FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and GAP information

Product code: SHA 2619 A

Product name(s): KONARK

Chemical active substances:

Flufenacet, 60 g/L
Pendimethalin, 300 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: March 2021

MS Finalisation date: January 2023; May 2023

Version history

When	What
01/2023	Draft assessment prepared by zRMS
05/2023	zRMS revision after commenting phase – final version of the RR

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application was submitted by Sharda Cropchem España S.L. for approval of KONARK, an emulsifiable concentrate formulation (EC) containing 60 g/L of Flufenacet and 300 g/L of Pendimethalin, for use as an herbicide on cereals.

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 for flufenacet and Regulation (EC) No. 283/2013 for pendimethalin and the data requirements for the plant protection product laid down in Regulation (EC) No. 284/2013.

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 KONARK	Germany KONARK
Southern zone	Malta KONARK	Greece Spain KONARK
Inter-zonal	-	-

0.1.3 Regulatory history of the active(s)

0.1.3.1 Flufenacet

Table 0.1-2: Summary of regulatory history of CAS No: 142459-58-3

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2003/84/EC or Commission Implementing Regulation (EU) No 540/2011
RMS	France

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.01.2004
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01.07.2004
Date of final Commission (re-registration) deadline (Step 2)	30.06.2005
Current expiration of approval	~~31.10.2021~~ 31.10.2021
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 protection of groundwater, when the active substance is applied in regions with vulnerable soil and/or climate conditions,
- the protection of algae and aquatic plants,
- the protection of operators.

Risk mitigation measures should be applied where appropriate.

The SANCO report for Flufenacet (SANCO/7469/VI/98-Final – 03/07/2003) is considered to provide the relevant information on the evaluation or a reference to where such information can be found. No EFSA Scientific Report is available.

Table 0.1-3: Information on minimum purity of Flufenacet

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 *, ** **
min. 950 g/kg	min. 980 g/kg Equivalence report available: Y RMS: RMS

* 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.

The endpoints used in the evaluation are the same as those from EU endpoints defined in the SANCO report for Flufenacet (SANCO/7469/VI/98 – 03/07/2003.

0.1.3.2 Pendimethalin

Table 0.1-4: Summary of regulatory history of CAS No: 40487-42-1

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Original inclusion: Commission Directive 2003/31/EC Renewal: Commission Implementing Regulation 2017/1114
RMS	RMS: NL, Co-RMS: ES

Status	
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.09.2017
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	01.12.2017
Date of final Commission (re-registration) deadline (Step 2)	31.12.2018
Current expiration of approval	31.08.2024
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, which must be confirmed and supported by appropriate analytical data. The test material used in the toxicity dossiers shall be compared and verified against the specification of the technical material,
- the protection of operators
- the protection of birds, mammals and aquatic organisms.

Conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report (7477/VI/98-final – 13/01/2003) and renewal report (SANTE/11656/2016 rev 2 – 18.05.2017) for pendimethalin are considered to provide the relevant information on the evaluation or a reference to where such information can be found. An EFSA Scientific Report is available for the renewal of the approval (EFSA Journal 2016;14(3):4420).

Table 0.1-5: Information on minimum purity of Pendimethalin

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 *, ** **
min. 900 g/kg	min. 980 g/kg Equivalence report available: Y RMS: UK

* 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.

The endpoints used in the evaluation are the same as those from EU endpoints defined in the EFSA's conclusion on pesticides peer review (EFSA Journal 2016;14(3):4420).

0.1.4 Regulatory history of the product (if relevant)

Not relevant as the product has not yet been authorised

0.2 zRMS conclusion

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

Efficacy section: 1-8
Residues section: 1-8
Environmental fate and behavior section: 1-8
Ecotoxicology section: 1-8 (the risk mitigations measure should be applied)

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

Efficacy section: none
Residues section: none
Environmental fate and behavior section: none
Ecotoxicology section: none

Metabolism and Residues:
All uses/ GAPs are covered by established MRLs

Conclusions:

Physical-chemical section:

Data gap: The shelf-life study is on-going. One-year conditional registration of the product is possible and proposed.

GHS Precautionary Statement: P280 Wear protective gloves/protective clothing/eye protection/face protection.

Efficacy section:
Acceptance of uses from GAP table proposed by Applicant is left to each cMS. Due to the limited number of results for weeds species, it is difficult to make a clear conclusion for the label, especially for weeds which are major. Therefore, the sufficiency of results should be considered on the national level based on importance of weed in their country. In Poland only post-emergence on winter wheat, winter triticale and winter barley are accepted.

Mammalian Toxicology:
- Classification of KONARK Skin Sens.1/H317; Repr..**2/H361d** and EUH066: Repeated exposure may cause skin dryness or cracking

According to the AOEM model, calculations, it can be concluded that the risk for the operator using KONARK is acceptable with PPE and no risk for worker wearing adequate work clothing and with work wear. According to the EFSA calculator, when a 5m buffer zone is employed and drift reduction technology is incorporated, the risk for residents can be considered as acceptable **and when used pre-emergence on exposed soil when sprayed on a tractor mounted boom outside Buffer zone: 2-3 (m).**

Metabolism and Residues:
There is no data gaps

Analytical methods for residues
Data gap:
• A method, including confirmation, for the determination of flufenacet + FOE thiadone in tissues is required according to Regulation (EU) 284/2013 (post-registration requirement).

Fate and Behavior:
No risk to groundwater is expected after application acccording to GAP.

Ecotoxicology:
Risk mitigation measures should be applied for all proposed uses at individual Member State level in accordance with their national requirements.

Appendix 1 ALL intended uses

PPP (product name/code):	KONARK / SHA 2619 A	Formulation type:	EC (Emulsifiable Concentrate)
Active substance 1:	Flufenacet	Conc. of as 1:	60 g/L
Active substance 2:	Pendimethalin	Conc. of as 2:	300 g/L
Safener:	-	Conc. of safener:	-
Synergist:	-	Conc. of synergist:	-
Applicant:	Sharda Cropchem España S.L.	Professional use:	☒
Zone(s):	Central	Non professional use:	☐
Verified by MS:	yes/no		

Field of use: Herbicide

1	2	3	4	5	6	7	8	9	10	11	12	13	14
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 safener/synergist per ha [f]
					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	CEU	**Winter wheat**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages **Eff sec**: in PL and DE not accepted
2	CEU	**Winter wheat**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages Eff. section: In DE only soft winter wheat accepted.

3	CEU	**Winter barley**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages **Eff sec**: in PL and DE not accepted
4	CEU	**Winter barley**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages
5	CEU	**Winter rye**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages **Eff sec**: in PL and DE not accepted
6	CEU	**Winter rye**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages **Eff sec**: in PL and DE not accepted
7	CEU	**Winter Triticale**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Pre emergence BBCH 00-09	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages **Eff sec**: in PL and DE not accepted
8	CEU	**Winter Triticale**	F	~~Broadleaved and grass weeds~~ **Annual** dicotyledonous and **annual** monocotyledonous weeds	Foliar Spray	Post emergence BBCH 11-25	a) 1 b) 1	NA	a) 4 b) 4	a) 0.24 flufenacet + 1.2 pendimethanil b) 0.24 flufenacet + 1.2 pendimethanil	200-400	-	Weeds at early stages
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)													
3													
4													

Minor uses according to Article 51 (zonal uses)													
5													
6													
Minor uses according to Article 51 (interzonal uses)													
7													
8													

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
(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.

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.
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