GERMAN FEDERAL INSTITUTE FOR RISK ASSESSMENT

20 YEARS

BfR
German Federal Institute for Risk Assessment

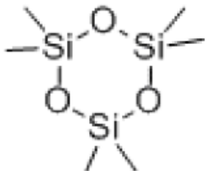
BfR activities on silicone

Stefan Merkel

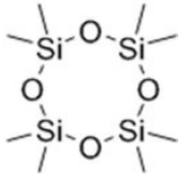
1. Silicone-Oligomers

2. Testing of volatile organic compounds

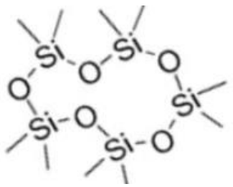
Overview



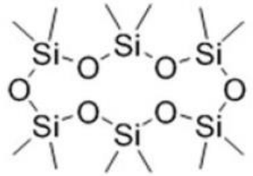
Hexamethyl-
cyclotrisiloxane
(D3)



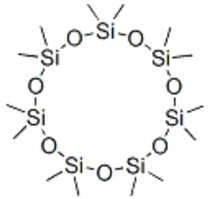
Octamethyl-
cyclotetrasiloxane
(D4)



Decamethyl-
cyclopentasiloxane
(D5)



Dodecamethyl-
cyclohexasiloxane
(D6)



Tetradecamethyl-
cycloheptasiloxane
(D7)

$((CH_3)_2SiO)_m$
m = 4, 5, 6…

+ HMDSO

$(CH_3)_3Si\text{-}O\text{-}[(CH_3)_2Si\text{-}O]_x\text{-}Si(CH_3)_3$

vulcanisation

Silicone-
Elastomer

$((CH_3)_2SiO)_nH$
n = 20 - 50

+ Catalyst

Toxicological Data

- What data is available and what data is needed?

Studies for migration < 5 mg/kg food	D3	D4	D5	D6	≥ D7
Not genotoxic	✓	✓	✓	✓	✘
Subchronic toxicity (90d study)	✓	✓	✓	✓	✘
No bioaccumulation (ADME)	✘	✓	✓	(✓)	✘
Chronic toxicity	✘	✓	✓	✘	✘
Carcinogenicity	✘	✓	✓	✘	✘
Reproduction toxcitity	(✓) **screening**	✓	✓	(✓) **screening**	✘

- D4 and D5 complete set of data, but
- Major studies only for inhalative exposure → additional uncertainty for assessment
- For D3 and D6 reduced set of data
- For ≥ D7 no data

Hazard assessment / toxikological effects

- Not genotoxic
- Increase of liver weight → considered as adaptive and not as adverse
- Increase of kidney weight in chronical study (persistent after recovery phase)
- Changed estrous cycle (but no effect on estrogen receptor)
- Increased growth of uterine mucosa (hyperplasy of endometrial epithelia)
- Increased number of benign and malignant tumors of the endometrium (endometrial adenomas and adenocarcinomas); threshold mechanism plausibel
- Relevance of observed effects for humans is unclear
- Possible accumulation of higher oligomers in humans is unclear

Health based guidance value

- **$BMDL_{05}$** (kindney weight, chronic inhalative study D4) = **84 ppm**

- Conversion to oral value: **$BMDL_{05}$ = 21 mg/kg body weight/day**
  $\rightarrow$ higher oral uptake than inhalative uptake considered

- If: body weight = 60 kg and daily consumption = 1 kg food:
  acceptable migration = 13 mg/kg food

- Indication of same mode of action $\rightarrow$ migration value for sum of probably absorbed oligomers
- Correction factor for increasing molecular weight F = $\frac{M_{D4}}{M_{Dn}}$

- $\sum_{n=3}^{13}\left(Migration_{Dn} * \frac{M_{D4}}{M_{Dn}}\right) \leq 13\ mg/kg$

Exposure Assessment / Risk Assessment

- Silicone oligomers show structural similarity, similar metabolites can be expected, comparable toxicological effects (not genotoxic, increase of liver and kidney weight) can be expected
- → Group assessment is considered useful
- → Oligomers up to D13 (<1000 Da) are considered as relevant
- → increase in kidney weight is considered as most sensitive toxicological endpoint

- High uncertainty due to limited migration data
- Migration data for cyclosiloxanes (D3-D7) from silicone bakings moulds into oil, MPPO, and tarte au chocolat show:
  - Results from oil and tarte au chocolat are comaparable with correction factor X/3 for fatty food
  - Sub-samples show different results probably due to inhomogeneous material
  - For samples that release less than 0,1% volatile organic components (testing 4 hours @ 200°C) no migration >50µg/kg in third migrate was observed

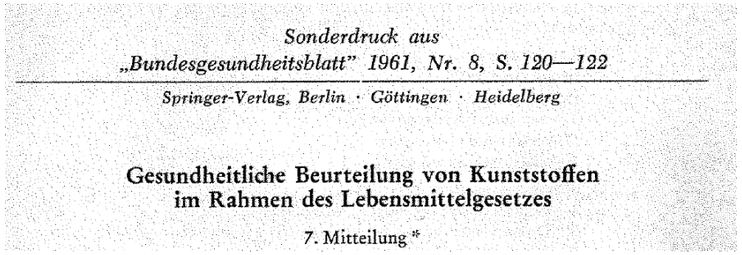
→ No exposure assessment with current data

→ A complete risk assessment can only be made with the availability of migration data from real foodstuffs

1. Silicone-Oligomers

2. Testing of volatile organic compounds

Testing of Silicone FCM



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Springer-Verlag, Berlin · Göttingen · Heidelberg

Gesundheitliche Beurteilung von Kunststoffen im Rahmen des Lebensmittelgesetzes

7. Mitteilung *

The following requirement is listed in BfR-Recommendation XV. Silicones:
"*The silicone elastomers must release no more than 0.5 % volatile organic…components*" (GMP requirement only)

→ Testing according to intendet use will be changed to testing for 4 hours @ 200°C for all uses

→ New gravimetric testing method developed by the NRL FCM with better reproducibility

Parameter	Value
sample amount	10 g for each repetition
sample preparation	cut into pieces of approximately 1x2 cm
forced convection/ air supply	No convection and closed air supply
weighing pan material	Electroconductive
conditioning	60 ± 5 min at 100 ± 5 °C
cooling after conditioning	30 ± 5 min in desiccator
tempering	4 h ± 5 min at 200 ± 5 °C
cooling after tempering	60 ± 5 min in desiccator

Testing of Silicone FCM

- Conditioning of 1h@100 °C necessary to avoid false positive results
- Swift handling is mandatory
- Electroconductive material for weighting pans recommended
- Labs (method validation study) performed satisfactory for all samples as long as ventilation is switched off
- Adapted methods works very well with small standard deviations
- Results of the MES allow the estimation of an expanded relative measurement uncertainty of only 25% at a probability of 95%

→ Method is available at BfR website: https://www.bfr.bund.de/cm/349/determination-of-volatile-compounds-in-silicone-consumer-products.pdf

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Thank you for your attention

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