



BioGenes GmbH Koepenicker Str. 325, 12555 Berlin

To whom it may concern

HR Berlin Charlottenburg 45983
Managing Directors:
Dr. A. Knoll, Dr. S. Ovodov

Website: www.biogenes.de

Tel. +49 (0) 30-6576 2396
Fax +49 (0) 30-6576 2397

12 October 2020

Notification of Change

Dear Valued Customer,

In June 2017, the European Chemicals Agency (ECHA) included "Octylphenol" (4-(1,1,3,3-Tetramethylbutyl)phenol, ethoxylated) on the "Authorization List", as amended on the Annex XIV of the Regulation (EC) No 1907/2006 of REACH (Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals). This step was decided due to the vast environmental hazard "Octylphenol" displays. As a consequence, the use and/or bringing this chemical and all its combinations, where this substance is part of a complex molecule, into circulation without permission is strictly prohibited within the European Union after the fixed deadline (January 4th, 2021).

The frequently used chemical substance Triton™ X-100 is affected by the aforementioned regulation and liable to registration. Triton™ X-100 is currently used by BioGenes as a non-ionic detergent in various ELISA buffers and also as a buffer additive during the production of further ELISA kit components.

The following table lists all the products and ELISA kit components which contain Triton™ X-100 and include a Triton™ X-100-based buffer production step, and thus are subject to potential substitution.

Product	Note
Washing buffer (master batch)	Triton™ X-100 buffer component at 0.05 % up to 0.5 % (10 X concentrate)
Assay buffer (sample buffer)	Triton™ X-100 buffer component at 0.05 %
ELISA standard (kit standard)	Triton™ X-100 as component of stabilizing buffer
Microtiter plate, covered with antibody	Triton™ X-100 as component of blocking and washing buffer

Due to this regulation, we have undertaken all necessary steps to suspend the use of Triton™ X-100 according to the previously mentioned deadline and have subsequently employed eligible chemicals as replacement detergents.

Henceforth, we use TWEEN®20 (Polysorbate 20) as an additive in buffers and other ELISA components as a congeneric replacement for Triton™ X-100. In this context, we also established the use of commercially available buffers containing the substituent TWEEN®20, which demonstrably showed equal quality to Triton™ X-100-supplemented buffers. Consequently, we also replaced Triton™ X-100-supplemented buffers in all internal ELISA tests and novel (HCP-) ELISA developments with commercial buffers containing TWEEN®20 as a supplement.

BioGenes would like to call attention to the changeover from Triton™ X-100 to TWEEN®20 but also emphasize the substantial equivalence of both substances with regard to the ELISA quality.

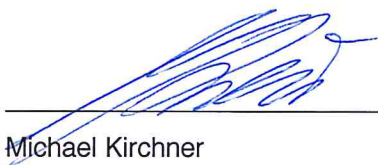
In a wide array of tests, we have been able to show that the replacement of Triton™ X-100 with TWEEN®20 and the use of commercially available TWEEN®20-based buffers does not alter the main characteristics of an ELISA (especially HCP ELISA). However, in general we recommend our customers the parallel in-house testing of relevant samples with both generic HCP ELISA kits “old” (Triton™ X-100-based) versus “new” (TWEEN®20-based).

Therefore, we still offer our customers the order option of “old” (Triton™ X-100-based) generic HCP ELISA kits probably **until December 31st, 2020**. These kits may be internally compared with appropriate “new” (TWEEN®20-based) generic HCP ELISA kits, which will be solely available from January 1st, 2021.

Please note, that the delivery of “old” (Triton™ X-100-based) generic HCP ELISA kits may not be guaranteed due to the current sell-off and termination of production, and we apologize for the inconveniences this may cause.

We thank you for your understanding and we are looking forward to a further successful cooperation.

Kind regards,



Michael Kirchner
Head of Production Control



Ismail Bayram
Head of Quality Management