# Draft Assessment Report

## Evaluation of Active Substances

Plant Protection Products

Prepared according to **Regulation (EC) 1107/2009**
as it applies in Great Britain (GB PPP)

# Cinmethylin (BAS 684 H)

## Volume 3 – B.3 (PPP) – BAS 684 03 H

## Data on Application & Efficacy

Great Britain

November 2020

# Version History

| When | What |
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| November 2020 | Initial DAR |
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# Table of contents

# B.3. DATA ON APPLICATION AND EFFICACY

'BAS 684 03 H' is a novel pre- and post-emergence, residual herbicide containing 750 g/l cinmethylin as an emulsifiable concentrate (EC). This document summarises information related to the efficacy of cinmethylin with the representative formulation BAS 684 03 H.

As this is the first submission for approval of the active substance cimethylin, a concise summary of efficacy will be included. Detailed efficacy data will be provided in the subsequent product authorisation process when full biological assessment dossiers will be submitted and considered.

## B.3.1. FIELD OF USE ENVISAGED

'BAS 684 03 H' contains 750 g/l cinmethylin and is a pre- and post-emergence, residual herbicide for use on a range of broad leaved and grass weeds in Winter Wheat (TRZAW) and Winter Barley (HORVW). Further uses in different crops will be sought in future product authorisations.

## B.3.2. EFFECTS ON HARMFUL ORGANISMS

Cinmethylin inhibits a unique and novel target enzyme in fatty acid (FA) biosynthesis for which no HRAC-classification have been assigned yet. FAs and FA-derived complex lipids are essential in living organisms. They are important components of cellular membranes and signalling molecules, and they serve as a major energy reserve in storage tissues. Therefore, depleting plants of FAs has dramatic physiological impact. Cell membranes are irreversibly disrupted, which has a detrimental effect on emerging plant tissue. In pre-emergence treatments, seedlings quickly become non-viable when FA storage is exhausted. In addition, transport and receptor functions, indispensable for photosynthetic activity can no longer be fulfilled. This results in a starvation of the plant, since absorbed sunlight can no longer be transformed into energy to sustain plant viability.

In plant cells, early FA biosynthesis is carried out in the plastids. Intermediate FAs with chain lengths of 16 or 18 carbon atoms bind to an acyl carrier protein (ACP) prior to export into the cytosol and further downstream processing. Before they can be exported, however, their chain elongation process must be terminated. This termination is carried out by an enzyme family called fatty acid thioesterase (FAT), which releases the FA from its acyl carrier protein. Cinmethylin uniquely targets the FAT enzyme family located in the plastid to prevent the termination process. Other known chemical classes (DIMs/FOPs) also inhibit fatty acid biosynthesis in the plastids. However, the enzyme target is acetyl-CoA carboxylase (ACCase), which is the first step in fatty acid biosynthesis and a distinctly different target site to FAT. In contrast, VLCFA inhibitors, which also affect lipid biosynthesis, exert their inhibition in the endoplasmic reticulum, which is a distinctly different compartment in the plant cell.

## B.3.3. DETAILS OF INTENDED USE

| Crop and/or situation (a) | Member State | Product Name | F G I (b) | Pests or group of pests controlled (c) | Formulation | | Application | | | | Application rate per treatment | | | PHI (days) (l) | Remarks (m) |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | Type (d-f) | Rate L/ha | Method kind (f-h) | Growth stage and season (j) | Number min max (k) | Interval between applications (min) | Kg a.i./ha min max (g/hl) | Water l/ha min max | Lk a.i./ha min max (*) (g/ha) | | |
| winter wheat (TRZAW), winter barley (HORVW) | **UK** | BAS 684 03 H | F | blackgrass (ALOMY), ryegrass (LOLSS), | - | 0.666 | SP | pre-emergence (BBCH 00-08) | a) 1<br>b) 1 | N/A | a) 0.500<br>b) 0.500 | 100 -400 | - | - | Representative use |
| winter wheat (TRZAW), winter barley (HORVW) | **UK** | BAS 684 03 H | F | blackgrass (ALOMY), ryegrass (LOLSS), | - | 0.666 | SP | post-emergence (BBCH 09-29 | a) 1<br>b) 1 | N/A | a) 0.500<br>b) 0.500 | 100 – 400 | - | - | Representative use |
| winter wheat (TRZAW), winter barley (HORVW) | **UK** | BAS 684 03 H | F | annual meadowgrass (POAAN) and annual dicots | - | 0.666 | SP | pre-emergence (BBCH 00-08) | a) 1<br>b) 1 | N/A | a) 0.250<br>b) 0.250 | 100 – 400 | - | - | Representative use |
| winter wheat (TRZAW), winter barley (HORVW) | **UK** | BAS 684 03 H | F | annual meadowgrass (POAAN) and annual dicots | - | 0.666 | SP | post-emergence (BBCH 09-29) | a) 1<br>b) 1 | N/A | a) 0.250<br>b) 0.250 | 100 - 400 | - | - | Representative use |

* For uses where the column „Remarks“ in marked in grey further consideration is necessary. Uses should be crossed out when the notifier no longer supports this use(s).

(a) For crops, the EU and Codex classification (both) should be taken into account ; where relevant, the use situation should be described (e.g. fumigation of a structure)

(b) Outdoor or field use (F), greenhouse application (G) or indoor application (I)

(c) *e.g.* biting and suckling insects, soil born insects, foliar fungi, weeds

(d) *e.g.* wettable powder (WP), emulsifiable concentrate (EC), granule (GR)

(e) GCPF Codes – GIFAP Technical Monograph N° 2, 1989

(f) All abbreviations used must be explained

(g) Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench

(h) Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plant – type of equipment used must be indicated

(i) g/kg or g/L. Normally the rate should be given for the active substance (according to ISO) and not for the variant in order to compare the rate for same active substances used in different variants (e.g. fluoroxypyr). **In certain cases, where only one variant synthesised, it is more appropriate to give the rate for the variant (e.g. benthiavalicarb-isopropyl).**

(j) Growth stage at last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application

(k) Indicate the minimum and maximum number of application possible under practical conditions of use

(l) The values should be given in g or kg whatever gives the more manageable number (e.g. 200 kg/ha instead of 200 000 g/ha or 12.5 g/ha instead of 0.0125 kg/ha

(m) PHI - minimum pre-harvest interval

## B.3.4. APPLICATION RATE AND CONCENTRATION OF THE ACTIVE SUBSTANCE

BAS 684 03 H is formulated as an emulsifiable concentrate (EC) and contains 750 g/L cinmethylin. Please see the table presented above within the section titled "B.3.3 Details of intended use" according to Regulation 1107/2009, Article 4 (3).

## B.3.5. METHOD OF APPLICATION

Cinmethylin containing products will be applied using hydraulic vehicle mounted spray equipment. The standard water rate for use in winter wheat is between 150 and 300 L/ha providing the equipment is in good working order and has been calibrated to manufacturer instructions.

The proposed application timings are at growth stages from BBCH 00 to BBCH 29.

## B.3.6. NUMBER AND TIMING OF APPLICATIONS AND DURATION OF PROTECTION

BAS 684 03 H is a residual herbicide with a single application proposed for use on winter wheat and winter barley up to the end of tillering (BBCH 29). A single application is also proposed for Oilseed rape as a representative use. However, oilseed rape has not been requested as an intended use in Great Britain (GB) under this application. Therefore, to add this use in the future it will need to be fully assessed in detail under subsequent GB product evaluations. Weeds may be treated from pre-emergence up to the development of first leaves (BBCH 11/12). There are no proposed claims relating to the duration of protection so it is concluded that the duration of protection is in line with the assessment timings tested as part of efficacy trials.

| | |
|---|---|
| Maximum number of applications and their timings: | 1 |
| Growth stages of crops or plants to be protected:<br>• Winter wheat and winter barley<br>• Winter oilseed rape* | <br>BBCH 00-29<br>BBCH 00-18 |
| Development stages of the harmful organism concerned: | BBCH 00-13 |
| Duration of protection afforded by each application: | during the most critical early development period of cereals and oilseed rape |
| Duration of protection afforded by the maximum number of applications: | --- |

NB. * = Currently not a proposed use in GB

## B.3.7. NECESSARY WAITING PERIODS OR OTHER PRECAUTIONS TO AVOID PHYTOTOXIC EFFECTS ON SUCCEEDING CROPS

A full succeeding crops assessment has been conducted in the associated product evaluation. The overall summary of this assessment has been copied below:

*The applicant did not provide any initial consideration of the biological activity or the properties of the active substance. As such, reference has been made to studies in the ecotoxicology sections.*

*The applicant has, however, summarised field data to address the risk to crops grown after normal rotation (rotational trials) and those grown after crop failure (replacement trials). The UK considers that the applicant has provided sufficient evidence to support the label wording regarding following crops after a normal harvest. However, based on the trials alone the applicant has not provided sufficient evidence to support the label wording regarding following crops in the event of crop failure. Nonetheless, after taking into account the biological activity of the active substance and crop sensitivity (as extracted from the Ecotoxicology assessment), the sowing of spring wheat and barley is acceptable in the event of crop failure.*

The proposed UK label wording is as follows:

***'4.1 Following crops after normal harvest***

*There are no restrictions on following crops after the normal harvest of crops treated with BAS 684 03H alone.*

***4.2 In the event of crop failure***
*In the event of crop failure for any reason, plough to at least 15cm. The following crops may then be sown: Spring barley and Spring wheat'*

This was sufficient to support a this data requirement in the UK.

## B.3.8. PROPOSED INSTRUCTIONS FOR USE

BAS 684 03 H is a soil residual herbicide for use against winter annual grasses and some broadleaved weeds in winter wheat, winter barley and oilseed rape.

Time of application

For applications on winter wheat and winter barley, BAS 684 03 H is applied from pre-emergence up to the end of tillering of the crop (BBCH 00-29).

For applications on winter oilseed rape, BAS 684 03 H is applied pre-emergence up to the eight-leaves unfolded stage of the crop (BBCH 00-18).

With regard to the target weeds, treatment up to two true leaves (BBCH 00-12) is requested.

Please refer to Document D1 for full use instructions.

## B.3.9. EFFECTIVENESS

In the UK, the product evaluation of BAS 684 03 H has been conducted in parallel with the active substance assessment. For efficacy, a more detailed assessment of effectiveness is within the product evaluation. However, HSE has summarised the conclusions of this assessment below.

The representative formulation BAS 684 03 H has been tested in development trials between 2015-201. The results of these trials show, acceptable efficacy against the target weeds. Phytotoxicity assessments were also conducted in the efficacy trials. The majority of effectiveness trials were conducted in winter cereals; however, 17 further trials were conducted in winter oilseed rape.

To evaluate the efficacy of BAS 684 03 H in the Maritime EPPO climatic zone, 154 field trials on winter wheat (TRZAW), 17 field trials on winter barley (HORVW), 6 field trials on winter triticale (TTLWI), 3 trials on winter rye (SECCW) and 17 trials in winter oilseed rape (BRSNW) were conducted in the period 2015-2017. These trials were undertaken by BASF country organisations and contract research organisations located in northern France (FR), Germany (DE), Austria (AT), Denmark (DK) and the United Kingdom (UK).

All trials have been conducted according to EPPO standards by GEP accredited organisations, either by field development staff of BASF country subsidiaries or by contract research organisations.
Trials were designed, conducted and reported in accordance with general EPPO standards PP1/225(2), PP1/135(4), PP1/152(4), PP1/278(1), and PP1/181(4) regarding design, analysis and reporting.

BAS 684 03 H was applied once either at 0.666 L/ha (corresponding to 500 g cinmethylin/ha) or 0.333 L/ha (corresponding to 250 g cinmethylin/ha) for the control of the main target weeds selected as targets for the representative uses. The proposed dose rate depends on the weed species targeted. The higher rate corresponds to the major grassweeds: blackgrass (ALOMY), perennial ryegrass (LOLPE) and Italian ryegrass (LOLMU). The lower dose rate is proposed for the control of annual meadowgrass (POAAN), loose silky bent (APESV) and common poppy (PAPRH). Efficacy was tested under a range of environmental conditions.

The effectiveness of BAS 684 03 H applied at both dose rates was comparable to or higher than that of the commercial standard reference products used. Overall the applicant provided sufficient data to demonstrate acceptable effectiveness at the proposed GAP against a range of broadleaved weeds and grass weeds.

The full UK assessment of the effectiveness trials will be included in the corresponding product assessment ; however, it has been copied below for reference.

EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY

| | |
|---|---|
| **Name of authority** | **Chemicals Regulation Division (CRD), HSE** |
| **Reviewer's comments** | **Effectiveness**<br><br>Under this application the proposed use of 'BAS 684 03 H' is a herbicide for use against grass and broadleaved weeds in winter varieties of wheat and barley. The proposed dose varies dependent on the weed species targeted. The weed control claims relate to applications made pre- and post-emergence of both the crop and weeds.<br><br>The applicant has submitted data from 197 efficacy field trials which were conducted between 2015-17. All efficacy trials were carried out within the Maritime EPPO climatic zone, with the majority in the proposed crops Winter wheat (154) and Winter barley (17). However, the applicant has also included trials in the minor UK cereals Winter Triticale (6) and Rye (3). In addition to this 17 efficacy trials were conducted in Winter Oilseed Rape. For pre-emergence application, it is possible to extrapolate between crops since there is no crop competition, so long as the timing of application is similar. However, HSE will consider whether for post-emergence application the crop species used has an impact on the product efficacy.<br><br>All the efficacy trials provided under this submission were conducted using the two preliminary formulations ('BAS 684 AC H' and 'BAS 684 02 H'). Bridging data were provided between these formulations and the final formulation. Overall, the formulations were comparable allowing extrapolation of the data. However, due to lack of data this is not acceptable for post-emergence use on black-grass (ALOMY). See the evaluation of the bridging data for further information.<br><br>According to the EPPO Standard PP1/226, a major target in a major crop must be supported by 10 trials (range 6-15 trials required depending on factors such as range of environmental and climatic conditions, levels of target pressure and consistency of results). A minor use/target must be supported by 3 trials (range 2-6 trials). This is similar to the UK National guidance where 10 acceptable trials results are required to support a claim against a major weed and 3 against a minor weed.<br><br>The applicant concludes the following in relation to weed importance in winter cereal crops:<br><br>**HSE Table 8 – Weed species of concern in the UK (drawn from applicant's Table 3.2-5)** |

| **Pest status** | |
|---|---|
| **Major** | **Minor** |
| Black-grass (ALOMY)<br>Annual Meadow Grass (POAAN)<br>Ryegrasses (LOLMU/LOLPE) | Loose Silky Bent (APESV)<br>Poppy, Common (PAPRH) |

As this is a UK only assessment, the data have been assessed in relation to the applicant's proposed claims of control using the UK weed susceptibility ratings as described under current UK guidance ('Efficacy Assessments: UK Product Labelling and National Issues/Addenda).

**HSE Table 9 – Levels of weed control expected for effectiveness claims**

| Label claim appropriate | Level of effectiveness |
|---|---|
| Susceptible (S) | Consistent control of 85% and above (see below †) |
| Moderately susceptible (MS) | More variable control, mean 75-85%, but with results often above 85% |
| Moderately resistant (MR) | Variable control, Mean 60-75%, but some results above this level. |
| Resistant (R) | Poor control below the levels given above |

† To ensure worthwhile levels of control of certain important weeds in field crops, all these categories are raised with the susceptible rating being as follows: pernicious grass weeds where seed return must be prevented, e.g. black-grass and wild-oats, 95% and above, cleavers 90% and above.

In order to provide a detailed evaluation, HSE has considered each weed claimed on the proposed UK label separately. The evaluation of the data is presented below.

**Black-grass (ALOMY)**

The applicant has requested a UK claim of 'Moderately susceptible' against black-grass (ALOMY) up to the first leaf stage. To support this claim a total of 93 trials have been conducted to demonstrate effectiveness against ALOMY. Of these 93 trials, 69 were conducted pre-emergence of the weed with the remaining 24 conducted after weed emergence. Due to a lack of suitable bridging data a post-emergence claim against ALOMY is not recommended for authorisation. Therefore, post-emergence data have not been considered.

In accordance with UK guidance to ensure worthwhile levels of control of certain important weeds in field crops (e.g. Black-grass), all the weed control categories are raised. The associated susceptible ratings are as follows: S = 95% and above, MS = 85-95% (but with results often above 95%), MR = 70-85% (but some results above this level) and R = Poor control below 70%.

<u>ALOMY – Pre-emergence</u>

69 pre-emergence trials were conducted across three different Member States of the Maritime EPPO zone: UK (15), Germany (26) and France (28). In a number of these trials both a heading assessment and an assessment of plant numbers has been conducted. HSE considers, in line with EPPO PP 1/93 (3), that heading assessments provide a better measure of the effectiveness of the product. Therefore, where available these assessments will be considered. Plant total values will also be evaluated, especially in trials where heading assessments were not conducted. Due to the importance of ALOMY in the UK, the UK data will be considered separately, with the trials provided from other Member States within the Maritime EPPO climatic zone acting as supporting data.

It is noted that the reference product used in the majority of the ALOMY trials is Herold/Fosburi. The applicant has stated the following in the BAD:

'*Herold is approved in Germany for full control of blackgrass. Application in approved post-em of the crop. Fosburi is approved in France. For the control of blackgrass efficacy is rated at 85-94% on label. Herold is approved in the UK, but with a different use pattern, i.e. the maximum individual approved dose is 0.3 L/ha but two applications can be made. No label claim is made for Blackgrass.*'

Although there is no claim against ALOMY on the UK authorisation of 'Herold', considering the

higher dose used within these trials (0.6 l/ha) and the extant authorisations in both DE and FR HSE considers Herold/Fosburi to be an acceptable reference product in the conducted trials.

*UK trials:*

15 trials were conducted in the UK over 3 years (2015-17). Each trial assessed the effect of the proposed product on the whole plant. In addition to this, in 13 of these trials valid heading assessments were carried out. A summary of these trials has been presented below for reference.

**HSE Table 10 – Summary of effectiveness of 'BAS 684 03 H' against ALOMY - UK (15 trials)**

| Country | Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.667 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|---|
| UK | 15 | Pre-em | Plant total | Percent coverage | 40.6 (9.3-103.7) | 90.9 (80-100) | 83.2 (61.7-100) |
| | | | | Number per sq. m | 38.7 (9.3-103.7) | | |
| | 13 | Pre-em | Ear | Number per sq. m | 144 (27.7-426.7) | 86.7 (66.9-97.1) | 77.5 (47.3-100) |

On average, the proposed product has provided a level of control above 85% when considering the plant total and heading assessments. However, it is noted that in a number of the individual trials the control level provided is reduced. On considering plant total assessments alone, 12 of the 15 trials provide greater than 85% control against ALOMY. This is in line with a UK claim of 'Moderate susceptible'. The three trials where control was below 85% have been copied below for discussion.

**HSE Table 11 – Effectiveness of 'BAS 684 03 H' against ALOMY- individual trials - UK (3 trials)**

| Trial ID | Date of treatment/ Growth stage crop (BBCH)/ Growth stage target (BBCH) water volume | Eval Date | Timing of assessment DAFT | Eval. Method | Plant part | Untreated | BAS 684 H 0.667 L/HA 500 g.ai.ha | Standard |
|---|---|---|---|---|---|---|---|---|
| DEV-H-2016-UK-501-B-01.0-UK-UK3-K01 | 02-OCT-2015 | 28-OCT-2015 | 26 | P%UCNT | PLANT,TOTAL | 4.7 | 86.7 | 83.3 |
| | 00 - 07 - 05 | 15-DEC-2015 | 74 | P%UCNT | PLANT,TOTAL | 7.7 | 66.7 | 66.7 |
| | 00-09 - 03 - - | 01-APR-2016 | 182 | P%UCNT | PLANT,TOTAL | 18.3 | 73.3 | 69.3 |
| | 200 L/HA | 09-JUN-2016 | 251 | P%UCNT | PLANT,TOTAL | 22.3 | **83.3** | **68.3** |
| | | 09-JUN-2016 | 251 | ZCOUNT | EAR | 100.7 | **71.5** | **81.1** |
| | | 09-JUN-2016 | 251 | ZCOUNT | EAR | 100.7 | 28.7 | 19.0 |
| DEV-H-2016-UK-508-A-01.0-UK-UK3-I05 | 08-OCT-2015 | 27-OCT-2015 | 19 | P%UCNT | PLANT,TOTAL | 38.3 | | |
| | 05 - 07 - 05 | 10-NOV-2015 | 33 | P%UCNT | PLANT,TOTAL | 66.0 | 70.0 | 66.7 |
| | 03-05 - 03 - 0 - | 09-DEC-2015 | 62 | P%UCNT | PLANT,TOTAL | 63.0 | 85.0 | 88.3 |
| | 200 L/HA | 03-MAR-2016 | 147 | P%UCNT | PLANT,TOTAL | 84.0 | **83.3** | **86.7** |
| | | 27-MAY-2016 | 232 | P%UCNT | EAR | 480.0 | 63.3 | 80.0 |
| | | 08-JUN-2016 | 244 | P%UCNT | EAR | **552.7** | **21.5** | **20.3** |
| DEV-H-2016-UK-530-A-01.0-UK-UK3-Z04 | 20-OCT-2015 | 19-NOV-2015 | 30 | P%UCNT | PLANT,TOTAL | 13.3 | 88.3 | 86.7 |
| | 00 - 07 - 00 | 08-DEC-2015 | 49 | P%UCNT | PLANT,TOTAL | 12.0 | 88.3 | 86.7 |
| | 00-00 - 00 - 0 - | 19-JAN-2016 | 91 | P%UCNT | PLANT,TOTAL | 32.3 | 80.0 | 80.0 |
| | 200 L/HA | 01-APR-2016 | 164 | P%UCNT | PLANT,TOTAL | 11.7 | **80.0** | **78.3** |
| | | 02-JUN-2016 | 226 | P%UCNT | PLANT,TOTAL | 56.7 | 78.3 | 70.0 |
| | | 03-JUN-2016 | 227 | P%UCNT | EAR | 136.3 | **88.3** | **71.4** |
| | | 03-JUN-2016 | 227 | ZCOUNT | EAR | 136.3 | 16.0 | 39.0 |

In each of these trials the proposed product demonstrates comparable or higher levels of effectiveness to that of the reference product used. Further to this at least 80% control is observed in each of these trials.

Effectiveness, equivalent to a claim of MS, is also observed in 9 of the 13 heading assessments. In the 4 remaining trials the percentage control provided by the proposed product was less than 85%. These trials have been presented below.

**HSE Table 12 – Effectiveness of 'BAS 684 03 H' against ALOMY – individual trials - UK (4 trials)**

| Trial ID | Date of treatment/ Growth stage crop (BBCH)/ Growth stage target (BBCH)/ water volume | Eval Date | Timing of assessment DAFT | Eval. Method | Plant part | Untreated | BAS 684 H 0.667 L/HA 500 g.ai.ha | Standard |
|---|---|---|---|---|---|---|---|---|
| DEV-H-2015-UK-503-A-02.0-UK-UK3-I02 | 15-OCT-2014 | 05-NOV-2014 | 21 | P%UCNT | PLANT,TOTAL | 25.3 | 100.0 | 96.7 |
| | 05 - 07 - 07 | 08-DEC-2014 | 54 | P%UCNT | PLANT,TOTAL | 27.0 | 100.0 | 100.0 |
| | 01-07 - 05 - 0 - | 10-APR-2015 | 177 | P%UCNT | PLANT,TOTAL | 30.0 | 86.7 | 75.0 |
| | 200 L/HA | 01-JUN-2015 | 229 | P%UCNT | PLANT,TOTAL | 35.0 | **90.7** | **83.3** |
| | | 01-JUN-2015 | 229 | P%UCNT | EAR | 260.0 | **66.9** | **67.1** |
| DEV-H-2016-UK-501-B-01.0-UK-UK3-K01 | 02-OCT-2015 | 28-OCT-2015 | 26 | P%UCNT | PLANT,TOTAL | 4.7 | 86.7 | 83.3 |
| | 00 - 07 - 05 | 15-DEC-2015 | 74 | P%UCNT | PLANT,TOTAL | 7.7 | 66.7 | 66.7 |
| | 00-09 - 03 - - | 01-APR-2016 | 182 | P%UCNT | PLANT,TOTAL | 18.3 | 73.3 | 69.3 |
| | 200 L/HA | 09-JUN-2016 | 251 | P%UCNT | PLANT,TOTAL | 22.3 | **83.3** | **68.3** |
| | | 09-JUN-2016 | 251 | ZCOUNT | EAR | 100.7 | **71.5** | **81.1** |
| | | 09-JUN-2016 | 251 | ZCOUNT | EAR | 100.7 | 28.7 | 19.0 |
| DEV-H-2017-UK-521-A-01.0-UK-UK4-R08 | 28-OCT-2016 | 05-DEC-2016 | 38 | P%UCNT | PLANT,TOTAL | 8.3 | 86.7 | 89.0 |
| | 10 - 12 - 11 | 07-FEB-2017 | 102 | P%UCNT | PLANT,TOTAL | 2.0 | 99.0 | 94.3 |
| | 00-07 - 02 - 0 - | 04-APR-2017 | 158 | P%UCNT | PLANT,TOTAL | 34.3 | **96.7** | **97.3** |
| | 200 L/HA | 30-MAY-2017 | 214 | P%UCNT | EAR | 51.0 | **84.3** | **93.7** |
| DEV-H-2017-UK-530-A-02.0-UK-UK4-R09 | 24-OCT-2016 | 13-FEB-2017 | 112 | P%UCC | PLANT,TOTAL | 10.0 | **94.3** | **96.7** |
| | 05 - 08 - 07 | 31-MAY-2017 | 219 | P%UCNT | EAR | 27.7 | **83.0** | **100.0** |
| | --- | | | | | | | |
| | 200 L/HA | | | | | | | |

In trial "DEV-H-2015-UK-603-A-02.0-UK-UK3-I02" the proposed product gave 90.7% control when considering the plant total assessment, although the control observed at the heading assessment was lower (66.9%). However, in this trial the untreated had a significant increase in weed pressure at this assessment timing, which may account for the reduced control provided. Further to this, a comparable level of control was provided by the standard reference product used (Herold/Fosburi). As the currently authorised reference product has not performed as expected, this may indicate that other aspects of the trial have affected the validity of the results.

In trial "DEV-H-2016-UK-501-B-01.0-UK-UK3-K01" control of plants was 83.3% with again a significantly lower level of control in the heading assessment (71.5%). The level of control of heading provided by the reference product within this trial was ~10% higher than that of the test product. The applicant has stated that this trial was exposed to dry weather in the month of October. It is generally accepted that dry conditions can inhibit the activity and performance of many pre-emergence herbicides. As a generally higher level of control has been observed in the other UK trials conducted HSE considers that the dry conditions may have affected the validity of this assessment.

In trials "DEV-H-2017-UK-621-A-01.0-UK-UK4-R08" and "DEV-H-2017-UK-630-A-02.0-UK-UK4-R09" the control provided is only slightly less than is expected for a claim of MS. However, HSE notes that within these trials the standard reference product used provides a significantly greater level of control.

*DE trials:*

26 trials were conducted in Germany across 3 years (2015-17). As with the UK trials each individual trial assessed the effect of the proposed product on the whole plant. In addition to this, heading assessments were carried out in 21 of these trials. A summary of these trials has been presented below for reference.

**HSE Table 13 – Summary of effectiveness of 'BAS 684 03 H' against ALOMY - DE (26 trials)**

| Country | Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated | | % control | |
|---|---|---|---|---|---|---|---|
| | | | | Mean (min & max) | | 0.667 L/ha | Standards |
| | | | | | | Mean (min - max) | |
| DE | 26 | Pre-em | Plant total | Percent coverage | 26.8 (2-75) | **91.8 (70-100)** | **91.1 (70-100)** |
| | | | | Number per sq. m | 131.8 (5.3-583.3) | | |
| | 21 | Pre-em | Ear | Number per sq. m | 664.7 (18.3-2000) | **88.3 (61.7-100)** | **87.7 (31-100)** |

On average, the proposed product has provided a level of control above 85% when considering the plant total and heading assessments. However, as in the UK trials the control level is variable with a

number of the individual trials showing reduced levels of control.

In 5 of the 26 total plant trials the control provided by the proposed product was less than the 85% required to support a claim of MS with 2 trials demonstrating effectiveness of less than 75%. However, in 4 of the 5 trials the effectiveness is comparable to the standard reference product. In trial "DEV-H-2016-DE-508-A-02.0-DE-D08-508" at the latest assessment timing the proposed product gave 70% compared to 90% from the standard reference product. However, it is noted that at this assessment timing a significant increase in weed infestation is observed in the untreated plot. Prior to this population increase comparable levels of control were observed between the test and reference products. Whilst this may explain the decrease in effectiveness from BAS 684 03 H it is concluded that within this trial the standard used provided higher control.

In 7 of the 21 trials in which heading assessments were conducted the efficacy observed was below the 85% control required to justify a claim of MS in the UK. These 7 trials are presented below for reference.

**HSE Table 14 – Effectiveness of 'BAS 684 03 H' against ALOMY – individual trials - DE (7 trials)**

| Trial ID | Date of treatment/ Growth stage crop (BBCH)/ Growth stage target (BBCH)/ water volume | Timing of assessment DAFT | Eval. Method | Plant part | Untreated | BAS 684 H 0.667 L/HA 500 g.ai.ha | Code | Standard |
|---|---|---|---|---|---|---|---|---|
| DEV-H-2016-DE-501-A-02.0-DE-D08-501 | 08-OCT-2015 | 11 | P%UCC | PLANT,TOTAL | 2.0 | 89.3 | 65 | 90.0 |
| | 07 - 08 - 08 | 11 | GCOUNT | PLANT,TOTAL | 143.3 | | | |
| | 07-08 - 08 - - | 60 | P%UCC | PLANT,TOTAL | 8.0 | 95.3 | | 95.7 |
| | 300 L/HA | 60 | GCOUNT | PLANT,TOTAL | 640.0 | | | |
| | | 165 | P%UCC | PLANT,TOTAL | 60.0 | **78.3** | | **83.3** |
| | | 165 | GCOUNT | PLANT,TOTAL | 696.7 | | | |
| | | 253 | P%UCNT | EAR | 645.0 | **78.3** | | **80.0** |
| DEV-H-2016-DE-501-A-02.0-DE-D09-644 | 05-OCT-2015 | 16 | GCOUNT | PLANT,TOTAL | 135.3 | | 65 | |
| | 00 - 00 - 00 | 16 | P%UCC | PLANT,TOTAL | 2.0 | 90.0 | | 95.0 |
| | 00-00 - 00 - - | 43 | GCOUNT | PLANT,TOTAL | 165.7 | | | |
| | 200 L/HA | 43 | P%UCC | PLANT,TOTAL | 3.0 | 81.0 | | 85.0 |
| | | 171 | GCOUNT | PLANT,TOTAL | 231.0 | | | |
| | | 171 | P%UCC | PLANT,TOTAL | 4.7 | **82.3** | | **79.0** |
| | | 214 | P%UCNT | EAR | 809.3 | **78.7** | | **77.7** |
| DEV-H-2016-DE-508-A-02.0-DE-D01-003 | 09-OCT-2015 | 17 | GCOUNT | PLANT,TOTAL | 687.0 | | 65 | |
| | 07 - 07 - | 17 | P%UCC | PLANT,TOTAL | 7.3 | 71.7 | | 60.0 |
| | - - 07 - - | 40 | GCOUNT | PLANT,TOTAL | 701.7 | | | |
| | 300 L/HA | 40 | P%UCC | PLANT,TOTAL | 8.0 | 86.0 | | 83.3 |
| | | 55 | GCOUNT | PLANT,TOTAL | 714.0 | | | |
| | | 55 | P%UCC | PLANT,TOTAL | 8.3 | 94.0 | | 90.7 |
| | | 158 | GCOUNT | PLANT,TOTAL | 806.7 | | | |
| | | 158 | P%UCC | PLANT,TOTAL | 16.0 | 94.0 | | 97.7 |
| | | 194 | P%UCC | PLANT,TOTAL | 75.0 | **91.3** | | **93.7** |
| | | 214 | P%UCNT | EAR | 1805.7 | **74.3** | | **84.7** |
| DEV-H-2016-DE-508-A-02.0-DE-D08-508 | 08-OCT-2015 | 13 | P%UCC | PLANT,TOTAL | 2.7 | 93.0 | 65 | 76.7 |
| | 07 - 09 - 08 | 13 | GCOUNT | PLANT,TOTAL | 238.3 | | | |
| | 07-09 - 08 - 0 - | 29 | P%UCC | PLANT,TOTAL | 3.7 | 97.3 | | 98.3 |
| | 300 L/HA | 29 | GCOUNT | PLANT,TOTAL | 380.0 | | | |
| | | 67 | P%UCC | PLANT,TOTAL | 6.7 | 99.0 | | 96.0 |
| | | 67 | GCOUNT | PLANT,TOTAL | 568.3 | | | |
| | | 165 | P%UCC | PLANT,TOTAL | **66.7** | **70.0** | | **90.0** |
| | | 165 | GCOUNT | PLANT,TOTAL | 741.7 | | | |
| | | 253 | P%UCNT | EAR | 688.3 | **61.7** | | **85.0** |
| DEV-H-2016-DE-530-A-02.0-DE-D05-530 | 12-OCT-2015 | 155 | P%UCC | PLANT,TOTAL | 38.3 | **98.3** | 40 | **73.3** |
| | 03 - 07 - 07 | 155 | GCOUNT | PLANT,TOTAL | 98.3 | | | |
| | 00-03 - 03 - - | 238 | P%UCNT | EAR | 1283.3 | **75.7** | | **31.0** |
| | 250 L/HA | | | | | | | |
| DEV-H-2017-DE-518-A-02.0-DE-D07-013 | 05-OCT-2016 | 68 | GCOUNT | PLANT,TOTAL | 117.7 | | 65 | |
| | 05 - 07 - 07 | 68 | P%UCC | PLANT,TOTAL | 7.0 | 70.0 | | 61.7 |
| | 05-07 - - 0 - | 154 | GCOUNT | PLANT,TOTAL | 112.0 | | | |
| | 300 L/HA | 154 | P%UCC | PLANT,TOTAL | 10.0 | **73.3** | | **75.0** |
| | | 230 | P%UCNT | EAR | 500.0 | **80.0** | | **78.3** |
| DEV-H-2017-DE-518-A-02.0-DE-D08-518 | 25-OCT-2016 | 52 | P%UCC | PLANT,TOTAL | 4.3 | 96.3 | 65 | 83.3 |
| | 05 - 07 - 07 | 52 | GCOUNT | PLANT,TOTAL | 126.7 | | | |
| | 05-07 - 07 - 0 - | 160 | P%UCC | PLANT,TOTAL | 16.7 | **94.3** | | **70.0** |
| | 300 L/HA | 160 | GCOUNT | PLANT,TOTAL | 541.7 | | | |
| | | 224 | P%UCNT | EAR | 608.3 | **78.3** | | **71.7** |

In 5 of these trials the effectiveness demonstrated by the proposed product is higher or comparable to that of the standard reference products. However, in trials "DEV-H-2016-DE-508-A-02.0-DE-D08-508" and "DEV-H-2016-DE-508-A-02.0-DE-D01-003" the effectiveness provided by the proposed product is lower than that of the reference products. As with the plant total assessments, in trial "DEV-H-2016-DE-508-A-02.0-DE-D08-508" a significant increase in weed infestation is noted before the

final assessment in the untreated. This may explain the significantly lower level of control provided. For trial "DEV-H-2016-DE-508-A-02.0-DE-D01-003" it is noted that the weed infestation is high in the untreated, especially at the heading assessment.

*FR trials:*

28 trials were conducted in Northern France (Maritime EPPO zone) between 2015 and 2017. Each individual trial assessed the effect of the proposed product on the whole plant and a further heading assessment was conducted. A summary of these trials has been presented below for reference.

**HSE Table 15 – Summary of effectiveness of 'BAS 684 03 H' against ALOMY - FR (28 trials)**

| Country | Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.667 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|---|
| FR | 28 | Pre-em | Plant total | Percent coverage | - | 91.8 (68.5-100) | 90.5 (68.3-99) |
| | | | | Number per sq. m | 121.6 (6.7-664.7) | | |
| | 28 | Pre-em | Ear | Number per sq. m | 287.9 (4.9-748.7) | 87.1 (41.6-100) | 84.3 (23.3-100) |

On average the proposed product provided control of over 85% when considering both the plant total and heading assessments. The average effectiveness is also observed to be higher to that of the standard reference product used.

In 10 of these 28 trials, control of less than 85% was provided by the proposed product in either the plant total or heading assessments. Of these 10, 5 trials demonstrated a comparable or greater reduction in those plots treated with the standard reference product which would call into question the validity of these trials. The 5 remaining trials have been presented below for discussion.

**HSE Table 16 – Effectiveness of 'BAS 684 03 H' against ALOMY – individual trials - FR (5 trials)**

| Trial ID | Date of treatment/ Growth stage crop (BBCH)/ Growth stage target (BBCH)/ water volume | Soil type | Timing of assessment DAFT | Plant part | Untreated | BAS 684 H 0.667 L/HA 500 g.ai.ha | Standard Code | Standard |
|---|---|---|---|---|---|---|---|---|
| DEV-H-2015-FR-503-A-01.0-FR-FR1-103 | 20-OCT-2014<br>00 - 00 - 00<br>---<br>188 L/HA | LOAM | 21 | PLANT,TOTAL | 202.0 | 90.7 | 65 | 45.0 |
| | | | 38 | PLANT,TOTAL | 212.7 | 84.3 | | 56.7 |
| | | | 149 | PLANT,TOTAL | 212.7 | 88.7 | | 81.0 |
| | | | 211 | PLANT,TOTAL | 221.0 | **86.3** | | **89.7** |
| | | | 211 | EAR | 271.7 | **84.7** | | **93.7** |
| | | | 211 | EAR | 271.7 | 41.7 | | 17.0 |
| DEV-H-2016-FR-501-A-01.0-FR-FR7-701 | 20-OCT-2015<br>05 - 06 - 06<br>00- - - -<br>180 L/HA | CALCAREOUS LOAM | 20 | PLANT,TOTAL | 580.7 | 83.3 | 65 | 80.0 |
| | | | 37 | PLANT,TOTAL | 580.7 | 82.7 | | 83.3 |
| | | | 155 | PLANT,TOTAL | 304.0 | **87.0** | | **95.7** |
| | | | 211 | EAR | 696.0 | 85.0 | | 95.0 |
| | | | 211 | EAR | 696.0 | **67.0** | | **82.5** |
| | | | 211 | EAR | 696.0 | 230.0 | | 122.0 |
| DEV-H-2017-FR-518-A-01.0-FR-FR7-715 | 05-OCT-2016<br>00 - 00 -<br>---<br>175 L/HA | LIME | 54 | PLANT,TOTAL | 18.0 | 45.0 | 65 | 65.0 |
| | | | 176 | PLANT,TOTAL | 33.5 | **68.5** | | **87.5** |
| | | | 223 | PLANT,TOTAL | 279.0 | 62.5 | | 75.0 |
| | | | 223 | EAR | 279.0 | **44.1** | | **73.5** |
| | | | 223 | EAR | 279.0 | 156.0 | | 74.0 |
| DEV-H-2017-FR-520-A-01.0-FR-FR6-619 | 02-NOV-2016<br>00 - 00 - 00<br>---<br>200 L/HA | SILTY SANDY CLAY | 27 | PLANT,TOTAL | 45.0 | 81.0 | 65 | 82.3 |
| | | | 84 | PLANT,TOTAL | 50.0 | 80.7 | | 86.3 |
| | | | 127 | PLANT,TOTAL | 60.0 | 85.0 | | 87.7 |
| | | | 202 | EAR | 155.3 | **85.0** | | **84.3** |
| | | | 202 | EAR | 155.3 | **41.6** | | **63.5** |
| | | | 202 | EAR | 155.3 | 90.7 | | 56.7 |
| DEV-H-2017-FR-530-A-03.0-FR-FR7-717 | 14-OCT-2016<br>00 - -<br>00- - - -<br>150 L/HA | LIME | 19 | PLANT,TOTAL | 32.7 | 78.0 | 65 | 76.0 |
| | | | 41 | PLANT,TOTAL | 32.7 | 70.0 | | 76.7 |
| | | | 168 | PLANT,TOTAL | 50.3 | **94.0** | | **99.0** |
| | | | 220 | EAR | 221.3 | 96.7 | | 98.7 |
| | | | 220 | EAR | 221.3 | **79.5** | | **93.4** |
| | | | 220 | EAR | 221.3 | 45.3 | | 14.7 |

The applicant has not provided an explanation of the reduced levels of control. HSE notes that in a number of these trials the level of control provided by the reference product was lower than expected; however, in each of these trials the effectiveness of the standard reference product was significantly higher than the level provided by the proposed formulation.

HSE conclusion: ALOMY

Overall HSE considers that sufficient data have been submitted to demonstrate effectiveness against the major weed black-grass (ALOMY). HSE considers that the data provided demonstrate sufficient effectiveness to justify a pre-emergence claim of "Moderately Susceptible" (MS) on the UK label.

The applicant has correctly highlighted that, on average, the product provides greater than 85% effectiveness against this weed. However, HSE has noted there are a number of cases across all the trials conducted in which control of <85% has been provided by the proposed product. In 24 of the 69 pre-emergence trials conducted across the UK, France and Germany the proposed product provided control below that required to support a claim of MS. Further to this, in 6 of these 24 trials control is below the 70% required to justify the lesser claim of MR. However, HSE also notes that in several trials control higher than the levels expected for a claim of MS has been observed in plots treated with the proposed product. Whilst a number of these results can be explained HSE still considers the data set presented to be variable.

HSE recognises that there will be some variability in efficacy pre-emergence. When considering the average control provided across the trials (and in the majority of the trials individually) the proposed product provided control equivalent to a claim of MS in the UK. Therefore HSE considers that the data support a pre-emergence claim of "Moderately Susceptible" (MS).

**Italian Ryegrass (LOLMU)**

The applicant has stated that the proposed product provides a level of control against LOLMU equivalent to a claim of "S" both pre- and post-emergence of the weed (up to 1 leaf stage). According to UK guidance, this equates to consistent control over 85%.

A total of 18 trials have been conducted to determine the level of control provided by the proposed product against the major grassweed LOLMU. Of these 18 trials, 10 were conducted pre-emergence with the remaining 8 conducted post-emergence. Trials were conducted in DE, FR and in the UK. However, HSE notes that only trials conducted in FR and DE have ultimately been considered valid by the applicant. In accordance with EPPO PP 1/241(2) 'Guidance on comparable climates' all the trials were conducted within the Maritime EPPO climatic zone, as such they can be considered in support of a UK authorisation.

In a number of these trials both a heading assessment and an assessment the plant as a whole has been conducted. The UK considers, in line with EPPO PP 1/93 (3), that heading assessments provide a better representation of the effectiveness of the product. Therefore, where available these assessments will be considered. Plant total values will also be evaluated, especially in trials where heading assessments have not been conducted.

HSE has considered both the pre- and post-emergence data separately below.

<u>LOLMU – Pre-emergence</u>

10 trials were conducted in pre-emergence situations across Germany and France over 3 years (2015-17). This is in line with the number of trials expected for a major weed according to EPPO PP1/226 (3). Each individual trial assessed the effect of the proposed product on the whole plant. In addition to this, in 8 of these trials heading assessments were carried out. A summary of these trials has been presented below for reference.

**HSE Table 17 – Summary of effectiveness of 'BAS 684 03 H' against LOLMU – Pre-emergence (10 trials)**

| Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.667 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|
| 10 | Pre-em | Plant total | Percent coverage | - | 94.6 (85.7-99) | 94.5 (89.3-99) |
| | | | Number per sq. m | 86.7 (12.3-170) | | |
| 8 | Pre-em | Ear | Number per sq. m | 272.1 (19.3-632.3) | 94.2 (84.8-99) | 91.7 (78.2-99) |

In the majority of the trials conducted >85% control was provided by the proposed product when considering both the plant total and ear assessments. HSE notes that in trial DEV-H-2016-FR-501-A-01.0-FR-FR1-F05 the level of control provided by the proposed product was slightly below 85% (84.8%). However, the level of control provided was comparable to that of the reference product used.

Overall, HSE considers that the applicant has provided sufficient evidence to support a pre-emergence claim of "S" against LOLMU.

LOLMU – Post-emergence

8 trials were conducted in post-emergence situations in France over 3 years (2015-17). This is in line with the number of trials expected for a major weed according to EPPO PP1/226 (3). Each individual trial assessed the effect of the proposed product on the whole plant. In addition to this, in 7 of these trials heading assessments were carried out. A summary of these trials has been presented below for reference.

**HSE Table 18 – Summary of effectiveness of 'BAS 684 03 H' against LOLMU – Post-emergence (8 trials)**

| Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.667 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|
| 8 | Post-em (11) | Plant total | Percent coverage | - | 90.3 (80-99.7) | 88.8 (63.3-98.7) |
| | | | Number per sq. m | 48.5 (15.7-108.7) | | |
| 7 | Post-em (11) | Ear | Number per sq. m | 195.8 (18-501) | 83.5 (59.1-94.8) | 72.6 (11-95.1) |

In the majority of the trials conducted >85% control was provided by the proposed product when considering both the plant total and ear assessments. However, in 3 of the trials conducted the control provided by the proposed product provided <85% control required for a claim of "S". This was observed in both the total plant (1 trial) and ear assessments (3 trials). These trials have been considered further below.

**HSE Table 19– Post-emergence effectiveness of 'BAS 684 03 H' against LOLMU – individual trials - FR (3 trials)**

| Trial ID | Date of treatment/ Growth stage crop (BBCH)/ Growth stage target (BBCH)/ water volume | Soil type | Timing of assessment DAFT | Plant part | Untreated | BAS 684 H 0.667 L/HA 500 g.ai.ha | Standard Code | Standard |
|---|---|---|---|---|---|---|---|---|
| DEV-H-2015-FR-504-A-01.0-FR-FRF-F04 | 06-NOV-2014<br>10 - 11 -<br>10-10 - - -<br>190 L/HA | LOAM | 18<br>138<br>194<br>194 | PLANT,TOTAL<br>PLANT,TOTAL<br>PLANT,TOTAL<br>EAR | 43.7<br>43.7<br>43.7<br>159.7 | 46.7<br>70.0<br>**88.3**<br>**79.1** | 66 | 40.0<br>70.0<br>**89.0**<br>**83.7** |
| DEV-H-2017-FR-502-A-01.0-FR-FR4-408 | 28-OCT-2016<br>10 - 11 - 11<br>09-10 - 10 - -<br>200 L/HA | LOAMY CLAY | 11<br>49<br>145<br>195<br>195 | PLANT,TOTAL<br>PLANT,TOTAL<br>PLANT,TOTAL<br>PLANT,TOTAL<br>EAR | 20.7<br>24.0<br>108.7<br>108.7<br>301.3 | 6.7<br>90.0<br>**92.3**<br>86.7<br>**74.3** | 49 | 5.0<br>97.7<br>**63.3**<br>20.0<br>**11.0** |
| DEV-H-2017-FR-519-A-01.0-FR-FR1-166 | 25-NOV-2016<br>11 - 11 - 11<br>10-11 - 10 - -<br>180 L/HA | SANDY CLAY LOAM | 12<br>39<br>117<br>171<br>171 | PLANT,TOTAL<br>PLANT,TOTAL<br>PLANT,TOTAL<br>PLANT,TOTAL<br>EAR | 116.0<br>145.3<br>148.0<br>501.0<br>501.0 | 30.0<br>71.7<br>**80.0**<br>60.0<br>**59.1** | 67 | 16.7<br>68.3<br>**95.0**<br>83.0<br>**83.4** |

In trial "DEV-H-2015-FR-504-A-01.0-FR-FRF-F04" when considering the ear assessments both the proposed product and the standard reference product provided a lower level of control than expected.

However, whilst the reference product provided a higher % control than the test product, HSE notes that the difference in control was not significant.

In trial "DEV-H-2017-FR-502-A-01.0-FR-FR4-408" although the level of control is lower than required when considering the ear assessments, the proposed product provides a higher level of control compared to the standard reference product used.

In trial "DEV-H-2017-FR-519-A-01.0-FR-FR1-166" when considering both the total plant and ear assessments the standard reference product gave higher % control than the proposed product. At heading the reference product gave 83% control compared to 59.1% from the test product. This is significantly less than is required to support a claim of "Susceptible" in the UK. However, HSE notes that in this trial the untreated control had 501 ears/$m^2$ and this may account for the reduced levels of control.

HSE conclusion: LOLMU

There is sufficient evidence to support a claim of "Susceptible" when the product is used pre-emergence. When the product is used post-emergence control is more variable. A "Susceptible" claim on a UK label requires consistent control of 85% and above. When considering the heading assessments the average level of control demonstrated by the proposed product was less than 85%. Therefore, HSE considers that the data provided instead justify a claim of "Moderately Susceptible" for post-emergence use.

**Perennial Ryegrass (LOLPE)**

The applicant has stated that the proposed product provides a level of control against LOLPE equivalent to a claim of "S" pre-emergence of the weed. According to UK guidance, this equates to consistent control over 85%.

A total of 6 trials have been conducted to determine the level of control provided by the proposed product against the major grassweed LOLPE. This is in line with the numbers specified within EPPO Standard PP 1/226(3). All trials were conducted pre-emergence. Trials were conducted in DE, AT and in the UK. In accordance with EPPO PP 1/241(2) 'Guidance on comparable climates' all the trials were conducted within the Maritime EPPO climatic zone, as such they can be considered in support of a UK authorisation.

In 3 of the 6 trials, heading and whole plant assessments were conducted. Both these assessments have been considered however, as described previously, where available heading assessments will be considered primarily. Plant total values will also be evaluated, especially in trials where heading assessments have not been conducted. The trials have been considered below.

**HSE Table 20– Pre-emergence effectiveness of 'BAS 684 03 H' against LOLPE (6 trials)**

| Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.667 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|
| 6 | Pre-em | Plant total | Percent coverage | 17.1 (2-30) | 94.1 (86.3-100) | 77.8 (50-100) |
| | | | Number per sq. m | 11 (11-11) | | |
| 3 | Pre-em | Ear | Number per sq. m | 201 (75.3-293.3) | 93.1 (86-100) | 84.2 (66.7-100) |

In each trial conducted >85% control was provided by the proposed product when considering both the plant total and ear assessments. Further to this, HSE notes that in each trial the level of control provided by the proposed product was higher or comparable to that of the reference product used. Therefore, HSE considers that the applicant has provided sufficient evidence to support a pre-

emergence claim of "S" against LOLPE.

**Annual Meadow Grass (POAAN)**

The applicant has stated that the proposed product provides a level of control against POAAN equivalent to a claim of "S" at both pre- and post-emergence of the weed (up to 3 leaves). According to UK guidance, this equates to consistent control over 85%.

A total of 24 trials have been conducted to determine the level of control provided by the proposed product against the major grassweed POAAN. Trials were conducted on different Cereal crops and Oilseed rape. UK Efficacy Guideline 405 outlines that extrapolation between these crops may be acceptable for effectiveness due to their similarity in regard to their competitiveness. Further to this, no significant difference in effectiveness against POAAN has been demonstrated within the trials irrespective of the crop planted. Therefore, HSE has considered the data from all crops together as the applicant has presented.

Of the 24 trials, 14 were conducted pre-emergence with the remaining 10 conducted post-emergence. Trials were conducted in DE, FR, DK and in the UK. In accordance with EPPO PP 1/241(2) 'Guidance on comparable climates' all the trials were conducted within the Maritime EPPO climatic zone, as such they can be considered in support of a UK authorisation.

In a number of the cereal trials both a heading assessment and an assessment the plant as a whole has been conducted. Both these assessments have been considered however, as described previously, where available heading assessments will be considered primarily. Plant total values will also be evaluated, especially in trials where heading assessments have not been conducted. The trials have been considered below.

HSE has considered both the pre- and post-emergence data separately below.

<u>POAAN – Pre-emergence</u>

14 trials were conducted in pre-emergence situations over 2 years (2016-17). This is in line with the number of trials expected for a major weed according to EPPO PP1/226 (3). Each individual trial assessed the effect of the proposed product on the whole plant. In addition to this, in 6 of these trials heading assessments were carried out. A summary of these trials has been presented below for reference.

**HSE Table 21 – Summary of effectiveness of 'BAS 684 03 H' against POAAN – Pre-emergence (14 trials)**

| Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated | | % control | |
|---|---|---|---|---|---|---|
| | | | Mean (min & max) | | 0.333 L/ha | Standards |
| | | | | | Mean (min - max) | |
| 14 | Pre-em | Plant total | Percent coverage | 8.5 (2.7-18.7) | 92.7 (84-100) | 95 (81.7-100) |
| | | | Number per sq. m | 14.7 (3.8-38.3) | | |
| 5 | Pre-em | Ear | Number per sq. m | 33.9 (9.5-61.3) | 90.2 (70-100) | 94.7 (83.3-100) |

On average, the proposed product provides a high level of control against POAAN when considering both the plant total and ear assessments. However, HSE notes in 3 trials lower levels of control were observed in plots treated with the proposed product (<85%). These trials have been copied below.

**HSE Table 22– Post-emergence effectiveness of 'BAS 684 03 H' against POAAN – individual trials - 3 trials**

| Trial ID | Date of treatment/ Growth stage crop (BBCH)/ Growth stage target (BBCH)/ water volume | Soil type | Timing of assessment DAFT | Plant part | Untreated | BAS 684 H 0.333 L/HA 250 g.ai.ha | Standard Code | Standard |
|---|---|---|---|---|---|---|---|---|
| DEV-H-2017-DE-503-A-02.0-DE-D13-503 | 30-SEP-2016<br>00 - 00 - 00<br>00-03 - 00 - 0 -<br>250 L/HA | SANDY LOAM | 181<br>181<br>255 | PLANT,TOTAL<br>PLANT,TOTAL<br>EAR | 11.0<br>2.7<br>56.0 | **100.0**<br>70.0 | 64 | **90.7**<br>90.0 |
| DEV-H-2017-FR-441-A-01.0-FR-FR1-103 | 16-SEP-2016<br>00 - 00 - 00<br>---<br>201 L/HA | LOAM | 82<br>181 | PLANT,TOTAL<br>PLANT,TOTAL | 31.0<br>38.3 | 65.0<br>**84.0** | 37 | 96.0<br>**95.0** |
| DEV-H-2017-UK-503-A-03.0-UK-UK3-K03 | 11-NOV-2016<br>01 - 05 - 03<br>00-00 - 00 - 0 -<br>200 L/HA | SANDY SILT | 35<br>105<br>133<br>195 | PLANT,TOTAL<br>PLANT,TOTAL<br>PLANT,TOTAL<br>EAR | 6.3<br>6.0<br>8.3<br>11.0 | 96.7<br>96.7<br>**96.7**<br>81.7 | 64 | 96.7<br>96.7<br>**96.7**<br>83.3 |

No explanation has been provided by the applicant as to why these trials demonstrate reduced levels of control. HSE notes that in one of these trials ("DEV-H-2017-UK-503-A-03.0-UK-UK3-K03") the level of control provided by the reference product was lower than expected; however, in each of these trials the effectiveness of the standard reference product was higher than the level provided by the proposed formulation.

POAAN – Post-emergence

10 trials were conducted in post-emergence situations with all trials were conducted in 2017. The number of trials is in line with the requirements as stated in EPPO PP1/226 (3). Each individual trial assessed the effect of the proposed product on the whole plant. In addition to this, in 3 of these trials heading assessments were carried out. A summary of these trials has been presented below for reference.

**HSE Table 23 – Summary of effectiveness of 'BAS 684 03 H' against POAAN – Post-emergence (10 trials)**

| Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.333 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|
| 10 | Post-em (up to 13) | Plant total | Percent coverage | 18.7 (18.7-18.7) | **94.9 (80-100)** | **95.6 (76.7-100)** |
| | | | Number per sq. m | 21.1 (6.3-51) | | |
| 3 | Post-em (up to 13) | Ear | Number per sq. m | 34.1 (21.3-49) | **86.8 (78.3-91.3)** | **87.6 (80-96.3)** |

As with the pre-emergence data, on average the proposed product provides a high level of control against POAAN when considering both the plant total and ear assessments. However, HSE notes in UK trial "DEV-H-2017-UK-604-A-02.0-UK-UK3-K04" a lower level of control was provided by the proposed product in both the plant total and heading assessments. However, a comparable decrease in the effectiveness has been observed in plots treated with the standard reference product.

HSE conclusion: POAAN

The applicant has submitted sufficient data to support a UK label claim against POAAN at both pre-emergence and post-emergence (up to the 3 leaf stage).

Although some variability has been observed, particularly in the pre-emergence trials, HSE considers that a high level of control has been demonstrated across the majority of the trials conducted and the averages presented.

The level of control demonstrated is in line with the UK claim of "Susceptible" as proposed by the applicant.

**Loose Silky Bent (APESV)**

The applicant has stated that the proposed product provides a level of control against POAAN equivalent to a claim of "S" at both pre- and post-emergence of the weed (up to 3 leaves). According to UK guidance, this equates to consistent control over 85%.

A total of 29 trials have been conducted to determine the level of control provided by the proposed product against the minor grassweed APESV. Trials were conducted on different Cereal crops and Oilseed rape. UK Efficacy Guideline 405 outlines that extrapolation between these crops may be acceptable for effectiveness data due to their similarity in regard to their competitiveness. Further to this, no significant difference in effectiveness against POAAN has been demonstrated within the trials irrespective of the crop planted. Therefore, HSE has chosen to consider the data from all crops together as the applicant has presented.

Of the 29 trials, 15 were conducted pre-emergence with the remaining 14 conducted post-emergence. Trials were conducted in DE, DK and AT. In accordance with EPPO PP 1/241(2) 'Guidance on comparable climates' all the trials were conducted within the Maritime EPPO climatic zone, as such they can be considered in support of a UK authorisation.

In a number of these trials both a heading assessment and an assessment the plant as a whole has been conducted. Both these assessments have been considered however, as described previously, where available heading assessments will be considered primarily. Plant total values will also be evaluated, especially in trials where heading assessments have not been conducted. The trials have been considered below.

HSE has considered both the pre- and post-emergence data separately below.

<u>APESV – Pre-emergence</u>

15 trials were conducted in pre-emergence situations over 2 years (2016-17). This exceeds the number of trials expected for a minor weed according to EPPO PP1/226 (3). Each individual trial assessed the effect of the proposed product on the whole plant. In addition to this, in 12 of these trials heading assessments were carried out. A summary of these trials has been presented below for reference.

**HSE Table 24 – Summary of effectiveness of 'BAS 684 03 H' against APESV – Pre-emergence (15 trials)**

| Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.333 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|
| 15 | Pre-em | Plant total | Percent coverage | 17.6 (2.3-60) | **95.6 (85-100)** | **99.2 (85-100)** |
| | | | Number per sq. m | 9.3 (5.7-14.7) | | |
| 12 | Pre-em | Ear | Number per sq. m | 72.4 (8.3-173.3) | **97.7 (83.3-100)** | **98.3 (83.3-100)** |

On average the proposed product provides a high level of control against APESV when considering both the plant total and ear assessments. However, HSE notes in trial "DEV-H-2017-EX-631-B-02.0-DE-VTH-009" a lower level of control was provided by the proposed product in the heading assessment. However, a comparable decrease in the effectiveness was observed in plots treated with the standard reference product.

<u>APESV – Post-emergence</u>

14 trials were conducted in post-emergence situations over 2 years (2016-17). This exceeds the number of trials expected for a minor weed according to EPPO PP1/226 (3). Each individual trial

assessed the effect of the proposed product on the whole plant. In addition to this, in 8 of these trials heading assessments were carried out. A summary of these trials has been presented below for reference.

**HSE Table 25 – Summary of effectiveness of 'BAS 684 03 H' against APESV – Post-emergence (14 trials)**

| Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.333 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|
| 14 | Post-em (up to 12) | Plant total | Percent coverage | 11 (2-46.7) | 96.5 (85-100) | 99.4 (95-100) |
| | | | Number per sq. m | 220.8 (25-416.7) | | |
| 8 | Post-em (up to 12) | Ear | Number per sq. m | 134 (26.7-216.7) | 98.1 (95.7-100) | 97.8 (83.3-100) |

In each trial conducted a good level of control was provided by the proposed product when considering both the plant total and ear assessments (>85%). Therefore, HSE considers that the applicant has provided sufficient evidence to support a post-emergence claim of "S" against APESV.

HSE conclusion: APESV

The applicant has submitted sufficient data to support a UK label claim against APESV at both pre-emergence and post-emergence (up to the 2 leaf stage). The level of control demonstrated is in line with the UK claim of "Susceptible" as claimed by the applicant.

**Common Poppy (PAPRH)**

The applicant has stated that the proposed product provides a level of control against PAPRH equivalent to a claim of "S" at both pre- and post-emergence of the weed (up to 2 leaves). According to UK guidance, this equates to consistent control over 85%.

A total of 14 cereal trials have been conducted to determine the level of control provided by the proposed product against the broadleaved weed PAPRH. Trials were conducted on different Cereal crops and Oilseed rape. UK Efficacy Guideline 405 outlines that extrapolation between these crops may be acceptable for effectiveness data due to their similarity in regard to their competitiveness. However, within the trials the applicant has noted differences in the effectiveness of the proposed product where different crops have been planted. As such the applicant has chosen to summarise the crops separately. Under this application there is no use proposed on Oilseed Rape. Therefore, as the Oilseed Rape trials are not considered supportive of the cereals data for this weed these trials have not been considered further. These trials may be included in any subsequent application for use on Oilseed rape.

Of the 14 trials, 8 were conducted pre-emergence with the remaining 6 conducted post-emergence. Trials were conducted in DE, DK and FR. In accordance with EPPO PP 1/241(2) 'Guidance on comparable climates' all the trials were conducted within the Maritime EPPO climatic zone, as such they can be considered in support of a UK authorisation.

HSE has considered both the pre- and post-emergence data separately below.

PAPRH – Pre-emergence

8 trials were conducted in pre-emergence situations over 2 years (2016-17). This exceeds the number of trials expected for a minor weed according to EPPO PP1/226 (3). Each individual trial assessed the effect of the proposed product on the whole plant. A summary of these trials has been presented below for reference.

**HSE Table 26 – Summary of effectiveness of 'BAS 684 03 H' against PAPRH – Pre-emergence (8 trials)**

| Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.333 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|
| 8 | Pre-em | Plant total | Percent coverage | 5.4 (2-12.3) | 96 (78.8-100) | 99.4 (95.3-100) |
| | | | Number per sq. m | 24.7 (24.7-24.7) | | |

In 7 of the 8 trials a high level of control is provided by the proposed product aligning with that expected of a "Susceptible" claim. However, in trial "DEV-H-2016-DK-604-A-02.0-DK-DK1-104" a lower level of control is provided by the proposed product (78.8%). No justification has been provided regarding the decreased control and it is noted that within this trial the standard reference product maintains a high level of effectiveness.

PAPRH – Post-emergence

6 trials were conducted in post-emergence situations over 2 years (2016-17). This exceeds the number of trials expected for a minor weed according to EPPO PP1/226 (3). Each individual trial assessed the effect of the proposed product on the whole plant. A summary of these trials has been presented below for reference.

**HSE Table 27 – Summary of effectiveness of 'BAS 684 03 H' against PAPRH – Post-emergence (6 trials)**

| Number of trials | Application timing (target) | Plant part | Ground cover in the Untreated Mean (min & max) | | % control 0.333 L/ha Mean (min - max) | % control Standards Mean (min - max) |
|---|---|---|---|---|---|---|
| 6 | Post-em (up to 12) | Plant total | Percent coverage | 6.8 (3-10) | 97.6 (92.5-100) | 92.7 (61.7-100) |
| | | | Number per sq. m | - | | |

In each trial conducted a good level of control was provided by the proposed product (>85%). This control level is equivalent to a UK label claim of "S".

HSE conclusion: PAPRH

The applicant has submitted sufficient data to support a UK label claim against PAPRH at both pre-emergence and post-emergence (up to the 2 leaf stage). The level of control demonstrated is in line with the UK claim of "Susceptible" as claimed by the applicant.

HSE notes that in a number of the trials conducted the weed infestation in the untreated plots was relatively low (<5% coverage). However, sufficient trials were included with challenging weed pressure to support a label claim against PAPRH.

**Water Volumes**

The applicant requested two separate water volume ranges. One for the pre-emergence application (100-300 l/ha) and one for post-emergence (150-300 l/ha). Data have been submitted by the applicant which only support a range of water volumes of 150-300 l/ha in both pre- and post-emergence situations. This range is supported by the data in both the efficacy and selectivity trials. Therefore, the use is supported in the UK at a water volume of 150-300 l/ha.

The proposed qualified recommendation regarding water volumes will be discussed in the appropriate section of this dRR.

| | |
|---|---|
| | **HSE label amendments relating to effectiveness:**<br><br>) Reference to post-emergence use against Black-grass must be deleted.<br><br>) In the Weed Control table, the post-emergence claim for Italian Ryegrass must be amended to 'MS to 1 leaf' |

## B.3.10. INFORMATION ON THE DEVELOPMENT OF RESISTANCE

A detailed consideration of the resistance situation was presented in Section Doc M-CA Section 3.7 and the Biological Assessment Document (BAD) for the associated product assessment for BAS 684 03 H.

**Mechanism of Resistance**

Principally, resistance to herbicides can be caused by target site modification or mechanisms not related to the target site, of which increased herbicide metabolism plays a major role.

An altered target site within a plant may mean that an herbicide no longer binds to its normal site of action due to a change in the structure of the target site, thereby allowing the plant to survive the herbicide treatment which relies on this site for its activity. This usually results in complete resistance to herbicides acting on that specific site but not to herbicides acting on different targets.

Non-target site resistance, e.g. enhanced metabolism is often not specific to a certain mode of action. The level of response to these mechanisms can greatly differ between products of the same chemistry or could affect in parallel products of different mode of action.
Enhanced metabolism means that the resistant plant can degrade a herbicide to non-phytotoxic substances faster than a normal sensitive plant, thereby surviving a herbicide treatment in much the same manner as many crop plants.
The impact of this resistance mechanism on the performance of individual herbicides is highly variable and tends to gradually increase over time.
Different mechanisms could occur in the same plant expressing resistance to one or several herbicidal active components.

**Evidence of Resistance, Cross-Resistance and Sensitivity Testing**

BAS 684 H is a new active substance in Europe and as such has never been used in Europe before. Furthermore, the novel Mode of Action of BAS 684 H is not related to any other herbicide class used by farmers for the control of grasses and broadleaf weeds. Therefore, no selection pressure has been ever exerted by this mode of action and no target-site cross-resistance to other herbicides currently exists.

Sensitivity testing on numerous *Alopecurus myosuroides* accessions from important cereal and oilseed growing region across different countries in Europe was conducted in the greenhouse to investigate potential cross-resistance patterns. The results were as follows;

- 77 biotypes out of a total tested 196 accessions were classified as being resistant (RR, RRR) to 'Atlantis WG' (mesosulfuron-methyl + iodosulfuron-methyl-sodium). At the reduced rates of 25% of the targeted field dose rate, BAS 684 H provided excellent activity on these accessions, irrespective of their R-classification for 'Atlantis WG'. Even though the impact of non-target site mechanisms on the 'Atlantis WG' resistance cannot be quantified, the low to moderate frequency level of the most important mutations at loci Pro197 and Trp574 suggest that the non-target-site mechanisms present in the tested biotypes do not confer cross-resistance to BAS 684 H.
- Baseline sensitivity testing on 21 accessions identified in general a higher variation in susceptibility between accessions but also across individual trials carried out. BAS 684 H provided ≥80% control at 25 % of the targeted dose rate, except for one accession which varied in the required dose rate between 25-50% of the field dose in different trials.
- Visual susceptibility assessments followed by an R-classification according to S. Moss were conducted on 288 accessions. At 25% of the BAS 684 H targeted dose rate, 17 accessions did show a slight decline in control level, while for the reference product the 25% dose rate indicated a slight control reduction already on 52 accessions with additional 25 / 1 accessions grouped into the resistance classes RR or RRR.

Overall it can be concluded that *Alopecurus* shows a smaller variation in the susceptibility to BAS 684 H than to the standard reference and that no incidences of biotypes resistant to BAS 684 H have currently been observed.

Additionally, in field trials performed by BASF in Europe, no herbicide-resistant weeds to BAS 684 H were identified.

**Resistance risk conclusion**

Cinmethylin is a new herbicide in the UK and EU and represents a novel mode of action. However, the active substance has been authorised for some years in Australia and Asia. Currently no cases of resistance have been recorded according to the International Survey of Herbicide Resistant Weeds (www.weedscience.org). The data presented in the baseline sensitivity trials above do not demonstrate any significant indication of a reduced activity in the biotypes tested. Therefore, HSE considers that the resistance risk of the active substance itself is low. However, the targets proposed include the major grassweed Blackgrass. Blackgrass is major agricultural weed of cereals with an extensive history of resistance issues. As such the inherent risk of this target is considered to be high. Therefore, HSE considers that the overall inherent risk of resistance developing to cinmethylin is moderate rather than low as proposed by the applicant. Therefore, resistance management strategies will need to be considered.

The applicant has proposed the following resistance management strategy:

- Always follow HRAC guidelines for preventing and managing herbicide resistant weeds.
- Maximize the use of cultural control measures wherever possible (e.g. crop rotation, ploughing, stale seedbeds, delayed drilling, etc).
- Adopt as diverse a rotation as possible using autumn and spring sown crops.
- Use a program of tank mixes or herbicide sequences with different modes of action within individual crops or succeeding crops. Do not rely on one herbicide mode of action for the control of grass or broad-leaved weeds in the same field over several years.
- Apply post-emergence products/mixtures to small, actively growing weeds to maximize the level of control.
- Scout fields regularly and investigate the reasons for any poor control.

HSE considers that the resistance management strategy proposed is acceptable. Due to this high-risk nature of the target weed Blackgrass HSE considers a monitoring strategy is required at product authorisation.

## B.3.11. ADVERSE EFFECTS ON TREATED CROPS

Field trials have been conducted to demonstrate the crop safety of BAS 684 03 H. These trials were carried out on winter wheat (TRZAW) and winter barley (HORVW). The trials were designed and conducted according to approved EPPO standards.

No trials were conducted on winter oilseed rape. Although selectivity trials are required to support a use on winter oilseed rape at product authorisation, for the active substance evaluation HSE considers that the proposed oilseed rape use falls within the risk envelope of the cereals assessment. Under Regulation 1107 Annex II point 3.2 it is stated that “an active substance alone or associated with a safener or synergist shall only be approved where it has been established for **one or more representative uses** that the plant protection product, consequent on application consistent with good plant protection practice and having regard to realistic conditions of use is sufficiently effective”. BASF have demonstrated efficacy and crop safety of the representative use on winter wheat. The proposed use on oilseed rape falls within that of the proposed uses on winter cereals. This is sufficient to meet the requirements set with Regulation 1107. However, the individual claims and uses will be assessed at product evaluation.

This is in line with the principles established in SANCO/10054/2013 - rev. 3’Guidance Document on Data Requirements on Efficacy for the Dossier to be Submitted for the Approval of New Active Substances Contained in Plant Protection Products’ where the ‘principal objective of the efficacy evaluation of an active substance is to confirm that the doses are realistic for the GAP submitted for risk evaluation and approval and representative for all subsequent authorisations.’

In the UK, the product evaluation of BAS 684 03 H has been conducted in parallel with the active substance assessment. For efficacy, a more detailed assessment of crop safety is conducted within the product evaluation. However, the appropriate evaluation is included below for reference.

| **EVALUATION, SUMMARY AND CONCLUSION BY REGULATORY AUTHORITY** | |
|---|---|
| **Name of authority** | **HSE Chemical Regulations Division (CRD), UK** |
| **Reviewer's comments** | **Phytotoxicity**<br><br>The applicant has carried out phytotoxicity assessments on both efficacy and selectivity trials. The effectiveness and crop safety trials were conducted across a range of countries within the Maritime EPPO climatic zone. HSE has considered the different crops in separate sections below.<br><br>**Winter Wheat (TRZAW)**<br><br>Pre-emergence application<br><br>A total of 76 efficacy trials and 34 selectivity trials were assessed for phytotoxicity. Of the 34 selectivity trials conducted, all were assessed, however only a proportion were yielded.<br><br>*Efficacy trials:*<br><br>Of the 76 efficacy trials conducted, 54 demonstrated no or <5% phytotoxicity after treatment with the test product at its proposed dose. In another 9 trials, those crops treated with the proposed product demonstrated <10% phytotoxicity. In the majority of these trials any crop injury appeared to be transient with no phytotoxic effect observed at the later assessment. However, in the 13 remaining trials >10% phytotoxic effects were observed with up to 61.7% phytotoxicity in some trials. HSE has summarised the trials with high levels of phytotoxicity below.<br><br>**HSE Table 31 – Efficacy trials with >10% phytotoxic effects** |

| Trial ID | Variety | Soil type | Eval Date | Assessed Variable (calculated) | Eval. Method | Untreated | BAS 684 H 0.667 L/HA 500 g.ai.ha | Standard Code | Standard |
|---|---|---|---|---|---|---|---|---|---|
| DEV-H-2015-FR-501-A-01.0-FR-FR7-708 | TRAPEZ | LIME | 13-NOV-2014 | PHYTOX | P%UCC | 15.0 | 61.7 | 65 | 21.7 |
| | | | 13-NOV-2014 | YWURED | P%EST | 0.0 | 15.0 | | 3.3 |
| | | | 09-DEC-2014 | PHYTOX | P%UCC | 20.0 | 58.3 | | 21.7 |
| | | | 09-DEC-2014 | AUSDUN | P%EST | 0.0 | 55.0 | | 21.7 |
| | | | 09-DEC-2014 | YWURED | P%EST | 0.0 | 12.0 | | 2.3 |
| | | | 01-APR-2015 | PHYTOX | P%UCC | 40.0 | 61.7 | | 26.7 |
| | | | 01-APR-2015 | YBIOMA | P%EST | 100.0 | 38.3 | | 73.3 |
| | | | 11-MAY-2015 | PHYTOX | P%UCC | 75.0 | 60.0 | | 18.3 |
| | | | 11-MAY-2015 | YBIOMA | P%EST | 100.0 | 40.0 | | 81.7 |
| DEV-H-2015-FR-520-A-01.0-FR-FR7-714 | MANAGER | CALCAREOUS LOAM | 03-NOV-2014 | PHYTOX | P%UCC | 15.0 | 1.7 | 65 | 0.0 |
| | | | 18-NOV-2014 | PHYTOX | P%UCC | 20.0 | 5.7 | | 15.0 |
| | | | 18-NOV-2014 | AUSDUN | P%EST | 0.0 | 5.7 | | 15.0 |
| | | | 18-NOV-2014 | YWURED | P%EST | 0.0 | 0.0 | | 4.0 |
| | | | 18-NOV-2014 | YFARBE | U0-10 | 5.0 | 5.0 | | 5.0 |
| | | | 09-DEC-2014 | PHYTOX | P%UCC | 20.0 | 13.3 | | 15.0 |
| | | | 09-DEC-2014 | AUSDUN | P%EST | 0.0 | 13.3 | | 15.0 |
| | | | 09-DEC-2014 | YWURED | P%EST | 0.0 | 4.0 | | 8.3 |
| | | | 09-DEC-2014 | YBLHEL | P%EST | 0.0 | 0.0 | | 0.0 |
| | | | 01-APR-2015 | PHYTOX | P%UCC | 40.0 | 8.3 | | 10.7 |
| | | | 11-MAY-2015 | PHYTOX | P%UCC | 75.0 | 1.7 | | 2.3 |
| DEV-H-2016-FR-501-A-01.0-FR-FR1-102 | ASCOTT | LOAM | 09-NOV-2015 | PHYTOX | P%UCC | 15.3 | 20.0 | 65 | 18.3 |
| | | | 09-NOV-2015 | AUSDUN | P%EST | 0.0 | 20.0 | | 18.3 |
| | | | 26-NOV-2015 | PHYTOX | P%UCC | 28.3 | 20.0 | | 20.0 |
| | | | 26-NOV-2015 | AUSDUN | P%EST | 0.0 | 20.0 | | 20.0 |
| | | | 26-APR-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | | 0.0 |
| | | | 26-MAY-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | | 0.0 |
| DEV-H-2016-FR-501-A-01.0-FR-FR7-701 | LEAR | CALCAREOUS LOAM | 09-NOV-2015 | PHYTOX | P%UCC | 25.0 | 10.0 | 65 | 9.7 |
| | | | 26-NOV-2015 | PHYTOX | P%UCC | 25.0 | 8.3 | | 8.3 |
| | | | 26-NOV-2015 | AUSDUN | P%EST | 0.0 | 8.3 | | 6.7 |
| | | | 23-MAR-2016 | PHYTOX | P%UCC | 65.0 | 0.0 | | 0.0 |
| | | | 18-MAY-2016 | PHYTOX | P%UCC | 85.0 | 0.0 | | 0.0 |
| DEV-H-2017-FR-501-A-01.0-FR-FR1-106 | OREGRAIN | LOAM | 29-NOV-2016 | PHYTOX | P%UCC | 10.0 | 12.3 | 47 | 10.7 |
| | | | 20-DEC-2016 | PHYTOX | P%UCC | 15.0 | 16.7 | | 11.7 |
| | | | 20-DEC-2016 | AUSDUN | P%EST | 0.0 | 16.7 | | 11.7 |
| | | | 16-MAR-2017 | PHYTOX | P%UCC | 86.7 | 11.7 | | 10.7 |
| | | | 16-MAR-2017 | AUSDUN | P%EST | 0.0 | 11.7 | | 10.7 |
| | | | 30-MAY-2017 | PHYTOX | P%UCC | 100.0 | 0.0 | | 1.7 |
| DEV-H-2017-FR-520-A-01.0-FR-FRF-F13 | BOREGAR | LOAMY SILT | 17-NOV-2016 | PHYTOX | P%UCC | 10.0 | 13.3 | 65 | 0.0 |
| | | | 17-NOV-2016 | AUSDUN | P%EST | 0.0 | 13.3 | | 0.0 |
| | | | 08-DEC-2016 | PHYTOX | P%UCC | 20.0 | 15.0 | | 0.0 |
| | | | 08-DEC-2016 | AUSDUN | P%EST | 0.0 | 15.0 | | 0.0 |
| | | | 20-MAR-2017 | PHYTOX | P%UCC | 75.0 | 21.7 | | 10.0 |
| | | | 20-MAR-2017 | AUSDUN | P%EST | 0.0 | 21.7 | | 10.0 |
| | | | 05-MAY-2017 | PHYTOX | P%UCC | 96.0 | 21.7 | | 8.3 |
| | | | 05-MAY-2017 | AUSDUN | P%EST | 0.0 | 21.7 | | 8.3 |
| | | | 05-MAY-2017 | YWURED | P%EST | 0.0 | 10.0 | | 0.0 |
| DEV-H-2017-UK-501-A-02.0-UK-UK3-M01 | CRUSOE | CLAY LOAM | 06-DEC-2016 | PHYTOX | P%UCC | 2.0 | 0.0 | 40 | 0.0 |
| | | | 10-JAN-2017 | PHYTOX | P%UCC | 5.0 | 43.3 | | 3.3 |
| | | | 10-JAN-2017 | AUSDUN | P%EST | 0.0 | 43.3 | | 3.3 |
| | | | 16-MAR-2017 | PHYTOX | P%UCC | 50.0 | 43.3 | | 3.3 |
| | | | 16-MAR-2017 | AUSDUN | P%EST | 0.0 | 43.3 | | 3.3 |
| | | | 19-APR-2017 | PHYTOX | P%UCC | 50.0 | 43.3 | | 3.3 |
| | | | 19-APR-2017 | AUSDUN | P%EST | 0.0 | 43.3 | | 3.3 |
| DEV-H-2016-DE-530-A-02.0-DE-D05-530 | SMARAGD | SANDY LOAM | 23-OCT-2015 | PHYTOX | P%UCC | 2.0 | 0.0 | 40 | 0.0 |
| | | | 23-OCT-2015 | AUSDUN | P%EST | | 0.0 | | 0.0 |
| | | | 07-DEC-2015 | PHYTOX | P%UCC | 15.0 | 0.0 | | 0.0 |
| | | | 07-DEC-2015 | AUSDUN | P%EST | | 0.0 | | 0.0 |
| | | | 15-MAR-2016 | PHYTOX | P%UCC | 4.3 | 14.0 | | 0.0 |
| | | | 06-JUN-2016 | PHYTOX | P%UCC | 18.3 | 5.0 | | 0.0 |
| DEV-H-2016-FR-501-A-01.0-FR-FR2-203 | CHEVRON | LCAREOUS CLAY LOAI | 22-OCT-2015 | PHYTOX | P%UCC | 3.0 | 0.0 | 65 | 0.0 |
| | | | 19-NOV-2015 | PHYTOX | P%UCC | 30.0 | 0.0 | | 0.0 |
| | | | 19-NOV-2015 | AUSDUN | P%EST | 0.0 | 0.0 | | 0.0 |
| | | | 17-MAR-2016 | PHYTOX | P%UCC | 53.3 | 10.7 | | 6.7 |
| | | | 30-MAY-2016 | PHYTOX | P%UCC | 100.0 | 7.3 | | 4.0 |
| DEV-H-2016-FR-501-A-01.0-FR-FRF-F05 | CELLULE | SANDY CLAY LOAM | 09-NOV-2015 | PHYTOX | P%UCC | 10.0 | 0.0 | 65 | 0.0 |
| | | | 03-DEC-2015 | PHYTOX | P%UCC | 30.0 | 0.0 | | 0.0 |
| | | | 03-DEC-2015 | AUSDUN | P%EST | 0.0 | 0.0 | | 0.0 |
| | | | 16-MAR-2016 | PHYTOX | P%UCC | 80.0 | 13.3 | | 10.0 |
| | | | 16-MAR-2016 | AUSDUN | P%EST | 0.0 | 13.3 | | 10.0 |
| | | | 24-MAY-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | | 0.0 |
| DEV-H-2017-DE-508-A-01.0-DE-D02-508 | HENDRICK | SILTY LOAM | 23-NOV-2016 | PHYTOX | P%UCC | 5.7 | 0.0 | 65 | 0.0 |
| | | | 19-APR-2017 | PHYTOX | P%UCC | 58.3 | 30.7 | | 4.3 |
| | | | 19-APR-2017 | AUSDUN | P%EST | 58.3 | 30.7 | | 4.3 |
| DEV-H-2017-FR-501-A-01.0-FR-FR6-653 | ACCROC | SILTY LOAM | 05-DEC-2016 | PHYTOX | P%UCC | 3.0 | 0.0 | 47 | 0.0 |
| | | | 10-JAN-2017 | PHYTOX | P%UCC | 10.0 | 3.3 | | 3.3 |
| | | | 10-JAN-2017 | AUSDUN | P%EST | 0.0 | 3.3 | | 3.3 |
| | | | 21-MAR-2017 | PHYTOX | P%UCC | 20.0 | 11.7 | | 6.7 |
| | | | 31-MAY-2017 | PHYTOX | P%EST | 0.0 | 0.0 | | 0.0 |
| DEV-H-2017-FR-520-A-01.0-FR-FR6-619 | CELLULE | SILTY SANDY CLAY | 29-NOV-2016 | PHYTOX | P%UCC | 30.0 | 0.0 | 65 | 0.0 |
| | | | 25-JAN-2017 | AUSDUN | P%EST | 0.0 | 0.0 | | 0.0 |
| | | | 25-JAN-2017 | PHYTOX | P%UCC | 35.0 | 0.0 | | 0.0 |
| | | | 09-MAR-2017 | PHYTOX | P%UCC | 45.0 | 10.0 | | 3.0 |
| | | | 09-MAR-2017 | AUSDUN | P%EST | 0.0 | 10.0 | | 3.0 |
| | | | 23-MAY-2017 | PHYTOX | P%UCC | 100.0 | 17.3 | | 5.7 |
| | | | 23-MAY-2017 | AUSDUN | P%EST | 0.0 | 17.3 | | 5.7 |

In the 5 trials highlighted in yellow, the plant damage appeared after winter with initial assessments showing no phytotoxic effects. Generally, in these trials the phytotoxic effects observed were less pronounced than in those trials demonstrating immediate effects post-emergence. Regardless, it is noted within these trials that those crops treated with the test product have significantly higher levels of phytotoxicity than both the untreated and the crops treated with the reference products.

In the remaining 7 trials plant damage was observed shortly after the emergence of the crop. In

| | |
|---|---|
| | the majority of these trials the damage tended to be higher in crops treated with the test product. However, in 4 of these trials phytotoxicity observed was not significantly different between the crops treated with either the test or reference products.<br><br>Of the 13 efficacy trials demonstrating significant levels of phytotoxicity, 10 were conducted in France. The applicant has stated the following within the BAD:<br>"*Most of the trials were conducted in France. Local cultural practices, linked to a relatively shallow drilling depth is thought to be the key contributing factor. In the six French efficacy trials where phytotoxicity was seen the drilling depth recorded was 2.67, 1.81, 2.05, 2.37, 2.28 & 2.48 cm (in order, as presented in table 3.4.1.1.1c, top to bottom). In comparison, in the UK (excluding trial 'UK-UK3-M04' for reasons explained below) the drilling depth was 3, 4, 2, 3, 3, 4, 3.5, 2.5, 3, 3, 4, 4, 3, 4, 3, 3, 3 & 5 cm. None of the UK trials suffered from >10% phytotoxicity. Although the difference between the UK and FR drilling depth is not massive, typically 1 – 0.5 cm, this appears to make a difference to the selectivity seen for BAS 684 H when applied pre-em in winter wheat.*"<br><br>HSE accepts that shallow drilling in France may have contributed to phytotoxicity in treated crops. However, within these French efficacy trials the proposed product provides a higher level of crop injury than this reference product when applied. This trend of higher phytotoxicity in shallow-planted crops is also reflected in the selectivity trials which are discussed in the section below. As such, HSE considers that label warnings are required to mitigate the risk of crop damage in shallow-planted crops.<br><br>In "DEV-2017-UK-501-A02.0-UK-UK3-M01" phytotoxicity of 43.3% is observed in crops treated with the test product from 56 DAT. The applicant has claimed "*In this trial the application was applied relatively late (on the 15th November – pre-emergence) to a site with a very cloddy seed bed. The soil type (clay loam) and late drilling prevented the farmer from rolling the crop and consolidating the soil. This effectively exposed the young seedling to the active ingredient. Part of the crop was effectively killed. The phytotoxicity was more pronounced for BAS 684 H than for the standard.*" This may explain the high levels of phytotoxicity observed within this trial. A similar issue was noted in two selectivity trials ('DEV-H-2016-DE-506-A-02.0-DE-D04-506' and 'DEV-H-2017-DE-505-A-01.0-DE-D04-505') where no consolidation was possible. In both these trials significant phytotoxicity and yield effects were recorded. Due to this, HSE considers label wording is required to mitigate this risk.<br><br>*Selectivity trials:*<br><br>34 selectivity trials were conducted. In 21 of these trials, little to no phytotoxic effects were recorded in crops treated with either the N or 2N doses of the proposed product. In the remaining 13 trials phytotoxicity was observed, either at the proposed or 2N dose. These trials have been presented below.<br><br>**HSE Table 32 – Selectivity trials with >10% phytotoxic effects** |

| Trial ID | Variety | Soil type | Eval Date | Assessed Variable calculated) | Eval. Method | Untreated | BAS 684 H 0.667 L/HA 500 g.ai.ha | BAS 684 H 1.33 L/HA 1000 g.ai.ha | Standard Code | Standard N | Standard 2N |
|---|---|---|---|---|---|---|---|---|---|---|---|
| DEV-H-2016-EX-511-C-02.0-DE-VTH-120 | KERUBINO | SANDY LOAM | 19-OCT-2015 | PHYTOX | P%UCC | 5.0 | 6.0 | 17.5 | 18 | 2.5 | 9.0 |
| | | | 06-NOV-2015 | PHYTOX | P%UCC | 12.0 | 5.0 | 10.0 | | 2.0 | 6.0 |
| | | | 06-NOV-2015 | AUSDUN | P%EST | 0.0 | 0.0 | 2.5 | | 0.0 | 0.0 |
| | | | 14-DEC-2015 | PHYTOX | P%UCC | 20.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 04-APR-2016 | PHYTOX | P%UCC | 40.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| DEV-H-2016-FR-507-A-02.0-FR-FR4-409 | CAPHORN | LOAMY CLAY | 23-OCT-2015 | PHYTOX | P%UCC | 10.0 | 12.5 | 27.5 | 24 | 7.5 | 8.8 |
| | | | 23-OCT-2015 | AUSDUN | P%EST | 0.0 | 12.5 | 27.5 | | 7.5 | 8.8 |
| | | | 09-NOV-2015 | PHYTOX | P%UCC | 20.0 | 16.3 | 32.5 | | 7.5 | 12.5 |
| | | | 09-NOV-2015 | AUSDUN | P%EST | 0.0 | 16.3 | 32.5 | | 7.5 | 12.5 |
| | | | 26-NOV-2015 | PHYTOX | P%UCC | 80.0 | 18.8 | 32.5 | | 6.0 | 10.5 |
| | | | 26-NOV-2015 | AUSDUN | P%EST | 0.0 | 18.8 | 32.5 | | 6.0 | 10.5 |
| | | | 26-NOV-2015 | YBLHEL | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 21-MAR-2016 | PHYTOX | P%UCC | 100.0 | 18.8 | 27.5 | | 0.0 | 0.0 |
| | | | 21-MAR-2016 | AUSDUN | P%EST | 0.0 | 17.5 | 27.5 | | 0.0 | 0.0 |
| | | | 21-MAR-2016 | YBLHEL | P%EST | 0.0 | 2.8 | 6.3 | | 0.0 | 0.0 |
| | | | 09-MAY-2016 | PHYTOX | P%UCC | 100.0 | 16.8 | 25.0 | | 0.0 | 0.0 |
| | | | 09-MAY-2016 | AUSDUN | P%EST | 0.0 | 16.8 | 25.0 | | 0.0 | 0.0 |
| | | | 09-MAY-2016 | YBLHEL | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| DEV-H-2016-FR-510-A-01.0-FR-FRE-E41 | ATOUPIC | LOAM | 29-OCT-2015 | PHYTOX | P%UCC | 10.0 | 12.5 | 16.0 | 24 | 10.0 | 11.0 |
| | | | 25-NOV-2015 | PHYTOX | P%UCC | 60.0 | 0.0 | 25.0 | | 0.0 | 3.5 |
| | | | 25-NOV-2015 | AUSDUN | P%EST | 0.0 | 0.0 | 15.0 | | 0.0 | 0.0 |
| | | | 17-DEC-2015 | PHYTOX | P%UCC | 80.0 | 0.0 | 15.0 | | 0.0 | 0.0 |
| | | | 16-MAR-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | 5.0 | | 0.0 | 0.0 |
| | | | 29-APR-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | 12.5 | | 0.0 | 0.0 |
| DEV-H-2016-FR-510-A-01.0-FR-FRE-E41 | BERMUDE | LOAM | 29-OCT-2015 | PHYTOX | P%UCC | 10.0 | 2.5 | 6.0 | 24 | 0.0 | 2.5 |
| | | | 25-NOV-2015 | PHYTOX | P%UCC | 60.0 | 0.0 | 17.5 | | 0.0 | 0.0 |
| | | | 25-NOV-2015 | AUSDUN | P%EST | 0.0 | 0.0 | 7.5 | | 0.0 | 0.0 |
| | | | 17-DEC-2015 | PHYTOX | P%UCC | 70.0 | 6.0 | 12.5 | | 0.0 | 0.0 |
| | | | 16-MAR-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | 17.5 | | 0.0 | 2.5 |
| | | | 29-APR-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | 15.0 | | 0.0 | 0.0 |
| DEV-H-2016-FR-510-A-01.0-FR-FRE-E42 | ATOUPIC | LOAM | 29-OCT-2015 | PHYTOX | P%UCC | 10.0 | 5.0 | 22.5 | 24 | 2.5 | 6.0 |
| | | | 25-NOV-2015 | PHYTOX | P%UCC | 60.0 | 2.5 | 22.5 | | 0.0 | 3.5 |
| | | | 25-NOV-2015 | AUSDUN | P%EST | 0.0 | 0.0 | 7.5 | | 0.0 | 0.0 |
| | | | 17-DEC-2015 | PHYTOX | P%UCC | 87.5 | 0.0 | 12.5 | | 0.0 | 0.0 |
| | | | 16-MAR-2016 | PHYTOX | P%UCC | 100.0 | 2.5 | 16.5 | | 0.0 | 0.0 |
| | | | 29-APR-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | 10.0 | | 0.0 | 0.0 |
| DEV-H-2016-FR-510-A-01.0-FR-FRE-E42 | BERMUDE | LOAM | 29-OCT-2015 | PHYTOX | P%UCC | 10.0 | 5.0 | 7.5 | 24 | 2.5 | 2.5 |
| | | | 25-NOV-2015 | PHYTOX | P%UCC | 60.0 | 7.5 | 16.5 | | 0.0 | 0.0 |
| | | | 25-NOV-2015 | AUSDUN | P%EST | 0.0 | 0.0 | 4.0 | | 0.0 | 0.0 |
| | | | 17-DEC-2015 | PHYTOX | P%UCC | 80.0 | 8.5 | 15.0 | | 0.0 | 0.0 |
| | | | 16-MAR-2016 | PHYTOX | P%UCC | 100.0 | 8.5 | 27.0 | | 0.0 | 0.0 |
| | | | 29-APR-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | 25.0 | | 0.0 | 0.0 |
| DEV-H-2017-FR-515-A-01.0-FR-FR4-411 | FRUCTIDOR | LOAM | 02-NOV-2016 | PHYTOX | P%UCC | 21.3 | 20.0 | 34.0 | 24 | 5.0 | 17.5 |
| | | | 12-DEC-2016 | PHYTOX | P%UCC | 58.8 | 40.0 | 71.3 | | 10.0 | 62.5 |
| | | | 12-DEC-2016 | AUSDUN | P%EST | 0.0 | 40.0 | 66.3 | | 10.0 | 53.8 |
| | | | 22-MAR-2017 | PHYTOX | P%UCC | 86.3 | 16.3 | 55.0 | | 10.5 | 32.5 |
| | | | 22-MAR-2017 | AUSDUN | P%EST | 0.0 | 16.3 | 55.0 | | 10.5 | 32.5 |
| | | | 27-APR-2017 | PHYTOX | P%UCC | 98.0 | 10.0 | 21.3 | | 5.0 | 9.8 |
| | | | 27-APR-2017 | AUSDUN | P%EST | 0.0 | 10.0 | 21.3 | | 5.0 | 9.8 |
| DEV-H-2016-FR-532-A-01.0-FR-FRE-E7( | ATOUPIC | LOAM | 06-NOV-2015 | PHYTOX | P%UCC | 15.0 | 2.8 | 4.3 | 18 | 0.5 | 1.5 |
| | | | 18-NOV-2015 | PHYTOX | P%UCC | 40.0 | 2.0 | 4.3 | | 0.0 | 2.0 |
| | | | 18-NOV-2015 | AUSDUN | P%EST | 0.0 | 2.0 | 4.3 | | 0.0 | 2.0 |
| | | | 09-DEC-2015 | PHYTOX | P%UCC | 40.0 | 7.3 | 10.0 | | 5.5 | 5.0 |
| | | | 09-DEC-2015 | AUSDUN | P%EST | 0.0 | 7.3 | 10.0 | | 5.5 | 5.0 |
| | | | 14-MAR-2016 | PHYTOX | P%UCC | 85.0 | 3.8 | 5.0 | | 0.0 | 0.0 |
| | | | 09-MAY-2016 | PHYTOX | P%UCC | 100.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| DEV-H-2016-DE-506-A-02.0-DE-D04-506 | MATRIX | SILT | 12-OCT-2015 | PHYTOX | P%UCC | 5.0 | 3.8 | 5.8 | 12 | 11.5 | 25.5 |
| | | | 12-OCT-2015 | YBLHEL | P%EST | | 2.5 | 3.8 | | 5.0 | 11.0 |
| | | | 12-OCT-2015 | YNECRO | P%EST | | 1.3 | 1.8 | | 5.3 | 11.3 |
| | | | 20-OCT-2015 | PHYTOX | P%UCC | 6.0 | 2.0 | 4.0 | | 10.0 | 22.0 |
| | | | 20-OCT-2015 | AUSDUN | P%EST | | 0.0 | 0.3 | | 1.3 | 3.0 |
| | | | 20-OCT-2015 | YBLHEL | P%EST | | 1.0 | 2.0 | | 3.8 | 8.5 |
| | | | 20-OCT-2015 | YNECRO | P%EST | | 1.0 | 1.8 | | 5.0 | 10.5 |
| | | | 07-DEC-2015 | PHYTOX | P%UCC | 25.3 | 22.8 | 44.5 | | 20.3 | 59.0 |
| | | | 07-DEC-2015 | YBLHEL | P%EST | | 4.0 | 4.3 | | 6.3 | 9.5 |
| | | | 07-DEC-2015 | YNECRO | P%EST | | 8.5 | 18.3 | | 5.5 | 14.0 |
| | | | 07-DEC-2015 | AUSDUN | P%EST | | 3.0 | 5.3 | | 2.3 | 6.5 |
| | | | 19-APR-2016 | PHYTOX | P%UCC | 57.0 | 39.3 | 79.3 | | 22.8 | 78.3 |
| | | | 11-MAY-2016 | PHYTOX | P%UCC | 88.8 | 49.3 | 70.0 | | 23.0 | 75.8 |
| DEV-H-2017-DE-505-A-01.0-DE-D04-505 | MATRIX | SILT | 17-OCT-2016 | PHYTOX | P%UCC | 5.0 | 0.0 | 0.0 | 12 | 0.0 | 0.0 |
| | | | 26-OCT-2016 | PHYTOX | P%UCC | 6.8 | 0.0 | 0.0 | | 0.0 | 0.5 |
| | | | 26-OCT-2016 | AUSDUN | P%EST | | 0.0 | 0.0 | | 0.0 | 0.5 |
| | | | 14-NOV-2016 | PHYTOX | P%UCC | 9.5 | 0.0 | 0.0 | | 0.0 | 0.5 |
| | | | 19-DEC-2016 | PHYTOX | P%UCC | 20.8 | 0.0 | 7.0 | | 0.0 | 1.8 |
| | | | 16-MAR-2017 | PHYTOX | P%UCC | 33.8 | 1.5 | 18.0 | | 16.5 | 52.5 |
| | | | 16-MAY-2017 | PHYTOX | P%UCC | 80.0 | 3.5 | 24.5 | | 15.0 | 41.3 |
| DEV-H-2017-DE-505-A-01.0-DE-D17-008 | MATRIX | LOAMY SILT | 28-OCT-2016 | PHYTOX | P%UCC | 15.0 | 0.0 | 0.0 | 12 | 0.0 | 0.0 |
| | | | 14-NOV-2016 | PHYTOX | P%UCC | 20.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 14-NOV-2016 | AUSDUN | P%EST | | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 12-DEC-2016 | PHYTOX | P%UCC | 25.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 12-DEC-2016 | AUSDUN | P%EST | | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 23-MAR-2017 | PHYTOX | P%UCC | 40.0 | 2.5 | 3.8 | | 2.8 | 6.0 |
| | | | 23-MAR-2017 | AUSDUN | P%EST | | 1.5 | 2.3 | | 1.5 | 4.0 |
| | | | 20-APR-2017 | AUSDUN | P%EST | | 6.3 | 10.5 | | 4.5 | 8.0 |
| | | | 20-APR-2017 | PHYTOX | P%UCC | 70.0 | 7.3 | 11.5 | | 5.5 | 9.0 |
| | | | 19-MAY-2017 | PHYTOX | P%UCC | 95.0 | 7.0 | 11.0 | | 4.0 | 6.5 |
| | | | 19-MAY-2017 | AUSDUN | P%EST | | 6.0 | 10.0 | | 3.0 | 5.5 |
| DEV-H-2017-EX-511-A-01.0-DE-VTH-126 | DESAMO | SILTY LOAM | 04-NOV-2016 | PHYTOX | P%UCC | 3.5 | 1.0 | 3.0 | 18 | 1.5 | 2.5 |
| | | | 15-NOV-2016 | PHYTOX | P%UCC | 10.0 | 2.0 | 6.5 | | 3.5 | 4.5 |
| | | | 15-NOV-2016 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 05-DEC-2016 | PHYTOX | P%UCC | 15.0 | 2.0 | 11.5 | | 2.0 | 5.5 |
| | | | 05-DEC-2016 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 15-MAR-2017 | PHYTOX | P%UCC | 65.0 | 4.0 | 35.0 | | 2.5 | 27.5 |
| | | | 15-MAR-2017 | AUSDUN | P%EST | 0.0 | 5.0 | 40.0 | | 0.0 | 32.5 |
| | | | 28-APR-2017 | PHYTOX | P%UCC | 55.0 | 0.0 | 27.5 | | 0.0 | 20.0 |
| DEV-H-2017-EX-511-B-01.0-DE-VTH-131 | JULIUS | SANDY LOAM | 04-NOV-2016 | PHYTOX | P%UCC | 5.0 | 2.0 | 5.0 | 18 | 0.0 | 0.0 |
| | | | 15-NOV-2016 | PHYTOX | P%UCC | 12.0 | 0.0 | 5.0 | | 0.0 | 2.5 |
| | | | 15-NOV-2016 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 05-DEC-2016 | PHYTOX | P%UCC | 20.0 | 0.0 | 7.5 | | 0.0 | 5.0 |
| | | | 15-MAR-2017 | PHYTOX | P%UCC | 45.0 | 27.5 | 15.0 | | 2.5 | 2.5 |
| | | | 15-MAR-2017 | AUSDUN | P%EST | 0.0 | 2.5 | 7.5 | | 0.0 | 0.0 |
| | | | 28-APR-2017 | PHYTOX | P%UCC | 50.0 | 10.0 | 12.5 | | 0.0 | 2.5 |

High levels of phytotoxic effects were observed in crops treated with both the N and 2N doses of the proposed product. Significant phytotoxicity was also observed in crops treated with both doses of the standard reference product. However, when considering all trials, the phytotoxicity observed is greater in those crops treated with the test product.

A high proportion of the selectivity trials in which significant phytotoxicity was observed were conducted in France. This reflects the data attained in the efficacy trials discussed previously. As in the efficacy trials the drilling depth of the French trials is lower than in trials conducted in other countries. HSE considers that a correlation has been demonstrated between shallow drilling depths and increased phytotoxicity. As such, label wording is required to mitigate

against the risk of shallow drilling of seeds. The following phrase is included on the proposed UK label: "*For pre-emergence treatments, seed should be sown into a fine, firm seedbed so that seed is adequately covered with a minimum of 3.0 cm of settled soil. With direct drilled crops, harrow across slits to cover the seed before spraying*." HSE considers that based on the results this wording is appropriate and relevant in all conditions.

In 3 of these trials a corresponding decrease in yield of over 5% was observed in crops treated with the N dose of the test product. In 2 of these trials an equivalent decrease in yield is observed in crops treated with the standard reference product. This suggests that another factor may have induced these negative crop effects. In trial "DEV-H-2017-DE-505-A-01.0-DE-D17-008" a yield decrease of 5.8% was observed in crops treated with the N dose of the proposed product. In this trial phytotoxicity of ~7% is observed at this dose. Whilst comparable levels of phytotoxicity were observed in crops treated with the reference product, no significant decrease in yield was recorded.

In each of these trials phytotoxicity of over 10% was observed in crops treated with the 2N dose. In 7 of these trials this corresponded to a yield decrease. Therefore, HSE considers that label warnings are required to warn against overlapping spray swaths leading to applications of 2N doses.

Post-emergence application

A total of 18 selectivity trials were assessed for phytotoxicity, with a proportion of these yielded.

No significant phytotoxicity was observed in any of the selectivity trials conducted. In 4 of the 18 trials minor (<5%) phytotoxic effects were observed. In these trials any crop injury appeared to be transient with no phytotoxic effect observed at the later trial assessments and no negative yield effects.

**Winter Barley (HORVW)**

A total of 47 selectivity trials were subjected to phytotoxicity assessments. Of the 47 selectivity trials conducted, 20 were carried out using pre-emergence application, a further 22 were conducted with an early post-emergence treatment (BBCH 10-14) and the final 5 were late post-emergence trials (BBCH 25-30). All trials were considered for phytotoxic effects, however only a proportion of these were yielded.

Pre-emergence application

20 selectivity trials were assessed for phytotoxicity following a pre-emergence application. All trials were conducted in the UK between 2016-18. All of these trials were subsequently yielded and quality parameters assessed.

In 14 of the 20 selectivity trials conducted, no phytotoxicity was observed in crops treated with the N dose of the product. In 3 of the remaining trials there was <5% phytotoxicity at the N dose. The remaining 3 trials in which >5% phytotoxicity was observed are presented below.

**HSE Table 33 – Selectivity trials with >5% phytotoxic effects (Pre-emergence)**

| Trial ID | Variety | Soil type | Eval Date | Assessed Variable (calculated) | Eval. Method | Untreated | BAS 684 H 0.667 L/HA 500 g.a.i.ha | BAS 684 H 1.333 L/HA 1000 g.a.i.ha | Standard Code | Standard 1n | Standard 2n |
|---|---|---|---|---|---|---|---|---|---|---|---|
| DEV-H-2017-UK-507-A03.0-UK-UK3-K05 | SY VENTURE | SANDY SILT | 01-DEC-2016 | PHYTOX | P%UCC | 15.0 | 0.0 | 0.0 | 28 | 0.0 | 0.0 |
| | | | 05-JAN-2017 | PHYTOX | P%UCC | 20.0 | 10.0 | 20.0 | | 0.0 | 0.0 |
| | | | 05-JAN-2017 | YGELBS | P%EST | 20.0 | 5.0 | 10.0 | | 0.0 | 0.0 |
| | | | 05-JAN-2017 | YNECRO | P%EST | 20.0 | 5.0 | 10.0 | | 0.0 | 0.0 |
| | | | 05-JAN-2017 | AUSDUN | P%EST | 0.0 | 10.0 | 20.0 | | 0.0 | 0.0 |
| | | | 20-JAN-2017 | PHYTOX | P%UCC | 20.0 | 20.0 | 32.5 | | 0.0 | 10.5 |
| | | | 20-JAN-2017 | AUSDUN | P%EST | 0.0 | 20.0 | 32.5 | | 0.0 | 10.5 |
| | | | 28-MAR-2017 | PHYTOX | P%UCC | 36.3 | 20.0 | 42.5 | | 2.8 | 10.0 |
| | | | 28-MAR-2017 | AUSDUN | P%EST | 0.0 | 20.0 | 42.5 | | 2.8 | 10.0 |
| | | | 04-MAY-2017 | PHYTOX | P%UCC | 70.0 | 20.0 | 42.5 | | 2.8 | 10.0 |
| | | | 04-MAY-2017 | AUSDUN | P%EST | 0.0 | 20.0 | 42.5 | | 2.8 | 10.0 |
| DEV-H-2017-UK-507-A03.0-UK-UK3-M04 | MARIS OTTER | SILTY SANDY LOAM | 05-OCT-2016 | PHYTOX | P%UCC | 10.0 | 0.0 | 0.0 | 28 | 0.0 | 0.0 |
| | | | 10-OCT-2016 | PHYTOX | P%UCC | 0.0 | 10.5 | 10.5 | | 5.0 | 0.0 |
| | | | 10-OCT-2016 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 10-OCT-2016 | YGELBS | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 10-OCT-2016 | YNECRO | P%EST | 0.0 | 10.5 | 10.5 | | 5.0 | 0.0 |
| | | | 24-OCT-2016 | PHYTOX | P%UCC | 10.0 | 10.5 | 10.5 | | 5.0 | 0.0 |
| | | | 24-OCT-2016 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 24-OCT-2016 | YGELBS | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 24-OCT-2016 | YNECRO | P%EST | 0.0 | 10.5 | 10.5 | | 5.0 | 0.0 |
| | | | 15-DEC-2016 | PHYTOX | P%UCC | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 13-APR-2017 | PHYTOX | P%UCC | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 27-APR-2017 | PHYTOX | P%UCC | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| DEV-H-2017-UK-507-A03.0-UK-UK3-Z02 | FLAGON | SILTY SANDY LOAM | 07-NOV-2016 | PHYTOX | P%UCC | 20.0 | 0.0 | 0.0 | 28 | 0.0 | 0.0 |
| | | | 07-NOV-2016 | YGELBS | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 25-NOV-2016 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 25-NOV-2016 | PHYTOX | P%UCC | 50.0 | 0.8 | 1.8 | | 0.0 | 0.0 |
| | | | 25-NOV-2016 | YGELBS | P%EST | 0.0 | 0.8 | 1.8 | | 0.0 | 0.0 |
| | | | 13-DEC-2016 | PHYTOX | P%UCC | 50.0 | 13.8 | 18.8 | | 0.0 | 0.0 |
| | | | 13-DEC-2016 | YGELBS | P%EST | 0.0 | 13.8 | 18.8 | | 0.0 | 0.0 |
| | | | 01-MAR-2017 | PHYTOX | P%UCC | 75.0 | 0.0 | 1.8 | | 0.0 | 0.0 |
| | | | 01-MAR-2017 | YGELBS | P%EST | 75.0 | 0.0 | 1.8 | | 0.0 | 0.0 |
| | | | 27-APR-2017 | PHYTOX | P%UCC | 100.0 | 0.0 | 5.0 | | 0.0 | 0.0 |
| | | | 27-APR-2017 | YGELBS | P%EST | 0.0 | 0.0 | 5.0 | | 0.0 | 0.0 |
| | | | 07-JUN-2017 | PHYTOX | P%UCC | 100.0 | 0.0 | 0.0 | | 0.0 | 0.0 |

In trial "DEV-H-2017-UK-507-A03.0-UK-UK3-K05" significant phytotoxicity was observed in crops treated with the N dose of the proposed product. Significantly lower phytotoxic effects were observed in those crops treated with the standard reference product. In addition to the crop injury observed, the yield was reduced in treated crops with a decrease of up to 21% in relation to the untreated. A significant decrease was also observed in those crops treated with the reference product; however, as with the phytotoxic effects this was not as pronounced as with the test product. The applicant has stated that the field was not consolidated after drilling. Similar phytotoxic effects were observed in Winter Wheat crops where no consolidation post-drilling was possible. As such, label warnings are required in the UK to avoid use of 'BAS 684 03 H' on non-consolidated soils.

In trial "DEV-H-2017-UK-507-A03.0-UK-UK3-M04" significant phytotoxicity of up to 10.5% was observed in crops treated with the N dose of the test product. In each assessment where phytotoxic effects were observed, effects were also seen in those crops treated with the reference product (5% phytotoxicity). The effects seen were transient in nature, with no negative symptoms observed at the later assessments. In this trial a yield reduction of 5.6% was observed in crops treated with the N dose of the proposed product. However, at the 2N dose, no significant yield reduction was observed. This suggests that the reason for this yield reduction is independent of the application of the test product.

In trial "DEV-H-2017-UK-507-A03.0-UK-UK3-Z02" significant phytotoxicity of up to 13.8% was observed in crops treated with the N dose of the test product. The effects seen were transient in nature, with no negative symptoms observed at the later assessments. Regardless of the crop injury observed, no negative yield effects were recorded in crops treated with the proposed product. No phytotoxicity was observed in crops treated with the standard reference product.

At the 2N dose, a much higher level of phytotoxicity was observed in a number of trials. This is similar to that recorded from selectivity trials in Winter Wheat and therefore stresses the importance of avoiding overlapping spray swaths leading to application of a 2N dose. A label warning is required to this effect.

Early post-emergence application (BBCH 10-14)

22 selectivity trials were assessed for phytotoxicity following a post-emergence application between crop growth stage (BBCH) 10-14. All trials were conducted in the UK between 2016-18. The majority of these trials were subsequently yielded and quality parameters assessed.

In 12 of the 22 selectivity trials conducted, no level of phytotoxicity was observed in crops treated with the N dose of the product. In 5 of the trials there was <5% phytotoxicity at the N dose. The remaining 5 trials in which significant phytotoxicity was observed are presented below.

**HSE Table 34 – Selectivity trials with >5% phytotoxic effects (early post-emergence)**

| | | | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| DEV-H-2017-UK-507-A-03.0-UK-UK3-K05 | SY VENTURE | SANDY SILT | | | | | | | 28 | | |
| | | | 05-JAN-2017 | PHYTOX | P%UCC | 20.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 05-JAN-2017 | YGELBS | P%EST | 20.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 05-JAN-2017 | YNECRO | P%EST | 20.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 05-JAN-2017 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 20-JAN-2017 | PHYTOX | P%UCC | 20.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 20-JAN-2017 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 28-MAR-2017 | PHYTOX | P%UCC | 36.3 | 7.5 | 16.8 | | 0.0 | 2.3 |
| | | | 28-MAR-2017 | AUSDUN | P%EST | 0.0 | 7.5 | 16.8 | | 0.0 | 2.3 |
| | | | 04-MAY-2017 | PHYTOX | P%UCC | 70.0 | 7.5 | 16.8 | | 0.0 | 2.3 |
| | | | 04-MAY-2017 | AUSDUN | P%EST | 0.0 | 7.5 | 16.8 | | 0.0 | 2.3 |
| DEV-H-2017-UK-507-A-03.0-UK-UK3-Z02 | FLAGON | SILTY SANDY LOAM | | | | | | | 28 | | |
| | | | 25-NOV-2016 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 25-NOV-2016 | PHYTOX | P%UCC | 50.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 25-NOV-2016 | YGELBS | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 13-DEC-2016 | PHYTOX | P%UCC | 50.0 | 8.8 | 15.0 | | 0.0 | 0.0 |
| | | | 13-DEC-2016 | YGELBS | P%EST | 0.0 | 8.8 | 15.0 | | 0.0 | 0.0 |
| | | | 01-MAR-2017 | PHYTOX | P%UCC | 75.0 | 1.3 | 20.0 | | 0.0 | 0.0 |
| | | | 01-MAR-2017 | YGELBS | P%EST | 75.0 | 1.3 | 20.0 | | 0.0 | 0.0 |
| | | | 27-APR-2017 | PHYTOX | P%UCC | 100.0 | 3.8 | 11.3 | | 0.0 | 0.0 |
| | | | 27-APR-2017 | YGELBS | P%EST | 0.0 | 3.8 | 11.3 | | 0.0 | 0.0 |
| | | | 07-JUN-2017 | PHYTOX | P%UCC | 100.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| DEV-H-2018-UK-508-C-01.0-UK-UK4-N12 | GLACIER | CLAY LOAM | 03-NOV-2017 | PHYTOX | P%UCC | 30.0 | 0.0 | 0.0 | 36 | 0.0 | 0.0 |
| | | | 03-NOV-2017 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 28-NOV-2017 | PHYTOX | P%UCC | 60.0 | 2.8 | 5.3 | | 0.3 | 0.0 |
| | | | 28-NOV-2017 | AUSDUN | P%EST | 0.0 | 2.8 | 5.3 | | 0.3 | 0.0 |
| | | | 22-JAN-2018 | PHYTOX | P%UCC | 80.0 | 9.3 | 15.0 | | 1.5 | 0.5 |
| | | | 22-JAN-2018 | AUSDUN | P%EST | 80.0 | 9.3 | 15.0 | | 1.5 | 0.5 |
| | | | 06-APR-2018 | PHYTOX | P%UCC | 90.0 | 6.3 | 11.3 | | 0.3 | 0.5 |
| | | | 06-APR-2018 | AUSDUN | P%EST | 0.0 | 6.3 | 11.3 | | 0.3 | 0.5 |
| DEV-H-2018-UK-521-A-01.0-UK-UK3-K05 | VENTURE | SANDY SILT | | | | | | | 34 | | |
| | | | 14-NOV-2017 | PHYTOX | P%UCC | 60.0 | 0.0 | 0.0 | | 2.0 | 8.0 |
| | | | 14-NOV-2017 | YGELBS | P%EST | 0.0 | 0.0 | 0.0 | | 2.0 | 8.0 |
| | | | 20-DEC-2017 | AUSDUN | P%EST | 0.0 | 5.0 | 7.5 | | 2.3 | 2.5 |
| | | | 20-DEC-2017 | PHYTOX | P%UCC | 25.0 | 5.0 | 7.5 | | 2.3 | 2.5 |
| | | | 18-JAN-2018 | PHYTOX | P%UCC | 30.0 | 4.3 | 10.0 | | 2.3 | 2.5 |
| | | | 18-JAN-2018 | AUSDUN | P%EST | 0.0 | 4.3 | 10.0 | | 2.3 | 2.5 |
| | | | 10-APR-2018 | PHYTOX | P%UCC | 60.0 | 0.0 | 35.0 | | 0.0 | 0.0 |
| | | | 10-APR-2018 | AUSDUN | P%EST | 0.0 | 0.0 | 35.0 | | 0.0 | 0.0 |
| | | | 24-APR-2018 | PHYTOX | P%UCC | 60.0 | 0.0 | 21.3 | | 0.0 | 0.0 |
| | | | 24-APR-2018 | AUSDUN | P%EST | 0.0 | 0.0 | 21.3 | | 0.0 | 0.0 |
| DEV-H-2018-UK-521-B-02.0-UK-UK3-J35 | BAZOOKA | CLAY LOAM | 30-OCT-2017 | PHYTOX | P%UCC | 10.0 | 0.0 | 0.0 | 34 | 0.0 | 0.0 |
| | | | 10-NOV-2017 | PHYTOX | P%UCC | 15.0 | 0.0 | 10.0 | | 0.0 | 0.0 |
| | | | 10-NOV-2017 | YBLHEL | P%UCC | 0.0 | 0.0 | 10.0 | | 0.0 | 0.0 |
| | | | 10-NOV-2017 | AUSDUN | P%EST | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 29-NOV-2017 | PHYTOX | P%UCC | 30.0 | 0.0 | 20.0 | | 0.0 | 0.0 |
| | | | 29-NOV-2017 | YBLHEL | P%UCC | 0.0 | 0.0 | 20.0 | | 0.0 | 0.0 |
| | | | 31-JAN-2018 | PHYTOX | P%UCC | 70.0 | 0.0 | 45.0 | | 0.0 | 0.0 |
| | | | 31-JAN-2018 | YBLHEL | P%UCC | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 31-JAN-2018 | AUSDUN | P%EST | 0.0 | 0.0 | 45.0 | | 0.0 | 0.0 |
| | | | 11-APR-2018 | PHYTOX | P%UCC | 80.0 | 5.0 | 63.8 | | 0.0 | 0.0 |
| | | | 11-APR-2018 | YBLHEL | P%UCC | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 11-APR-2018 | AUSDUN | P%EST | 0.0 | 5.0 | 63.8 | | 0.0 | 0.0 |
| | | | 08-MAY-2018 | PHYTOX | P%UCC | 95.0 | 8.0 | 70.0 | | 0.0 | 0.0 |
| | | | 08-MAY-2018 | YBLHEL | P%UCC | 0.0 | 0.0 | 0.0 | | 0.0 | 0.0 |
| | | | 08-MAY-2018 | AUSDUN | P%EST | 95.0 | 5.0 | 63.8 | | 0.0 | 0.0 |

In trial "DEV-H-2017-UK-507-A03.0-UK-UK3-K05" phytotoxicity of 7.5% was observed in the final two assessments in crops treated with the proposed dose of the test product. A yield reduction of 19.2% was also observed in these crops. Crops treated with the N dose of the standard reference product did not demonstrate any symptoms of phytotoxicity, although a significant decrease in yield of 6.2% was recorded. Whilst the yield effect observed is less in those crops treated with the standard reference product, as there was no evidence of crop injury in these crops this suggests that another factor may be contributing to the decrease in yield in treated crops. The applicant has stated

that the field was not consolidated after drilling. Similar phytotoxic effects were observed in Winter Wheat crops where no consolidation post-drilling was possible. As such, label warnings are required in the UK to avoid use of 'BAS 684 03 H' on non-consolidated soils.

In trial "DEV-H-2017-UK-507-C-01.0-UK-UK3-Z02" a maximum phytotoxicity of 8.8% was observed. The effects seen were transient in nature, with no negative symptoms observed at the later assessments. Further to this, no negative yield effects were observed at either the N or 2N dose.

In trial "DEV-H-2018-UK-508-A03.0-UK-UK4-N12" phytotoxicity of up to 9.3% was observed in crops treated with the proposed dose of 'BAS 684 03 H'. However, in this trial a significant yield increase was recorded in crops treated with the N and 2N doses of both the test and reference product. This suggests this trial was not truly 'weed-free' and as such questions the validity of the trial.

In trial "DEV-H-2018-UK-521-A-01.0-UK-UK3-K05" 5% phytotoxicity was recorded in crops treated with the N dose of 'BAS 684 03 H'. The effects appeared to be transient in nature, with no negative symptoms observed at the later assessments. However, a yield reduction of 5.1% was also recorded in these crops. No significant phytotoxic/yield effects were observed in crops treated with the reference product. The applicant has stated that the field was not consolidated after drilling.

In trial "DEV-H-2018-UK-521-B-02.0-UK-UK3-J35" phytotoxicity of up to 8% was observed in crops treated with the proposed dose of the test product. A yield reduction of 11.9% was also observed in these crops. A higher level of phytotoxicity and yield reduction was observed at the 2N dose. Crops treated with the N and 2N doses of the standard reference product did not demonstrate any symptoms of phytotoxicity, although a significant decrease in yield of 6.1% was recorded at the 2N dose. The applicant has stated that the field was not consolidated after drilling. Similar phytotoxic effects were observed in both Winter Wheat and other Winter barley trials where no consolidation post-drilling was practiced. As such, label mitigations are required in the UK to prohibit use of 'BAS 684 03 H' on non-consolidated soils.

As in the pre-emergence trials in Winter Barley and Winter Wheat, at the 2N dose a significantly higher level of phytotoxicity was observed in a number of the trials. This highlights the importance of avoiding overlapping spray swaths, leading to 2Napplications. Label wording is required to this effect.

<u>Late post-emergence application (BBCH 25-30)</u>

5 selectivity trials were assessed for phytotoxicity following a post-emergence application between crop growth stage (BBCH) 25-30. All trials were conducted in the UK between 2016-18. All trials were subsequently yielded and quality parameters assessed.

In 3 of the 5 selectivity trials conducted, no phytotoxicity was observed in crops treated with the both the N and 2N doses of the product. <5% levels of phytotoxicity were recorded in a single trial. The remaining trial in which significant phytotoxicity was observed is presented below.

**HSE Table 35 – Selectivity trials with >5% phytotoxic effects – (Late Post-emergence)**

| Trial ID | Variety | Soil type | Eval Date | Assessed Variable (calculated) | Eval. Method | Untreated | BAS 684 H 0.667 L/HA 500 g.a.i.ha | BAS 684 H 1.333 L/HA 1000 g.a.i.ha | Standard Code | Standard 1n | Standard 2n |
|---|---|---|---|---|---|---|---|---|---|---|---|
| DEV-H-2018-UK-508-D-01.0-UK-UK3-A10 | CARAT | CLAY | 13-APR-2018 | PHYTOX | P%UCC | 100.0 | 18.0 | 21.3 | 36 | 7.5 | 8.0 |
| | | | 13-APR-2018 | AUSDUN | P%EST | 0.0 | 18.0 | 21.3 | | 7.5 | 8.0 |
| | | | 08-MAY-2018 | PHYTOX | P%UCC | 100.0 | 3.0 | 0.5 | | 0.0 | 0.5 |
| | | | 08-MAY-2018 | AUSDUN | P%EST | 0.0 | 3.0 | 0.5 | | 0.0 | 0.5 |

In this trial significant phytotoxicity was observed in crops treated with the N dose of the test

| | |
|---|---|
| | product. Significant crop injury was also recorded in the N dose of the reference product; however, this is lower than the test product. The 2N doses of both products demonstrated a higher level of phytotoxicity at the 2N dose, with the test product causing more phytotoxicity. However, no significant yield decrease was recorded in any of the treated crops.<br><br>**HSE conclusion**<br><br>Phytotoxicity was observed in a number of the trials after application with the proposed and 2N doses. Therefore, HSE considers that extensive label warnings are required to mitigate the risk. These are discussed below.<br><br>In the pre-emergence Winter Wheat trials significant phytotoxicity was observed in a number of the French trials. In each of these trials seeds were shallow drilled to less than 3 cm. Although no Winter Barley trials were conducted to a shallow drilling depth it can be assumed that similar phytotoxicity would be expected if this was practiced. Therefore, label warnings are required to avoid application on crops drilled at a depth of less than 3 cm. The proposed UK label contains the phrase "*For pre-emergence treatments, seed should be sown into a fine, firm seedbed so that seed is adequately covered with a minimum of 3.0 cm of settled soil. With direct drilled crops, harrow across slits to cover the seed before spraying*." HSE considers that based on the results this wording is appropriate and relevant in all conditions. In addition to this, the phrase "*Shallow drilled crops should only be treated post-emergence*" must be added to the label.<br><br>In a number of the trials where significant phytotoxicity was observed the soils had not been consolidated post-drilling. These effects were present in both cereal crops tested. Therefore, HSE considers that label mitigations are required to avoid use of 'BAS 684 03 H' on non-consolidated soils. The following phrase appears on the proposed UK label "*Loose or cloddy seedbeds should be consolidated before treatment otherwise reduced weed control or crop damage may occur*". This must be amended to the following "*Loose or cloddy seedbeds must be consolidated before application otherwise reduced weed control or crop damage may result due to inadequate seed cover. Crop damage may lead to effects on yield.*"<br><br>Crops treated with the 2N dose generally demonstrated a significantly higher level of phytotoxicity compared to the N dose. This highlights the importance of avoiding spray overlaps. The phrase "*Do not overlap spray swathes*" has been included on the UK label. This must be amended to "*Care should be taken to avoid spray overlap, as crop damage may occur which may not be outgrown and may lead to reduced yield*". HSE considers that based on the high phytotoxicity and yield effects observed at the 2N dose this wording is appropriate and relevant in all conditions.<br><br>HSE notes that in the majority of these trials the soil types were recorded as sandy or light soils. It is not uncommon for residual herbicides to cause levels of phytotoxicity in lighter soil types. Use of this product in these situations is therefore not recommended. The phrase "*BAS 684 03 H is suitable for use on all soil types as defined by Soil Texture (85) System, except sands, very light soils and very stony or gravelly soils as there is an increased risk of crop damage*" is present on the proposed UK label. HSE considers that based on the results this wording is appropriate and relevant in all conditions.<br><br>The following statements are also present on the proposed UK label to address the phytotoxicity observed in the trials:<br><br>- *Do not use on water-logged soil or soils prone to water logging.* |

| | |
|---|---|
| | - *Do not disturb the soil after application.*<br><br>- *Do not apply BAS 684 03 H when heavy rain is forecast and do not use on waterlogged soil or soils prone to waterlogging. Crop thinning or reductions in crop vigour, which may result in yield reductions, can occur if there is very wet weather after application. If a crop check has occurred, this normally grows out after a few weeks and yields are normally unaffected.*<br><br>- *Do not apply BAS 684 03 H either alone or in tank mixture to crops suffering from stress, which may be caused, for example, by pests, disease, poor seedbed conditions, wind abrasion, nutrient deficiences or previous chemical treatment.*<br>*.*<br><br>- *Do not spray during periods of prolonged or severe frosts.*<br><br>- *Do not incorporate BAS 684 03H into the soil.*<br><br>These are considered sufficient to address further risks of phytotoxicity.<br><br>**HSE label amendments relating to phytotoxicity:**<br><br>) The phrase "*Loose or cloddy seedbeds should be consolidated before treatment otherwise reduced weed control or crop damage may occur*". must be amended to "*Loose or cloddy seedbeds must be consolidated before application otherwise reduced weed control or crop damage may result due to inadequate seed cover. Crop damage may lead to effects on yield.*"<br><br>) The phrase "*Do not overlap spray swathes*" must be amended to "*Care should be taken to avoid spray overlap, as crop damage may occur which may not be outgrown and may lead to reduced yield*".<br><br>) The phrase "*Shallow drilled crops should only be treated post-emergence*" must be added to the label. |

## B.3.12. OBSERVATIONS ON OTHER UNDESIRABLE OR UNINTENDED SIDE-EFFECTS

Rotational crop trials were conducted with the recommended dose rate of BAS 684 03 H (500 g cinmethylin/ha) in a range of other potential succeeding crops from various crop groups (brassicas, cereals, legumes, vegetables and cover crops). It can be concluded that, after a normal crop rotation, there are no negative effects on the following crops tested. The details of succeeding crops which may be planted following crop failure and subsequent to a normal harvest will be considered at product evaluation stage.

Trials were conducted to determine the potential impact on a range of adjacent crops. BASF have demonstrated that there is no substantive risk against any of the crops tested, even the most sensitive crops with the highest ER values. A more detailed assessment of the effects on adjacent crops will be included in the appropriate product evaluations.

## B.3.13. REFERENCES RELIED ON

| Data Point | Author(s) | Year | Title<br>Company<br>Report No.<br>Source (where different from company)<br>GLP or GEP status<br>Published or not | Vertebrate study Y/N | Data protection claimed Y/N | Justification if data protection is claimed | Owner | Previous evaluation |
|---|---|---|---|---|---|---|---|---|
| Document MCP section 3. | Mayer, F | 2018 | BAS 684 03 H: Data on application | N | | | BASF | N/A |