

Table 2

**REGULATION (EU) 2021/1297 AMENDING ANNEX XVII TO REACH AS
REGARDS PERFLUOROCARBOXYLIC ACIDS CONTAINING 9 TO 14
CARBON ATOMS IN THE CHAIN (C9-C14 PFCAS),
THEIR SALTS AND C9-C14 PFCA-RELATED SUBSTANCES**

Test	Sample	Temperature/Time	Ratio sample/ Simulant ¹	Simulant	Migrate to be analyze
N-nitrosamines, Nitrosatable substances	Bottle teats, nipples and soothers ²	40 °C, 24 h	5 g/20 mL	Saliva	First
	Balloons ³	40 °C, 1 h	4 g/40 mL		
	Toys, teether rings, bite guards, mouthpieces	40 °C, 24 h			
Primary aromatic amines (PAAs)	All	40 °C, 24 h	1 dm ² /200 mL	Deionized water	First
Specific migration guide values	Toys ⁴	Room temp., 1 h 'Head-over-heels (60 rpm)	10 cm ² /100 mL (min. 100 mL)	Deionized water	Third ⁵
	Bottle teats, breast caps	40 °C, 24 h	1 dm ² /200 mL	Deionized water, 3% acetic acid, milk (3.5% fat) ⁶	
	Samples other than bottle teats and breast caps	40 °C, 24 h	1 dm ² /200 mL	Deionized water	
Overall migration	Bottle teats, breast caps	40 °C, 24 h	1 dm ² /200 mL	Deionized water, 3% acetic acid,	Third ⁵
	Samples other than bottle teats and breast caps	40 °C, 24 h	1 dm ² /200 mL	Deionized water	

¹Use actual contact surface

²DIN EN 12868:2017-04 'Determining the release of N-nitrosamines and N-nitrosatable substance from elastomer or rubber teats and soothers'

³DIN EN 71-12:2017-03, 'N-nitrosamines and n-nitrosatable substances', taking Annex C (A – Deviations) into account

⁴Compare DIN EN 71-10:2006-03 'Organic chemical compounds – sample preparation and extraction'

⁵Unless otherwise specified, a detection limit of 0.01 mg/kg applies for not-detected (ND) for the specific migration limit (SML). Materials or articles must comply with SML in the first test

⁶50% ethanol can be used as simulant in analogy to Regulation (EU) 10/2011. A test in milk is required to determine non-conformity.