SIREX® PE - declaration of Integrity

Based on our current knowledge and many years of use of our products for consumer and healthcare products, we can confirm that cross-linked PE foams with a closed cell structure are from the product group.

SIREX® PE

Non-toxic and non-irritating to the skin. They do not support the growth of fungi and bacteria, as these microorganisms cannot attack them.

The safety of SIREX® PE is also confirmed by the following tests carried out on certain types of foam:

- biological examination of medical instruments (skin irritation, skin sensitivity, cell damage), in accordance with ISO 10993 / EN 30993,
- food approval, in accordance with European Directive 97/48/EC;
- SG-approval (test for the presence of harmful substances),
- resistance to fungal growth in accordance with ISO 846,
- toy safety (limit values for heavy metals) in accordance with EN 71-3,
- resistance to sweat and saliva in accordance with DIN 53160.

Imbema, based in the Netherlands, manufactures and sells foam products based on raw materials that comply with the provisions of 95/3/EEC (food approval), 94/63/EEC (free of hazardous substances), 89/109/EEC and 90/128/EEC (food packaging). Imbema uses manufacturing methods that ensure hygienically safe products.

We further confirm that SIREX® PE foams have a long history of safe use for medical purposes and applications where they come into contact with the skin.

The above foams do not contain hazardous substances that can be released into aqueous solutions; a fact that is confirmed by the approvals for certain types of foams used for food packaging, orthopedic purposes and general use, namely the Food Approval and the SG Approval (test for the presence of harmful substances).

The foams do not contain any of the following substances – neither in the raw material nor after the processing:

- As (arsenic)
- Cd (cadmium)
- Cr, CR* (chromium, hexavalent chromium)
- Pb (lead)
- Hg (mercury)
- Ni (nickel)
- Co (cobalt)
- other heavy metals
- PCP (pentachlorophenol)
- azo dyes (dye)
- ozone-depleting substances, including CFC, HCHC, halon
- formaldehyde
- vinyl chloride monomers

- BCP (polychlorinated biphenyls)
- phthalates (plasticizer)
- PVC
- PAH (polycyclic aromatic hydrocarbons)
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- PFOS (perfluorooctane sulfonate)

Our physically crosslinked PC foams are produced in a 3-step process (extrusion, foaming), and we do not use any form of fluoro-chloro-hydrocarbons (FCKW) as the foaming agent.

In contrast to conventional foaming processes, the foaming agent we use consists of an ecologically acceptable additive in solid form. This is mixed with the basic components (such as polyethylene, color pigments, etc.) before extrusion.

After extrusion and crosslinking, the foaming agent is activated by heat in the foaming oven and the extruded film (matrix) expands into a closed-cell foam. The following gases are formed from the foaming agent: Nitrogen (N2) and carbon dioxide (CO2).
Due to diffusion, the cell gas is eventually replaced by ambient air. The gas exchange takes place slowly (a few weeks) and has no significant effect on the properties of the foam.

We further confirm that we do not use fluoro-chloro-hydrocarbons (FCKW) as a blowing agent in the production of our chemically cross-linked polyethylene foams, in the block foam production process. The blowing agents we use and the cell gases that are produced are the same as in the production of physically cross-linked polyolefin foams.