

# 21CFR 170.39 (Threshold of Regulation (TOR) #000315) LAURAMID® FPM

**Regarding 21 CFR170.39, Lauramid® FPM (Polyamid 12 Cast / CAS No. 2937-16-4) as a component of repeat use food contact articles intended to contact all foods at temperatures not to exceed 90°C. Infant formula or human milk is locked out from the intended use of Lauramid® FPM. The submission to the FDA was inquiry under pre-notification consultation (PNC) No. 2329.**

The polymer Lauramid® FPM was tested according to 21CFR § 177.1500 of the FDA regulation onto extractable substances, by an independent laboratory. Regarding to 21 CFR § 177.1500, Water, Ethanol 95%, Ethylacetat and Toluol were tested. A 3g sample quantity was weighed in, and 8h under reflow extracted.

## Result of the extraction:

Solvent	(mg/g sample)	(% per weight)	(% per weight limit value)
Water	0,8	0,08	1,0
Ethanol 95%	1,2	0,12	2,0
Ethylacetat	1,0	0,1	1,5
Toluol	1,2	0,12	1,5

The results of the values are noticeably below the limit value according to 21CFR § 177.1500b



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