NETHERLANDS

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11. NETHERLANDS **PETROLEUM WAXES**

USAGE : **In/on food** - As coating

CHEESE-WAXES

Hard-paraffin wax, petrolatum and micro-crystalline wax are allowed to be used in cheese wax formulations, according to the "Landbouw Kwaliteits-beschikking kaasprodukten" of 28 December 1981 (agricultural quality decree-cheese products), provided they comply with the purity requirements (*) of the "Verpakkingen en gebruiksartikelen besluit - Warenwet" (Packaging and Food Ustensils Decree) of 1 October 1979.

(*) The same as FDA § 172.886.

11. NETHERLANDS **PETROLEUM WAXES**
NATURAL ESTER WAXES

USAGE : **In contact with food** - In/on packaging materials

PARAFFINS AND WAXES IN CONTACT WITH FOOD - GENERAL

The usage of hard paraffins and micro-crystalline waxes in contact with foodstuffs in general regulated by the "Decision of 1 October 1979 by the Minister of Public Health and the Environment concerning Packaging and Food Utensils" - (This decision complies with the agreement M 73/17 d.d 31-08-73 of the Committee of the Ministers of the Benelux Economic Union).

Packaging materials which come into direct contact with foodstuffs and certain specified articles will contaminate these foodstuffs/articles by migration of components from the packaging material into the foodstuffs/articles.

Overall (gross and global) migration as well as the migration of individual components (specific migration) have to comply with the limits as stated in the regulation.

Overall migration, under normal conditions, from the packaging as determined by the prescribed methods shall in general not exceed the value of 10 mg/dm^2.

Specific migration, under normal conditions, of each of the components from the packaging material as determined by the prescribed methods shall not exceed the value indicated in the regulations.

No specific migration limits have been stipulated for hard paraffins (incl. synthetic), micro-crystalline waxes and refined petrolatums which comply with UV absorbance requirements equivalent to FDA 172.886 (formerly FDA 121.1156).

Also no specific migration limits have been stipulated for montan wax, liquid paraffin and various animal/vegetable waxes provided they comply with the purity requirements as stated in the regulations.

For the packaging of fatty foods these materials are only allowed, if the fatcontent is less than 40 % and also the contact between packaging material and packed goods is predominantly discontinuous.

Superseded by note of October 20, 1998.

11. NETHERLANDS — PARAFFIN WAX

USAGE : **In pharmacy**

REGULATIONS

Nederlandse Pharmacopee 1978, 8e uitgave (Dutch Pharmacopoeia 1978, 8th edition)

QUALITY REQUIREMENTS

1. Paraffinum solidum (hard paraffin)

Definition : Purified mixture of solid, saturated hydrocarbons from petroleum.

Description : A colourless or white substance with a crystalline structure. Odourless, even when freshly cut. When melted the liquid at 60°C is clear, colourless and free from fluorescence by daylight.

Solidifying point : Solid in a water bath at 54°C but molten in a water bath at 57°C.

Solubility : Insoluble in water; nearly insoluble in alcohol; slightly soluble in ether and chloroform.

Acidity/alkalinity : Boil 5 g with 5 ml alcohol (90 % v/v). Add 10 ml water and shake. Upon addition of 0.1 ml standard phenolphthalein solution no red colour may appear but the water layer must colour red after addition of 0.1 ml of 0.1 N Na OH solution.

Sulphated ash : Not more than 0.1 % on a sample of 1.0 g.

Carbonisable substances : Sulphuric acid test. Warm 5 g with a mixture of 4 ml sulphuric acid (94-96 %) plus 1 ml water in a waterbath to a temperature of 60°C. Maintain this temperature for 10 minutes while shaking the mixture regularly. The paraffin and the sulphuric acid must stay colourless.

Reducing substances : Warm 5 g with 5 ml water in a boiling water bath for a period of 10 minutes. Add 0.1 ml sodium permanganate solution 0.1 N and shake for 5 minutes while maintaining the temperature. The water layer should not be discoloured.

2. White petroleum jelly (vaselinum album)
Yellow petroleum jelly (vaselinum flavum)

Definition : Mixture of hydrocarbons obtained from the distillation residues of petroleum. Clay treated.

Description : **White petroleum jelly** : Unctuous mass. White or nearly white. More or less translucent.

Yellow petroleum jelly : Unctuous mass. Pale yellow.

Melting/congealing range : 40 - 65°C.

Sulphuric acid test : Specified for white petroleum jelly only. 5 g molten petroleum jelly warmed with 3 ml of a mixture of 11 volumes 95/97 % sulphuric acid and 5 volumes water at 60°C for 10 minutes, shaking the mixture regularly. There must be no coloration of either layer.

Fluorescence : Faintly fluorescent at 75°C in daylight.

11. NETHERLANDS — NATURAL ESTER WAXES

USAGE : **Pharmacy**

REGULATIONS

The European Pharmacopoeia, 2nd Edition, includes monographs for white beeswax and yellow beeswax; for details refer to Section 19 - European Economic Community - as at August 1987 these are the only sections on waxes in the European Pharmacopoeia although it is understood that a monograph on carnauba wax is to be issued.

The Pharmacopoeia requirements for beeswax in all countries adopting the European Pharmacopoeia are therefore now identical and as given in Section 19; these requirements supersede those of the individual national pharmacopoeias.

It is understood that the following countries have agreed to adopt the requirements of the European Pharmacopoeia, either as original parties to the Convention on the Elaboration of a European Pharmacopoeia or through subsequent decisions (the European Pharmacopoeia has official status in the laws of the European Economic Community) :

Austria	Germany	Portugal
Belgium	Greece	Spain
Denmark	Italy	Sweden
EIRE	Luxembourg	Switzerland
Finland	Netherlands	United Kingdom
France	Norway	

METALS

(Non-authorised Translation of The Netherlands Packaging and Food-Utensils Regulation)

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CHAPTER IV METALS

1. Description:

1.1. For the purpose of this regulation, metallic packaging materials and utensils, provided or not with a coating other than of enamel.

2. Packaging Materials:
In manufacturing and processing, may be only used the following materials:

a. Basic materials:
aluminium, alloyed or not with chromium, copper, iron, magnesium, manganese, silicon, titanium and a maximum of 0.25% of other elements
copper
steel, alloyed or not

b. Solders:
Alloys, substantially consisting of copper, lead, tin, silver and zinc, and satisfying the following specifications:
antimony content: not to exceed 3%
arsenic content: not to exceed 0.05%
bismuth content: not to exceed 0.1%
cadmium content: not to exceed 0.5%
Lead-containing solders shall be used exclusively on the outside of the packaging material, insofar as the soldered seam is not covered with a metallic coating according to c., with a lacking film according to 2.2.g. or with adhesive tape as described under 2.2.e.

c. Metallic coatings:
Only coatings of the following metals shall be applied to the basic materials mentioned under a. and to the solders specified under b.:
aluminium, alloyed or not and may or may not be anodized
chromium, alloyed or not
copper, alloyed or not
nickel, alloyed or not
tin, insofar as satisfying the following specification:
tin content: at least 99,75%
arsenic content: not to exceed 0.03%
cadmium content: not to exceed 0.05%
lead content: not to exceed 0.05%
The above-mentioned basic materials and metallic coatings may be passivated by means of chemical or electrochemical aftertreatment.

2.2 Rules governing the manufacture of the end product:

The end product shall be manufactured and processed with the exclusive use of the above-mentioned starting agents and of the additives specified hereafter. All materials and additives shall be of a good technical quality. Additives shall not be used in larger amounts than are strictly needed for the manufacture of the end product. The end product shall contain no substances other than the basic materials and solders mentioned above and the additives specified hereinafter, the condensation products obtained there from as well as the possible decomposition products of the additives.

e. Adhesive tape for covering the side seam:
Base materials:
aluminium, as described under 2.1.a.
polypropylene, according to Chapter I
terephthalic acid esters, according to Chapter I
Adhesives:
Only the materials specified under g. may be used.

f. Sealants for end double-seams:
Besides the materials mentioned under d. and under g., only the following additives may be used:
alkyl(C_8-C_{18})benzene sulfonates, sodium salts
alkyl(C_8-C_{18})difenyletherdisulfonic acid, sodium salts
ammonium alginate
arabic gum
ascorbic acid, sodium salt
1,2-benzisothiazoline-3-on
benzoic acid, potassium- and sodium salts
butadiene-styrene-fumaric acid copolymers, containing no additives other than those approved in Chapter I
calcium- and zinc salts of colophony (wood rosin, gum rosin, tall rosin, dark wood rosin and dark tall rosin), obtained from pine trees of the Pinus genus, Pinaceae family, modified or not by hydrogenation, dimerization or dismutation (disproportionation)
carboxymethylcellulose, sodium salt
2,2'-dibenzamidophenyl disulphide, not to exceed 0.7%
N,N'-di-2-naphthyl-p-phenylenediamine, containing not to exceed 10 mg/kg 2-naphthylamine, not to exceed 0.6%
ethylenediaminetetraacetic acid, sodium salt
o-phenylphenol, sodium salt
formaldehyde
glycerol
gutta-percha
1,6-hexanediol
hexamethylenetetramine
4-hydroxybenzoic acid, methyl ester
karaya gum
paraffin, liquid (refined mineral oil), satisfied the following specification:
colour fainter than Standard Saybolt 30
virtually no odour
and the absorption of with satisfies the values stipulated in Part B (Methods of Investigations).
paraffin, solid, including synthetics, the UV absorption of which satisfies stipulated in Part B (Methods of Investigations)
polyethylene, molecular weight > 200
polyoxy(ethylene- and/or propylene- and/or butylene)ethers of nucleus sulphonated mono-, di- and trialkyl(C_4-C_{18})phenols
polystyrene mix- and copolymers
proteins: bone-glue, casein, gelatin, glue from hide, isinglass and zein
rubber products, according Chapter III, Category I and II
sodium sulphite
sorbic acid and the potassium- and sodium salts
sulphosuccinic acid, esterified with polyoxy(ethylene- and/or propylene- and/or butylene) ethers of alcohols, C_4-C_{18}
2,4,7,9-tetramethyl-5-decyn-4,7-diol, ethylene oxide adduct
triethylene glycol
tris(mono- and dinonylphenyl)phosphite, with a content of tris(2-hydroxypropyl)amine not exceeding 1%

polycarbonate, according to Chapter I
polyethylene, according to Chapter I
polyesters, obtained by a reaction between one or more of the following polyhydric acids and one or more of the following poyhydric alcohols, the reaction can be finished with one of the following monobasic acids or monohydric alcohols:
1) *polybasic acids*:
adipic acid
azelaic acid
1,2,4-benzenetricarbonic acid
p.tert.butylbenzoic acid
cyclohexane-1,2-dicarboxylic acid
decanedicarboxylic acid
maleic acid
phthalic acids
sebacic acid
succinic acid
2) *monohydric acids*:
benzoic acid
4,4-bis(4'-hydroxyphenyl)pentanecarboxylic acid
fatty acids as described under 2.2.c.
3) *polyhydric alcohols*:
1,3-butanediol
1,4-butanediol
diethyleneglycolmonoethyl ether
2,2-dimethylpropanediol
di-, tri- en polypropanediol-1,2
ethanediol
glycerol
1,6-hexanediol
mannitol
1,2-propanediol
triethyleneglycolmonoethyl ether
1,1,1-tris(hydroxymethyl)ethane
1,1,1-tris(hydroxymethyl)propane
4) *monohydric alcohols*:
monohydric, aliphatic alcohols C_8-C_{18}
polyesters obtained from the methylester of colophony, maleic anhydride, phthalic anhydride and ethanediol, acid number 4-11, colour K or lighter, Drop Softening Point 70°-90°C
polyesters, unsaturated, according to Chapter I
polypropylene, according to Chapter I
polyurethane, according to Chapter I
polyvinylacetate, according to Chapter I
polyvinyl acetals, prepared from polyvinyl alcohol and aliphatic, saturated aldehydes, C_1-C_8, molecular weight > 10.000, containing no other additives than those approved in Chapter I
polyvinyl alcohol (viscosity of the 4% solution in water at 20°C to be at least 5 mPas)
polyvinyl chloride, according to Chapter I
polyvinylidene chloride, according to Chapter I
ricinus oil, which may or may not be hydrogenated or dehydrated, and may or may not be condensed or polymerized with adipic acid, citric acid, maleic acid, phthalic acids and sebacic acid
rubber products, synthetic, according to Chapter III, chlorinated or cyclized
terpene resins, prepared from α-pinene, ß-pinene and/or dipentene, modified or not with phenol, satisfied the following specification:
acid number < 5
saponification number < 5
colour of a 50% solution in petroleum spirits less than 4 Gardner

6° *other additives:*
fatty acids, as described under c., esterified with polyols, C_3-C_6
fatty acids, as described under c., vinyl esters of
organopolysiloxanes, containing two methyl groups at each silicon atom (silicones)
oxides of aluminium, calcium, iron, silicon, titanium and zinc
silicates of aluminium, calcium, potassium and sodium, including clay, diatomaceous earth, fibrous glass, infusorial earth, kaolin, mica and talc
zinc carbonate

7° *Dyes and pigments*:
according to Chapter I paragraph 4.

8° *Solvents and inks*:
- solvents: so far as the end product complies with the requirements of article 2, first section, part c of the Packaging and food-utensils Regulation (Food Law)
- inks: concerning the requirements of Chapter I paragraph 4

3 Utensils:
These utensils shall be manufactured only from the following materials:

a. basic materials:
- aluminium, alloyed or not, and anodized or not
- cast iron, alloyed or not
- copper alloyed or not, lead content not to exceed 2%. Notwithstanding the provisions of copper alloys may have a lead content not exceeding 5% in applications where self-lubricating properties are required
- gold, platinum and silver, mixed or not or alloyed or not with copper, nickel, tin or zinc and with a cadmium content not exceeding 0.5%
- magnesium, alloyed or not
- nickel, alloyed or not
- steel, alloyed or not
- tin, alloyed or not, with a lead content not exceeding 0.05%
- titanium, alloyed or not
- zinc, alloyed or not

b. solders:
Alloys substantially consisting of copper, lead, tin, silver or zinc and meeting the following specifications:
antimony content: not exceeding 3%
arsenic content: not exceeding 0.05%
bismuth content: not exceeding 0.1%
cadmium content: not exceeding 0.5%
Notwithstanding the provisions above-mentioned use may be made of solders having a cadmium content not exceeding 20%, but only if the soldered places are completely sealed with a metallic layer.

c. Welding material:
of such a composition that the soldered joint complies with the requirements of article 2, first section, part c the Packaging and food-utensils Regulation (Food Law)

formaldehyde and hexamethylenetetramine, total:	15
lithium compounds (as lithium):	1
lead:	0.1
manganese:	3
melamines:	6
nickel:	1
phenolic compounds (as phenol):	15
phenylphenol, sodium salt:	0.1
2,4,7.9-tretramethyl-5-decyn-4,7-diol, ethylene oxide adduct:	0.05
vanadium:	1
zirconium compounds (as zirconium):	0.05

4.4 If materials covered by other chapters of this regulation are used in the manufacture of metals and or utensils of this chapter, specific migration limits set out for constituents of these materials shall also be satisfied.

4.5 Notwithstanding the provisions of 4.3 foods and/or beverages packaged in tin plate may have a lead content not exceeding 0.5 mg/kg, in milk and milk-products not exceeding 0.3 mg/kg, in tomato-puree and concentrated tomato-juice not exceeding 1.5 mg/kg and the tin content not exceeding 150 mg/kg.

4.6 If the packaging materials and utensils are intended to come exclusively into contact with a specific food or beverage, the specific migration of the metals mentioned under 4.3. shall be determined with the use of that food or beverage using the conditions mentioned in Part B (Methods of Investigations), Chapter I under 1.3.2.
If the packaging materials and utensils are intended for contact with foods and/or beverages not identified by name, the migration tests must be carried out with 3% acetic acid, notwithstanding the provisions laid down in Part B, Chapter I, under 1.3.1.

4.7 The migration of metals from the packaging materials and utensils described in this chapter which already are in contact with a food or beverage shall be determined in that food or beverage.

4.8 The migrations requirements concerning 4.2. and 4.3. are not relevant to sealants for end double-seams mentioned under paragraph 2.2.f.