

25th September 2023

Change Notification

EU BPR Authorisation of Contec HydroPure (6% Hydrogen Peroxide)

Removal of Spore Claim

Dear Customer

In July 2022, Contec's dossier for all products containing 6% hydrogen peroxide received Union Authorisation from the EU Commission. At this time, we informed all distributors and end-users that the biocidal claims for the product would change in line with the authorisation.

Whilst Contec HydroPure's formulation had not changed, nor had the product packaging, raw materials, or manufacturing processes been altered in any way, changes in the EN efficacy test methods that were required for submission to the Biocidal Product Regulation (BPR) affected efficacy claims for all Hydrogen Peroxide products in the market.

A comparison of the old and new HydroPure claims was subsequently communicated. This information was reflected on the product labels and technical and marketing information.

Organism	Previous Claim	New BPR Claim
Bacteria	5 mins	15 mins
Yeasts	5 mins	30 mins
Fungi	15 mins	30 mins
Viruses	15 mins	No claim
Spores	15 mins	60 mins (suspension only)

Current Situation

Unfortunately a non-conformance to our BPR authorised claim was discovered during a label and artwork review of Contec's HydroPure products. This was immediately investigated according to our Quality System deviation procedure under deviation NCR735.

As a result of the test method update, Contec's application process for BPR authorisation was not straightforward, and our dossier was planned for submission into different workflows. Our internal quality investigation indicated that the sporicidal claim had not been submitted as intended and subsequently was not included in our current BPR authorisation.

Contec Inc Ave Paul Duplaix, 56000 VANNES, France
tel: +33 (0) 2 97 43 76 98

email: infoeu@contecinc.com | contecinc.com/eu

Clean counts most

However, the 60 minute spore claim was erroneously still included on the product labels and technical information. All test work to substantiate the sporicidal claim had been carried out but was not submitted as a 60-minute contact time was deemed impractical in use.

We are, however, now submitting this test work to ECHA to add to our BPR claims for HydroPure since the market has requested it.

ECHA’s application process allows data to be submitted only during specific timepoints throughout the calendar year. Our sporicidal data will be submitted into the next available workflow with initial estimates indicating that authorisation will likely be granted in January 2025.

In the meantime, Contec is removing the BPR sporicidal claim from all marketing and technical literature. We anticipate that this will take a few months to complete.

We are amending product labels to remove the current BPR sporicidal claim, and we expect that the first batch of products with new labels will be manufactured after 1st January 2024. Any product manufactured before this label change will be delivered under deviation.

Implication for end-users

Contec recognises that customers wish to use HydroPure as a sporicidal disinfectant. To that end, our independent sporicidal test data supporting a 60 minute suspension claim is available upon request, as this is the data we are currently submitting to ECHA.

As a 60 minute contact time is impractical in use, it is highly likely that most end-users have their own efficacy data validated at shorter contact times. However, if there are any end-users who would like to discuss this further, please contact us for more information.

EN13704: 2018– interfering substance WFI *

Organism	Pass Criteria	Test Results Log Reduction	Contact Time	Result	Method Used
<i>B.subtilis</i>	Log 3	<2.11	30 mins	FAIL	Dilution neutralisation
<i>B.subtilis</i>	Log 3	2.15	45 mins	FAIL	Dilution neutralisation
<i>B.subtilis</i>	Log 3	> 3.48	60 mins	PASS	Dilution neutralisation

Affected Regions

This change affects HydroPure products sold with BPR authorised labelling.

If you require additional information concerning this notice, please do not hesitate to contact us.

Table 1 Contec HydroPure products affected by this change

Part Nr	Description
SBT16HPW	Contec Sterile HydroPure with Water for Injection, Trigger Spray, 1L
SBC16HP	Contec Sterile HydroPure, Capped, 1L
SBC56HP	Contec Sterile HydroPure Capped, 5L
FBT16HP	Contec HydroPure Trigger Spray, 1L
FBC16HP	Contec HydroPure Capped, 1L
FBC56HP	Contec HydroPure Capped, 5L
SSWC16HP	Contec Sterile Amplitude Theta SATWIPES System with HydroPure 100 wipes

Sincerely,



Toine van der Noord
EMEA Business Unit Director
 Contec Inc.
 Email: tvandernoord@contecinc.com
 Office: +33 (0) 297 437 698



Amy Russ
Global Product Manager
 Contec Inc.
 aruss@contecinc.com
 +1 864 699 8371