

CONFIRMATION

Date
11 November 2016

Our reference
5.1.3-B15-00185

File No Authorisation No
F-3988 5122

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FRANCE

Notification of confirmation of a minor change for Jade Paste

The Swedish Chemicals Agency received the 11th of May 2015 in accordance with Regulation (EU) no 354/2013, an application for mutual recognition of a minor change consisting in the addition of a new packaging size for the product Jade Paste. The application for the minor change was submitted to Ireland, who acted as Reference Member State.

Product name	Jade Paste
Product authorisation no	5122
Case no (R4BP3)	BC-NM017148-32

This minor change was evaluated and finally authorised the 10th of October 2015 in accordance with Article 50 in Regulation (EU) no 528/2012 by the Competent Authority in Ireland.

The Swedish Chemicals Agency agrees with the decision from Ireland and confirms that the product may be placed on the Swedish market in accordance with the terms and conditions regarding packing size as granted by Ireland (product name Jade Paste, case no BC-YG017147-35). The authorisation in Sweden does not include any restrictions regarding the packaging size. This implicates that Sweden will not make changes to the current authorisation. Jade Paste was authorised in Sweden in accordance with directive 98/8/EC, and the decision to authorise did not include a summary of product characteristics (SPC), as this was not a legal requirement at the time. A SPC will be established if the product authorisation is renewed.

Yours sincerely

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Swedish Chemicals Agency

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