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Toxicological and Safety Summary of Softcare Textile Protector

Softcare Textile Protector are based on volatile solvents and active matter (“*A.M.*”). As the volatile solvents will evaporate rapidly, only the special active matter will remain on the finished textile and provide the efficacy of oil, water and dirt repellency.

The volatile solvents in Softcare Textile Protector have been selected to provide fast evaporation and favorable toxicological profile. These volatile solvents act as the carrier agent of the active matter in Softcare Protectors, and their effects relate mainly to the the application phase of Softcare Protectors. Like most volatile solvents, the volatile solvents in Softcare Textile Protector can in excessive concentrations during application cause CNS depression, dizziness or long oedema. Therefore during the industrial application process, good industrial hygiene and personal protection shall be observed during the application and dry-out. Generally the most important aspect is avoiding breathing, respiration or aspiration of the fumes and/or aerosols formed during the application process. Application and dry-out must be done in well-ventilated areas only. Safety data sheet available for professional user on request.

Consumer Safety and Exposure

The acute oral toxicity (LD50) of the A.M. is estimated to be > 2000 mg/kg bw. On practical level this means that the A.M. of Softcare Textile Protector is nontoxic.

Finite dose based systemic exposure dose (SED) is based on the industrial strength Softcare Textile Protector, and based on the long history of practical experience it is known that a one (1) kilogram of Softcare Textile Protector can treat approximately ten (10) square meters of textile. The following calculations take into the account the volatility of the solvents, and are therefore about the safety of Softcare Textile Protector treated textiles in consumer use.

Table 1: Systemic Exposure Dose (SED) - finite dose – based on human defaults [1]

A.M. per m^2	A.M. per cm^2	A.M. per cm^2
1.4 grams per m^2	0.14 milligram per cm^2	140 microgram per cm^2
SED – Adults (65 kg)	SED – Adults (65 kg)	SED – Adults (65 kg)
0.0215 gram/kg bw/m^2	0.00215 microgram/kg bw/cm^2	2.15 microgram/kg bw/cm^2
SED – Children 1.5 – 3 years	SED – Children 1.5 – 3 years	SED – Children 1.5 – 3 years
0.142 gram/kg bw/m^2	0.0142 microgram/kg bw/cm^2	14.213 microgram/kg bw/cm^2

1 BREMMER et al., Rijksinstituut voor Volksgezondheid en Milieu (RIVM), Report 320104002/2006

Consideration of potential nongenotoxic effects using the TTC approach developed by Kroes et al. (2004) demonstrates, that even if the active matter in Softcare Textile Protector would belong to Cramer structural Class III, it would not be expected to be any safety concern even if a a small child would suck 6 cm^2 and manage to ingest all active matter ("*A.M.")* of Softcare Protector treated textile daily. [2]

This 6 cm^2 ***daily*** oral intake using highly unrealistic worst case scenario demonstrates that even with WHO recommended safety factor of 100 (10 for interspecies variations and 10 for intraspecies variations) the Softcare Textile Protector does not lead to risk for human health.

In further studies it has been demonstrated that the A.M. of Softcare Textile Protector is not a skin irritant, skin sensitiser or mutagenic.

CONCLUSION: Softcare Textile Protector, after application on and dry-out in textile goods and upholstery, even with WHO recommended safety factor of 100 (10 for interspecies variations and 10 for intraspecies variations), Softcare Textile Protector does not lead to elevated risk for adverse effects in human health.

Additionally it is noted that most of the active matter (*"A.M."*) of Softcare Textile Protector remains bound to the textile fibers. During normal consumer exposure the oral intake is considered to be negligible.

2 KROES et al., The Threshold of Toxicological Concern Concept in Risk Assessment, Toxicol Sci. (August 2005) 86 (2): 226-230

Fire Test – Effect on Flammability of Textiles

Fire testing was conducted using 100 % wool, 100 % polyester and 100 % Trevira CS (flame retardant textile). Test method FAR 25-32, 25,853 b.

Test Method Requirements	
Ignition time	12 seconds
Material position	Vertical
Extinguishing time	15 seconds
Burn length	203 mm
Drip extinguishing	5 seconds

Test Results

Samples 1-4 treated with Softcare Textile Protector – Samples 5-8 without treatment

Material	**Extinguishing time *(seconds)***	**Burn length *(mm)***	**Drip extinguishing *(seconds)***
Wool – Sample 1 *(T)*	0	54	-
Wool – Sample 2 *(T)*	1	47	-
Wool – Sample 3 *(T)*	0	54	-
Wool – Sample 4 *(T)*	0.3	52	-
Wool – Sample 5 *(NT)*	0	51	-
Wool – Sample 6 *(NT)*	0	48	-
Wool – Sample 7 *(NT)*	4	46	-
Wool – Sample 8 *(NT)*	1.3	48.3	-
Polyester - Sample 1 *(T)*	0	72	-
Polyester - Sample 2 *(T)*	13	72	-
Polyester - Sample 3 *(T)*	2	86	-
Polyester - Sample 4 *(T)*	5	76.6	-
Polyester - Sample 5 *(NT)*	8	90	-
Polyester - Sample 6 *(NT)*	10	90	-
Polyester - Sample 7 *(NT)*	6	90	-
Polyester - Sample 8 *(NT)*	8	90	-
Trevira CS - Sample 1 *(T)*	0	88	-

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Trevira CS - Sample 2 *(T)*	0	92	-
Trevira CS - Sample 3 *(T)*	0	96	-
Trevira CS - Sample 4 *(T)*	0	92	-
Trevira CS - Sample 5 *(NT)*	0	89	-
Trevira CS - Sample 6 *(NT)*	0	71	-
Trevira CS - Sample 7 *(NT)*	0	94	-
Trevira CS - Sample 8 *(NT)*	0	84.6	-

(T) Treated with Softcare Textile Protector

(NT) Not Treated – Control Without Treatment

CONCLUSION: Softcare Textile Protector, in the fire test conditions, did not affect the flammability of the tested textile materials 100% wool, 100% Trevira CS and 100% polyester. Samples treated with Softcare Textile Protector passed the test method requirements in fire test. [3]

3 Finnair Engineering Department, 22.10.1993, Reports 24/93, 25/93, 26/93.

Regulatory and Safety Summary on Softcare Textile Protectors

We at Oy Soft Protector Ltd want to emphasize the most important principle of our product development: To provide high quality and safe products.

We are committed both to the science of safety and to the art of creating products that are gentle on people and the environment. Like You, we have a healthy skepticism, when it comes to the use of any chemicals – whether they are found in nature or made in a factory.

All of our ingredient choices are supported by the best available science, as well as by a team of scientists who specialize in ingredient safety. We actively monitor all of our products and their constituents, to ensure they reflect the latest science, as well as our customers' preferences and concerns.

The ingredients used in Softcare Protectors (e.g. Softcare Textile Protector, Softcare Carpet Protector and Softcare Leather Protector) are well-defined and their efficacy and safety have been studied extensively. Softcare Protectors effectively protect the textiles, upholstery, clothing and leather. In addition, this protection extends the life cycle of the textile and enhances its aesthetics, keeping the textile looking newer for a longer time. As a result, the protected textile has a significantly reduced environmental footprint, particularly in the use and maintenance phase.

Textile protection technologies can be roughly divided into fluorinated compounds, hydrocarbons, silicones, dendrimers, wax based treatments and nanoparticle technologies.

From these technologies the fluorinated textile protection technologies are the most effective protective technology for textiles, as only they provide an effective, long-lasting protection and excellent repellency against water, oil, soil and dirt. In addition, they are long lasting and more resistant to washing, light, rain, abrasion and other environmental factors to which textiles are exposed to during their life cycle.

Fluorotelomers are based on perfluorinated alkyl chain $F(CF_2)_n$-, where n is the number of the fluorinated carbons, and which can be attached to a non-fluorinated polymer backbone (e.g. acrylic polymer).

This chain length "n" of fluorotelomers is very important for the safety and biodegradability of the fluorotelomers. Long-chain ($n \geq 8$) perfluorinated alkyl compounds, such as PFOA (perfluorooctanoic acid) and PFOS (perfluorooctane sulfonate) are not used in Softcare protectors.

It has been known to us that perfluorinated alkyl compounds with long-chain ($n \geq 8$) are questionable both in regards of user safety and environmental safety. For this reason our Softcare protectors only utilize so-called short-chain C6 ($n \leq 6$) perfluorinated alkyl acrylate polymer technology.

This has been a conscious design and development choice Oy Soft Protector Ltd has made as a part of our company's values and responsible product development. We do not use

PFOS, PFOA or other long-chain ($n \geq 8$) based perfluorinated compounds. Therefore Oy Soft Protector Ltd has during its responsible product development made this decision well before the authorities in different countries began to evaluate the long-chain ($n \geq 8$) perfluorinated substances according to newer scientific studies.

It should be noted also that the environmental authorities in Finland have concluded that PFOS-related compounds have not been prepared in Finland, and since 2000, Finnish companies have introduced only two such compound containing product. PFOS and PFOA compounds have been used, for example, at civil and military airports in fire-fighting foams. Oy Soft Protector Ltd has never manufactured or imported such products – any kind of fire fighting foams have never been in Softcare product portfolio.

PFOS and other long-chain perfluorinated alkyl compounds

As stated previously, the Softcare Protectors do ***not*** contain or make use of long-chain perfluorinated alkyl compounds (e.g. PFOA or PFOS, which have $n = 8$).

Long-chain perfluorinated alkyl compounds are at the present under scientific and regulatory reviews, and have restrictions and/or prohibitions of use in e.g.

- EU
- Norway
- Germany
- United States
- Canada
- Australia
- Japan

Softcare protectors do not contain any such compounds which have restrictions and/or prohibitions.

Amongst other things, the US Environmental Protection Agency EPA (Environmental Protection Agency) has stated the following: "PFAC chemicals with fewer than C8 carbons, such as perfluorohexanoic acid (PFHxA), are not considered long chain chemicals. These shorter-chain PFAC are not part of this action plan, because data in non-human primates indicate that they have substantially shorter half-lives in these animals than PFOA and are less toxic than long-chain PFAC chemicals."

Additionally, in the European Union, PFOA ($n = 8$) compounds are listed on the European Chemicals Agency ECHA's list of "Substances of Very High Concern" (SVHC) list and their use is also limited, for example, in Norway.

It is important to emphasize that despite the similar sounding names, not all perfluorinated compounds can be stereotypically grouped into one single category, because particularly the chain length (n) of the fluorotelomer and the attachment to the polymer backbone have significant impact on both physicochemical and toxicological properties.

Softcare Protectors are based on C6 fluorotelomer chemistry

Softcare protectors are based on C6 (n = 6) fluorotelomer chemistry. These short-chain fluorotelomers ($n \leq 6$) cannot degrade to longer chain-length compounds, such as PFOA or PFOS compounds.

In addition, these short-chain fluorotelomers in Softcare protectors are attached to a polymer backbone during manufacturing process, thus Softcare protectors do not contain freely available fluorotelomers.

Since these polymers in Softcare protectors are quite large, with molecular weight well over 1000 Daltons, the polymer of this size are generally too large to penetrate cell membranes and thus is generally not bioaccumulate, that is, do not accumulate in the human body.

C6 based perfluorinated compounds (n = 6) are short-chain, for example, 6:2 FTOH, 6:2 FTAC and - at least theoretically possible - a breakdown product perfluorohexanoic acid (PFHxA). The toxicity to humans, mammals and animals has been extensively studied and reported in scientific literature.

C6 (n = 6) based perfluorinated compound toxicity, for example acute and chronic toxicity, neurotoxicological effects, the effect on reproduction, the effect on the fetus, the effect of pregnant mammals, etc. have been extensively studied. Studies have demonstrated C6 based perfluorinated substances to be safe in normal and reasonably foreseeable use of and exposure to Softcare protectors. C6 perfluorinated compounds - and their theoretically potential degradation products such as perfluorohexanoic acid - have harmless effect levels (NOAEL, BDL10) at least a magnitude higher than the long-chain perfluorinated compounds.

Exposure to Softcare Protectors

Based on our empirical experience, one (1) kilogram of Softcare protector is generally enough for treating about ten (10) square meters of typical textile.

The amount of Softcare protector remaining on one (1) square meter after treatment, under normal and reasonably foreseeable conditions, is estimated to be about 1.4 grams of a textile protective agent per one (1) square meter of treated fabric.

When this estimated concentration of 1.4 g per m2 per standard toxicological calculation methods taking into account in example body weight, systemic exposure and duration of exposure is calculated, the systemic exposure dose (SED) expressed in mg/kg body weight/day remains low.

This systemic exposure dose (SED) is then compared to established no adverse effect levels (NOAEL) - that is, to the dose levels at which no adverse effects have been found in toxicological *in vivo* testing.

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The Margin of Safety of the C6 perfluorinated compounds and their theoretically possible degradation products present in Softcare protectors are calculated by comparing these no adverse effect levels to systemic exposure dose.

Softcare Protectors in waste treatment

Scientific studies have been conducted to understand the effects of perfluorinated alkyl compound treated textiles in municipal waste such as waste incineration plants.

Studies have shown that such textiles treated protectant did not cause any significant release of perfluorinated compounds into the environment.

CONCLUSION: In practice Softcare Protectors, in normal and reasonably foreseeable use and exposure conditions, are many times safer than levels that did not cause any adverse health effects established in toxicological *in vivo* studies.

Safety Data Sheet (MSDS) available for professional users on request.

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