

Table 2

FEDERAL INSTITUTE FOR RISK ASSESSMENT
'SPECIAL CONSUMER GOODS MADE OF NATURAL AND SYNTHETIC
RUBBER AND LATTICES MADE OF NATURAL AND SYNTHETIC
RUBBER (FORMERLY SPECIAL CATEGORY)', AS OF JULY 1, 2021

| Test | Sample | Temperature/Time | Ratio sample/ Simulant ¹ | Simulant | Migrate to be analyzed |
|---|---|---|---|--|---------------------------|
| 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.