

Read across options for rhenium substances

Six rhenium substances are currently being registered under REACH. Of these, ammonium perrhenate is being registered at 10 – 100 tpa and requires Annex VII and Annex VIII endpoints to be filled. The remaining rhenium substances either have Annex III exemptions and therefore require only Annex VII physico-chemical endpoints plus *'any other relevant physico-chemical, toxicological and ecotoxicological information that is available'*, or are intermediates under strictly controlled conditions (SCC) and therefore require only available data.

Although substances that are Annex III exempt or intermediates under SCC do not require mammalian toxicology endpoints to be filled, data have been generated for Annex VII and VIII endpoints for ammonium perrhenate and as indicated in the Rhenium ITS (Rhenium ITS Nov10_wca_rev 11), these could be read across to the other rhenium substances if necessary.

The following options are available for those substances that are Annex III exempt or being registered as intermediates under SCC:

1. Read across data for mammalian toxicology endpoints from ammonium perrhenate

- By reading across the data from ammonium perrhenate this would provide a full Annex VII and VIII mammalian toxicology dataset, which currently would support the non-classification of the rhenium substances.
- However, if ECHA request further investigation of the results from the OECD 422 study with ammonium perrhenate, and this leads to a classification for ammonium perrhenate, classification could also be required for any other rhenium substances that have used these data for read across.

2. Do not read across data for mammalian toxicology endpoints from ammonium perrhenate

- If the ammonium perrhenate data are not read across then any uncertainties relating to the results from the OECD 422 study would not be associated with the other rhenium substances.
- However, if any further investigation of the ammonium perrhenate results is requested by ECHA, and this leads to a classification for ammonium perrhenate, we would recommend that read across is reconsidered at this point as a 'duty of care'. If the review does not lead to a classification for ammonium perrhenate, read across could be

applied too, ensuring that all relevant Annex VII and VIII information requirements are fulfilled for all rhenium substances and intermediates.

3. Only use unequivocal data for read across from ammonium perrhenate to the other rhenium substances

- This approach would not be recommended. The dataset should either be read across in full or not at all, unless there is a particular reason why read across is not appropriate for a certain endpoint. Using read across for some endpoints and not others is likely to lead to further scrutiny from ECHA if they review the dossier.

4. Only read across data from ammonium perrhenate to those substances that are not SCC intermediates (ie only those that are Annex III exempt)

- REACH articles 17 and 18 on on-site and transported isolated (SCC) intermediates states that *'any available existing information on physico-chemical, human health or environmental properties of the intermediate'* should be provided. This is a slightly different wording to the Annex III exempt substances (see the first paragraph above) and could be seen to justify not using the ammonium perrhenate data for read across to the SCC intermediates.
- Nevertheless, depending on any future discussions concerning ammonium perrhenate, a decision can be made subsequently as to whether the data for APR could be used post-registration for the SCC intermediates.

As there is currently no REACH requirement to fill the toxicology endpoints for the SCC intermediates or those substances that have Annex III exemptions, wca's recommendation would be not to read across the data from ammonium perrhenate at this point. If the non-classification of ammonium perrhenate is challenged in the future then the relevance of reading across the data to the other rhenium substances can be further evaluated. The data could then be read across at this point if it is considered to be appropriate. This is a pragmatic approach that does not impact on the hazard profile of the SCC intermediates/Annex III exemptions, and allows for future review of ammonium perrhenate if necessary.

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