

SCHEDULE 1

Regulation 2(5)

New Schedule 6 to the Materials and Articles in Contact with Food (Wales) Regulations 2012

“SCHEDULE 6

Regulation 12(1) and (2)

LIST OF SUBSTANCES AUTHORISED IN THE
MANUFACTURE OF REGENERATED CELLULOSE FILM

Notes:

- The percentages in this Schedule are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film.
- The usual technical denominations are given in square brackets.
- The substances used shall be of good technical quality as regards the purity criteria.

Table 1

Uncoated regenerated cellulose film

<i>Denominations</i>	<i>Restrictions</i>
A. Regenerated cellulose	Not less than 72% (w/w)
B. Additives	
1. <i>Softeners</i>	Not more than 27% (w/w) in total
— Bis (2-hydroxyethyl) ether [= diethyleneglycol]	Only for films intended to be coated and then used for foods which are not moist, namely which do not contain water which is physically free at the surface. The total amount of bis(2-hydroxyethyl)ether and ethanediol present in foods that have been in contact with film of this type may not exceed 30mg/kg of the foodstuff.
— Ethanediol [= monoethyleneglycol]	
— 1,3-butanediol	
— Glycerol	
— 1,2-propanediol [= 1,2 propyleneglycol]	
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1200.
— 1,2-polypropylene oxide [= 1,2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1,3-propanediol content not greater than 1% (w/w) in substance.
— Sorbitol	
— Tetraethyleneglycol	
— Triethyleneglycol	
— Urea	

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Denominations	Restrictions
2. Other Additives	Not more than 1% (w/w) in total.
<i>First class</i>	The quantity of the substance or group of substances in each indent may not exceed 2mg/dm ² of the uncoated film.
— Acetic acid and its NH ₄ , Ca, Mg, K and Na salts	
— Ascorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
— Benzoic acid and sodium benzoate	
— Formic acid and its NH ₄ , Ca, Mg, K and Na salts	
— Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic and ricinoleic acids and the NH ₄ , Ca, Mg, K, Na, Al and Zn salts of these acids	
— Citric, d- and l-lactic, maleic, l-tartaric acids and their Na and K salts	
— Sorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
— Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic and ricinoleic acids	
— Natural edible starches and flours	
— Edible starches and flours modified by chemical treatment	
— Amylose	
— Calcium and magnesium carbonates and chlorides	
— Esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids	
— Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
— Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
— Mono-and/or di-esters of stearic acid with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol	
— Oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium	

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Denominations	Restrictions
— Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 1200 and 4000.
— Sodium propionate	
<i>Second class</i>	The total quantity of the substances may not exceed 1mg/dm ² of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0.2mg/dm ² (or a lower limit where one is specified) of the uncoated film.
— Sodium alkyl (C ₈ -C ₁₈) benzene sulphonate	
— Sodium isopropyl naphthalene sulphonate	
— Sodium alkyl (C ₈ -C ₁₈) sulphate	
— Sodium alkyl (C ₈ -C ₁₈) sulphonate	
— Sodium dioctylsulphosuccinate	
— Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0.05mg/dm ² of the uncoated film.
— Ammonium, magnesium and potassium lauryl sulphates	
— N,N'-distearoyl diaminoethane, N,N'-dipalmitoyl diaminoethane and N,N'-dioleoyl diaminoethane	
— 2-heptadecyl-4,4-bis(methylene-stearate) oxazoline	
— Polyethylene-aminostearamide ethylsulphate	Not more than 0.1 mg/dm ² of the uncoated film.
<i>Third class — Anchoring agent</i>	The total quantity of substances may not exceed 1mg/dm ² of the uncoated film.
— Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products: <ul style="list-style-type: none"> • butanol • diethylenetriamine • ethanol • triethylenetetramine • tetraethylenepentamine • tri-(2-hydroxyethyl) amine • 3,3'-diaminodipropylamine • 4,4'-diaminodibutylamine 	Free formaldehyde content not greater than 0.5mg/dm ² of the uncoated film. Free melamine content not greater than 0.3mg/dm ² of the uncoated film.
— Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine	Free formaldehyde content not greater than 0.5mg/dm ² of the uncoated film.

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Denominations	Restrictions
	Free melamine content not greater than 0.3mg/dm ² of the uncoated film.
<p>— Cross-linked cationic polyalkyleneamines:</p> <ul style="list-style-type: none"> • polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin • polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine • polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of epichlorhydrin and ammonia • polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine • polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropylmethylamine 	
— Polyethyleneamines and polyethyleneimines;	Not more than 0.75mg/dm ² of the uncoated film.
<p>— Condensation product of urea-formaldehyde unmodified, or which may be modified with one or of the following products:</p> <ul style="list-style-type: none"> • aminomethylsulphonic acid • sulphanilic acid • butanol • diaminobutane • diaminodiethylamine • diaminodipropylamine • diaminopropane • diethylenetriamine • ethanol • guanidine • methanol • tetraethylenepentamine • triethylenetetramine • sodium sulphite 	Free formaldehyde content not greater than 0.5mg/dm ² of the uncoated film.
<i>Fourth class</i>	The total quantity of substances may not exceed 0.01mg/dm ² of the uncoated film.
— Products resulting from the reaction of the amines of edible oils with polyethylene oxide	
— Monoethanolamine lauryl sulphate	

Table 2**Coated regenerated cellulose film**

<i>Denominations</i>	<i>Restrictions</i>
A. Regenerated cellulose	See Table 1.
B. Additives	See Table 1.
C. Coating	
1. <i>Polymers</i>	The total quantity of substances may not exceed 50mg/dm ² of the coating on the side in contact with food.
— Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
— Cellulose nitrate	Not more than 20mg/dm ² of the coating on the side in contact with food; nitrogen content between 10.8% (w/w) and 12.2% (w/w) in the cellulose nitrate.
2. <i>Resins</i>	The total quantity of substances may not exceed 12.5mg/dm ² of the coating on the side in contact with food and solely for the preparation of regenerated cellulose films with cellulose nitrate based coatings.
— Casein	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C ₂ to C ₆ polyvalent alcohols, or mixtures of these alcohols	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation condensed with acrylic, maleic, citric, fumaric and/or phthalic acids and/or 2,2 bis (4-hydroxyphenyl) propane formaldehyde and esterified with methyl ethyl or C ₂ to C ₆ polyvalent alcohols or mixtures of these alcohols	
— Esters derived from bis(2-hydroxyethyl) ether with addition products of betapinene, and/or dipentene, and/or diterpene and maleic anhydride	
— Edible gelatine	
— Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids	
— Natural gum [= damar]	

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Denominations	Restrictions
— Poly-beta-pinene [= terpenic resins]	
— Urea-formaldehyde resins (see anchoring agents)	
3. Plasticisers	The total quantity of substances may not exceed 6mg/dm ² of the coating on the side in contact with food.
— Acetyl tributyl citrate	
— Acetyl tri(2-ethylhexyl) citrate	
— Di-isobutyl adipate	
— Di-n-butyl adipate	
— Di-n-hexyl azelate	
— Dicyclohexyl phthalate	Not more than 4.0mg/dm ² of the coating on the side in contact with food.
— 2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2 ethylhexyl ester)	The amount of 2-ethylhexyl diphenyl phosphate shall not exceed: (a) 2.4mg/kg of the foodstuff in contact with this type of film; or (b) 0.4mg/dm ² in the coating on the side in contact with food.
— Glycerol monoacetate [= monoacetin]	
— Glycerol diacetate [= diacetin]	
— Glycerol triacetate [= triacetin]	
— Di-butyl sebacate	
— Di-n-butyl tartrate	
— Di-isobutyl tartrate	
4. Other additives	The total quantity of substances may not exceed 6mg/dm ² in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with food.
4.1 Additives listed in Table 1	Same restrictions as in Table 1 (however the quantities in mg/dm ² refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with food).
4.2 Specific coating additives	The quantity of the substance or group of substances in each indent may not exceed 2mg/dm ² (or a lower limit

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Denominations	Restrictions
	where one is specified) of the coating on the side in contact with food.
— 1-hexadecanol and 1-octadecanol	
— Esters of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
— Montan waxes, comprising purified montanic (C ₂₆ to C ₃₂) acids and/or their esters with ethanediol and/or 1,3 butanediol and/or their calcium and potassium salts	
— Carnauba wax	
— Beeswax	
— Esparto wax	
— Candelilla wax	
— Dimethylpolysiloxane	Not more than 1mg/dm ² of the coating on the side in contact with food.
— Epoxidised soya-bean oil (oxirane content 6 to 8%)	
— Refined paraffin and microcrystalline waxes	
— Pentaerythritol tetrastearate	
— Mono and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0.2mg/dm ² of the coating on the side in contact with food.
— Aliphatic acids (C ₈ to C ₂₀) esterified with mono- or di-(2-hydroxyethyl)amine	
— 2- and 3-tert.butyl-4-hydroxyanisole [= butylated hydroxyanisole — BHA]	Not more than 0.06mg/dm ² of the coating on the side in contact with food.
— 2,6-di-tert.butyl-4-methylphenol [= butylated hydroxytoluene — BHT]	Not more than 0.06mg/dm ² of the coating on the side in contact with food.
— Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0.06mg/dm ² of the coating on the side in contact with food.
5. Solvents	The total quantity of substances may not exceed 0.6mg/dm ² of the coating on the side in contact with food.
— Butyl acetate	
— Ethyl acetate	
— Isobutyl acetate	

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Denominations	Restrictions
— Isopropyl acetate	
— Propyl acetate	
— Acetone	
— 1-butanol	
— Ethanol	
— 2-butanol	
— 2-propanol	
— 1-propanol	
— Cyclohexane	
— Ethyleneglycol monobutyl ether	
— Ethyleneglycol monobutyl ether acetate	
— Methyl ethyl ketone	
— Methyl isobutyl ketone	
— Tetrahydrofuran	
— Toluene	Not more than 0.06mg/dm ² of the coating on the side in contact with food.”