

English translation of the State Health Institute regarding the health safety of Gaia Cup.

TIERRA VERDE s.r.o.
Hněvkovského 39a, 617 00 Brno

Your letter no.
from date 5th Feb 2013
Our no. SZÚ 469/2013
CTZB 187-469/13-32
EX 130179
Person responsible: RNDr. M. Rucki, PhD.
Tel. +420 267 082376
E-mail: rucki@szu.cz
Date: 20th Feb 2013

Subject: **EXPERT REVIEW regarding the health safety of an intimate hygiene product for women**

The subject of the request:

Your demand from 5th February 2013 to review the health safety of an intimate hygiene product for women according to the requirement of the Czech law no. 102/2001, On the general safety of products, as amended, we declare the following:

THE SAMPLE PROVIDED: Intimate hygiene products for women (material - silicone)

Country of origin: China

Documentation provided:

Biocompatibility certificate from 28th Dec 1998 and Wacker Silicones were included to the request from 5th Feb 2013.

Tests performed:

Chemical tests (pH of the solution according to Czech state norm - ISO 3071), detection of overall migration in the water solution according to Czech state norm 621156, contents of the reductive compounds in water solution according to Czech state norm 621156 and a test of cytotoxicity according to Czech state norm - ISO 10993-5:2005 Part 5

were performed in the Test labs no. 1206, accredited by Czech institute for Accreditation (ČIA), the Centre of Toxicology and Health Safety.

Tests were performed in the range according to the methodological recommendation of Czech Health Institute no. 1/2000 to judge products that come into direct contact with human organism via skin and mucous membranes.

The sample was destroyed ("consumed") to perform these tests.

Expert review:

The subject of the review is to find possible adverse biological effects of the material in contact with human skin.

pH value of the solution of the silicone is in the range suitable for contact with skin.

Overall migration in water solution is under the limit specified for a safe product.

Contents of reducing substances in water solution is safe for contact with skin.

Cytotoxicity tests proved that the material is not toxic for cells of a tissue culture.

Conclusion:

Based on the judgment of the documentation presented, chemical inspection and cytotoxicity test we conclude that the products provided - an intimate hygienic tool for women - is in the range of the tests performed **SAFE FOR HUMAN HEALTH BY CONTACT WITH SKIN**. It complies with the basic requirement for the material safety according to the Czech law no. 102/2001, On general products' safety, as amended.

This claim is relevant only for the sample provided and the results drawn from it can be applied only on the products of the same kind that are completely equivalent to the sample by its contents and properties.

MUDr. Dagmar Jirova, CSc.
head of the Centre of Toxicology
and Health Safety

[Stamp: State Health Institute
Centre of Toxicology
and Health Safety
Šrobvárova 48, 100 42 Praha 10]

Attachments:

protocol of chemical inspection no. CTZB 187-469/13-32
protocol of cytotoxicity test no. CTZB 187-469/13-32