 400 cps (0.5%) / Sodium Lauryl Sulfate (0.5%) / Water (DI)	Rat	PO (gavage)	28 days	10 ml/kg QD	None	Age 8 weeks; ♂/♀	New contributed data
148	Methylparaben (0.17%) / Propylparaben (0.03%) / Acetyl cysteine (0.5%) / in Citrate Buffer (100 mM, pH 6.5) / Sodium Hydroxide (10%) added to pH 6.0	Minipig	SC	56 days	0.138 ml/kg QD	Temporary dose-site irritation post-injection, resolved within a few minutes	GLP; Age 4-7 months; 3♂/3♀	New contributed data
149	NaCl (0.9%) / Propylene glycol / ETOH (50/40/10)	Dog	IV		5ml/kg at a rate of 0.3ml/kg	Hemolys <i>in vitro</i> Dog Blood.		New contributed data

150	NaCl (0.9%) / ETOH (60/40)	Rat	IV		5ml/kg at a rate of 0.3ml/kg	Hematuria		New contributed data
151	NaCl (0.9%) / ETOH (70/30)	Rat	IV		5ml/kg at a rate of 0.3ml/kg	Hematuria		New contributed data
152	NaCl (0.9%) / ETOH / PEG 400 (50/30/20)	Dog	IV		5ml/kg at a rate of 0.3ml/kg	Partial Hemolysis in vitro dog blood, RBC discolored		New contributed data
153	NaCl (0.9%) / ETOH / PEG 400 (50/40/10)	Dog	IV		5ml/kg at a rate of 0.3ml/kg	Partial Hemolysis in vitro dog blood, RBC discolored		New contributed data
154	NaCl (0.9%) / ETOH / Propylene glycol (60/30/10)	Dog	IV		5ml/kg at a rate of 0.3ml/kg	Hemolys <i>in vitro</i> Dog Blood.		New contributed data
155	NaCl (0.9%) / ETOH / Propylene glycol (50/30/20)	Dog	IV		5ml/kg at a rate of 0.3ml/kg	Hemolys <i>in vitro</i> Dog Blood.		New contributed data
156	NaCl (0.9%) / ETOH / Propylene glycol (50/40/10)	Dog	IV		5ml/kg at a rate of 0.3ml/kg	Hemolys <i>in vitro</i> Dog Blood.		New contributed data
157	NaCl (0.9%) / Propylene glycol / ETOH (50/30/20)	Dog	IV		5ml/kg at a rate of 0.3ml/kg	Hemolys <i>in vitro</i> Dog Blood.		New contributed data
158	NaCL / DMSO / Tetraglycol (90/5/5)	Rat	IV	14 days	4.3 ml/kg SD	None	GLP; Age 8 weeks; 5♂/5♀	New contributed data
159	NaCL / DMSO / Tetraglycol (90/5/5)	Minipig	IV	16 days	2.6 ml/kg SD	None	GLP; Age 2-4 months; 1♂/1♀	New contributed data
160	NaCl for Injection (USP) / Mannitol (20 mg/ml) / Tween ® 80 (4 mg/ml), sterile filtered	Rat	IV (infusion)	Single dose	6.67 ml/kg/dose	None	0.9% solution	Contributed data, 2006
161	NaCl for Injection, USP / 10% ETOH and 0.9%	Dog	IV (bolus)	Single dose	5 ml/kg	None	10% solution	Contributed data, 2006
162	NaCl for Injection/10% ETOH	Rat	IV	Single dose	5 ml/kg	None	10% solution	Contributed data, 2006
163	NaCl for Injection/20% PET in 0.9%	Rat	IV (slow bolus)	7 doses	0.6 ml/kg	None	20% solution	Contributed data, 2006

164	NaCl USP: 15.00% / Potassium Chloride: 7.50% / L-Arginine HCl USP: 7.50% / Glyceryl Stearate SE: 7.00% / Cetyl Alcohol NF: 7.00% / Propylene glycol: 5.00% / Squalene NF: 4.00% / Tween-20 NF: 2.00% / Sodium Hydroxide: 1.30% / Oleic Acid NF: 1.00% / Isopropyl Myristate: 1.00% / Keltrol RD: 0.50% (Xanthan Gum) / Keltrol BT: 0.30% (Xanthan Gum)/ Water (Purified): 40.90%	Minipig	Topical	7 days	3.0 g/kg BID	Severe dose-site erythema in 2/6 animals	GLP; Age 3-5 months; 3♂/3♀	New contributed data
165	Neobee 1053 Oil / ETOH / BHT (94.95/5/0.05)	Mouse	IV	28 days	10 ml/kg	Not toxic		Contributed data, 2006
166	Neobee 1053 Oil / ETOH / BHT (94.95/5/0.05)	Rat	PO	28 days	5 ml/kg	Not toxic		Contributed data, 2006
167	NMP/ NaCL	Mouse	IV		MTD: 1.3 g/kg; LD50: 54-3600 mg/kg; NOEL: 257 mg/kg		CD-1 mice; 25% of a 5 mL/kg dose volume at MTD; (%v/v) in NaCL	Sambrone ⁵
168	Octoxynol-40, Vitamin E	Dog	Ocular (Topical)	q1h x 8 doses over 14 days	0.35 µL (one drop)/eye	None	GLP; Age 8 Months; 4♂/6♀	New contributed data
169	Octoxynol-40, Vitamin E	Rabbit	Ocular (Topical)	q1h x 8 doses over 14 days	0.35 µL (one drop)/eye	None	GLP; 5-6 Months; 5♂/5♀	New contributed data
170	Octoxynol-40, Vitamin E	Rabbit	Ocular (Topical)	q1h x 8 doses over 13 weeks	0.35 µL (one drop)/eye	None	GLP; Age 6 months; 6♂/6♀	New contributed data
171	Oleic Acid / PEG 400 / Kolliphor EL (80/10/10, w/w)	Dog	PO (capsule)	9 months	0.6 ml/kg QD	None	Age 6 months; ♂/♀	New contributed data
172	Oleic Acid / PEG 400 / Kolliphor EL (80/10/10, w/w)	Rat	PO (gavage)	104 weeks	2 ml/kg QD	Decreases in body weight gain (non-adverse)	Age 4 weeks: ♂/♀	New contributed data
173	Oleic Acid / PEG 400 / Kolliphor EL (80/10/10, w/w)	Mouse	PO (gavage)	13 weeks	2 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data

174	Oleic Acid / PEG 400 / Kolliphor EL (80/10/10, w/w)	Non-human Primate	PO (gavage)	14 days	2ml/kg/dose BID	Emesis and fecal changes	Age 2-3 years; ♂/♀	New contributed data
175	Olive Oil: 28.25% / Tween 80: 11.25-13.5% / Oleyl Alcohol NF: 10.00% / Lanolin Alcohol NF: 8.00% / Cyclomethicone NF: 3.00% / Cetyl Acetate: 1.5-3.75% / Shea Butter: 2.00% / 0.50% Sorbitan Tristearate / Acetylated lanolin Alcohol: 0.15-0.75% / Methylparaben NF: 0.20% / Propylparaben NF: 0.05% / Water (USP Purified): 33.00%	Minipig	Topical	14 days	0.32 ml/kg QD	4/6 experienced persistent mild (Draize score 1/4) dose-site erythema or miliary erythema	GLP; Age 3-5 Months; 5♂/5♀	New contributed data
176	Peanut oil / ETOH 100 (8:1)	Dog	SC		0.33 ml/kg	Well tolerated	Beagle	Contributed data, 2006
177	Peceol (Gattefosse) / Tween 80 / PEG 400 / Vitamin E (TPPE) (50/40/10/0.2)	Rat	PO (gavage)	91 days	10 ml/kg/dose BID	None	Age 6 weeks; ♂/♀	New contributed data
178	Peceol (Gattefosse) / Tween 80 / PEG 400 / Vitamin E (TPPE) (50/40/10/0.2)	Dog	PO (gavage)	91 days	5 ml/kg/dose BID	None	Age 7-8 months; ♂/♀	New contributed data
179	PEG (5%) / Methylcellulose (0.5%)	Pig	PO (gavage)	28 doses	5 ml/kg	None	5% solution	Contributed data, 2006
180	PEG / DAM (70/30, v/v)	Dog	IV	2 weeks	0.32 ml/kg for sinlge iv injection	well tolerated		Gad et al ¹
181	PEG / DAM (70/30, v/v)	Rat	IV	3 week	bolus 0.8-1.07 ml/kg infusion 0.266-0.356 ml/kg intravenous injection (into tail vein) following by an intravenous injection for 6 hours	well tolerated		Gad et al ¹
182	PEG / DAM (70/30, v/v)	Dog	IV (into cephalic of saphenous vein) following by an iv injection for 6 hours	2 weeks	bolus 0.24-0.33 ml/kg infusion 0.08-0.11 ml/kg/hours	well tolerated		Gad et al ¹

183	PEG / DAM (70/30, v/v)	Rat	IV	3 weeks	bolus 0.8-1.07 ml/kg infusion 0.266-0.356 ml/kg intravenous injection (into tail vein) following by an intravenous injection for 6 hours	Well tolerated		Gad et al ¹
184	PEG 200 / 95% Methylcellulose (0.5%)	Rat	PO	3 doses	5 ml/kg of body weight	None	5% solution	Contributed data, 2006
185	PEG 200 / ETOH / Dextrose (5%) (70/15/15, v/v/v)	Minipig	IV	2 weeks	1 ml/kg	Well tolerated		Contributed data, 2006
186	PEG 300 (40%) / Cavisol W7 (25/75 v/v)	Dog	PO	28 days	10 ml/kg	Not toxic		Contributed data, 2006
187	PEG 300 (40%) / Cavisol W7 (25/75 v/v)	Rat	PO	28 days	10 ml/kg	Not toxic		Contributed data, 2006
188	PEG 300 / DMA (90/10)	Rat	PO (gavage)	14 days	2.5 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
189	PEG 300 / DMA (90/10)	Dog	PO (gavage)	14 days	2.5 ml/kg QD	Body weight loss (>20%) (adverse)	Age 5-6 months; ♂/♀	New contributed data
190	PEG 300 / NaCl (0.9%) (40/60, v/v)	Rat	PO (gavage)	ADME	5 ml/kg/day	Well tolerated		Contributed data, 2006
191	PEG 300 / Propylene Glycol / Water (DI) (55/25/20)	Rat	PO (gavage)	7 days	10 ml/kg QD	None	Age 9-10 weeks; ♂/♀	New contributed data
192	PEG 400 / Captisol ® / ETOH / Water (pH 3) (45/7/5/43)	Dog	IV (Infusion)		1 ml/kg	Well tolerated		Strickley ¹¹
193	PEG 400 / DMA (50/50)	Dog	IV (Infusion)		0.1 ml/kg	Well tolerated		Strickley ¹¹
194	PEG 400 / DMSO (20%)	Mouse	IV (into tail vein)	Acute	1128 mg/kg (dose vol 5 ml/kg)	NOEL	20% PEG 400	Thackaberry ₂₀
195	PEG 400 / DMSO (20%)	Mouse	IV (into tail vein)	Acute	3948 mg/kg (dose vol 5 ml/kg)	MTD; Ventral recumbancy, ataxia, tremors and hypoactivity shortly after dosing. Tremors for up to 4 mins, hypoactivity for up to 10 mins is typical	70% PEG 400	Thackaberry ₂₀
196	PEG 400 / DMSO (95/5)	Rabbit	PO (gavage)	12 doses	0.33 ml/kg	None	5% solution	Contributed data, 2006

197	PEG 400 / ETOH (10%) / DMSO (10%)	Mouse	IV (into tail vein)	Acute	1692 mg/kg (dose vol 5 ml/kg)	NOEL	30% PEG 400	Thackaberry ₂₀
198	PEG 400 / ETOH (10%) / DMSO (10%)	Mouse	IV (into tail vein)	Acute	2820 mg/kg (dose vol 5 ml/kg)	MTD; Ventral recumbancy, tremors, ataxia and hypoactivity shortly after dosing, recovery by 10 mins is typical	50% PEG 400	Thackaberry ₂₀
199	PEG 400 / ETOH (20%)	Mouse	IV (into tail vein)	Acute	3384 mg/kg (dose vol 5 ml/kg)	MTD; Vocalization and struggling at dosing, ventral recumbancy, rapid breathing, tremors and ataxia shortly after dosing, recovery by 5 mins is typical	60% PEG 400	Thackaberry ₂₀
200	PEG 400 / ETOH (200 proof) (95/5, v/v)	Rat	PO	14 days	10ml/kg BD	Abnormal clinical observations included anogenital or urogenital staining, soft feces/watery diarrhea, stained body surface, apparent dehydration, staining around mouth or nose/nares, and wet body surface	Wistar Han (CRL) Rats Age ~8-10 weeks at study initiation; ♂/♀	New contributed data
201	PEG 400 / ETOH / Propylene glycol / Water (sterile) (30/20/20/30)	Rat	IP	7 days	2 ml/kg QD	None	Non-GLP; Age 7-8 weeks; 6♂	New contributed data
202	PEG 400 / ETOH / Water (pH 3-11) (45/5/50)	Rat	IV (bolus)		2 ml/kg	Well tolerated		Strickley ¹¹
203	PEG 400 / ETOH / Water (pH 3-11) (45/5/50)	Rat	IV (infusion)		5 ml/kg	Well tolerated		Strickley ¹¹
204	PEG 400 / ETOH / Water (pH 3-11) (45/5/50)	Dog	IV (bolus)		1 ml/kg	Well tolerated		Strickley ¹¹
205	PEG 400 / ETOH / Water (pH 3-11) (45/5/50)	Dog	IV (Infusion)		2 ml/kg	Well tolerated		Strickley ¹¹
206	PEG 400 / ETOH / Water (Sterile) (1:1:1)	Guinea Pig	IV	28 days	2 ml/kg	Not toxic		Contributed data, 2006

207	PEG 400 / Kolliphor RH40 (70/30)	Rat	PO (gavage)	91 days	10 ml/kg/dose	Sporadic incidences of fecal changes (soft and/or loose/watery); slight brown/orange staining around anus; fluid contents in the cecum; 10% decrease in mean body weights (male rats); lowered food consumption; mildly increase serum urea; minimally decreased serum sodium and chloride values (male rats); minimally increased total serum cholesterol values (females); alterations in urine electrolytes; organ weight changes; minimal, focal or multifocal coagulative hepatocellular necrosis (in 3 females and 1 male)	6♂/6♀	Stokes et al ²⁰³
208	PEG 400 / Kolliphor RH40 (90/10)	Dog	PO (gavage)	28 days	2 ml/kg/dose	Emesis; Administration associated with minimal lamina propria hemorrhage in gastric glandular mucosa in 1/3 dogs	♂; Beagle dogs	Stokes et al ²⁰³
209	PEG 400 / Kolliphor RH40 (90/10)	Dog	PO (gavage)	28 days	5 ml/kg/dose	Fecal alterations (loose/watery, mucoid or red) present beginning on day one; Emesis; Administration associated with minimal lamina propria hemorrhage in gastric glandular mucosa in 2/3 dogs; single/multifocal red areas in stomach; Minimal increase in group mean serum urea	♂; Beagle dogs	Stokes et al ²⁰³
210	PEG 400 / Labrasol / Kolliphor EL (50/30/20)	Mouse	PO (gavage)	182 days	10 ml/kg QD	Unkempt appearance (potential effect)	Age 6 weeks; ♂/♀	New contributed data
211	PEG 400 / NaCL	Mouse	IV		MTD: 4.5 g/kg; LD50: 8.6-9.7; NOEL: 1.7 g/kg	Over tested range, expect hypoactivity, tremors, mild ataxia with increasing duration with dose	CD-1 mice; 80% of a 5 mL/kg dose volume at MTD; (%v/v) in NaCL	Sambrone ⁵
212	PEG 400 / NaCl (0.9%) /	Dog	IV		5ml/kg at a rate of	Partial Hemolysis <i>in vitro</i>		New

	ETOH (50/40/10)				0.3ml/kg	dog blood, RBC discolored		contributed data
213	PEG 400 / Propylene Glycol / ETOH / Water (pH 3) (40/20/5/35)	Dog	IV (infusion)		2.5 ml/kg	Well tolerated		Strickley ¹¹
214	PEG 400 / Propylene Glycol / Tween 80 / Water (25/15/6/54)	Rat	IV	28 days	10 ml/kg	Not toxic		Contributed data, 2006
215	PEG 400 / Propylene Glycol / Tween 80 / Water (25/15/6/54)	Guinea Pig	IV	28 days	10 ml/kg	Not toxic		Contributed data, 2006
216	PEG 400 / Propylene Glycol / Tween 80 / Water (25/15/6/54)	Mouse	IV	28 days	10 ml/kg	Not toxic		Contributed data, 2006
217	PEG 400 / PVP K30 / TPGS (90/5/5)	Dog	PO (gavage)	28 doses	2.5 ml/kg/day	None	90% solution	Contributed data, 2006
218	PEG 400 / PVP K30 / TPGS (90/5/5)	Rat	PO (gavage)	28 doses	5 ml/kg/day	None	90% solution	Contributed data, 2006
219	PEG 400 / Solutol HS15 (70/30)	Rat	PO (gavage)	91 days	10 ml/kg	Males: Sporadic fecal changes (soft and/or loose/watery); slight brown/orange staining around anus; 6% decrease in mean body weight; lower food consumption; organ weight changes; increased urine volume; alterations in urine electrolytes (both genders); fluid contents in the cecum (both genders)	6♂/6♀	Stokes et al ²⁰³
220	PEG 400 / Solutol HS15 (70/30)	Dog	PO (gavage)	28 days	2 ml/kg/dose	Intermittant loose/watery feces; Sporadic emesis starting on day one; 1/3 animals had minimal mucus cell hypertrophy of the ileal mucosa (direct effect of vehicle or effect of loose stools?)	3♀; Beagle dogs	Stokes et al ²⁰³
221	PEG 400 / Solutol HS15 (70/30)	Dog	PO (gavage)	28 days	5 ml/kg/dose	Consistent incidence of loose/watery feces starting on day one; sporadic emesis starting on day one; 2/3 animals had minimal	3♀; Beagle dogs	Stokes et al ²⁰³

						mucus cell hypertrophy of the ileal mucosa (direct effect of vehicle or effect of loose stools?); Increase in RBC mass; decrease in urine volume		
222	PEG 400 / Solutol HS15 (90/10)	Dog	PO (gavage)	28 days	2 ml/kg/dose	Intermittant loose/watery feces; Sporadic emesis starting on day one	3♀; Beagle dogs	Stokes et al ²⁰³
223	PEG 400 / Solutol HS15 (90/10)	Dog	PO (gavage)	28 days	5 ml/kg/dose	Consistent incidence of loose/watery feces starting on day one; sporadic emesis starting on day one; all had minimal mucus cell hypertrophy of the ileal mucosa (direct effect of vehicle or effect of loose stools?)	3♀; Beagle dogs	Stokes et al ²⁰³
224	PEG 400 / TPGS / PVP VA 64 / ETOH (80/10/5/5)	Rat	PO (gavage)	182 days	2 ml/kg QD	White feces (non-adverse)	Age 8 weeks; ♂/♀	New contributed data
225	PEG 400 / TPGS / PVP VA 64 / ETOH (80/10/5/5)	Dog	PO (gavage)	9 months	1 ml/kg QD	None	Age 10-11 months; ♂/♀	New contributed data
226	PEG 400 / Tween 20 / Poloxamer 124 (70/20/10)	Rat	PO (gavage)	26 weeks	2 ml/kg/dose BID	None	Age 6 weeks; ♂/♀	New contributed data
227	PEG 400 / Tween 20 / Poloxamer 124 (70/20/10)	Dog	PO (gavage)	26 weeks	0.5 ml/kg/dose BID	None	Age 6.5-7.5 months; ♂/♀	New contributed data
228	PEG 400 / Tween 20 / TPGS / Poloxamer 124 (50/20/20/10)	Mouse	PO (gavage)	91 days	2 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
229	PEG 400 / Tween 20 / TPGS / Poloxamer 124 (50/20/20/10)	Dog	PO (capsule)	91 days	≤ 5 ml of vehicle QD	Soft/watery feces (non adverse)	Age 6-7 months; ♂/♀	New contributed data
230	PEG 400 / Tween 80 (95/5)	Mouse	PO	2-year care	5 ml/kg BD	During the early stages of the study, a number of mice receiving the vehicle developed gastrointestinal atony resulting in severe bloating and sometimes death.	CD-1 (Harlan) mice age ~7 weeks at study initiation; ♂/♀	New contributed data

231	PEG 400 / Tween 80 (95/5)	Rat	PO	2-year carc	5 ml/kg BD	Well tolerated	Vacuolation of the tubular epithelium in the kidney associated with PEG-linked proteins; Sprague Dawley (Harlan) rats age ~6 weeks at study initiation; ♂/♀	New contributed data
232	Phosal 53 MCT / PEG 400 / Poloxamer 124 / Kolliphor RH40 (40/20/20/20)	Rat	PO (gavage)	99 weeks	2 ml/kg QD	None	Age 6-110 weeks; ♂/♀	New contributed data
233	Phosphate (50 mM) / NaCl (100mM) / Tween-80 (0.01%)	Non-human Primate	SC	Prelim / 2 week	1 ml/kg/injection	Well tolerated		Contributed data, 2006
234	Phosphate buffer 0.5 M at pH 7.5 / 0.4% Mannitol	Rat	SC	Segment I	0.5 ml/animal/injection	Well tolerated		Contributed data, 2006
235	Polawax: 4.80% / Alcohol Denatured SDA 40-2 (190 Proof): 4.25% / Propylene Glycol: 4.00% / Isopropyl Myristate: 2.50% / Sodium Hydroxide Solution (10.0): 1.20% / Phenoxyethanol: 1.00% / Carbomer 974P: 0.55% / Water (purified): 81.7%	Minipig	Topical	210 days	0.4 g/kg QD	None	GLP; Age 3 months; 5♂/5♀	New contributed data
236	Polawax: 4.80% / propylene glycol: 4.00% / ETOH 200 proof: 4.00% / Isopropyl myristate: 2.50% / Sodium Hydroxide 10% solution in purified water: 1.20% / Phenoxyethanol: 1.00% / Carbomer 974P: 0.55%	Mouse	Topical	90 days	3.4 ml/kg QD	None	GLP; Age 7-8 Weeks; 18♂/18♀	New contributed data
237	Poloxamer 188 (0.5%) / NaCl for Injection (USP, 0.9%)	Rat	SC	Single dose	2.5 ml/kg	None	Age 6 weeks; ♂/♀	New contributed data
238	Poloxamer 188 (0.5%) / NaCl for Injection (USP, 0.9%)	Minipig	SC		1 ml/kg	None	Gottingen Minipigs age 5 months; ♂/♀	New contributed data
239	Poloxamer 188 (1%, w/v) / Citrate Buffer (100 mM, pH 3)	Rat	PO (gavage)	14 days	10 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data

240	Propylene Glycol (USP) / Glycerol (USP) / ETOH (200 Proof, USP) (65/25/10, w/w/w)	Rabbit	SC	2x/wk over 3 weeks	1 ml/kg	None	Age 6.5 months; ♂/♀	New contributed data
241	Propylene Glycol (USP) / Glycerol (USP) / ETOH (200 Proof, USP) (65/25/10, w/w/w)	Non-human Primate	SC	1x/wk over 3 weeks	0.5 ml/kg	Scratching and red skin discoloration at the dose site (non-adverse)	Age 3-6 years; ♂/♀	New contributed data
242	Propylene Glycol / Capmul PG8 / ETOH / Water (75/12.5/10/2.5)	Dog	PO (gavage)	7 days	5 ml/kg QD	None	Age 5 months; ♂/♀	New contributed data
243	Propylene Glycol / Capmul PG8 / ETOH / Water (75/12.5/10/2.5)	Rat	PO (gavage)	21 days	10 ml/kg QD	Aspiration, salivation, material around the mouth/nose, audible breathing, stereotypical behavior (scratching in the cage following dosing), death	Consistency of vehicle considered to have contributed to aspiration risk & related observations in the rat; Age 6-9 weeks; ♂/♀	New contributed data
244	Propylene Glycol / ETOH / Water (20/5/75)	Rat	IV (bolus)		1 ml/kg	Well tolerated		Strickley ¹¹
245	Propylene glycol / ETOH / Water (30/20/50)	Dog	IV		5ml/kg at a rate of 0.3ml/kg	Hemolyis <i>in vitro</i> Dog Blood.		New contributed data
246	Propylene glycol / ETOH / Water (50/10/40)	Dog	IV	14 days	4ml/kg/day at a rate of 6ml/min	Frank red urine after first dose, this was occasionally observed throughout the 2 week period, decreases in hematocrit, hemoglobin, and erythrocyte count. Urinalyses were positive for occult blood, bilirubin, ketones and proteins. Swelling at injection site.		New contributed data
247	Propylene Glycol / ETOH / Water (60/20/20)	Dog	IV (bolus)		0.5 ml/kg	Well tolerated		Strickley ¹¹
248	Propylene Glycol / ETOH / Water (pH 3-11) (40/5/55)	Rat	IV (bolus)		2 ml/kg	Well tolerated		Strickley ¹¹
249	Propylene Glycol / ETOH / Water (pH 3-11) (40/5/55)	Rat	IV (Infusion)		5 ml/kg	Well tolerated		Strickley ¹¹
250	Propylene Glycol / ETOH / Water (pH 3-11) (40/5/55)	Dog	IV (bolus)		1 ml/kg	Well tolerated		Strickley ¹¹

251	Propylene Glycol / ETOH / Water (pH 3-11) (40/5/55)	Dog	IV (infusion)		2 ml/kg	Well tolerated		Strickley ¹¹
252	Propylene Glycol / NaCl	Rat	PO (gavage)	4 weeks	2 ml/kg/day	Well tolerated		Contributed data, 2006
253	Propylene Glycol / NaCL	Mouse	IV		MTD: 1.5 g/kg; LD50: 5.0-8.6 g/kg; NOEL: 1 g/kg		CD-1 mice; 30% of a 5 mL/kg dose volume at MTD; (%v/v) in NaCL	Sambrone ⁵
254	Propylene glycol / NaCl (0.9%) / ETOH (50/40/10)	Dog	IV		5ml/kg at a rate of 0.3ml/kg	Hemolysis <i>in vitro</i> Dog Blood.		New contributed data
255	Propylene glycol / PEG 400 / Water / ETOH (40/25/25/10)	Non-human Primate	PO (gavage)	4 weeks	2 ml/kg/day	Well tolerated		Contributed data, 2006
256	Propylene glycol / TPGS / Capmul MCM NF (5:5:2 by weight)	Dog	PO	13-weeks	5ml/kg BD	Administration of the vehicle was associated with emesis and abnormal fecal quality throughout the 13-weeks of the study	Beagle Dogs (Marshall) Age ~6 months at study initiation; ♂/♀	New contributed data
257	PVP K30 (10%) / Sodium Citrate Buffer (50 mM, pH 5)	Rat	PO (gavage)	1 day	10 ml/kg Single dose	None	Age 6 weeks; ♂/♀	New contributed data
258	PVP K30 (10%) / Sodium Citrate Buffer (50 mM, pH 5)	Non-human Primate	PO (gavage)	4 weeks	5 ml/kg Once Weekly	None	Age 5-7 years; ♂/♀	New contributed data
259	PVP K30 (10%) / Sodium Citrate Buffer (50 mM, pH 5)	Non-human Primate	PO (gavage)	28 days	5 ml/kg QD	None	Age 2-3 years; ♂/♀	New contributed data
260	Sesame Oil / ETOH (96/4)	Dog	PO	28 days	2 ml/kg	Not toxic		Contributed data, 2006
261	Sesame Oil / ETOH (96/4)	Rat	PO	28 days	2 ml/kg	Not toxic		Contributed data, 2006
262	Sodium Acetate (25 mM, USP) / Lactose (70 mg/ml) / Water (sterile for injection, USP, pH 4.5)	Dog	SC	14 doses	1 ml/kg	Red discoloration and swelling at injection sites; chronic active inflammation and hemorrhage		Contributed data, 2006
263	Sodium Acetate (25 mM, USP) / Lactose (70 mg/ml) / Water (sterile for injection, USP, pH 4.5)	Rat	SC	14 doses	10 ml/kg	Scabbing at injection site		Contributed data, 2006

264	Sodium Acetate (25 mM, USP) / Lactose (70 mg/ml) / Water (sterile for injection, USP, pH 4.5)	Rat	SC	14 doses	4 ml/kg	None		Contributed data, 2006
265	Sodium Acetate (USP, 25 mM) / Lactose (USP/EP, 70 mg/ml) / Water (pH 4.5)	Rat	SC	28 days	10 ml/kg	Not toxic		Contributed data, 2006
266	Sodium Acetate in NaCL, 5 mM	Rat	IV	1 month	1 ml/kg	Not toxic		Contributed data, 2006
267	Sodium acetate trihydrate buffer (50 mM) / Tween 80 (1%)	Mouse	PO (gavage)	26 weeks	10 ml/kg/day	Well tolerated		Contributed data, 2006
268	Sodium acetate trihydrate buffer (50 mM) /Tween 80 (1%)	Mouse	PO (gavage)	7 days	10 ml/kg/day	Well tolerated		Contributed data, 2006
269	Sodium citrate / NaCl Buffer	Rat	IV	2 weeks	4ml/kg bolus, 2/10min	Well tolerated		Contributed data, 2006
270	Sodium CMC (0.1%) / Methylparaben Sodium (0.1%) / Propylparaben Sodium (0.02%) / Water (purified) (w/v)	Mouse	PO (gavage)	105 Weeks	10 ml/kg/dose BID	None	Age 7 weeks; ♂/♀	New contributed data
271	Sodium CMC (0.1%) / Methylparaben Sodium (0.1%) / Propylparaben Sodium (0.02%) / Water (purified) (w/v)	Rat	PO (gavage)	104 weeks	10 ml/kg/dose BID	None	Age 6 weeks; ♂/♀	New contributed data
272	Sodium Hydroxide (0.1 M) / NaCl for Injection, USP (0.9%)	Non-human Primate	IV (30 minute infusion)	14 days	10 ml/kg QD	None	Age 2-4.5 years; ♂/♀	New contributed data
273	Sodium Hydroxide (10% solution): 2% / Phenoxyethanol: 1% / Carbomer 974P NF: 1% / in purified water	Mouse	Topical	28 days	3.4 ml/kg QD	None	GLP; Age 7 weeks; 12♂/12♀	New contributed data
274	Sodium Phosphate (10 mM) / NaCl (0.8%) / Tween 20 (0.05%) / Water (sterile for injection, USP, pH 6.0 ± 0.3)	Rat	SC	26 weeks	1500 mL/kg Twice Weekly	None	Age 6 weeks; ♂/♀	New contributed data
275	Sodium Phosphate (20 mM) / Sucrose (1%) / Mannitol (4%) / Water (for injection)	Rat	SC	26 weeks	1.38 ml/kg QD	None	Age 7 weeks; ♂/♀	New contributed data

276	Sodium Phosphate (20 mM) / Sucrose (1%) / Mannitol (4%) / Water (for injection)	Rabbit	SC	39 weeks	0.58 ml/kg QD	None	Age 5-6 months; ♂/♀	New contributed data
277	Sodium phosphate buffer (0.3 M) / PEG 400, pH:8 (70:30, w/w)	Non-human Primate	PO (gavage)	4 weeks	2 ml/kg/day (0.4 ml/min/kg)	Well tolerated		Contributed data, 2006
278	Sodium Phosphate buffer (20 mM) / Dextrose (4%) / Sodium Hydroxide (pH 7.9-8.1)	Rat	Infusion	4 days	2 ml/kg/hr	None	Age 8 weeks; ♀	New contributed data
279	Sodium Succinate (25 mM) / Lactose (45 mg/ml) / NaCl (0.45%) / Water (sterile for injection, USP)	Dog	IV	7 doses	1 ml/kg	None		Contributed data, 2006
280	Sodium Succinate (25 mM) / Lactose (45 mg/ml) / NaCl (0.45%) / Water (sterile for injection, USP)	Dog	Sc	14 doses	1 ml/kg	None		Contributed data, 2006
281	Sodium Succinate (25 mM) / Lactose (45 mg/ml) / NaCl (0.45%) / Water (sterile for injection, USP)	Rat	IV	7 doses	1 ml/kg	None		Contributed data, 2006
282	Sodium Succinate (25 mM) / Lactose (45 mg/ml) / NaCl (0.45%) / Water (sterile for injection, USP)	Rat	SC	14 doses	1 ml/kg	None		Contributed data, 2006
283	Sodium Succinate (25 mM) / Mannitol (250 mM) / Water (sterile for injection, pH 4.6)	Rat	SC	Single dose	4 ml/kg	None		Contributed data, 2006
284	Solutol HS 15 / ETOH / Water (40/10/50, v/v/v)	Dog	PO	q7d over 8 weeks	1.5 ml/kg	None	Non-GLP; Age 1-4 Years; 3♂/3♀	New contributed data
285	Solutol HS 15: 15% / ETOH: 5% / PBS	Dog	PO	5 days	20 ml/kg QD	May cause vomiting, loose stool	Non-GLP; Age 1-2 years; 2♂	New contributed data
286	Solutol: 10% / in NaCL	Rat	IV	14 days	6 ml/kg SD	None	Non-GLP; Age 10 weeks; 3♂/3♀	New contributed data
287	Solutol® HS15 / ETOH / Water (40/10/50)	Non-human Primate	PO (gavage)	9 months	3 ml/kg/day	Well tolerated		Contributed data, 2006

288	Sorbitol (5%) / Histidine (10 mM) / Tween 80 (0.01%) / Water (sterile for injection, USP, pH 5.8)	Dog	IV (bolus)	5 weeks	4.98 ml/kg Once Weekly	None	Age 2-3 years; ♂/♀	New contributed data
289	Soybean oil: 50.00% / Coconut oil: 23.60% / Mineral oil: 5.80% / Cyclomethicone: 5.00% / Cetostearyl alcohol: 3.50% / Stearic acid: 3.00% / Myristyl alcohol: 2.50% / Hydrogenated castor oil: 2.00% / White wax (beeswax): 2.00% / Stearyl alcohol: 1.50% / Docosanol: 1.10%	Minipig	Topical	3 weeks	0.25 ml/kg QD	None	GLP; Age 3-4 Months; 5♂/5♀	New contributed data
290	Sucrose (1%) / NaCl (100 mM) / L-arginine hydrochloride (25 mM) / Sodium Phosphate (25 mM, pH 6.3) / Water (for injection, USP)	Non-human Primate	SC	4 weeks	2 ml/kg Twice Weekly	Soft/watery feces	Age 2.5-3.5 years; ♂/♀	New contributed data
291	Sucrose Acetate Isobutyrate / ETOH / PEG 300 (90/5/5)	Cat	Oral mucosa	8 hours	0.1 ml SD	None	Non-GLP; Age >6 months; 3♀	New contributed data
292	TPGS (2%) / HPMC Acetate Succinate (1% HF grade) / PVP K30 (0.25%) / Water (DI)	Rat	PO (gavage)	91 days	10 ml/kg QD	None	Age 6 weeks; ♂/♀	New contributed data
293	TPGS (2%) / HPMC Acetate Succinate (1% HF grade) / PVP K30 (0.25%) / Water (DI)	Dog	PO (gavage)	91 days	10 ml/kg QD	None	Age 6-7 months; ♂/♀	New contributed data
294	TPGS (2%) / HPMC Acetate Succinate (1% HF grade) / PVP K30 (0.25%) / Water (DI)	Rabbit	PO (gavage)	14 days	10 ml/kg QD	None	Age 5-8 months; ♂/♀	New contributed data
295	TPGS (2%) / HPMC Acetate Succinate (1.5% HF grade) / PVP VA 64 (1.5%) / Sodium Citrate (50 mM pH 5) / Water (DI)	Rat	PO (gavage)	28 days	10 ml/kg QD	None	Age 6-8 weeks; ♂/♀	New contributed data
296	TPGS (5%) / Methylcellulose 400 cps (0.5%) / Water (DI)	Rat	PO (gavage)	1 day	10 ml/kg Single dose	None	Age 6 weeks; ♂/♀	New contributed data

297	Trehalose (9%) / Lactic acid (10mM)	Dog	IA	q28d x 4 doses over 85 days	0.4 ml	None	GLP; Age 9-11 Months; 5♂/5♀	New contributed data
298	Trehalose (9%) / Lactic acid (10mM)	Dog	IV	2x / wk x 8 doses over 28 days	0.5 ml/kg	None	GLP; Age 1 Year; 3♀	New contributed data
299	Trehalose (9%) / Lactic acid (10mM)	Rat	IV	14 days	0.5-5 ml/kg SD	None	GLP; Age 16-20 weeks; 6♂/6♀	New contributed data
300	Tween 20 (0.01%) / Sodium Acetate (10 mM) / Sorbitol (5%, pH 5)	Non-human Primate	IV (bolus)	12 weeks	5 ml/kg Once Weekly	None	Age 2-4 years; ♂/♀	New contributed data
301	Tween 20 (0.01%) / Sodium Acetate (10 mM) / Sorbitol (5%, pH 5)	Rat	IV (bolus)	12 weeks	5 ml/kg Once Weekly	None	Age 7 weeks; ♂/♀	New contributed data
302	Tween 80 / CMC / Dimethicone (0.01 %) (Ratio PS80/CMC of 1:1, 0.2 % de PS80 and CMC)	Rabbit	PO (gavage)	1 month	3 ml/kg/day	Well tolerated		Contributed data, 2006
303	Tween 80® (10%) / Citric acid (10.5 mg/ml) / Water (sterile solution)	Rat	IV	2 doses	3 ml/kg	None		Contributed data, 2006
304	Vitamin E (20%) / Sodium Citrate Buffer (50 mM, pH 5)	Rat	PO (gavage)	28 days	10 ml/kg QD	None	Age 8 weeks; ♂/♀	New contributed data
305	Water (sterile for injection, USP) / Sodium Hydroxide	Rat	SC	Single dose	1 ml/kg	Necrosis of the subcutaneous muscle panniculus carnosus, inflamed injection		Contributed data, 2006
306	Xanthan Gum NF (aka: Xantural 180)(0.2%, w/v) / Tween 80 NF (0.255%, w/v) / Water (sterile for injection, USP)	Rat	PO (gavage)	5 days	10 ml/kg/dose BID	None	Age 8-10 weeks; ♀	New contributed data