

Committee for Risk Assessment
RAC

Annex 2

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

**Foramsulfuron (ISO); 2-{\[(4,6-dimethoxypyrimidin-
2-yl)carbamoyl]sulfamoyl}-4-formamido-N,N-
dimethylbenzamide;
1-(4,6-dimethoxypyrimidin-2-yl)-3-(2-
dimethylcarbamoyl-5-formamidophenylsulfonyl)urea**

EC Number: -
CAS Number: 173159-57-4

CLH-O-0000006964-62-01/F

Adopted
18 March 2021

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-
 {[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL}-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE;
 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA**

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.

ECHA accepts no responsibility or liability for the content of this table.

**Substance name: foramsulfuron (ISO); 2-
 {[(4,6-dimethoxypyrimidin-2-yl)carbamoyl]sulfamoyl}-4-formamido-N,N-dimethylbenzamide; 1-(4,6-
 dimethoxypyrimidin-2-yl)-3-(2-dimethylcarbamoyl-5-
 formamidophenylsulfonyl)urea**

EC number: -

CAS number: 173159-57-4

Dossier submitter: Finland

GENERAL COMMENTS

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	1
Comment received				
FR: No comment.				
Dossier Submitter's Response				
Noted.				
RAC's response				
Noted.				

CARCINOGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	2
Comment received				
Bayer disagrees with the proposal of a classification as Carcinogen category 2 (H351) and comments on this proposal for classification with new arguments and new data which are submitted as attachments				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-[[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL]-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE; 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z
Dossier Submitter’s Response
The dossier submitter considers that classification with Carc. 2; H351 is appropriate due to increase in the incidences of malignant astrocytomas, which is outside the historical control data. Further increases in lymphomas and thyroid neoplasms were seen in the rat carcinogenicity study, although the increase was not big. Although the possibility of a chance cannot be fully ruled out, positive association is interpreted to be in line with the CLP regulation: “A positive association has been observed between exposure to the substance and neoplasms for which a causal interpretation is considered to be credible, but chance, bias or confounding could not be ruled out with reasonable confidence.”
RAC’s response
Thank you for your comment. RAC agrees that the increase in the incidence of malignant astrocytoma is of concern and provides limited evidence for classification. The increase in lymphomas and thyroid tumours also support a classification, but RAC acknowledges that there are uncertainties on the toxicological significance of these lesions.

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	3
Comment received				
Bayer disagrees with the proposal of a classification as Carcinogen category 2 (H351) and comments on this proposal for classification with new arguments and new data which are submitted as attachments.				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter’s Response				
Please see response to comment no. 2.				
RAC’s response				
Please see response to comment no. 2.				

Date	Country	Organisation	Type of Organisation	Comment number
15.05.2020	Germany		MemberState	4
Comment received				
The proposal to classify foramsulfuron as Carc. 2; H351 is supported. Our main argument for the classification in this category is the slightly increased incidence of astrocytomas in rats of both sexes, which is outside the historical control data. In addition, the although small number of tumours in the thyroid gland of rats justifies classification. Although the tumor incidence is not clearly dose-dependent a correlation between the occurrence of tumors in rats of both sexes and the oral administration of foramsulfuron is very likely. For this reason, a classification of foramsulfuron as Carc. 2; H351 is considered to be sufficiently justified.				
Additionally we would like to point out that:				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-[[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL]-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE; 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA

<p>1) It is not clear in Table 58 (p54) that it is spermatozoa that are reduced or absent. Perhaps the word "spermatozoa" was accidentally omitted from this table. Given that this is a critical point, please confirm that this is the case. From Vol 3 of the dRAR (p75 Jan 2016): Very severe reduction in the number of spermatozoa was observed at 6000 and 20000 ppm. This effect did not differ statistically significantly from the control but was outside the historical control range. There was a progression in the severity of the effect at the levels of 6 000 and 20 000 ppm. The effect of severe reduction or severe and very severe reduction together were not increased in the incidence.</p> <p>2) It would be useful, if, regarding the concluding sentences following Table 58 (p54), a clear statement could be made as to whether each of the non-neoplastic effects detailed were considered treatment-related or not. For example, from Vol 3 of the RAR (p75 Jan 2016): Increased incidences of endometrial stromal polyps were not considered to be clearly treatment-related in the absence of dose-response relationship.</p> <p>3) The lack of "progression of lesions to malignancy" in Table 72 (p61) should also be detailed for the astrocytomas and lymphomas. It should also be mentioned that no non-neoplastic pathological changes such as hyperplasia were reported.</p>
Dossier Submitter's Response
Thank you for your support. Regarding point 1, thank you for pointing out this omission. Concerning points 2 and 3 we agree that this additional information would be useful.
RAC's response
Thank you for your comment. The absence of preneoplastic lesions are discussed in the RAC opinion. RAC considers that they may not be seen with this type of tumours and that the absence of preneoplastic lesions are not a reason for no classification.

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	5
Comment received				
FR: This section was not reviewed.				
Dossier Submitter's Response				
Noted.				
RAC's response				
Noted.				

MUTAGENICITY

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	6
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-
 {[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL}-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE;
 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA**

ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z
Dossier Submitter’s Response
Thank you for your comments.
RAC’s response
Thank you for your comments.

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	7
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter’s Response				
Thank you for your comments.				
RAC’s response				
Thank you for your comments.				

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	8
Comment received				
FR: This section was not reviewed.				
Dossier Submitter’s Response				
Noted.				
RAC’s response				
Noted.				

TOXICITY TO REPRODUCTION

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	9
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter’s Response				
Thank you for your comments.				
RAC’s response				
Thank you for your comments.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-[[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL]-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE; 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	10
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	11
Comment received				
FR: This section was not reviewed.				
Dossier Submitter's Response				
Noted.				
RAC's response				
Noted.				

RESPIRATORY SENSITISATION

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	12
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	13
Comment received				
Bayer agrees with the rapporteur				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-[[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL]-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE; 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z
Dossier Submitter’s Response
Thank you for your comment.
RAC’s response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	14
Comment received				
FR: This section was not reviewed.				
Dossier Submitter’s Response				
Noted.				
RAC’s response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Acute Toxicity

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	15
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter’s Response				
Thank you for your comment.				
RAC’s response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	16
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-
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 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA**

Dossier Submitter's Response
Thank you for your comment.
RAC's response
Noted.

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	17
Comment received				
FR: This section was not reviewed.				
Dossier Submitter's Response				
Noted.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Skin Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	18
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	19
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your support				
RAC's response				
Noted.				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-
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 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA**

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	20
Comment received				
FR: This section was not reviewed.				
Dossier Submitter's Response				
Noted.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Eye Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	21
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	22
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	23
Comment received				
FR: This section was not reviewed.				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-
 {[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL}-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE;
 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA**

Dossier Submitter's Response
Noted.
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Skin Sensitisation Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	24
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	25
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comment.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	26
Comment received				
FR: This section was not reviewed.				
Dossier Submitter's Response				
Noted.				
RAC's response				
Noted.				

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-
 {[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL}-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE;
 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA**

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Single Exposure

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	27
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	28
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	29
Comment received				
FR: This section was not reviewed.				
Dossier Submitter's Response				
Noted.				
RAC's response				
Noted.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-[[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL]-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE; 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA

OTHER HAZARDS AND ENDPOINTS – Specific Target Organ Toxicity Repeated Exposure

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	30
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	31
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
15.05.2020	Germany		MemberState	32
Comment received				
A NOAEL of 5000 ppm for female rats (KCA5.3.1 /01) is given in Table 88 (p79) and in section 10.12.1 of this CLH Report. This is inconsistent with the NOAEL given in the conclusion under the heading "28 days, rat (OECD TG 407)" on p82. Presumably, the NOAEL is in fact 1000 ppm for female rats based on the decreased body weight gain (< 90 % of control) at 20000 and 5000 ppm. This would also be in agreement with the final RAR from January 2016 (Section 2.6.3 of Vol 1, p 31 and B.6.3.1.1 of Vol 3, p 40) and the conclusion of the EFSA Pesticides Peer Review Meeting 134. Please confirm.				
Dossier Submitter's Response				
Thank you for pointing out this inconsistency. The correct NOAEL is indeed 1000 ppm.				
RAC's response				
Thank you for your comment. Noted.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-[[(4,6-DIMETHOXPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL]-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE; 1-(4,6-DIMETHOXPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	33
Comment received				
FR: This section was not reviewed.				
Dossier Submitter's Response				
Noted.				
RAC's response				
Noted.				

OTHER HAZARDS AND ENDPOINTS – Aspiration Hazard

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	34
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	35
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Noted.				

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	36
Comment received				
FR: This section was not reviewed.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-[[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL]-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE; 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA

Dossier Submitter's Response
Noted.
RAC's response
Noted.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Aquatic Environment

Date	Country	Organisation	Type of Organisation	Comment number
19.05.2020	Belgium		MemberState	37
Comment received				
BE CA supports the proposed environmental classification with Aquatic chronic 1, H400 (M=1000) and Aquatic Chronic 1, H410 (M=100).				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for your comment. The support of DS proposal for classification of the substance is noted by RAC. RAC agrees.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	38
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your support.				
RAC's response				
Thank you for your comment. The support of DS proposal for classification of the substance is noted by RAC. RAC agrees.				

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	39
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your support.				

ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-[[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL]-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE; 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA

RAC's response
Thank you for your comment. The support of DS proposal for classification of the substance is noted by RAC. RAC agrees.

Date	Country	Organisation	Type of Organisation	Comment number
15.05.2020	Germany		MemberState	40

Comment received
We agree with the proposal of classification for environmental hazards as Aquatic Acute 1 (H400) with an M-factor of 1000 and Aquatic Chronic 1 (H410) with an M-factor of 100.

Dossier Submitter's Response
Thank you for your support.

RAC's response
Thank you for your comment. The support of DS proposal for classification of the substance is noted by RAC. RAC agrees.

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	41

Comment received

FR: FR agrees with the proposition for Foramsulfuron to be classified as acute category 1 and chronic category 1 and with the associated M-factors (1000 for acute and 100 for chronic). For acute classification, FR also agrees with not using the value of the metabolite.

Dossier Submitter's Response
Thank you for your support.

RAC's response
Thank you for your comment. The support of DS proposal for classification of the substance is noted by RAC. RAC agrees.

RAC also agree with not using the toxicity data for degradation products for classification of the substance.

OTHER HAZARDS AND ENDPOINTS – Hazardous to the Ozone Layer

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	42

Comment received
Bayer agrees with the rapporteur

ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-
 {[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL}-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE;
 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA**

Dossier Submitter's Response
Thank you for your comments.
RAC's response
Thank you for your comment. The support of DS proposal for classification of the substance is noted by RAC. RAC agrees.

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	43

Comment received
Bayer agrees with the rapporteur
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z
Dossier Submitter's Response
Thank you for your comments.
RAC's response
Thank you for your comment. The support of DS proposal for classification of the substance is noted by RAC. RAC agrees.

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	44

Comment received
FR: No comment.
Dossier Submitter's Response
Noted.
RAC's response
Thank you for your comment. Noted by RAC.

OTHER HAZARDS AND ENDPOINTS – Physical Hazards

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	45

Comment received
Bayer agrees with the rapporteur
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z
Dossier Submitter's Response
Thank you for your comments.
RAC's response
Thank you for your comment. Noted by RAC.

**ANNEX 2 - COMMENTS AND RESPONSE TO COMMENTS ON CLH PROPOSAL ON FORAMSULFURON (ISO); 2-
 {[(4,6-DIMETHOXYPYRIMIDIN-2-YL)CARBAMOYL]SULFAMOYL}-4-FORMAMIDO-N,N-DIMETHYLBENZAMIDE;
 1-(4,6-DIMETHOXYPYRIMIDIN-2-YL)-3-(2-DIMETHYLCARBAMOYL-5-FORMAMIDOPHENYLSULFONYL)UREA**

Date	Country	Organisation	Type of Organisation	Comment number
18.05.2020	Germany	Bayer AG	Company-Manufacturer	46
Comment received				
Bayer agrees with the rapporteur				
ECHA note – An attachment was submitted with the comment above. Refer to public attachment Foramsulfuron Comments Bayer_non-confidential.7z				
ECHA note – An attachment was submitted with the comment above. Refer to confidential attachment Foramsulfuron Comments Bayer_confidential.7z				
Dossier Submitter's Response				
Thank you for your comments.				
RAC's response				
Thank you for your comment. Noted by RAC.				

Date	Country	Organisation	Type of Organisation	Comment number
20.05.2020	France		MemberState	47
Comment received				
FR: No comment.				
Dossier Submitter's Response				
Noted.				
RAC's response				
Thank you for your comment. Noted by RAC.				

PUBLIC ATTACHMENTS

1. Foramsulfuron Comments Bayer_non-confidential.7z [Please refer to comment No. 2, 6, 9, 12, 15, 18, 21, 24, 27, 30, 34, 38, 42, 45]
2. Foramsulfuron Comments Bayer_non-confidential.7z [Please refer to comment No. 3, 7, 10, 13, 16, 19, 22, 25, 28, 31, 35, 39, 43, 46]

CONFIDENTIAL ATTACHMENTS

1. Foramsulfuron Comments Bayer_confidential.7z [Please refer to comment No. 2, 6, 9, 12, 15, 18, 21, 24, 27, 30, 34, 38, 42, 45]
2. Foramsulfuron Comments Bayer_confidential.7z [Please refer to comment No. 3, 7, 10, 13, 16, 19, 22, 25, 28, 31, 35, 39, 43, 46]