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XXXVI/3. Absorber pads based on cellulosic fibres for food packaging

As of 01.07.2016

Preamble

This Recommendation applies to fibrous materials (section I A) and overall production aids (section I B) used in the production process for paper, paperboard and board that comes into contact with foodstuffs, and final products (section III). Moreover, in the paper production process substances are used to keep manufacturing devices clean and to protect them from corrosion. This Recommendation shall not apply for these substances. The manufacturer or distributor of the paper is responsible to comply to food regulations (especially Regulation (EU) No. 1935/2004) for these substances¹. However, substances listed in this Recommendation subject to the above stated applications were listed before 2013.

Substances that are used for manufacturing of fibrous materials listed in section I A or substances that are used for formulation of active ingredients listed in section I B (e.g. emulsifiers, solvents, set-up chemicals, stabilizer, pH modifiers) are not subject to this BfR-Recommendation. For their application requirements of article 3 of the Regulation (EU) No. 1935/2004 shall be used¹. However, substances listed in this Recommendation subject to the above stated applications were listed before 2013. Preservatives that are used to prevent microbial spoilage of formulations and slimicides are still covered by this Recommendation. If the following Recommendation is observed, it may be assumed that the duty of care required in the manufacture, treatment and placing on the market of absorber pads based on cellulosic fibres has been complied with.

I. Requirements to the materials used in the manufacture of the absorbent core

A. Fibrous materials:

1. Natural and synthetic fibres based on wood pulp and cellulose derivatives
2. Synthetic fibres made of
 - a) plasticizer-free copolymer of vinyl chloride and vinyl acetate
 - b) Polyethylene
 - c) Polypropylene
 - d) Polyesterprovided they comply with the prevailing requirements of food law^{2,3}.

¹ For guidance on compliance of the manufacturer's responsibility the following guidelines and assessments of substances may be used exemplarily: other Recommendations of the BfR, assessments of the European Food Safety Authority or the Scientific Committee on Food (SCF), Regulation (EU) No. 10/2011, European rules on food additives and drinking water. Moreover, an assessment can be made by the manufacturer on his own responsibility.

² If other auxiliary agents, for example for fibre preparation, are necessary, they must be submitted for approval.

³ Going beyond the requirements laid down in Recommendation III, in the manufacture of polyethylene, polyvinyl alcohol may also be used as a protective colloid. Viscosity of 4 % aqueous solution of the polyvinyl alcohol at 20 °C, min. 5 mPa·s.

B. Overall production aids

1. Slimicides:

- a) Enzymatic agents
Fructose polysaccharide (levan)-hydrolase, 12.5 mg dry substance per kg paper. No more than one unit of levanase activity per gram paper must be detectable.
- b) Anti-microbial agents:
 1. Chlorine dioxide
 2. Hydrogen peroxide
 3. 1,2-Benzisothiazolin-3-one (not detectable in cold water extract, detection limit of analysis method $10 \mu\text{g}/\text{dm}^2$)^{4,5}
 4. Mixture of 5-chloro-2-methyl-4-isothiazolin-3-one and 2-methyl-4-isothiazolin-3-one in the ratio of 3:1, max. 4 mg/kg (not detectable in cold water extract, detection limit of analysis method $0.5 \mu\text{g}/\text{dm}^2$ for the sum of the mentioned isothiazolinones)^{4,5}.
 5. 2-Methyl-4-isothiazolin-3-one^{4,5} (not detectable in the cold water extract, detection limit of analysis method $1 \mu\text{g}/\text{dm}^2$)

2. Paper-refining agents

- 2.1 Polyacrylamide, provided it contains no more than 0.1 % monomeric acrylamide, max. 0.015 %
- 2.2 Copolymer of acrylamide and (2-(methacryloyloxy)ethyl)trimethylammonium chloride, max. 0.1 %, provided it contains no more than 0.1 % residual acrylamide and no more than 0.5 % residual (2-(methacryloyloxy)ethyl)trimethylammonium chloride
- 2.3 Copolymer of acrylamide and (2-(acryloyloxy)ethyl)trimethylammonium chloride, max. 0.1 %, provided it contains no more than 0.1 % residual acrylamide and no more than 0.5 % residual (2-(acryloyloxy)ethyl)trimethylammonium chloride
- 2.4 Cross-linked, cationic polyalkylene amines⁶, i.e.
 - a) Polyamine-epichlorohydrin resin, produced from epichlorohydrin and diaminopropyl methylamine
 - b) Polyamide-epichlorohydrin resin, produced from epichlorohydrin and adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine
 - c) Polyamide-epichlorohydrin resin, produced from adipic acid, diethylenetriamine and epichlorohydrin or from a mixture of epichlorohydrin and ammonia
 - d) Polyamide-polyamine-epichlorohydrin resin, produced from epichlorohydrin, adipic acid, dimethyl ester and diethylenetriamine
 - e) Polyamide-epichlorohydrin resin, produced from epichlorohydrin, diethylenetriamine, adipic acid and ethyleneimine, max. 0.3 %
 - f) Polyamide-epichlorohydrin resin, produced from adipic acid, diethylenetriamine and a mixture of epichlorohydrin and dimethylamine, max. 0.1 %
 - g) Polyamide-epichlorohydrin resin, produced from diethylenetriamine, adipic acid, glutaric acid, succinic acid and epichlorohydrin, max. 4.0 %

⁴ Production of the cold water extract according to DIN EN 645.

⁵ Methods for testing commodities (materials and articles) made of paper or paperboard are available under http://www.bfr.bund.de/de/methodensammlung_papier_karton_und_pappe-32620.html.

⁶ Ethyleneimine must not be detectable in the resins (detection limit: 0.1 mg/kg). 1,3-Dichloro-2-propanol must not be detectable in aqueous extract from the finished product (detection limit: 2 $\mu\text{g}/\text{l}$). The transfer of 3-monochloro-1,2-propanediol into the water extract of the finished products must be as low as technically achievable, a limit of 12 $\mu\text{g}/\text{l}$ must not be exceeded in any case.

- h) Polyamide-epichlorohydrin resin, produced from diethylenetriamine, triethylene-tetramine, adipic acid and epichlorohydrin, max. 4.0 %
- i) Polyamide-epichlorohydrin resin, produced from adipic acid, diethylenetriamine, aminoethylpiperazine and epichlorohydrin, max. 1.0 %. In the resin the proportion of aminoethylpiperazine in relation to adipic acid must not exceed 10 mol%.

Of the wet-strength agents referred to in a) - i), in total max. 4 %, based on dry fibre in the finished product, may be used.

- 2.5 Copolymer of vinyl formamide and vinyl amine, max. 1.0 %
- 2.6 Polyethyleneimine, modified with ethylene glycol and epichlorohydrin, max. 0.2 %⁶
- 2.7 Polyhexamethylene-1,6-diisocyanate, modified with ethylene glycol monomethyl ether, max. 1.2 %
- 2.8 Polyhexamethylene-1,6-diisocyanate, modified with ethylene glycol monomethyl ether and N,N-dimethylaminoethanol, max. 1.2 %
- 2.9 Galactomannan, max. 0.5 %
- 2.10 Copolymer of styrene, butylacrylate and methylmethacrylate, max. 5.0 %
- 2.11 Copolymer of acrylamide and acrylic acid, cross-linked with N-methylene-bis(acrylamide), max. 1.0 %
- 2.12 Melamine-formaldehyde resin, max. 3 %
No more than 1 mg formaldehyde/dm² must be detectable in extract from finished product.

3. Preservatives

- 1. Sorbic acid
- 2. 2-Bromo-2-nitropropane-1,3-diol, max. 0.003 %, based on the dry fibres weight. This substance must not be detectable in extract of the finished product
- 3. 2,2'-dithiobis[N-methylbenzamide], max. 22 µg/dm². The sum of 2,2'-dithiobis[N-methylbenzamide] and its hydrolysis products 2-methyl-1,2-benzothiazol-3(2H)-one and 2-mercapto-N-methylbenzamide must not exceed 30 µg/dm², determined in dimethyl sulfoxide extract of the finished product

The listed preservatives must only be used in amounts necessary to protect the raw materials and processing aids from deterioration and decay.

4. Dewatering accelerators

Lignosulfonic acid

Water-glass, stabilised with 0.42 % sodium tetraborate, based on the formulation

5. Dispersing agents

Calcium stearate, max. 0.4 %

6. Defoamers

- a) 2,4,7,9-tetramethyl-5-decyne-4,7-diol
- b) 3,6-dimethyl-4-octyne-3,6-diol
- c) 2,5,8,11-tetramethyl-6-dodecyne-5,8-diol

The transfer of these three substances from the final product (in)to foodstuff may not exceed 0.05 mg/kg foodstuff (sum of the three substances).

N,N'-ethylene-bis-stearamide

Linear primary alkan-1-oles/alken-1-oles with 8-26 carbon-units (fatty alcohols), also in emulsified form⁷

II. Requirements to further materials used in the manufacture of absorber pads

Further materials used in the manufacture of absorber pads like plastics, non-woven materials, glues etc. have to comply with the legal requirements for food contact applicable to them.

III. Requirements on the final products

1. No more than 10 µg/l lead and 5 µg/l cadmium must be detectable in the cold water extract of the finished product.
2. The absorber pads paperboard must have no preserving effect on the foodstuffs with which they come into contact⁸.

⁷ Max. 2 % paraffin and max. 2 % alkyl and alkyaryloxethylates and their esters with sulfuric acid (as emulsifiers) may be added to 20 - 25 % aqueous solution of this antifoam agent. The liquid paraffins must comply with the "Purity requirements for liquid paraffins" in the 155th Communication of Bundesgesundheitsblatt 25 (1982) 192

⁸ Determination of transfer of antimicrobial constituents according to DIN EN 1104