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Update on RIVM-report 2015-0100 "Silicone breast implants in the Netherlands - A market surveillance study"

State of affairs October 2017

On June 9th, 2016 RIVM published the results of a study on breast implants, commissioned by the Dutch Health Care Inspectorate. RIVM performed laboratory analyses on the implants and evaluated the technical files. The Inspectorate urgently called upon the manufacturers to clarify some of the laboratory findings and to resolve shortcomings in the technical files.
This document provides the current state of affairs. In addition, upon request of the Inspectorate, the manufacturers have agreed to lift their anonymity. This document provides a table with the names and corresponding identification numbers of the manufacturers.

Shortcomings in the technical files

Manufacturers and their notified bodies have been working on improving their technical files. The Inspectorate has commissioned RIVM to carry out a follow-up study on the improvements made in the technical files. RIVM expects to report on this before the end of 2017.

Discrepancy silicone gel manufacturer SBI06 resolved

Upon submission of the technical file in 2014, manufacturer SBI06 mistakenly added a 'technical specification sheet' to the technical file which belonged to a different type of (also medical grade) silicone gel than is actually used in the implant included in the RIVM study. Nusil Technologies, the supplier of the raw material, has confirmed that they provided silicone gel to manufacturer SBI06 corresponding to the one found by RIVM. As a consequence, it was concluded that the discrepancy in the report concerning the gel used by this manufacturer was based on unintentionally provided erroneous information and does no longer exist.

Discrepancy silicone gel manufacturer SBI08 resolved

In the technical file submitted in 2014, manufacturer SBI08 described their gel as equivalent to another gel. However, RIVM findings showed that the chemical hallmarks of the two gels were different. In response to this discrepancy, the manufacturer confirmed the two gels were different in chemistry and different in performance. Nusil Technologies (the current owner of Applied Silicone which supplied the raw material at the time), has confirmed that they provided a silicone gel to manufacturer SBI08 that chemically corresponds to the one found by RIVM. As a consequence, it was concluded that the discrepancy in the report concerning the gel used by this manufacturer was based on unintentionally provided erroneous information and does no longer exist.

Implant with cyclosiloxanes from manufacturer SBI08

One of the conclusions of the 2016 report stated that in one implant, the level of cyclosiloxanes was higher than specified in the technical file

submitted in 2014. The submitted documentation specified the levels of D4 and D5 cyclosiloxanes to be <20 ppm. However, one implant from manufacturer SBI08 contained >150 ppm D5 cyclosiloxanes. This specific implant was manufactured in 2009 and its shelf-life expired in 2014. Implants from the same batch or era were no longer available at the manufacturer rendering exact comparisons impossible. A further 17 implants from SBI08 manufactured between 2011 and 2015 were evaluated and did not contain detectable levels of cyclosiloxanes. According to manufacturer SBI08, every manufacturer had the same specifications in 2009 and any manufacturer could have produced implants with similar levels of cyclosiloxanes. Nusil Technologies (the current owner of Applied Silicone which supplied the raw material at the time), has confirmed that manufacturer SBI08 received the same raw material as other manufacturers. Nusil Technologies also stated that the maximum volatile content (a mixture of volatile substances including D4/D5) was lowered from 1.0% to 0.5% in 2009. Furthermore, that it was lowered to 0.2% in 2012, which resulted in a 20 ppm maximum allowable D4/D5 content. However, the statement does not specify the levels of D4/D5 in Applied Silicone gels in 2009. Therefore, it is not possible to compare the >150 ppm D5 found in one implant of SBI08 with the gels produced at that time.

Transparency of study results

The results in the 2016 RIVM report are anonymized. In order to obtain transparency, the Inspectorate called upon involved manufacturers to agree with lifting the anonymity. Following discussion with each manufacturer, agreement was reached on publishing the numbers and corresponding manufacturer names, see the table below.

Number	Name
SBI01	Groupe Sebbin SAS, France
SBI02	Nagor Ltd, UK
SBI03	Polytech Health & Aesthetics GmbH, Germany
SBI04	Allergan, UK
SBI05	Pérouse Plastie SAS, France
SBI06	Establishment Labs SA, Costa Rica
SBI07	Laboratoires Arion SAS, France
SBI08	Silimed, Brazil
SBI09	Eurosilicone SAS, France
SBI10	Mentor Medical Systems BV, Netherlands