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Information PUR Raw Material

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Declaration of absence / safety statement / flammability / mechanical values / chemical resistance / ozone resistance on the basis of VW TL and VDA 675311, certificate of non-objection (according to EN ISO 10993-1 and directive 93/42/EG)

Dear Sir or Madam,

In response to your request please find attached proof of the physiological features and the certificate of non-objection (according to EN ISO 10993-1 and Directive 93/42/EG), information on the mechanical values, chemical resistance and the flammability of the polyurethane foam (Elastofoam[®] I) as well as the test of the ozone resistance on the basis of VW TL und VDA 675311.

Certificate of non-objection for PUR

The materials used are non-hazardous to health.

Polyurethane is a product of the reaction between diisocyanates and long-chained alcohols. Processing aids (catalysts, additives) are used which depend on the technical process applied.

In numerous applications (e.g. soft foam in mattresses, integral foam seats, arm rests) polyurethane is generally regarded as non-hazardous to health and certain types are occasionally used for the manufacturing of commodities (see recommendation of the "Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin" (federal institute for consumer protection and veterinary medicine) no. 39).

Diisocyanates and many tertiary amines are classified as hazardous materials. The material characteristics underlying this classification are hardly transferred at all to the polyurethane. The diisocyanate is firmly built into the polyurethane matrix, i.e. the relatively small diisocyanate molecules become macro molecules which can hardly be absorbed at all by the body and which can no longer be detected in the foam 48 hours after the production. Our experience has shown that 5 days max. after production it is no longer possible to detect monomeric diisocyanate with polyurethane (concentration <1ppm). The biological-toxicological safety of the inpatient is not effected by soluble material-ingredients during the application. The insolubility of the material components of the foam-system PUR Elastofoam[®] I is according the requirements of the EN ISO 10993-1 for the applications intended. (certificate: test report Medical Device Services Nr. 063572-40)



The materials used do not give off emissions after their processing.

Information about diisocyanate see above.

The amine catalysts used (1.5% max. in polyurethane) show a certain volatility. Previous experience has shown that their emission from soft foams after the foam has been produced decreases rapidly and as a result they can no longer be detected after 20 days or have reached a concentration which makes a detriment to health very unlikely. This also coincides with the experiences made during decades of producing polyurethane soft foams.

As the polyurethane system Elastofom[®] I is an integral foam, a considerably smaller emission of the materials mentioned above can be expected due to its skin formation.

Skin contact with these materials does not cause skin irritation.

For many years polyurethane integral foams have been used for steering wheels, seats, toilet seats, etc. and as such come into direct contact with human skin. In general polyurethane is well tolerated. Although the amine catalysts used in Elastofom[®] I are in their pure form classified as a health risk if swallowed and as a source of irritation to the eyes and respiratory tract, no negative skin reactions could be detected. In addition the foam only contains catalysts up to 1% max. which are enclosed by the polyurethane matrix.

Individual cases of skin reactions that have been described can be attributed to the person's predisposition (allergic person) and are not typical product characteristics.

The materials used may be treated with disinfectants.

If necessary, polyurethane soft foam may be disinfected with max. 70 % solution of ethyl or propyl alcohol. We do not recommend the use of other disinfectants. The following agents are recommended:

- Microx (combination of cleaning and disinfecting agent)
- Meltan (Company ECO point, Schüttdorf)
- cleaning agent: Terralin Liquid, antifact N Liquid and meliseptol as disinfecting agent for plain areas. Please consider that disinfecting agents for plain areas are applied by wiping

Heat resistance

We recommend avoiding temperatures above 80°C (except for foam systems specifically designed for higher temperatures).

According to information from our material manufacturer (system supplier) the substances listed below are not constituents of the formula for the foam system FR 1 used by Froli.

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|--|-------------------------------------|
| - Phenylendimine | - Flame retardants |
| - Mercaptobenzothiazol | - Fluorocarbon |
| - Latex constituents or materials | - Heavy metals according to EN 71/3 |
| - Thiurams used as reaction accelerators | - Halogens |
| - Polyvinyl amide | |



Test for resistance to saliva and sweat

The test requirements acc. to § 64 LFGB B 82.101 (former Din 53 160) were passed. LGA test report No. 569 1257.1 dated 7.4.2009

Mechanical values for the Elastofoam[®] I - System

Test	Measured value	Unit	Method
<u>of the sample body</u>			
Overall apparent density	300	kg/m ³	DIN EN ISO 845
Shore hardness	25°	A	DIN 53 505
<u>On the skin (d = 1.5mm)</u>			
Density	700	kg/m ³	DIN 53 479
Tensile strength	724	KPa	DIN 53 504
Stretching	195	%	DIN 52 504
Resistance to tear propagation	3.1	N/mm	DIN ISO 34-1
<u>On the foam</u>			
Apparent density	230	kg/m ³	DIN EN ISO 845
Tensile strength	206	Kpa	DIN EN ISO 1798
Stretching	139	%	DIN EN ISO 1798
Resistance to tear propagation	0,9	N/mm	DIN ISO 34-1
Residual percentage of compressive set	24,9	%	DIN EN ISO 1856

Behaviour in fire of PUR

We hereby confirm that the foam system Elastofoam[®] I Standard

1. complies with the fire protection behaviour according to RL 95/28 EG, Appendix 4 FMVSS 302. The requirements of DIN 75 200 for a maximum flame propagation speed of 101.6mm/min. are fulfilled with an actual speed of < 70mm/min.
2. accords with the requirements of DIN 1021 T 1 + 2

We confirm as well, that the foam-systems Elastofoam[®] I with special Additives (35°-60° Shore A) have passed the Crib V-Test (on the basis of BS 5852 part.2 from 1982).

Chemical resistance

Measurement of the surface hardness acc. to Shore A

Initial value	75 Shore A		
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Reaction time:	24h	100h	500h
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Solvent

Sea water	57	57	57
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Inorganic acid

Phosphoric acid, aqueous 10%	60	58	58
Nitric acid, aqueous 10%	55	50	33
Hydrochloric acid, aqueous 10%	64	62	62
Sulphuric acid, aqueous 10%	60	60	60

Organic acid

Formic acid, aqueous 10%	57	54	53
Acetic acid, aqueous 10%	55	53	53
Lactic acid, aqueous 10%	55	51	51

Inorganic bases

Ammonia, aqueous 10%	54	54	52
Caustic soda solution, aqueous 10 %	55	55	55



Inorganic chemicals in aqueous solution

Hydrogen peroxide, 3%	51	51	51
Chlorinated lime, saturated solution	56	56	56
Bleaching lye, concentrated	67	67	-*

Hydrocarbons

Regular petrol	44	43	-*
4-star petrol	52	52	-*
Diesel fuel	66	64	64
Motor oil	75	75	75

*) irreversible damage

Chlorinated hydrocarbons

Dichloromethane	-*	-*	-*
1.1.1. trichlorethane	47	47	-*

Alcohol

Methyl alcohol	34	31	-*
Ethanol	34	34	-*
Isopropanol	48	48	-*
Glycerine	78	78	78
Ethylenglycol	77	70	62

Ketones and Aldehydes

Acetone	57	28	-*
Formaldehyde, aqueous 10 %	60	58	58

Amides

Formamide	78	56	48
Dimethylformamide	-*	-*	-*
N-methylpyrrolidon	-*	-*	-*

Ester

Acetic ether	36	35	-*
Ethylglycol acetate	-*	-*	-*
Ricinoleic acid	76	75	73

*) irreversible damage

Ozone resistance

Test conditions:

Sample body stretched by 20%, storage at 25°C 48hrs with an ozone concentration of 200pphm.

Result:

Sample body without tears after ozone aging.

UV- Protection

In order to protect the PUR foam part against corrosive UV-rays, a UV-stabilisator can be added to the material/ lacquer