

# **BfR activities on rubber**

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## BfR Recommendation XXI

### Commodities based on Natural and Synthetic Rubber

- Applies to elastomer articles for contact with food and with mucuous membranes:  
tubings, sealing rings, bottle caps and stoppers, linings of storage containers, conveyor belts,  
rubber parts in milking machines, gloves  
bottle teats, pacifiers, toys for children up to 3 years, toy balloons ...



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### Commodities based on Natural and Synthetic Rubber

- 4 categories according to contact time with food
  - Category 1: > 24 hours (storage containers, sealing rings for cans ...)
  - Category 2: ≤ 24 hours (flexible tubing for conducting foodstuffs)
  - Category 3: ≤ 10 minutes (rubbers teats, tubing for milking machines)
  - Category 4 : very short period of time or with a very small part of its surface, and does not belong in Categories 1 to 3 (conveyor belts, suction and pressure lines).
  
- Special category
  - commodities intended or can be expected to be put in the mouth (bottle teats, pacifiers, toys for children up to 3 years, toy balloons)
  
- Does not apply to silicone rubbers.

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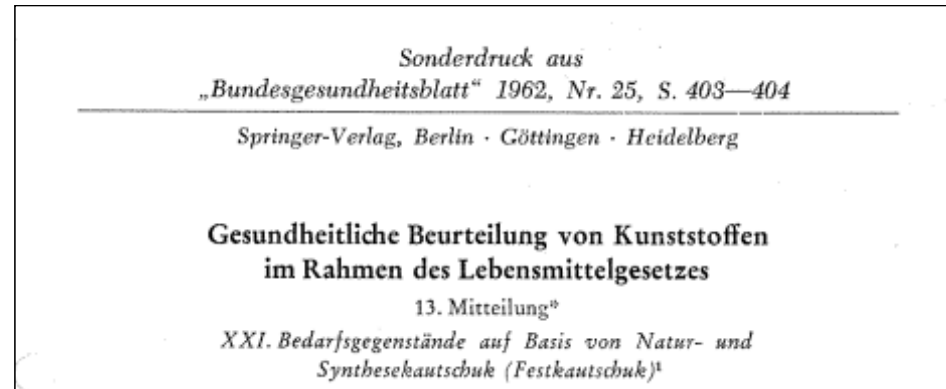
### Commodities based on Natural and Synthetic Rubber

#### Current approach:

- Positive list with limitation of the quantities to be used  
Risk assessment refers to the transfer of substances under worst case conditions of use of the finished materials (quantity used, t/T, type of food, type of elastomer)
- Classification of the substances corresponding to their function in the manufacture of elastomers  
Starting materials, vulcanising agents, anti-aging agents, fillers ...
- Additional requirements on finished products
  - e. g. limits for N-nitrosamines, primary aromatic amines, secondary aliphatic and cycloaliphatic amines, zinc, lead
  - Labelling instructions for products with dermal contact in terms of the risk of allergic reactions caused by latex proteins

## Why is a revision necessary?

- Established in 1962



- Generally revised in 1978 (i.a. introduction of categories)
- Only very few petitions for new substances after 1990 (introduction of the evaluation principles of the SCF Note for Guidance)

➔ The evaluation of substances listed in XXI is not in accordance with the current state of risk evaluation on food contact materials.

- Editorial update is necessary (confusing structure, long and confusing list of footnotes ...)

## Objectives of the revision

- Adaptation to the current state of risk assessment of substances migrating from FCM
- information on the state of evaluation for the substances of the positive list
- Improvement / simplification of the structure
- Inclusion of new materials (TPE-V)

## Key points of revision

- Taking into account the results of substance evaluations by SCF/EFSA, international risk assessment bodies, and evaluations by BfR
- Replacement of restrictions for use amounts by specific guidance values for migration into food (SMR) as far as available
- Separate recommendations for commodities of the special category and for thermoplastic elastomers (TPE-V)
- Subdivision of all substances into two lists:
  - List A: substances evaluated according to the state of the art with SMRs
  - List B: provisional list of substances not evaluated according to the state of the art maintaining the current types of restrictions
  - Listing of substances in tabular format with CAS No., FCM No., and limits

## Key points of revision – continued

- Inclusion of general lists of different elastomer types
- Description of synthetic rubber types used as starting material by a list of monomers
- Update on norms for analytical methods
- Addition of further migration simulants (10% ethanol, 3% acetic acid + 20% ethanol, 50% ethanol, vegetable oil and Tenax)



## Structure of the revised Recommendations XXI – overview

**XXI. Commodities based on elastomers, manufactured from natural and synthetic rubber (“Framework“)**

**XXI/1: Commodities manufactured from natural and synthetic rubber for food contact**

**XXI/2: Special commodities manufactured from Natural and Synthetic Rubber**

XXI/3: Commodities for food contact manufactured from thermoplastic elastomers (TPE-V)

# Thermoplastic elastomers

## European Commission (2014)

### Union Guidelines on Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food

#### NOTE:

Thermoplastic elastomers (TPE) are co-polymers made of polymers which fall under the definition of polymers set out in the Plastics Regulation. They are composed of substances identical to plastics, even though they may differ in physico-chemical properties. ... TPE should be manufactured with monomers and additives listed in Plastics Regulation and should respect the specific migration limits (SMLs).

- ➡ TPEs manufactured from substances listed in Regulation (EU) No 10/2011 are not covered by recommendation XXI. It is intended to develop a specific recommendation for thermoplastic vulcanisates (TPE-V).

## Structure of the revised Recommendations XXI

„Framework“ recommendation:

### **XXI. Commodities based on elastomers, manufactured from natural and synthetic rubber**

- Scope and explanation of the structure.
- Provisions for the addition of new substances (following EFSA Note for Guidance)
- Definitions

**It is intended to introduce SMR for all substances. For this purpose manufacturers are requested to file petitions for the substances of the B-lists by which a final evaluation is enabled.**

## Structure of the revised Recommendation XXI

### **XXI/1: Commodities manufactured from natural and synthetic rubber for food contact**

Covers materials and articles of categories 1 – 4 in the current version

Additional aspects:

- Results of migration testing with food prevail over the results obtained with simulants.
- Expression of SMR for caps, gaskets, stoppers according to Regulation (EU) 10/2011 Art. 17 No 3.
- Deletion of requirements which are not relevant for risk assessment (e. g. limits for extracts with acetone and methanol).
- List of monomers instead of extensive descriptions of copolymers used as starting materials.

## Structure of the revised Recommendation XXI

### **XXI/2: Special commodities manufactured from Natural and Synthetic Rubber**

Covers materials and articles of the special category in the current version

### **XXI/3: Commodities for food contact manufactured from thermoplastic elastomers (TPE-V)**

(to be developed at a later stage)

## Structure of the revised Recommendation XXI

### XXI: Commodities manufactured from natural and synthetic rubber for food contact – List A

Gleitmittel- und Formtrennmittel							
FCM-Stoff-Nr.	CAS Nr.	Chemischer Name	XXI/1	XXI/2	SMR (mg/kg)	SMR (T), Nr.	Bemerkungen
575	0063148-62-9	Polydimethylsiloxane (Mw> 6800)	X	X			Viskosität bei 25 °C: mindestens 100 cSt (100 × 10 <sup>-6</sup> m <sup>2</sup> /s)
	0000557-05-1	Zinkstearat	X	X		1	
		Fettsäuren, C <sub>12</sub> -C <sub>20</sub> , Na- und/oder K-Salze	X	X			
561	0009004-67-5	Methylcellulose	X	X			
638	0025322-68-3	Polyethylenglykol	X	X			Darf höchstens 0,2 % Monoethylenglykol enthalten. Bestimmungsmethode s. 28. Mitteilung über die Untersuchung von Kunststoffen, Bundesgesundheitsblatt 16 (1973) 362.
639	0025322-69-4	Polypropylenglykol	X	X			
250	0000110-30-5	Bis-stearoyl-ethylendiamin	X	X			Nur für Butadien-Styrol-Sequenzpolymere.

## Structure of the revised Recommendation XXI

### XXI/1: Commodities manufactured from natural and synthetic rubber for food contact – List B

Zusatzbeschleuniger						
CAS Nr.	Chemischer Name	Kategorie 1	Kategorie 2	Kategorie 3	Kategorie 4	Bemerkungen
0000149-30-4	2-Mercaptobenzothiazol	(4)				
0000120-78-5	Dibenzothiazylsulfid	(4)		höchstens 1,0%		Für Kategorien 3-4: Es darf entweder Dibenzothiazylsulfid oder Zink-2-mercaptobenzothiazol eingesetzt werden.
0000155-04-4	Zink-2-mercaptobenzothiazol			höchstens 1,0%		
Oberflächenhärter						
CAS Nr.	Chemischer Name	Kategorie 1	Kategorie 2	Kategorie 3	Kategorie 4	Bemerkungen
0000098-77-1	Pentamethylen-ammonium-N-pentamethylen-dithiocarbamat	Die beiden Stoffe dürfen im Fertigerzeugnis nicht nachweisbar sein.				Die Prüfung erfolgt nach Teil B II, XXI, Abschnitt 32.5.2.2.6 der in Fußnote 3 angegebenen Veröffentlichung.
0005459-93-8	Cyclohexylethylamin					
000111-92-2	Dibutylamin					Beschränkungen gemäß 4.5 sind zu beachten

### XXI/2: Special commodities manufactured from Natural and Synthetic Rubber – List B

Vulkanisationshilfsmittel			
Oberflächenhärter			
CAS Nr.	Chemischer Name	Begrenzung	Bemerkungen
Stoffe wie in Empfehlung XXI/1			
Vulkanisierungsbeschleuniger			
CAS Nr.	Chemischer Name	Begrenzung	Bemerkungen
0000137-30-4	Zink-(N-N-dimethyl-dithiocarbamat)		Die Zusatzmenge ist so zu beschränken, dass schwefelhaltige Beschleuniger im Extrakt der Fertigerzeugnisse nicht nachweisbar sind. Die Untersuchung erfolgt nach Abschnitt 7.1.1 der in Fußnote 8 angegebenen Veröffentlichung. Für die Abgabe der aus diesen Beschleunigern entstehenden N-Nitrosamine und N-nitrosierbaren Stoffe gelten die Bestimmungen gem. Anlagen 4 und 5 der Bedarfsgegenständeverordnung. Die Anforderung hinsichtlich des Gesamtübergangs von Zink nach Abschnitt 4.1 dieser Empfehlung ist zu beachten.
0014324-55-1	Zink-(N-N-diethyl-dithiocarbamat)		
0000136-23-2	Zink-(N-N-dibutyl-dithiocarbamat)		
0013878-54-1	Zink-(N-N-pentamethylen-dithiocarbamat)		
0014634-93-6	Zink-N-ethyl-phenyl-dithiocarbamat	höchstens 0,4%	
0014726-36-4	Zink-N-dibenzyl-dithiocarbamat	höchstens 0,5%	
0084604-96-6	Zink-N-diisononyl-dithiocarbamat	höchstens 0,5%	
0053880-86-7	Dimethyldiphenylthiuramsulfid		Die Zusatzmenge ist so zu beschränken, dass schwefelhaltige Beschleuniger im Extrakt der Fertigerzeugnisse nicht nachweisbar sind. Die Untersuchung erfolgt nach Abschnitt 7.1.1 der in Fußnote 8 angegebenen Veröffentlichung. Für die Abgabe der aus diesen Beschleunigern entstehenden N-Nitrosamine und N-nitrosierbaren Stoffe gelten die Bestimmungen gem. Anlagen 4 und 5 der Bedarfsgegenständeverordnung.
0000120-54-7	Dipentamethylen-thiuramtetrasulfid		

## **Thank you for your attention**

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