

FINAL REGISTRATION REPORT

Part B

Section 0

Product Background, Regulatory Context and
GAP information

Product code: SHA 6800 A

Product name(s): DUKES

Chemical active substance(s):

Dithianon, 700 g/kg

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

Applicant: Sharda Cropchem España S.L.

Submission date: September 2020

MS Finalisation date: August 2021; December 2021; May 2022

Version history

When	What
August 2021	RMS finalised the dRR assessment
December 2021	Final registration report after commenting period
May 2022	Revision with regard to consumer risk assessment

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0 Product background, regulatory context and GAP information

0.1 Introduction

0.1.1 Reason for application

This application is submitted by SHARDA CROP CHEM ESPAÑA S.L. for approval of DUKES, a water dispersible granule formulation containing 700 g/kg of dithianon, for use as a fungicide in pome fruits in central Europe

This application follows the data requirements for the active substance laid down in Regulation (EC) No. 544/2011 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)
Central zone	DUKES Poland	

0.1.3 Regulatory history of the active(s)

Table 0.1-2: Summary of regulatory history of CAS No: 3347-22-6

Status	
Approved in EU	Y
Original Inclusion Directive or Commission Implementing Regulation	Commission Directive 2011/41/EU or Commission Implementing Regulation (EU) No 540/2011
RMS	GR
Date of Approval (or most recent renewal) of Active Substance (date of Regulation to be applied)	01.06.2011
Date of first Commission (re-registration) deadline (Step 1) or date of deadline for renewal of authorization (renewal)	30.11.2011
Date of final Commission (re-registration) deadline (Step 2)	31.05.2015
Current expiration of approval	31.05.2024
Low risk substance or Candidate for Substitution?	N/A

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

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

- the protection of aquatic organisms; conditions of use shall include risk mitigation measures, where appropriate,
- the operator safety; conditions of use shall include the application of adequate personal protective equipment, where appropriate,
- the long-term risks to birds; conditions of use shall include risk mitigation measures, where appropriate.

The SANCO report for Dithianon (SANCO/10349/2011 – 11 March 2011) 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 2010.

Table 0.1-3: Information on minimum purity of Dithianon

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 *, **
930 g/kg	Minimum purity of active substance: 975 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 identical to the EU agreed endpoints.

0.1.4 Regulatory history of the product

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
Residues section: 1 (apples)
Environmental fate and behavior section: 1
Ecotoxicology section: 1

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

Efficacy section: none
Residues section: none-1 (pears)
Environmental fate and behavior section: none
Ecotoxicology section: none

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:

The risk mitigation measures for aquatic organism and the risk for vole should be decided at MSs level.

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

Residues section:

Use/ GAP on apples is covered by established MRL.

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Conclusions:

Section Phys-chem:

No data gaps.

Efficacy section:

For N-E and MED EPPO zone Applicant submitted enough number of trials. cMS from S-E and MAR should decide if submitted number of trials can be acceptable, in view of the importance of SCAB and apples and any national extrapolations.

In Poland only use on apple can be accepted. For other pome fruits, ex. pear – at least 1-2 selectivity/phytotoxicity trials are required. Without any trials, pear in Poland can be accepted according to Article 51. In the opinion of Evaluator, in cMS pome fruits can be accepted (extrapolations from apple to other pome crops is possible, without additional trials).

Section Toxicology:

Classification of product and assessment operator, worker and bystander/resident is acceptable.

Metabolism and Residues

Use on apple is accepted. Use on pears is not acceptable

Section Fate:

The use of DUKES according GAP doesn't pose a risk for ground water.

Ecotox Section:

The use of Dukes are considered as an acceptable for non-target organism, except the risk for mammal species - vole which needs further refinement at MSs level.

GAP rev. 0, date: 2020-August-17th

Formulation type:	WG (Water dispersible granules)
Conc. of as 1:	700 g/L
Conc. of as 2:	-
Conc. of safener:	-
Conc. of synergist:	-
Professional use:	<input checked="" type="checkbox"/>
Non professional use:	<input type="checkbox"/>

[illegible]

- (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 ap-
plication
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