

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: AKO 600 SC

Product name(s): Tanger 600 SC, Libretto 600 SC

Chemical active substance:

Aclonifen, 600g/L

Central

Zonal Rapporteur Member State: Poland

Co-Rapporteur Member State: Hungary, Slovakia, Germany,
Romania

CORE ASSESSMENT

(authorization)

Applicant: Innvigo Sp. z o.o.

Submission date: 18.11.2024

zRMS Assessment : 28/06/2025

Following commenting period: 01/10/2025

Final Version: 29/06/2026

Version history

When	What
June 2025	zRMS evaluation
October 2025	Following commenting period
June 2026	Final Version

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0 Product background, regulatory context and GAP information

According to Regulation 1107/2009 data protection for data at European level lasts for 10 years. Due to the fact that the aclonifen annex I was approved on 1/08/2009, data protection has expired 1/08/2019. Therefore, Innvigo can use the European data for aclonifen for the registration of the product AKO 600 SC [Libretto 600 SC, Tanger 600 SC]

0.1 Introduction

This document describes the acceptable use conditions required for authorization of AKO 600 SC (Tanger 600 SC, Libretto 600 SC) containing Aclonifen in Poland (zRMS).

The risk assessment conclusions are based on the information, data and assessments provided in Registration Report, Part B Sections 1-10. The information, data and assessments provided in Registration Report, Parts B includes assessment of further data or information as required by the EU review. It also includes assessment of data and information relating to AKO 600 SC where that data has not been considered in the EU review. Assessments for the safe use of AKO 600 SC have been made using endpoints agreed in the EU review.

This document describes the specific conditions of use and labelling required for registration of (Tanger 600 S.C., Libretto 600 SC), product code AKO 600 SC.

0.1.1 Reason for application

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 283/2013 and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

In addition to the submission of studies as listed in sections B1-B10, exemption from the submission of studies is requested in accordance with Article 34 of Regulation (EC) No. 1107/2009

0.1.2 Details of zRMS(s) and concerned MS

Table 0.1-1: Overview of zRMS and cMS

	zRMS, product name and authorization no. (if relevant)	(if relevant) Concerned MS, MS' product name and authorization number (if applicable)
Northern zone	-	-
Central zone	Poland AKO 600 SC Tanger 600 SC, Libretto 600 SC	-
Southern zone	-	-
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

Table 0.1-2: Summary of regulatory history of CAS No: 74070-46-5

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Reg. (EU) 2023/918
RMS	Poland (zRMS)
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01/08/2009
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	31/10/2026
Date of final Commission (re-registration) deadline (Step 2)	31/10/2026
Current expiration of approval	31/10/2026
Low risk substance or Candidate for Substitution?	CfS

Issues that need to be considered as part of the EU approval are listed below.

In this overall assessment Member States must pay particular attention to:

- the specification of the technical material as commercially manufactured must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers should be compared and verified against this specification of the technical material
- the protection of the operators safety. Authorised conditions of use must prescribe the application of adequate personal protective equipment and risk mitigation measures to reduce the exposure
- the residues in rotational crops and evaluate the dietary exposure of consumers
- the protection of birds, mammals, aquatic organisms and non-target plants. In relation to these identified risks, risk mitigation measures, such as buffer zones, should be applied where appropriate

The SANCO report for aclonifen (SANCO/161/08 – rev. 2) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report was made available on 31 July 2008 - EFSA Scientific Report (2008) 149, 1-80.

Table 0.1-3: Information on minimum purity of aclonifen

EU agreed minimum purity from Inclusion Directive or Implementing regulation	(if different) Minimum purity of active substance used in the product / information on available equivalency report *, **
970 g/kg RMS: NL	970 g/kg Please refer to PART C. Information confidential

* Since EU approval new studies on the active substance have been performed (e.g. new manufacturing site, new specification) and as a result the purity of the active substance has changed (see Part C).

**. If the specification of the active substance is different to that used as reference specification for EU approval then please refer to the equivalency document from the RMS.

0.1.4 Regulatory history of the product

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

The product Tanger 600 SC containing 600 g/l aclonifen is classified for human health as H317 - May cause an allergic skin reaction and H351 - Suspected of causing cancer and for environmental reasons as H410 - Very toxic to aquatic life with long lasting effects. According to the model calculations, it can be concluded that the risk for the operator, worker and bystander is acceptable. The proposed uses of aclonifen do not represent unacceptable risk for the consumers. No unacceptable risk to birds, mammals, non-target aquatic organisms, bees, non-target arthropods, non-target plants is expected following the application of Tanger 600 SC according to proposed use. Aclonifen doesn't have metabolites requiring assessment of relevance in ground water.

Uses to be considered safe on the basis of EU methodology:

Uses in the GAP table no 1,3 are to be confirmed by CMSs.

Uses 1, 2 are considered safe for PL.

Efficacy: use in the GAP table no 2, 4 is to be confirmed by CMSs

Insert relevant use number from GAP table in Appendix 1.

Uses to be considered non-safe on the basis of EU methodology:

Efficacy: use 2 not acceptable for DE; use 4 not acceptable for HU.

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with identified risk.

Uses for which safety has been established only following additional risk mitigation at a national (non-core) level or for which the evaluation is to be confirmed by relevant CMS:

Insert relevant use number from GAP table in Appendix 1 and refer to relevant RR chapter with assessment to be confirmed.

The following text is to be shortened or to be amended as necessary.

All uses/ GAPs are covered by established MRLs ~~except for use in crop. An application for amending the MRL has been submitted by MS to EFSA EFSA Project Number (if applicable).~~

zRMS may insert more details of the overall summary of the assessment, focusing on the main conclusions only.

Appendix 1 ALL intended uses

GAP ver. 1.4 date: 22.05.2024

PPP (product name/code): AKO 600 SC / Tanger 600 SC, Libretto 600 SC
Active substance 1: Aclonifen
Safener:
Synergist:
Applicant: Innvigo sp. z o.o.
Zone(s): Central Zone
Verified by MS:
Field of use: Herbicide

Formulation type: SC
Conc. of as 1: 600 g/L
Conc. of as 2: (c)
Conc. of as: (c)
Conc. of safener: (c)
Conc. of synergist: (c)
Professional use:
Non professional use:

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Use -No. (e)	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F, Fn, Fpn G, Gn, Gpn 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 safen- er/synergist per ha (f)	Conclusion Groundwa- ter
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. inter- val 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	Potato <i>Solanum tuberosum</i> SOLTU	F	Mono and dicots weeds	Spray	BBCH 01-09	a) 1 b) 1	n/a	a) 1.95- 3.0 L/ha b) 1.95- 3.0 L/ha a) 2.0 l/ha b) 2.0 L/ha(**)	a) 1.17 - 1.8 kg as/ha b) 1.17 - 1.8 kg as/ha a) 1.2 kg as/ha b) 1.2 kg as/ha(**)	200- 400 300	40		
2	DE	Potato <i>Solanum tuberosum</i> SOLTU	F	Mono and dicots weeds	Spray	BBCH 01-09	a) 1 b) 1	n/a	a) 1.95 L/ha b) 1.95 L/ha a) 2.0 l/ha b) 2.0 L/ha(**)	a) 1.17 kg as/ha b) 1.17 kg as/ha a) 1.2 kg as/ha b) 1.2 kg as/ha(**)	200- 400 300	40		

3	PL	Potato <i>Solanum tuberosum</i> SOLTU	F	Mono and dicots weeds	Spray	BBCH 01-09	a) 1 b) 1	n/a	a) 0.8 2.0 L/ha AKO 600 SC + 0.2 L/ha Boa Pro 480 EC (clomazon 480 g/L) b) 0.8 2.0 L/ha AKO 600 SC + 0.2 L/ha Boa Pro 480 EC (clomazon 480 g/L)	a) 0.48 1.2 + 0.096 kg as/ha b) 0.48 1.2 + 0.096 kg as/ha	200- 400 300	40		
4	HU, RO, SK	Sunflower <i>Helianthus annuus</i> HELAN	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 - 3.0 L/ha b) 1.95 - 3.0 L/ha a) 2.0 l/ha b) 2.0 L/ha(**)	a) 1.17 - 1.8 kg as/ha b) 1.17 - 1.8 kg as/ha a) 1.2 kg as/ha b) 1.2 kg as/ha(**)	200- 300	n/a		
Interzonal uses (use as seed treatment, in greenhouses (or other closed places of plant production), as post-harvest treatment or for treatment of empty storage rooms)														
5														
6														
Minor uses according to Article 51 (zonal uses)														
7	PL	Sunflower <i>Helianthus annuus</i> HELAN	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 - 3.0 L/ha b) 1.95 - 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 - 1.8 kg as/ha b) 1.17 - 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
8	PL, SK	Spring rapeseed BRSNN	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 - 3.0 L/ha b) 1.95 - 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 - 1.8 kg as/ha b) 1.17 - 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
9	DE	Spring rapeseed BRSNN	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 L/ha b) 1.95 L/ha	a) 1.17 kg as/ha b) 1.17 kg as/ha	200- 300	n/a		
10	PL, HU, RO, SK	Flax LIUUT	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 - 3.0 L/ha b) 1.95 - 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 - 1.8 kg as/ha b) 1.17 - 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		

11	PL, HU, RO, SK	Opium poppy <i>Papaver somniferum</i> PAPSO	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
12	DE	Opium poppy <i>Papaver somniferum</i> PAPSO	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 L/ha b) 1.95 L/ha	a) 1.17 kg as/ha b) 1.17 kg as/ha	200- 300	n/a		
13	PL, RO, SK	Mustard 3MUSC	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
14	PL	Soybeans GLXMA	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
15	PL, HU, RO, SK	Pumpkin CUUPE	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
16	DE	Pumpkin CUUPE	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 L/ha b) 1.95 L/ha	a) 1.17 kg as/ha b) 1.17 kg as/ha	200- 300	n/a		
17	PL, HU, RO, SK	Hemp CNISA	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
18	DE	Hemp CNISA	F	Mono and dicots weeds	Spray	BBCH 00-08	a) 1 b) 1	n/a	a) 1.95 L/ha b) 1.95 L/ha	a) 1.17 kg as/ha b) 1.17 kg as/ha	200- 300	n/a		

19	PL, HU, RO, SK	Tobacco <i>Nicotiana tabacum</i> NIOTA	F	Mono and dicots weeds	Spray	Before planting	a) 1 b) 1	n/a	a) 1.8 – 2.5 L/ha b) 1.8 – 2.5 L/ha a) 1.8 - 2.0 L/ha b) 1.8 - 2.0 L/ha (**)	a) 1.08 – 1.50 kg as/ha b) 1.08 – 1.50 kg as/ha a) 1.08 - 1.2 kg as/ha b) 1.08 - 1.2 kg as/ha (**)	150- 400	n/a		
20	PL, HU, RO, SK	Forest nurseries plants (pine tree, spruce, fir tree, larch) YPFLG	F	Mono and dicots weeds	Spray	Immediately after planting, when trees are dormant	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
21	PL, HU, RO, SK	Ornamental shrubs NNNZG	F	Mono and dicots weeds	Spray	Immediately after planting, when trees are dormant	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
22	PL, HU, RO, SK	Basket willow <i>Salix</i> sp. SAXSS	F	Mono and dicots weeds	Spray	Immediately after planting, when trees are dormant	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
23	PL, HU, RO, SK	Purple willow SAXPU	F	Mono and dicots weeds	Spray	Immediately after planting, when trees are dormant	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
24	PL, HU, RO, SK	Forest tree 3FORC	F	Mono and dicots weeds	Spray	Immediately after planting, when trees are dormant	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		

25	PL, HU, RO, SK	Christmas tree PIEAB	F	Mono and dicots weeds	Spray	Immediately after planting, when trees are dormant	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
26	PL, HU, RO, SK	Energetic willow SAXSS	F	Mono and dicots weeds	Spray	Immediately after planting, when trees are dormant	a) 1 b) 1	n/a	a) 1.95 – 3.0 L/ha b) 1.95 – 3.0 L/ha a) 1.95 - 2.0 L/ha b) 1.95 - 2.0 L/ha (**)	a) 1.17 – 1.8 kg as/ha b) 1.17 – 1.8 kg as/ha a) 1.17 - 1.2 kg as/ha b) 1.17 - 1.2 kg as/ha (**)	200- 300	n/a		
Minor uses according to Article 51 (interzonal uses)														
27														

* The crop numbering omits non-national crop uses. Overall numbering hasn't changed.

**** as a result of unacceptable risk to mammals for the proposed uses, the dose was limited to maximum of 2 L/ha (1.2 kg as/ha)**

Remarks table heading:

(a) e.g. wettable powder (WP), emulsifiable concentrate (EC), granule (GR)
(b) Catalogue of pesticide formulation types and international coding system CropLife International Technical Monograph n°2, 6th Edition Revised May 2008
(c) g/kg or g/l

Remarks columns:

1 Numeration necessary to allow references
2 Use official codes/nomenclatures of EU Member States
3 For crops, the EU and Codex classifications (both) should be used; when relevant, the use situation should be described (e.g. fumigation of a structure)
4 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
5 Scientific names and EPPO-Codes of target pests/diseases/ weeds or, when relevant, the common names of the pest groups (e.g. biting and sucking insects, soil born insects, foliar fungi, weeds) and the developmental stages of the pests and pest groups at the moment of application must be named.
6 Method, e.g. high volume spraying, low volume spraying, spreading, dusting, drench
Kind, e.g. overall, broadcast, aerial spraying, row, individual plant, between the plants - type of equipment used must be indicated.

(d) Select relevant
(e) Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0 should be given in column 1
(f) No authorization possible for uses where the line is highlighted in grey, Use should be crossed out when the notifier no longer supports this use.

7 Growth stage at first and last treatment (BBCH Monograph, Growth Stages of Plants, 1997, Blackwell, ISBN 3-8263-3152-4), including where relevant, information on season at time of application
8 The maximum number of application possible under practical conditions of use must be provided.
9 Minimum interval (in days) between applications of the same product
10 For specific uses other specifications might be possible, e.g.: g/m³ in case of fumigation of empty rooms. See also EPPO-Guideline PP 1/239 Dose expression for plant protection products.
11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).
12 If water volume range depends on application equipments (e.g. ULVA or LVA) it should be mentioned under “application: method/kind”.
13 PHI - minimum pre-harvest interval
14 Remarks may include: Extent of use/economic importance/restrictions