

REGISTRATION REPORT

Part C

Confidential Information

Product code: GLOB2111F

Product name(s): Starinta

Chemical active substance(s):

Bixafen, 125 g/L

Central Zonel

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: Globachem NV

Submission date: December 2023

zRMS Assessment : 09/08/2024

Version after commenting : 15/11/2024

Version history

When	What
August 2024	zRMS assessment
November 2024	zRMS: after first round of commenting

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CONFIDENTIAL DATA RELATING TO THE FORMULATED PRODUCT

Sufficient data on the identity of the plant protection product and the contained technical active substance(s) and formulant(s) are ~~not~~ available.

Noticed data gaps are:

- no data gap

State whether or not submitted confidential data are sufficient for evaluation. Data gaps and conditions for authorization should be listed, when relevant. If possible, confidential information should be avoided in the wording of these gaps and/or conditions.

Request for data confidentiality in accordance with Article 63 of Regulation (EU) No. 1107/2009

Globachem NV hereby requests data confidentiality for all the information listed in the attached document on the basis that this information is regarded as proprietary. This request takes into account the provision Article 63 of Regulation (EU) No. 1107/2009.

1 Identity of the Plant Protection Product

1.1 Producer of the plant protection product and of the active substances (KCP 1.2)

1.1.1 Producer(s) of the preparation (KCP 1.2)

Name: Globachem N.V.
Address: Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden
Belgium

Contact: [REDACTED]
Telephone number: +32 11 78 57 17
Fax: +32 11 68 15 65
E-mail: [REDACTED]

Location of the manufacturing site:

Name: Agrokémia
Address: Sósvertikei út 1 - 7960 Sellye - Hungary

Name: AgroSmart Ltd.
Address: Unit 1C Victoria Court, Colliers Way, Clayton West, HD8 9TR Huddersfield, West Yorkshire, United Kingdom

Name: Althaller Italia s.r.l.
Address: Strada Comunale Per Campagna, San Colombano Al Lambro, MI 20078, Italy

Name: Arysta Lifescience Ougrée Production Sprl
Address: Rue de Renory 26/2, 4102 Ougrée, Belgium

Name: Ascenza Agro s.a.
Address: Avenida do Rio Tejo – Herdade das Praias, 2910-440 Setúbal, Portugal

Name: Chemark Kft
Address: 8182 Peremarton Gyártelep, Pf 31, Hungary

Name: Chemia
Address: Via Statale 327, 44047 Dosso, Italy

Name: Chromos Agro d.o.o.
Address: Radnička cesta 173n, 10000 Zagreb, Croatia

Name: Ciech Sarzyna S.A.

Address:	ul. Chemików 1, 37-310 Nowa Sarzyna, Poland
Name:	Exwold Technology
Address:	PO Box 270, Brenda Road, Hartlepool TS25 2BW, UK
Name:	Formichem GmbH
Address:	Anna-von-Philipp-Strasse B33, 86633 Neuburg a.d. Donau, Germany
Name:	Globachem NV
Address:	Montenakenweg 541, 3800 Sint-Truiden, Belgium
Name:	Industrial Química Key s.a.
Address:	Avda. Cervera 17, 25300 Tàrraga (Lleida), Spain
Name:	Kwizda Agro GmbH
Address:	Werk Leobendorf, Laaer Bundesstraße/Kwizda Allee 1, 2100 Leobendorf, Austria
Name:	MED Agrochemicals srl
Address:	Via La Doccia 15, 47897 Fiorentino, San Marino Republic (RSM)
Name:	Phyteurop
Address:	ZI de Champagne, 49260 Montreuil-Bellay, France
Name:	Phytorgan s.a.
Address:	Perivias str. 6, Nea Kifissia 14564, Athens, Greece
Name:	SBM Formulation Manufacturing Plant
Address:	ZI Avenue Jean Foucault, CS621, 34500 Beziers, France
Name:	Schirm GmbH Baar-Ebenhausen
Address:	Dieselstrasse 8, 85107 Baar-Ebenhausen, Germany
Name:	Schirm GmbH
Address:	Division Sideco, Mecklenburger Strasse 229, D-23568 Lübeck
Name:	Schirm GmbH
Address:	Geschwister-Scholl-Strasse 127, D-39218 Schönebeck (Elbe), Germany
Name:	SIPC - Société industrielle de produits chimiques
Address:	Rue J.-Coste, Courchelettes, B.P. 613, 59506 Douai, France
Name:	S.T.I. Solfotecnica Italiana S.p.A
Address:	Via E. Torricelli, 2-I-48010 Cotignola (RA), Italy

1.1.2 Producer(s) of the active substance(s) (KCP 1.2)

Name: Globachem N.V.
Address: Brustem Industriepark
Lichtenberglaan 2019
3800 Sint-Truiden
Belgium
Contact: [REDACTED]
Telephone number: +32 11 78 57 17
Fax: +32 11 68 15 65
E-mail: [REDACTED]

Agent 1

Agro-Lead Co., Ltd.
Rm 2105 Jnb1558 Trend Center 29-31 Cheung Lee St Chai Wan, Hong Kong, PR China

Agent 2

Ningbo Agroskyrun Group
Room 1805, Guting Building, Hefeng Creative Square, No. 495, North Jiangdong Road,
Ningbo, Zhejiang, China.

Agent 3

Agroamigo
Room 808, 8/F, Hangzhou Kerry Centre, No.385 Yan An Road, Xiacheng District,
Hangzhou, 310005, PR China

Location of manufacturing site

Henan Jinpeng Chemicals Co. Ltd.
Suzhou Road Jinpeng Chemical Industry Cluster District, Yuwangtai District, Kaifeng
City, Henan Province, PR China.

1.1.3 Statement of purity (and detailed information on impurities) of the active substance(s) (KCP 1.2)

The equivalence of bixafen technical from Globachem N.V. to that of the reference source has already been evaluated by the RMS Poland. The technical equivalence report prepared by the RMS has been uploaded on CIRCA on 2024. It was concluded that the source produced by Globachem NV is considered technically equivalent to the reference source. The purity is minimum 98%.

Bixafen contains no relevant impurities.

zRMS

Accepted

The source of Bixafen technical used by applicant (location of manufacturing site: Henan Jinpeng Chemicals Co. Ltd., Suzhou Road Jinpeng Chemical Industry Cluster District, Yuwangtai District, Kaifeng City, Henan Province, PR China) have been found by RMS Poland equivalent to the current reference specification in the RAR.

1.2 Detailed quantitative and qualitative information on the composition of the preparation (KCP 1.4)

1.2.1 Composition of the plant protection product (KCP 1.4.1)

Table 1.2-1: Composition of GLOB2111F

Component	CAS no.	Trade name	Function	g/L	% w/w *
Bixafen	581809-46-3	-	Fungicide	pure 125	pure 12.4
				technical 127.6	technical 12.6
Mixture of anionic and non-ionic surfactants	-	Geronol TE/777	Emulsifier	150	14.9
N-Octyl-2-pyrrolidone	2687-94-7	Surfadone LP-100	Co-solvent	200	19.89
Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate	-	Rhodiasolv RPDE	Co-solvent	532.4	52.79

* Based on the density of the formulation = 1.006 ~~1.01~~ g/mL

In the dRR Part B Section 6 (Toxicology) one study (Ashwini J., 2023) is used which was conducted with the closely related formulation GLOB2020aF. Therefore the composition of this product is given below for completeness.

Table 1.2-2: Composition of GLOB2020aF

Component	CAS no.	Trade name	Function	g/L	% w/w *
Bixafen	581809-46-3	-	Fungicide	pure 100	pure 9.9
				technical 102.0	technical 10.1
Difenoconazole	119446-68-3	-	Fungicide	pure 100	pure 9.9
				technical 104.2	technical 10.3
Mixture of anionic and non-ionic surfactants	-	Geronol TE/777	Emulsifier	150	14.9
N-Octyl-2-pyrrolidone	2687-94-7	Surfadone LP-100	Co-solvent	200	19.8
Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate	-	Rhodiasolv RPDE	Co-solvent	453.8	44.9

* Based on the density of the formulation = 1.01 g/mL

1.2.2 Information on co-formulants (KCP 1.4.3)

Please refer to table 1.2-1.

RMS

Assessment, according to art. 3.1 Commission Implementing Regulation (EU) 2023/574, whether co-formulants contained in plant protection products could be considered an unacceptable co-formulant.

Co-formulant - **Geronol TE/777 (trade name)** is a mixture which consists, according to SDS, of the following ingredients:

- Benzenesulfonic acid, C10-13-(linear)alkyl derivs., calcium salt, WE: 932-231-6,
- 2-ethylhexan-1-ol, CAS: 104-76-7.

Ingredients of co-formulant Geronol TE/777 are not listed in Annex III (List of co-formulants which are not accepted for inclusion in plant protection products as referred to in Article 27) of Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products.

Co-formulant - Geronol TE/777 - according to Safety Data Sheets is classified, according to Regulation (EC) No 1272/2008 – CLP as hazardous:

Skin Irrit. 2, H315 (Causes skin irritation),

Eye Irrit. 2, H319 (Causes serious eye irritation).

According to the information found in the SDS the co-formulant does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

According to the information in SDS the co-formulant contains no substance considered to be persistent, bioaccumulating and toxic (PBT) and no substance considered to be very persistent and very bioaccumulating (vPvB).

According to information found in REACH Registration dossier of Benzenesulfonic acid, C10-13-(linear)alkyl derivs., calcium salt: “The substance is not regarded as a PBT or vPvB as it is readily biodegradable, very water soluble, and is not expected to bioaccumulate.”

According to the information found in REACH Registration dossier of 2-ethylhexan-1-ol “the substance is not PBT / vPvB

Justification

Based on evaluation of the data described in this section it is concluded here that the submission substance

- is readily biodegradable and is considered not to fulfill the P and vP criterion
- is not fulfilling the B (or vB) criterion
- is not fulfilling the T criterion

and therefore is evaluated to be neither a PBT nor a vPvB substance.

Overall conclusion:

Based on the data presented, the submission substance is not considered to be PBT /vPvB”.

Ingredients of co-formulant - Geronol TE/777 are not classified in Part 3 of Annex VI to Regulation (EC) No 1272/2008 as CMR (Ingredients of co-formulant are not classified, according to CLP Regulation, as mutagen category 1A or 1B. Ingredients of co-formulant are not classified, according to CLP Regulation, as carcinogen category 1A or 1B. Ingredients of co-formulant are not classified, according to CLP Regulation, as toxic for reproduction category 1A or 1B).

Ingredients of co-formulant - Geronol TE/777 - are not listed in Annexes I to V to Regulation (EU) 2019/1021 (Regulation of The European Parliament and of The Council of 20 June 2019 on persistent organic pollutants).

Ingredients of co-formulant - Geronol TE/777 - are not included in the list referred to in Article 59(1) of Regulation (EC) No 1907/2006 (candidate list) (it is not identify as persistent, bioaccumulative and toxic in accordance with Article 57, point (d), of that Regulation; it is not identify as very persistent and very bioaccumulative in accordance with Article 57, point (e), of that Regulation; it is not identify as a substance of very high concern in accordance with Article 57, point (f), of that Regulation due to endocrine

disrupting properties).

The use of a substance as a co-formulant - Geronol TE/777 - in plant protection products is not included in Annex XVII to Regulation (EC) No 1907/2006. Geronol TE/777 is not restricted for the use in plant protection products.

Additionally taking into account article 3.1 of Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council “When assessing applications for authorisation of plant protection products, Member States shall verify whether co-formulants contained in plant protection products could be considered an unacceptable co-formulant based on the criteria set out in the Annex.” co-formulant Geronol TE/777 can be treated as acceptable co-formulant.

Co-formulant - **N-(n-octyl)-2-pyrrolidone**, CAS: 2687-94-7 - is not listed in Annex III (List of co-formulants which are not accepted for inclusion in plant protection products as referred to in Article 27) of Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products.

Co-formulant - N-(n-octyl)-2-pyrrolidone, CAS: 2687-94-7 - according to Safety Data Sheets is classified, according to Regulation (EC) No 1272/2008 – CLP as hazardous:

- Skin Corr. 1; H314 (Causes severe skin burns and eye damage),
- Aquatic Chronic 2; H11 (Toxic to aquatic life with long lasting effects).

According to the information found in the SDS the co-formulant does not meet vPvB (very persistent and very bioaccumulating) or PBT (persistent, bioaccumulating and toxic) criteria of Annex XIII of Regulation (EC) No 1907/2006 (REACH).

According to the information found in the SDS the co-formulant does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

According to the information found on ECHA webpage - registration dossier - concerning PBT status of co-formulant N-(n-octyl)-2-pyrrolidone, CAS: 2687-94-7:

“the substance is not PBT / vPvB

Justification

Regarding all available data on biodegradation, bioaccumulation and toxicity it can be stated that the substance does not fulfill the PBT criteria (not PBT) and not the vPvB criteria (not vPvB).”

Co-formulant - N-(n-octyl)-2-pyrrolidone, CAS: 2687-94-7 - is included in Part 3 of Annex VI to Regulation (EC) No 1272/2008 but is not classified as CMR. (Co-formulant is not classified, according to CLP Regulation, as mutagen category 1A or 1B. Co-formulant is not classified, according to CLP Regulation, as carcinogen category 1A or 1B. Co-formulant is not classified, according to CLP Regulation, as toxic for reproduction category 1A or 1B).

Co-formulant - N-(n-octyl)-2-pyrrolidone, CAS: 2687-94-7 - is not listed in Annexes I to V to Regulation (EU) 2019/1021 (Regulation of The European Parliament and of The Council of 20 June 2019 on persistent organic pollutants).

Co-formulant - N-(n-octyl)-2-pyrrolidone, CAS: 2687-94-7 - is not included in the list referred to in Article 59(1) of Regulation (EC) No 1907/2006 (candidate list) (it is not identify as persistent, bioaccumulative and toxic in accordance with Article 57, point (d), of that Regulation; it is not identify as very persistent and very bioaccumulative in accordance with Article 57, point (e), of that Regulation; it is not identify as a substance of very high concern in accordance with Article 57, point (f), of that Regulation due to endocrine disrupting properties).

The use of a substance as a co-formulant - N-(n-octyl)-2-pyrrolidone, CAS: 2687-94-7 - in plant protection products is not included in Annex XVII to Regulation (EC) No 1907/2006. N-(n-octyl)-2-pyrrolidone, CAS: 2687-94-7 is not restricted for the use in plant protection products.

Additionally taking into account article 3.1 of Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council “When assessing applications for authorisation of plant protection products, Member States shall verify whether co-formulants contained in plant protection products could be considered an

unacceptable co-formulant based on the criteria set out in the Annex.” co-formulant N-(n-octyl)-2-pyrrolidone, CAS: 2687-94-7 can be treated as acceptable co-formulant.

Co-formulant - **Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate**, EC: 906-170-0 - is not listed in Annex III (List of co-formulants which are not accepted for inclusion in plant protection products as referred to in Article 27) of Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009 of the European Parliament and of the Council listing co-formulants which are not accepted for inclusion in plant protection products.

Co-formulant - Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate, EC: 906-170-0 - according to Safety Data Sheets is not classified, according to Regulation (EC) No 1272/2008 – CLP as hazardous.

According to the information found in the SDS the co-formulant does not meet vPvB (very persistent and very bioaccumulating) or PBT (persistent, bioaccumulating and toxic) criteria of Annex XIII of Regulation (EC) No 1907/2006 (REACH).

According to the information found in the SDS the co-formulant does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

According to the information found on ECHA webpage - registration dossier - concerning PBT status of co-formulant Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate, EC: 906-170-0:

“the substance is not PBT / vPvB.”

Co-formulant - Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate, EC: 906-170-0 - is not included in Part 3 of Annex VI to Regulation (EC) No 1272/2008. (Co-formulant is not classified, according to CLP Regulation, as mutagen category 1A or 1B. Co-formulant is not classified, according to CLP Regulation, as carcinogen category 1A or 1B. Co-formulant is not classified, according to CLP Regulation, as toxic for reproduction category 1A or 1B).

Co-formulant - Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate, EC: 906-170-0 - is not listed in Annexes I to V to Regulation (EU) 2019/1021 (Regulation of The European Parliament and of The Council of 20 June 2019 on persistent organic pollutants).

Co-formulant - Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate, EC: 906-170-0 - is not included in the list referred to in Article 59(1) of Regulation (EC) No 1907/2006 (candidate list) (it is not identify as persistent, bioaccumulative and toxic in accordance with Article 57, point (d), of that Regulation; it is not identify as very persistent and very bioaccumulative in accordance with Article 57, point (e), of that Regulation; it is not identify as a substance of very high concern in accordance with Article 57, point (f), of that Regulation due to endocrine disrupting properties).

The use of a substance as a co-formulant - Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate, EC: 906-170-0 - in plant protection products is not included in Annex XVII to Regulation (EC) No 1907/2006. Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate, EC: 906-170-0 is not restricted for the use in plant protection products.

Additionally taking into account article 3.1 of Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 setting out detailed rules for the identification of unacceptable co-formulants in plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council “When assessing applications for authorisation of plant protection products, Member States shall verify whether co-formulants contained in plant protection products could be considered an unacceptable co-formulant based on the criteria set out in the Annex.” co-formulant Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate, EC: 906-170-0 can be treated as acceptable co-formulant.

Co-formulant- Trade name / chemical name / CAS no / EC no	Information on co-formulant provided in SDS: Hazard identification (SECTION 2 of SDS) / Composition/information on ingredients (SECTION 3 of SDS: Section 3.1: - co-formulant is substance Section 3.2: - co-formulant is mixture) / REACH registration no.	Notified or harmonized classification and labelling according to CLP criteria (ECHA data-base/Annex VI to CLP)	Regulation (EC) No 1907/2006 (REACH Regulation) Annex XIV (including ECHA candidate list) Annex XVII Compliance Check	Regulation (EU) 2019/1021 (POPs) Annex I to V	Biocide active substance Regulation (EU) No 528/2012 (BPR)	Pesticide active substance Regulation (EC) No 1107/2009	Cosmetic ingredient Regulation (EC) No 1223/2009 Feed additive Regulation (EC) No 1831/2003 Food additive Regulation (EC) No 1333/2008 Food contact material Directive 2007/42/EC (Annex II) Regulation (EU) 2011/10 (Annex I) Excipient with a known action or effect SANTE-2017-11668
Geronol TE/777 (trade name)	Hazard identification (Section 2 of SDS): Classified as hazardous according to CLP Regulation: Skin Irrit. 2, H315 (Causes skin irritation), Eye Irrit. 2, H319 (Causes serious eye irritation). Identification: Co-formulant is mixture Ingredients of the co-formulant, according to SDS: - Benzenesulfonic acid, C10-13- (linear)alkyl derivs., calcium salt, WE: 932-231-6, 5-10%, REACH Registration number: 01-2119560592-37-XXXX Classification: Skin Irrit. 2; H315 Eye Dam. 1; H318 Aquatic Chronic 3; H412 - 2-ethylhexan-1-ol, CAS: 104-76-7, 1-5%, Classification: Acute Tox. 4; H332	Not applicable (co-formulant is a mixture. Notification or harmonized classification is only applicable for substances).	Ingredients of co-formulant are not included in Annex XIV and Annex XVII of REACH Regulation and also is not included in ECHA candidate list.	Not included	Ingredients of co-formulant are not identified as having endocrine-disrupting properties.	Taking into account article 3.1 of Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 co-formulant can be treated as acceptable co-formulant.	Ingredients of co-formulant are not cited in above mentioned regulations.

Co-formulant- Trade name / chemical name / CAS no / EC no	Information on co-formulant provided in SDS: Hazard identification (SECTION 2 of SDS) / Composition/information on ingredients (SECTION 3 of SDS: Section 3.1: - co-formulant is substance Section 3.2: - co-formulant is mixture) / REACH registration no.	Notified or harmonized classification and labelling according to CLP criteria (ECHA data-base/Annex VI to CLP)	Regulation (EC) No 1907/2006 (REACH Regulation) Annex XIV (including ECHA candidate list) Annex XVII Compliance Check	Regulation (EU) 2019/1021 (POPs) Annex I to V	Biocide active substance Regulation (EU) No 528/2012 (BPR)	Pesticide active substance Regulation (EC) No 1107/2009	Cosmetic ingredient Regulation (EC) No 1223/2009 Feed additive Regulation (EC) No 1831/2003 Food additive Regulation (EC) No 1333/2008 Food contact material Directive 2007/42/EC (Annex II) Regulation (EU) 2011/10 (Annex I) Excipient with a known action or effect SANTE-2017-11668
	Skin Irrit. 2; H315 Eye Irrit. 2; H319 STOT SE 3; H335 REACH Registration number: 01-2119487289-20-XXXX						
Surfadone™ LP-100 (trade name) N-(n-octyl)-2-pyrrolidone CAS: 2687-94-7	Hazard identification (Section 2 of SDS): Classified as hazardous according to CLP Regulation: Skin Corr. 1; H314 (Causes severe skin burns and eye damage), Aquatic Chronic 2; H11 (Toxic to aquatic life with long lasting effects).irritation) Identification: Co-formulant is substance N-(n-octyl)-2-pyrrolidone CAS number: 2687-94-7 EC number: 403-700-8 Index No: 613-098-00-0 REACH Registration number: 01-0000015335-74-XXXX	Annex VI to CLP: Skin Corr. 1B; H314 Aquatic Chronic 2; H411 ECHA C&L Inventory Skin Corr. 1B; H314 Aquatic Chronic 2; H411 (Numbers of notifiers: 154)	Co-formulant is not included in Annex XIV and Annex XVII of REACH Regulation and also is not included in ECHA candidate list.	Not included	Co-formulant is not identified as having endocrine-disrupting properties.	Taking into account article 3.1 of Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 co-formulant can be treated as acceptable co-formulant.	Not cited in above mentioned regulations.

Co-formulant- Trade name / chemical name / CAS no / EC no	Information on co-formulant provided in SDS: Hazard identification (SECTION 2 of SDS) / Composition/information on ingredients (SECTION 3 of SDS: Section 3.1: - co-formulant is substance Section 3.2: - co-formulant is mixture) / REACH registration no.	Notified or harmonized classification and labelling according to CLP criteria (ECHA data-base/Annex VI to CLP)	Regulation (EC) No 1907/2006 (REACH Regulation) Annex XIV (including ECHA candidate list) Annex XVII Compliance Check	Regulation (EU) 2019/1021 (POPs) Annex I to V	Biocide active substance Regulation (EU) No 528/2012 (BPR)	Pesticide active substance Regulation (EC) No 1107/2009	Cosmetic ingredient Regulation (EC) No 1223/2009 Feed additive Regulation (EC) No 1831/2003 Food additive Regulation (EC) No 1333/2008 Food contact material Directive 2007/42/EC (Annex II) Regulation (EU) 2011/10 (Annex I) Excipient with a known action or effect SANTE-2017-11668
Rhodiasolv RPDE (trade name) Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate EC: 906-170-0	Hazard identification (Section 2 of SDS): Not classified as hazardous according to CLP Regulation Identification: Co-formulant is substance Reaction mass of dimethyl adipate and dimethyl glutarate and dimethyl succinate EC: 906-170-0 REACH Registration number 01-2119475445-32-XXXX Impurity of substance: methanol (CAS: 67-56-1)	Annex VI to CLP: not included ECHA C&L Inventory: not classified	Co-formulant is not included in Annex XIV and Annex XVII of REACH Regulation and also is not included in ECHA candidate list.	Not included	Co-formulant is not identified as having endocrine-disrupting properties.	Taking into account article 3.1 of Commission Implementing Regulation (EU) 2023/574 of 13 March 2023 co-formulant can be treated as acceptable co-formulant.	Not cited in above mentioned regulations.

MS-PL conclusion on assessment of co-formulants according to Article 3 of Regulation (EU) 2023/574:
Based on the currently available MSDSs and other information provided by applicant or manufacturer of co-formulant, the product **Product code: GLOB2111F (Product name(s): Starinta)** does not contain any unacceptable co-formulant/ingredient listed in the Commission Regulation (EU) 2021/383 of 3 March 2021 amending Annex III to Regulation (EC) No 1107/2009.
According to the current knowledge and available information, none of the co-formulants in the plant protection product **Product code: GLOB2111F (Product name(s): Starinta)** meets the Annex to Regulation (EU) 2023/574 criteria for identification of co-formulants that are unacceptable for inclusion in a plant protection products.

1.2.3 Description of formulation process (KCP 1.4.3)

Add Rhodiasolv RPDE and N-Octyl-2-pyrrolidone dist. and stir together. Dissolve the ~~bixafen difenoconazole~~ while stirring ~~and afterwards dissolve the bixafen (keep stirring)~~. When the solution becomes clear, add the Geronol TE/777. Keep sitting until it is a clear and homogeneous liquid.

1.2.4 Description of the analytical methods for the determination of relevant formulants (KCP 5.1.1)

The product GLOB2111F does not contain a relevant co-formulants.

1.3 Data on Formulants

1.3.1 Material safety data sheets (KCP 1.4.3)

Material safety data sheets are provided in KCP 1.4.3.

1.3.2 Available toxicological data for each formulant (KCP 7.4)

Table 1.3-1: Toxicological data for each co-formulant

Formulant (Chemical name, CAS No.)	Content in the product		Classification	Consequence for the product classification (Y/N)
	g/L or g/kg	% w/w		
Bixafen, 581809-46-3	127.6	12.6	Not classified (Aquatic Chronic 1; H410. M=10)	Y
Geronol TE/777	150	14.9	Skin Irrit. 2; H315	Y
			Eye Dam./Irrit. 1; H318	Y
N-Octyl-2-pyrrolidone	200	19.89	Skin Corr./Irrit. 1B; H314	Y
			Eye Dam./Irrit. 1; H318	Y
			Aquatic Chronic 3; H411	Y
Rhodiasolv RPDE	528.4	52.79	Not classified	N

6.3 Toxicological Evaluation of Plant Protection Product

No tests were performed on GLOB2111F in the interest of animal welfare. For the acute oral toxicity, acute dermal toxicity, eye irritation and skin sensitisation the assessments have been conducted according to Regulation (EC) 1107/2009 (amended by Commission Regulation (EU) No 286/2011). For skin corrosion/irritation, in vitro testing was carried out (reference is made to dRR B6).

6.3.1 Acute oral toxicity (KCP 7.1.1)

As GLOB2111F does not contain any substance (active or formulant) classified for acute oral toxicity the preparation is **not classified** for acute oral toxicity according to Regulation EC 1272/2008.

6.3.2 Acute percutaneous (dermal) toxicity (KCP 7.1.2)

As GLOB2111F does not contain any substance (active or formulant) classified for acute dermal toxicity the preparation is **not classified** for acute oral toxicity according to Regulation EC 1272/2008.

6.3.3 Acute inhalation toxicity (KCP 7.1.3)

As GLOB2111F does not contain any substance (active or formulant) classified for acute inhalation toxicity the preparation is not classified for acute inhalation toxicity according to Regulation EC 1272/2008.

6.3.4 Skin irritation (KCP 7.1.4)

The co-formulants N-Octyl-2-pyrrolidone and Geronol TE/777 are classified for skin corrosion/irritation as category 1B and 2 respectively. Geronol TE/777 contains Benzenesulfonic acid, C10-13-(linear)alkyl derivs., calcium salt and 2-ethylhexan-1-ol which are classified as Skin Irrit. 2; H315. None of the other ingredients attract skin irritation classification.

According to Table 3.2.3 (copied below) in Regulation EC 1272/2008, the ingredient concentration is compared to the generic concentration limits.

Table 3.2.3

Generic concentration limits of ingredients classified for skin corrosive/irritant hazard (Category 1 or 2) that trigger classification of the mixture as corrosive/irritant to skin

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Skin Corrosive	Skin Irritant
	Category 1 (see note below)	Category 2
Skin Corrosive Categories 1A, 1B, 1C	≥ 5 %	≥ 1 % but < 5 %
Skin irritant Category 2		≥ 10 %
(10 × Skin Corrosive Category 1A, 1B, 1C) + Skin irritant Category 2		≥ 10 %

Sum of ingredients classified as Skin Corrosive Category 1A, 1B, 1C = 19.8%

As the content of N-Octyl-2-pyrrolidone is more than 5%, GLOB2111F should be classified for skin corrosion according to Regulation EC 1272/2008 as Skin Corr./Irrit. 1; H314. However, reference is made to the *in vitro* testing carried out with the closely related formulation GLOB2020aF, also containing - N-Octyl-2-pyrrolidone at exactly the same concentration. In this study, GLOB2020aF was shown to be not corrosive (reference is made to dRR Part B6). Considering that both formulations are closely related (reference is made to their detailed compositions in table 1.2-1 and 1.2.2 above), the negative result of this study can also be used in support of GLOB2111F, therefore excluding this formulation as being corrosive for the skin. However, as no *in vitro* testing was carried out to exclude classification as Skin Irrit. Catego-

ry 2 (H315), GLOB2111F should be classified for skin irritation according to Regulation EC 1272/2008 as Skin Irrit. 2, H315.

6.3.5 Eye irritation (KCP 7.1.5)

The co-formulants N-Octyl-2-pyrrolidone and Geronol TE/777 are classified for eye damage/irritation as Category 1; H318. Geronol TE/777 contains Benzenesulfonic acid, C10-13-(linear)alkyl derivs., calcium salt classified as Eye Dam. 1; H318 and 2-ethylhexan-1-ol classified as Eye Irrit. 2; H319. Additionally, co-formulant N-Octyl-2-pyrrolidone is also classified as Category 1B; H314 for skin corrosion/irritation. None of the other ingredients attract eye irritation classifications.

According to Table 3.3.3 (copied below) in Regulation EC 1272/2008, the ingredient concentration is compared to the generic concentration limits.

Table 3.3.3

Generic concentration limits of ingredients of a mixture classified as Skin corrosive Category 1 and/or eye Category 1 or 2 for effects on the eye that trigger classification of the mixture for effects on the eye (Category 1 or 2)

Sum of ingredients classified as:	Concentration triggering classification of a mixture as:	
	Irreversible Eye Effects	Reversible Eye Effects
	Category 1	Category 2
Eye Effects Category 1 or Skin Corrosive Category 1A, 1B, 1C	≥ 3 %	≥ 1 % but < 3 %
Eye Effects Category 2		≥ 10 %
(10 × Eye Effects Category 1) + Eye effects Category 2		≥ 10 %
Skin Corrosive Category 1A, 1B, 1C + Eye effects Category 1	≥ 3 %	≥ 1 % but < 3 %
10 × (Skin Corrosive Category 1A, 1B, 1C + Eye Effects Category 1) + Eye Effects Category 2		≥ 10 %

Sum of ingredients classified as Eye Effects Category 1 or Skin Corrosive Category 1A, 1B, 1C = 34.721.3%

This is clearly more than 3%, indicating that GLOB2111F should be classified for eye irritation according to Regulation EC 1272/2008 as Eye Irrit. 1, H318.

6.3.6 Skin sensitisation (KCP 7.1.6)

None of the co-formulants nor the active ingredient are classified for skin sensitization. Therefore, GLOB2111F should not be classified for skin sensitization according to Regulation EC 1272/2008.

9.5. Effects on aquatic organisms

9.5.1 Toxicity data

Classification of GLOB2111F was performed according to the EU Regulation 1272/2008 (CLP labelling).

Acute toxicity tests were performed with the formulation. Reference is made to the table 9.5-2 provided under point 9.5 of section B9 for a summary table of the acute toxicity studies to daphnia and algae performed with GLOB2111F. No chronic toxicity data with the formulation is available. No acute classification proposed as all measured L(E)C₅₀ values for the formulation were above 1 mg product/L.

For chronic classification, the summation method in accordance with EU Regulation 1272/2008 (CLP labelling) was applied. The active substance bixafen is not classified for chronic aquatic toxicity. However, according to the available toxicity data (NOEC for *Pimephales promelas* of 0.0046 mg/L), the active substance bixafen should be classified as Aquatic chronic 1 (H410) with a M factor of 10. Additionally, co-formulant N-Octyl-2-pyrrolidone also attracts classification for chronic aquatic toxicity (Aquatic Chronic 3, H412). In consequence, according to Table 4.1.2 (copied below) in EU Regulation 1272/2008 (CLP labelling), GLOB2111F should be classified as Aquatic Chronic 1 (H410).

Table 4.1.2

Classification of a mixture for chronic (long term) hazards, based on summation of classified components

Sum of components classified as:	Mixture is classified as:
Chronic Category 1 × M ^(a) ≥ 25 %	Chronic Category 1
(M × 10 × Chronic Category 1) + Chronic Category 2 ≥ 25 %	Chronic Category 2
(M × 100 × Chronic Category 1) + (10 × Chronic Category 2) + Chronic Category 3 ≥ 25 %	Chronic Category 3
Chronic Category 1 + Chronic Category 2 + Chronic Category 3 + Chronic Category 4 ≥ 25 %	Chronic Category 4
^(a) For explanation of the M-factor, see 4.1.3.5.5.5.	

zRMS comments

For formulation GLOB2111F the toxicity data are available for invertebrate, algae. No data are available for fish.

According to the Guidance on the Application of the CLP Criteria: *Where a classification is made based on the test data, valid data should be normally be available on each of fish, crustacea and algae or other aquatic plants, unless a decision to classify in the most stringent category(ies) (Acute 1 and Chronic 1) can be made without a full dataset.*

Because of based on the available data the formulation cannot be classified in the most stringent categories this approach cannot be used in classification.

According to the Guidance on the Application of the CLP Criteria, Version 5.0, July 2017: *When information on the classification of the components and test data on the mixture as a whole are available for*

some, but not all three trophic levels: classification based on the summation method.

The active substance bixafen has no harmonised classification, however based on the acute toxicity data for fish LC₅₀ at 0.095 mg/L and for algae EC₅₀ at 0.0965 mg/L the following classification is proposed:

Aquatic acute toxicity Category 1, H 400 Very toxic to aquatic life with M = 10.

Table 4.1.1

Classification of a mixture for short-term (acute) hazards based on summation of classified components

Sum of components classified as:	Mixture is classified as:
Acute 1 × M (a) ≥ 25 %	Acute 1

Based on the concentration of bixafen in GLOB2111F equal 12.6% and M factor at 10 and in accordance with CLP Regulation the following classification for formulation is proposed:

Aquatic acute toxicity Category 1, H 400 Very toxic to aquatic life.

The classification of formulation as: *Aquatic chronic toxicity Category 1, H 410 Very toxic to aquatic life with long lasting effects* is accepted.

Acute toxicity to fish

No formulation study has been carried out on fish in order to avoid conducting studies on vertebrates. As based on the active substance data the acute toxicity of bixafen to algae and fish has been found similar, a formulation endpoint for algae is considered to be protective enough for both groups of aquatic organisms. The calculation is given in table 9.5.1-1 below.

However, to reduce uncertainty around the use of the formulation endpoint for algae to predict toxicity of the product to fish, a formulation endpoint for fish has been calculated based on the toxicity data available for the active substance bixafen and the co-formulants of GLOB2111F by means of the concentration addition model (CA model). For the toxicity data of the co-formulants of GLOB2111F, reference is made to the SDS provided by the producers.

The CA model is based on the following equation, for deriving a predicted EC_x or NOEC value for a mixture of (active) substances with known toxicity (EC_{xmix-CA} or NOEC_{mix-CA}), assuming concentration additivity:

$$EC_{xmix-CA} = \left(\sum_{i=1}^n \frac{p_i}{EC_{x_i}} \right)^{-1}$$

where:

n: number of mixture components

i: index from 1...n mixture components

p_i: the ith component as a relative fraction of the mixture composition (note: Σ p_i must be 1)

EC_{x_i}: concentration of component i provoking x % effect.

It is also worth mentioning that the calculated EC_{xmix-CA} for fish and algae according to the CA model have also been found to be similar.

Furthermore, in order to confirm that the toxicity of the formulation can effectively be predicted from the toxicity of its individual components, the measured mixture toxicity of the formulation to aquatic invertebrates and algae was compared to the predicted mixture toxicity expected by CA model by means of the MDR formula (MDR = EC_{xmix-ca}/EC_{xppp}). The calculation is given in table 9.5.1-1 below.

Comparison of the acute toxicity of GLOB2111F to the predicted one based on the ingredients

Species	Substance	Concentration (C _i) in formulation (g a.s./L)	Fraction of sub- stance in the formu- lation mixture X(a.s.)	Acute toxicity end- point (mg a.s./L)	EC _{Xmix-CA} (mg sum a.s. /L)	EC _{XPPP} (mg sum a.s. /L)	MDR*
Fish	Bixafen	125	0.15	0.095	0.63**		
	Rhodiasolv RPDE	532.4	0.62	18			
	N-Octyl-2-pyrrolidone	200	0.23	17.8			
Invertebrates	Bixafen	125	0.15	1.2	6.34	4.24455	1.49
	Rhodiasolv RPDE	532.4	0.62	112			
	N-Octyl-2-pyrrolidone	200	0.23	7.59			
Algae	Bixafen	125	0.15	0.0965	0.65	0.84891	0.77
	Rhodiasolv RPDE	532.4	0.62	85			
	N-Octyl-2-pyrrolidone	200	0.23	19			

* MDR = (L/EC₅₀ theoretical) / (L/EC₅₀ measured)

** Endpoint used in the acute risk assessment for fish.

If MDR is between 0.2 and 5, the observed and calculates toxicities are considered in agreement. If MDR is > 5, the observed toxicity of mixture is higher than that calculated assuming dose additivity. If MDR is < 0.2, the mixture is less toxic than expected. Between 0.2 and 5, toxicity of the formulation is approximately hold by the toxicity of mixture (sum of a.s.). For both situation, risk assessment can be based on a.s..

For aquatic invertebrates and and Algae, the calculated MDR have be found to be not only between 0.2 and 5 but almost equal to 1 (1.49 and 0.77, respectively). From this results it is clear that the toxicity of GLOB2111F can be effectively predicted from the individual toxicity of its components, rejecting that the formulation may act more (i.e. synergistically) or less than additive (i.e. antagonistically) than expected by CA.

2 Statement on the regulatory status of formulants

None of the formulants is approved for use in feeding stuffs, etc.

Appendix 1 Lists of studies 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 1.4.3	Anonymous	2023	MSDS of GLOB2111F and its formulants Globachem N.V. Not GLP Unpublished	N	Globachem NV
KCP 2.2.1, KCP 2.2.2	Kishora	2023	Theoretical certificate of explosive and oxidizing properties for an EC formulation containing 125 g/L bixafen Eurofins Advinus Agrosciences Services India Private Limited Not GLP unpublished	N	Globachem NV

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

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 XX	Author	YYYY	Title	Y/N	Owner

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
			Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished		

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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on and 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
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner