Active substance source =

| **Data requirement point / reference number** | **Study or test considered as relied upon and for which data protection has been claimed** | | | | **Title of alternative study or case referenced / submitted by applicant** | | | **Reason for equivalence / justification for non-provision3,4** | **Cat. 4 data5** | | **RMS Opinion4,6,7**   1. **GLP-compliant?** 2. **Guideline-compliant?** 3. **Equivalent endpoint?** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Author(s)** | **Year** | **Title**  **Company Report No.**  **Source (where different from company)**  **GLP or GEP status**  **Published or not** | **Vertebrate study**  **Y/N** | **Author(s)** | **Year** | **Title**  **Company Report No.**  **Source (where different from company)**  **GLP or GEP status**  **Published or not** | **Y/N** | **Submission deadline** |
|  |  |  |  |  |  |  |  |  |  |  | *Acceptable/Not acceptable*   1. *Y/N* 2. *Y/N* 3. *Y/N* |
|  |  |  |  |  |  |  |  |  |  |  |  |

**Notes on completion of table**

1. Strike out in case of data matching for a new active substance.
2. Where relevant, please include the variant name of the active substance.
3. The list of studies according to Article 60(1) of the Regulation for which data protection is sought must be carefully checked. For more information, refer to the specific Guidance Document[[1]](#footnote-1)
4. Any alternative studies / cases submitted or referenced by the applicant must *match* those data requirements. Checks should establish that they satisfactorily address the regulatory requirement:
   1. Does the protocol to the study follow the GLP guidelines?
   2. Does the study follow the appropriate protocol/modelling?
   3. Do(es) the proposed end-point(s) in the study fall within the same range as the EU-agreed end-point(s)[[2]](#footnote-2)?
5. Columns to be filled out only for data matching performed according to art. 43. Where no cat. 4 data are sought, please delete.
6. Opinion of the RMS (see point 4 for criteria)
7. In case cat. 4 data matching studies are agreed, the RMS should update their opinion after the submission deadline.

1. Guidance document on preparing lists of test and study reports according to Article 60 of Regulation (EC) No 1107/2009 (Document SANCO/12580/2012– rev. 3.1 or later) [↑](#footnote-ref-1)
2. Note if another applicant derives a significantly more critical end-point from their study, then they are under obligation to report this to the COM as adverse data, according to art. 56 [↑](#footnote-ref-2)