

**SILLITIN / SILFIT (all grades)
AKTISIL (excl. AKTISIL WW) / AKTIFIT (all grades)
Compliance with Code of Federal Regulations / FDA / 21 CFR § 177.2600**

We checked our above-mentioned products with regard to the following document:

"PART 177 -- INDIRECT FOOD ADDITIVES: POLYMERS
Subpart C – Substances for Use Only as Components of Articles Intended for Repeated Use
Sec. 177.2600 Rubber articles intended for repeated use"

SILLITIN / SILLIKOLLOID / SILFIT

Neuburg Siliceous Earth, sold by Hoffmann Mineral GmbH under the trademarks SILLITIN and SILLIKOLLOID, is a naturally occurring mineral composition that is extracted from quarries near Neuburg in Bavaria, Germany. The mineral's main components are kaolinite (aluminum silicate) and silica. SILFIT is produced through calcination of SILLITIN. Water is driven off the aluminum silicate platelets during this process, fusing them, but leaving the structure otherwise untouched.

Both components are explicitly listed as GRAS-Substances, i.e. substances which are generally recognized as safe in food. **Therefore, we can confirm that all grades of SILLITIN, SILLIKOLLOID and SILFIT comply with this rule without any restriction.**

AKTISIL (excl. AKTISIL WW) / AKTIFIT

All types of the product lines with the trademarks AKTISIL and AKTIFIT are based on SILLITIN and SILFIT, respectively, and have been surface-treated with a monomeric organosilane („coupling agent"). Alcohol formed due to the polymerization reaction was removed in the production process.

Although the coupling agent is not listed explicitly, we believe by reason of chemical similarity to other listed rubber chemicals that a safe use according to rule 177.2600 can be assured. In addition, a worst-case analysis shows that there is not enough coupling agent present in rubber articles of a certain thickness to exceed the limit of two-step (7+2 hours) hexane extraction (max. 175+4 mg per square inch) stipulated in the rule (f).

The table shows the maximum thickness of a rubber layer in millimeters as a function of the content of each surface-treated filler. As long as the rubber article's thickness remains below the value given in this table, the amount of all extractable products stemming from the type of AKTISIL or AKTIFIT used cannot exceed the threshold limit stipulated by the rule.

n-Hexane Extraction (Extractables)												
AC	Maximum Thickness of Rubber Layer [mm]											
	Aktisil										Aktifit	
[%]	AM	EM	MAM	MM	PF 216	PF 777	VE	VM 56	Q	AM	VM	
5	255,0	347,5	382,5	273,0	191,0	191,0	637,5	255,0	191,0	255,0	382,5	
10	127,5	173,5	191,0	136,5	95,5	95,5	318,5	127,5	95,5	127,5	191,0	
15	85,0	115,5	127,5	91,0	63,5	63,5	212,5	85,0	63,5	85,0	127,5	
20	63,5	86,5	95,5	68,0	47,5	47,5	159,0	63,5	47,5	63,5	95,5	
25	51,0	69,5	76,5	54,5	38,0	38,0	127,5	51,0	38,0	51,0	76,5	
30	42,5	57,5	63,5	45,5	31,5	31,5	106,0	42,5	31,5	42,5	63,5	
35	36,0	49,5	54,5	39,0	27,0	27,0	91,0	36,0	27,0	36,0	54,5	
40	31,5	43,0	47,5	34,0	23,5	23,5	79,5	31,5	23,5	31,5	47,5	
45	28,0	38,5	42,5	30,0	21,0	21,0	70,5	28,0	21,0	28,0	42,5	
50	25,5	34,5	38,0	27,0	19,0	19,0	63,5	25,5	19,0	25,5	38,0	
55	23,0	31,5	34,5	24,5	17,0	17,0	57,5	23,0	17,0	23,0	34,5	
60	21,0	28,5	31,5	22,5	15,5	15,5	53,0	21,0	15,5	21,0	31,5	
65	19,5	26,5	29,0	21,0	14,5	14,5	49,0	19,5	14,5	19,5	29,0	
70	18,0	24,5	27,0	19,5	13,5	13,5	45,5	18,0	13,5	18,0	27,0	
75	17,0	23,0	25,5	18,0	12,5	12,5	42,5	17,0	12,5	17,0	25,5	
80	15,5	21,5	23,5	17,0	11,5	11,5	39,5	15,5	11,5	15,5	23,5	
85	15,0	20,0	22,5	16,0	11,0	11,0	37,5	15,0	11,0	15,0	22,5	
90	14,0	19,0	21,0	15,0	10,5	10,5	35,0	14,0	10,5	14,0	21,0	
95	13,0	18,0	20,0	14,0	10,0	10,0	33,5	13,0	10,0	13,0	20,0	

AC: AKTISIL / AKTIFIT content in the rubber compound.

We do not know, however, which components other than the coupling agent of AKTISIL / AKTIFIT (curing agents, waxes, etc.) contribute to the total amount of extractable ingredients and to which extent.

Yours faithfully

HOFFMANN MINERAL GmbH



Dr. Christian Seeger
Riskmanagement

Neuburg an der Donau
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