

AVOIDANCE OF PVC-CONTAINING MEDICAL PRODUCTS IN THE CHILDREN'S HOSPITAL KINDERKLINIK GLANZING

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Polyvinylchloride (PVC) plastic is a synthetic polymer resin, originating by polymerisation of the monomer vinylchloride (VCM) with the formula $CH_2=CHCl$. PVC has therefore practically the same structure like polyethylene, but additionally it contains chlorine. 57% of the weight of the polymer resin is caused by chlorine. 35% of the chlorine of a chlorine-alkali-electrolysis are finally manufactured to PVC, thus being the biggest single-product. Pure PVC is a stiff material, mechanically resistant. On the other hand PVC is relatively instable against heat and light. After exposition against heat and UV-light chlorine is lost as (hydro)chloride acid, a process which can be prevented by the addition of stabilizers, consisting often of a salt of metals like lead, barium, calcium or cadmium and from tin organics binding.

The mechanical properties of PVC can be altered by the addition of low molecular substances to PVC, mixed with the polymer matrix. The addition of the so called softener in different amounts leads to materials with a big variety of qualities. The mostly used softeners are ester of organic acids, mainly phthalates and adipates. We differentiate two groups between the numerous applications of PVC. Hard-PVC (two third of all applications) and soft-PVC (one third). Hardly another synthetic material causes so many risks concerning environment and health like PVC. The only advantage of PVC against other not so dangerous plastics is the low price. Chlorine increases the danger of chemicals dramatically. Most of organic compounds therefore are carcinogen and mutagen. Nowadays 11.000 chlorine organic chemicals are produced worldwide.

PVC used in medical products

Medical concerns against the use of PVC are based on the migration of the softener DEHP (Di-(2-ethylhexyl) phosphate). DEHP is soluble in fat-containing liquids like blood and may cause liver diseases, diseases of the skin and the cardiovascular system. In animal experiments DEHP was carcinogenic.

Different therapeutic substances like tranquillizers and cytostatica accumulate by the surface of PVC-containing medical products or are taken into the matrix of the synthetic material (plastics). Therefore a part of the medicaments remain in the bags and the tubes instead being taken up by the body of the patient. Using PVC in medical fields additional danger is caused by the element chlorine and the different compounds of chlorine. VC is causing cancer, damaging the skin, the bones, the liver and the

genes. During the production of monomer-VC toxic hydrocarbons are produced as side effect.

The high solubility of softeners in fat is the reason, to forbid the use of PVC as packing material for foods. But also blood contains a lot of fat. Patients suffering from kidney disease are taking up in ten years approximately 150g DEHP from tubes of the artificial kidney. Giving only one blood transfusion 50mg DEHP can be detected in the blood.

Actual measurements of the British ministry of health show enormous high values of PVC softeners in umbilical cord blood of newborn. Especially high is the portion of DEHP, causing cancer and showing potentially hormonal function.

A Swedish study could show already in 1987, that in patients needing dialysis liver diseases are more common. Under the microscope increase of peroxysomes could be observed within twelve months after start of dialysis. Furthermore cysts in kidney could be demonstrated. Several examinations show that DEHP after transfusion is also bound in cell tissue

Animal experiments showed a significant increase of liver tumours in mice and rats if the food was mixed with DEHP. Therefore DEHP is classified in the United States as causing cancer in "animal experiments". Because of the lack of epidemiological studies in humans DEHP is classified as "potentially human carcinogen" (group B2 of the classification schema of the US ministry of environment and health). DEHP is degraded in the human body to different substances, like for example to monoethylhexyl-phthalat (MEHP).

An other possibility for DEHP to come into the human body is artificial ventilation with PVC containing tubes. DEHP is very volatile and can come from the inner surface of the PVC tubes in respectively concentrations into the lung. Especially in infants and mainly in premature born babies. DEHP therefore can damage the lung tissue.

Examinations of commonly used PVC medical products from eight EU-states (Denmark, Germany, France, Greece, Great Britain, Netherlands, Austria and Spain) as well as examinations from Brazil, India, the Philippines and the USA show that DEHP is widely used. PVC medical products contain between 12 and 80 weight-percent DEHP. Similar results from former analyses of PVC medical products from the USA showed 29 to 81 weight percent.

Regarding the medical needs PVC shows poorer results than other plastics. PVC has a high permeability for oxygen and (water-)steam. Sterilisation with ethylenoxyde can lead to deformities. Gamma-sterilisation changes the colour of PVC to brown and produces hydrochloric acid. Medical gloves containing PVC are less flexible and are more prone to perforate, therefore less suitable than latex gloves.

Strategy to avoid PVC

With the EU-directive 2001/59/EC from August 6, 2001, DEHP was classified in category 2 as "dangerous for reproduction". In the Vienna Hospital Association it is mandatory to declare PVC concentration in each product to identify the necessity of changing this products in the future. The use of PVC in neonatology and in dialysis is considered to be very dangerous.

Results of risk assessment and healthcare

Risk assessment for humans revealed alarming effects on health damaging the kidney, the testicles, fertility and fetal development. Considering the bad affects of DEHP on fertility in human development, mainly fetal development DEHP was classified by the EU-directive 2001/59/EC 6.8.2001 category 2 as dangerous for reproduction. Many medical products contain DEHP, for example catheters for dialysis and transfusions, implants like artificial heart valves, syringes and material in ophthalmology and dentistry. Repeated blood transfusions are of special risk for children. During transfusions or during parenteral nutrition in premature or newborn babies DEHP can cause heavy burden for the immature organs.

The international medical product market

Four main manufacturers dominate the medical product market in Europe:

Fresenius, B. Braun, Baxter/Clintec and Pharmacia. Baxter, the world largest producer of medical products announced the stop of PVC use, starting with infusionsvax.

PVC-free products are produced by Codan, Ohmeda, Clinoco, Plasti Medical, Baird, Corpak and Asta Productos Medicos. According to the EU-medical product guideline 98/79/EWG PVC-free products should be used for infusions and application of medicaments so that patients are not contaminated with DEHP.



Preterm child in intensive care

PVC avoidance in the Childrens Hospital Glanzing, Vienna, Austria

A reduction of PVC in medical waste of the Children's Hospital Kinderklinik Glanzing (Wilhelminenspital der Stadt Wien) in the year 2003 could be achieved to only 0,37 % (concerning weight). In 1990 it was 10% and in 1995 still 2,5%.

PVC in medical products was 4,6% in 2001 and 3% in 2003, respectively. The number of PVC containing products used per year in our neonatal intensive care unit (NICU) was 15,9% in 2001 and 5,4% in 2003, respectively.

Attempts of several hospital organisations should be done to increase the pressure on the industry to increase the production of PVC free medical products and to lower the price, so that complete avoidance of PVC containing (medical) products will be reached as soon as possible.