

DeLaval NV
Industriepark-Drongen 10,
9031 Gent,
Belgium

Oslo, 03.11.2021

Your ref.:

Our ref.:
2015/4008

Contact person:
Marianne Stave Sekkenes

Acceptance of administrative change – DeLaval iodine-based teat disinfectant family – NO-2019-0177

We refer to your notification for an administrative change to the biocidal product family authorisation for DeLaval iodine-based teat disinfectant family – NO-2019-0177, R4BP 3 Case number BC-DP070172-40. The Norwegian Environment Agency hereby accepts the notification.

Background

According to Article 50 (2) in Regulation (EU) No. 528/2012 concerning the making available on the market and use of biocidal products, changes to the conditions laid down in a biocidal product authorisation shall be accepted by the Competent Authority. Changes to a product authorisation are further described in Regulation (EU) No. 354/2013.

Regulation (EU) No. 528/2012 and Regulation (EU) No. 354/2013 are implemented in Norwegian law through the Norwegian Biocide Regulation of 18 April 2017 No. 480.

Decision

We hereby confirm that we accept the notification for an administrative change to DeLaval iodine-based teat disinfectant family. The notification concerns addition of the trade name "Dipal Plus" for the product "GMP36" in Meta SPC 4 referred to in Section 1 of Title 1 to the Annex to Regulation (EU) No 354/2013. No other changes than the above mentioned is accepted with this letter.

The revised Norwegian Summary of Product Characteristics (SPC) is uploaded to R4BP 3.

Label

In cases where the changes concerned in this letter have any consequences for the content on, or the design of the label, you are kindly requested to submit an electronic copy of the revised label with the Norwegian authorisation number NO-2019-0177-04-01 to biocides@miljodir.no within three months from the date of this letter.

Best regards
Norwegian Environment Agency

This document has been signed electronically

Marianne Stave Sekkenes
Senior Adviser