***RMS note and overall conclusion (Ctgb, The Netherlands)***

16-07-2019

**Conclusion on the data matching request by Sharda CropChem Ltd, for the dossier of the active substance acetamiprid.**

RMS (the Netherlands) has assessed the proposals and statements, waivers and matching reasoning of the applicant.

Conclusion of the RMS is that not all data matching reasoning and waivers can be accepted.

This is indicated as follows:

- Accepted data matching study or argumentation
- Accepted Cat.4 studies with agreed date of submission
- Argumentation for Cat. 4 or alternative study not acceptable. LoA or alternative study must be submitted.

The RMS shall evaluate whether the (cat. 4) studies/statements of the applicant are matching with the studies of the notifier(s) upon submission.
The RMS for the active substance did not consider whether or not data protection applies to all studies for which data protection has been claimed. It is the responsibility of MSs to ensure that data protection standards as laid down in Regulation (EC) No 1107/2009 are respected.

The conclusion is stated in the table below, for each aspect.
Details can be found in the data matching tables for each aspect.

**Conclusion on data matching for the active substance acetamiprid – Sharda:**

| Aspect | Is current dossier acceptable for matching? | Cat. 4 data applied for? | Can all Cat. 4 data be granted? | Deadline submission Category 4 data | Conclusion |
|---|---|---|---|---|---|
| Physical and chemical properties | N[1] | Y | Y[2] | September 2019 (additional 4 months), and May 2020 (additional 24 months). | Data matching can be shown sufficiently (depending on Cat. 4 data to be submitted). |
| Toxicology | N | Y | N | Not applicable. | A period of 8 months was already granted for the submission of the study. In may 2019 applicant claims another 4 months for performance of the study. No justification was provided why the study has not yet been submitted and the RMS considers that sufficient time has passed in which the study could have been conducted (in vitro mammalian gene mutation study). |
| Residuen | N[3] (depending on the intended uses at product level) | Y | N | Not applicable. | No data matching conclusion possible[3]. Cat. 4 data not acceptable. |

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|---|---|---|---|---|---|
| Environmental Fate and Behaviour | N | Y | N<br>(1 acceptable, 1 not acceptable)<br>(furthermore 1 extra study could be accepted to cover a data gap.) | Not applicable. | No data matching possible. Cat. 4 data not acceptable.<br>Update May 2019: Conclusion unchanged. Three studies are currently ongoing, 1 is not accepted as Cat 4 however:<br>- aerobic mineralization of parent (OECD 309 (the other 2 are:<br>- aerobic rate of degradation of I-M-05 (OECD 307);<br>- adsorption of I-M-05 (OECD 106)); |
| Ecotox | N<br>(depending an agreement / letter of access between the Task Force and the notifier) | Y | (Cat. 4 data have been submitted and were accepted) | Not applicable. | Data matching can be shown sufficiently (depending on an agreement / letter of access between the Task Force and the notifier). |

[1] Information should be provided at product level (or before May 2020), to show acceptance to the guidance document. This was not provided at the time of the data matching check, but needs to be submitted by the applicant (in an addendum) to studies CA 4.2/04 and CA 4.2/05.

[2] Studies still need to be provided for acceptance.

[3] The applicant did not match all studies that address the magnitude of residues in various crops. At the moment, the applicant does not intend uses in all representative uses as evaluated during the active substance renewal so that the non-provision of matching data is considered acceptable by the RMS. With regard to the studies addressing rotational crops, a justification for non-provision cannot be assessed by the RMS; it can only be assessed by MSs in connection with the application for product authorisation and its intended uses.