

Table 6

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This is a paper for discussion. This does not represent the views of the Committee and should not be cited.

Table 6 Acute toxicity studies for PFSA's - PFOS

*Derived by contractor; ** calculated according to EFSA. (2012); NR – not reported; NA – not applicable; # - no. of animals studied per endpoint differs to the no. of animals treated.

Substance / CAS no. / purity / reference	Strain & species / sex / no. of animals	Dose (mg/kg bw/day) / vehicle / route of admin / duration / Guideline (GL) study / Good Laboratory Practice (GLP) status	PFAS concentration (µg/mL / µg/g)	Observed effects at LOAEL (controls vs treated groups). Recovery (controls vs treated groups).	Published NOAEL / LOAEL (mg/kg bw/day)	Study author conclusion
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PFOS (potassium salt)	CAS no. Not given 86.9%.	Cynomolgus monkeys. Male and female 6/sex/dose.	Gavage Single dose, animals not sacrificed, Non-GLP study, GLP not stated. Recovery period: 294 days.	At 9 mg/kg bw in males on day 113 (mean \pm SD)			Males: No adverse effects in liver reported. Females: No adverse effects in liver reported. Recovery: No adverse effects in liver reported.	Males: 9 / NA* Recovery Males: 9 / NA* Females: 9 / NA*	There were no treatment related changes in serum liver enzymes during the study.
				Group 1 and 2: 0 or 9	Serum: 67.7 \pm 7.5.				
				0.5% Tween® 20 + 5% absolute ethanol in water.	At 9 mg/kg bw in males on day 420, Serum: 14.1 \pm 2.0				
					Liver: 7.8 \pm 5.5. At 9 mg/kg bw in females on day 113 Serum: 68.8 \pm 2.5. At 9 mg/kg bw/day in females on day 420 Serum: 9.5 \pm 4.4 Liver: 8.3 \pm 3.3.				

PFOS (potassium salt) CAS no. Not given 86.9%. Chang et al. (2017)	Cynomolgus monkeys, Male and female, 4-6/sex/dose.	Group 1 and 3: 0, 14, 14.8 / 17.2 (male/female) and 11 0.5% Tween 20 + 5% EtoH. Gavage, Single doses on days 43, 288 and 358, animals not sacrificed, Non-GL study GLP not stated.	At 14 mg/kg bw/day in males on day 50 (mean \pm SD)			
			Serum: 104.8 \pm 5.2.			
			At 14 mg/kg bw/day in females on day 50			
			Serum: 96.5 \pm 6.2.			
			At 14.8/17.2 bw/day in males on day 295			
			Serum: 141.0 \pm 13.1.	Males: No adverse effects in liver reported.	Males: 14.8 or 17.2 / NA*.	
			At 14.8/17.2 bw/day in females on day 295	Females: No adverse effects in liver reported.	Females: 14.8 or 17.2 / NA*.	There were no treatment related
			Serum: 147.6 \pm 17.5.			
			At 11 mg/kg bw in males on day 365	No adverse effects in liver reported.	Recovery Males: 14.8 or 17.2 / NA*.	changes in serum liver enzymes during the study.
			Serum: 160.8 \pm 14.2.	Recovery: No adverse effects in		
			At 11 mg/kg bw in females on day 365		Females: 14.8 or	