

Development of Polyvinyl Chloride Blood Circuit Tubes for Medical Use with Advanced Safety Features

Toyobo has recently developed new blood circuit tubes with outstanding safety features that are manufactured with Hexamoll® DINCH®* (1,2-cyclohexane dicarboxylic acid diisononyl ester) as the plasticizer for polyvinyl chloride (PVC). PVC blood circuit tubes for medical use produced using Hexamoll® DINCH® as the plasticizer are the first in Japan to receive the approval of the Ministry of Health, Labour and Welfare.

*Hexamoll® and DINCH® are both trademarks of German company BASF.

1. Development Background

PVC is the basic material for these medical tubes, and since it has outstanding flexibility and is chemically stable, it is widely used in medical equipment applications, such as flexible blood circuit tubes, medical containers, blood bags, and other items. To have these PVC products maintain their flexibility, plasticizer “DEHP” (di-2-ethylhexyl phthalate) is frequently used as an additive.

However, in September 2001, the U.S. Food and Drug Administration (FDA) issued a report that pointed out that “There is a possibility that, while in use, a portion of DEHP may be absorbed into the blood and body fluids and be injurious to health.” Thus far, there have been no reports that the use of medical equipment containing PVC has resulted in direct damage to health, but it has been confirmed already in experiments with rodents that there is a high testicular toxicity and gametogenesis toxicity. In particular, it has been pointed out that, in the case of persons who are believed likely to be affected by exposure to DEHP, such as newly born babies, suckling babies, pregnant women, lactating women, and infants, other products made from different basic materials should be substituted.

On the other hand, in October 2002, the Japanese Ministry of Health, Labour and Welfare issued guidance stating that “While the clinical effectiveness of medical devices made from PVC produced with DEHP as the plasticizer cannot be denied, it will be desirable to minimize the exposure of patients to such devices as much as possible. Therefore, the development of such devices made

from materials other than PVC or made with PVC produced with safer plasticizers should proceed.”

In view of these circumstances, Toyobo developed the first blood circuit tubes for medical use made from PVC produced using highly safe Hexamoll® DINCH® in place of DEHP.



Toyobo’s newly developed medical grade tubes

2. Features of the Newly Developed Medical Grade Tubes

- (a) Plasticizer Hexamoll® DINCH® used in the newly developed tubes is highly safe, and no instances of testicular toxicity or gametogenesis toxicity, which are characteristic of tubes made with previous plasticizers, have been identified.
- (b) These newly developed tubes have the same or better transparency (external), flexibility, and physical properties as well as stability when kept in storage as previous blood circuit tubes for medical use. They have superior usability as medical devices and visibility of the materials inside the tube.

3. Examples of Usage

For the time being, these tubes will be used as blood circuit tubes and catheters that are used in general heart surgery.

4. Future Directions

Beginning in June 2012, Toyobo will begin to supply these products to medical equipment manufacturers in Japan and will aim for sales of ¥1.0 billion annually. In addition, looking to the future, Toyobo plans to work to develop markets for these products in fields other than medical equipment.

For more information, contact:

The Toyobo Public Relations Group

pr_g@toyobo.jp