

SILLITIN / SILFIT / SILLIKOLLOID (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 (all grades)

Neuburg Siliceous Earth - known by the trade names SILLITIN and SILLIKOLLOID, the thermal treated grade as SILFIT - is an inorganic compound originated in nature and made up of amorphous and cryptocrystalline silica and lamellar kaolinite.

In the above mentioned chapter its mineralogical components are explicitly listed as ‘Silica’ and as ‘Aluminum Silicate’ which justifies the usage 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	
Typical range	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

May 11th, 2017