

## FOI 23/781

Dear

Thank you for your correspondence dated 16 October, where you submitted a refined request for information.

*“Request on Alkyl-Sulfonate Impurities in Sulfonate-Salt Drug Substances and Drug Products*

*Could you restrict the search for assessment reports on sulfonate-salt APIs to the last two years? If I specify just two PL numbers then I feel that I could miss important information on the variety of sulfonate counterions*

*And please provide the training slide deck that deals with sulfonate salts.”*

Unfortunately, we estimate that compliance with the refined request would still exceed the appropriate costs limit under S.12 Freedom of Information Act 2000. Public authorities are not obliged to work past the appropriate costs limit under section 12(1) of the Freedom of Information Act 2000.

This is because your refined request in its present form covers:

- Assessment reports on sulfonate-salt APIs for Marketing Authorisations granted in the last two years
- The training slide deck that deals with sulfonate salts.

A search of our records for part 1 of the request (going back 2 years) has revealed that this still covers over 25 Marketing Authorisations for products that contain drug substances that are sulfonate salts (mesilate, besilate, tosylate). We would have to manually check our records for each of the Marketing Authorisations to locate the original assessment reports that were compiled at the time of authorisation.

We would again advise you to narrow this part of the request to one or two specific Marketing Authorisation numbers and the training pack as a refined request. We appreciate that you do not want to miss valuable information by limiting the request to one or two PL numbers, but the appropriate limit is there to assist public authorities to manage the burden of requests asking for large amounts of information in one go; however further PL numbers can be requested in future requests.

We would also like to re-iterate that detailed quality data and any details of the drug substance synthesis are likely to be considered to be commercially confidential and so may be exempt from release under Section 43 (Commercial Interests) of the FOI act. The quality assessment reports may, therefore, not include the specific information that you are interested in. The Public Assessment Reports (PARs) that we publish on our website are based on the assessment reports, but with commercially confidential information removed. The Summary of Product Characteristics (SmPC) also covers non-confidential quality information. These can be found here:

[MHRA Products | Home](#)

If you do submit a refined request, then we will treat it as a substitute request to your original request and the 20 working day statutory time limit will begin from the date your refined request is received. In the absence of a refined request, we will send an official response to your original request, engaging the costs limit exemption under section 12(1) of the Freedom of Information Act 2000 within the 20 working day limit.

If you disagree with how we have interpreted the Freedom of Information Act 2000 in answering your request, you can ask for an internal review. Please reply to this email, within two months of this reply, specifying that you would like an Internal Review to be carried out.

Please remember to quote the reference number above in any future communications.

If you were to remain dissatisfied with the outcome of the internal review, you would have the right to apply directly to the Information Commissioner for a decision. Please bear in mind that the Information Commissioner will not normally review our handling of your request unless you have first contacted us to conduct an internal review.

The Information Commissioner can be contacted online via an electronic form: <https://ico.org.uk/make-a-complaint/foi-and-eir-complaints/foi-and-eir-complaints/>

Or by writing to:

Information Commissioner's Office  
Wycliffe House  
Water Lane  
Wilmslow  
Cheshire  
SK9 5AF

Yours sincerely,  
FOI Team