REGISTRATION REPORT

Part B

Section 1: Identity
Section 2: Physical and chemical properties
Section 4: Further information

Detailed summary of the risk assessment

Product code: **Nordox 75 WG**

Chemical active substance(s):

Copper (I) oxide (Cu_2O), 750 g/kg

NATIONAL ASSESSMENT

Poland

(Authorization in accordance to Art. 43)

Applicant: Nordox AS

Submission date: 31/01/2022

Evaluation date: December 2022

MS Finalisation date: dd/mm/yyyy

Version history

When	What
31/01/2022	Original version from the applicant Nordox AS for Art. 43 submission. All new data and information are marked in yellow.
12/2022	zRMS version for comments

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Submission and Evaluation of Copper compounds under Art.43 of 1107/2009

General observation: Deviation from standard Guidance Documents and EFSA conclusion is necessary and unavoidable for Copper.

The RMS and EFSA are held to assess plant protection products according to the existing methodology described in a series of guidance documents (GDs). Those have been developed for synthetic, organic molecules, and are in most cases not applicable to minerals and Copper. This has led to an EFSA conclusion that indicated a number of critical concerns, or assessments that could not be finalized, which do not reflect any realistic risk, but rather illustrate the inappropriateness of the current GDs for the assessment of Copper. This can easily be seen in a number of endpoints that suggest a high risk exists at concentrations below natural background of this essential micronutrient. **This has been recognized by EFSA, the RMS and several MS (see comments from DE and IT in the Peer review Report), and the EU Commission has mandated EFSA with the development with a Copper specific guidance (Mandate No. 2019-0036).**

Art.43 submissions and their evaluation by MS are unfortunately due before this GD will be available. The current EFSA conclusion and list of endpoints could at best be considered as a first tier, and applicants as well as MS are required to deviate from the standard procedures described in the GD for the following reasons:

- The current GD do not consider bio-availability; for an essential, ubiquitous micronutrient that is a metal it is indispensable to provide assessment methodologies that consider the bioavailability and the potentially toxic fraction in each real-world exposure scenario. Total concentrations do not result in any meaningful outcome.
- Data normalisation to enable comparison of toxicological lab and field data as well as data obtained with different bioavailable fractions is a pre-requisite to allow a realistic assessment of potential risk. Simplistic worst-case scenarios will always indicate a high risk already at naturally occurring concentrations.
- For a homeostatically tight controlled essential element the application of assessment factors is meaningless. The question whether an excess exposure or deficiency leads to an adverse disruption of the homeostatic control cannot be approached in this way. Further, the exceptional data richness of the Copper dossier and more than 100 years of experience with the use as fungicide make safety factors unnecessary.

These unique features of Copper are already considered in the assessment of Copper under separate legislation (REACH, BPD). While COM directed EFSA in their mandate to take advantage of those methodologies, TF members have to anticipate their use and in their proposed assessments of the critical areas of concern identified in the EFSA conclusion. This should be reviewed once the new GD is available and no use should be cancelled until then.

Submission and Evaluation of Copper compounds under Art.43 of 1107/2009

General observation: Copper compounds should not be considered as Candidate for Substitution (CfS).

The implementing Regulation (EU) 2018/1981 is renewing the approval of the active substance Copper compounds as candidate for substitution (CfS), in accordance with Regulation (EC) 1107/2009. Whereas (12) considers that Copper compounds are persistent and toxic in accordance with points 3.7.2.1 and 3.7.2.3 of Annex II to Regulation (EC) 1107/2009 (PBT assessment), and fulfil the condition set in the second indent of point 4 of Annex II to Regulation (EC) 1107/2009.

The EUCuTF disagrees with the approval as CfS. The conditions in Annex to Regulation (EC) 1107/2009 lack the exemption of inorganic compounds like Copper minerals from the PBT assessment as it has been established under other chemical legislations like REACh and BPD. As laid down in those legislations, the term persistence is meaningless for an element or mineral, due to its natural occurrence. Persistence per se is therefore not a relevant parameter and consequently a PBT assessment is not carried out for inorganic compounds under REACh and BPD. The recent mandate from COM to EFSA directs the development of a guidance towards methods and procedures available under those legislations better adapted for the assessment of inorganic compounds, where the relevant parameter is their bioavailability. This should include an exempt statement regarding the PBT assessment to harmonize the assessment of the same compounds under different legislations.

It should be noted that persistence of minerals is considered not relevant for being categorized as low-risk active substance according to Regulation (EU) 2017/1432. This is clearly not compatible with the same parameter leading to a classification as CfS under the same Regulation (EC) 1107/2009.

The EUCuTF is of the opinion that Copper compounds should not be considered CfS, and have lodged an action for annulment against Regulation (EU) 2018/1981 and renewing the approval of the active substance Copper compounds as candidate for substitution (case number T-153/19 European Union Task Force v. European Commission).

Sufficient data on identity, physical and chemical properties and other information are available for the plant protection product and the contained technical active substance(s).

Noticed data gaps are:

- ~~data gap 1~~
- ~~data gap 2~~
- ~~data gap 3~~

1 Section 1: Identity of the plant protection product

1.1 Applicant (KCP 1.1)

Name:	Nordox AS
Address:	Ostensjoveien 13 N-0661 Oslo Norway
Contact:	
Name:	xxx
Fax:	xxx
Phone:	xxx
E-mail:	xxxx

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

1.2.1 Producer(s) of the preparation

Confidential information or data are provided separately (Part C).

1.2.2 Producer(s) of the active substance(s)

Confidential information or data are provided separately (Part C).

1.2.3 Statement of purity (and detailed information on impurities) of the active substance(s)

1.2.3.1 Copper

Minimum purity (as copper)	85.0 % (w/w)
Minimum purity as manufactured	858 g/kg

1.3 Trade names and producer's development code numbers for the preparation (KCP 1.3)

Trade name:	Please refer to Registration Report Part A for the relevant country

Company code number: Nordox 75 WG

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

1.4.1 Composition of the plant protection product (KCP 1.4.1)

Nordox 75 WG is a formulation which contains 750 g Copper/kg where Copper is under the form of Copper (I) oxide.

Table 1.4-1: Active substance(s) and variant(s) of the active substance(s)

Active substance / variant	Declared content of the pure active substance / variant (g/kg)	FAO Limits (min – max)	Technical content* (g/kg)	Technical content (%w/w)
Copper (I) oxide	750	FAO limit: ± 5 % 712.5 - 787.5	862.5	86.25

* Based on the minimum purity of the active substance declared for registration in the active substance dossiers (85 %)

Table 1.4-2: Safener and synergists

Confidential information or data are provided separately (Part C).

Table 1.4-3: Relevant impurities

Relevant impurity	Maximum content (g/L or g/kg)
Arsenic	0.1 mg/g Cu
Cadmium	0.1 mg/g Cu
Lead	0.3 mg/g Cu
Nickel	1 mg/g Cu
Cobalt	3 mg/kg
Mercury	5 mg/kg
Chromium	100 mg/kg
Antimony	7 mg/kg

Details of significant impurities are provided in Part C.

1.4.2 Information on the active substance(s) (KCP 1.4.2)

Table 1.4-4: Information on copper as copper oxide

Type	**Name/Code Number**
ISO common name	Copper oxide
CAS No.	1317-39-1
EC No.	215-270-7
CIPAC No.	44.603

1.4.3 Information on safeners, synergists and co-formulants (KCP 1.4.3)

Confidential information or data are provided separately (Part C).

1.5 Type and code of the plant protection product (KCP 1.5)

Type: Water dispersible granule [Code: WG]

1.6 Function (KCP 1.6)

Fungicide and bactericide.

2 Section 2: Physical, chemical and technical properties of the plant protection product

All studies have been performed in accordance with the current requirements and the results are deemed to be acceptable. The appearance of the product is that of a red-brown free flowing granule free from foreign matter with a vanilla ordour. It is not explosive and has no oxidising properties. The product is not flammable. It has a self-ignition temperature of 234 °C. In aqueous solution, it has a pH value around 7.1 at 21°C. There is no effect of high temperature on the stability of the formulation, since after 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 aluminium laminate sachets. Its technical characteristics are acceptable for a Water dispersible granule (WG) formulation.
The intended concentration of use is 0.075 – 0.375 % (0.75 kg product/ha in 200 – 1000 L water/ha).

Justified Proposals for Classification and Labelling (KCP 12) for physical chemical part only

Not required.

Notifier Proposals for Risk and Safety Phrases (KCP 12)

Not required.

Compliance with FAO specifications:

The product Nordox 75 WG complies with FAO specifications.

Formulation used for tests

The following tests were conducted with the products Nordox 75 WG (750 g/kg Copper). The product Nordox 75 WG was the representative formulation evaluated for Annex I inclusion of copper oxide. All the studies described in this section have been reviewed during EU review.

Table 2-1: Physical, chemical and technical properties of the plant protection product

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
Colour and physical state (KCP 2.1)	RLA 11803 RLA 12647	Nordox 75 WG, (Copper 75 % w/w) Batch 050811	Red-brown free flowing granule free from foreign matter with vanilla odour.	Y	Seaman, G.D. (2014) Report No. XN/12/001/2	Accepted
Explosive properties (KCP 2.2.1)	Copper (I) oxide is not considered to exhibit explosive properties. Nordox 75 WG is composed of Copper (I) oxide as the major component (> 86%) and inert materials and dispersants as the remaining components (14%). Since Nordox 75 WG is not composed of explosive or oxidising materials it is not considered capable of violent exothermic reactions and is unlikely to exhibit explosive properties.					Accepted
Oxidizing properties (KCP 2.2.2)	Copper (I) oxide is not considered to exhibit oxidising properties. Nordox 75 WG is composed of Copper (I) oxide as the major component (> 86%) and inert materials and dispersants as the remaining components (14%). Since Nordox 75 WG is composed of non oxidising materials it is considered incapable of reacting exothermically with combustible materials.					Accepted
Flash point (KCP 2.3.1)	Not relevant for a solid preparation.					
Flammability (KCP 2.3.2)	Copper (I) oxide is not considered to be flammable. Nordox 75 WG is composed of Copper (I) oxide as the major component (> 86%) and inert materials and dispersants as the remaining components (14%). Since Nordox 75 WG is largely composed of non-flammable materials it is not considered to be flammable itself.					Accepted
Self-heating (KCP 2.3.3)	EEC A16	Copper (I) oxide Batch 041102	The relative self-ignition temperature was 234°C.	Y	Baker, D. (2003) Report No.14603 rev.1	
Acidity or alkalinity and pH (KCP 2.4.1)	Not required since the pH of a 1% dispersion was not <4 or >10.					
pH of a 1% aqueous dilution, emulsion or dispersion (KCP 2.4.2)	CIPAC MT 75.3	Nordox 75 WG, (Copper 75 % w/w) Batch 050811	The initial pH of a 1 % aqueous dispersion is 7.7 at 21°C.	Y	Seaman, G.D. (2014) Report No. XN/12/001/2	Accepted
Viscosity (KCP 2.5.1)	Not relevant for a solid preparation.					

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td>Surface tension
(KCP 2.5.2)</td><td colspan="5">Not relevant for a solid preparation.</td><td></td></tr>
<tr><td>Relative density
(KCP 2.6.1)</td><td colspan="5">Not relevant for a solid preparation.</td><td></td></tr>
<tr><td>Bulk density
(KCP 2.6.2)</td><td>CIPAC MT 186</td><td>Nordox 75 WG,
(Copper 75 % w/w)
Batch 050811</td><td>1.68 g/mL (pour density at 21°C)
1.76 g/mL (tap density at 21°C)</td><td>Y</td><td>Seaman, G.D. (2012)
Report No. XN/12/001/1</td><td>Accepted</td></tr>
<tr><td>Storage Stability after 14 days at 54º C
(KCP 2.7.1)</td><td>CIPAC 44/WP/M/3.2
CIPAC MT 75.3
CIPAC MT 191
CIPAC MT 186
CIPAC MT 184
CIPAC MT 174
CIPAC MT 53.3.1
CIPAC MT 185
CIPAC MT 170
CIPAC MT 187
CIPAC MT 171
CIPAC MT 178.2
CIPAC MT 47.2
CIPAC MT 172</td><td>Nordox 75 WG,
(Copper 75 % w/w)
Batch 050811</td><td>Samples have been stored in Aluminium laminate sachets containing 1 kg product. CIPAC water D was used. Results were as follows:
<table>
<tr><th>Parameter</th><th>Initial</th><th>2weeks at 54°C</th></tr>
<tr><td>Cu content [% w/w]</td><td>75.3</td><td>74.4</td></tr>
<tr><td>pH (21°C)</td><td>7.7</td><td>7.6</td></tr>
<tr><td>Physical state</td><td colspan="2">Red-brown free flowing granule free from foreign matter with vanilla odour.</td></tr>
<tr><td>Wettability</td><td><1 second</td><td><1 second</td></tr>
<tr><td>Suspensibility
0.14% w/v
0.5% w/v</td><td>
73%
90%</td><td>
60%
75%</td></tr>
<tr><td>Wet sieve</td><td><0.01% retained on 75µm sieve</td><td>0.02% retained on 75µm sieve</td></tr>
<tr><td>Dispersion</td><td>82%</td><td>48%</td></tr>
<tr><td>Friability</td><td>99.8%</td><td>99.8%</td></tr>
<tr><td>Dust content</td><td>Nearly dust free</td><td>Nearly dust free</td></tr>
<tr><td>Particle size distribution D90</td><td>5.0 µm</td><td>5.3 µm</td></tr>
</table></td><td>Y</td><td>Seaman, G.D. (2012)
Report No. XN/12/001/1</td><td>Accepted</td></tr>
</table>

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td></td><td></td><td></td><td>
<table>
<tr><td>D50
D10</td><td>2.3 µm
0.4 µm</td><td>2.5 µm
0.5 µm</td></tr>
<tr><td>Persistent foam
0.14%
0.5%</td><td>(1min)

8 mL
6 mL</td><td>(1min)

36 mL
34 mL</td></tr>
<tr><td>Stability of packaging</td><td colspan="2">The pack appearance of sachets was as initial. No significant weight change.</td></tr>
</table>

The physical and chemical properties of Nordox 75 WG when stored in an aluminium laminate sachet, as determined in this study, have not changed adversely except for the reduction in degree of dispersion to 48%, after accelerated storage for up to 2 weeks at 54°C.</td><td></td><td></td><td></td></tr>
<tr><td>Stability after storage for other periods and/or temperatures
(KCP 2.7.2)</td><td colspan="5">Not required because the preparation has been tested for 14 days at 54°C and found to be stable.</td><td></td></tr>
<tr><td>Minimum content after heat stability testing
(KCP 2.7.3)</td><td>CIPAC 44/WP/M/3.2</td><td>Nordox 75 WG, (Copper 75 % w/w) Batch 050811</td><td>Nordox 75 WG was stable during storage at 54°C for 14 days. No decrease in the active substance content was observed. Therefore, it is not necessary to state a minimum content.</td><td>Y</td><td>Seaman, G.D. (2012) Report No. XN/12/001/1</td><td>Accepted</td></tr>
<tr><td>Effect of low temperatures on stability
(KCP 2.7.4)</td><td colspan="5">Not required for a solid preparation.</td><td></td></tr>
<tr><td>Ambient temperature shelf life
(KCP 2.7.5)</td><td>CIPAC 44/WP/M/3.2
CIPAC MT 75.3
CIPAC MT 191
CIPAC MT 184
CIPAC MT 174</td><td>Nordox 75 WG, (Copper 75 % w/w) Batch 050811</td><td>Samples have been stored in Aluminium laminate sachets containing 1 kg product. CIPAC water D was used. Results were as follows:
<table>
<tr><th>Parameter</th><th>Initial</th><th>104 weeks at 20°C</th></tr>
<tr><td>Cu content</td><td>75.3</td><td>75.5</td></tr>
</table></td><td>Y</td><td>Seaman, G.D. (2014) Report No. XN/12/001/2</td><td>Accepted</td></tr>
</table>

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td></td><td>CIPAC MT 53.3.1
CIPAC MT 185
CIPAC MT 170
CIPAC MT 187
CIPAC MT 171
CIPAC MT 178.2
CIPAC MT 47.2</td><td></td><td>
<table>
<tr><td>[% w/w]</td><td></td><td></td></tr>
<tr><td>pH (21°C)</td><td>7.7</td><td>7.8</td></tr>
<tr><td>Physical state</td><td colspan="2">Red-brown free flowing granule free from foreign matter with vanilla odour.</td></tr>
<tr><td>Wettability</td><td><1 second</td><td><1 second</td></tr>
<tr><td>Suspensibility
0.14% w/v
0.5% w/v</td><td>
73%
76%</td><td>
90%
76%</td></tr>
<tr><td>Wet sieve</td><td><0.01% retained on 75µm sieve</td><td>0.01% retained on 75µm sieve</td></tr>
<tr><td>Dispersion</td><td>82%</td><td>48%</td></tr>
<tr><td>Friability</td><td>99.8%</td><td>>99.9%</td></tr>
<tr><td>Dust content</td><td>Nearly dust free</td><td>Nearly dust free</td></tr>
<tr><td>Particle size distribution
D90
D50
D10</td><td>
5.0 µm
2.3 µm
0.4 µm</td><td>
5.7 µm
2.3 µm
0.5 µm</td></tr>
<tr><td>Persistent foam
0.14%
0.5%</td><td>(1min)
8 mL
15 mL</td><td>(1min)
36 mL
39 mL</td></tr>
<tr><td>Stability of packaging</td><td colspan="2">The pack appearance of sachets was as initial. No significant weight change.</td></tr>
</table>

The physical and chemical properties of Nordox 75 WG when stored in an aluminium laminate sachet, as determined in this study, have not changed adversely except for the reduction in the degree of dispersion to 48% after storage for up to 104 weeks at 20°C.</td><td></td><td></td><td></td></tr>
</table>

<table>
<tr><th>Annex point</th><th>Method used / deviations</th><th>Test material</th><th>Findings</th><th>GLP Y/N</th><th>Reference</th><th>Acceptability / comments</th></tr>
<tr><td>Shelf life in months (if less than 2 years) (KCP 2.7.6)</td><td colspan="5">Not relevant.</td><td></td></tr>
<tr><td>Wettability (KCP 2.8.1)</td><td>CIPAC MT 53.3.1</td><td>Nordox 75 WG, (Copper 75 % w/w) Batch 050811</td><td><1 second by CIPAC Standard water D.</td><td>Y</td><td>Seaman, G.D. (2014) Report No. XN/12/001/2</td><td>Accepted</td></tr>
<tr><td>Persistence of foaming (KCP 2.8.2)</td><td>CIPAC MT 47.2</td><td>Nordox 75 WG, (Copper 75 % w/w) Batch 050811</td><td><table><tr><td>Persistence of foam</td><td colspan="2">% w/v</td></tr><tr><td></td><td>0.14</td><td>0.5</td></tr><tr><td>10 sec</td><td>16 mL</td><td>38 mL</td></tr><tr><td>1 min</td><td>8 mL</td><td>36 mL</td></tr><tr><td>3 min</td><td>6 mL</td><td>34 mL</td></tr><tr><td>12 min</td><td>6 mL</td><td>22 mL</td></tr></table></td><td>Y</td><td>Seaman, G.D. (2014) Report No. XN/12/001/2</td><td>Accepted</td></tr>
<tr><td>Suspensibility (KCP 2.8.3.1)</td><td>CIPAC MT 184</td><td>Nordox 75 WG, (Copper 75 % w/w) Batch 050811</td><td><table><tr><td></td><td colspan="2">CIPAC water D</td></tr><tr><td>Dilution</td><td>0.14 % w/v</td><td>0.5 % w/v</td></tr><tr><td>Suspensibility [%]</td><td>73</td><td>90</td></tr></table></td><td>Y</td><td>Seaman, G.D. (2014) Report No. XN/12/001/2</td><td>Accepted</td></tr>
<tr><td>Spontaneity of dispersion (KCP 2.8.3.2)</td><td>CIPAC MT 174</td><td>Nordox 75 WG, (Copper 75 % w/w) Batch 050811</td><td>At 1% w/v in standard water D: 82%</td><td>Y</td><td>Seaman, G.D. (2014) Report No. XN/12/001/2</td><td>Accepted</td></tr>
<tr><td>Dispersion stability (KCP 2.8.3.3)</td><td colspan="5">Not relevant for a WG formulation.</td><td></td></tr>
<tr><td>Degree of dissolution and dilution stability (KCP 2.8.4)</td><td colspan="5">Not relevant for a WG formulation.</td><td></td></tr>
<tr><td rowspan="2">Particle size distribution / nominal size range of granules (KCP 2.8.5.1.1)</td><td>CIPAC MT 170</td><td rowspan="2">Nordox 75 WG, (Copper 75 % w/w) Batch 050811</td><td>Sieve sizes 3350, 2000, 1000, 500, 250, 125, and 75 µm were used.
≥80% of the particle is in the range 75-250 µm.</td><td rowspan="2">Y</td><td rowspan="2">Seaman, G.D. (2014) Report No. XN/12/001/2</td><td>Accepted</td></tr>
<tr><td>CIPAC MT 187</td><td>D90 = 5.0 µm
D50 = 2.3 µm</td><td></td></tr>
</table>

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
			D10 = 0.4 µm			
Wet sieve test (KCP 2.8.5.1.2)	CIPAC MT 185	Nordox 75 WG, (Copper 75 % w/w) Batch 050811	<0.01% was retained on a 75 µm sieve.	Y	Seaman, G.D. (2014) Report No. XN/12/001/2	Accepted
Dust content (KCP 2.8.5.2.1)	CIPAC MT 171	Nordox 75 WG, (Copper 75 % w/w) Batch 050811	Category 1: Nearly dust free	Y	Seaman, G.D. (2014) Report No. XN/12/001/2	Accepted
Particle size of dust (KCP 2.8.5.2.2)	Not relevant.					
Attrition (KCP 2.8.5.3)	CIPAC MT 178.2	Nordox 75 WG, (Copper 75 % w/w) Batch 050811	Attrition resistance: 99.8%	Y	Seaman, G.D. (2014) Report No. XN/12/001/2	Accepted
Hardness and integrity (KCP 2.8.5.4)	Not relevant for a WG formulation.					
Emulsifiability (KCP 2.8.6.1)	Not relevant for a WG formulation.					
Emulsion stability (KCP 2.8.6.2)	Not relevant for a WG formulation.					
Re-emulsifiability (KCP 2.8.6.3)	Not relevant for a WG formulation.					
Flowability (KCP 2.8.7.1)	CIPAC MT 172	Nordox 75 WG, (Copper 75 % w/w) Batch 050811	After storage at 54ºC for 2 weeks, on initial transfer of the sample to the sieve no granules were retained.	Y	Seaman, G.D. (2012) Report No. XN/12/001/1	Accepted
Pourability (KCP 2.8.7.2)	Not relevant for a WG formulation.					
Dustability following	Not relevant for a WG formulation.					

Annex point	Method used / deviations	Test material	Findings	GLP Y/N	Reference	Acceptability / comments
accelerated storage (KCP 2.8.7.3)						
Physical compatibility of tank mixes (KCP 2.9.1)	No tank mix is forseen.					
Chemical compatibility of tank mixes (KCP 2.9.2)	No tank mix is forseen.					
Adhesion to seeds (KCP 2.10.1)	Not relevant for a WG formulation.					
Distribution to seed (KCP 2.10.2)	Not relevant for a WG formulation.					
Other/special studies (KCP 2.11)	PSD efficacy guideline 305	Nordox 75 WG, (Copper 75 % w/w) Batch 050811	Effectiveness of cleaning procedures: >99.9 % of the formulation was removed in a triple rinse procedure without tank cleaner.	Y	Seaman, G.D. (2012) Report No. XN/12/001/1	Accepted

3 Section 3 is presented as a separate document

Please refer to the separate file “dRR Part B3”.

4 Section 4: Further information on the plant protection product

4.1 Packaging and Compatibility with the Preparation (KCP 4.4)

The following package sizes are intended:

Table 4.1-1: Packaging information for 8, 10, 25 kg bags

Type	Description
Material:	Paper lined multi-layer sacks
Shape/size:	1, 10, 25 kg bags
Opening:	Not applicable
Closure:	Not applicable
Seal:	Not applicable
Manner of construction	Inside layer in PET, two middle layers in paper, an outside paper laminated
UN/ADR	Not applicable

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP 2.3.3/01	Baker, D.	2003	Regulatory testing on a sample of Cuprous Oxide Technical Report No. 14603 revision 1 GLP Unpublished	N	Nordox AS
KCP 2.7.1/01	Seaman, G. D.	2012	Physical and Chemical Properties of Nordox 75 WG: Storage Stability for up to 2 weeks at 54°C. Report No. XN/12/001/1 GLP Unpublished	N	Nordox AS
KCP 2.7.5/01	Seaman, G. D.	2014	Physical and Chemical Properties of Nordox 75 WG: Storage Stability for up to 104 weeks at 20°C. Report No. XN/12/001/2 GLP Unpublished	N	Nordox AS

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

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Verte-brate study Y/N	Owner
KCP XX	Author	YYYY	Title Company Report No Source GLP/non GLP/GEP/non GEP Published/Unpublished	Y/N	Owner

Appendix 2 Additional data on the physical, chemical and technical properties of the active substance

None.