CUSTOMIZED
SOLUTIONS

Schill+Seilacher
struktol®

FIBRE

SPIN FINISHES AND FOOD CONTACT

INTRODUCTION – LEGAL BASIS

Substances, which get in contact with foodstuffs, must fulfill certain legal requirements as defined by consumer protection. Here, both international and national jurisprudence come into play.

THE MOST COMMON REGULATIONS ARE:

- **CODE OF FEDERAL REGULATION (CFR), TITLE 21 OF THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)**
- **COMMISSION REGULATION (EU) NO. 10/2011 BY THE EUROPEAN COMMISSION DATED JANUARY, 2011 ON PLASTIC MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD**

Both regulations list the chemical substances that are allowed under certain conditions for contact with food.

FDA

Especially in the classification according to FDA, it must be distinguished whether it is a food additive or a substance for application with indirect food contact. Food additives are components of food. Substances for use with indirect food contact can become a food additive by migration or change the organoleptic properties of the food.

- **FOR DIRECT FOOD CONTACT, PARTS 170-173 AND 180, 181, 182, 184**
- **FOR INDIRECT FOOD CONTACT, PARTS 174-178 AND 186**

SAFETY TESTING RECOMMENDATIONS FOR FOOD CONTACT SUBSTANCES (FCSs) AND THEIR CONSTITUENTS

CEDI (CUMULATIVE ESTIMATED DAILY INTAKE)	MINIMUM TESTING RECOMMENDATIONS
≤ 0.5 ppb	No safety studies
0.5 – 50 ppb	*In vitro* genotoxicity tests (in bacteria and mammalian cells)
50 ppb – 1 ppm	*In vitro* genotoxicity tests (in bacteria and mammalian cells) *In vitro* test for chromosomal damage (rodent hematopoietic cells) Sub-chronic oral toxicity tests (rodent and non-rodent species)
> 1 ppm	Submission of a food additive petition

EDIBLE DAILY INTAKE

When a substance is not specifically listed in CFR 21 for food contact, authorization must be sought in pendency of the dietary concentrations (see table above). If concentrations are below the limit of 0.5 ppb, part 170.39 (Threshold of regulation for substances in food contact articles) an admittance can be achieved by inquiring the FDA.

The Food and Drug Administration (FDA or USFDA) is an agency of the United States Department of Health and Human Services, one of the United States federal executive departments. The FDA is responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the-counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, electromagnetic radiation emitting devices (ERED), veterinary products and cosmetics.

SCHILL+SEILACHER INSIDE

EU REGULATION NO. 10/2011

The EU Regulation (10/2011) is based on considerations in which migration limits are allowed for a substance. It applies to both, a limit on overall migration as well as a specific migration limit.

Even substances that are not authorized in the Union list (Annex I) may be used, – as long as a barrier layer (interlayer) is part of the multiple layermaterial.

However, a maximum level of 0.01 mg/kg migration in foods should not be exceeded. In this case usually migration tests at suitable authorized institutions are obligate.

When a product comes into contact with food, it is ideally clarified beforehand whether all of its components are within the statutory requirements, and all substances (e.g. the components of the Spin Finish) are listed in Annex I (auxiliaries) of the European Regulation (EU) No. 10/2011.

Otherwise, costly and time-consuming investigations can become necessary.

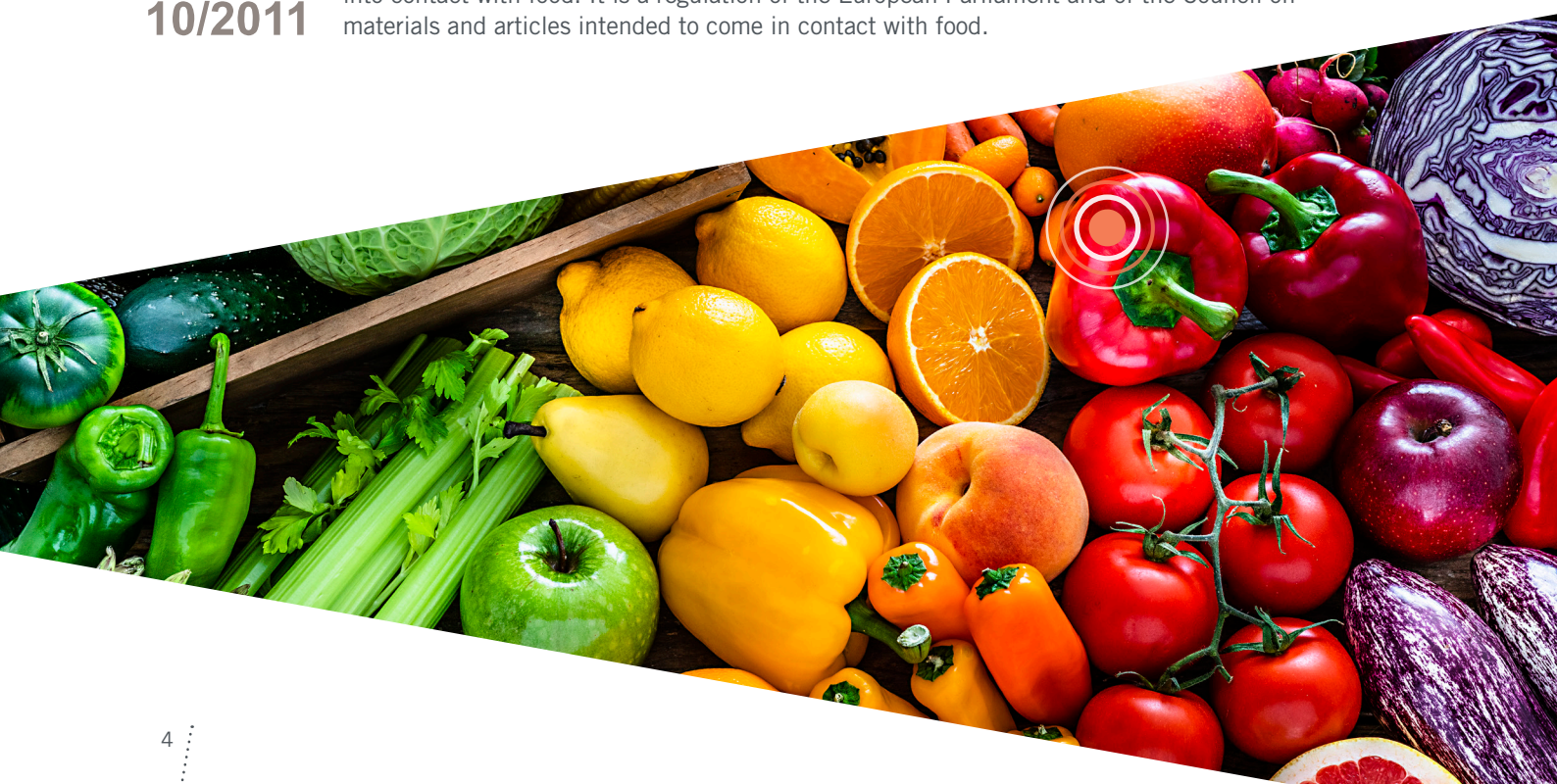
APPLICATION EXAMPLES

In most cases direct food contact is considered. Within that the Nonwovens meet various tasks. On the one hand, the food is protected from contamination or mechanical abrasion. On the other hand, a hydrophilic Spin Finish can control the fluid management of such an article.

- **FOOD PACKAGING**
- **TEABAGS, COFFEE PADS**
- **ABSORBENT MATERIALS (E.G. FOR FRUIT OR MEAT)**
- **FILTRATION**

EU 10/2011

The directive (EU) No. 10/2011 is a regulation on plastic materials and articles intended to come into contact with food. It is a regulation of the European Parliament and of the Council on materials and articles intended to come in contact with food.



PRODUCT RECOMMENDATIONS COMPLYING WITH FDA AND (EU) NO. 10/2011*

FDA AND (EU) NO. 10/2011*	POLYMER	APPLICATION	FUNCTION
DESPUMOL EC	All	All	Defoamer
LIMANOL BF 29 EU	PP, PBT, PET, PLA	Filament, Flat+BCF	Spin Finish
SILASTOL 163	PP, Bico	Spunlaid Nonwoven	Spin Finish
SILASTOL 360	PP, Bico	Staple Fibre	Hydrophilic Lubricant
SILASTOL CUT 60	PP, Bico	Short Cut Fibre	Spin Finish
SILASTOL GF 2011	PP, Bico	Staple Fibre	Spin Finish
SILASTOL PHP 32	PP, Bico	Spunlaid Nonwoven	Spin Finish
SILASTOL R 641	PP, Bico, PET	Spunlaid Nonwoven	Hydrophilic Lubricant
SILASTOL PHP 207 F	PP, Bico	Spunlaid Nonwoven	Spin Finish
SILASTOL R 522	PET	Staple Fibre	Hydrophilic Lubricant
SILASTOL SL 85	PET, PP, Viscose	Staple Fibre, Spunlace	Lubricant
SILASTOL SL 300	PET	Staple Fibre	Hydrophilic Lubricant

* All components are listed in the Code of Federal Regulations, Title 21 (FDA) for indirect food contact and in Annex I (auxiliaries) European Regulation (EU) No. 10/2011. Each component may be listed in different FDA paragraphs. Depending on the application specific restrictions should be considered.

PRODUCT RECOMMENDATIONS COMPLYING WITH (EU) NO. 10/2011**

(EU) NO. 10/2011**	POLYMER	APPLICATION	FUNCTION
SILASTOL M 12	PP, PBT	Staple Fibre	Antistatic Agent
SILASTOL SL 20	PET, PP	Staple Fibre	Antistatic Agent

** All components are listed in Annex I (auxiliaries) European Regulation (EU) No. 10/2011. Depending on the application specific restrictions should be considered.

PRODUCT RECOMMENDATIONS COMPLYING WITH FDA*

FDA*	POLYMER	APPLICATION	FUNCTION
AFROTIN MBT	All	All	Biocide
AFROTIN TBN	All	All	Biocide
DESPUMOL FDA	All	All	Defoamer
DRYFI MG 2-F	PET	Filament, Texturized	Spin Finish
LIMANOL BF 29	PP, PBT, PET, PLA	Filament, Flat+BCF	Spin Finish
PRODUCT A-LM	PET	Staple Fibre	Hydrophilic Lubricant
SILASTOL 80 G92	PP, PET	Staple Fibre	Hydrophilic Lubricant
SILASTOL A 77 M	PET	Staple Fibre	Spin Finish
SILASTOL BIO 223	Bico, PLA	Spunlaid Nonwoven	Spin Finish
SILASTOL BIO 7	Bico, PLA	Spunlaid Nonwoven	Spin Finish
SILASTOL CUT 8	PP, PET	Short Cut Fibre	Hydrophilic Lubricant
SILASTOL CUT 11	PP, PET, Bico	Short Cut Fibre	Antistatic Agent
SILASTOL DL 5	PET, PP	Staple Fibre	Spin Finish
SILASTOL GF 16	PP, Bico	Spunlaid Nonwoven	Spin Finish
SILASTOL GF 18	PP, Bico	Staple Fibre	Spin Finish
SILASTOL GF 23 T	PP, Bico	Staple Fibre	Spin Finish
SILASTOL GF 30	PP, Bico	Staple Fibre	Spin Finish
SILASTOL K 18	PP, Bico	Staple Fibre	Spin Finish
SILASTOL LMF 8	PP, Bico, PET	Staple Fibre	Spin Finish
SILASTOL P 800 E	PP, PET	Staple Fibre	Spin Finish
SILASTOL PMM-2	PA 6.12	Filament	Spin Finish
SILASTOL PE	PP, Bico, PET	Staple Fibre	Antistatic Lubricant
SILASTOL SL 15	PP, PET	Staple Fibre, spunlace	Antistatic Agent
UKANOL AA 500	All	All	Defoamer

* All components are listed in the Code of Federal Regulations, Title 21 (FDA) for indirect food contact.
Each component may be listed in different FDA paragraphs. Depending on the application specific restrictions should be considered.

LOCATIONS.

BÖBLINGEN
GERMANY

DIN EN ISO 9001:2015
DIN EN ISO 14001:2015
DIN EN ISO 50001:2011
RSPO Certification Mass Balance

- SPIN FINISHES FOR MAN-MADE FIBRES
- CHEMICALS FOR TECHNICAL TEXTILES
- LEATHER CHEMICALS
- PAPER CHEMICALS
- COSMETIC, HI&I, SPECIAL CHEMICALS

HAMBURG
GERMANY

DIN EN ISO 9001:2015
DIN EN ISO 14001:2015
DIN EN ISO 50001:2011

- RUBBER ADDITIVES
- ANTIFOAMS
- REACTIVE POLYMERS & FLAME RETARDANTS
- LATEX ADDITIVES
- SILICONES
- RELEASE AGENTS

PIRNA
GERMANY

- SILICONES
- PU INDUSTRY
- PAPER
- TEXTILES
- COSMETICS
- FIBRES
- LEATHER

STOW
USA

DIN EN ISO 9001:2008

- RUBBER ADDITIVES
- PLASTIC ADDITIVES
- PVC ADDITIVES
- ENGINEERED THERMOPLASTIC ADDITIVES
- WOOD PLASTIC
- COMPOSITE ADDITIVES
- LEATHER CHEMICALS

VILLA RICA

- RUBBER ADDITIVES

DISCLAIMER

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CONTACT US.

Schill+Seilacher GmbH
Schönaicher Strasse 205
71032 Böblingen / Germany

Phone: + 49 7031 282-0
E-Mail: ctv@schillseilacher.de

schillseilacher.de