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XXI/2. Special consumer goods made of natural and synthetic rubber and of latices made of natural and synthetic rubber (formerly special category)

As of 01.09.2024

1. Preliminary remarks

Recommendation XXI. Consumer goods based on natural and synthetic rubber must be observed.

- a) This Recommendation applies to consumer products which
- come into contact with the human mucous membrane,
 - come into contact with the human mucous membrane and additionally into contact with food,
 - come into contact with the human mucosa and are intended as toys for children under 36 months.

Examples:

1. Toys intended to be put in the mouth or intended for children under 36 months of age and which are therefore experientially or foreseeably put in the mouth.^{1,2}
 2. Balloons²
 3. Bottle teats²
 4. Soothers (dummies)²
 5. Breast caps
 6. Teething rings
 7. Denture protection
- b) For articles with exclusive skin contact, only the requirements set out in 4.7 apply.
- c) Unless otherwise specified in the Annex to Recommendation XXI, a migration guideline value of 60 mg/kg food or simulant applies for the respective substance.
- d) The total migration of substances shall not exceed 60 mg/kg simulant.

¹ Recommendation XLVII. "Toys made from plastics and other polymers and from paper, cardboard and paperboard".

² With regard to the release of *N-nitrosamines* or substances that can be converted into *N-nitrosamines*, the requirements according to Annex 4 or Annex 5 of the Consumer Goods Ordinance (Bedarfsgegenständeverordnung) apply.

2. Substances for the manufacture of consumer goods from natural and synthetic rubber

2.1 For examples 1 - 2

Only the substances listed in the Annex to Recommendation XXI for Recommendation XXI/2, those listed in Recommendation XXI/1 for Category 1 and those listed in Table 2 of this Recommendation may be used for the manufacture of toys and balloons (Examples Nos. 1 and 2).

2.2 For examples 3 - 7

2.2.1 Starting materials for examples 3 - 7

The types of rubber recommended for use are listed in Table 1. Only the substances listed in the Annex to Recommendation XXI for Recommendation XXI/2 and in Table 2 of this Recommendation may be used to pre-stabilise latices.

2.2.2 Additives, production aids for examples 3 - 7

Only the substances listed in the Annex to Recommendation XXI for Recommendation XXI/2 and those listed in Table 2 may be used, subject to the restrictions specified therein.

Explanations to tables 1 and 2

FCM substance no.: Identification number of the substance according to the Regulation (EU) No 10/2011

CAS No.: Registration number of the Chemical Abstracts Service (CAS)
If CAS numbers are specified, only substances with the specified CAS numbers may be used.

Table 1: List of rubbers/latices

FCM substance no.	CAS No.	Chemical name	Requirements/restrictions
574	0009006-04-6	Natural rubber	Light non-smoked varieties, also pre-cured varieties ^{3,4} , also natural rubber latex
	0009003-31-0 0104389-31-3 0104389-32-4	Polymerisates of isoprene (polyisoprene) (IR)	
	0009003-55-8	Polymerisates of butadiene and styrene (SBR)	
	25038-32-8 0025038-32-8	Polymerisates of isoprene and styrene (SIS)	

³ These must not contain p-nitrophenol, boric acid and pentachlorophenol sodium. Hydroxylamine shall not be detectable in the finished product. Testing for these substances shall be carried out in accordance with sections 2.3.1, 3.7, 3.8 and 3.9 of the publication referred to below:

Franck, R. Plastics in food traffic. Cologne: Carl Heymanns Verlag - loose-leaf edition, Part B II XXI: Investigation of rubber consumer goods, ISBN: 978-3-452-16045-4.

Other validated analytical methods can also be used to check the guide values.

⁴ Only substances listed in Recommendations XXI, XXI/1 and XXI/2 may be used for pre-crosslinking. The restrictions on the use of additives and manufacturing aids in the manufacture of certain product groups described in points 3.1 and 3.2 must be observed.

Table 2: Additives and manufacturing aids not conclusively evaluated

Vulcanization accelerator			
CAS No.	Chemical name	Limitation	Requirements/restrictions
0000137-30-4	Zinc (N-N-dimethyl dithiocarbamate)		The quantity added must be limited in such a way that accelerators containing sulphur are not detectable in the extract of the finished products. The test shall be carried out in accordance with section 7.1.1 of the publication referred to in footnote 3 of Table 1. For the release of <i>N-nitrosamines</i> and <i>N-nitrosatable</i> substances resulting from these accelerators, the provisions of Annexes 4 and 5 of the Consumer Goods Ordinance apply. The requirement regarding the total transfer of zinc according to section 4.1 of this Recommendation must be observed.
0014324-55-1	Zinc (N-N-diethyl dithiocarbamate)		
0000136-23-2	Zinc (N-N-dibutyl dithiocarbamate)		
0014634-93-6	Zinc N-ethyl phenyl dithiocarbamate	maximum 0.4 %	
0014726-36-4	Zinc N-dibenzyl dithiocarbamate	maximum 0.5 %	
0084604-96-6	Zinc N-diisononyl dithiocarbamate	maximum 0.5 %	
0000120-54-7	Dipentamethylene thiuramtetrasulfide		
0023847-08-7	Caprolactam disulfide	maximum 1 %	The quantity added must be limited in such a way that accelerators containing sulphur are not detectable in the extract of the finished products. The test is carried out in accordance with section 7.1.1 of footnote 3 of Table 1 specified publication. A guideline value of 100 mg/kg elastomer must be observed for the release of ϵ -caprolactam. Consumer goods manufactured using caprolactam disulphide must be washed at 90 °C for 1 hour. Regulation (EU) No. 10/2011 has a SML of 15 mg/kg food or food simulant for caprolactam defined.
0000149-30-4	2-mercaptobenzothiazole		The content of 2-mercaptobenzothiazole (MBT) in the commodity must be minimized as far as technically possible so that only technically unavoidable quantities are detectable in the extract of the finished products. For analysis, reference is made to DIN EN 1400. There, a limit value of 8 mg per kg rubber and 24 h is specified for the release from suction cups.
Processing aids			
CAS No.	Chemical name	Limitation	Requirements/restrictions
0009003-19-4	Polyvinyl ether		According to Recommendation XVI "Polyvinyl ether". Only for latexes and rubber dispersions.
Emulsifiers and dispersants			
CAS No.	Chemical name	Limitation	Requirements/restrictions
0104376-75-2	Distyrylphenol, ethoxylated		
0068130-72-3	Benzylated hydroxybiphenyl, ethoxylated		
0009084-06-4	Naphthalenesulfonic acid, polymer with formaldehyde, sodium salt		see 4.5 of this Recommendation
Precipitant			
CAS No.	Chemical name	Limitation	Requirements/restrictions
0009003-09-2	Polyvinyl methyl ether		

3. Migration testing

Compliance with the temperature must be checked in the food or simulant.

Table 3. Migration testing

Test	Sample	Time / Temperature conditions	Ratio sample / Simulant ⁵	Test medium	Migrate to be checked
<i>N</i> -nitrosamines, Nitrosatable substances	Bottle teats and soothers, nipples ⁶	24 h/40 °C	5 g/20 ml	Saliva simulant	first
	Balloons ⁷	1 h/40 °C	4 g/40 ml		
	Toys, teething rings, bite guards, mouthpiece ⁷	24 h/40 °C			
Primary aromatic amines	All	24 h/40 °C	1 dm ² /200 ml	deionised water	
Specific migration guide values	Toys ⁸	1 h / room temperature, "head-over-heels" (60 rpm/min)	10 cm ² /100 ml (min. 100 ml)	deionised water	third ^{9,10}
	Bottle teats, breast caps	24 h/40 °C	1 dm ² /200 ml	deionised water, 3 % by weight acetic acid, Milk (3.5 % fat) ¹¹	
	all remaining	24 h/40 °C	1 dm ² /200 ml	deionised water	
Total migration of substances	Bottle teats, Breast caps	24 h/40 °C	1 dm ² /200 ml	deionised water, 3 wt.% acetic acid	
	all remaining	24 h/40 °C	1 dm ² /200 ml	deionised water	

⁵ When specifying a surface/volume ratio, the actual contact surface must be used.

⁶ The test is carried out in accordance with DIN EN 12868:2017-04 (Child use and care articles - Method for determining the release of N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers).

⁷ The test is carried out in accordance with DIN EN 71-12:2017-03 (Safety of toys - Part 12: N-nitrosamines and N-nitrosatable substances), taking into account Annex C (A - Deviations).

⁸ Compare DIN EN 71-10:2006-03 (Safety of toys - Part 10: Organic chemical compounds - Sample preparation and extraction)

⁹ If non-detectable (NN) is specified for the specific migration limit, a detection limit of 0.01 mg substance per kg foodstuff shall apply, unless otherwise specified for an individual substance. For these substances, the material or article must already comply with the specific migration limit in the first test.

¹⁰ Consumer goods for single use must already comply with the specific migration guide value in the first test.

¹¹To confirm the conformity of an article, 50 % ethanol by volume can be used as a test simulant in analogy to Regulation (EU) No 10/2011. A test in milk is required to determine non-conformity.

4. Finished products

In addition to the requirements and specifications already mentioned in the individual sections, the consumer goods must comply with the following further conditions:

- 4.1 The total transfer of zinc from finished products shall not exceed 25 mg/kg of food or simulant.
- 4.2 The total transfer of aluminium from finished products shall not exceed 1 mg/kg food or simulant.
- 4.3 A transfer of lead from finished products shall not be detectable with a detection limit of 0.01 mg/kg food or simulant. The test shall be carried out in the first migration.
- 4.4 The following also applies to consumer goods in accordance with this Recommendation:

The migrates shall not contain primary aromatic amines classified as carcinogenic substances of categories 1A and 1B according to Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures in a detectable amount. The detection limit is 0.002 mg/l.

In total, primary aromatic amines shall not be detectable in the migrates above 0.01 mg/l.

- 4.5 The total transfer of formaldehyde from finished products must not exceed 6 mg/kg food or food simulant.
- 4.6 When testing consumer articles covered by this Recommendation, with the exception of bottle teats, soothers, balloons and toys for children under 36 months of age which are intended or foreseeably placed in the mouth, for which the limitation of the transfer of *N*-nitrosamines and nitrosatable substances is laid down by the Consumer Goods Ordinance, - to comply with the following for *N*-nitrosamines:
 - Non-detectable with a detection limit of 10 µg per kg of commodity.
 - The test is carried out according to Annex 10 No. 6 of the Consumer Goods Ordinance.
 - When testing consumer articles in accordance with this recommendation, the limit on the release of nitrosatable substances (non-detectable with a detection limit of 0.1 mg/kg consumer article) specified in Annex 4 of the Consumer Article Ordinance must also be observed. Toys that are neither intended nor foreseeably placed in the mouth are exempt from this.
 - The testing of the transition of *N*-nitrosamines and nitrosatable substances from nipples is carried out according to DIN EN 12868, toys and balloons are to be tested according to DIN EN 71-12, whereby the deviation in Annex C is to be observed.

- 4.7 In order to prevent the risk of allergies, the soluble protein content of articles made of natural rubber materials in accordance with this Recommendation and for articles in contact with the skin shall be reduced to a minimum. In the case of products manufactured from natural rubber latex, the materials and articles or their packaging shall bear a statement to the effect that the product is manufactured using natural rubber latex which may cause allergies.
- In the case of bottle teats and soothers, this reference to the possible triggering of allergies can be omitted if a release of latex proteins is not detectable (< 20 ppm according to the method published with the 59th Communication on the testing of plastics "Bestimmung des extrahierbaren Proteins aus Bedarfsgegenständen aus Naturkautschuk" (Bundesgesundheitsblatt, Gesundheitsforschung, Gesundheitsschutz, 43 (2000) 77) or < 0.15 ppm (as latex allergens) according to ASTM D7427-08 "Immunological Measurement of Four Principal Allergenic Proteins (Hev b 1, 3, 5 and 6.02) in Natural Rubber and Its Products Derived from Latex").
- In the case of products made of natural rubber, the articles or their packaging shall bear a statement to the effect that the product has been manufactured using natural rubber.
- 4.8 Some of the substances listed in this Recommendation may produce an antimicrobial effect in the finished product. However, no substances may be used for the purpose of intentionally imparting antimicrobial properties to finished products, including those listed in the Recommendation.