REGISTRATION REPORT

Part A

Risk Management

Product code: COCOH 10 SC

Product name(s): EIPHAGE

Chemical active substance(s):

Copper, 272 g/L

(from Copper oxychloride + Copper hydroxide)

Southern Zone

Zonal Rapporteur Member State: France

NATIONAL ASSESSMENT FRANCE

(new application)

Applicant: Gowan France SAS

Date: 15/07/2025

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PART A
RISK MANAGEMENT

1 Details of the application

The company Gowan France SAS has requested a marketing authorisation in France for the product EIPHAGE (product code: COCOH 10 SC), containing 272 g/kg copper[1] (136 g/L in the form of copper oxychloride (CAS n° 1332-65-6 or 1332-40-7) and 136 g/L in the form of copper hydroxide (CAS 20427-59-2)) as a fungicide for professional uses.
Appendix 1 of this document provides a copy of the product authorisation.

Appendix 2 of this document contains a copy of the product label (draft as proposed by the applicant).

1.1 Application background

The present registration report concerns the evaluation of Gowan France SAS's application submitted on 02/11/2022 to market EIPHAGE (COCOH 10 SC) in France (product uses described under point 2.3). France acted as a zonal Rapporteur Member State (zRMS) for this request and assessed the application submitted for the first authorisation of this product in France and in other Member States (MSs) of the Southern zone.

The present application (2023-0104) was evaluated in France by the French Agency for Food, Environmental and Occupational Health & Safety (Anses), according to the Regulation (EC) no 1107/2009[2], the implementing regulations, and French regulations. This application was assessed in the context of the zonal procedure for all MSs of the Southern zone, taking into account the worst-case uses ("risk envelope approach")[3]. When risk mitigation measures were necessary, they are adapted to the situation in France.

The data taken into account are those deemed to be valid either at European level (Review Report and EFSA conclusion) or at zonal/national level. The assessment of EIPHAGE (COCOH 10 SC) has been made using endpoints agreed in the EU peer review of Copper compounds. It also includes assessment of data and information related to EIPHAGE (COCOH 10 SC) where those data have not been considered in the EU peer review process.

The conclusions of the assessment published by EFSA 2018[4,5], as part of the procedure for the renewal of the approval of copper compounds, based on the available information, identify risk for non-taget organisms for the representative uses on grapevine, cucurbits and tomatoes, as well as to workers for the grapevine use.

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1 COMMISSION IMPLEMENTING REGULATION (EU) 2018/1981 of 13 December 2018 renewing the approval of the active substances copper compounds, as candidates for substitution, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, and amending the Annex to Commission Implementing Regulation (EU) No 540/2011

2 REGULATION (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC

3 SANCO document "risk envelope approach", European Commission (14 March 2011). Guidance document on the preparation and submission of dossiers for plant protection products according to the "risk envelope approach"; SANCO/11244/2011 rev. 5

4 Peer review of the pesticide risk assessment of the active substance copper compounds Copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture, EFSA Journal 2018;16(1):515

5 Outcome of the consultation with Member States, the applicant and EFSA on the pesticide risk assessment for copper compounds copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, Bordeaux mixture in light of confirmatory data. EFSA supporting publication 2018:EN-1486.

In the framework of MRL review for copper compounds under Article 12 of Regulation (CE) 396/2005, EFSA published a reasoned opinion (EFSA, 2018[6]). Based on an evaluation of the available data MRL have been proposed and a consumer risk assessment has been conducted. Some information required by the regulation has not been transmitted and a chronic risk for the consumers was identified. Therefore the consumer risk assessment is only tentative and some of the proposed MRL still require a decision by risk managers. Exposure reduction measures could also be investigated.

This part A of the RR presents a summary of essential scientific points upon which recommendations are based and is not intended to show the assessment in detail. The risk assessment conclusions provided in this document are based on the information, data and assessments provided in the Registration Report, Part B Sections 1-10 and Part C, and where appropriate the addendum for France.

The conclusions on the acceptability of risk are based on the criteria provided in Regulation (EU) No 546/2011[7], and are expressed as “acceptable” or “not acceptable” in accordance with those criteria.

This document also describes the specific conditions of use and labelling required for France for the registration of EIPHAGE (COCOH 10 SC).

1.2 Letters of Access

The applicant has provided a letter of access for active substance. This letter of access is available upon request.

1.3 Justification for submission of tests and studies

According to the applicant: « The current dossier for authorization of product EIPHAGE (COCOH 10 SC) was submitted under article 33 of Regulation (EC) No. 1107/2009, therefore new studies were performed specifically to support the current registration. The study reports submitted within this application are in agreement with the data requirements of the Regulation (EU) 284/2013. Unless specifically indicated, all tests and studies have been submitted to address mandatory data requirements for the authorisation of the plant protection product ».

1.4 Data protection claims

Where protection for data is being claimed for information supporting registration of EIPHAGE (COCOH 10 SC), it is indicated in the reference lists in Appendix 1 of the Registration Report, Part B Sections 1-7..

2 Details of the authorisation decision

2.1 Product identity

Product code	COCOH 10 SC
Product name in MS	EIPHAGE
Authorisation number	N/A : no marketing authorisation granted

[6] REASONED OPINION ADOPTED: 1 March 2018. Review of the existing maximum residue levels for copper compounds according to Article 12 of Regulation (EC) No 396/2005 European Food Safety Authority (EFSA).

[7] COMMISSION REGULATION (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products

Kind of use	Professional use
Low risk product (article 47)	No
Function	Fungicide
Applicant	Gowan France SAS
Active substance(s) (incl. content)	Copper, 272 g/L (from Copper Oxychloride and Copper Hydroxide)
Formulation type	Suspension Concentrate [SC]
Packaging	N/A : no marketing authorisation granted
Coformulants of concern for national authorisations	The product contains a formaldehyde releaser coformulant
Restrictions related to identity	-
Mandatory tank mixtures	None
Recommended tank mixtures	None

2.2 Conclusion

The evaluation of the application for EIPHAGE (COCOH 10 SC) resulted in the decision **to refuse** the authorisation.

2.3 Substances of concern for national monitoring

Refer to 5.1.1.

2.4 Classification and labelling

2.4.1 Classification and labelling under Regulation (EC) No 1272/2008

N/A : no marketing authorisation granted

2.4.2 Standard phrases under Regulation (EU) No 547/2011

SP 1	Do not contaminate water with the product or its container (Do not clean application equipment near surface water/Avoid contamination via drains from farmyards and roads).
	For other restrictions refer to 2.5

2.4.3 Other phrases (according to Article 65 (3) of the Regulation (EU) No 1107/2009)

None.

2.5 Risk management

According to the French law and procedures, specific conditions of use are set out in the Decision letter. The French Order of 4 May 2017[8] provides that:

- unless otherwise stated in the product authorisation, the pre harvest interval (PHI) is at least 3 days;
- unless otherwise stated in the product authorisation, the minimum buffer zone alongside a water body is 5 metres for products applied through spraying or dusting;
- unless otherwise stated in the product authorisation, the minimum re-entry period is 6 hours for field uses and 8 hours for indoor uses.

Drift reduction measures such as low-drift nozzles are not considered within the decision-making process in France. However, non-spraying buffer zones may be reduced under some circumstances as explained in appendix 3 of the above-mentioned French Order.

Finally, the French Order of 12 April 2021[9] provides that:

- an authorisation granted for a "reference" crop applies also for "related" crops, unless formally stated in the Decision
- the "reference" and "related" crops are defined in Appendix 1 of that French Order.

Thus, at French national level, possible extrapolation of submitted data and the corresponding assessment from "reference" crops to "related" ones are undertaken even if not clearly requested by the applicant in their dRR, and a conclusion is also reached on the acceptability of the intended uses on those "related" crops. The aim of this Order, mainly based on the EU document on residue data extrapolation[10] is to supply "minor" crops with registered plant protection products.

Therefore the GAP table (Section 2.3) and Decision may include uses on crops not originally requested by the applicant.

The Decision, as reproduced in Appendix 1, takes also into account national provisions, including national mitigation measures.

2.5.1 Restrictions linked to the PPP

The authorisation of the PPP is linked to the following conditions:

Operator protection:	
-	Refer to the Decision in Appendix 1 for the details.
Worker protection:	
-	Refer to the Decision in Appendix 1 for the details.
Integrated pest management (IPM)/sustainable use:	
-	-
Environmental protection	
-	-

[8] Arrêté du 4 mai 2017 relatif à la mise sur le marché et à l'utilisation des produits phytopharmaceutiques et de leurs adjuvants visés à l'article L. 253-1 du code rural et de la pêche maritime, amended by the arrêté du 27 décembre 2019 relatif aux mesures de protection des personnes lors de l'utilisation de produits phytopharmaceutiques https://www.legifrance.gouv.fr/eli/arrete/2017/5/4/AGRG1632554A/jo/texte ; https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000039686039&categorieLien=id

[9] https://www.legifrance.gouv.fr/jorf/id/JORFTEXT000043401456

[10] SANCO document "guidance document:- Guidelines on comparability, extrapolation, group tolerances and data requirements for setting MRLs": SANCO/ 7525/VI/95 - rev.9

Other specific restrictions	
Re-entry period	6 hours
Storage	- The product must be homogenised before use
	- Rinse the packaging several times.
Risk mitigation measures	-

2.5.2 Specific restrictions linked to the intended uses

Some of the authorised uses are linked to the following conditions in addition to those listed under point 2.5.1 (mandatory labelling):

None.

2.6 Intended uses (only NATIONAL GAP)

Please note: The GAP Table below reports the intended uses proposed by the applicant, and possible extrapolation according to French Order of 12 April 2021 (highlighted in green), evaluated and concluded as safe uses by France as zRMS. Those uses are then granted in France.
When the conclusion is "not acceptable", the intended use is highlighted in grey and the main reason(s) reported in the remarks.
When a use is "acceptable" with GAP restrictions, the modifications of the GAP are in bold.
Use should be crossed out when the applicant no longer supports this use.

GAP rev. 1, date: 2025-07-15

PPP (product name/code):	EIPHAGE / COCOH 10 SC	Formulation type:	SC [a, b]
Active substance 1:	Copper (from Copper Oxychloride and Copper Hydroxide)	Conc. of a.s. 1:	272 g/L [c]
Applicant:	Gowan France SAS	Professional use:	☒
Zone(s):	Southern Zone [d]	Non-professional use:	☐
Verified by MS:	Yes		
Field of use:	Fungicide		

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 a.s./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	FR	Sugar beet roots	F	Leaf Spot (*Cercospora beticola*)	Spray	BBCH 10-49	a) 3 b) 3	14	a) 3.68 b) 11.04	a) 1000 b) 3000	500-800	14	**Not acceptable** (MRL, product composition, analytical methods, aquatic organisms, birds, mammals, non-target arthropods, bees,, bumblebees, soil macro-organisms other than earthworms)

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 authorisation 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

3 Background of authorisation decision and risk management

3.1 Physical and chemical properties (Part B, Section 2)

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The studies have been performed on coloured version of p.f. EIPHAGE (COCOH 10 SC). For details regarding the comparison between formulations and the reasons why the formula-tions can be considered equivalent see dRR Part C.
The appearance of the product is that of a homogeneous fluid paste, odourless and with a blue/green colour (or uncoloured for formulation EIPHAGE (COCOH 10 SC) without Prussian Blue). It is not explosive, has no oxidising properties. The product is not flammable. It has a self-ignition temperature above 654 °C. In aqueous solution, it has a pH value around 9.19 at 20 °C. It wets rapidly and forms a stable suspension with water, which washes through a 45 µm sieve. There is no effect of low and high temperature on the stability of the formulation, since after 7 days at 0 °C and 14 days at 54 °C, neither the active ingredient content nor the technical properties were changed. The stability data indicate a shelf life of at least 2 years at ambient temperature when stored in commercial packaging (1L HDPE-EVOH). As the formulation is SC, the HDPE packaging can be considered as acceptable as the stability was performed on HDPE-EVOH packaging. However, little separation of brown liquid phase at the top of bottle and little sedimentation on the bottom of the bottle were observed after the storage. Its technical characteristics are acceptable for a SC formulation.
-For small volumes up to 5L the formulation must be shaked before use.
- For large volumes over 20L packaging must be able to accommodate a stirring system.
- Rinse each empty pesticide container several times, pour the rinse solution (rinsate) into the spray tank mixture.
For some co-formulants included in the composition of the product, the information provided does not guarantee compliance with Regulation (EU) No 2021/383. Consequently, the assessment of EIPHAGE (COCOH 10 SC) cannot be finalised. The product also contains a formaldehyde generator. It should be substituted.

3.2 Efficacy (Part B, Section 3)

Considering the data submitted:

The effectiveness level of EIPHAGE (COCOH 10 SC) is considered acceptable for the requested use against *Cercospora beticola* on sugar beet.

The phytotoxicity level of EIPHAGE (COCOH 10 SC) is considered acceptable for the requested use.

The risks of negative impact on yield, quality, propagation, succeeding crops and adjacent crops are considered negligible.

The risk of resistance to copper does not require a monitoring for the requested use.

3.3 Methods of analysis (Part B, Section 5)

3.3.1 Analytical method for the formulation

-Analytical methods for the determination of total Copper content ,Copper oxychloride and the relevant impurities in the formulation are available and validated.

-Analytical method for the determination of copper hydroxide by deduction is giving but it is not suitable to confirm the identity of the variant.

3.3.2 Analytical methods for residues

-Analytical methods for pre registration (residue trials, ecotox) have been submitted and considered validated,except for (CA 4.2/01: W.J.M. Maas (2012 & 2015) and Schafers, C. (2000)) they cannot be considered fully validated .

-The analytical méthode (Maccaferri L., 2009, Report No RA.08.25) and other pre-registration studies used in other sections. **In particular, many residue and ecotoxicological trials mentioned in dRR B7 and B9 are not validated since the report is missing and it should be provided.**

-Analytical methods for monitoring are available in the Draft Assessment Report/Report and validated for the determination of residues of copper compounds in plants, soil, water (surface and drinking),air and in body fluids and tissues.**To update the dossier, an analytical method with ILV for the determination of the relevant impurities of copper compounds in foodstuff of animal origin, is required .Furthermore an ILV method for the determination of the relevant impurities of copper compounds in plants and drinking water has to be submitted.**

3.4 Mammalian toxicology (Part B, Section 6)

Endpoints used in risk assessment

Agreed EU endpoints		
Active substance	**Copper dihydroxide**	**Copper oxychloride**
AOEL systemic	0,08	0,08
AAOEL	-	-
Oral absorption	50%	50%
Vapour pressure	-	-
Reference	EFSA 2018: EFSA Journal 2018;16(1):5152 EU 2018 : SANTE/10506/2018 Rev. 5	EFSA 2018: EFSA Journal 2018;16(1):5152 EU 2018 : SANTE/10506/2018 Rev. 5
Dermal absorption	Concentrate: 1% Diluted: 9%	Concentrate: 1% Diluted: 9%

3.4.1 Acute toxicity

EIPHAGE has a low toxicity in respect to acute oral, inhalation and dermal toxicity and is not irritating to skin or eye and is not a skin sensitiser.

3.4.2 Operator exposure

Long term exposure

		Copper	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**
downward application outdoor Buffer zone: 2-3 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 14 days			
Application rate		3 x 1,001 kg a.s./ha	
Tractor mounted boom spray application to Low vegetables			
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg Minimum volume water for application: 500L/ha	Work wear (arms, body and legs covered) M/L and A	0.03	36.4
Manual-hand held spray application to Low vegetables			
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg Minimum volume water for application: 500L/ha	Work wear (arms, body and legs covered) M/L and A	0.05	58.1
Manual-knapsack spray application to Low vegetables			
Spray application (AOEM**;** 75th percentile) Body weight: 60 kg Minimum volume water for application: 500L/ha	Work wear (arms, body and legs covered) M/L and A	0.02	22.9

According to the exposure assessment using the EFSA model[11], the operator exposure to EIPHAGE (CO-COH 10 SC) is below the AOEL value of copper, with a working coverall and gloves during mixing/loading and application.

For details of personal protective equipment for operators, refer to the Decision in Appendix 1

3.4.3 Worker exposure

Workers may have to enter into treated areas after treatment for crop removing bolting sugar beets activities. Therefore, estimation of worker exposure was calculated according to EFSA model.

[11] EFSA Journal 2022;20(1):7032

		Copper		
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of systemic AOEL**	**Re-entry restriction [days]***
Removing bolting sugar beets/outdoor Work rate: 8 hours/day DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 14 days				
Application rate		3 x 1,001 kg a.s./ha		
Body weight: 60 kg	Work wear (arms, body and legs covered) and gloves TC: 430 cm²/h	0.03	43.6	0

According to the exposure assessment using the EFSA model, the worker exposure to EIPHAGE (COCOH 10 SC) is below the AOEL value of copper, with a working coverall and gloves.

For details of personal protective equipment for workers, refer to the Decision in Appendix 1.

3.4.4 Bystander exposure

According to EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products (EFSA Journal 2022;20(1):7032):
"When an acute risk assessment is not triggered (i.e. for PPPs containing active substances that are not acutely toxic, and for which the setting of an AAOEL was not necessary), no bystander risk assessment is required. Exposure in this case will be determined by average exposure over a longer duration, and higher exposures on one day will tend to be offset by lower exposures on other days. Therefore, exposure assessment for residents also covers bystander exposure."

3.4.5 Resident exposure

Resident exposure was assessed according to the EFSA model .

		Copper	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of systemic AOEL**
Low vegetables			
Downward application Outdoor Buffer zone: 2-3 m Drift reduction technology: no DT_{50}: 30 days DFR: 3 µg/cm²/kg a.s./ha Interval between treatments: 14 days Volume min: 500 L/ha			
Number of applications and application rate		3 x 1,001 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.005	6.1
	Vapour (75th perc.)	0.0008	1

	Deposits (75th perc.)	0.004	4.8
	Re-entry (75th perc.)	0.03	42.8
	Sum (mean)	0.03	42
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.001	1.5
	Vapour (75th perc.)	0.0003	0.3
	Deposits (75th perc.)	0.001	1.7
	Re-entry (75th perc.)	0.02	23.8
	Sum (mean)	0.02	21.2

According to the exposure assessment performed with EFSA model, the resident exposure to EIPHAGE (COCOH 10 SC) is below the AOEL value of copper with a buffer zone of 3 meters and without drift reduction technology.

3.4.6 Combined exposure

Not relevant

3.5 Residues and consumer exposure (Part B, Section 7)

Due to insufficient data, the use on sugar beet root cannot be recommended.

The acute exposure calculations were not carried out because an acute reference dose (ARfD) was not deemed necessary for copper. Due to insufficient data on the on the magnitude of copper residue in plants, the chronic intakes of copper residues cannot be performed.

As far as consumer health protection is concerned, zRMS disagrees with the authorization of the intended use.

Information on EIPHAGE (COCOH 10 SC) (KCA 6.8)

Crop	**PHI for EIPHAGE (COCOH 10 SC) proposed by applicant**	**PHI/ Withholding period* sufficiently supported for** **Copper**	**PHI for EIPHAGE (COCOH 10 SC) proposed by zRMS**	**zRMS Comments (if different PHI proposed)**
Sugar beet roots	14	No	-	Not recommended use

NR: not relevant
* Purpose of withholding period to be specified

Waiting periods before planting succeeding crops

Not relevant

3.6 Environmental fate and behaviour (Part B, Section 8)

The fate and behaviour in the environment have been evaluated according to the requirements of Regulation (EC) No 1107/2009.

The PEC of copper in soil, surface water and groundwater have been assessed according to methodology agreed by the experts during the renewal approval of the active substance. The EU-agreed endpoints recommended in the EFSA journal (EFSA Journal 2018;16(1):5152) were considered.

PEC_{soil} and $PEC_{soil,\ accumulation}$ (derived for 10 years) can be used for the risk assessment for the non-target terrestrial organisms.

The FOCUS STEP 1-2 PECsw for the water column which were derived according to the agreed-EU methodology (EFSA Journal, 2018) can be used for the ecotoxicological risk assessment.

Given the uncertainties identified by zRMS in the notifier's exposure calculation (FOCUS STEP 1-2 for all entries to water bobies and FOCUS STEP 1-2 PECsed/$PEC_{sediment,\ accumulation}$ including mitigation measures, PECsw/$PEC_{sediment,\ accumulation}$ derived for the active substance cannot be used for the ecotoxicological risk assessment. As a consequence, the risk assessment cannot be finalised for the non-target aquatic organisms for the intended uses.

PECgw for copper do not occur at levels exceeding those mentioned in regulation EU No 546/2011 . Therefore, no unacceptable risk of groundwater contamination is expected for the intended uses.

Based on vapour pressure, no significant contamination of the air compartment is expected for the intended uses.

3.7 Ecotoxicology (Part B, Section 9)

The ecotoxicological risk assessment of the formulation was performed according to the requirements of Regulation (EC) No 1107/2009. Appropriate endpoints from the EU conclusions for the active substance were used for the intended use patterns. In cases where deviations from the EU agreed endpoints were considered appropriate (for example when additional studies are provided), such deviations were highlighted and justified accordingly.

For aquatic organisms, no reliable PECsed were provided by the applicant. In addition, as the toxicity reference values for copper proposed by the applicant was based on an approach rejected at European level, they could not be used. **Therefore, the risk assessment for aquatic organisms could not be finalised.**

Based on the guidance documents, the risks for non-target terrestrial plants are acceptable.

For birds and mammals, the risk is not acceptable at Tier 1, based on the risk envelop proposed by the applicant. The arguments provided by the applicant to refine the risk assessment are identical to those that were considered insufficient at the European level. Therefore, without further data, **the risk assessment for birds and mammals cannot be finalised.**

For non-target arthropods other than bees, no toxicity data could be validated due to the lack of study report submitted by the applicant. Therefore the risk assessment could not be finalised.

For bees, according to new requirements of Reg. No. 284/2013, information on chronic effects on adult bees and on development of bees should have been submitted as exposure of bees to the formulation cannot be excluded. The risk assessment proposed by the applicant is not considered acceptable. As no reliable toxicity data are available, it is not possible to finalise the risk assessment for non-target arthropods.

For earthworms, the higher tier earthworm field trial data from a study conducted over 10 years with copper application every year demonstrates that there is an acceptable risk to earthworms for applications up to 4kg cu/ha/yr. Therefore, an acceptable risk for earthworms is demonstrated for the intended use of EIPHAGE (COCOH 10 SC).
For other soil meso- and macro-organisms, no reliable formulation data are available for bees and non-target arthropods and then it cannot be excluded that the formulation EIPHAGE (COCOH 10 SC) is not more toxic than the active substance. In addition, no higher-tier studies are available and extrapolating the results of the multiyear field study with earthworms to other soil meso- and macro-organisms was not supported by the experts at the Peer Review experts' meeting 169. In addition, according to the new requirement of the regulation (EU) 284/2013, chronic formulation studies on soil organisms other than earthworms are required for *Folsomia candida* and *Hypoaspis aculeifer*. **Therefore, the risk for soil meso- and macro-organisms other than earthworms could not be finalised.**

For soil micro-organisms, based on a lack of effect at field level, the risks to soil micro-organisms are acceptable for the intended uses.

3.8 Relevance of metabolites (Part B, Section 10)

An assessment was conducted according to the SANCO/221/2000 guidance document. Please refer to environmental fate and behaviour above for conclusion on the risk of groundwater contamination.

4 Conclusion of the national comparative assessment (Art. 50 of Regulation (EC) No 1107/2009)

In accordance with Article 50, paragraphs 1.b) 1.c) and 1.d) of Regulation (EC) N°1107/2009,

- considering the absence of plant protection products or non-chemical methods of prevention or control allowing to consider a substitution of the product without major practical or economic disadvantage, and especially in the frame of organic farming,
- considering also the need to guarantee a diversity of the modes of action to reduce the emergence of resistance in target microorganisms,

The substitution of the product will not be considered for the intented use.

5 Further information to permit a decision to be made or to support a review of the conditions and restrictions associated with the authorisation

When the conclusions of the assessment is "Not acceptable", please refer to relevant summary under point 3, "Background of authorisation decision and risk management".

5.1.1 Post-authorisation monitoring

None.

5.1.2 Post-authorisation data requirements

None.

Appendix 1 Copy of the product authorisation

Docusign Envelope ID: FC7739F8-B4CA-483B-91C6-ABB17ACC82B9

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Décision relative à une demande d'autorisation de mise sur le marché d'un produit phytopharmaceutique

Vu les dispositions du règlement (CE) n° 1107/2009 du 21 octobre 2009 et de ses textes d'application,

Vu le code rural et de la pêche maritime, notamment le chapitre III du titre V du livre II des parties législative et règlementaire,

Vu la demande d'autorisation de mise sur le marché du produit phytopharmaceutique ***EIPHAGE***

de la société	*GOWAN FRANCE*
enregistrée sous le	*n° 2023-0104*

Vu les conclusions de l'évaluation de l'Anses du 25 novembre 2024,

Considérant que les données disponibles ne permettent pas d'exclure un risque de dépassement des limites maximales de résidus,

Considérant qu'en application de l'article 27 du règlement (CE) n° 1107/2009, les coformulants inscrits à l'annexe III de ce règlement ne peuvent pas entrer dans la composition d'un produit phytopharmaceutique,

Considérant que les éléments disponibles relatifs à la composition du produit ne permettent pas de s'assurer que le produit EIPHAGE ne contient pas de coformulant figurant à l'annexe III du règlement (CE) n° 1107/2009,

Considérant qu'il ne peut pas être établi que les exigences mentionnées à l'article 29 du règlement (CE) n° 1107/2009 sont respectées,

La mise sur le marché du produit phytopharmaceutique désigné ci-après **n'est pas autorisée** en France.

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Informations générales sur le produit	
Nom du produit	EIPHAGE
Type de produit	Produit de référence
Titulaire	GOWAN FRANCE 5 Rue du Gué 77139 PUISIEUX France
Formulation	Suspension concentrée (SC)
Contenant	272 g/L – cuivre (sous la forme d'oxychlorure de cuivre et hydroxyde de cuivre)
Numéro d'intrant	022-2023.01
Numéro d'AMM	-
Fonction	Fongicide
Gamme d'usage	Professionnel

A Maisons-Alfort, le 15/07/2025

DocuSigned by:
Charlotte Grastilleur
AE281A955A42454...

Directrice générale déléguée
en charge du pôle produits réglementés
Agence nationale de sécurité sanitaire de
l'alimentation, de l'environnement et du travail (ANSES)

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ANNEXE : Conditions de mise sur le marché demandées

Liste des usages refusés

Usages	Dose d'emploi	Nombre maximum d'applications	Délai avant récolte (jours)
15053202 Betterave industrielle et fourragère*Trt Part.Aer.*Maladies du feuillage	3,68 L/ha	3/an	14
	Motivation du refus : L'usage est refusé car les données disponibles ne permettent pas d'exclure un dépassement des limites maximales de résidus, ni de s'assurer que le produit ne contient pas de coformulant figurant à l'annexe III du règlement (CE) n° 1107/2009.		

Appendix 2 Copy of the product label

The draft product label as proposed by the applicant is reported below. The draft label may be corrected with consideration of any new element. The label shall reflect the detailed conditions stipulated in the Decision.

EIPHAGE

EIPHAGE
Autorisation de Mise sur le Marché (A.M.M.) N° XXXXXXX
Délivrée le XX/XX/XXXX
Détenteur de l'A.M.M. : Gowan France S.A.S.
5 rue du Gué, 77139 Puisieux, France

Suspension concentrée (SC)
contient 272 g/L de cuivre (sous forme d'oxychlorure de cuivre 136 g/l et d'hydroxyde de cuivre 136 g/l)

EIPHAGE

SGH07

ATTENTION

H410	**Très toxique pour les organismes aquatiques, entraîne des effets néfastes à long terme.**
EUH401	**Respectez les instructions d'utilisation pour éviter les risques pour la santé humaine et l'environnement.**
P273	Éviter le rejet dans l'environnement.
P501	Eliminer le contenu/récipient conformément à la réglementation locale/régionale/nationale/internationale.
SP1	Ne pas polluer l'eau avec le produit ou son emballage. Ne pas nettoyer le matériel d'application près des eaux de surface. Éviter la contamination *via* les systèmes d'évacuation des eaux à partir des cours de ferme ou des routes. Une attention particulière doit être apportée pour éviter la dérive de pulvérisation sur les cultures non-cibles adjacentes à la culture traitée.

Distribué par : GOWAN France SAS
5, rue du Gué - 77139 PUISIEUX Tél : 01 64 36 61 61 - Fax : 01 60 44 70 61

En cas d'urgence, appelez le 15 ou le centre anti-poison puis signalez vos symptômes au réseau Phyt'attitude, N° vert 0 800 887 887 (appel gratuit depuis un poste fixe).
Fiche de Données de Sécurité disponible sur le site internet : www.quickfds.com.

N° de lot et date de fabrication : voir emballage
5L,10L ou 20

Lire attentivement les recommandations d'emploi avant toute utilisation.

Tableau des usages:

Cultures	Usage	Dose d'emploi	Nombre maximal d'applications	Délai avant récolte (DAR)
Betterave industrielle et fourragère*Trt Part.Aer.*Maladies du feuillage	***Betteraves fourragères et industrielles***	***3.5 L/ha***	***3***	***14 jours***

Les limites maximales de résidus sont consultables à l'adresse suivante :
http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/

RECOMMANDATIONS D'EMPLOI
Conditions d'application : traiter en dehors des périodes chaudes et des périodes de gel
Ne pas traiter en cas de risque de pluie imminente (délai minimum à la pluie de 2 heures).
Traiter par temps calme et sans vent (<à 3 sur l'échelle de Beaufort soit 19 km/h), sur un feuillage sec.

Précautions d'emploi :
Mélanges extemporanés : Les mélanges extemporanés doivent être mis en œuvre conformément à la réglementation en vigueur.
Préparation de la bouillie : Bien agiter le bidon avant utilisation. Verser EIPHAGE dans la cuve remplie aux ¾ d'eau puis compléter avec la quantité d'eau nécessaire et maintenir l'agitation jusqu'à la fin de l'application.

PRÉVENTION ET GESTION DE LA RÉSISTANCE
L'utilisation répétée, sur une même parcelle, de préparations à base de substances actives de la même famille chimique Ou ayant le même mode d'action, peut conduire à l'apparition d'individus résistants.
Pour réduire ce risque, l'utilisateur doit raisonner en premier lieu les pratiques agronomiques et respecter les conditions d'emploi du produit.
Il est conseillé d'alterner ou d'associer, sur une même parcelle, des préparations à base de substances actives de familles chimiques différentes ou à modes d'action différents. En dépit du respect de ces règles, on ne peut pas exclure une altération de l'efficacité des programmes avec cette préparation liée à ces phénomènes de résistance.
De ce fait, Gowan décline toute responsabilité quant à d'éventuelles conséquences qui pourraient être dues à de telles résistances.

MISE EN ŒUVRE RÉGLEMENTAIRE ET BONNES PRATIQUES
Stockage du produit :
Conserver le produit uniquement dans son emballage d'origine, dans un local phytopharmaceutique conforme à la réglementation en vigueur, à l'écart des aliments et boissons, y compris ceux pour animaux.
Les locaux doivent être frais et ventilés.
Conserver hors de la portée des enfants et des personnes non autorisées.

Précautions d'emploi :

Pendant le mélange/chargement

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

Pendant l'application :

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN ISO 374-2 (types A, B ou C) à usage unique, dans le cas d'une intervention sur le matériel pendant la phase de pulvérisation. Dans ce cas, les gants ne doivent être portés qu'à l'extérieur de la cabine et doivent être stockés après utilisation à l'extérieur de la cabine.
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

Pendant le nettoyage du matériel de pulvérisation

- Gants en nitrile certifiés NF EN ISO 374-1/A1 et NF EN 16523-1+A1 (type A).
- EPI vestimentaire conforme à la norme NF EN ISO 27065/A1.

L'EPI VESTIMENTAIRE préconisé peut être remplacé par tout autre EPI vestimentaire, spécifique aux produits phytopharmaceutiques, conformes aux exigences essentielles de santé et de sécurité de la directive 89/686/CEE.

Bonnes pratiques phytosanitaires :

Les symptômes sur les cultures dus aux chevauchements de rampe lors de la pulvérisation sont en général transitoires. Éviter toutefois les chevauchements de rampe et les surdosages, cela pouvant entraîner des dégâts sur la culture et affecter les rendements.
Éviter la dérive de pulvérisation sur les cultures adjacentes, en particulier pour l'avoine et autres cultures de graminées, levées ou sur le point de lever, car elles sont particulièrement sensibles.

Nettoyage du pulvérisateur :

Après chaque traitement avec EIPHAGE, nettoyer soigneusement l'extérieur du pulvérisateur. Rincer soigneusement la cuve du pulvérisateur à l'eau claire conformément à la législation en vigueur. Il est conseillé d'effectuer 3 rinçages, le dernier rinçage s'effectuant avec de l'eau additionnée d'un nettoyant (recommandé pour le nettoyage des pulvérisateurs).

Élimination du produit et de l'emballage :

- Pour l'élimination des produits non utilisables, faire appel à une entreprise habilitée pour la collecte et l'élimination des produits dangereux.
- Réemploi de l'emballage interdit. Lors de l'utilisation du produit, bien vider et rincer le bidon en veillant à verser l'eau de rinçage dans la cuve du pulvérisateur. Éliminer les emballages vides *via* par un service de collecte spécifique (exemple : ADIVALOR, 08 10 12 18 85, numéro Azur prix d'un appel local).
- Éliminer les fonds de cuve conformément à la réglementation en vigueur.

Premiers secours

En cas d'inhalation :
Transporter la victime à l'air libre et la garder au chaud et au repos.
Appeler immédiatement un médecin ou un centre Anti-poison.

En cas de contact avec les yeux :
Laver abondamment avec de l'eau douce et propre durant au minimum 15 minutes en maintenant les paupières écartées. Retirer les lentilles de contact si la victime en porte après 5 minutes de rinçage.
En cas d'irritation, consulter un médecin.

En cas de contact avec la peau :
Enlever les vêtements imprégnés et laver soigneusement la peau avec de l'eau et du savon ou utiliser un nettoyant connu. Ne pas utiliser de solvants ou de diluants.
En cas d'irritation, consulter un médecin.

En cas d'ingestion :
Rincer la bouche avec de l'eau et consulter un médecin ou un centre anti-poison. Montrer l'étiquette. Garder au repos.
Ne pas faire vomir.

IMPORTANT: Respectez les usages, doses, conditions et précautions d'emploi mentionnés sur l'emballage qui ont été déterminés en fonction des caractéristiques du produit et des applications pour lesquelles il est préconisé. Conduisez sur ces bases la culture et les traitements selon la bonne pratique agricole en tenant compte, sous votre responsabilité, de tous les facteurs particuliers concernant votre exploitation tels que la nature du sol, les conditions météorologiques, les méthodes culturales, les variétés végétales, la résistance des espèces… Le fabricant garantit la qualité de ses produits vendus dans leur emballage d'origine ainsi que leur conformité à l'autorisation de vente des autorités compétentes.