

Table 11

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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 11. Repeated dose toxicity studies for PFCAs - PFDA

*Derived by contractor; ** calculated according to EFSA. (2012); NR – not reported; NA – not applicable.

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 comments
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PFDA		0, 0.125, 0.25, 0.5, 1 or 2.				The data under consideration are not indicative of exposure chain polyfluoroalkyl substances may include effects consistent with class.
CAS No. 335-76-2	Sprague-Dawley rats.	Deionized water/2%, Tween 80,		Males (mean ± SE): ↑ relative liver weight (%): 3.42 ± 0.09 vs 3.77 ± 0.10.	Females: NA / 0.125	
97.8%.	Female	Gavage,	NR			
Frawley et al. (2018)	8/group.	28 days,		Recovery not assessed.		
		Non-GLP study,				
		GLP not stated.				

		0, 0.31, 0.625, 1.125, 2.5 or 5.			
PFDA				Males (mean \pm SE):	
CAS No.	B6C3F1	Deionized		\uparrow absolute liver	
335-76-2	mice,	water/2%,		weight (g):	
		Tween 80,		1.122 ± 0.031	
97.8%.	Female	Gavage,	NR	vs 1.42 ± 0.054	Females:
Frawley et	8/group.	28 days,		\uparrow relative liver	0.31 /
al. (2018)		Non-GL		weight (%): 4.83	0.625.
		study,		± 0.08 vs 5.61	
		GLP not		± 0.06 .	
		stated.		Recovery not	
				assessed.	

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PFDA	CAS No. 335-76-2	Sprague-Dawley rats.	Tween® 80 in deionized water.	At 0 mg/kg bw/day in males (mean ± SE). Plasma: 0.022 ± 0.004 Liver: <LOD.	At 0.156 mg/kg bw/day in males. Plasma: 8.5 ± 0.6 Liver: 44.7 ±	Males (mean ± SD): ↑ absolute liver weight (g): 11.89 ± 0.51 vs 13.54 ± 0.40. ↑ relative liver weight (g): 35.50 ± 0.97 vs 39.32 ± 0.53. ↓ TP (g/dL): 6.4 ± 0.1 vs 6.2 ± 0.1. ↓ globulin (g/dL): 2.2 ± 0.1 vs 1.9 ± 0.0. ↑ albumin/globulin ratio: 1.9 ± 0.1 vs 2.2 ± 0.1. ↓ cholesterol (mg/dL): 107 ± 5 vs 78 ± 3.	↑ gene expression of Acox1: 1.03 ± 0.10 vs 1.70 ± 0.17. ↑ gene expression of Cyp4a1: 1.04 ± 0.10 vs 10.85 ± 1.11.	Males: NA / 0.156.	A major toxicity liver. Cyp2b1 activation mediated by Acox1/ suggests
						0, 0.156, 0.312, 0.625, 1.25 or 2.5.			