

Table 11

In this guide

[In this guide](#)

1. [Table 3 - Annex A](#)
2. [Table 4 - Annex A](#)
3. [Table 5 - Annex A](#)
4. [Table 6 - Annex A](#)
5. [Table 7 - Annex A](#)
6. [Table 8 - Annex A](#)
7. [Table 9 - Annex A](#)
8. [Table 10 - Annex A](#)
9. [Table 11 - Annex A](#)
10. [Table 12 - Annex A](#)
11. [Table 13 - Annex A](#)
12. [Table 14 - Annex A](#)
13. [Table 15 - Annex A](#)
14. [Table 16 - Annex A](#)
15. [Table 17 - Annex A](#)
16. [Table 18 - Annex A](#)
17. [Table 19 - Annex A](#)
18. [Table 20 - Annex A](#)
19. [Table 21 - Annex A](#)

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 comment
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PFDA		0, 0.125, 0.25, 0.5, 1 or 2.				
CAS No. 335-76-2	Sprague-Dawley rats.	Deionized water/2%, Tween 80,				
97.8%.	Female	Gavage,	NR			
Frawley et al. (2018)	8/group.	28 days,		Males (mean \pm SE): \uparrow relative liver weight (%): 3.42 \pm 0.09 vs 3.77 \pm 0.10. Recovery not assessed.	Females: NA / 0.125	The data under c not ind exposu chain polyflu may inc effects consist class.
		Non-GL study,				
		GLP not stated.				

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

The data under consideration are not indicative of an exposure chain. polyfluorinated compounds may induce effects consistent with the class.

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.

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 ±

↑ 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.

↑ gene expression of Cyp2b1: 1.06 ± 0.21 vs 3.33 ±

0, 0.156, 0.312, 0.625, 1.25 or 2.5.

Tween® 80 in deionized water.

Sprague-Dawley rats.

Males: NA / 0.156.

A major toxicity liver.

Cyp2b1 activation mediated by Acox1/...

PFDA

CAS No. 335-76-2