

Committee for Risk Assessment
RAC

Annex 2
Response to comments document (RCOM)
to the Opinion proposing harmonised classification and
labelling at EU level of

**Aqueous extract from the germinated seeds
of sweet *Lupinus albus***

EC Number: -
CAS Number: -

CLH-O-0000007261-81-01/F

Adopted
16 March 2023

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON AQUEOUS EXTRACT FROM THE GERMINATED SEEDS OF SWEET LUPINUS ALBUS

COMMENTS AND RESPONSE TO COMMENTS ON CLH: PROPOSAL AND JUSTIFICATION

Comments provided during consultation are made available in the table below as submitted through the web form. Any attachments received are referred to in this table and listed underneath, or have been copied directly into the table.

All comments and attachments including confidential information received during the consultation have been provided in full to the dossier submitter (Member State Competent Authority), the Committees and to the European Commission. Non-confidential attachments that have not been copied into the table directly are published after the consultation and are also published together with the opinion (after adoption) on ECHA's website. Dossier submitters who are manufacturers, importers or downstream users, will only receive the comments and non-confidential attachments, and not the confidential information received from other parties. Journal articles are not confidential; however they are not published on the website due to Intellectual Property Rights.

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Substance name: Aqueous extract from the germinated seeds of sweet *Lupinus albus*

EC number: -

CAS number: -

Dossier submitter: The Netherlands

GENERAL COMMENTS

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---------|--------------|----------------------|----------------|
| 17.05.2022 | Germany | | MemberState | 1 |
| Comment received | | | | |
| The potential hazard of <i>Lupinus albus</i> aqueous extract to human health was assessed and discussed in the EU pesticide peer review process. We remain of the opinion that – as proposed by the DS – the available data do not require classification for the human health related hazard categories addressed in the present CLH report. | | | | |
| Dossier Submitter's Response | | | | |
| Thank you for agreeing that the available data do not require classification for the human health related hazard categories addressed in the present CLH report. | | | | |
| RAC's response | | | | |
| Noted. | | | | |

| Date | Country | Organisation | Type of Organisation | Comment number |
|--|-------------|--------------|----------------------|----------------|
| 18.05.2022 | Switzerland | FSVO | National Authority | 2 |
| Comment received | | | | |
| The term "BLAD" is used to describe the 210 kDa oligomer as well as the 20 kDa polypeptide. A more clear distinction would be preferable to avoid confusion. | | | | |
| Dossier Submitter's Response | | | | |
| β-conglutin is a storage protein in <i>Lupinus albus</i> seeds (actually, is the main storage protein in these seeds). It is cleaved during germination originating smaller polypeptides, that are further cleaved into peptides, originating in the end aminoacids. This is the natural catabolic process of storage proteins in seeds (the goal is to provide to the | | | | |

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| <p>aminoacids required for the initial stages of growth). BLAD is one polypeptide that is formed during the catabolism of β-conglutin. So, we cannot call β-conglutin to a specific fragment of β-conglutin's catabolism.</p> <p>The lead component of the Aqueous extract from the germinated seeds of sweet Lupinus albus is a 210 kDa hetero-oligomer called BLAD. It is composed of different polypeptides bound together, with a clear dominance of a 20 kDa polypeptide directly derived from the catabolism of the major storage protein in Lupinus albus seeds, β-conglutin. So, 'BLAD' should exclusively refer to the 210 kDa heteromer, whereas the '20 kDa polypeptide' presents the clearest way to refer to BLAD's dominant constituent.</p> |
| RAC's response |
| Noted. |

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

| Date | Country | Organisation | Type of Organisation | Comment number |
|--|-------------|--------------|----------------------|----------------|
| 18.05.2022 | Switzerland | FSVO | National Authority | 3 |
| Comment received | | | | |
| <p>p. 17: Concerning the position paper (R. Boavida Ferreira (2011)): The trigger dose derived for lupin is for the total amount of lupin. It does not specify the actual allergenic content of the total amount. Therefore it is not possible to compare the trigger dose for lupins with the residue amounts of the potential allergen BLAD.</p> <p>p17: Concerning the clinical study (Anonymous, 2013): The mentioned study contains uncertainties, especially concerning the quality of the sera analysed. The study therefore only indicates that BLAD is not a potential allergen, but does not confirm it.</p> | | | | |
| Dossier Submitter's Response | | | | |
| <p>The trigger doses mentioned in the EFSA scientific opinion were 50 mg and 1.6 g of lupin <u>proteins</u> and not the total amount of lupin, which could be implied from the CLH report and DAR. Considering the BLAD protein and total protein content in the active substance it is possible to compare the trigger dose for lupin protein with the residue amounts of the BLAD protein. Further DS notes that allergenicity is not a data requirement for pesticides nor a classification end point according to the CLP regulation, however correcting the residue amounts of the BLAD protein to total protein content would still result in values below the trigger dose.</p> <p>Thank you, noted. Although the clinical study might have some limitations, the DS considers that the results of the study gave some indications that no allergenic reaction was observed. Further DS notes that allergenicity is not a data requirement for pesticides nor a classification end point according to the CLP regulation.</p> | | | | |
| RAC's response | | | | |
| Noted. Food allergenicity issues are not considered for skin sensitization assessment. | | | | |

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

| Date | Country | Organisation | Type of Organisation | Comment number |
|---|---------|--------------|----------------------|----------------|
| 17.05.2022 | Germany | | MemberState | 4 |
| Comment received | | | | |
| We agree to the proposal that the substance should not be classified as hazardous to the aquatic environment. | | | | |
| Dossier Submitter's Response | | | | |

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| Thank you for agreeing to the classification proposal for the aquatic environment. |
| RAC's response |
| Thank you for your comment. Support for no classification of the substance as hazardous to the aquatic environment is noted by RAC. RAC agrees. |