

CoCh REPORT

According to Article 43 of **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:**

Renewal of authorization

Plant Protection Product: Captan 80% WG
Trade names in cMS: AT: SCAB 80 WG
 BE: CAPITAL, POMCAP, TAVTA
 CZ: SCAB 80 WG, Ventur 80 WG, Ventola
 DE: CAPTION 80 WG
 HU: KARÁT 80 WDG
 IE: SCAB 80 WG
 NL: SCAB 80 WG, CAPITAL, POMCAP
 PL: SCAB 80 WG, KAPER 80 WG, KAPMAN 80 WG, KAPSILAR 80 WG, NAPREM 80 WG
 RO: SCAB 80 WG, CAPTION 80 WG
 SK: SCAB 80 WG
 SI: SCAB 80 WG

Formulation/Development code: Captan 80% WG /SHA 1300 B

Registration Holder: Sharda Cropchem España S.L./ Sharda Europe b.v.b.a/ Sharda Hungary Kft.
 Owner: Sharda Cropchem Ltd.

Content of Active substance/es: Captan 800 g/kg

Type of formulation: WG (Water dispersible granules)

ZRMS: the Czech Republic
cMS: Austria, Belgium, Germany, Hungary, Ireland, Netherlands, Poland, Romania, Slovakia, Slovenia
Date of submission: January 2025

Information	Y/N	Information, summary or justification provided
(a) a copy of the authorisation of the plant protection product;	Y	
(b) any new information required as a result of amendments in data requirements or criteria;	N	In part, complete information will be submitted at the submission of renewal dossier when all Cat 4 studies are complete.
(c) evidence that the new data submitted are the result of data requirements or criteria which were not in force when the authorisation of the plant protection product was granted or necessary to amend the conditions of approval;	N	In part, complete information will be submitted at the submission of renewal dossier when all Cat 4 studies are complete.
(d) any information required to demonstrate that the plant protection product meets the requirements set out in the Regulation on the renewal of the approval of the active substance, safener or synergist contained therein;	N	In part, complete information will be submitted at the submission of renewal dossier when all Cat 4 studies are complete.
(e) a report on the monitoring information, where the authorisation was subject to monitoring.(monitoring information regarding the a.s. approval and national	N	Not required

Information	Y/N	Information, summary or justification provided
monitoring programs for information)		

Additionally, the following information must be submitted to facilitate the evaluation process:

Information	Y/N	Information, summary or justification provided
A GAP list in English with the already authorized uses in the zone For each GAP, concerned MS must be reported	Y	
A notifier declaration that there is no modification of the GAP requested or justification of the modification (new endpoints, outcome of risk assessment, risk envelop approach)	Y	
Declaration signed by the manufacturer that there has not been any modification with regard to the composition of the authorized product under uniform principles, or justification of the need to make a minor change due to the renewal of the approval of the active	Y	
Updated DRR (Part A; B and C) indicating where there is new information not previously reviewed in the zone	N	As there is proposal of Cat 4 studies, updated dRR (part A, B, C) is proposed to be sent when all studies will be available (please refer to Cat 4 studies proposal)
Justification for each data point for which not all information can be submitted	Y	
List of cat 4 studies and submission date and justification for each of them with a proof that the studies have been initiated or commissioned.	Y	
A signed statement confirming that the authorized plant protection products and uses are in compliance with the conditions and restrictions of the renewal of the approval.	Y	
A statement confirming accessing to Annex II data	Y	

Conclusion of the ZRMS: *[CLICK IN THE GREY BOXES AS APPROPRIATE AND SELECT THE APPROPRIATE TEXT]*

☐ Complete

☐ Not Complete

The zRMS _____, appointed to coordinate the renewal of authorization of the plant protection product _____, whose authorization holder is _____, on behalf of the SOUTHERN ZONE confirms that the authorization holder applied to renew the authorization of the plant protection product above mentioned within three months after the date of application of the decision on the renewal of the active substance _____.

The zRMS _____, informs that the applicant **has NOT submitted** a justification for which not all information has been submitted at the three months deadline

☐ **Postponed**

The zRMS _____, appointed to coordinate the renewal of authorization of the plant protection product _____, whose authorization holder is _____, on behalf of the **NORTHERN/CENTRAL/SOUTHERN ZONE** confirms that the authorization holder applied to renew the authorization of the plant protection product above mentioned within three months after the date of application of the decision on the renewal of the active substance _____.

The zRMS _____, informs that the applicant has submitted a justification for which not all information has been submitted at the three months deadline

[SELECT AS APPROPRIATE]

- *due to new endpoints decided at the time of the renewal of approval of the active substance (cat 4 studies)*
- *due to new guidance document published before the time of the renewal of approval of the active substance (cat 4 studies)*
- *due to the presence of a second active substance, _____, for which is expected to expire within twelve months of the renewal of approval of _____*

The zRMS _____, has checked the appropriateness of this justification and has considered **ACCEPTABLE** the postponement of the submission of the following studies in the indicated date:

Annex Point	Study title (if available) or study type	Study duration	Completion date/report number (if available)	Justification (including if study is a cat4 study)
KCP 5.2	Validation in animal matrices	4 months	May 2025	<u>Proposed as CAT 4 study</u> <u>Justification of the necessity of the study:</u> Due to a modification in the residue definition for monitoring in animal matrices after the renewal of approval, which includes relevant metabolites. <u>Evidence that the study has been contracted:</u> See study plan provided <u>Justification why the study has not been started before:</u> CRO's duly qualified for doing these kind of studies were over loaded and they didn't have capability available for sooner dates
KCP 5.2	Independent Laboratory Validation in animal matrices	9 months	October 2025	<u>Proposed as CAT 4 study</u> <u>Justification of the necessity of the study:</u> Due to a modification in the residue definition for monitoring in animal matrices after the renewal of approval, which includes relevant metabolites. <u>Evidence that the study has been contracted:</u>

Annex Point	Study title (if available) or study type	Study duration	Completion date/report number (if available)	Justification (including if study is a cat4 study)
				See contract provided <u>Justification why the study has not been started before:</u> CRO's duly qualified for doing these kind of studies were over loaded and they didn't have capability available for sooner dates
KCP 5.2	Independent Laboratory Validation in drinking water	7 months	August 2025	<u>Proposed as CAT 4 study</u> <u>Justification of the necessity of the study:</u> Due to a change in the residue definition for monitoring in drinking water after the renewal of approval, since at inclusion no residue definition was considered to be relevant. <u>Evidence that the study has been contracted:</u> See contract provided <u>Justification why the study has not been started before:</u> CRO's duly qualified for doing these kind of studies were over loaded and they didn't have capability available for sooner dates.
KCP 5.2	Validation body fluids	3 months	April 2025	<u>Proposed as CAT 4 study</u> <u>Justification of the necessity of the study:</u> Due to a change in the residue definition for monitoring in animal fluids and tissues after the renewal of approval, which includes relevant metabolites. <u>Evidence that the study has been contracted:</u> See study plan provided <u>Justification why the study has not been started before:</u> CRO's duly qualified for doing these kind of studies were over loaded and they didn't have capability available for sooner dates.
	Trials on orchards for application of captan formulation comparing precision and accuracy achieves via conventional application equipment versus other application equipment and practice reducing	2 years	February 2027	<u>Proposed as CAT 4 study</u> <u>Justification of the necessity of the study:</u> In Commission Implementing Regulation (EU) 2024/2186 renewing the approval of the active substance captan, certain

Annex Point	Study title (if available) or study type	Study duration	Completion date/report number (if available)	Justification (including if study is a cat4 study)
	exposure			conditions are applied. For outdoor application on orchards only certain uses will be authorised, <i>uses via pesticide application equipment that increases the precision and accuracy of the application and, while maintaining the application rate on the target surfaces, achieves an average reduction of at least 61% of the applied plant protection product (per hectare) and a minimum of 20% reduction of plant protection product loss to the ground, compared to applications via conventional application equipment and practices, therefore, minimises the drift to areas outside the target surface of the crop (e.g. canopy).</i> To comply with such conditions, it is necessary to conduct studies on orchards with captan product to compare effectiveness of different application equipments and to obtain information on appropriate application equipments that allow to achieve the conditions applied in the Renewal Regulation 2024/2186 <u>Evidence that the study has been contracted:</u> The type of study to be conducted needs to be discussed and agreed with the authorities, which is currently underway. Once agreed, will be contracted. Therefore it is not possible to submit evidence at this time. <u>Justification why the study has not been started before:</u> There was not time enough from the publication of the Renewal Regulation for captan to get a feedback and agreement from the authorities on the type of studies that need to be conducted.

In accordance with the assessment of the provisions in the planning of the applicant, the submission of the documentation is expected by *MONTH YEAR in ZRMS*. Therefore, the zRMS _____ postpones that start of the assessment to *DAY MONTH YEAR*.

This is reported to concerned Member states, to make a decision on the extension of expiry dates of the authorizations of plant protection products which can be affected by this evaluation.

Date and signature