

# Birthsparks



Comfortable upright birth

## CUB Technical information

Updated January 2024

- **Material**

The CUB is made from 0.500mm thermoplastic, bio-compatible PVC that meets all EU standards.

The CUB is manufactured from medical grade PVC which is the same material as many hospital chair seats and hospital bed mattresses; IV tubing, urinary catheters, and artificial heart valves. PVC is commonly used in healthcare for screening, diagnosis, treatment, and care, as well as in building safe healthcare environments. In fact, nearly 30% of all plastic-based medical devices are made of PVC. Whenever plastics are used in direct contact with the patient's tissue or blood, a high degree of compatibility is essential between the tissue/blood and the material. PVC is characterized by high biocompatibility.

PVC is compatible with virtually all pharmaceutical products in healthcare facilities today due to its excellent water and chemical resistance. Not only does PVC offer the flexibility necessary for applications such as blood bags, mattresses or intravenous (IV) tubing, but it can also be relied upon for its strength and durability, even under changing temperatures and conditions. These properties are essential to provide convenience in use by healthcare professionals and performance thereby benefiting patient comfort and quality hospital care.

- **Standards for PVC use**

The CUB meets the 6P Standard for PVC Concerns from Europe and the USA regarding Phthalates. Phthalates refers to Phthalate Esters / PAEs, which are common additive to soften plastics especially PVC in past 40 years and 80% of Phthalates are used in plastic products. Based on the application and customer's safety concerns, there are various tests based on different Phthalates. The common testing is: 3P, **6P**, 7P, 15P and 16P.

- **3P and 6P** are based on ECC Directive 2005/84/EEC, CPSIA and AB 1108
- **6P** refers to 6 types of Phthalates below.
- Standard: No more than 0.1% or 1000ppm
- DEHP – Di-(2-ethylhexyl) Phthalate
- DBP – Dibutyl Phthalate
- BBP – Benzylbutyl Phthalate
- DINP – Diisononyl Phthalate
- DNOP – Di-n-Octyl Phthalate

- DIDP – Diisodecyl Phthalate
- Toys and childcare products that can be placed in the mouth.
- The CUB complies with: EN 71-1: Mechanical and physical properties; EN 71-2: Flammability; EN 71-3: Specification for migration of certain elements as required in the European Union.
- The official flammability rating of PVC (polyvinyl chloride) is **UL 94 V-0**, which means that it is regarded as a self-extinguishing material.
- **Physio balls:** (this includes those used as birth balls/peanut balls/any shape) do contain much higher levels of these toxic plasticizers (phthalates, PCBS, that are contra-indicated for use by pregnant people). These are used to decrease costs and increase flexibility/stretch in balls; the more stretch and flexibility a product has the higher the levels of plasticizers. It is high levels of these plasticizers that make physio balls stretchy, rubbery, and often feel slightly 'sticky' to touch. The CUB is certified Phthalate and PCB free to no more than 0.1% or 1000ppm (parts per million) so is a little less stretchy and does not have the same rubbery/sticky feeling to touch that most physio balls do. Most physio balls do not meet the common testing standards or EN regulations on the targets for the lowest levels of toxic chemicals that the CUB does. It is for these reasons that it is not recommended that physio balls are in contact with skin during pregnancy as plasticizers are known to leach into the skin and are well documented hormone disruptors.
- **The CUB can be recycled.** Plastic materials are divided to Thermoplastic Vs Thermoset. Thermoplastics are plastics that can be re-melted and re-molded into new products, therefore, recycled. Thermoset plastics are cross-linked to form an irreversible chemical bond. They cannot be re-formed and are non-recyclable.
- **It is 100% Natural Latex Free.**  
There are two types of latex – natural rubber latex and synthetic rubber latex. Natural rubber latex is obtained from the milky fluid from a rubber tree called the Hevea Brasiliense. Natural rubber latex should not be confused with synthetic rubber (for example, butyl or petroleum-based). Synthetic latex materials include polyvinyl chloride (vinyl or PVC), nitrile rubber (acrylonitrile-butadiene copolymers), and polychloroprene known by its trade name, Neoprene™
- Synthetic latex (PVC) is made from petroleum and does not contain the naturally occurring proteins found in natural rubber latex. As such PVC (synthetic rubber) does not contain natural latex and is, therefore, safe for contact with people suffering from a latex allergy.
- **Quality Control.** The CUB is manufactured in an ISO 9001:2008 certificated factory
- **CE Marked. MHRA registered**
- **Active GMDR registration**
- **Product Weight**  
The CUB weighs 2 KG
- **Recommended Maximum user weight**  
The recommended maximum user weight is 120 KG
- **Box contents**  
CUB support, manual or battery inflation pump, storage bag, user information guide
- **Durability**  
The CUB is re-usable, however as with all inflatable products it is not designed for very long-

term function and durability will depend on how well it is cared for. We recommend regular inspection and regular replacement if used by more than one user in a healthcare facility.

### **Cleaning**

The CUB can be cleaned with any antibacterial, sporicidal or hypochlorite (bleach) 10,000 ppm cleaner; either spray or wipes (any cleaner used on hospital delivery beds can be used). However, it should be noted that cleaning products used on the CUB may degrade the material over time. We recommend that the product should be regularly inspected for signs of degradation and replaced as required.

- **The decontamination process for the CUB** We recommend that a clean, disposable incontinence sheet is placed onto the CUB if the mother is sitting on it and has any PV loss that may come into direct contact with the CUB .
- **The CUB should be thoroughly cleaned between users using the process below.**
- Personal protective equipment (PPE) such as gloves and aprons should be worn during the cleaning process.
- While the CUB is still inflated: Rinse off all visible surface contamination with a clean, disposable cloth and water; paying attention to the area around the seams and valves and including the base. There should be no visible contamination left. Dry the CUB with a clean disposable cloth, such as paper hand towels. Spray or wipe with an antibacterial cleaner, a bleach solution or wipe thoroughly with antibacterial household cleaning wipes.
- Allow the CUB to air dry completely before deflating and storing.