

Art. 51

Extension of authorisation for minor uses

REGISTRATION REPORT

Part A

Risk Management

Product code: -

Product name: Cuprozin progress

Active Substances: Copper hydroxide 383 g/L

COUNTRY: Germany

Central Zone

Zonal Rapporteur Member State: Germany

NATIONAL ASSESSMENT

Applicant: Spiess-Urania Chemicals GmbH

Date: 28.01.2020

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PART A – Risk Management

This document describes the acceptable use conditions required for extension of the registration of Cuprozin progress containing Copper hydroxide in Germany.

The risk assessment conclusions are based on the already existing registration of the PPP. The following sections of Registration Report, Part B were prepared on basis of new data:

- Section 7.

Assessments for the safe use of Cuprozin progress have been made using endpoints agreed in the EU reviews of Copper hydroxide.

Appendix 1 of this document provides a copy of the final product authorisation in Germany.

1 Details of the application

Application to extend the authorisation of a plant protection product (PPP) already authorised in Germany to minor uses not yet covered by that authorisation.

The application is intended for use in AT and Germany.

1.1 Application background

Details on applicant and application

Plant protection product	Cuprozin progress
Type of application	Zonal application according to Article 51, ZRMS=DE, first application (GV1)
Registration number	006895-00/23
Applicant	Spiess-Urania Chemicals GmbH, Frankenstraße 18b, 20097 Hamburg, Deutschland
Authorisation holder	Spiess-Urania Chemicals GmbH, Frankenstraße 18b, 20097 Hamburg, Deutschland
Function	Fungicide
Type of formulation	Suspension concentrate (SC)
Expiration of authorisation	2021-12-31

1.2 Annex I inclusion

The active substances included in the plant protection product are approved according Regulation (EC) No 1107/2009. The present application is in line with the provisions of the approvals.

Active substance (BVL Number)

Copper hydroxide (0347)

Content in PPP	383 g/l
Approval status	Approved according Regulation (EC) No 1107/2009
Approval	Regulation (EC) No 540/2011
Expiration of approval	31.12.2025

1.3 Regulatory approach

The PPP is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles. Therefore the evaluation of the actual application is limited to the points not covered by the existing registration.

1.3.1 Uses applied for and registration decision

Number of use	Plant/commodity/object	Harmful organism/purpose	decision
001	flowering brassicas	downy mildew of crucifers (Peronospora parasitica)	Authorise

1.3.2 Public interest and minor use

According to Article 51 (2) a and c of the Regulation (EC) No. 1107/2009 an extension of authorisation is only possible if the intended use applied for is minor in nature and in the public interest.

In Germany the cultivated area of flowering brassicas is about 6100 ha, of which 2440 ha need to be controlled.

Calculations show that the authorisation holder will not profit from an authorisation in this use.

Considering this calculation and the examination of available alternative measures for the applied use, it can be stated that the use is minor in nature and that an authorisation would be in the public interest.

1.4 Data protection claims

The applicant is owner of the new studies submitted and claims data protection.

1.5 Letters of Access

The applicant is owner of the new studies submitted. No letter of access required. The applicant is authorisation holder.

2 Details of the authorisation

2.1 Product identity

Product name	Cuprozin progress
Authorisation number	006895-00
Composition	Copper hydroxide 383 g/L (g/kg)
Type of formulation	Suspension concentrate (SC)
Function	Fungicide
Authorisation holder	Spiess-Urania Chemicals GmbH, Frankenstraße 18b, 20097 Hamburg, Deutschland

2.2 Classification and labelling

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

<i>Hazard classes and categories:</i>	
Eye Dam. 1, Acute Tox. 4, Care. 2	
<i>Hazard pictograms:</i>	
GHS05	corrosion
GHS07	exclamation mark
GHS09	environment
<i>Signal word:</i>	
Danger	
<i>Hazard statements:</i>	
H318	Causes serious eye damage.
H332	Harmful if inhaled.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
<i>Precautionary statements:</i>	
P101	If medical advice is needed, have product container or label at hand.
P102	Keep out of reach of children.
P271	Use only outdoors or in a well-ventilated area.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
P308+P310	IF exposed or concerned: Immediately call a POISON CENTER or a doctor/physician.
P391	Collect spillage.
P501	Dispose of contents/container to ..
<i>Special rule for labelling of PPP:</i>	
EUH401	To avoid risks to man and the environment, comply with the instructions for use.
	10.4 percent of the mixture consist of ingredient(s) of unknown inhalation toxicity.
<i>Further labelling statements under Regulation (EC) No 1272/2008:</i>	
None	

2.2.2 R and S phrases under Regulation (EC) No 547/2011

EO005-2 SPo 5: Ventilate greenhouses thoroughly before re-entry.

2.2.3 Other phrases

2.2.3.1 Restrictions linked to the PPP

The authorization of the PPP is linked to the following conditions (mandatory labelling):

Human health protection

- SB001 Avoid any unnecessary contact with the product. Misuse can lead to health damage.
- SB005 If medical advice is needed, have product container or label at hand.
- SB010 Keep out of the reach of children.
- SB111 Concerning the requirements for personal protective gear for handling the plant protection product the material safety data sheet and the instructions for use of the plant protection product as well as the guideline "Personal protective gear for handling plant protection products" of the Federal Office of Consumer Protection and Food Safety (www.bvl.bund.de) must be observed.
- SB166 Do not eat, drink or smoke when using this product.
- SB199 When applying the product with tractor-mounted, trailed or self-propelled application equipment, only vehicles with closed pressurized cabins (e.g. cabin category 3, if no respiratory protective equipment or particle-filtering masks are necessary or category 4, if gas-tight respiratory protective equipment is needed acc. to EN 15695-1 and -2) are suited to replace personal protective equipment during application. During all other activities outside of the cabin the prescribed personal protective equipment must be worn. In order to avoid contamination of the cabin, it is not permitted to enter the cabin with contaminated personal protective equipment (it should be deposited e.g. in an appropriate storage facility). Contaminated gloves should be washed before removing the gloves and hands should be washed before entering the cabin with pure water, respectively.
- SE110 Wear tight fitting eye protection when handling the undiluted product.
- SF194 When re-entering the treated bush and tree cultures on the day of application the protective suit for working with plant protection products and universal protective gloves (plant protection) must be worn. Successive work on/in the crops stated above may not be carried out until 24 hours after applying the product. During the first week, the standard protective suit for working with plant protection products and universal protective gloves (plant protection) must be worn.
- SF245-02 It must be ensured that treated areas/crops may not be entered until the film of the plant protection product has dried.
- SS110 Wear standard protective gloves (plant protection) when handling the undiluted product.
- SS120 Wear standard protective gloves (plant protection) when handling/applying the product ready for application.
- SS2101 Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when handling the undiluted product.
- SS2202 Wear a protective suit against pesticides and sturdy shoes (e.g. rubber boots) when applying/handling the product ready for application.
- SS610 Wear a rubber apron when handling the undiluted product.

Ecosystem protection

- NH621 In addition to the information on the type and amount of active substance, the content of pure copper in the product must be stated on the containers and retail packaging. This information must be stated directly below the directions for use under NT620.
- NO686 The product is classified as damaging for populations of earthworms

- NT620-1 The maximum total application rate of 3000 g pure copper per hectare per year on the same area - even if combined with other plant protection products containing copper - shall not be exceeded (with the exception of 4000 g pure copper per hectare per year in hop cultivation and against black rot in viticulture).
- NT621-1 Within a five-year period (including the current year and the preceding four calendar years), the sum of the total application rate of 17,500 g pure copper per hectare in viticulture shall not be exceeded.
- NT622 In the years in which a total application rate of 3000 g pure copper per hectare is exceeded in viticulture, the competent authority of the country must be informed of the quantity effectively used and the exact size of the treated vine-growing area until 30 November of each year.
- NT623 In viticulture, the total application rates per hectare per year, indicating the exact area shall be documented in a suitable form. The records shall be kept for a minimum period of five years
- NW262 The product is toxic for algae.
- NW264 The product is toxic for fish and aquatic invertebrates.
- NW468 Fluids left over from application and their remains, products and their remains, empty containers and packaging, and cleansing and rinsing fluids must not be dumped in water. This also applies to indirect entry via the urban or agrarian drainage system and to rain-water and sewage canals.

Integrated Pest Management (IPM)

- NN3842 The product is classified as harmful for populations of the species *Aphidius rhopalosiphi* (braconid wasp).
- NN370 The product is classified as harmful for populations of the species *Chrysoperla carnea* (lacewing).

Mode of action: WMFM1

Active substance

None

The authorization of the PPP is linked to the following conditions (voluntary labelling):

Integrated Pest Management (IPM)

- NN134 The product is classified as harmless for populations of the species *Typhlodromus pyri* (predatory mite).

Honeybee

- NB6641 The product is classified as non-hazardous to bees, even when the maximum application rate, or concentration if no application rate is stipulated, as stated for authorisation is applied. (B4)

2.2.3.2 Specific restrictions linked to the intended uses

Some of the authorized uses are linked to the following conditions (mandatory labelling):
See 2.3 (Product uses)

Ecosystem protection

- NW605-1 When applying the product on areas adjacent to surface waters - except only occasionally but including periodically water bearing surface waters - the product must be applied with equipment which is registered in the index of 'Loss Reducing Equipment' of 14 October 1993

('Bundesanzeiger' [Federal Gazette] No 205, p. 9780) as amended. Depending on the drift reduction classes for the equipment stated below, the following buffer zones must be kept from surface waters. In addition to the minimum buffer zone from surface waters stipulated by state law, the ban on application in or in the immediate vicinity of waters must be observed at all times for drift reduction classes marked with "*".

Driftreduction: 90%: *
75%: *
50%: 5m

NW606 The only case in which the product may be applied without loss reducing equipment is when at least the buffer zone stated below is kept from surface waters - except only occasionally but including periodically water bearing surface waters. Violations may be punished by fines of up to 50 000 Euro.

Bufferzone: 5m

2.3 Product uses

PPP (product name/code) **Cuprozin progress (006895-00/22)** Formulation type: **SC**
active substance **Copper hydroxide** Conc. of as: **383.0 g/L**

Applicant: **Landesanstalt Sachsen-Anhalt** professional use
Zone(s): **central EU** non professional use

Verified by MS: j

Field of use: fungicide

1	2	3	4	5	6	7	8	10	11	12	13	14
Use- No.	Member state(s)	Crop and/ or situation (crop destination / purpose of crop)	F G 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. safener/synergist per ha e.g. recommended or mandatory tank mixtures
					Method / Kind	Timing / Growth stage of crop & season	Max. number (min. interval between applications) a) per use b) per crop/ season	kg, L product / ha a) max. rate per appl. b) max. total rate per crop/season	g, kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
001	DE	flowering brassicas NNNKL*	F	downy mildew of crucifers (<i>Peronospora parasitica</i>) PEROPA	spraying	from BBCH 13; at beginning of infestation and/or when first symptoms become visible until shortly before flowering of the main umbel	7-10 days a) 4 b) 4	a) 2 L/ha b) 8 L/ha	a) 0.766 kg as/ha b) 3.064.kg as/ha	200- 600	7	Restrictions (see 2.2.3.2) ..

*no EPPO code

3 Risk management

3.1 Reasoned statement of the overall conclusions taken in accordance with the Uniform Principles

3.1.1 Physical and chemical properties

Not relevant for extension of authorisation according article 51.

3.1.2 Methods of analysis

3.1.2.1 Analytical method for the formulation

Not relevant for extension of authorisation according article 51.

3.1.2.2 Analytical methods for residues

Acceptable analytical methods in high water content commodities such as flowering brassicas are available for enforcing copper residues.

3.1.3 Mammalian Toxicology

The PPP is already registered in Germany according to Directive 91/414/EEC.

If used properly and according to the intended conditions of use, adverse health effects for operators, workers, bystanders and residents will not be expected.

3.1.4 Residues and Consumer Exposure

The residue behaviour of the active substance copper hydroxide has been evaluated within the EU review process. Information about intake in plants is sufficient to evaluate the intended use in flowering brassicas.

3.1.4.1 Residues

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 20 mg/kg for copper in flowering brassica as laid down in Reg. (EC) No 396/2005 is not expected.

3.1.4.2 Consumer exposure

An estimation of dietary intake using EFSA PRIMo results in a maximum consumption of the respective ADI of below 100 %. An ARfD was not deemed necessary

TMDI (% ADI) according to EFSA PRIMo	Not calculated
IEDI (% ADI) according to EFSA PRIMo rev. 2 (EFSA, 2018, ASB2018-2445)	Scenario 1 (without risk mitigation measure): 107% (based on WHO cluster diet B, mean body weight) Scenario 2 (with risk mitigation measure): 91% (based on WHO cluster diet B, mean body weight)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	Scenario 1 (without risk mitigation measure): 165% (based on NL toddlers, mean body weight) Scenario 2 (with risk mitigation measure): 162% (based on NL toddlers, mean body weight)
IESTI (% ARfD) according to EFSA PRIMo	Not necessary – no ARfD allocated

The calculated exposure for German children is significantly lower (77% ADI). Furthermore, the contribution of flowering brassica to the total chronic exposure is insignificant (<1% ADI for all diets). Thus, it can be concluded that the intended use of Cuprozin progress in flowering brassica does not pose unacceptable risks to consumer health in Germany. Extensive calculation sheets are presented in Part B, Section 7, **Fehler! Verweisquelle konnte nicht gefunden werden.**

The long-term and the short-term intake of copper residues are unlikely to present a consumer health concern.

3.1.5 Environmental fate and behaviour

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 006895-00/00 according the uniform principles of directive 91/414/EEC.

3.1.6 Ecotoxicology

No new studies are presented; all data were reviewed within the EU review and approval of the national authorisation 006895-00/00 according the uniform principles of directive 91/414/EEC.

The PPP Cuprozin progress and the active substance copper-hydroxyd are toxic to the aquatic environment (Oncorhynchus mykiss: LC10 = 3,7 µg/L and natural background concentration of the testwater: 1 µg/L). Subsequently no additional entries as those according to the evaluated use pattern and good agricultural practise are acceptable. Therefore the safety phrases and conditions of use NW262, NW264, NW468, NH621, NT620-1, NT621-1, NT622, NT623 and NW605-1/606 are assigned, see also 2.2.

The honeybee risk assessment for the main application covers the use in accordance with Article 51 of regulation (EC) No 1107/2009 (see also point 2.2).

3.1.7 Efficacy

Labelling in accordance with the requirements of ANNEX III General principles of integrated pest management under directive 2009/128/EC (see also point 2.2):

- In accordance with Article 51 of Regulation (EC) No. 1107/2009 the classification for beneficial arthropods is covered by the main application.

-The labelling for the mode of action is consistent with the main application and covers the use in accordance with Article 51 of Regulation (EC) No. 1107/2009.

-According to Article 51 of the Regulation (EC) No. 1107/2009, the requirements for authorisation regarding the product's effectiveness and unacceptable effects on plants and plant products do not have to be met.

3.2 Conclusions

PPP Cuprozin progress is already registered in Germany according to Directive 91/414/EEC taking into account the uniform principles of Annex VI.

The intended use is minor in nature and the extension of authorisation is in the public interest. Effects on bees and other beneficials were evaluated within the framework of the already authorised uses. No additional effects are anticipated because of the extension of authorisation).

With respect to toxicology, residues and consumer protection an authorisation can be granted.

Considering an application in accordance with the evaluated use pattern and good agricultural practise as well as strict observance of the conditions of use no harmful effects on groundwater or adverse effects on the ecosystem are to be apprehended.

An authorisation is granted.

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

None

Appendix 1 – Copy of the product authorisation

See Appendix 4.

Appendix 2 – Copy of the product label

No product label available. Not mandatory according to Article 51 (5)

Appendix 3 – Letter of Access

No letter of access necessary. The applicant is owner of the new studies submitted. Authorisation holder is the applicant of the current application to extend the authorisation.

Appendix 4 – Copy of the product authorisation



Bundesamt für Verbraucherschutz und Lebensmittelsicherheit
Dienstszitz Braunschweig • Postfach 15 64 • 38005 Braunschweig

Spiess-Urania Chemicals GmbH
Frankenstraße 18 b
20097 Hamburg

Dr. Birgit Schreiber
Referentin

TELEFON +49 (0)531 299-3457
TELEFAX +49 (0)531 299-3002
E-MAIL birgit.schreiber@bvl.bund.de

IHR ZEICHEN
IHRE NACHRICHT VOM

AKTENZEICHEN 200.22200.006895-00/23.253894
(bitte bei Antwort angeben)

DATUM 28. Januar 2020

GV1 006895-00/23

Cuprozin progress

**Verfahren zur Erweiterung einer Zulassung nach Artikel 51 Abs. 1 der Verordnung (EG)
Nr. 1107/2009**

Bescheid

Die Zulassung des oben genannten Pflanzenschutzmittels

mit dem Wirkstoff: 383 g/l Kupferhydroxid

Zulassungsnummer: 006895-00

Versuchsbezeichnungen: SPU-02700-F-1-SC

Antrag vom: 22. November 2018

wird wie in Anlage 1 beschrieben auf der Grundlage von Art. 51 der Verordnung (EG) Nr. 1107/2009 des Europäischen Parlaments und des Rates vom 21. Oktober 2009 über das Inverkehrbringen von Pflanzenschutzmitteln und zur Aufhebung der Richtlinien 79/117/EWG und 91/414/EWG des Rates (Abl. L 309 vom 24.11.2009, S. 1) um folgende Anwendungsgebiete bzw. Anwendungen erweitert:

Anwendungsnummer	Schadorganismus/ Zweckbestimmung	Pflanzen/-erzeugnisse/ Objekte	Verwendungszweck
006895-00/23-001	Falscher Mehltau (Peronospora parasitica)	Blumenkohle	

Festgesetzte Anwendungsbestimmungen

Es werden folgende Anwendungsbestimmungen gemäß § 36 Abs. 1 S. 1 des Gesetzes zum Schutz der Kulturpflanzen (Pflanzenschutzgesetz - PflSchG) vom 6. Februar 2012 (BGBl. I S. 148, 1281), zuletzt geändert durch Artikel 4 Absatz 84 des Gesetzes vom 18. Juli 2016 (BGBl. I S. 1666), festgesetzt:

Siehe anwendungsbezogene Anwendungsbestimmungen in Anlage 1, jeweils unter Nr. 3.

Auflagen

Die Zulassung wird mit folgenden Auflagen gemäß § 36 Abs. 3 S. 1 PflSchG verbunden:

Siehe Anlage 1, jeweils unter Nr. 2.

Vorbehalt

Dieser Bescheid wird mit dem Vorbehalt der nachträglichen Aufnahme, Änderung oder Ergänzung von Anwendungsbestimmungen und Auflagen verbunden.

Abgelehnte Anwendungsgebiete bzw. Anwendungen

Für folgende Anwendungsgebiete bzw. Anwendungen lehne ich Ihren Antrag ab (siehe Anlage 2):

- keine -

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, Messeweg 11/12, 38104 Braunschweig, schriftlich oder zur Niederschrift einzulegen.

Mit freundlichen Grüßen
im Auftrag

gez. Dr. Martin Streloke
Abteilungsleiter

Dieses Schreiben wurde maschinell erstellt und ist daher ohne Unterschrift gültig.

Anlage

Anlage 1 zugelassene Anwendung: 006895-00/23-001

1 Anwendungsgebiet

Schadorganismus/Zweckbestimmung: Falscher Mehltau (*Peronospora parasitica*)

Pflanzen/-erzeugnisse/Objekte: Blumenkohle

Verwendungszweck:

2 Kennzeichnungsauflagen

2.1 Angaben zur sachgerechten Anwendung

Einsatzgebiet: Gemüsebau

Anwendungsbereich: Freiland

Anwendung im Haus- und
Kleingartenbereich: Nein

Stadium der Kultur: ab 13

Anwendungszeitpunkt: Bei Infektionsgefahr bzw. ab Warndiensthinweis

Maximale Zahl der Behandlungen

- in dieser Anwendung: 4

- für die Kultur bzw. je Jahr: 4

- Abstand: 7 bis 10 Tage

Anwendungstechnik: spritzen

Aufwand:

- 2 l/ha in 400 bis 600 l Wasser/ha

2.2 Sonstige Kennzeichnungsauflagen

- keine -

2.3 Wartezeiten

7 Tage Freiland: Blumenkohle

3 Anwendungsbezogene Anwendungsbestimmungen

(NW605-1)

Die Anwendung des Mittels auf Flächen in Nachbarschaft von Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - muss mit einem Gerät erfolgen, das in das Verzeichnis "Verlustmindernde Geräte" vom 14. Oktober 1993 (Bundesanzeiger Nr. 205, S. 9780) in der jeweils geltenden Fassung eingetragen ist. Dabei sind, in Abhängigkeit von den unten aufgeführten Abdriftminderungsklassen der verwendeten Geräte, die im Folgenden genannten Abstände zu Oberflächengewässern einzuhalten. Für die mit "*" gekennzeichneten Abdriftminderungsklassen ist, neben dem gemäß Länderrecht verbindlich vorgegebenen Mindestabstand zu Oberflächengewässern, das Verbot der Anwendung in oder unmittelbar an Gewässern in jedem Fall zu beachten.

reduzierte Abstände: 50% 5 m, 75% *, 90% *

Begründung:

Unter Berücksichtigung der aktuell geltenden Abdrifteckwerte und der maximal zulässigen zusätzlichen Konzentration von 2,7 µg Cu/L (abgeleitet aus ELS-Test mit O. mykiss, LC10 = 3,7 µg Cu/L, natürliche Hintergrundkonzentration des Testwassers = 1 µg Cu/L) errechnen sich für die beantragte Indikation des Pflanzenschutzmittels die im UBA-Bewertungsbericht dargestellten Konzentrationen im Oberflächengewässer mit den jeweils korrespondierenden TER-Werten. Nach dem Stand der wissenschaftlichen Erkenntnisse ist die ebendort ausgewiesene indikationsspezifische Anwendungsbestimmung erforderlich, um einen ausreichenden Schutz von Gewässerorganismen vor Einträgen des Wirkstoffs Kupferhydroxid in Oberflächengewässer zu gewährleisten.

(NW606)

Ein Verzicht auf den Einsatz verlustmindernder Technik ist nur möglich, wenn bei der Anwendung des Mittels mindestens unten genannter Abstand zu Oberflächengewässern - ausgenommen nur gelegentlich wasserführende, aber einschließlich periodisch wasserführender Oberflächengewässer - eingehalten wird. Zuwiderhandlungen können mit einem Bußgeld bis zu einer Höhe von 50.000 Euro geahndet werden.

5 m

Begründung:

Siehe unter NW605-1.

REGISTRATION REPORT

Part B

Section 7: Metabolism and Residues

Detailed summary of the risk assessment

Product name: Cuprozin progress
Active Substance: Copper hydroxide 383 g/kg
(Copper 250 g/kg)

Central Zone
Zonal Rapporteur Member State: Germany

CORE ASSESSMENT
Extension of use according to article 51

Applicant: Spiess-Urania Chemicals GmbH
Date: June 2019

Version history

When	What
June 2019	Draft Registration Report: zRMS assessment

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General comment of zRMS

Germany as zRMS has written this section of dRR as part of the application for extension of uses according to article 51 of Regulation (EC) No 1107/2009 for the present product. Thus, the document represents completely the results of the exposure and risk assessment conducted by the zRMS regarding the above-mentioned product in the intended uses according to the application submitted by the applicant, unless stated otherwise.

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

7.1.1 Critical GAP and overall conclusion

Selection of critical use and justification

The critical GAP with respect to consumer intake and risk assessment for the preparation Cuprozin progress is presented in Table 7.1-1.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 20 mg/kg for copper in flowering brassica as laid down in Reg. (EC) No 396/2005 is not expected.

The chronic and the short-term intakes of copper residues via flowering brassica are unlikely to present a public health concern.

As far as consumer health protection is concerned, BfR/Germany agrees with the authorization of the intended use.

Data gaps

No data gaps were noticed.

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7	8	9	10	11	12	13	14
Use- No.	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)	Conclusion / Remarks: e.g. g safener/synergist per ha
					Method / Kind	Timing / Growth stage of crop & season	Max. number a) per use b) per crop/ season	Min. interval between applications (days)	L product / ha a) max. rate per appl. b) max. total rate per crop/season	kg as/ha a) max. rate per appl. b) max. total rate per crop/season	Water L/ha min / max		
Minor uses according to Article 51 (zonal uses)													
1	DE	Flowering brassica (0241000)	F	downy mildew of crucifers (<i>Peronospora parasitica</i>)	from BBCH 13	from BBCH 13	a) 4 b) 4	7	a) 2 b) 8	Copper hydroxide: a) 0.77 b) 3.1 Copper: a) 0.5 b) 2.0	400 / 600	7	A

Remarks columns:

<p>1 Use number in accordance with the list of all intended GAPs in Part A / Part B, Section 0 should be given in column 1.</p> <p>2 Use official codes/nomenclatures of EU Member States</p> <p>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). Use also code numbers according to Annex I of Regulation (EU) No 396/2005.</p> <p>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</p> <p>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.</p> <p>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.</p>	<p>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</p> <p>8 The maximum number of application possible under practical conditions of use must be provided.</p> <p>9 Minimum interval (in days) between applications of the same product</p> <p>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.</p> <p>11 The dimension (g, kg) must be clearly specified. (Maximum) dose of a.s. per treatment (usually g, kg or L product / ha).</p> <p>12 If water volume range depends on application equipments (e.g. ULVA or LVA), it should be mentioned under “application: method/kind”.</p> <p>13 PHI - minimum pre-harvest interval</p> <p>14 Remarks may include: Extent of use/economic importance/restrictions</p>
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Explanation for Column 14 “Conclusion”

A	Sufficient data available, exposure acceptable, safe use
R	Data gap
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation Cuprozin progress contains the active ingredient copper hydroxide.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of copper

Reference value	Source	Year	Value	Study relied upon	Safety factor
Copper					
ADI	EFSA Conclusion ASB2018-1406	2018	0.15 mg/kg bw/d	based on human data (WHO value of 0.15 mg Cu/kg bw/day for children)	No SF for human data
ARfD					

7.1.2.1 Summary for copper hydroxide (copper)

Table 7.1-3: Summary for copper hydroxide

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Flowering brassica	N/A	Yes (10 trials)	Yes	N/A	Yes	No	No

* Use number(s) in accordance with the list of all intended GAPs in Part A / Part B, Section 0 should be given in column 1

Copper is a mono-atomic element and therefore considered inherently stable. As no metabolites are expected, the nature of residues in primary crops, rotational crops and processed commodities as well as its stability during storage are considered addressed and specific studies were not required. Data on effects of processing on the magnitude of residues, which have been evaluated during the peer-review, the renewal and the MRL review show a slight decrease of residues during cooking.

The relevant residue for monitoring and risk assessment was defined as total copper, including copper residues arising from all forms of copper. Analytical methods for enforcement of mineral copper independently from its chemical form are available.

Copper is a plant micro-nutrient which is naturally taken up from soil via roots. Hence, uptake of geogenic copper from soil is a relevant issue in principle for all soil grown crops and is not necessarily associated to treatments of former crops.

7.1.2.2 Summary for Cuprozin progress

Table 7.1-4: Information on Cuprozin progress (KCA 6.8)

Crop	PHI for Cuprozin progress proposed by applicant	PHI sufficiently supported for copper	PHI for Cuprozin progress proposed by zRMS	zRMS Comments (if different PHI proposed)
Flowering brassica	7 days	Yes	7 days	--

Assessment

7.2 Copper hydroxide

An evaluation of the active substance copper hydroxide was not conducted in the framework of this application according to Article 51 of Regulation (EC) No 1107/2009. It is referred instead to the outcome of the recently issued peer review of the copper compounds copper(I), copper(II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper(I) oxide, and Bordeaux mixture ([ASB2018-1406](#)). In addition, it is also referred to the results of the review of the existing MRLs for copper compounds according to Article 12 of Regulation (EC) No 396/2005 ([ASB2018-2445](#)). Further general data on the active ingredient copper hydroxide are summarized in the table below.

Table 7.2-1: General information on copper hydroxide

Active substance (ISO Common Name)	Copper hydroxide
IUPAC	Copper (II) hydroxide
Chemical structure	<chem>Cu(OH)2</chem>
Molecular formula	<chem>CuH2O2</chem>
Molar mass	97.6 g/mol
Chemical group	Copper compounds
Mode of action (if available)	Cu ⁺⁺ is taken up by the spores during germination and accumulates until a concentration is achieved to kill the spore cell. It is a foliar fungicide with preventive action. Deposits must be on the crop before fungal spores begin to germinate. Similar action in bacteria.
Systemic	No
Companies*	European Union Copper Task Force (EUCuTF)
Rapporteur Member State (RMS)	France
Approval status	Approved (01/01/2019) Regulation (EU) 2018/1981
Restriction	Only uses resulting in a total application of maximum 28 kg of copper per hectare over a period of 7 years shall be authorised.
Review Report	SANTE/10506/2018 Rev. 5 27 November 2018
Current MRL regulation	Regulation (EC) No 149/2008
Peer review of MRLs according to Article 12 of Reg. No 396/2005 EC performed	Yes (EFSA, 2018b, ASB2018-2445)
EFSA Journal: Conclusion on the peer review	Yes (EFSA, 2018a, ASB2018-1406)
Current MRL applications on intended uses	Not applicable

* Notifier in the EU process to whom the a.s. belong(s)

7.2.1 Magnitude of residues in plants (KCA 6.3)

Available data

A summary of the magnitude of residues of copper hydroxide is given in the following table. For the detailed evaluation of new/additional studies on the magnitude of residues it is referred to Appendix 2.

Table 7.2-2: Summary of EU reported and new data supporting the intended uses of Cuprozin progress and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance		
Flowering brassica (cauliflower and broccoli)	New trials ASB2018-2819 ASB2019-5325 ASB2019-5326 ASB2019-5327 ASB2019-5328 ASB2019-5329 ASB2019-5330 ASB2019-5331 ASB2019-5332 ASB2019-5333 ASB2019-5334 ASB2019-5335	N-EU	<i>Cauliflower:</i> Trials GAP: 4x 0.51 kg Cu/ha, PHI 7d, outdoor E/RA: 5x <2.0 mg/kg <i>Broccoli:</i> Trials GAP: 4x 0.46-0.53 kg Cu/ha, PHI 7d, outdoor E/RA: 5x <2.0 mg/kg	N/A						
	Overall supporting data for cGAP	N-EU	E/RA: 10x <2.0 mg/kg	E/RA: 2.0	E/RA: 2.0	N/A	20.0	Yes		

* Source of EU MRL: Regulation (EC) No 149/2008

Conclusion on the magnitude of residues in plants

The data available are considered sufficient for risk assessment. A total of five supervised residue trials on each cauliflower and broccoli were available all conducted according to the critical GAP. According to the extrapolation guideline (SANCO 7525/VI/95 Rev. 10.3, 13 June 2017) four trials on cauliflower and four trials on broccoli are necessary to cover the whole subgroup of flowering brassica, which is the case here. At harvest (PHI: 7 days), residues of copper were always below the LOQ of 2 mg/kg. The data submitted show that no exceedance of the current MRL of 20 mg/kg for flowering brassica is likely.

The maximum storage period of deep-frozen samples is not an issue for copper. Analytical methods for commodities of high water content such as flowering brassica are available and acceptable for enforcing all compounds given in the residue definition.

According to the available data, the intended use on flowering brassica is considered acceptable.

7.2.2 Magnitude of residues in livestock

The crop under evaluation or parts thereof are normally not fed to livestock. Investigation of residues in commodities of animal origin is therefore not necessary.

7.2.3 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

Studies investigating the magnitude of residues in processed commodities were reported in the framework of the first peer review (EFSA, 2008) and during the renewal (EFSA, 2018a) as well as in the framework of the MRL review according to Article 12 (EFSA, 2018b). Processing factors were derived for a lot of commodities including cooking and heating processes relevant for the intended use. Based on these data it can be concluded that copper residues are expected to slightly decrease during cooking of flowering brassica. Further data are not considered necessary.

7.2.4 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation. In EFSA's Conclusion on the peer review ([ASB2018-1406](#)) it was stated that "the experts agreed that plant would not absorb more than the essential nutritional amount. Therefore, field trials on rotational crops were not deemed necessary and a comprehensive survey on the copper background levels in plant commodities was used as a surrogate to assess the residue levels in all off-label crops (including rotational crops)." Further investigation of residues in rotational crops is therefore not required.

7.2.5 Other / special studies (KCA 6.10, 6.10.1)

The available data for the copper hydroxide sufficiently address aspects of the residue situation that might arise from the use of Cuprozin progress. Therefore, other special studies are not needed.

7.2.6 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2). As an ARfD was not deemed necessary, an acute risk assessment is not relevant.

7.2.6.1 Input values for the consumer risk assessment

A review of MRLs for copper according to article 12 of Reg. (EC) No 396/2005 has recently been finalised by EFSA (EFSA, 2018b). The MRL proposals derived in the framework of this complex project are based on either discrete agricultural uses or are drawn from monitoring data or from an indicative literature survey for endogenous levels.

Even though the MRL proposals made by EFSA in their assessment are not yet implemented in EU residue legislation, reference is made to EFSA's evaluation as the most comprehensive and up-to-date compilation of copper levels in food and feed.

Table 7.2-3: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: total copper				
All commodities	STMR or STMR-P	Data as compiled in Table D.2 in EFSA Journal 2018;16(3):5212	Not applicable as no ARfD is allocated.	

7.2.6.2 Conclusion on consumer risk assessment

Existing uses of copper compounds according to article 12 of Reg. (EC) No 396/2005 (EFSA, 2018b) were recently evaluated. In the framework of this comprehensive exercise, the MRLs based on defined GAPs were compared to monitoring data and maximum background levels (Appendix F of EFSA's RO).

Using revision 2 of the EFSA PRIMo the overall long-term dietary intake was exceeding the ADI for only one 'consumer group' (107% ADI for WHO cluster diet B - which is deemed a rather artificial diet) while for all other diets the chronic exposure is below the ADI, ranging from 14-84% ADI (scenario 1). Several risk mitigation options were rehearsed by EFSA for decision making by risk managers. EFSA identified the main contributors to chronic exposure. For two of the most important contributors (wheat and maize), the copper levels used in this calculation are not associated with a pesticide use in particular. The consumer intake of copper via wheat and maize is due to the background occurrence of copper in these commodities. For sunflower seeds and soya bean, risk migration measures (e.g. withdrawing of the current authorisations) could be proposed. However it was not possible to quantify the effect of such a risk mitigation measure since no GAP-compliant trials were available. The other main drivers of the chronic exposure (lettuce, tomatoes, wine grapes and potatoes) make up 19.9% of the ADI. For these crops several GAPs were reported and EFSA made an attempt to assess the possible impact of eventual risk mitigation measures which could be taken on these crops. A theoretical exposure calculation considering all the above risk mitigation measures was performed (scenario 2). According to the results of this calculation, the highest chronic exposure declined to 91% of the ADI for WHO Cluster diet B. (EFSA, 2018b)

EFSA PRIMo was revised in the meantime and PRIMo revision 3 (update version 3.1) is used for new applications as from 1 February 2018. The calculation of the chronic consumer exposure was therefore updated using the new model version and the same input values as EFSA in the framework of the MRL review according to article 12 of Reg. (EC) No 396/2005 (EFSA, 2018b). The highest chronic exposure was now calculated for NL toddlers (165% ADI). Chronic exposure for all other diets was below the ADI (8-98% ADI). When using the risk mitigation measures proposed by EFSA, only a slight decrease of the chronic exposure was observed (162% ADI for NL toddler), as the highest contributors were maize, spinach and oil palm kernels. The intake of copper via maize is attributed to background occurrence of

copper in this commodity and no refinement is possible. No risk mitigation measures for spinach and oil palm kernels can be proposed. A refinement of the calculation of the overall long-term dietary intake based on EFSA PRIMo rev. 3.1 should be initiated on EU level considering all authorised use as well as European monitoring data.

However, the proposed use on flowering brassica is intended for Germany only. The calculated exposure for German children is significantly lower (77% ADI). Furthermore, the contribution of flowering brassica to the total chronic exposure is insignificant (<1% ADI for all diets). Thus, it can be concluded that the intended use of Cuprozin progress in flowering brassica does not pose unacceptable risks to consumer health in Germany. Extensive calculation sheets are presented in Appendix 3.

TMDI (% ADI) according to EFSA PRIMo	Not calculated
IEDI (% ADI) according to EFSA PRIMo rev. 2 (EFSA, 2018, ASB2018-2445)	<i>Scenario 1</i> (without risk mitigation measure): 107% (based on WHO cluster diet B, mean body weight) <i>Scenario 2</i> (with risk mitigation measure): 91% (based on WHO cluster diet B, mean body weight)
IEDI (% ADI) according to EFSA PRIMo rev. 3.1	<i>Scenario 1</i> (without risk mitigation measure): 165% (based on NL toddlers, mean body weight) <i>Scenario 2</i> (with risk mitigation measure)*: 162% (based on NL toddlers, mean body weight)
IESTI (% ARfD) according to EFSA PRIMo	Not necessary – no ARfD allocated

* Contribution of flowering brassica is <1% ADI

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

COM, 2009. Review report for the active substance Copper compounds. SANCO/150/08 final. [ASB2013-16042](#).

EFSA (European Food Safety Authority), 2008. Conclusion regarding the peer review of the pesticide risk assessment of the active substance Copper (I), copper (II) variants namely copper hydroxide, copper oxychloride, tribasic copper sulfate, copper (I) oxide, Bordeaux mixture. EFSA Scientific Report (2008) 187. [ASB2012-3573](#)

EFSA (European Food Safety Authority), 2018a. Conclusion on the 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):5152, 25pp. <https://doi.org/10.2903/j.efsa.2018.5152>. [ASB2018-1406](#)

EFSA (European Food Safety Authority), 2018b. Reasoned opinion on the review of the existing maximum residue levels for copper compounds according to Article 12 of Regulation (EC) No 396/2005. EFSA Journal 2018;16(3):5212, 135 pp. <https://doi.org/10.2903/j.efsa.2018.5212>. [ASB2018-2445](#)

France, Germany, 2017. Copper compounds: Renewal Assessment Report revised Vol. 1-3. [ASB2017-11786](#)

Appendix 1 Lists of data considered in support of the evaluation

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
KCA 6.3	Anon.	2018	Vorabbericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln - Blumenkohl LR-G-16-KG-F-01-BON-01 GLP: No, Published: No BVL-3676028, ASB2019-5326	N	DLR - Rheinfalz
KCA 6.3	Anon.	2018	Vorabbericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln - Blumenkohl LR-G-16-KG-F-01-WET-01 GLP: No, Published: No BVL-3676029, ASB2019-5327	N	DLR - Rheinfalz
KCA 6.3	Anon.	2018	Vorabbericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln - Brokkoli LR-G-16-KG-F-03-SCH-01 GLP: No, Published: No BVL-3676030, ASB2019-5328	N	DLR - Rheinfalz
KCA 6.3	Anon.	2018	Vorabbericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln - Brokkoli LR-G-16-KG-F-03-WET-01 GLP: No, Published: No BVL-3676031, ASB2019-5329	N	DLR - Rheinfalz
KCA 6.3	Anon.	2018	Vorabbericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln Blumenkohl LR-G-17-KG-F-01-BON-01 GLP: No, Published: No BVL-3676032, ASB2019-5330	N	DLR - Rheinfalz

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
KCA 6.3	Anon.	2018	Vorabbericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln - Blumenkohl LR-G-17-KG-F-01-BON-02 GLP: No, Published: No BVL-3676033, ASB2019-5331	N	DLR - Rheinpfalz
KCA 6.3	Anon.	2018	Vorabbericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln - Blumenkohl LR-G-17-KG-F-01-WET-01 GLP: No, Published: No BVL-3676034, ASB2019-5332	N	DLR - Rheinpfalz
KCA 6.3	Anon.	2018	Vorabbericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln - Brokkoli LR-G-17-KG-F-03-SCH-01 GLP: No, Published: No BVL-3676035, ASB2019-5333	N	DLR - Rheinpfalz
KCA 6.3	Anon.	2018	Vorabbericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln - Brokkoli LR-G-17-KG-F-03-SCH-02 GLP: No, Published: No BVL-3676036, ASB2019-5334	N	DLR - Rheinpfalz
KCA 6.3	Anon.	2018	Bericht für Rückstandsuntersuchungen mit Pflanzenschutzmitteln - Brokkoli LR-G-17-KG-F-03-WET-01 GLP: No, Published: No BVL-3676037, ASB2019-5335	N	DLR - Rheinpfalz
KCA 6.3	Hildebrand, A.	2018	Residue analysis of Copper hydroxide (Cuprozin Progress) in cauliflower and broccoli AP 01/17 GLP: Yes, Published: No BVL-3676026, ASB2019-5325	N	DLR - Rheinpfalz
KCA 6.3	Offenbächer, G.	2017	Residue analysis of Copper hydroxide (Cuprozin Progress) in cauliflower, broccoli and spring onions - Final report AP 01/16 GLP: Yes, Published: No BVL-3676025, ASB2018-2819	N	DLR - Rheinpfalz

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
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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
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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
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Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Stability of residues

No new study submitted nor required.

A 2.2 Nature of residue in plants

No new study submitted nor required.

A 2.3 Nature of residues in livestock

No new study submitted nor required.

A 2.4 Magnitude of residues in plants

A 2.4.1 Flowering brassica

Table A 1: Comparison of intended and critical EU GAPs

Type of GAP	Number of applications	Application rate per treatment (precise unit)	Interval between application	Growth stage at last application	PHI (days)
cGAP EU (RAR, France, 2017)	Flowering brassica were not an intended use during the peer review				
cGAP EU (Art. 12, EFSA, 2018)	Flowering brassica were not an intended use for northern Europe during the MRL review.				
Intended cGAP (number 1*)	4	0.77 kg copper hydroxide/ha (0.5 kg copper/ha)	7-10 days	From BBCH 13	7 days

* Use number(s) in accordance with the list of all intended GAPs in Part B, Section 0

Reference: OECD KIIA 6.3

Report: see authority registration numbers cited in the remarks columns of the tables below (and study identification as laid down in the reference list)

Guideline(s): in accordance with agreed guidance unless stated otherwise in the commenting box

Deviations: no relevant deviations unless stated otherwise in the commenting box

GLP: see reference list

Acceptability: acceptable unless stated otherwise in the commenting box

Table A 2: Summary of residue trials with copper hydroxide

RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)
(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 250 g/L (383 g/L copper hydroxide)
Formulation (e.g. WP) : SC (suspension concentrate)
Commercial product (name) : Cuprozin progress
Applicant : Spiess-Urania Chemicals

Active ingredient : copper
Crop / crop group : cauliflowers
Crop Code : BRSOB

Submission date : 2019-03-26

Indoors / Outdoors : Outdoors (Northern and Central Europe)
Other a.i. in formulation (content and common name) :
Residues calculated as : copper

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)	(a)		(d)	(e)	
study AP 01/16, trial LR-G-16-KG-F-01- WET-01 Germany (DE) 35516 Münzenberg 2018-08-06	Synergy	1) 2016-05-11 (planting) 3) 2016	0.51 0.51 0.51 0.51	600 600 600 600	0.085 0.085 0.085 0.085	2016-06-27 ⁴⁾ 2016-07-04 ⁴⁾ 2016-07-11 ⁴⁾ 2016-07-18 ⁴⁾	BBCH 47	flower	< 2.0 < 2.0 < 2.0 < 2.0	0 3 7 10	4) spraying analytical method: SOP 6078 Version 01 LUFA Speyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 10 ASB2019-5327 ASB2018-2819 (analytical part)

Cuprozin progress / 006895-00/23
Part B – Section 7 - Core Assessment
zRMS version

1 Report-No. Location incl. Postal code and date	2 Commodity/ Variety	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest	4 Application rate per treatment			5 Dates of treatments or no. of treatments and last date	6 Growth stage at last treatment or date	7 Portion analysed	8 Residues (mg/kg)	9 PHI (days)	10 Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)	(d)	(e)	
study AP 01/16, trial LR-G-16-KG-F-01- BON-01 Germany (DE) 53229 Bonn, Roleber 2018-08-06	Clarify F1	1) 2016-05-19 (sowing) 2016- 06-24 (planting) 3) 2016	0.51 0.51 0.51 0.51	600 600 600 600	0.085 0.085 0.085 0.085	2016-08-01 ⁴⁾ 2016-08-08 ⁴⁾ 2016-08-15 ⁴⁾ 2016-08-23 ⁴⁾	BBCH 43	flower	< 2.0 < 2.0 ≤ 2.0 < 2.0	0 3 7 10	4) spraying analytical method: SOP 6078 Version 01 LUFA Speyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 9 ASB2019-5326 ASB2018-2819 (analytical part)
study AP 01/17, trial LR-G-17-KG-F-01- WET-01 Germany (DE) 35516 Münzenberg 2018-08-06	Synergy	1) 2017-06-08 (planting) 3) 2017	0.51 0.51 0.51 0.51	600 600 600 600	0.085 0.085 0.085 0.085	2017-07-18 ⁴⁾ 2017-07-27 ⁴⁾ 2017-08-02 ⁴⁾ 2017-08-09 ⁴⁾	BBCH 49	flower	≤ 2.0	7	4) spraying analytical method: SOP 6078 Version 01 LUFA Speyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 10 ASB2019-5332 ASB2019-5325 (analytical part)
study AP 01/17, trial LR-G-17-KG-F-01- BON-01 Germany (DE) 50765 Bonn, Roleber 2018-08-06	Clarify F1	1) 2017-05-31 (sowing) 2017- 06-29 (planting) 3) 2017	0.51 0.51 0.51 0.51	600 600 600 600	0.085 0.085 0.085 0.085	2017-08-14 ⁴⁾ 2017-08-22 ⁴⁾ 2017-08-29 ⁴⁾ 2017-09-05 ⁴⁾	BBCH 41	flower	≤ 2.0	7	4) spraying analytical method: SOP 6078 Version 01 LUFA Speyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 9 ASB2019-5330 ASB2019-5325 (analytical part)
study AP 01/17, trial LR-G-17-KG-F-01- BON-02 Germany (DE) 32051 Herford 2018-08-06	Lecanu	1) 2017-04-13 (planting) 3) 2017	0.51 0.51 0.51 0.51	600 600 600 600	0.085 0.085 0.085 0.085	2017-06-14 ⁴⁾ 2017-06-21 ⁴⁾ 2017-06-28 ⁴⁾ 2017-07-05 ⁴⁾	BBCH 42-43	flower	≤ 2.0	7	4) spraying analytical method: SOP 6078 Version 01 LUFA Speyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 11 ASB2019-5331 ASB2019-5325 (analytical part)

- (a) According to CODEX Classification / Guide
- (b) Only if relevant
- (c) Year must be indicated
- (d) Days after last application (Label pre-harvest interval, PHI, underline)
- (e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable. Trials conducted according to the critical GAP.
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RESIDUES DATA SUMMARY FROM SUPERVISED TRIALS (SUMMARY)

(Application on agricultural and horticultural crops)

Federal Institute for Risk Assessment, Berlin
Federal Republic of Germany

Content of a.i. (g/kg or g/l) : 250 g/L (383 g/L copper hydroxide)
Formulation (e.g. WP) : SC (suspension concentrate)
Commercial product (name) : Cuprozin progress
Applicant : Spiess-Urania Chemicals

Active ingredient : copper
Crop / crop group : asparagus broccoli
Crop Code : BRSOK

Submission date : 2019-03-26

Indoors / Outdoors : Outdoors (Northern and Central Europe)
Other a.i. in formulation (content and common name) :
Residues calculated as : copper

1 Report-No. Location incl. Postal code and date	2 Commodity/ Variety	3 Date of 1) Sowing or planting 2) Flowering 3) Harvest	4 Application rate per treatment			5 Dates of treatments or no. of treatments and last date	6 Growth stage at last treatment or date	7 Portion analysed	8 Residues (mg/kg)	9 PHI (days)	10 Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
(a)	(b)	(b)			(c)		(a)		(d)	(e)	
study AP 01/16, trial LR-G-16-KG-F-03- WET-01 Germany (DE) 35516 Münzenberg 2018-08-06	SV1002BL	1) 2016-06-07 (planting) 2) 2016 3) 2016	0.51 0.51 0.51 0.51	600 600 600 600	0.085 0.085 0.085 0.085	2016-07-18 ^{d)} 2016-07-25 ^{d)} 2016-08-01 ^{d)} 2016-08-08 ^{d)}	BBCH 49	flower	3.9 3.3 ≤ 2.0 < 2.0	0 3 7 10	4) spraying analytical method: SOP 6078 Version 01 LUFA Speyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 9 ASB2019-5329 ASB2018-2819 (analytical part)
study AP 01/16, trial LR-G-16-KG-F-03- SCH-01 Germany (DE) 67105 Schifferstadt 2018-08-06	Steel	1) 2016-07-18 (planting) 2) 2016 3) 2016	0.51 0.51 0.51 0.51	600 600 600 600	0.085 0.085 0.085 0.085	2016-08-29 ^{d)} 2016-09-05 ^{d)} 2016-09-15 ^{d)} 2016-09-23 ^{d)}	BBCH 43-47	flower	< 2.0 < 2.0 ≤ 2.0 < 2.0	0 3 7 11	4) spraying analytical method: SOP 6078 Version 01 LUFA Speyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 8 ASB2019-5328 ASB2018-2819 (analytical part)
study AP 01/17, trial LR-G-17-KG-F-03- WET-01 Germany (DE) 35516 Münzenberg 2018-08-06	Ironman	1) 2017-06-08 (planting) 2) 2017 3) 2017	0.51 0.51 0.51 0.51	600 600 600 600	0.085 0.085 0.085 0.085	2017-07-18 ^{d)} 2017-07-27 ^{d)} 2017-08-02 ^{d)} 2017-08-09 ^{d)}	BBCH 49	flower	≤ 2.0	7	4) spraying analytical method: SOP 6078 Version 01 LUFA Speyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 10 ASB2019-5335 ASB2019-5325 (analytical part)

Cuprozin progress / 006895-00/23
Part B – Section 7 - Core Assessment
zRMS version

1	2	3	4			5	6	7	8	9	10
Report-No. Location incl. Postal code and date	Commodity/ Variety	Date of 1) Sowing or planting 2) Flowering 3) Harvest	Application rate per treatment			Dates of treatments or no. of treatments and last date	Growth stage at last treatment or date	Portion analysed	Residues (mg/kg)	PHI (days)	Remarks
			kg a.i./ha	Water l/ha	kg a.i./hl						
	(a)	(b)				(c)		(a)		(d)	(e)
study AP 01/17, trial LR-G-17-KG-F-03- SCH-01 Germany (DE) 67105 Schifferstadt 2018-08-06	Steel	1) 2017-07-03 (planting) 3) 2017	0.46 0.53 0.46 0.46	370 420 370 370	0.13 0.13 0.13 0.13	2017-08-14 ⁴⁾ 2017-08-21 ⁴⁾ 2017-08-28 ⁴⁾ 2017-09-04 ⁴⁾	BBCH 46-48	flower	<u>< 2.0</u>	7	4) spraying analytical method: SOP 6078 Version 01 LUFASpeyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 9 ASB2019-5333 ASB2019-5325 (analytical part)
study AP 01/17, trial LR-G-17-KG-F-03- SCH-02 Germany (DE) 67105 Schifferstadt 2018-08-06	Naxos	1) 2017-07-03 (planting) 3) 2017	0.48 0.51 0.46 0.46	380 410 370 370	0.13 0.13 0.13 0.13	2017-08-14 ⁴⁾ 2017-08-21 ⁴⁾ 2017-08-28 ⁴⁾ 2017-09-04 ⁴⁾	BBCH 48-49	flower	<u>< 2.0</u>	7	4) spraying analytical method: SOP 6078 Version 01 LUFASpeyer (ICP-MS), LOQ(s): 2 mg/kg max. sample storage time in month(s): 9 ASB2019-5334 ASB2019-5325 (analytical part)

- (a) According to CODEX Classification / Guide
(b) Only if relevant
(c) Year must be indicated
(d) Days after last application (Label pre-harvest interval, PHI, underline)
(e) Remarks may include: Climatic conditions; Reference to analytical method and information which metabolites are included

Comments of zRMS:	Acceptable. Trials conducted according to the critical GAP.
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A 2.5 Livestock feeding studies

No new study submitted nor required.

A 2.6 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new study submitted nor required.

A 2.7 Magnitude of residues in representative succeeding crops

No new study submitted nor required.

A 2.8 Other/Special Studies

No new study submitted nor required.

Appendix 3 Pesticide Residue Intake Model (PRIMO)

A 3.1 TMDI calculation

Not calculated.

A 3.2 IEDI calculations

A 3.2.1 Scenario 1 (EFSA PRIMo rev. 2)

copper compounds			
Status of the active substance:		Code no.:	
LOQ (mg/kg bw):		proposed LOQ:	
Toxicological end points			
ADI (mg/kg bw/day):	0.15	ARID (mg/kg bw):	n.n.
Source of ADI:	EFSA	Source of ARID:	EFSA
Year of evaluation:	2018	Year of evaluation:	2018

Prepare workbook for refined calculations

Undo refined calculations

The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pTMRL). The pTMRLs have been submitted to EFSA in September 2006.

Chronic risk assessment - refined calculations								
TMDI (range) in % of ADI minimum - maximum								
No of diets exceeding ADI:								
14 1								
Highest calculated TMDI values in % of ADI	MS Diet	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	p1 MRLs at LOQ (in % of ADI)
100.0	WHO cluster diet B	23.6	Wheat	9.1	Sunflower seed	8.3	Lettuce	
89.8	IT adult	15.8	Sheep liver	8.4	Milk	8.4	Milk	
83.1	NL child	13.1	Wheat	8.5	Spinach	7.9	Potatoes	
70.2	DE child	11.4	Wheat	11.3	Apples	7.4	Table grapes	
60.0	FR toddler	18.3	Spinach	7.3	Wheat	7.0	Lentil	
59.9	WHO cluster diet E	10.9	Wheat	5.1	Potatoes	4.6	Soya bean	
58.5	WHO cluster diet D	18.0	Wheat	8.1	Sunflower seed	5.4	Potatoes	
54.5	DK child	15.2	Wheat	12.2	Rye	7.4	Pork loin	
53.6	ES child	12.3	Wheat	9.6	Lettuce	3.0	Poultry meat	
53.2	UK toddler	19.1	Sugar beet (root)	10.8	Wheat	4.7	Potatoes	
51.7	WHO cluster diet F	10.0	Wheat	6.9	Lettuce	5.2	Soya bean	
50.3	WHO regional European diet	8.7	Lettuce	8.2	Wheat	5.4	Potatoes	
47.8	PT general population	10.0	Wheat	7.1	Potatoes	4.2	Wine grapes	
42.1	ES adult	12.1	Lettuce	6.5	Wheat	1.9	Beet leaves (chard)	
42.1	UK infant	8.4	Sugar beet (root)	7.3	Wheat	5.3	Pork loin	
41.1	NL general	5.7	Wheat	3.7	Potatoes	3.6	Coffee beans	
40.2	FR infant	18.2	Spinach	5.5	Potatoes	4.1	Milk and milk products: Cattle	
39.0	IT infant/toddler	18.4	Wheat	8.7	Lettuce	2.4	Tomatoes	
36.1	FR all population	9.1	Wheat	6.8	Wine grapes	4.0	Sunflower seed	
34.0	IT adult	11.4	Wheat	8.7	Lettuce	2.2	Spinach	
31.8	SE general population 90th percentile	8.9	Wheat	5.6	Potatoes	2.0	Milk and milk products: Cattle	
27.8	UK vegetarian	5.7	Wheat	3.3	Lettuce	3.1	Sugar beet (root)	
24.5	UK adult	4.8	Wheat	3.3	Sugar beet (root)	2.7	Lettuce	
22.1	LI adult	4.2	Potatoes	3.0	Rye	2.9	Wheat	
20.9	UK adult	5.8	Wheat	3.1	Bonnie-Liner	2.4	Wine grapes	
18.0	IT adult	2.7	Wheat	2.8	Coffee beans	1.9	Rye	
14.0	IT general population	4.6	Potatoes	1.9	Apples	1.9	Table grapes	

Conclusion:
 The estimated Theoretical Maximum Daily Intakes based on MS and WHO diets and pTMRLs were in the range of 14 % to 107 % of the ADI. For 1 diet the ADI is exceeded. Further refinements of the dietary intake estimates have not been performed. A public health risk cannot be excluded at the moment.

A 3.2.2 Scenario 2 (EFSA PRIMo rev. 2)

copper compounds		Prepare workbook for refined calculations	
Status of the active substance: LOQ (mg/kg bw):	Code no. proposed LOQ:		
Toxicological end points			
ADI (mg/kg bw/day): 0,15	ARND (mg/kg bw): n.n.		
Source of ADI: EFSA 2018	Source of ARND: EFSA 2018		
Year of evaluation: 2018	Year of ARND evaluation: 2018		
<p>The risk assessment has been performed on the basis of the MRLs collected from Member States in April 2006. For each pesticide/commodity the highest national MRL was identified (proposed temporary MRL = pMRL). The pMRLs have been submitted to EFSA in September 2006.</p>			
Chronic risk assessment - refined calculations			
TMDI (range) in % of ADI minimum - maximum 11 - 91			
No. of diets exceeding ADI: —			
Highest calculated TMDI values in % of ADI	Highest contributor to MS diet (in % of ADI)	2nd contributor to MS diet (in % of ADI)	3rd contributor to MS diet (in % of ADI)
MS Diet 91,0 WHO cluster diet F 78,3 IE adult 77,7 NL child 66,4 DT child 57,6 FR toddler 53,1 WHO cluster diet E 52,9 WHO cluster diet D 50,3 UK toddler 49,5 DK child 47,2 FS child 41,7 WHO cluster diet F 40,1 UK infant 38,3 WHO regional European diet 38,1 FR infant 36,0 NL general 35,4 PT general population 31,1 IT infant/child 29,0 SE general population 90th percentile 28,1 FS infant 26,2 FR all population 24,7 IT adult 22,1 UK vegetation 19,1 UK adult 18,1 LI adult 17,7 DK adult 12,8 FI adult 11,1 PL general population	Commodity / group of commodities 29,9 Wheat 13,6 Sheep Liver 13,1 Wheat 11,4 Wheat 16,3 Spinach 10,9 Wheat 10,0 Wheat 19,1 Sugar beet (root) 15,2 Wheat 12,3 Wheat 10,0 Wheat 8,4 Sugar beet (root) 5,2 Wheat 10,2 Spinach 5,7 Wheat 10,0 Wheat 10,4 Wheat 8,9 Wheat 6,5 Wheat 9,1 Wheat 11,4 Wheat 5,7 Wheat 4,6 Wheat 3,0 Rye 5,8 Wheat 2,7 Wheat 3,0 Pulses	Commodity / group of commodities 9,1 Sunflower seed 6,4 Maize 8,6 Sorghum 11,3 Aquile 7,3 Wheat 4,6 Soya bean 6,1 Sunflower seed 10,8 Wheat 12,2 Rye 3,0 Poultry Meat 5,2 Soya bean 7,3 Wheat 3,5 Pulses 4,1 Milk and milk products: Cattle 3,5 Coffee beans 4,6 Pulses 1,4 Root leaves (dried) 3,6 Pulses 1,9 Root leaves (dried) 4,0 Sunflower seed 2,2 Sorghum 3,1 Sugar beet (root) 3,3 Sugar beet (root) 2,9 Wheat 3,1 Nuts 2,5 Coffee beans 1,9 Aquile	Commodity / group of commodities 6,8 Maize 6,4 Maize 6,0 Apples 7,4 Table grapes 7,0 Leaf 4,3 Sunflower seed 3,5 Pulses 3,7 Beans 7,4 Nuts: hazelnut 2,0 Milk and milk products: Cattle 3,3 Coffee beans 5,3 Nuts: hazelnut 2,0 Poultry Meat 2,0 Leaf 3,0 Spinach 3,5 Sunflower seed 1,3 Spinach 2,0 Milk and milk products: Cattle 1,7 Spinach 1,4 Poultry Meat 1,4 Beet leaves (chard) 1,7 Beans 1,4 HOPS (dried) 2,5 Pulses 1,9 Rye 1,9 Beans 1,9 Table grapes
<p>Conclusion: The estimated theoretical Maximum Daily Intakes (TMDI), based on pMRLs were below the ADI. A long-term intake of residues of copper compounds is unlikely to present a public health concern.</p>			

A 3.2.3 Scenario 1 (EFSA PRIMo rev. 3.1)

copper compounds		Input values	
Status of the active substance: LOQs (mg/kg bw) from:	Code no. proposed LOQ:		
Toxicological reference values			
ADI (mg/kg bw/day): 0,35	ARND (mg/kg bw): n.n.		
Source of ADI: EFSA 2018	Source of ARND: EFSA 2018		
Year of evaluation: 2018	Year of ARND evaluation: 2018		
<p>Details - chronic risk assessment Supplementary results - chronic risk assessment Details - acute risk assessment/children Details - acute risk assessment/adults</p>			
<p>Comments:</p>			
<p>Normal mode</p>			
Chronic risk assessment: JMPR methodology (EDI/TMDI)			
No. of diets exceeding the ADI: 1			
Calculated exposure (% of ADI)	Exposure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	2nd contributor to MS diet (in % of ADI)
55% M infant	277,67	19%	19%
90% SLANZ 005 EW	147,06	10%	10%
90% SLANZ 005 F11	143,29	20%	20%
90% ZPUSP 001 C10	140,83	20%	20%
90% SLANZ 005 EW	135,09	14%	14%
80% SLANZ 005 EW	125,17	15%	15%
79% ZPUSP 001 C10	118,70	14%	14%
77% T adult	112,40	17%	17%
75% T adult	112,14	61%	2%
72% L adult	107,25	14%	6%
67% FR child 14-18 y	82,13	19%	4%
55% M general	83,81	5%	5%
50% UK child	73,00	12%	12%
54% FR adult	70,59	19%	12%
50% PT general	77,73	14%	8%
48% FR toddler 2-3 y	72,07	9%	9%
46% M general	67,00	11%	7%
44% SE general	66,12	6%	6%
43% SP - mean 14-18 y	65,46	6%	6%
43% UK infant	64,06	7%	6%
43% UK general	64,07	9%	9%
42% SE adult	63,38	12%	6%
42% UK toddler	63,02	11%	9%
40% T toddler	59,05	19%	7%
35% FR adult	59,70	6%	4%
35% T adult	59,19	11%	9%
29% T 12 y	49,32	6%	3%
29% UK infant	47,47	6%	2%
26% UK vegetation	38,48	6%	3%
25% FR 9 y	37,06	6%	3%
24% UK adult	36,10	4%	3%
22% T adult	33,45	4%	3%
21% UK adult	30,60	2%	2%
14% PL general	20,10	2%	2%
8% FR child	19,79	3%	0,8%
<p>Conclusion: The estimated TMDI/NL/MLU was in the range of 0% to 100,1 % of the ADI. For 1 diet(s) the ADI is exceeded.</p>			

A 3.2.4 Scenario 2 (EFSA PRIMo rev. 3.1)



copper compounds			
LOQs (mg/kg) crop item			
Toxicological reference values			
ADI (mg/kg bw/day)	0.05	ADI (mg/kg bw/day)	n.a.
Source of ADI	EFSA	Source of ADI	EFSA
Year of evaluation	2018	Year of evaluation	2018

Input values

- Details - chronic risk assessment
- Supplementary results - chronic risk assessment
- Details - acute risk assessment/children
- Details - acute risk assessment/adults

Chronic risk assessment: JMPR methodology (IEDI/TMDI)											
Normal mode											Exposure resulting from
No. of diets exceeding the ADI											1
Calculated exposure (µg/kg bw per day)	Mt. diet	Exposure (µg/kg bw per day)	Highest contributor to MFC diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MFC diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MFC diet (in % of ADI)	Commodity / group of commodities	MFC diet (in % of ADI)	Commodity / group of commodities	MFC diet (in % of ADI) Commodity not under assessment (in % of ADI)
100%	ML toddler	442.67	0%						0%		
94%	ML child	141.19	10%	Oil palm nuts	1%	Wheat	1%	Oil palm nuts	12%	Oil palm nuts	
91%	OPUSFruit CAR	135.89	20%	Wheat	10%	Speltwheat	4%	Sugar beet roots	4%	Sugar beet roots	
87%	OPUSFruit CH1	131.01	20%	Speltwheat	10%	Wheat	4%	Speltwheat	4%	Speltwheat	
84%	SLM2H seed 1010	126.27	20%	Speltwheat	1%	Wheat	2%	Wheat	2%	Wheat	
79%	OPUSFruit CAR	109.96	14%	Speltwheat	17%	Wheat	6%	Speltwheat	6%	Speltwheat	
74%	OPUSFruit CH8	111.54	10%	Speltwheat	11%	Wheat	6%	Speltwheat	6%	Speltwheat	
73%	SL child	109.21	12%	Apples	12%	Wheat	6%	Apples	6%	Apples	
72%	SLM2H seed 1010	107.07	14%	Speltwheat	17%	Wheat	7%	Speltwheat	7%	Speltwheat	
70%	FL adult	105.79	61%	Coffee beans	2%	Rice	1%	Coffee beans	1%	Coffee beans	
65%	FL adult	100.42	14%	Speltwheat	6%	Wheat	3%	Speltwheat	3%	Speltwheat	
64%	ML child 2-10 yr	101.09	12%	Wheat	4%	Milk, Cattle	2%	Wheat	2%	Wheat	
64%	ML general	100.97	6%	Oil palm nuts	5%	Wheat	4%	Oil palm nuts	4%	Oil palm nuts	
63%	ML adult	100.01	1%	Wheat	1%	Wheat	1%	Wheat	1%	Wheat	
61%	ML toddler 2-3 yr	100.21	6%	Wheat	6%	Milk, Cattle	4%	Wheat	4%	Wheat	
60%	ML general	100.24	14%	Wheat	0%	Sunflower seeds	2%	Wheat	2%	Wheat	
67%	FL child	93.47	17%	Wheat	3%	Peanut, in-shell	5%	Wheat	5%	Wheat	
61%	UK child	61.09	7%	Wheat	6%	Milk, Cattle	4%	Wheat	4%	Wheat	
59%	UK toddler	59.07	1%	Wheat	4%	Wheat	2%	Wheat	2%	Wheat	
50%	UK general	54.99	2%	Wheat	5%	Coffee beans	4%	Wheat	4%	Wheat	
38%	FL woman 14-50 y	57.34	6%	Wheat	6%	Coffee beans	4%	Wheat	4%	Wheat	
36%	FL general	53.78	11%	Wheat	6%	Peanut	4%	Wheat	4%	Wheat	
33%	SL general	49.04	3%	Wheat	4%	Peanut	2%	Wheat	2%	Wheat	
33%	FL adult	46.71	1%	Wheat	1%	Cereals and products	4%	Wheat	4%	Wheat	
31%	FL adult	46.09	6%	Wheat	4%	Coffee beans	5%	Wheat	5%	Wheat	
29%	SL adult	42.25	6%	Wheat	2%	Cereals and products	2%	Wheat	2%	Wheat	
27%	ML general	39.19	6%	Cereals	3%	Milk, Cattle	2%	Wheat	2%	Wheat	
26%	FL 3 y	37.81	4%	Peanut	3%	Wheat	2%	Wheat	2%	Wheat	
26%	FL adult	36.78	11%	Wheat	2%	Speltwheat	1%	Wheat	1%	Wheat	
23%	FL 3 y	36.17	2%	Speltwheat	2%	Wheat	2%	Wheat	2%	Wheat	
20%	UK vegetable	29.08	6%	Wheat	2%	Wheat	1%	Wheat	1%	Wheat	
18%	FL adult	27.70	3%	Wheat	3%	Wheat	3%	Wheat	3%	Wheat	
10%	UK adult	17.42	2%	Wheat	1%	Wheat (TMDI)	1%	Wheat	1%	Wheat	
10%	FL adult	17.11	3%	Wheat	1%	Rice	1%	Wheat	1%	Wheat	
11%	FL general	16.58	3%	Peanut	2%	Apples	2%	Wheat	2%	Wheat	
6%	SL child	11.57	2%	Wheat	0.6%	Rice	0.6%	Wheat	0.6%	Wheat	

Conclusion:
 The exposure from MFC diets is in the range of 0% to 161.7% of the ADI. For 1 diet the ADI is exceeded.