Annex I: Summary of solvent/vehicle control data

All studies analyzed used immunomagnetic separation for mutant analysis and at least 5 rats per group. All usable studies had primary data in the *Pig-a* data base and had at least pretreatment mutant frequencies and an approx. 28-day data point. All useful studies were conducted with rats. Most results compare pretreatment mutant frequencies with approx. 28-day responses for vehicle controls; propylene glycol used concurrent sham-treated rats for comparison. Historical pretreatment 95% one-sided Tolerance Intervals were available for four labs: Litron, Janssen, Novartis, and NCTR.

Vehicle/solvent	**Number of studies**	**Number labs**	**Number of daily treatments**	**Treatment route**	**Rat strains tested: all males, except males and females marked with ***	**Significantly increased RETs/no. of studies**	**Significantly increased RBCs/no. of studies**
0.9% saline/physiological saline	9	4	1, 3, 28	Iv, ip	SD, F344	0/9	0/9
10% Ethyl alcohol	4	3	1, 3, 28	po	SD, HW	0/4	0/4
Phosphate Buffered Saline (pH 6.0)	5	4	5+3, 1, 3, 28	po	F344, SD*, HW/*gpt*-delta, CD	0/5	0/5

Vehicle/solvent	Number of studies	Number labs	Number of daily treatments	Treatment route	Rat strains tested: all males, except males and females marked with *	Significantly increased RETs/no. of studies	Significantly increased RBCs/no. of studies
Phosphate Buffered Saline (neutral or not specified)	6	3	1, 3, 28	po, ip	F344, CD, SD	2/6[a]	2/6[a]
Water	34	14	1, 3, 28	po, ip	SD*, HW, CD, F344, Wistar	5/34[b]	4/34[b]
Propylene glycol	1	1	7, 35, 63, 90	Inhalation	SD*	0/5	0/5
Sesame oil	15	4	1, 3, 28	po	SD, CD	2/15[a]	1/15[c]
Corn oil	3	2	1	po	SD, CD	0/3	0/3
Olive oil	3	3	1, 28	po	HW, SD, Wistar	0/3	0/3
0.5% HPMC/0.1% Tween 80	1	1	28	po	HW	0/1	0/1
0.5% Methyl Cellulose	2	2	1, 28	po	SD	1/2[c]	0/2

Vehicle/solvent	Number of studies	Number labs	Number of daily treatments	Treatment route	Rat strains tested: all males, except males and females marked with *	Significantly increased RETs/no. of studies	Significantly increased RBCs/no. of studies
0.5% HPMC	6	2	3, 15, 29	po	SD	1/6[a]	1/6[a]
1.25% HPMC, 0.18% methylparaben, 0.02% polyparaben, 0.1% docusate sodium in water	1	1	5	po	Wistar	1/1[c]	0/1
10% designated solvent for etoposide	1	1	1	iv	SD	0/1	0/1

Abbreviations: HPMC, hydroxypropyl methyl cellulose; iv, intravenous; ip, intraperitoneal; po, per os (gavage); SD, Sprague Dawley; F344, Fisher 344; HW, Han Wistar; CD, Cesarean derived; RET, reticulocytes; RBC, red blood cells.

[a]All significant RET and total RBC results had no more than one rat exceeding the historical pretreatment 95% one-sided Tolerance Interval for the lab that generated the response.

[b]4 of 5 significant RET results and 3 of 4 significant RBC results had no more than one rat exceeding the historical pretreatment 95% one-sided Tolerance Interval for the lab that generated the response; the remaining significant results could not be checked due to a lack of historical pretreatment databases.