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| FINAL REGISTRATION REPORT  Part B  Section 3  Efficacy Data and Information  Concise summary |
| Product code: NIC-HER 060 OD  Product name: -  Chemical active substance:  nicosulfuron, 60 g/L |
| Central Zone  Zonal Rapporteur Member State: Poland |
| CORE ASSESSMENT  (authorization) |
| Applicant:  Pestila Spółka z ograniczoną odpowiedzialnością  Submission date: November 2021  MS Finalisation date: September 2023; December 2023 |

Version history

|  |  |
| --- | --- |
| When | What |
| September 2023 | ZRMs evaluated dRR submitted by Applicant. |
| December 2023 | The final Registration Report |
|  |  |
|  |  |

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# Efficacy Data and Information (including Value Data) on the Plant Protection Product (KCP 6)

**Transformation of the dRR (applicant version) into the RR (zRMS version)**

The process chosen by the zRMS to transform the dRR into a RR should be explained. Options are to rewrite the document (with track change or not) or to use commenting boxes such as the following:

|  |  |
| --- | --- |
| Comments of zRMS: | Comments of zRMS are presented in commenting boxes at the end of each chapter. The text of dRR was generally not changed or rewritten (small changes in the document are marked by grey colour). |

## Summary and conclusions of zRMS on Section 3: Efficacy (KCP 6)

Abstract

Comments of zRMS: Overall summaries are not necessary here. It was provided at the end of each chapter of the dRR.

| Table 3.1‑1: Acceptability of intended uses (and respective fall-back GAPs, if applicable) | | | | | | | | | | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 2 | 3 | 4 | 5 | 6 | 7 | 8 | 9 | 10 | 11 | 12 | 13 | 14 | 15 |
| Use-No. \* | Member state(s) | Crop and/ or situation  (crop destination / purpose of crop) | F, Fn, Fnp G, Gn, Gnp or I \*\* | Pests or Group of pests controlled  (additionally: developmental stages of the pest or pest group) | Application | | | | Application rate | | | PHI (days) | Remarks:   e.g. g safener/ synergist per ha, other dose rate expression, dose range (min-max) | zRMS  Conclusion  (efficacy) |
| Method / Kind | Timing / Growth stage of crop & season | Max. number  a) per use  b) per crop/ season | Min. interval between applications (days) | kg or L product / ha  a) max. rate per appl.  b) max. total rate per crop/season | g or kg as/ha  a) max. rate per appl.  b) max. total rate per crop/season | Water L/ha  min / max |
| Zonal uses (field or outdoor uses, certain types of protected crops) | | | | | | | | | | | | | | |
| 1 | PL | Maize | F | **Susceptible weeds at rate 0.5 L/ha:**  CAPBP – *Capsella bursa-pastoris* (Shepherds purse)  ECHCG - *Echinochloa crus-galli* (Common barnyard grass)  ~~LAMPU –~~ *~~Lamium purpureum~~* ~~(Purple deadnettle)~~  THLAR – *Thlaspi arvense* (Fanweed)  BRSNN *-Brassica napus* oilseed rape  **Susceptible weeds at rate 0.7 L/ha:**  CAPBP – *Capsella bursa-pastoris* (Shepherds purse)  ECHCG - *Echinochloa crus-galli* (Com-mon barnyard grass)  GALAP - *Galium aparine* (cleavers)  LAMPU – *Lamium purpureum* (Purple deadnettle)  STEME -*Stellaria media* (Common chickweed)  THLAR – *Thlaspi arvense* (Fanweed)  VIOAR – *Viola arvensis* (Field violet)  BRSNN *-Brassica napus* oilseed rape  *MATIN - Tripleurospermum inodorum*  **Moderately susceptible weeds at rate 0.5 L/ha:**  VIOAR – *Viola arvensis* (Field violet)  STEME – *Stellara media* (Common chickweed)  LAMPU – *Lamium purpureum* (Purple deadnettle)  **Moderately susceptible weeds at rate 0.7 L/ha:**  CHEAL – *Chenopodium album* (Fat-hen)  GERPU - *Geranium pusillum*  **Moderately tolerant at rate 0.5 L/ha**  CHEAL – *Chenopodium album* (Fat-hen)  **Resistant at rate 0.5 L/ha:**  ~~CHEAL –~~ *~~Chenopodium album~~* ~~(Fat-hen)~~  POLCO - *Fallopia convolvulus* (wild buckwheat)  GERPU - *Geranium pusillum*  *MATIN - Tripleurospermum inodorum*  **Moderately Resistant at rate 0.7 L/ha:**  POLCO - *Fallopia convolvulus* (wild buckwheat) | spraying | Spring  BBCH 12-17 | 1 | n.a | Spring  0.5-0.7 L/ha | Spring  30-42 g nicosulfuron | 200-300 L/ha | not relevant | not relevant | Acceptable |

\* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1.

\*\* F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

Column 15: zRMS conclusion.

|  |  |
| --- | --- |
| A | Acceptable |
| R | Acceptable with further restriction |
| C | To be confirmed by cMS |
| N | Not acceptable / evaluation not possible |
| n.r. | Not relevant for section 3 |

## Efficacy data (KCP 6)

Introduction

This is the application for registration of a plant protection product under working name NIC-HER 060 OD according to Article 33 of Regulation 1107/2009. NIC-HER 060 OD is a oil dispersion (OD) formula, containing 60g/L of active substance - nicosulfuron, to be used as a herbicide to control broadleaved weeds in maize. This is a core dossier in order to allow the approval of product NIC-HER 060 OD in Poland (zRMS).

Description of active substances

Active substances in NIC-HER 060 OD herbicide are: nicosulfuron (60 g/L) which is included into Annex I of Directive 91/414. Nicosulfuron is on the list of approved active substances (*Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances*). The active substance of the product is well known and commonly used in Poland and other EU countries. The efficacy of the substances has been proved in many trials and in crop protection practice.

Mode of action

The herbicide nicosulfuron is a substance which is rapidly absorbed by leaf tissue and later translocated via phloem and xylem to meristems. With its selective mode of action, which is acetolactate synthase inhibition, it inhibits the production of three branched-chain amino acids: isoleucine, leucine and valine. Nicosulfuron belongs to acetolactate synthase (ALS) inhibitors group of herbicides and belongs to HRAC group 2. It belongs to sulfonylureas chemical family, to which also belongs f.e. rimsulfuron and mesosulfuron methyl. Nicosulfuron controls a wide array of broadleaved weeds in maize, a crop which has an ability to metabolize it into inactive metabolites.

Table 3.2‑1: Details of the active substances

| Active substance | Nicosulfuron |
| --- | --- |
| Concentration | 60 g/L |
| Chemical group | Sulfonylurea |
| Mode of action | Acetolactate synthase inibition (ALS) |
| Biological action | Post-emergence herbicide |

Description of the plant protection product

NIC-HER 060 OD is a oil dispersion (OD) containing 60 g/L nicosulfuron active substance.

Table 3.2‑2: Simplified table of requested uses for the product code.

| Uses | | Member State | Requested rate(s) | Comments / Other relevant details on GAPs |
| --- | --- | --- | --- | --- |
| Crop(s) | Target(s) |
| Maize | CAPBP – *Capsella bursa-pastoris* (shepherd’s purse)  CHEAL - *Chenopodium album* (fat-hen)  ECHCG – *Echinochloa crus-galli* (common barnyard grass)  GALAP - *Galium aparine* (cleavers)  LAMPU – *Lamium purpureum* (purple deadnettle)  POLCO - *Fallopia convolvulus* (wild buckwheat)  STEME – *Stellaria media* (common chickweed)  THLAR – *Thlaspi arvense* (fanweed)  VIOAR – *Viola arvensis* (Field violet) | PL | 0.5 – 0,7 L/ha | - |

The applicant carried out efficacy trials on maize. Required selectivity trials are presented in point 3.4 – Adverse effects on treated crop.

Further details are in the table “All intended uses” in Part B - Section 0.

Description of the target pests

Table 3.2‑3: Glossary of pests mentioned in the dossier.

| EPPO code | Scientific name | Common name\* |
| --- | --- | --- |
| ARBTH | *Arabidopsis thaliana* | Common wallcress |
| BRSNN | *Brassica napus* | Oilseed rape |
| CAPBP | *Capsella bursa-pastoris* | Shepherd’s purse |
| CENCY | *Centaurea cyanus* | Cornflower |
| CHEAL | *Chenopodium album* | Fat-hen |
| CONAR | *Convulvulus arvensis* | Field bindweed |
| ECHCG | *Echinochloa crus-galli* | Common barnyard grass |
| GAETE | *Galeopsis tetrahit* | Common hemp nettle |
| GALAP | *Galium aparine* | Cleavers |
| GERPU | *Geranium pusillum* | Small-flower geranium |
| LYCAR | *Anchusa arvensis* | Small bugloss |
| LAMPU | *Lamium puprureum* | Purple deadnettle |
| MATIN | *Tripleurospermum inodorum* | False chamomile |
| PAPRH | *Papaver rhoeas* | Common poppy |
| POLCO | *Fallopia convolvulus* | Wild buckwheat |
| POLPE | *Persicaria maculosa* | Red-leg |
| RAPRA | *Rahanus raphanistrum* | Jointed charlock |
| STEME | *Stellaria media* | Common chickweed |
| THLAR | *Thlaspi arvense* | Fanweed |
| VICCR | *Vicia cracca* | Tinegrass |
| VERHE | *Veronica hederifolia* | Ivy-leaved speedwell |
| VERPE | *Veronica persica* | Bird’s-eye speedwell |
| VIOAR | *Viola arvensis* | Field pansy |

\* optional

Agricultural crop production has been the main branch of plant production in Poland for years. Season 2020 was analysed in this document since some data for 2021 have not been issued yet. Taking into consideration season 2020, following numbers were presented by the Statistics Poland:

Total arable land area reached 18 741 500 ha;

Total amount of sown area 13 603 022 ha.

In case of maize, in comparison to cereals, the situation differs significantly. Although, neither maize for grain nor for forage has a large proportion in the sown area structure of crops, it still has a great impact on agriculture in Poland. Maize is the most important fodder plant in our climatic zone, especially in terms of feed for dairy cattle.

|  |  |  |
| --- | --- | --- |
| **Maize:** | **Crop yield (t):** | **Sowing area (ha):** |
| For grain | 6 757 400 | 598 890 |
| For forage | 21 482 870 | 522 160 |

The above presented numbers show that sown area of maize in total exceeded 1.12 mln ha in 2020, which means that area of maize sown for grain and forage have decreased sligtly compared to 2019 (ca. 664,9k ha grain maize and 599,9k ha maize for forage).

Hence, an appropriate protection in terms of weeds, fungal diseases and to control insects in the aforementioned crop, is inevitable. Chemical control of weeds is highly important in production of agricultural crops, especially in maize because of its late sowing time and wide row spacing. Most of weeds species, which are present in maize, cause not only significant reduction of yield, but also deterioration of its quality parameters. Dicotyledonous (aka broadleaf) weeds are harmful for the crops, either because of their abundance, their competitiveness or difficulties involved in their control. Weeds are also known as intermediate host to many diseases and insects. In the case of some species, the problem is more due to their abundance (associated with a very large seed production and a high persistence of these seeds on the soil surface) rather than competitiveness with the crop. However, there are species, which produce high numbers of seeds although the competition with the crop can be quite high, especially in the early development stages of maize. Other weeds have very fast growing pace and can outcompete maize almost completely.

Weeds, which were present in field trials of NIC-HER 060 OD are the known as serious maize competitors. The results are showing that a lot of broadleaved weeds can be controlled by the product.

|  |  |
| --- | --- |
| **Weeds presented in field trials** | **Maize**  **Dose rate (l/ha)** |
| ARBTH *Arabidopsis thaliana* common walcress | x |
| BRSNN *Brassica napus* oilseed rape | x |
| CAPBP *Capsella bursa-pastoris* shepherd’s purse | 0,5-0,7 |
| CENCY *Centaurea cyanus* cornflower | x |
| CHEAL *Chenopodium album* fat-hen | 0,5R-0,7ms |
| CONAR ­*Convolvulus arvensis* field bindweed | x |
| ECHCG *Echinochloa crus-galli* common barnyard grass | 0,5-0,7 |
| GAETE ­*Galeopsis tetrahit* common hemp-nettle | x |
| GALAP *Galium aparine* cleavers | 0,7 |
| GERPU *Geranium pusillum* small-flower geranium | x |
| LYCAR *Anchusa arvensis* small bugloss | x |
| LAMPU *Lamium purpureum* purple deadnettle | 0,5-0,7 |
| MATIN *Tripleurospermum indorum* false chamomile | x |
| PAPRH *Papaver rhoeas* common poppy | x |
| POLCO *Fallopia convolvulus* wild buckwheat | 0,5R-0,7R |
| POLPE *Persicaria maculosa* red-leg | x |
| RAPRA *Raphanus raphanistrum* jointed charlock | x |
| STEME *Stellaria media* common chickweed | 0,5ms-0,7 |
| THLAR *Thlaspi arvense* fanweed | 0,5-0,7 |
| VICCR *Viccia cracca* tinegrass | x |
| VERHE *Veronica hederifolia* ivy-leaved speedwell | x |
| VERPE *Veronica persica* bird’s-eye speedwell | x |
| VIOAR *Viola arvensis* field pansy | 0.65ms-0,7 |

ms – moderately susceptible

R – resistant

x – not present

According to Statistics Poland means of production in agriculture in the farming year 2019 (latest year with sulfonylurea herbicides data available) such as herbicides, were commonly used in Poland. Sales of plant protection products (in commodity mass) such asherbicides, haulm destructors and moss killers aimed 11705,4 tonnes, out of whichherbicides based on sulfonylurea, such as nicosulfuron, reached 1296,2 tonnes.

Table 3.2‑4: Major / minor status of intended uses (for all cMS and zRMS).

| Crop and/or situation | Crop status | | Pests or group of pests controlled (included in GAP table by Applicant) | Pest status | |
| --- | --- | --- | --- | --- | --- |
| Major | minor | Major | minor |
| Maize | PL | - | Dicotyledonous weeds | PL | - |
| *Stellaria media, Capsella bursa-pastoris; Lamium purpureum; Thlaspi arvense; Galium aparine; Viola arvensis* | - | PL |
| *Echinochloa crus-galli; Chenopodium album; Fallopia convolvulus* | PL |  |

Compliance with the Uniform Principles

The assessment was performed according to the uniform principles and EPPO guidelines and with the principles of GEP.

Information on trials submitted (3.1 Efficacy data)

Table 3.2‑5: Presentation of trials (efficacy trials, preliminary trials...)

| Crop(s) \* | Target(s)\* | Country | Years | Type of trial\*\* | Number of trials  (number of valid trials) | GEP, non-GEP, official\*\*\* | Comments (any other relevant information) |
| --- | --- | --- | --- | --- | --- | --- | --- |
| North-East zone |
| Maize (post-emergence) | Dicotyledonous weeds | Poland | 2014; 2020; 2021 | MED + E | 12 (12) | GEP | - |
| TOTAL | Dicotyledonous weeds | Poland | 2014; 2020; 2021 | MED + E | 12 (12) | GEP | - |

\* According to the GAP table. Timing of the application(s) can be added if relevant (e.g. Pre-mergence vs post-emergence, spring vs autumn).

\*\* P = preliminary trial, MED = minimum effective dose, E = efficacy trial.

\*\*\* GEP: Good Experimental Practices. Official: carried out by a national official organisation.

Efficacy trials of NIC-HER 060 OD herbicide were carried out during three growing seasons, 2014, 2020 and 2021 in different regions of Poland. Map below presents locations of the trials in maize.

**Picture 1. A map of efficacy trial locations in maize (season 2014; 2020; 2021)**

Obraz zawierający mapa

Opis wygenerowany automatycznie

NIC-HER 060 OD trails in maize were made on 10 maize varieties in regions of Poland: Greater Poland, Kuiavian-Pomeranian voivodeship, Łódź voivodeship and Lower Silesia, differentiated on type of soil and climatic conditions.

In 2014 efficacy trials conducted by ANADIAG POLSKA were set in 2 different locations: Jerzmionki (Kuiavian-Pomeranian voivodeship) and Urzecze (Łódź voivodeship).

Trials PL 14 003 PL1; PL2 and PL6 were conducted on loamy sand, varieties sown there were: Subito, Nimba and LG 22 44. Trial PL 14 003 PL5 was situated in Jerzmionki (Kuiavian-pomeranian voivodeship), variety DKC 971 was sown there on sandy loam.

In 2020 all five efficacy trials, conducted by Eurofins Agroscience Services sp. z o. o., were set in Greater Poland, in 4 different locations on 5 different maize varieties:

1. Wychowaniec, LG Perley variety sown on sandy loam;
2. Brodziszewo, SY Werena variety sown on sandy loam and SY TALISMAN sown on loamy sand;
3. Sokolniki Małe, SY Multipass variety sown on loamy sand;
4. Morwino, SY Campona variety sown on sandy loam;

2021 efficacy trials conducted by Agreco Sp. z o.o., were set in Lower Silesia, on 3 maize varieties:

1. Pawłów, SY Talisman variety, grown on sand
2. Okrzeszyce, DKC 4098 variety, grown on loam
3. Wiązów, ES Faraday variety, grown on silt loam

All trials were conducted in randomized complete block design in four replications. Weed infestation Assessments were done between crop BBCH 12 and 85 in accordance with EPPO PP 1/50 (3) guideline.

Table 3.2‑6: Presentation of reference standards used in trials (efficacy trials)

| Crop(s) | Reference standard | Country(ies) where the product is registered (1) | Authorization number | Active substance(s) | Formulation | | Registered application  rate(3) | Application  rate in trials (per treatment) | Remark(4) |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Type(2) | Concentration of a.s. |
| Maize | Narval 040 OD | PL | R-19/2010 | nicosulfuron | OD | 40 g/L | 1 L/ha | 1 L/ha | 1. application per season;  200-400 L/ha of spray volume; foliar spray |
| Maize | Nikosar 060 OD | PL | R-869/2019b | nicosulfuron | OD | 60 g/L | 0.5-0,7 L/ha | 0.7 L/ha | 1. application per season;  200-300 L/ha of spray volume; foliar spray |
| Maize | Nicorn 040 SC | PL | R-R-57/2019d | nicosulfuron | SC | 40 g/L | 1 L/ha | 1 L/ha | 1. application per season;  200-300 L/ha of spray volume; foliar spray |

(1) only on use(s) applied for (with the test product).

(2) e.g. WP (wettable powder), EC (emulsifiable concentrate), etc.

(3) dose(s) / dose range authorized on that use in the country.

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application, etc.).

|  |  |
| --- | --- |
| Comments of zRMS: | This document summarizes the information related to the efficacy of the plant protection product – Nicorn Grande 060 OD (product code: NIC-HER 060 OD).  Nicorn Grande 060 OD is an oil dispersion (OD) formulation containing 60 g/L nicosulfuron. For now, this mentioned active substance is on the list of approved active substances. What is important, a large-scale efficacy trials are available to evaluate the effectiveness of products containing this active compound (nicosulfuron).  All necessary information’s about tested plant protection products, active substance, studied weed species, used reference products, etc. are correctly presented in this drr by Applicant.  Nicosulfuron belongs to acetolactate synthase (ALS) inhibitors group of herbicides and belongs to HRAC group 2. It belongs to sulfonylureas chemical family, to which also belongs i.e. rimsulfuron and mesosulfuron methyl. Nicosulfuron controls a wide array of broadleaved weeds in maize, a crop which has an ability to metabolize it into inactive metabolites.  In Poland 81 plant protection products containing nicosulfuron (based on the register of plant protection products, dated 31.08.2023) are already registered. The product – Nicorn Grande (product code: NIC-HER 060 OD) containing nicosulfuron by Pestila Spółka z ograniczoną odpowiedzialnością has not been previously evaluated in any country according to Uniform Principles. Poland is a ZRMs. |

### Preliminary tests (KCP 6.1)

No results of the preliminary range-finding tests are presented since no screening trials were carried out. However, the active substances of NIC-HER 060 OD, nicosulfuron, have been commonly used in agricultural practice for many years.

|  |  |
| --- | --- |
| Comments of zRMS: | Preliminary range-finding tests were not submitted by the Applicant. The active substances of Nicorn Grande 060 OD (product code: NIC-HER 060 OD) – nicosulfuron is registered and have been commonly used in agricultural practice for many years. Large scale efficacy trials are available to evaluate the effectiveness of products containing this active compound, so preliminary tests were not necessary in this case in our opinion. |

### Minimum effective dose tests (KCP 6.2)

Minimum effective dose tests were not carried out. However, several doses of NIC-HER 060 OD were tested during efficacy studies and the lowest effective dose was selected. The tests were conducted in accordance with EPPO standard PP 1/225 (2) ‘*Minimum effective dose’,* which advises on the minimum requirements necessary to ensure consistency of decision making.

Maize and dicotyledonous weeds

12 field trials were established to present the control of the dicotyledonous weeds in maize. NIC-HER 060 OD was tested in rates from 0.35 L/ha to 0.7 L/ha (21 – 42 g of nicosulfuron per hectare) in order to determine the minimum effective dose in maize for the control of dicotyledonous weeds. The rates reflect the proposed label rates, 60% and 80% of the lowest recommended rate, which in this case was 0,35/0.4 L/ha and 0,5 L/ha, of NIC-HER 060 OD, in accordance with the EPPO standard PP 1/225 (2) ‘*Minimum effective dose’*.

For the BBCH 12-17, the doses 0,35 and 0,4 L/ha of NIC-HER 060 OD provided inferior control when compared to 0.5-0.7 L/ha of NIC-HER 060 OD in 8 trials out of 8 trials.

Results of 2014 Nicorn 040 SC (NSF-GEN 040 SC) efficacy trials were used for this registration purposes. According to EPPO PP 1/307 and SANCO/12638/2011 such situation is allowed since non-significant change of the formulation occurs. According to EPPO PP 1/307 less than 10% difference in the amount of active substance is allowed. FAO spec for nicosulfuron in OD formulation also permits +/-10% difference of the declared content. Hence, the choice of specific doses for registration purposes. To compensate 50% higher amount of active substance in NIC-HER 060 OD formulation per 1L, dose of 0,7L/ha (42g of nicosulfuron/ha) was selected. In comparison to Nicorn 040 SC (NSF-GEN 040 SC) when used in dose of 1L/ha (40g of nicosulfuron) the amount of active substances in proposed label dose of 0,7 L/ha is 5% (2g of a.s.) more. This difference closes within 10% of tolerance mentioned in both EPPO PP 1/307, and FAO spec for nicosulfuron. Also, Nicorn 040 SC (NSF-GEN 040 SC) was selected as the one of reference product in 2020 efficacy field trials of the product NIC-HER 060 OD.

Table 3.2‑7: Minimum effective dose. Efficacy of NIC-HER 060 OD at proposed label rates, at 60% and 80% of the lowest recommended dose rate at BBCH 12-17 against dicotyledonous weeds in maize

| Grouping  \* | Number of trials | Infestation of the untreated control (unit) | |  | | % control with NIC-HER 060 OD | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 0,35/0.4 L/ha (60% of the lowest recommended rate) | | 0.5 L/ha (The lowest recommended rate) | | 0.7 L/ha  (Full rate) | |
| Mean | Min & Max | Mean | Min & Max | Mean | Min & Max | Mean | Min & Max |
| ARBTH | 1 | 6 | 6-6 | 93,5 | 93,5-93,5 | 97 | 97-97 | 100 | 100-100 |
| BRSNN | 2 | 6,4 | 5,4-7,7 | 97,3 | 97,3-97,3 | 100 | 100-100 | 100 | 100-100 |
| CAPBP | 4 | 5,7 | 5,4-6 | 85,9 | 81,5-88,5 | 88 | 73-95,3 | 97 | 93-100 |
| CENCY | 1 | 5 | 5-5 | - | - | - | - | 81,3 | 81,3-81,3 |
| CHEAL | 12 | 15,2 | 5,3-48,8 | 62,3 | 40-72 | 69 | 60-81,5 | 81,9 | 40-94,5 |
| CONAR | 1 | 8 | 8-8 | ~~60 -~~ | ~~60-60-~~ | ~~7,5-~~ | ~~7,5-7,5-~~ | ~~0~~ 7,5 | 0-0 7,5 |
| ECHCG | 7\* | 11,4 | 5,7-20 | 77,1 | 71-80,8 | 87,4 | 83-91,5 | 97,4 | 94-100 |
| GAETE | 1 | 6,8 | 6,8-6,8 | - | - | - | - | 100 | 100-100 |
| GALAP | 4 | 7,9 | 5,3-13 | - | - | - | - | 93,1 | 82,5-100 |
| GERPU | 2 | 9 | 8-10 | 45,5 | 43-48 | 56 | 54-58 | 75,5 | 73-78 |
| LAMPU | 4 | 5,6 | 5-6 | 79,4 | 70-89,5 | 85 | 73-95,3 | 92,6 | 85-100 |
| LYCAR | 1 | 10 | 10-10 | 68 | 68-68 | 73 | 73-73 | 89 | 89-89 |
| MATIN | 2 | 6,1 | 5,2-7 | 77,7 | 63-92,3 | 81 | 66-96 | 98 | 96-100 |
| PAPRH | 1 | 10 | 10-10 | 65 | 65-65 | 73 | 73-73 | 80 | 80-80 |
| POLPE | 1 | 5,5 | 5,5-5,5 | 50 | 50-50 | 58,3 | 58,3-58,3 | 71,5 | 71,5-71,5 |
| POLCO | 9 | 7,5 | 5-11 | 26,6 | 0-51 | 37,7 | 10-55 | 62,4 | 17,5-100 |
| RAPRA | 1 | 6 | 6-6 | 76 | 76-76 | 81,5 | 81,5-81,5 | 87,8 | 87,8-87,8 |
| STEME\*\* | 4 | 7,3 | 5,3-11 | 70,3 | 50-82,8 | 80,7 | 71-90 | 94,5 | 86-100 |
| THLAR | 4 | 5,5 | 5-6,1 | 81,8 | 65-90 | 88,7 | 71-96,3 | 96 | 88-100 |
| VERHE | 1 | 7 | 7-7 | 59 | 59-59 | 65 | 65-65 | 76 | 76-76 |
| VERPE | 1 | 8 | 8-8 | 36 | 36-36 | 46 | 46-46 | 66 | 66-66 |
| VICCR | 1 | 9 | 9-9 | 60 | 60-60 | 61 | 61-61 | 86 | 86-86 |
| VIOAR | 8 | 6,7 | 3,8-10 | 70,6 | 63-81,5 | 81,4 | 69-91,5 | 90,2 | 76,3-99 |

\*only monocot weed that occurred in the efficacy field trials

\*\* for the 0,5L/ha rate of NIC-HER 060 OD, there are only 3 trials in which common chickweed occurs. Such situation is allowed since this species in maize is listed as an minor pest for major crop in PL.

Summary and conclusions on the minimum effective dose

According to the presented results, 0.5-0.7 L/ha dosage of NIC-HER 060 OD provided the optimum overall control (higher dose is to be used when demanding weed species occur or infestation level is high) and should be considered as effective against dicotyledonous (and one monocotyledonous) weeds in maize, for which activity of NIC-HER 060 OD is claimed.

As a result, the proposed rate of 0.5 L/ha should be considered as the minimum effective dose to deliver broad spectrum control of dicotyledonous weeds under a wide range of environmental conditions.

|  |  |
| --- | --- |
| Comments of zRMS: | The applicant has proposed doses of Nicorn Grande 060 OD (product code: NIC-HER 060 OD) that reflect those of currently authorised nicosulfuron products across the EU. In order to provide information to establish the minimum effective dose, some of the trials conducted to demonstrate efficacy should include at least two lower dose(s) than recommended dose. In the appropriate research of efficacy were tested differ doses and to register was chosen the lowest effective, which is in accordance to EPPO 1/225 (2). Nicorn Grande 060 OD (product code: NIC-HER 060 OD) was tested at a range of dose rates, but to demonstrate minimum effective dose rate, the control obtained with NIC-HER 060 OD applied at maize during 12 trials (in total). Those trials were carried out in 2014, 2020 and 2021 in Poland (N-E EPPO zone).  Three different standard reference products in total were used during trials: Narval 040 OD (at dose 1,0 L/ha); Nikosar 060 OD (at dose 0,7 L/ha) and Nicorn 040 SC (at dose 1,0 L/ha).  Following doses were studied: 0,35 L/ha; 0,40 L/ha; 0,5 L/ha (the lowest recommended rate) and 0,7 L/ha (full rate).  Following varieties of maize were studied: in 2014 – Subito, Nimba, DKC 971, LG 2244; in 2020 – LG Perley, SY Werena, SY Multipass, SY Campona, SY Talisman and in 2021 – SY Talisman, DKC 4098, ES Forady.  Crop stage application at BBCH 13-15. Studied water volume: 200-400 L/ha.  Following weed species were studied: ARBTH (1 trial), BRSNN (2), CAPBP (4), CENCY (1), CHEAL (12), CONAR (1), ECHCG (7), GAETE (1), GALAP (4), GERPU (2), LAMPU (4), LYCAR (1), MATIN (2), PAPRH (1), POLPE (1), POLCO (9), RAPRA (1), STEME (4), THLAR (4), VERHE (1), VERPE (1), VICCR (1) and VIOAR (8).  Based on results achieved on dicotyledonous weeds and ECHCG in the 12 maize trials, it can be concluded that to consistently control frequently occurring weeds in maize, NIC-HER 060 OD should be applied early post-emergence at 0,5 l/ha and 0,7 L/ha. However, in the opinion of ZRMs, higher dose should be used in the case of higher infestation. |

### Efficacy tests (KCP 6.2)

A total of 12 trials were carried out in years 2014\*, 2020\*\* and 2021 to evaluate the efficacy of NIC-HER 060 OD for the control of weeds in maize in four different regions of Poland which were different by the type of soil and climatic conditions.

All trials were conducted in randomized complete block design in four replications. All treatments were performed using specialized plot application equipment, with 200-400 litres of working solution per hectare. All trials were conducted in compliance with GEP principles and following appropriate EPPO guidelines: EPPO PP 1/50 (3), EPPO PP 1/135 (4), EPPO PP 1/152 (4), EPPO PP 1/181 (4), EPPO PP 1/225 (2).

\* Results of 2014 Nicorn 040 SC (NSF-GEN 040 SC) efficacy trials were used for this registration purposes. According to EPPO PP 1/307 and SANCO/12638/2011 such situation is allowed since there is non-significant change of the formulation. According to EPPO PP 1/307 less than 10% in the amount of active substance is allowed. FAO spec for nicosulfuron in OD formulation also permits +/-10% difference of the declared content. Hence, the choice of specific doses for registration purposes. To compensate 50% higher amount of active substance in NIC-HER 060 OD formulation per 1L 0,7L/ha dose (42g of nicosulfuron/ha) was selected. In comparison to Nicorn 040 SC (NSF-GEN 040 SC) when used in dose of 1L/ha (40g of nicosulfuron) the amount of active substances in proposed label doses is 5% more for the dose 0,7L/ha. In both cases the difference closes within 10% of tolerance mentioned in both EPPO PP 1/307, and FAO spec for nicosulfuron.

\*\* In 2020 NIC-HER 060 OD efficacy trials, the product Nicorn 040 SC (NSF-GEN 040 SC) was used as reference product to show the fact that performance of NIC-HER 060 OD and NSF-GEN 040 SC is similar.

Table 3.2‑8: Details on methodology of efficacy trials in maize

|  |  |  |
| --- | --- | --- |
| **Guidelines** | General guidelines | EPPO PP 1/135 (4), 1/152 (4), 1/181 (4), |
| Specific guidelines | EPPO PP 1/50 (3) |
| **Experimental design** | Plot design | Randomized Complete Block RCBD |
| Plot size | 19,6-30 m² |
| Number of replications | 4 |
| **Crop** | Trials per crop | Maize (12) |
| Varieties per crop | Maize: LG Perley, SY Werena, SY Multipass, SY Campona, SY TALISMAN, Subito, Nimba, DKC 971, LG 22 44, DKC 4098, ES Faraday. |
| Sowing period | Maize: 8.04.2014 – 29.04.2014; 15.04.2020 – 21.04.2020; 24.04.2021-07.05.2021 |
| **Application** | Crop stage (BBCH)\*at application | Maize: BBCH 13 -15 |
| Timing  Pest stage at application (1) | ARBTH (BBCH 13-19)  BRSNN (BBCH 17)  CAPBP (BBCH 10-63)  CENCY (BBCH 23)  CHEAL (BBCH 13-22)  CONAR (BBCH 13)  ECHCG (BBCH 12-23)  GAETE (BBCH 16)  GALAP (BBCH 13-21)  GERPU (BBCH 14)  LAMPU (BBCH 14-22)  LYCAR (BBCH 14)  MATIN (BBCH 13)  PAPRH (BBCH 16)  POLPE (BBCH 11-21)  POLCO (BBCH 12-22) RAPRA (BBCH 13-19)  STEME (BBCH 14-33)  THLAR (BBCH 13)  VERHE (BBCH 13)  VERPE (BBCH 13)  VICCR (BBCH 12)  VIOAR (BBCH 12-23) |
| Number of applications  Intervals between applications | 1  N/A |
| Spray volumes | 200 - 400 L/ha |
| **Assessment** | Assessment types | weeds infestation level (no/m2) |
| Assessment dates | 0 DA-A, 14 DA-A, 27 DA-A, 28 DA-A, 29 DA-A, 52 DA-A, 56 DA-A, 87 DA-A, 91 DA-A, 93 DA-A, 98 DA-A, 108 DA-A |
| **Other relevant information** | e.g. Soil type, pH (in case of soil active substance …) | 1. Sandy loam pH 4.4 – 7,8  2. Loamy sand pH 7,5  3. Sandy clay loam pH 5,8 - 6,5  4. Sand pH 6,4  5. Loam pH 6.1  6. Silt loam pH 6,2 |
| e.g. Natural / artificial innoculation… | Natural |
| e.g. Field / Greenhouse... | Field |

\* BBCH for weeds, pre-emergence, preventive / curative application, insect stage…

Table 3.2‑9: Efficacy of active substance components in NIC-HER 060 OD

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Grouping  \* | Number of trials | Infestation of the untreated control (number of plants) | | % control | | | | | | | | No of trials where NIC-HER 060 OD at full recommended dose  is >, <, =  compared to standard(s)\*\* |
| NIC-HER 060 OD  30g nicosulfuron /ha | | NIC-HER 060 OD  42g nicosulfuron /ha | | Nikosar 060 OD  42g nicosulfuron /ha | | Nicorn 040 SC  40g nicosulfuron /ha | |
| Mean | Min & Max | Mean | Min & Max | Mean | Min & Max | Mean | Min & Max | Mean | Min & Max |
|  | [-] | Plants/m2 | Plants/m2 | % | % | % | % | % | % | % | % | [-] |
| ARBTH | 1 | 6 | 6-6 | 97 | 97-97 | 100 | 100-100 | 100 | 100-100 | - | - | - |
| BRSNN | 2 | 6,4 | 5,4-7,3 | 100 | 100-100 | 100 | 100-100 | 98 | 98-98 | - | - | - |
| CAPBP | 4 | 5,7 | 5,4-6 | 88 | 73-95,3 | 97 | 93-100 | 97,5 | 94-100 | 86 | 86-86 | 1 trials >  2 trials =  1 trials < |
| CENCY | 1 | 5 | 5-5 | - | - | 81,3 | 81,3-81,3 | - | - | - | - | - |
| CHEAL | 12 | 15,2 | 9-48,8 | 69 | 60-81,5 | 81,7 | 40-94,5 | 85,6 | 85-91,5 | 76,6 | 75-80 | 3 trials >  5 trials =  0 trials < |
| CONAR | 1 | 8 | 8-8 | - | - | 7,5 | 7,5-7,5 | - | - | - | - | - |
| ECHCG | 7 | 11,4 | 5,7-20 | 87,4 | 83-91,5 | 97,4 | 95-100 | 96 | 93,5-99 | 94,7 | 89-99 | 4 trials >  0 trials =  1 trials < |
| GAETE | 1 | 6,8 | 6,8-6,8 | - | - | 100 | 100-100 | - | - | - | - | - |
| GALAP | 4 | 7,9 | 5,3-13 | - | - | 93,1 | 82,5-100 | - | - | - | - | - |
| GERPU | 2 | 9 | 8-10 | 56 | 54-58 | 75,5 | 73-78 | 76 | 73-79 | 71 | 68-74 | 0 trials >  1 trials =  1 trials < |
| LAMPU | 4 | 5,6 | 5-6 | 84,5 | 73-95,3 | 92,6 | 85-100 | 93,8 | 89-98,8 | 83 | 81-85 | 2 trials >  0 trials =  2 trials < |
| LYCAR | 1 | 10 | 10-10 | 73 | 73-73 | 89 | 89-89 | 89 | 89-89 | 89 | 89-89 | 0 trials >  1 trials =  0 trials < |
| MATIN | 2 | 6,1 | 5,2-7 | 81 | 66-96 | 98 | 96-100 | 97,5 | 95-100 | 89 | 89-89 | 1 trials >  1 trials =  0 trial < |
| PAPRH | 1 | 10 | 10-10 | 73 | 73-73 | 80 | 80-80 | 80 | 80-80 | 80 | 80-80 | 0 trials >  1 trials =  0 trial < |
| POLCO | 9 | 7,5 | 5-11 | 37,7 | 10-55 | 62,4 | 17,5-100 | 48,8 | 15-74 | 81,6 | 75-89 | 4 trials >  0 trials =  3 trial < |
| STEME | 4 | 7,3 | 5,3-11 | 80,7 | 71-90 | 94,5 | 86-100 | 93 | 86-99 | 91 | 85-97 | 2 trials >  1 trials =  0 trials < |
| THLAR | 4 | 5,5 | 5-6,1 | 88,7 | 71-96,3 | 96 | 88-100 | 96,1 | 89-100 | 86 | 86-86 | 1 trials >  2 trials =  1 trials < |
| VERHE | 1 | 7 | 7-7 | 65 | 65-65 | 76 | 76-76 | 78 | 78-78 | 76 | 76-76 | 0 trial >  0 trials =  1 trials < |
| VERPE | 1 | 8 | 8-8 | 46 | 46-46 | 66 | 66-66 | 64 | 64-64 | 60 | 60-60 | 1 trial >  0 trials =  0 trials < |
| VICCR | 1 | 9 | 9-9 | 61 | 61-61 | 86 | 86-86 | 85 | 85-85 | 81 | 81-81 | 1 trial >  0 trials =  0 trials < |
| VIOAR | 8 | 6,7 | 3,8-10 | 81,4 | 69-91,5 | 90,2 | 76,3-99 | 89,7 | 89-96 | 87,7 | 84-90 | 4 trial >  0 trials =  2 trials < |

\* A, B, C can be a “trial group” (as defined in page 10, e.g. EPPO climatic zone A) or a specific target (e.g. weed A, weed B...). In order to adapt the table to the data presented, it is possible:

- to add lines or columns,

- to duplicate the table (e.g. one table for “trial group 1”, one table for “trial group 2”, one table for “all”).

\*\* Optional (only compared to Nikosar 060 OD)

According to statistical analysis, data assessed in trials demonstrated that the efficacy of NIC-HER 060 OD in control of weeds in maize at the proposed rate of 0.7 L/ha was equivalent (there was no statistically significant difference between the results) to the efficacy of Nikosar 060 OD at rate of 0.7 L/ha.

Statistical analysis also shows that the performance of NIC-HER 060 OD in dose 0,7 L/ha and Nicorn 040 SC (NSF-GEN 040 SC, in 1 L/ha rate) was comparable or similar for 5 weed species listed in GAP: 4 dicots (CHEAL, STEME, VIOAR, POLCO) and 1 monocot (ECHCG).

Also within the rest of weeds species which occurred in 2020 trials (GERPU, VERPE, PAPRH, LYCAR, THLAR, VERHE, CAPBP, LAMPU), after statistical analysis, performance was comparable, if not the same, for NIC-HER 060 OD in dose of 0,7 L/ha and Nicorn 040 SC (NSF-GEN 040 SC) in dose of 1L/ha.

Minor use

Not relevant.

Yield (and relevant quality indicators), from efficacy trials (in the presence of challenging pest populations)

Not relevant.

Summary and conclusion

12 trials were conducted to confirm efficacy of NIC-HER 060 OD in control of dicotyledonous and monocotyledonous weeds in maize. NIC-HER 060 OD showed its effectiveness in control of weed species listed below, in maize at the proposed label rates:

0,5 L/ha –

Susceptible weeds:

Shepherd’s purse (*Capsella bursa-pastoris*), common barnyard grass (*Echinochloa crus-galli*), purple deadnettle (*Lamium purpureum*), fanweed (*Thlaspi arvense*)

Moderately susceptible weeds:

Field pansy (*Viola arvensis*), common chickweed (*Stellaria media*)

Resistant weeds:

Fat hen (*Chenopodium album*), wild buckwheat (*Fallopia convolvulvulus*),

0,7 L/ha –

Susceptible weeds:

Shepherd’s purse (*Capsella bursa-pastoris*), common barnyard grass (*Echinochloa crus-galli*), cleavers (*Galium aparine*), purple deadnettle (*Lamium purpureum*), common chickweed (*Stellaria media*), fanweed (*Thlaspi arvense*), field pansy (*Viola arvensis*)

Moderately susceptible weeds:

Fat hen (*Chenopodium album*)

Resistant weeds:

Wild buckwheat (*Fallopia convolvulvulus*)

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Comments of zRMS: | EPPO Standard PP 1/226 Number of efficacy trials provides guidance on the number of trials in target crops needed to demonstrate the efficacy of a plant protection product at the recommended dose. Where authorization is sought across a range of diverse conditions, such as across an authorization zone (PP 1/278 Principles of zonal data production and evaluation), then the number of trials conducted may need to increase. These trials should be done across the range of climatic and environmental conditions likely to be encountered, and over at least 2 years.  The applicant was notified that according to PP 1/226 at least 6 trials are required**.** Applicant submitted in total 12 efficacy trials carried out in Poland (N-E EPPO zone) in 2014, 2020 and 2021.Only trials with greater than 5 weeds/m2 were taken for assessment. In all trials level of infestation was acceptable.  The field experiments of the herbicide – NIC-HER 060 OD were carried out by testing unit mandated to conduct research in the field of efficacy of plant protection products by the Chief Inspector of Plant Health and Seed Inspection and are officially GEP recognized. The reports include a detailed data about conditions, agro-technological procedures, fore-crop as well as technical details etc. Submitted efficacy trials are correctly performed according to appropriate EPPO standards (some exceptions will be described later).  Following varieties of maize were studied: in 2014 – Subito, Nimba, DKC 971, LG 2244; in 2020 – LG perley, SY Werena, SY Multipass, SY Campona, SY Talisman and in 2021 – SY Talisman, DKC 4098, ES Forady.  Three different standard reference products in total were used during trials: Narval 040 OD (at dose 1,0 L/ha); Nikosar 060 OD (at dose 0,7 L/ha) and Nicorn 040 SC (at dose 1,0 L/ha).  Crop stage application at BBCH 13-15. Studied water volume: 200-400 L/ha.  For Poland we should use different scale: S (susceptible) > 85%; MS (moderately susceptible) 70-85%; MT (moderately tolerant) 60-70%; T (tolerant) < 60%.  We are dealing with the active substances used commonly for many years in many countries. So, in the list of weeds controlled should include only those species that occurred (with appropriate intensity) a minimum of two localizations, and in the case of the species with the highest hazard of the plants at least in four locations.  The applicant submitted a statement that the trade name of the plant protection product Nicorn Grande 060 OD and the working names of the product NIC-HER 060 OD and Nevada 60 OD, which appears in the registration dossiers refer to the same mixture. Also, the names Nicorn Grande 060 OD and NIC-HER 060 OD and Nevada 60 OD are the same. NIC-HER was studied in 5 efficacy reports carried out in 2020 and Nevada 60 OD was studied in 3 efficacy reports performed in 2021.  In 4 reports from 2014 – NSF-GEN 040 SC at dose 1,0 L/ha was studied. Keeping in mind the allowable deviation in dose per hectare, in efficacy tests (+/- 5%) the agent NIC-HER 060 OD was tested at a dose of 0.7 L/ha - which gives 42 g/ha of active ingredient. The dose of active ingredient per hectare for NSF-GEN 040 SC is 40 g. Thus, the difference in the content of the active ingredient in the efficacy tests of the two formulations is 2g/ha, which is exactly the acceptable +/- 5%-t deviation. Also, in Part C for both products, the only difference in the formulations is that 20 g/L more of the active ingredient nicosulfuron was added to NIC-HER 060 OD relative to NSF-GEN 040 SC, subtracting rapeseed oil at this point. Additionally, analysing Volume 1 of the DAR for the active ingredient nicosulfuron also shows that the representative formulation for the approval of this active ingredient was the product code SL-950 4% SC however, section 1.4.3 indicates that: "The formulated product is referred by notifier (and in this document) as an SC formulation. However, according to Crop Life International it is in fact Oil dispersion (OD) formulation."  **ZRMs accepted all trials for evaluating process.** Below, ZRMs presented efficacy from a field studies. In trials from 2014 only dose 0,7 l/ha was studied, in trials from 2020 – doses: 0,4 l/ha; 0,5 l/ha; 0,65 l/ha; 0,7 l/ha and in trials from 2021 following doses were studied: 0,35 l/ha; 0,5 l/ha and 0,7 l/ha.   |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | | **Weed species**  **(EPPO code)** | **Eff. of dose**  **0,35 L/ha** | **Eff. of dose**  **0,40 l/ha** | **Eff. of dose**  **0,5 l/ha** | **Eff. of dose**  **0,65 l/ha** | **Eff. of dose**  **0,7 l/ha** | | **ARBTH** (1) | 93,5 | - | 97 | - | 100 | | **BRSNN** (2) | 97,3 | - | 100 | - | 100; 100 | | **CAPBP** (4) | 88,5; 87,8; 81,5 | 70 | 73; 95,3; 93,5; 90 | 88 | 93; 100; 100; 95 | | **CENCY** (1) | - | - | - | - | 81,3 | | **CHEAL** (12) | 72; 69 | 60; 63; 65; 40; 64 | 64; 65; 70; 60; 85; 81,5; 75,3 | 74; 78; 74; 74; 70 | 85; 88; 85; 85; 92,5; 85; 94,5; 91,5; 40; 89,8; 66,3; 76,3 | | **CONAR** (1) | - | - | - | - | 7,5 | | **ECHCG** (7) | 80,8 | 76; 80; 71 | 85; 88; 83; 91,5 | 93; 95; 91 | 97; 100; 95; 97; 97; 100; 98,8 | | **GAETE** (1) | - | - | - | - | 100 | | **GALAP** (4) | - | - | - | - | 97,5; 100; 82,5; 66,3 | | **GERPU** (2) | - | 43; 48 | 54; 58 | 60; 60 | 73; 78 | | **LAMPU** (4) | 89,5; 87 | 71; 70 | 78; 73; 95,3; 91,5 | 85; 75 | 81; 85; 100; 94,5 | | **LYCAR** (1) | - | 68 | 73 | 80 | 89 | | **MATIN** (2) | 92,3 | 63 | 66; 46 | 85 | 96; 100 | | **PAPRH** (1) | - | 65 | 73 | 79 | 80 | | **POLPE** (1) | 50 | - | 58,3 | - | 71,5 | | **POLCO** (9) | 25; 0 | 24; 20; 28; 38; 51 | 38; 31; 41; 55; 55; 33,8; 10 | 51; 44; 55; 68; 63 | 54; 50; 61; 17,5; 100; 75; 69; 37,5; 97,3 | | **RAPRA** (1) | 76 | - | 81,5 | - | 87,8 | | **STEME** (4) | 82,8 | 78; 50 | 81; 71; 90 | 97; 74 | 100; 86; 94,5; 81,3 | | **THLAR** (4) | 90; 89,3; 82,8 | 65 | 71; 96,3; 95,8; 91,5 | 85 | 88; 100; 100; 96 | | **VERHE** (1) | - | 59 | 65 | 74 | 76 | | **VERPE** (1) | - | 36 | 46 | 61 | 66 | | **VICCR** (1) | - | 60 | 61 | 78 | 86 | | **VIOAR** (8) | 81,5; 76,3; 71,5 | 65; 66; 63 | 75; 78; 69; 91,5; 87,8; 87,3 | 85; 86; 79 | 90; 90; 88; 99; 76,3; 81,3; 96; 93,5 |   Following weed species should be deleted due to not enough number of trials: ARBTH (1 trial), CENCY (1 trial), CONAR (1 trial), GAETE (1 trial), LYCAR (1 trial), PAPRH (1 trial), VERHE (1 trial), VERPE (1 trial) and VICCR (1 trial).  **Below we present a list of weed species for which at least two studies have been submitted:**   * **BRSNN** – minor weed – 2 trials (average: 6,4 weeds/m2) – S at 0.5 L/ha (average: 100%) and 0,7 L/ha (average: 100%). * **CAPBP** – minor weed – 4 trials (average: 5,7 weeds/m2) – S at 0.5 L/ha (average: 87,95%) and 0,7 L/ha (average: 97,0%) * **CHEAL** – major weed – 12 trials (average: 15,2 weeds/m2) – MT (average: 68,69%) at 0.5 L/ha and MS (average: 81,58%) at 0,7 L/ha * **ECHCG** – major weed – 7 trials (average: 11,4 weeds/m2) – S at 0.5 L/ha (average: 86,88%) and 0,7 L/ha (average: 97,83%) * **GALAP** – minor weed – 4 trials (average: 7,9 weeds/m2) – S (average: 86,58%) at 0.7 L/ha. Dose 0,5 L/ha was not studied. * **GERPU** – minor weed – 2 trials (average: 9.0 weeds/m2) – T (average: 56,0%) at 0.5 L/ha and MS (average: 75,5%) at 0,7 L/ha * **LAMPU** – minor weed – 4 trials (average: 5,6 weeds/m2) – MS (average: 84,45%) at 0.5 L/ha and S (average: 90,13%) at 0,7 L/ha * **MATIN** – minor weed – 2 trials (average: 6,1 weeds/m2) – T (average: 56,0%) at 0.5 L/ha and S (average: 98,0%) at 0,7 L/ha * **POLCO** – major weed – 9 trials (average: 7,5 weeds/m2) – T (average: 37,69%) at 0.5 L/ha and MT (average: 62,37%) at 0,7 L/ha * **STEME** – minor weed – 4 trials (average: 7,3 weeds/m2) – MS (average: 80,67%) at 0.5 L/ha and S (average: 90,45%) at 0,7 L/ha * **THLAR** – minor weed – 4 trials (average: 5,5 weeds/m2) – S at 0.5 L/ha (average: 88,65%) and 0,7 L/ha 9average: 96,0%) * **VIOAR** – minor weed – 8 trials (average: 6,7 weeds/m2) – MS (average: 81,43%) at 0.5 L/ha and S (average: 89,26%) at 0,7 L/ha.   **In Polish label following weeds species can be included:**   * **Dose 0,5 L/ha**: *Susceptible weeds*: BRSNN, CAPBP, ECHCG, THLAR; *Moderately susceptible weeds*: LAMPU, STEME, VIOAR; *Moderately tolerant weeds*: CHEAL; *Tolerant weeds*: GERPU, POLCO, MATIN. * **Dose 0,7 L/ha:** *Susceptible weeds:*BRSNN, CAPBP, ECHCG, GALAP, LAMPU, MATIN, STEME, THLAR, VIOAR; *Moderately susceptible weeds:* CHEAL, GERPU; *Moderately tolerant weeds*: POLCO.   This plant protection product (NIC-HER 060 OD) can be used on corn crops intended for grain, silage or bioethanol production (as such varieties were tested). |

## Information on the occurrence or possible occurrence of the development of resistance (KCP 6.3)

According to the HRAC code list active substance of NIC-HER 060 OD, nicosulfuron, is an ALS-inhibiting herbicide (Chemical Family: Sulfonylurea) classified in Group 2. ALS is a key enzyme responsible for biosynthesis of amino acids such as valine, leucine and isoleucine. Susceptible weeds exposed to nicosulfuron show various injuries as: inhibition of plant growth, shortening of internodes, purplish foliage, and shortening of lateral roots, resulting in plant death, caused by deficiency in branched-chain amino acids.

ALS-inhibiting herbicides are used in all major agronomic crops and have been widely adopted due to their low dose rates and high efficacy against a broad spectrum of weeds, relatively low mammalian toxicity, mild toxicological profile, and excellent crop selectivity. However, the widespread use of ALS-inhibiting herbicides led to rapid selection of many resistant weed populations. ALS-resistant weeds represent the fastest-growing group of herbicide-resistant weeds worldwide, with 41 (12 in Europe) monocot and dicot weeds found worldwide to be resistant to just nicosulfuron.

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Comments of zRMS: | Nicorn Grande (product code: NIC-HER 060 OD) contain nicosulfuron. Its activity is based on the inhibition of the acetolactate synthase enzyme (ALS). Nicorn Grande 060 OD (NIC-HER 060 OD) is a post-emergence herbicide for the control of weeds in maize.  Nicosulfuron, with the chemical name 2-[(4,6-dimethoxypyrimidin-2-ylcarbamoyl)sulfamoyl]-*N*,*N*-dimethylnicotinamide (IUPAC), belongs to the chemical group of Sulfonylureas. Nicosulfuron is a selective herbicide for post emergence applications against weeds in maize across all climatic zones of Europe.  Nicosulfuron acts by inhibiting the action of acetolactate synthase (ALS), also known as acetohydroxyacid synthase (AHAS). Without this enzyme, the plant cannot produce specific amino acids (isoleucine, leucine and valine) thereby preventing protein formation. This effectively prevents growth at the growing points of the plant, namely the apical meristem and root tip. Due to the primary target site and the chemical subgroup, rimsulfuron is classified as a HRAC group B herbicide (Imidazolinones and others). In the WSSA resistance classification system the Sulfonylureas are classified as group 2.  There are a couple of mechanisms known to cause resistance towards the ALS’s. As mentioned earlier crop tolerance is mainly caused by rapid metabolism of the herbicide. There has been reports of the same type of resistance in *Lolium rigidum* (Annual Ryegrass) (Christopher et al., 1991), but most reports concurrent describes changes in the target site as the reason for weed resistance (Hanson et al, 2004, Reed et al., 1989; Saari et al., 1990; Saari et al. 1992, Smith et al, 1988; Thill et al., 1989; Tranel & Wright, 2002). Whether it might be a combination of enhanced metabolism and target site changes (Manley et al., 1999) or an overproduction of ALS (Harms et al. 1992) causing resistance has also been aired.  Target site resistance is caused by alterations in the ALS gene. ALS functions in the plastids but is coded in the nucleus, therefore it follows normal Mendelian inheritance. Mutations in the ALS gene, causing herbicide resistance, can therefore be spread by both pollen and seeds (Smith et al. 1988; Tranel & Wright, 2002). The ALS gene is to a high degree conserved in between plant biotypes. So far, at least five conserved amino acids have been identified in the ALS gene and substitution in one of them is known to cause resistance in various plants (Tranel & Wright, 2002). Whether other mutations in the plant can cause resistance is most likely, both regarding enhanced metabolism and especially target site alterations. Since all the ALS’s are active towards a single target site, cross resistance is a well-known phenomenon in this group of chemicals. It is therefore important to keep the label recommended limitations concerning the frequency by which the ALS should be used.  Resistance toward herbicides with different modes of action has also been proven. Studies of *Amaranthus hybridus* showed that resistance towards atrazine (Photosystem II inhibitor) and ALS inhibiting herbicides occurred in the same biotypes but that the reason for resistance was located on different genes (Maertens et al., 2003).  Multiple-resistance between ALS inhibiting herbicides, ACCase inhibitors e.g. clodinafop and Arylaminopropionic acids e.g. Flamprop-M was reported in 1994 in the UK in several wild oats biotypes (Heap, 2012).  The following table shows the current worldwide resistance weeds according to <http://www.weedscience.org>:  **Reported cases of resistance to nicosulfuron**   | **#** | [**Year**](javascript:__doPostBack('ctl00$Main$RadGrid1$ctl00$ctl02$ctl00$ctl01','')) | [**Species**](javascript:__doPostBack('ctl00$Main$RadGrid1$ctl00$ctl02$ctl00$ctl02','')) | [**Country**](javascript:__doPostBack('ctl00$Main$RadGrid1$ctl00$ctl02$ctl00$ctl03','')) | [**MOAs**](javascript:__doPostBack('ctl00$Main$RadGrid1$ctl00$ctl02$ctl00$ctl06','')) | [**Actives**](javascript:__doPostBack('ctl00$Main$RadGrid1$ctl00$ctl02$ctl00$ctl07','')) | [**Situations**](javascript:__doPostBack('ctl00$Main$RadGrid1$ctl00$ctl02$ctl00$ctl08','')) | | --- | --- | --- | --- | --- | --- | --- | | **1** | 2011 | [*Echinochloa crus-galli var. crus-galli*](http://www.weedscience.org/Pages/Case.aspx?ResistID=6747) | Austria | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **2** | 1993 | [*Bidens pilosa*](http://www.weedscience.org/Pages/Case.aspx?ResistID=42) | Brazil | ALS inhibitors (B/2) | imazethapyr, imazaquin, pyrithiobac-sodium, chlorimuron-ethyl, nicosulfuron | Soybean | | **3** | 1996 | [*Bidens subalternans*](http://www.weedscience.org/Pages/Case.aspx?ResistID=1195) | Brazil | ALS inhibitors (B/2) | imazethapyr, chlorimuron-ethyl, nicosulfuron | Soybean | | **4** | 2001 | [*Raphanus sativus*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5201) | Brazil | ALS inhibitors (B/2) | imazethapyr, chlorimuron-ethyl, metsulfuron-methyl, nicosulfuron, cloransulam-methyl | Wheat | | **5** | 2004 | [*Euphorbia heterophylla*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5215) | Brazil | ALS inhibitors (B/2), PPO inhibitors (E/14) | imazethapyr, metsulfuron-methyl, nicosulfuron, diclosulam, flumetsulam, cloransulam-methyl, fomesafen, lactofen, acifluorfen-sodium, flumiclorac-pentyl, saflufenacil | Corn (maize), Soybean | | **6** | 2000 | [*Solanum ptycanthum*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5211) | Canada (Ontario) | ALS inhibitors (B/2) | imazethapyr, prosulfuron, nicosulfuron, rimsulfuron, primisulfuron-methyl, flumetsulam, imazamox | Corn (maize), Soybean | | **7** | 2001 | [*Setaria viridis*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5124) | Canada (Ontario) | ALS inhibitors (B/2) | imazethapyr, pyrithiobac-sodium, nicosulfuron, flucarbazone-sodium | Corn (maize), Soybean | | **8** | 2009 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5693) | Chile | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **9** | 2010 | [*Digitaria sanguinalis*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5656) | China | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **10** | 2014 | [*Alopecurus aequalis*](http://www.weedscience.org/Pages/Case.aspx?ResistID=10954) | China | ACCase inhibitors (A/1), ALS inhibitors (B/2) | quizalofop-P-ethyl, fenoxaprop-P-ethyl, nicosulfuron, flucarbazone-sodium, mesosulfuron-methyl, penoxsulam, pinoxaden | Wheat | | **11** | 2014 | [*Alopecurus japonicus*](http://www.weedscience.org/Pages/Case.aspx?ResistID=10955) | China | ACCase inhibitors (A/1), ALS inhibitors (B/2) | fenoxaprop-P-ethyl, pyribenzoxim, sulfosulfuron, nicosulfuron, mesosulfuron-methyl, pyroxsulam | Wheat | | **12** | 1996 | [*Kochia scoparia*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5050) | Czech Republic | ALS inhibitors (B/2), Photosystem II inhibitors (C1/5) | imazapyr, sulfosulfuron, thifensulfuron-methyl, chlorsulfuron, triflusulfuron-methyl, tribenuron-methyl, prosulfuron, metsulfuron-methyl, nicosulfuron, rimsulfuron, atrazine | Railways, Roadsides | | **13** | 2011 | [*Setaria viridis*](http://www.weedscience.org/Pages/Case.aspx?ResistID=9933) | France | ALS inhibitors (B/2) | nicosulfuron, foramsulfuron | Corn (maize) | | **14** | 2015 | [*Digitaria sanguinalis*](http://www.weedscience.org/Pages/Case.aspx?ResistID=11010) | France | ALS inhibitors (B/2) | nicosulfuron, foramsulfuron | Corn (maize) | | **15** | 2011 | [*Stellaria media*](http://www.weedscience.org/Pages/Case.aspx?ResistID=6744) | Germany | ALS inhibitors (B/2) | thifensulfuron-methyl, amidosulfuron, triflusulfuron-methyl, tribenuron-methyl, nicosulfuron, imazamox, florasulam, iodosulfuron-methyl-sodium, tritosulfuron, mesosulfuron-methyl, pyroxsulam | Spring Barley, Wheat, Rapeseed | | **16** | 2012 | [*Echinochloa crus-galli var. crus-galli*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5738) | Germany | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **17** | 2012 | [*Amaranthus retroflexus*](http://www.weedscience.org/Pages/Case.aspx?ResistID=6742) | Germany | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **18** | 2009 | [*Echinochloa phyllopogon (=E. oryzicola)*](http://www.weedscience.org/Pages/Case.aspx?ResistID=13052) | Greece | ALS inhibitors (B/2) | bispyribac-sodium, nicosulfuron, rimsulfuron, imazamox, foramsulfuron, penoxsulam | Rice | | **19** | 2015 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=17119) | Hungary | ALS inhibitors (B/2) | nicosulfuron, foramsulfuron | Corn (maize), Fallow | | **20** | 2003 | [*Amaranthus retroflexus*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5248) | Italy | ALS inhibitors (B/2) | imazethapyr, thifensulfuron-methyl, nicosulfuron, oxasulfuron, imazamox | Soybean | | **21** | 2005 | [*Echinochloa crus-galli var. crus-galli*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5356) | Italy | ALS inhibitors (B/2) | bispyribac-sodium, azimsulfuron, nicosulfuron, imazamox, penoxsulam | Corn (maize), Rice | | **22** | 2007 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=8905) | Italy | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **23** | 2009 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5475) | Mexico | ALS inhibitors (B/2) | nicosulfuron, rimsulfuron, primisulfuron-methyl, foramsulfuron | Corn (maize) | | **24** | 2014 | [*Ixophorus unisetus*](http://www.weedscience.org/Pages/Case.aspx?ResistID=9925) | Mexico | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **25** | 2014 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=15065) | Serbia | ALS inhibitors (B/2) | nicosulfuron, rimsulfuron, imazamox, pyroxsulam, propoxycarbazone-sodium | Corn (maize) | | **26** | 2015 | [*Echinochloa crus-galli var. crus-galli*](http://www.weedscience.org/Pages/Case.aspx?ResistID=11016) | Spain | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **27** | 2015 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=11000) | Spain | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **28** | 2016 | [*Amaranthus palmeri*](http://www.weedscience.org/Pages/Case.aspx?ResistID=18204) | Spain | ALS inhibitors (B/2) | nicosulfuron | Corn (maize), Roadsides | | **29** | 2017 | [*Echinochloa crus-galli var. crus-galli*](http://www.weedscience.org/Pages/Case.aspx?ResistID=17113) | Ukraine | ALS inhibitors (B/2) | imazapyr, nicosulfuron, imazamox, penoxsulam | Rice | | **30** | 2000 | [*Sorghum bicolor*](http://www.weedscience.org/Pages/Case.aspx?ResistID=7861) | United States (Illinois) | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **31** | 2007 | [*Setaria faberi*](http://www.weedscience.org/Pages/Case.aspx?ResistID=7862) | United States (Illinois) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron | Corn (maize), Soybean | | **32** | 2004 | [*Setaria faberi*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5520) | United States (Indiana) | ALS inhibitors (B/2) | nicosulfuron, rimsulfuron | Corn (maize) | | **33** | 2005 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5282) | United States (Indiana) | ALS inhibitors (B/2) | nicosulfuron | Corn (maize), Soybean | | **34** | 2006 | [*Sorghum bicolor*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5281) | United States (Indiana) | ALS inhibitors (B/2) | nicosulfuron, foramsulfuron | Corn (maize), Soybean | | **35** | 1996 | [*Sorghum bicolor*](http://www.weedscience.org/Pages/Case.aspx?ResistID=500) | United States (Kansas) | ALS inhibitors (B/2) | nicosulfuron, primisulfuron-methyl | Corn (maize) | | **36** | 1992 | [*Amaranthus hybridus (syn: quitensis)*](http://www.weedscience.org/Pages/Case.aspx?ResistID=490) | United States (Kentucky) | ALS inhibitors (B/2) | imazethapyr, imazaquin, thifensulfuron-methyl, chlorimuron-ethyl, nicosulfuron, primisulfuron-methyl, flumetsulam | Soybean | | **37** | 2006 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=7880) | United States (Kentucky) | ALS inhibitors (B/2) | nicosulfuron, primisulfuron-methyl, foramsulfuron | Corn (maize) | | **38** | 2006 | [*Setaria faberi*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5290) | United States (Michigan) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, foramsulfuron | Corn (maize), Soybean | | **39** | 1996 | [*Setaria faberi*](http://www.weedscience.org/Pages/Case.aspx?ResistID=503) | United States (Minnesota) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, primisulfuron-methyl | Corn (maize), Soybean | | **40** | 1996 | [*Setaria viridis var. major (=var. robusta-alba, var. robustapurpurea)*](http://www.weedscience.org/Pages/Case.aspx?ResistID=504) | United States (Minnesota) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, primisulfuron-methyl | Corn (maize), Soybean | | **41** | 2013 | [*Amaranthus spinosus*](http://www.weedscience.org/Pages/Case.aspx?ResistID=16081) | United States (Mississippi) | ALS inhibitors (B/2) | imazethapyr, pyrithiobac-sodium, nicosulfuron, trifloxysulfuron-sodium | Cotton, Soybean | | **42** | 1994 | [*Amaranthus tuberculatus (=A. rudis)*](http://www.weedscience.org/Pages/Case.aspx?ResistID=1083) | United States (Missouri) | ALS inhibitors (B/2) | imazethapyr, imazaquin, thifensulfuron-methyl, chlorimuron-ethyl, prosulfuron, nicosulfuron, halosulfuron-methyl, primisulfuron-methyl, flumetsulam, imazamox | Corn (maize), Cotton, Soybean | | **43** | 2015 | [*Ambrosia artemisiifolia*](http://www.weedscience.org/Pages/Case.aspx?ResistID=13036) | United States (North Carolina) | ALS inhibitors (B/2), EPSP synthase inhibitors (G/9), PPO inhibitors (E/14) | nicosulfuron, cloransulam-methyl, fomesafen, lactofen, acifluorfen-sodium, glyphosate | Corn (maize), Soybean | | **44** | 2000 | [*Sorghum bicolor*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5235) | United States (Ohio) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, primisulfuron-methyl | Corn (maize) | | **45** | 2002 | [*Amaranthus tuberculatus (=A. rudis)*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5156) | United States (Oklahoma) | ALS inhibitors (B/2) | imazethapyr, imazaquin, chlorimuron-ethyl, nicosulfuron, primisulfuron-methyl | Corn (maize), Soybean | | **46** | 2001 | [*Sorghum bicolor*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5121) | United States (Pennsylvania) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron, oxasulfuron, primisulfuron-methyl, imazamox | Corn (maize), Soybean | | **47** | 2004 | [*Setaria faberi*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5259) | United States (Pennsylvania) | ALS inhibitors (B/2) | nicosulfuron, imazamox, foramsulfuron | Corn (maize) | | **48** | 2000 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5091) | United States (Texas) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron | Corn (maize) | | **49** | 2003 | [*Sorghum bicolor*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5204) | United States (Virginia) | ALS inhibitors (B/2) | imazethapyr, imazapyr, nicosulfuron | Corn (maize) | | **50** | 2004 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=7775) | United States (West Virginia) | ALS inhibitors (B/2) | nicosulfuron | Corn (maize) | | **51** | 1999 | [*Setaria faberi*](http://www.weedscience.org/Pages/Case.aspx?ResistID=1171) | United States (Wisconsin) | ALS inhibitors (B/2) | imazethapyr, nicosulfuron | Corn (maize), Soybean | | **52** | 2004 | [*Rottboellia cochinchinensis (=R. exaltata)*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5566) | Venezuela | ALS inhibitors (B/2) | nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron | Corn (maize) | | **53** | 2010 | [*Sorghum halepense*](http://www.weedscience.org/Pages/Case.aspx?ResistID=5553) | Venezuela | ALS inhibitors (B/2) | nicosulfuron, iodosulfuron-methyl-sodium, foramsulfuron | Corn (maize) |   Resistance to sulfonylureas is well documented, with the first case recorded in United States in 1987. Since then, further cases have been reported including grass and broad-leaved weed resistance in Europe.  Weeds vary in their sensitivity towards herbicides both between and within populations, and this natural variation should be understood before shifts in sensitivity can be assessed. ALS inhibitors have been tested and used worldwide for almost 40 years, and it is therefore difficult to find unexposed weed populations. No true base line sensitivity data can therefore be established.  It can be concluded that the overall agronomic resistance risk implemented by NIC-HER 060 OD has to be regarded as high under current normal European agricultural practice.  The increasing occurrence of dicotyledonous biotypes with ALS resistance in Europe emphasizes an increasing risk of resistance evolution for ALS active sub- stances. In addition, many target species can be regarded as high-risk species and ALS inhibitors are frequently used in other main crop species in central Europe. The general resistance risk of NIC-HER 060 OD is therefore assessed as being high.  The ZRMs suggests general management strategies according to Good Agricultural Practice and to reduce selection pressure to minimize the risk of resistance development to NIC-HER 060 OD in dicotyledonous weeds and *Echinochloa crus-galli*.  **To avoid resistance, it is important to have a reasonable crop rotation and respect the label recommended application rates and doses. Resistance has often developed where mono-cropping, reduced tillage and subsequent use of ALS inhibitors has been practiced.**  In order to responsibly manage and maintain the activity of the active substances in NIC-HER 060 OD, it is recommended that resistance management strategies are applied. The commercial product should be used in rotation with herbicides with a different mode of action that are also active against the target weeds, cultural and mechanical practices should be implemented when possible and appropriate, monoculture situations should be avoided, destruction of all seeds produced by the weeds not controlled by the herbicide application is recommended. In addition, a monitoring program to determine any shifts in sensitivity toward the product will be also implemented**.** |

## Adverse effects on treated crops (KCP 6.4)

The applicant carried out 6 selectivity trials of maize.

EPPO PP 1/226(3) standard also states - it is required to conduct at least 8 phytotoxicity trials per major crop, usually within 2 years/2 growing seasons. For the object of this registration, herbicide NIC-HER 060 OD, only 6 phytotoxicity trials were made. PP 1/226 allows such reduction of trial number if the formulations are very similar. Also Polish national regulations are saying that at least 6 selectivity trials are required for the products with active substance already known and registered to be used in crops. Minimal amount of crop safety trials for such situation is listed in EPPO PP 1/307 which states that typically 3-5 trials are required. Additionally one of the submitted selectivity trials is from 2014 and was carried out with use of NSF-GEN 040 SC, to show the fact that NIC-HER 060 OD performs the same also in the matters of selectivity.

According to SANCO/12638/2011 and EPPO PP 1/307, products are very simillar if there is less than 10% difference in the amount of active substance in the product. FAO spec for nicosulfuron in OD formulation also permits +/-10% difference of the declared active ingredient content. Intended dosage for NIC-HER 060 OD is 0,5-0,7 L/ha, for the phytotoxicity trials higher dose was selected. 0,7 L/ha of NIC-HER 060 OD contains 42g of nicosulfuron per hectare, while Nicorn 040 SC (NSF-GEN 040 SC) in dose of 1L/ha contains 40 g of nicosulfuron per hectare. The difference between products and doses listed above is 5%, and it closes within 10% of tolerance mentioned in both EPPO PP 1/307 and FAO spec for nicosulfuron.

All the trials have been presented in point 3.4 – 1.

Table 3.4‑1: Presentation of trials (selectivity trials, transformation trials...)

| **Crop\*** | **Country** | **Type of trial\*\*** | **Number of trials**  **(North-East zone)** | **Years** | **GEP, non-GEP, official\*\*\*** | **Comments (any other relevant information)** |
| --- | --- | --- | --- | --- | --- | --- |
| Maize | Poland | S | 12 | 2014; 2020; 2021 | GEP |  |
| S + Y | 6 |
| S + Y + Q | 6 |
| **TOTAL** | - | S | **12** | - | - |  |
| S + Y | **6** |
| S + Y + Q | **6** |

According to the GAP table

\*\* S = selectivity trial, Y = trial with yield assessment, Q = trial with quality assessment, T = trial on the basis of the study of impact on transformation process (TP: Physical transformation, TF: transformation involving microbial fermentation), P = trial with assessment of impact on propagation

\*\*\* Official: carried out by a national official organisation

Table 3.4‑2: Presentation of reference standards used in trials (selectivity trials, transformation trials...)

| **Trial number** | **Crop(s)** | **Reference standards** | **Country(ies) where the product is registered(1)** | **Authorization number** | **Active substance(s) (a.s)** | **Formulation** | | **Registered application**  **rate(3)** | **Application**  **rate in trials (per treatment)** | **Remark(4)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Type(2)** | **Concentration  of a.s.** |
| III 6.2.1/01  (S-M-PL-2020-S20-03780-01) | Maize | Nikosar 060 | Poland | R-34/2016 | Nicosulfuron | OD | 60 g/l (nicosulfuron) | 0.7 L/ha | 0,7-1,4 L/ ha |  |
| III 6.2.1/02  (S-M-PL-2020-S20-03780-02) | Maize | Nikosar 060 | Poland | R-34/2016 | Nicosulfuron | OD | 60 g/l (nicosulfuron) | 0.7 L/ha | 0,7-1,4 L/ ha |  |
| III 6.2.1/03  (S-M-PL-2020-S20-03780-03) | Maize | Nikosar 060 | Poland | R-34/2016 | Nicosulfuron | OD | 60 g/l (nicosulfuron) | 0.7 L/ha | 0,7-1,4 L/ ha |  |
| III 6.2.1/04  (S-M-PL 14 007 PL1) | Maize | Narval 040 OD | Poland | R-19/2010 | Nicosulfuron | OD | 40 g/l (nicosulfuron) | 1 L/ha | 1-2 L/ha |  |
| III 6.2.1/05  (S-M-PL-2021- 21PRO0927-1) | Maize | Nikosar 060 | Poland | R-34/2016 | Nicosulfuron | OD | 60 g/l (nicosulfuron) | 0.7 L/ha | 0,7-1,4 L/ ha |  |
| III 6.2.1/06  (S-M-PL-2021- 21PRO0927-2) | Maize | Nikosar 060 | Poland | R-34/2016 | Nicosulfuron | OD | 60 g/l (nicosulfuron) | 0.7 L/ha | 0,7-1,4 L/ ha |  |

(1) only on use(s) applied for (with the test product)

(2) e.g.WP (wettable powder), EC (emulsifiable concentrate), etc.

(3) Dose / dose range authorized in the country

(4) Other relevant information (e.g. uses, number of applications, spray volume, method of application…)

### Phytotoxicity to host crop (KCP 6.4.1)

Table 3.4‑3: Phytotoxicity of product

| **Number of trials with…** | | **Selectivity trials (~~4~~ 6 trials)** | | | | **Efficacy trials (~~8~~ 12 trials)** | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **Test product** | | **Standard 1** | | **Test product** | **Standard 1** |
| **N** | **2N (or other)** | **N** | **2N (or other)** | **N** | **N** |
| **Maximum of phytotoxicity recorded during the trials** | 0% to 5% | 6 | 6 | 6 | 6 | 12 | 12 |
| >5% to 10% | 0 | 0 | 0 | 0 | 0 | 0 |
| >10% to 15% | 0 | 0 | 0 | 0 | 0 | 0 |
| >15 % | 0 | 0 | 0 | 0 | 0 | 0 |
| **Level of symptoms at the last assessments** | 0% to 5% | 6 | 6 | 6 | 6 | 12 | 12 |
| >5% to 10% | 0 | 0 | 0 | 0 | 0 | 0 |
| >10% to 15% | 0 | 0 | 0 | 0 | 0 | 0 |
| >15 % | 0 | 0 | 0 | 0 | 0 | 0 |

18 trials were carried out on maize in Poland, in years 2014, 2020 and 2021 on a wide range of commercially grown varieties.

No phytotoxicity symptoms caused by NIC-HER 060 OD at the proposed dose rate of 0,5 and 0,7 L/ha, nor by NSF-GEN 040 SC at the rate of 1 L/ha, were recorded in all trials.

|  |  |
| --- | --- |
| Comments of zRMS: | In the evaluation process the fact that the active ingredient –nicosulfuron is used in many plant protection products and have been commonly used in crop protection for many years were taken into consideration by ZRMs.  The Applicant submitted in total 6 selectivity studies conducted in different seasons (2014, 2020 and 2021) on herbicide (NIC-HER 060 OD) containing this active substance. The selectivity evaluation of the herbicide was performed according to appropriate EPPO guidelines. The evaluation of herbicide selectivity was carried out 4-5 per season. Results were described in percent of destruction of plant for herbicides treatment compared to plant for untreated, where 0% means no phytotoxicity and 100% - complete destruction.  Phytotoxicity assessment was carried out with the use of different cultivars (commercially grown varieties: DKC 3969; ES Perspective; LG 30.233; Talisman; Verena and Perley). Dosages N (recommended) and 2N (doubled recommended) were studied in all trials. Experimental details and assessments methods were in accordance to EPPO standards. Detailed information’s are presented by Applicant. The trials were conducted in the North-East EPPO zone (Poland) to evaluate the crop safeties of NIC-HER 060 OD in maize crops. BBCH of crop during application: 12-18. Also, phytotoxicity effect was studied during 12 efficacy trials at dose 0,5 L/ha (lower recommended dose) and 0,7 L/ha (full N dose).  In the opinion of Evaluator Applicant submitted sufficient documentation for Poland for maize. **No phytotoxicity symptoms caused by NIC-HER 060 OD at the proposed dose rate of 0,5 and 0,7 L/ha, nor by NSF-GEN 040 SC at the rate of 1 L/ha, were recorded in all trials. However, due to the possibility of phytotoxicity symptoms on some corn varieties (especially new varieties), before applying Nicorn Grande 060 OD to these varieties, it is recommended to carry out a trial treatment on each crop to check for symptoms of plant damage or contact your advisor or representative of the authorization holder. Under unfavourable conditions for the growth and development of corn after the application of the product, transient leaf distortion, discoloration and plant stunting may occur.** Such a provision was also proposed by the Applicant in the label. |

### Effect on the yield of treated plants or plant product (KCP 6.4.2)

Table 3.4‑4: Relationship between phytotoxicity and yield

6 trials were carried out on maize in Poland in 2014, 2020 and 2021 seasons, on a range of commercially grown varieties.

| **Test report** | **Variety** | **Maximum phyto. at 1N rate (%) (DAA)** | | **Maximum phyto. at 2N (or other) rate (%) (DAA)** | | **Yield in the untreated control**  **Absolute figures (unit)** | **Yield at 1N as % of untreated** | | **Yield at 2N (or other) rate as % of untreated** | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Test product** | **Standard 1** | **Test product** | **Standard 1** | **Test product** | **Standard 1** | **Test product** | **Standard 1** |
| III 6.2.1/01  (S-M-PL-2020-S20-03780-01) | Talisman | n.a. | n.a. | n.a. | n.a. | 8,27 t/ha | 100% | 99,1% | 101,2% | 98,4% |
| III 6.2.1/02  (S-M-PL-2020-S20-03780-02) | Verena | n.a. | n.a. | n.a. | n.a. | 8,24 t/ha | 100% | 105,4% | 100,9% | 100,6% |
| III 6.2.1/03  (S-M-PL-2020-S20-03780-03 | Perley | n.a. | n.a. | n.a. | n.a. | 9,37 t/ha | 98,3% | 100,1% | 99,4% | 100,8% |
| III 6.2.1/04  (S-M-PL 14 007 PL1) | LG 30.233 | n.a. | n.a. | n.a. | n.a. | 4,3 t/ha | 100% | 102,3% | 100% | 100% |
| III 6.2.1/05  (S-M-21PRO0927-1) | DKC 3969 | n.a. | n.a. | n.a. | n.a. | 8,7 t/ha | 103,4% | 102,3% | 104,6% | 100% |
| III 6.2.1/06  (S-M-21PRO0927-1) | ES Perspective | n.a. | n.a. | n.a. | n.a. | 9,7 t/ha | 101% | 102,1% | 100% | 101% |

In 6 trials listed above, NIC-HER 060 OD at the proposed label rate of 0.7 L/ha, and NSF-GEN 040 SC at the rate of 1 L/ha, had no negative effect on the maize grain yield in the absence of weed.

|  |  |
| --- | --- |
| Comments of zRMS: | The effect of the test product on maize yield was assessed in six selectivity trials carried out in the North-East EPPO zone (PL). Dose N (0,7 L/ha) and 2N (1,4 L/ha) was studied during selectivity trials. Submitted trials are sufficient. Summary of the data on yield can be found at Table 3.4 4. The evaluation was carried out in accordance with EPPO guidelines. No negative effect on the maize grain yield was observed.  **Nicorn Grande 060 OD (product code: NIC-HER 060 OD) can be consider as safe for maize crops on the basis on the submitted documentation by Applicant.** |

### Effects on the quality of plants or plant products (KCP 6.4.3)

6 selectivity studies conducted in 2014, 2020 and 2021 seasons in Poland on maize revealed that the both products, NIC-HER 060 OD and NSF-GEN 040 SC, had no negative impact on quality of plants. Application of NIC-HER 060 OD in a dose of 0.7 L/ha and NSF-GEN 040 SC in a dose of 1 L/ha, caused no adverse effects on yield quantity and quality (grain yield, the weight of thousand grain, moisture content of grain) in selectivity trials.

Moreover, no phytotoxic effect (changes in growth, plant height, tillering, dates of succeeding growth stages, thinning out of plants, discolorations, necroses, deformations, yield quantity and quality) of NIC-HER 060 OD nor NSF-GEN 040 SC, was recorded in efficacy trials.

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Comments of zRMS: | Statement accepted. The evaluation was carried out in accordance with EPPO guidelines. Parameters such as grain yield, the weight of thousand grain, moisture content of grain was assessed during 6 trials. Detailed results were presented by ZRMs in table below. Quality of yield of maize in recommended dose of tested product – Nicorn Grande 060 OD (NIC-HER 060 OD) were similar to objects, which used standard reference product.   |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  | | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | | **Grain moisture, TGW and yield per plot** | | Grain moisture [%] | TGW3 [g] | Yield [kg/ plot] | Grain moisture [%] | TGW3 [g] | Yield [kg/ plot] | Grain moisture [%] | TGW3 [g] | Yield [kg/ plot] | Grain moisture [%] | TGW3 [g] | Yield [kg/ plot] | Grain moisture [%] | TGW3 [g] | Yield [kg/ plot] | Grain moisture [%] | TGW3 [g] | Yield [kg/ plot] | | Control | — | 28,1 | 250,83 | 14,67 | 26,5 | 287,97 | 14,29 | 29,9 | 232,59 | 17,04 | 18,1 | 295,28 | 5,65 | 29,5 | 312,8 | 8,7 | 27,8 | 316,2 | 9,7 | | NIC-HER 060 OD/NSF-GEN 040 SC | 42g nicosulfuron/ha / 40g nicosulfuron/ha | 28,1 | 238,18 | 14,84 | 27,1 | 276,05 | 14,4 | 29,7 | 227,78 | 16,7 | 17,9 | 294,81 | 6,23 | 28,5 | 314,3 | 9 | 27,7 | 317,8 | 9,8 | | NIC-HER 060 OD/NSF-GEN 040 SC | 84g nicosulfuron/ha / 80g nicosulfuron/ha | 28,1 | 242,55 | 14,66 | 27,3 | 281,02 | 14,57 | 30 | 226,86 | 16,97 | 17,8 | 300,83 | 6,29 | 28,7 | 315,1 | 8,9 | 27,5 | 318,3 | 9,9 | | Nikosar 060 OD / Narval 040 OD | 42g nicosulfuron/ha / 40g nicosulfuron/ha | 28,3 | 242,78 | 14,58 | 27,5 | 280,87 | 15,26 | 29,5 | 239,91 | 16,96 | 18 | 304,39 | 5,94 | 28,6 | 316,4 | 9,1 | 28 | 315,1 | 9,7 | | Nikosar 060 OD / Narval 040 OD | 84g nicosulfuron/ha / 80g nicosulfuron/ha | 28,8 | 246,37 | 14,57 | 27,6 | 279,29 | 14,59 | 29,6 | 229,47 | 17,1 | 18 | 304,15 | 5,7 | 29,1 | 313,8 | 8,7 | 27,8 | 320 | 9,8 |   1 - reference product Nikosar 060 OD with authorisation number R-869/2019b was used  2 - reference product Narval 040 OD with authorisation number R-19/2010 was used  3 - the weight of thousand grain |

### Effects on transformation processes (KCP 6.4.4)

According to the EPPO guideline PP 1/243(1) “ […] regulation (e.g. Commission Regulation 284/2013, EU, 2013) may require investigation of possible adverse effects if there are indications that the use of a plant protection product could have an influence on transformation processes (e.g. use of plant growth regulators or fungicides close to harvest or after harvest), or where use of similar products has been found to have an adverse influence. [...] If the applicant can demonstrate that residues are undetectable, or that any residues will not affect yield, a reasoned case may be sufficient to address these requirements.”

For NIC-HER 060 OD no processing trials were performed. There is no indication from agricultural practice that herbicides with the active substances nicosulfuron have affected the processing of harvested cereal grains in the past. Furthermore, the test product is intended for application in BBCH 12-17 of maize and, not close to harvest or after harvest.

|  |  |
| --- | --- |
| Comments of zRMS: | Maize is usually not subject to transformation processes. EPPO Standard PP1/243 states that if no residues are detected in the harvested product, a reasoned case may be sufficient to address this point. As the applicant states, no negative impact of herbicides containing nicosulfuron on the processing of maize has been recorded in the past. **It can be concluded that no further information on transformation processes is needed.** |

### Impact on treated plants or plant products to be used for propagation (KCP 6.4.5)

6 studies conducted in 2014, 2020 and 2021 seasons in Poland on maize revealed no negative impact of NIC-HER 060 OD nor NSF-GEN 040 SC on propagation material – cereal seed.

Summary and conclusion

No adverse effects on treated plants such as phytotoxicity symptoms, negative impact on yield quality/ quantity and transformation processes were observed in efficacy and selectivity trials of NIC-HER 060 OD and NSF-GEN 040 SC.

|  |  |
| --- | --- |
| Comments of zRMS: | According to EPPO Standard PP1/135, data on plant parts for propagation is only needed when application occurs at or after seed initiation or when detectable residues occur in harvested seed. As the application occurs at early growth stages (BBCH 12-17), no further data is required. |

## Observations on other undesirable or unintended side-effects (KCP 6.5)

### Impact on succeeding crops (KCP 6.5.1)

NIC-HER 060 OD (containing nicosulfuron) is not harmful for succeeding plants since its active substance decomposes relatively quick (According to PPDB by University of Hertfordshire[[1]](#footnote-1), DT90 ranges between 29,7 and 210 days). Consequently, the product decomposes within the growing season without making any damage to succeeding plants. It is concluded that after the appropriate application of NIC-HER 060 OD in maize, all the possible following crops can be grown when usual crop rotation and seedbed preparation is used.

Considering raised arguments and the fact that the literature does not say anything about the adverse impact on succeeding crops after application of herbicides containing this active substance, no specific plant-back restrictions related to NIC-HER 060 OD are required. However, in case of the need to sift the treated plantation (as a result of crop damage by frost, disease or pest), only maize and spring cereals can be grown on the same field after seedbed preparation (at the depth of min. 5 cm).

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| --- | --- |
| Comments of zRMS: | The EU requirements on plant protection products requires, that sufficient data must be reported to permit an evaluation of possible adverse effects of a treatment with the plant protection product on succeeding crops if studies and evaluations presented in the other part of the dossier, show that significant residues of the active substance, its metabolites or degradation products, which have or may have biological activity on succeeding crops, remain in soil or in plant materials up to sowing or planting time of possible succeeding crops. Therefore, the Applicant should present the assessment of the possible effect of Nicorn Grande (product code: NIC-HER 060 OD) on crops grown as rotational or replacement crops following crops treated with that product, prepared in accordance to the EPPO Standard Efficacy evaluation of plant protection products.  Effects on succeeding crops (PP 1/207 (2)). This standard is intended as a general standard on the methods used to examine whether the active substance of a plant protection product can cause negative effects on crops grown after a crop treated with that product. These crops can be grown as normal rotational crops as well as replacement crops in case of crop failure.  The half-life (DT50) for nicosulfuron is about 16.4 days. Therefore, the impact on succeeding crops is unlikely to occur. No risk of phytotoxicity for succeeding crops is expected, in the opinion of Evaluator. However, necessary precautions to prevent the negative impact on succeeding crops should be included in the label claim.  Applicant proposed following entry to label (accepted by ZRMs):  If it is necessary to liquidate the plantation treated with the product earlier (as a result of damage to plants by frost, disease or pests) after pre-sowing cultivation can be grown corn or:   * cereals - after 3 months - on acidic soils; after 9 months - on neutral and alkaline soils, * legumes - after 9 months, * alfalfa - after 12 months.   In the spring of the following year, all crops can be grown.  Details are presented in different section. |

### Impact on other plants including adjacent crops (KCP 6.5.2)

None of the efficacy/crop safety trials reported any effects on adjacent crops or plants. Application of both NIC-HER 060 OD and NSF-GEN 040 SC, according to the requirements of “Good Agricultural Practice” excludes lapses, e.g. overspray of boundary stripes, overdose or applications in other than the registered crops or at other application times. Furthermore, GAP rules say that to avoids spray drift to adjacent crops the wind speed, the droplet size and positioning of the spray boom have to be taken into account. As NIC-HER 060 OD is intended for control of dicotyledonous weeds, the product may cause damages on dicotyledonous adjacent crops if it is misused.

Therefore, it is not expected that appropriate applications of NIC-HER 060 OD will lead to adverse effects on adjacent crops.

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| Comments of zRMS: | Results on the impact on adjacent crops should been provided according to EPPO Standard PP1/256. An application of Nicorn Grande (product code: NIC-HER 060 OD) in respect of the GAP rules say that: to avoids spray drift to adjacent crops the wind speed, the droplet size and positioning of the spray boom have to be taken into account. Generally, the product is a foliar herbicide effective on broadleaved weeds. **Therefore, warnings to avoid spray drift on adjacent crops should appear on the label.** |

**Tank cleaning**

There are no special requirements for cleaning application equipment and protective clothing. Normal procedures should be followed for the cleaning and use of protective clothing and equipment.

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| Comments of zRMS: | Normal procedures for tank cleaning can be accepted in the opinion of ZRMs. |

### Effects on beneficial and other non-target organisms (KCP 6.5.3)

Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

In efficacy and phytotoxicity trials no adverse effects of NIC-HER 060 OD on beneficial organisms were observed. Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology).

**3.5.4 Compatibility with current management practices including IPM**

This is not an EC data requirement/not required by Regulation 1107/2009.

Summary and conclusion

Products which are containing nicosulfuron has been used for many years, not only Poland but also in other European countries. According to current knowledge of NIC-HER 060 OD does not pose any unacceptable risk to other plants also there was no adverse impact on beneficial organisms.

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| Comments of zRMS: | Detailed studies on the possible adverse effects to beneficial organisms are submitted and summarised in Part B, Section 9 (Ecotoxicology). |

## Other/special studies

Not relevant.

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| Comments of zRMS: | ZRMs agrees |

## List of test facilities including the corresponding certificates

Table 3.7‑1: List of test facilities

| Test facility | Address | Certificate (Yes or No) |
| --- | --- | --- |
| Anadiag S.A. Oddział w Polsce | ul. Sadowa 16/22  95-100 Zgierz  Poland | Yes |
| Eurofins Agroscience Services Sp. z o.o. | ul. Parkowa 6  64-530 Kaźmierz | Yes |
| AGRECO Sp. z o.o. | al. Lipowa 21, lok. 1  53-124 Wrocław | Yes |

1. Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

| **Data point** | **Author(s)** | **Year** | **Title Company Report No.  Source (where different from company) GLP or GEP status** Published or not | **Vertebrate study Y/N** | **Owner** |
| --- | --- | --- | --- | --- | --- |
| KCP 3.2/01 | Jatczak J. | 2014 | Field study to evaluate the efficacy of NSF-GEN 040 SC when applied for the control of weeds in maize. Trial season 2014;  ANADIAG POLSKA., Poland;  Report No.: PL 14 003 PL1  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.2/02 | Jatczak J. | 2014 | Field study to evaluate the efficacy of NSF-GEN 040 SC when applied for the control of weeds in maize. Trial season 2014;  ANADIAG POLSKA., Poland;  Report No.: PL 14 003 PL2  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.2/03 | Jatczak J. | 2014 | Field study to evaluate the efficacy of NSF-GEN 040 SC when applied for the control of weeds in maize. Trial season 2014;  ANADIAG POLSKA., Poland;  Report No.: PL 14 003 PL5  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.2/04 | Jatczak J. | 2014 | Field study to evaluate the efficacy of NSF-GEN 040 SC when applied for the control of weeds in maize. Trial season 2014;  ANADIAG POLSKA., Poland;  Report No.: PL 14 003 PL6  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.2/05 | Głowacki G. | 2020 | Determination of efficacy of NIC-HER 060 OD applied against broadleaved weeds in maize. Poland 2020;  Eurofins Agroscience Services Sp. z o.o., Poland;  Report No.: S20-03779-01  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.2/06 | Głowacki G. | 2020 | Determination of efficacy of NIC-HER 060 OD applied against broadleaved weeds in maize. Poland 2020;  Eurofins Agroscience Services Sp. z o.o., Poland;  Report No.: S20-03779-02  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.2/07 | Głowacki G. | 2020 | Determination of efficacy of NIC-HER 060 OD applied against broadleaved weeds in maize. Poland 2020;  Eurofins Agroscience Services Sp. z o.o., Poland;  Report No.: S20-03779-03  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.2/08 | Głowacki G. | 2020 | Determination of efficacy of NIC-HER 060 OD applied against broadleaved weeds in maize. Poland 2020;  Eurofins Agroscience Services Sp. z o.o., Poland;  Report No.: S20-03779-04  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.2/09 | Głowacki G. | 2020 | Determination of efficacy of NIC-HER 060 OD applied against broadleaved weeds in maize. Poland 2020;  Eurofins Agroscience Services Sp. z o.o., Poland;  Report No.: S20-03779-05  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.2/10 | Kukuła A. | 2021 | Field study to evaluate the efficacy of Nevada 60 OD against weeds in maize;  AGRECO Sp. z o.o.;  Report No.: 21PRO0926-1  GEP: Yes  Published: No | N | ProAgri\*\*  Pestila\* |
| KCP 3.2/11 | Kukuła A. | 2021 | Field study to evaluate the efficacy of Nevada 60 OD against weeds in maize;  AGRECO Sp. z o.o.;  Report No.: 21PRO0926-2  GEP: Yes  Published: No | N | ProAgri\*\*  Pestila\* |
| KCP 3.2/12 | Kukuła A. | 2021 | Field study to evaluate the efficacy of Nevada 60 OD against weeds in maize;  AGRECO Sp. z o.o.;  Report No.: 21PRO0926-3  GEP: Yes  Published: No | N | ProAgri\*\*  Pestila\* |
| KCP 3.4/01 | Głowacki G. | 2020 | Determination of selectivity of NIC-HER 060 OD applied once in Maize. Poland 2020.  Eurofins Agroscience Services Sp. z o.o., Poland;  Report No.: S20-03780-01  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.4/02 | Głowacki G. | 2020 | Determination of selectivity of NIC-HER 060 OD applied once in Maize. Poland 2020.  Eurofins Agroscience Services Sp. z o.o., Poland;  Report No.: S20-03780-02  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.4/03 | Głowacki G. | 2020 | Determination of selectivity of NIC-HER 060 OD applied once in Maize. Poland 2020.  Eurofins Agroscience Services Sp. z o.o., Poland;  Report No.: S20-03780-03  GEP: Yes  Published: No | N | Pestila\* |
| KCP  3.4/04 | Jatczak J. | 2014 | Field study to evaluate the selectivity of NSF-GEN 040 SC when applied in maize. Trial season 2014;  ANADIAG POLSKA., Poland;  Report No.: PL 14 007 PL1  GEP: Yes  Published: No | N | Pestila\* |
| KCP 3.4/05 | Kukuła A. | 2021 | Field study to evaluate the selectivity of Nevada 60 OD in maize;  AGRECO Sp. z o.o.;  Report No.: 21PRO0927-1  GEP: Yes  Published: No | N | ProAgri\*\*  Pestila\* |
| KCP 3.4/06 | Kukuła A. | 2021 | Field study to evaluate the selectivity of Nevada 60 OD in maize;  AGRECO Sp. z o.o.;  Report No.: 21PRO0927-2  GEP: Yes  Published: No | N | ProAgri\*\*  Pestila\* |

\* Pestila Spółka z ograniczoną odpowiedzialnością

\*\* ProAgri Sp. z o.o.

The following tables are to be completed by MS

List of data submitted by the applicant and not relied on

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
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List of data relied on not submitted by the applicant but necessary for evaluation

| Data point | Author(s) | Year | Title Company Report No.  Source (where different from company) GLP or GEP status Published or not | Vertebrate study  Y/N | Owner |
| --- | --- | --- | --- | --- | --- |
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1. http://sitem.herts.ac.uk/aeru/ppdb/en/Reports/484.htm [↑](#footnote-ref-1)