ATTRIBUT SG70
(700 g/kg propoxycarbazone-sodium)

Herbicide

Dossier for Renewal of Approval according to Commission Regulation 844/2012

Document M-CP, Section 7

Toxicological studies on the plant protection product

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Version history

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CP 7  TOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

This document reviews the toxicological studies and human exposure for the plant protection product Attribut SG70 (formulation code MKH 6561) containing the active substance propoxycarbazone-sodium (700 g/kg) formulated as water soluble granular formulation.

The product Attribut SG70 was not the representative formulation during the Annex I listing process of the active substance propoxycarbazone-sodium. Anyway Attribut SG70 is considered to be similar to MKH 6561 WG 70 which has been the representative use during the approval of propoxycarbazone-sodium. Please refer to the Document J of this dossier for an evaluation of the similarity of both formulations. It is proposed to use environmental fate data from MKH6561 WG 70 to support Attribut SG70.

Based on the intended uses, the risk for the operator using Attribut SG70 is considered acceptable and there is no undue risk to workers in occupational settings or to bystanders or residents after accidental short-term exposure.

CP 7.1  Acute toxicity

The following tests were performed on MKH 6561 70 WG: acute LD$_{50}$ oral (rat), acute LD$_{50}$ dermal (rat), acute LC$_{50}$ inhalation (rat), skin irritation (rabbit), eye irritation (rabbit) and Sensitization of the skin [Buehler test (guinea pig) and Maximization test (guinea pig)]. The results are summarised in Table CP 7.1-1 and individual study reports are presented in CP 7.1.1 to 7.1.6.

For information on studies already evaluated during the first EU review of propoxycarbazone-sodium, please refer to the corresponding section in the Baseline Dossier provided by Dr. Knoell Consult on behalf of Bayer CropScience and in the Monograph.

An additional skin sensitisation study was performed, which was not submitted during the first Annex I inclusion process and is submitted within this Supplemental Dossier for the propoxycarbazone-sodium Annex I Renewal. This study is summarized in CP 7.1.6. The new study has been performed with adjuvant-type test (Guinea-Pig Maximisation Test) since according to the Commission Directive 96/54/EC (22nd Adaptation of Council Directive 67/548/EEC) Method B4 adjuvant-type tests are likely to be more accurate in predicting a probable skin sensitising effect of a substance in humans and are thus the preferred method.

All studies, previously evaluated and new, were assessed according to the Regulation (EC) No 1272/2008 (CLP), as amended.

Attribut SG70 is considered to be similar to MKH 6561 70 WG. Please refer to the Document J of this dossier for an evaluation of the similarity of both formulations. It is proposed to use acute toxicity data from MKH6561 70 WG to support Attribut SG70.
### Table CP 7.1-1: Acute toxicological data obtained with MKH 6561 70 WG

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Species</th>
<th>Result mg/kg or mg/m³ or effect</th>
<th>Classification EU</th>
<th>CLP classification</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute oral toxicity</td>
<td>Rat</td>
<td>LD₅₀ &gt; 2000 mg/kg 2500 mg/kg (LD₅₀ cut-off value according to the interpretation of OECD 423)</td>
<td>none</td>
<td>none</td>
<td>For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)</td>
</tr>
<tr>
<td>Acute dermal toxicity</td>
<td>Rat</td>
<td>&gt;2000 mg/kg</td>
<td>none</td>
<td>none</td>
<td>For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)</td>
</tr>
<tr>
<td>Acute inhalation toxicity; 4-hour, nose-only</td>
<td>Rat</td>
<td>&gt;4995 mg/m³ (maximum technically attainable concentration)</td>
<td>none</td>
<td>none</td>
<td>For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)</td>
</tr>
<tr>
<td>Skin irritation</td>
<td>Rabbit</td>
<td>Not irritating</td>
<td>none</td>
<td>none</td>
<td>For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)</td>
</tr>
<tr>
<td>Eye irritation</td>
<td>Rabbit</td>
<td>Not irritating</td>
<td>none</td>
<td>none</td>
<td>For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)</td>
</tr>
<tr>
<td>Skin sensitisation; Buehler test</td>
<td>Guinea pig</td>
<td>Not sensitising</td>
<td>none</td>
<td>none</td>
<td>For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)</td>
</tr>
<tr>
<td>Skin sensitisation; Maximization test</td>
<td>Guinea pig</td>
<td>Not sensitising</td>
<td>none</td>
<td>none</td>
<td>For details refer to CP 7.1.6/02</td>
</tr>
</tbody>
</table>

MKH 6561 70 WG containing 700 g/kg propoxycarbazone-sodium has a low toxicity in respect to acute oral, dermal and inhalatory toxicity and is not irritating to the rabbit skin and eye, it is not skin sensitisers to the guinea pig.
CP 7.1.1  Oral toxicity

Acute oral toxicity study, performed on MKH 6561 70 WG, was already evaluated during the first EU review of propoxycarbazone-sodium, please refer to the corresponding section in the Baseline Dossier provided by the applicant and in the Monograph from 2001.

The report is added to this review, but since the study was considered acceptable during the first EU review of propoxycarbazone-sodium, a summary of the respective study has not been provided.

Report: KCP 7.1.1 /01; F.;1998;M-005537-01
Title: MKH 6561 70 WG 05780/0031 - Study for acute oral toxicity in rats
Report No: 27722
Document No: M-005537-01-1
Deviations: None
GLP/GEP: yes

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (SANCO dossier of former representative formulation ATTRIBUT 70WG: P-010244-01).

The test substance is non-toxic after acute oral exposure. The oral LD₅₀ value of MKH 6561 70 WG in SPF-Wistar rats was established to exceed 2000 mg/kg body weight. According to the OECD 423 test guideline, the LD₅₀ cut-off value was considered to be 2500 mg/kg body weight.

The study result triggers the following classification/labelling:
- Regulation (EC) No 1272/2008 (CLP), as amended: none

CP 7.1.2  Dermal toxicity

Acute dermal toxicity study, performed on MKH 6561 70 WG, was already evaluated during the first EU review of propoxycarbazone-sodium, please refer to the corresponding section in the Baseline Dossier provided by Dr. Knoell Consult on behalf of Bayer CropScience and in the Monograph.

The report is added to this review, but since the study was considered acceptable during the first EU review of propoxycarbazone-sodium, a summary of the respective study has not been provided.

Report: KCP 7.1.2 /01; F.;1998;M-005539-01
Title: MKH 6561 70 WG 05780/0031 - Study for acute dermal toxicity in rats
Report No: 28234
Document No: M-005539-01-1
Deviations: None
GLP/GEP: yes

Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (SANCO dossier of former representative formulation ATTRIBUT 70WG: P-010244-01).

The test substance is non-toxic after acute dermal application. The dermal LD₅₀ value of MKH 6561 70 was established to exceed 2000 mg/kg body weight.
According to the Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures, MKH 6561 70 WG does not have to be classified and has no obligatory labelling requirement for acute dermal toxicity.

The study result triggers the following classification/labelling:
- Regulation (EC) No 1272/2008 (CLP), as amended: none

**CP 7.1.3 Inhalation toxicity**

Acute inhalation toxicity study, performed on MKH 6561 70 WG, was already evaluated during the first EU review of propoxycarbazone-sodium, please refer to the corresponding section in the Baseline Dossier provided by Dr. Knoell Consult on behalf of Bayer CropScience and in the Monograph.

The report is added to this review, but since the study was considered acceptable during the first EU review of propoxycarbazone-sodium, a summary of the respective study has not been provided.

**Studies shaded in grey have been reviewed as part of the first EU review of propoxycarbazone-sodium (SANCO dossier of former representative formulation ATTRIBUT 70WG: P-010244-01).**

![Report: KCP 7.1.3 /01; J.1998.M-005538-08](image)

| Title: MKH 6561 70 WG 09/80/0031 (c.n.: --) - Study on acute inhalation toxicity in rats according to OECD No. 403, 92/69/EEC and FIFRA §83-3 |
| Report No: 28129 |
| Document No: M-005538-02-1 |
| Guidelines: OECD No. 403; 92/69/EEC; FIFRA §83-3 |
| Deviations: None |
| GLP/GEP: yes |

The test substance is of no toxicity after acute inhalation exposure. The inhalatory LC$_{50}$ value of MKH 6561 WG 70 was established to exceed 4995 mg/m$^3$.

The study result triggers the following classification/labelling:
- Regulation (EC) No 1272/2008 (CLP), as amended: none

**CP 7.1.4 Skin irritation**

Acute skin irritation study, performed on MKH 6561 70 WG, was already evaluated during the first EU review of propoxycarbazone-sodium, please refer to the corresponding section in the Baseline Dossier provided by Dr. Knoell Consult on behalf of Bayer CropScience and in the Monograph.

The report is added to this review, but since the study was considered acceptable during the first EU review of propoxycarbazone-sodium, a summary of the respective study has not been provided.

| Title: MKH 6561 70 WG 09/80/0031 (c.n.: --) - Study on acute skin irritation in rabbits according to OECD No. 404, 92/69/EEC and FIFRA §83-19 |
| Report No: 28129 |
| Document No: M-005538-02-1 |
| Guidelines: OECD No. 404; 92/69/EEC; FIFRA §83-19 |
| Deviations: None |
| GLP/GEP: yes |

The test substance is of no skin irritation potential. The skin irritation value of MKH 6561 WG 70 was established to exceed 2500 mg/m$^2$. 

The study result triggers the following classification/labelling:
- Regulation (EC) No 1272/2008 (CLP), as amended: none

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Based on the study results, the test substance MKH 6561 70 WG is not irritating to the skin of rabbits.

The study result triggers the following classification/labelling:
- Regulation (EC) No 1272/2008 (CLP), as amended: none

CP 7.1.5  Eye irritation

Acute eye irritation study, performed on MKH 6561 70 WG, was already evaluated during the first EU review of propoxycarbazone-sodium, please refer to the corresponding section in the Baseline Dossier provided by Dr. Knoell Consult on behalf of Bayer CropScience and in the Monograph.

The report is added to this review, but since the study was considered acceptable during the first EU review of propoxycarbazone-sodium, a summary of the respective study has not been provided.

Based on the study results, the test substance MKH 6561 WG 70 is not irritating to the eyes of rabbits.

The study result triggers the following classification/labelling:
- Regulation (EC) No 1272/2008 (CLP), as amended: none

CP 7.1.6  Skin sensitization

A skin sensitisation study performed on MKH 6561 70 WG, was already evaluated during the first EU review of propoxycarbazone-sodium, please refer to the corresponding section in the Baseline Dossier provided by Dr. Knoell Consult on behalf of Bayer CropScience and in the Monograph.

The report is added to this review, but since the study was considered acceptable during the first EU review of propoxycarbazone-sodium, a summary of the respective study has not been provided.
MKH 6561 WG 70 exhibits no skin-sensitisation potential under the conditions of the Buehler Patch Test.

**The study result triggers the following classification/labelling:**

- **EU Directive 2001/59/EC:** none
- **Regulation (EC) No 1272/2008 (CLP), as amended:** none

An additional skin sensitisation study was performed which was not submitted during the first Annex I inclusion process and is submitted within this Supplemental Dossier for the propoxycarbazine-sodium Annex I Renewal. This study is summarized below.

The new study has been performed with adjuvant-type test (Guinea-Pig Maximisation Test) since according to the Commission Directive 96/54/EC (22 nd Adaptation of Council Directive 67/548/EEC) Method B6 adjuvant-type tests are likely to be more accurate in predicting a probable skin sensitising effect of a substance in humans and are thus the preferred method.

**Executive Summary**

The skin sensitizing potential of MKH 6561 70 WG (content: 68.6% w/w) was assessed in young adult female SPF-bred Crl:HA guinea pigs (20 animals for the test item group and 10 control animals) using the Maximisation test according to Magnusson and Kligman.

The intradermal induction was performed using three injections of 0.1 mL 5% MKH 6561 70 WG each, corresponding to 20 mg test item/animal, in row on the left and the right side of the spinal column.

The topical induction using 0.5 mL 25% MKH 6561 70 WG, corresponding to 125 mg test item/animal, was performed one week after the intradermal induction.

First topical challenge was performed three weeks after the intradermal induction with 0.5 mL of 6% test item formulation, corresponding to 30 mg test item/animal, which were placed on the right flank of the animals of the test item group and the control group and held securely in place on the skin with a self-adhesive tape for 24 hours. As control a patch loaded only with the vehicle was placed also on the right flank. The skin reactions were assessed 48 and 72 hours after the start of the application to induce the challenge.

Due to equivocal results of the first challenge, second challenge was performed one week after the first challenge.
Second topical challenge was performed in the same way as the first one with the exception that the left flank of the animals was used.

No mortality was observed during the study. The 1st challenge with the 6% suspension led to skin effects (slight localized redness, moderate confluent redness) in 6 of 20 animals (30%) in the test item group. No skin effects were seen in the control group animals. The 2nd challenge with the 6% suspension led to skin effects (slight localized redness) in 3 of 20 animals (15%) in the test item group. No skin effects were seen in the control group animals.

Under the experimental conditions of the Maximization test, MKH 6561 70 WG is considered to be non-sensitizing in the guinea pig. The sensitisation rate is below the threshold of significance (30%) as laid out in Regulation (EC) No 1272/2008 and EU directive 2001/59/EC.

The study result triggers the following classification/labelling:  
- EU directive 2001/59/EC: None.

I. MATERIALS AND METHODS

A. MATERIALS

1. Test material:
   Identification: MKH 6561 70 WG
   Description: Beige granule
   Lot/Batch #: 05780/0122(0057)
   Purity: 68.6% w/w
   Stability of test compound: Expiry date: July 23, 2003

2. Vehicle and/or positive control:
   Vehicle: sterile physiological saline solution;
   positive control: alpha-hexyl cinnamaldehyde

3. Test animals:
   Species: Guinea pig
   Strain: SPF Ctrl BA
   Source: Germany
   Age: 3-4 weeks
   Sex: Female
   Weight at dosing: 284-367 g
   Acclimation period: At least 5 days
   Diet/Food: Provimi Kliba 3420 – Maintenance Diet for Guinea Pigs, ad libitum
   Water: Tap water, ad libitum
   Housing: IV Makrolon® cages; in groups of five during the adaptation period; in groups of two or three per cage throughout the study period. Bedding of low-dust shavings (J4)IP/zlz:zjFg?gcä4 8wD, Soest, Germany)
Environmental conditions: Temperature: 22±3°C
Humidity: 40-70%
Air changes: > 10 times/h
12 hours light/dark cycle

B. STUDY DESIGN AND METHODS

In life dates
2003-02-11 – 2003-03-14

Animal assignment and treatment:
The skin sensitizing potential of MKH 6561 70 WG (content: 68.6% w/w) was assessed in young adult female SPF-bred CrI:HA guinea pigs (20 animals for the test item group and 10 control animals) using the Maximisation test according to Magnusson and Kligman. Additional two animals were used for dose-finding.

The following concentrations were used:
Intradermal induction: 5% (= 20 mg test item/animal)
Topical induction: 25% (= 125 mg test item/animal)
1st challenge: 6% (= 30 mg test item/animal)
2nd challenge: 6% (= 30 mg test item/animal)

The test substance was formulated in sterile physiological saline solution to yield a suspension.

Intradermal induction: The dorsal region and the flanks of the guinea pigs were shorn one day prior to the application. Three injections of 0.1 mL each in a row were made on the left and the right side of the spinal column.

The following groups were treated as follows:
Test item group:
- Complete Freund’s adjuvant diluted 1:1 with sterile physiological saline solution;
- 5% MKH 6561 70 WG formulated in sterile physiological saline solution
- 5% MKH 6561 70 WG formulated at equal parts in sterile physiological saline solution and complete Freund’s adjuvant

Control group:
- Complete Freund’s adjuvant diluted 1:1 with sterile physiological saline solution;
- Sterile physiological saline solution;
- Equal parts of sterile physiological saline solution and complete Freund’s adjuvant.

Topical induction: The topical induction was performed one week after the intradermal induction. One day prior to the topical treatment, the test areas of the animals were shorn.

Hypoallergenic patches (2 x 4 cm) were placed between and on the injection sites, covered with aluminium foil and held securely in place on the skin using a self-adhesive tape.

The patches were treated as follows:
Test item group:
- 0.5 mL 25% MKH 6561 70 WG.

Control group:
- 0.5 mL sterile physiological saline solution.

At the end of the 48-hour period, the remaining test item was removed with sterile physiological saline solution.

Topical challenges: The first challenge was performed three weeks after the intradermal induction.
The test item concentrations for the challenge had been determined in a dose-finding study using two guinea pigs that were treated during the inductions in the same manner as the control animals.

The dorsal region and the right flank of the animals were shorn one day prior to the challenge. During the challenge a hypoallergenic patch loaded with the 6% test item formulation was placed on the right flank of the animals of the test item group and the control group and held securely in place on the skin with a self-adhesive tape for 24 hours. A patch loaded only with the vehicle was placed also on the right flank as control. The volume applied in each case was 0.5 mL.

The remaining test item was removed after 24 hours using physiological saline solution, and 21 hours later the application site was shorn.

The second challenge with the 6% test item formulation was performed one week after the first challenge in the same way with the exception that the left flank of the animals were shorn and the patches were applied on the left flank. As control a patch loaded only with the vehicle was placed also on the left flank.

The skin reactions were assessed 48 and 72 hours after the start of the application to induce the challenge and for the range-finding studies to establish concentrations for the topical induction and challenge.

Positive Control: To confirm the reliability of the test system used, alpha-hexyl cinnamaldehyde formulated in sterile physiological saline solution was used as a positive control. The tested concentrations were: for the intradermal induction 5% test item formulation, for topical induction a 25% formulation. After the challenge with a 12% test item formulation 100% of the animals exhibited dermal reactions in the challenge treatment.

II. RESULTS AND DISCUSSION

A. MORTALITY

No mortality was observed during the study.

B. CLINICAL OBSERVATIONS

48 hours after the intradermal induction the animals in the control group showed red wheal. The animals in the test item group showed red wheal, red injection site and white wheal with red surrounding. After 7 days wheals and encrustations were recorded at the injection sites in the control group and in the test item group.

The 1st challenge with the 6% suspension led to skin effects (slight localized redness, moderate confluent redness) in 6 of 20 animals (30%) in the test item group. No skin effects were seen in the control group animals.

The 2nd challenge with the 6% suspension led to skin effects (slight localized redness) in 3 of 20 animals (15%) in the test item group. No skin effects were seen in the control group animals.

The incidence of skin reactions following the challenge is summarized in the Table CP 7.1-2.
Table CP 7.1-2: Number of animals exhibiting skin effects

<table>
<thead>
<tr>
<th></th>
<th>Test item group (20 animals)</th>
<th>Control group (10 animals)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test item patch</td>
<td>Control patch</td>
</tr>
<tr>
<td>Hours</td>
<td>Hours</td>
<td>Total</td>
</tr>
<tr>
<td>1st challenge</td>
<td>48</td>
<td>72</td>
</tr>
<tr>
<td>6%</td>
<td>6</td>
<td>4</td>
</tr>
<tr>
<td>2nd challenge</td>
<td>3</td>
<td>1</td>
</tr>
<tr>
<td>6%</td>
<td>3</td>
<td>1</td>
</tr>
</tbody>
</table>

C. BODY WEIGHT
At the end of the study, the mean body weight of the treatment group of animals was in the same range than that of the control group animals.

III. CONCLUSION
Under the experimental conditions of the Maximization test, MKH 6561 70 WG is considered to be non-sensitizing in the guinea pig. The sensitisation rate is below the threshold of significance (30%) as laid out in Regulation (EC) No 1272/2008 and EU directive 2001/59/EC.

The study result triggers the following classification/labelling:
- Regulation (EC) No 1272/2008 (CLP), as amended: none

CP 7.1.7 Supplementary studies for combinations of plant protection products
No supplementary studies are required.

CP 7.1.8 Supplementary studies for combinations of plant protection product
No supplementary studies are required.

CP 7.2 Data on exposure
CP 7.2.1 Operator exposure
The plant protection product Attribut SG70 is a soluble granule formulation containing 700 g/kg of propoxycarbazone-sodium intended to be used on cereals as an herbicide. Usage information pertinent to operator exposure is summarised in Table CP 7.2-1.

Table CP 7.2-1: Summary of critical use patterns of Attribut SG70

<table>
<thead>
<tr>
<th>Crop</th>
<th>F/G</th>
<th>Max.</th>
<th>kg product/ha</th>
<th>Water volume L/ha</th>
<th>Method of application</th>
<th>Max. no of appl.</th>
<th>Interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cereals</td>
<td>F</td>
<td>0.6</td>
<td>0.1</td>
<td>150</td>
<td>Tractor-mounted boom sprayer</td>
<td>1</td>
<td>-</td>
</tr>
</tbody>
</table>

F – field, G – greenhouse
Estimations of potential operator exposure have been undertaken for propoxycarbazone-sodium using the list of intended uses (Table CP 7.2-1) and the following predictive models:

- Uniform Principles for Safeguarding the Health of applicators of Plant Protection Products (Uniform Principles for Operator Protection), Mitteilungen aus der Biologischen Bundesanstalt für Land-und Forstwirtschaft, Berlin-Dahlem, Heft 277, 1992. (“German model”).


The estimations were compared to following data:

<table>
<thead>
<tr>
<th>End-Point</th>
<th>Active substance: propoxycarbazone-sodium</th>
</tr>
</thead>
<tbody>
<tr>
<td>AOEL</td>
<td>0.3 mg/kg bw/day</td>
</tr>
<tr>
<td>Dermal penetration</td>
<td>Concentrate: 25% (default value)</td>
</tr>
</tbody>
</table>

Summarized estimates are presented in the following Table CP 7.2-2.

Table CP 7.2-2: Estimated operator exposure to propoxycarbazone-sodium

<table>
<thead>
<tr>
<th>Model data</th>
<th>Level of PPE</th>
<th>Total absorbed dose (mg/kg bw/day)</th>
<th>% of AOEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tractor-mounted boom sprayer application outdoors to low crops. Application rate: 0.1 kg/ha product (0.070 kg propoxycarbazone-sodium/ha)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UK POEM</td>
<td>no PPE</td>
<td>0.328</td>
<td>109.3</td>
</tr>
<tr>
<td></td>
<td>Gloves during mixing/loading</td>
<td>0.246</td>
<td>82.0</td>
</tr>
<tr>
<td>German Model</td>
<td>no PPE</td>
<td>0.0408</td>
<td>13.6</td>
</tr>
</tbody>
</table>

No PPE: German Model: Operator wearing T-shirt and shorts.
UK POEM: Operator wearing long sleeved shirt, long trousers (“permeable”) but no gloves.

CONCLUSION

According to the UK POEM model calculations, it can be concluded that the risk for the operator using Attribut SG 70 on cereals is acceptable with the use of personal protective equipment – gloves during mixing/loading.

According to the German model calculations, it can be concluded that the risk for the operator using Attribut SG 70 on cereals is acceptable without the use of personal protective equipment.
CP 7.2.1.1 Estimation of operator exposure
Exposure estimation according to the UK POEM

Assumptions to assess operator exposure according to the UK POEM are summarised below:

Application method: Tractor-mounted boom sprayer
Treated area: 50 ha/day
Max. dose rate: 0.1 kg/ha Attribut SG70 (0.07 kg/ha propoxycarbazone-sodium)
Application volume: 150 L/ha
Dermal absorption: 25% for the concentrate; 75% for the in-use dilution
Operator body weight: 60 kg
No PPE: Operator wearing long sleeved shirt, long trousers (“permeable”) but no gloves
PPE: Gloves are worn during mixing/loading

The results are summarized in Table CP 7.2-2 in Section CP 7.2.1 above.
Detailed calculations are presented in Table CP 7.2-3 and Table CP 7.2-5.

Estimation according to the German model

Assumptions to assess operator exposure according to the German model are summarised below:

Application method: Tractor-mounted boom sprayer
Treated area: 20 ha/day
Max. dose rate: 0.1 kg/ha Attribut SG70 (0.07 kg/ha propoxycarbazone-sodium)
Dermal absorption: 25% for the concentrate; 75% for the in-use dilution
Operator body weight: 70 kg
No PPE: Operator wearing T-shirt and shorts

* The German model does not contain data for SG formulation but since both formulations WG and SG are solid granule formulations, the expected exposure during mixing/loading activities is considered the same. Therefore, WG formulation data can be used for the risk assessment of SG formulation.

The results are summarized in Table CP 7.2-2 in Section CP 7.2.1 above.
Detailed calculations are presented in Table CP 7.2-3 and Table CP 7.2-4.
**Table CP 7.2-3: Calculation of operator exposure to propoxycarbazone-sodium using Attribut SG70; application with tractor-mounted boom sprayer (UK POEM, without PPE) on 50 ha of cereals**

<table>
<thead>
<tr>
<th>THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Application method</th>
<th>Tractor-mounted/trailed boom sprayer: hydraulic nozzles</th>
</tr>
</thead>
<tbody>
<tr>
<td>Product</td>
<td>Attribut SG 70</td>
</tr>
<tr>
<td>Formulation type</td>
<td>WG or SG a.s. concentration 700 mg/g</td>
</tr>
<tr>
<td>Dermal absorption from product</td>
<td>25%</td>
</tr>
<tr>
<td>PPE during mix/loading</td>
<td>None</td>
</tr>
<tr>
<td>Dose</td>
<td>0.1 kg product/ha</td>
</tr>
<tr>
<td>Application volume</td>
<td>150 l/ha</td>
</tr>
<tr>
<td>Work rate/day</td>
<td>Duration of spraying</td>
</tr>
</tbody>
</table>

**DERMAL EXPOSURE DURING MIXING AND LOADING**

- Hand contamination/kg a.s.: 5.72 mg/kg a.s.
- Hand contamination/day: 20.02 mg/day
- Protective clothing: None
- Transmission to skin: 100%
- Dermal exposure to a.s.: 20.02 mg/day

**INHALATION EXPOSURE DURING MIXING AND LOADING**

- Inhalation exposure/kg a.s.: 0.0358 mg/kg a.s.
- Inhalation exposure/day: 0.1253 mg/day
- RPE: None
- Transmission through RPE: 100%
- Inhalation exposure to a.s.: 0.1253 mg/day

**DERMAL EXPOSURE DURING SPRAY APPLICATION**

- Application technique: Tractor-mounted/trailed boom sprayer: hydraulic nozzles
- Application volume: 150 l/ha
- Volume of surface contamination: 10 m²
- Distribution: Hand 63%, Face 19%, Leg 25%
- Percutaneous penetration: 100%
- Dermal exposure: 19.39 mg/day
- Duration of exposure: 6 h
- Concentration of a.s. in spray solution: 0.466666667 mg/ml
- Concentration of a.s. in spray: 0.466666667 mg/ml
- Inhalation exposure to a.s.: 19.39 mg/day
- Duration of exposure: 6 h
- Concentration of a.s. in spray: 0.466666667 mg/ml
- Inhalation exposure to a.s.: 0.028 mg/day
- Percent absorbed: 100%
- Absorbed dose: 0.028 mg/day

**ABSORBED DOSE**

- Dermal exposure to a.s.: 19.39 mg/day
- Absorbed dose (dermal route): 14.5425 mg/day
- Inhalation exposure to a.s.: 0.028 mg/day
- Absorbed dose: 0.028 mg/day
- Predicted exposure: 14.5705 mg/day

**PREDICTED EXPOSURE**

- Total absorbed dose: 19.7008 mg/day
- Operator body weight: 60 kg
- Operator exposure: 0.326 mg/kg bw/day
- AOEL: 0.3 mg/kg bw/day
- % of AOEL: 109.3%
Table CP 7.2-4: Calculation of operator exposure to propoxycarbazone-sodium using Attribut SG70; application with tractor-mounted boom sprayer (German model, without PPE) on 20 ha of cereals*

THE GERMAN MODEL (GEOMETRIC MEAN VALUES)

<table>
<thead>
<tr>
<th>Application method</th>
<th>Product</th>
<th>Formulation type</th>
<th>Active substance</th>
<th>a.s. concentration</th>
<th>Dermal absorption from product</th>
<th>RPE during mixing/loading</th>
<th>PPE during mixing/loading</th>
<th>PPE during application:</th>
<th>Dose</th>
<th>mg product/ha</th>
<th>Work rate/day</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tractor-mounted/trailed boom sprayer: hydraulic nozzles</td>
<td>Attribut SG70</td>
<td>Active substance</td>
<td>propoxycarbazone-sodium</td>
<td>700 g/kg</td>
<td>75%</td>
<td>None</td>
<td>None</td>
<td>Head</td>
<td>2.1 kg product/ha</td>
<td>Work rate/day</td>
<td>20 hrs/day</td>
</tr>
</tbody>
</table>

DERMALEXPOSURE DURING MIXING AND LOADING

Hand contamination/kg a.s. | 2 mg/kg a.s. | 0.006 mg/kg a.s. | 0.0115 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.0001 mg/kg a.s. | 0.0001 mg/kg a.s. | 2.856 mg/day |

Hand contamination/day | 2.8 mg/day | 0.007 mg/day | 0.0119 mg/day | 0.001 mg/day | 0.001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 2.856 mg/day |

Protective clothing | none | none | none | none | none | none | none | none |

Transmission to skin | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

Total dermal exposure to a.s. | 2.856 mg/day | 0.007 mg/day | 0.0119 mg/day | 0.001 mg/day | 0.001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 2.856 mg/day |

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s. | 0.008 mg/kg a.s. | 0.015 mg/kg a.s. | 0.0001 mg/kg a.s. | 0.0001 mg/kg a.s. | 0.0001 mg/kg a.s. | 0.0001 mg/kg a.s. | 0.0001 mg/kg a.s. | 0.002 mg/day |

Inhalation exposure/day | 0.001 mg/day | 0.005 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.001 mg/day |

RPE | 2.25 mg/day | 0.015 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.001 mg/day |

Transmission through RPE | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

Inhalation exposure to a.s. | 0.002 mg/day | 0.001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.0001 mg/day | 0.001 mg/day |

DERMALEXPOSURE DURING SPRAY APPLICATION

Application technique | Tractor-mounted/trailed boom sprayer: hydraulic nozzles | Head | Hands | Body | Head | Hands | Body | 2.24 mg/day |

Dermal contamination/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. |

Dermal contamination/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day |

Protective clothing | none | none | none | none | none | none | none | none |

Transmission to skin | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

Total dermal exposure to a.s. | 0.084 mg/day | 0.532 mg/day | 2.24 mg/day | 0.084 mg/day | 0.532 mg/day | 2.24 mg/day | 0.084 mg/day | 0.532 mg/day | 2.24 mg/day |

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. | 0.001 mg/kg a.s. |

Inhalation exposure/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day |

RPE | none | none | none | none | none | none | none | none |

Transmission through RPE | 100% | 100% | 100% | 100% | 100% | 100% | 100% | 100% |

Inhalation exposure to a.s. | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day |

ABSORBED DOSE

Dermal exposure to a.s. | 2.8 mg/day | 2.8 mg/day | 2.24 mg/day | 2.8 mg/day | 2.8 mg/day | 2.24 mg/day | 2.8 mg/day | 2.24 mg/day |

Percent absorbed | 25% | 75% | 100% | 25% | 75% | 100% | 25% | 100% |

Absorbed dose (dermal route) | 0.7 mg/day | 2.142 mg/day | 2.142 mg/day | 0.7 mg/day | 2.142 mg/day | 2.142 mg/day | 0.7 mg/day | 2.142 mg/day |

Inhalation exposure to a.s. | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day | 0.001 mg/day |

Total systemic exposure | 0.7112 mg/day | 2.1434 mg/day | 2.1434 mg/day | 0.7112 mg/day | 2.1434 mg/day | 2.1434 mg/day | 0.7112 mg/day | 2.1434 mg/day |

PREDICTED EXPOSURE

Operator body weight | 70 kg | 70 kg | 70 kg | 70 kg | 70 kg | 70 kg | 70 kg | 70 kg |

Operator exposure | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day |

AOEL | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day | 0.3 mg/kg bw/day |

% of AOEL | 13.6 | 13.6 | 13.6 | 13.6 | 13.6 | 13.6 | 13.6 | 13.6 |

* The German model does not contain data for SG formulation but since both formulations WG and SG are solid granule formulations, the expected exposure during mixing/loading activities is considered the same. Therefore, WG formulation data can be used for the risk assessment of SG formulation.
**Table CP 7.2-5**: Calculation of operator exposure to propoxycarbazone-sodium using Attribut SG70; application with tractor-mounted boom sprayer (UK POEM, with PPE) on 50 ha of cereals

<table>
<thead>
<tr>
<th>Application method</th>
<th>Product</th>
<th>Attribut SG70</th>
<th>Active substance a.s. concentration</th>
<th>propoxycarbazone-sodium 700 mg/g</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Application method</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Product</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Formulation type</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dermal absorption from product</strong></td>
<td>70 %</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>PPE during mix/loading</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Dose</strong></td>
<td></td>
<td>0.1</td>
<td>kg product/ha</td>
<td></td>
</tr>
<tr>
<td><strong>Application volume</strong></td>
<td></td>
<td>150</td>
<td>ha</td>
<td></td>
</tr>
</tbody>
</table>

**DERMAL EXPOSURE DURING MIXING AND LOADING**

Hand contamination/kg a.s. 5.72 mg/kg a.s.
Hand contamination/day 20.02 mg/day

**Protective clothing**

Transmission to skin 1 %

Dermal exposure to a.s. 0.2002 mg/day

**INHALATION EXPOSURE DURING MIXING AND LOADING**

Inhalation exposure/kg a.s. 0.0079 mg/kg a.s.
Inhalation exposure/day 0.0358 mg/day

RPE None
Transmission through RPE 0.1253 mg/day
Inhalation exposure to a.s. 0.1253 mg/day

**DERMAL EXPOSURE DURING SPRAY APPLICATION**

Application technique Tractor-mounted/trailed boom sprayer: hydraulic nozzles
Application volume 150 l/ha

**Volume of surface contamination** 30 ml

Distribution

**Clothing**

Transmission to skin 0%

Dermal exposure 0.65 ml

Duration of exposure 0.075 ml/h

Total dermal exposure to spray 41.55 ml/day

Concentration of a.s. in spray solution 0.466666667 mg/ml

Dermal exposure to a.s. 19.39 mg/day

**INHALATION EXPOSURE DURING SPRAYING**

Inhalation exposure to spray 0.01 ml/h
Duration of exposure 6 h

Concentration of a.s. in spray 0.466666667 mg/ml

Inhalation exposure to a.s. 0.028 mg/day
Percent absorbed 100%
Absorbed dose 0.028 mg/day

**ABSORBED DOSE**

Absorbed dose Mix/load Application
Dermal exposure to a.s. 0.2002 mg/day 19.39 mg/day
Percent absorbed 75 %
Absorbed dose (dermal route) 0.05005 mg/day 14.5425 mg/day
Inhalation exposure to a.s. 0.1253 mg/day 0.028 mg/day
Absorbed dose 0.1253 mg/day 14.5705 mg/day

**PREDICTED EXPOSURE**

Total absorbed dose 14.74585 mg/day
Operator body weight 60 kg
Operator exposure 0.246 mg/kg bw/day

AOEL 0.3 mg/kg bw/day % of AOEL 82
CP 7.2.1.2 Measurement of operator exposure
Since the risk assessment carried out indicated that the acceptable operator exposure level (AOEL) for propoxycarbazone-sodium will not be exceeded under practical conditions of use, a study to provide a measure of operator exposure under field conditions is not deemed necessary.

CP 7.2.2 Bystander and resident exposure
Estimation of bystander and resident exposure has been undertaken for Attribut SG 70 using the critical uses (see Table CP 7.2-1) and according to the German guidance (Martin et al. 2008)1.

A summary of the estimated bystander/resident exposure to propoxycarbazone-sodium is presented in Table CP 7.2-6.

Table CP 7.2-6: Estimated bystander and resident exposure to propoxycarbazone-sodium

<table>
<thead>
<tr>
<th></th>
<th>Bystander (AOEL = 0.3 mg/kg bw/day)</th>
<th>Resident</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Adult</td>
<td>Child</td>
</tr>
<tr>
<td>Dermal exposure (mg/kg bw/day)</td>
<td>0.0000185</td>
<td>0.0000002</td>
</tr>
<tr>
<td>Inhalation exposure (mg/kg bw/day)</td>
<td>0.0000000</td>
<td>0.0000002</td>
</tr>
<tr>
<td>Total systemic exposure (mg/kg bw/day)</td>
<td>0.0000185</td>
<td>0.00000253</td>
</tr>
<tr>
<td>% of AOEL</td>
<td>0.01%</td>
<td>0.01%</td>
</tr>
</tbody>
</table>

CONCLUSION
It is concluded that there is no undue risk to any bystander and resident after accidental short-term exposure to Attribut SG 70.

CP 7.2.2.1 Estimation of bystander and resident exposure

The following definitions and assumptions for bystanders and residents may be applied.

Bystanders may inadvertently be present within or directly adjacent to an area for a short period of time, typically a matter of minutes, where application of a plant protection product is in progress or has recently taken place. They may be exposed to plant protection products mainly via the dermal route from spray drift and by inhalation of drifting spray droplets.

Residents may possibly live or work near areas of the application of plant protection products (e.g. standing, working or sitting in a garden in the vicinity of the application). They may be exposed to plant protection products mainly via the dermal route from spray drift deposits and by inhalation of vapour drift (depending on the vapour pressure of the active substance). For infants and toddlers exposure might also occur orally (e.g. through hand-to-mouth transfer and/or object-to-mouth transfer, the so-called mouthing and/or pica behaviour).

Bystander/resident exposure may occur following foliar spray application. Exposure is calculated for adult and child bystanders as well as adult and child residents.

**Bystander exposure**

Bystander exposure is calculated using the German guidelines (Martin *et al.* 2008). Application with tractor-mounted boom sprayer is presented as a worst case scenario.

Assumptions to assess bystander exposure according to the German guidance are summarised below:

- **Application method:** Tractor-mounted boom sprayer
- **Max. dose rate:** 0.1 kg/ha Attribut SG70 (0.07 kg/ha propoxycarbazone-sodium)
- **Drift:** 0.29% at 10 m (90th percentile; 1 application)
- **Exposure duration:** 5 minutes
- **Exposed body surface area:**
  - Adult: 1 m²
  - Child: 0.21 m²
- **Dermal absorption:** 75% for the in-use dilution
- **Inhalation absorption:** 100%
- **Specific inhalation exposure:**
  - Adult: 0.001 mg/kg a.s. (6 hours)
  - Child: 0.00057 mg/kg a.s. (6 hours)
- **Body weight:**
  - Adult: 60 kg
  - Child: 16.15 kg

The results are summarized in Table CP 7.2-6 in Section CP 7.2.2 above. Detailed calculations are provided in Table CP 7.2-7.
### Table CP 7.2-7: Estimated bystander exposure to propoxycarbazone-sodium

Input parameters considered for the estimation of bystander exposure:

<table>
<thead>
<tr>
<th>Intended use(s):</th>
<th>cereals</th>
<th>Drift (D): 0.29 % (FCTM, 10 m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application rate (AR):</td>
<td>0.07 kg a.s./ha</td>
<td>Exposed Body Surface Area (BSA): 1 m² (adults)</td>
</tr>
<tr>
<td>Body weight (BW):</td>
<td>60 kg/person (adults)</td>
<td>Specific Inhalation Exposure (I*A): 0.00057 mg/kg a.s. (6 hours, adults)</td>
</tr>
<tr>
<td>Dermal absorption (DA):</td>
<td>75.00 % ('worst case')</td>
<td>Expiration duration (T): 5 min</td>
</tr>
<tr>
<td>Inhalation absorption (IA):</td>
<td>100 %</td>
<td>AOEL: 0.3 mg/kg bw/d</td>
</tr>
</tbody>
</table>

#### Bystander exposure towards propoxycarbazone-sodium

- **Adults**
  - Bystander: Dermal exposure after application in cereals (via spray drift)
    - \( SDE_a = \frac{(AR \times D \times BSA \times DA)}{BW} \)
    - \( = \frac{(7 \times 0.07 \times 1 \times 75\%)}{60} \)
    - \( = \frac{1944E-05}{60} \) mg/person
  - **Children**
    - Bystander: Dermal exposure after application in cereals (via spray drift)
      - \( SDE_a = \frac{(AR \times D \times BSA \times DA)}{BW} \)
      - \( = \frac{(7 \times 0.07 \times 0.21 \times 75\%)}{16.15} \)
      - \( = \frac{11175E-05}{16.15} \) mg/person

#### Absorbed dose:

- **Adults**
  - \( = 0.0002538 \) mg/kg bw/d
  - **Children**
    - \( = 0.0001980 \) mg/kg bw/d

#### Total systemic exposure: \( SEB = SDE_a + SIE_a \)

- **Adults**
  - \( SEB = 1.9444E-05 \) mg/kg bw/d
  - **Children**
    - \( SEB = 1.1175E-05 \) mg/kg bw/d

- **% of AOEL:**
  - **Adults:** \( = 0.08\% \)
  - **Children:** \( = 0.07\% \)
Resident exposure
Resident exposure is calculated using the German guidance (Martin et al. 2008). Application with tractor-mounted boom sprayer is presented as a worst case scenario.

Assumptions to assess bystander exposure according to the German guidance are summarised below:

Application method: Tractor-mounted boom sprayer
Max. dose rate: 0.1 kg/ha Attribut SG70 (0.07 kg/ha propoxycarbazone-sodium)
Drift: 0.29% at 10 m (90th percentile; 1 application)
Exposure duration: 2 hours
Vapour pressure: < 1 x 10^-8 Pa at 20°C (extrapolated)*
Dermal absorption: 75% for the in-use dilution
Oral absorption: 25%
Body weight:
- Adult: 60 kg
- Child: 16.15 kg

* Inhalation exposure has only to be considered for semi-volatile (vapor pressures VP of 1 x 10^-5 - 5 x 10^-3 Pa) and volatile (VP > 5 x 10^-3 Pa) active substances (Martin et al.). The active substance propoxycarbazone-sodium contained in Attribut SG 70 is considered non-volatile according to the above given definition. Thus, inhalation exposure for residential exposure assessment is not relevant.

The results are summarized in Table CP 7.2-6 in Section CP 7.2.2 above. Detailed calculations are provided in Table CP 7.2-8.
Table 7.2-8: Estimated resident exposure to propoxycarbazone-sodium

<table>
<thead>
<tr>
<th>Intended use(s):</th>
<th>cereals</th>
<th>Drift (D): 0.29% (FCTM, 10 m)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application rate (AR):</td>
<td>0.07 kg a.s./ha</td>
<td>Transfer coefficient (TC): 7300 cm²/h (adults)</td>
</tr>
<tr>
<td>Number of applications (NA):</td>
<td>1</td>
<td>Turf Transferable Residues (TTR): 5%</td>
</tr>
<tr>
<td>Body weight (BW):</td>
<td>60 kg/person (adults)</td>
<td>Exposure Duration (H): 2 h</td>
</tr>
<tr>
<td>Dermal absorption (DA):</td>
<td>75.00% (% worst case)</td>
<td>Inhalation Rate (IR): 15.26 m³/d (adults), 31.31 m³/d (children)</td>
</tr>
<tr>
<td>Inhalation absorption (IA):</td>
<td>100%</td>
<td>Daytime Exposure: none</td>
</tr>
<tr>
<td>Oral absorption (OA):</td>
<td>25%</td>
<td>Saliva Extraction Factor (SE): 50%</td>
</tr>
<tr>
<td>AOEL:</td>
<td>0.3 mg/kg bw/d</td>
<td>Surface Area of Hands (SA): 0.20 cm²</td>
</tr>
<tr>
<td>Frequency of Hand to Mouth (Freq):</td>
<td>20 events/h</td>
<td>Frequency of Mouth to Hands (Freq): 20 events/h</td>
</tr>
<tr>
<td>Dislodgable foliar residues (DFR):</td>
<td>20%</td>
<td>Absorption of DFR: none</td>
</tr>
<tr>
<td>Ingestion Rate for Mouthing of Grass/Day (IR):</td>
<td>25 cm²/d</td>
<td>Absorption of IR: none</td>
</tr>
<tr>
<td>Internal exposure: External exposure:</td>
<td>0.0000406 m g/person</td>
<td>Aryeh's system exposure: 0.00001015 m g/person</td>
</tr>
<tr>
<td>Total systemic exposure: Absorbed dose:</td>
<td>0.0000006 mg/kg bw/d</td>
<td>Aryeh's system exposure: 0.0000245 mg/kg bw/d</td>
</tr>
<tr>
<td>Total systemic exposure (absorbed dose):</td>
<td>0.0001185 mg/kg bw/d</td>
<td>Absorbed dose:</td>
</tr>
<tr>
<td>Total systemic exposure (absorbed dose):</td>
<td>0.00040854 mg/kg bw/d</td>
<td>Absorbed dose:</td>
</tr>
<tr>
<td>% of AOEL:</td>
<td>0.01%</td>
<td>% of AOEL:</td>
</tr>
</tbody>
</table>

\[ SDE_{\text{R}} = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW \]
\[ SIER = (ACV \times IR \times IA) / BW \]
\[ SDER = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW \]
\[ SOEH = (AR \times NA \times D \times SE \times SA \times Freq \times H \times OA) / BW \]
\[ SOEO = (AR \times NA \times D \times DFR \times IgR \times OA) / BW \]

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CP 7.2.2.2 Measurement of bystander and resident exposure
As the estimation of bystander and resident exposure has not given any concern for unacceptable exposure measurements of bystander and resident exposure are not deemed necessary.

CP 7.2.3 Worker exposure
Estimation of worker exposure has been undertaken for Attribut SG70 using the critical uses (Table CP 7.2-1) and according to the EUROPOEM II approach.

Crops treated with Attribut SG70 potentially have to be re-entered by workers shortly after the application. Regarding the intended crops, the work activities include re-entry activity as inspection/scouting of the crop.

Exposure assessment of a worker during inspection/scouting activities of cereals treated with the highest recommended one-time application rate of 0.1 kg product/ha (i.e., 0.07 kg propoxycarbazine sodium/ha) is presented.

Corresponding results of the exposure calculations are presented in Table CP 7.2-9.

Table CP 7.2-9: Estimated worker exposure to propoxycarbazine-sodium (no PPE)

<table>
<thead>
<tr>
<th>Scenario</th>
<th>AOEL [mg/kg bw/day]</th>
<th>Exposure parameter</th>
<th>Absorbed dose [mg/kg bw/day]</th>
<th>% of AOEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspection/scouting</td>
<td>0.3</td>
<td></td>
<td>0.013125</td>
<td>4.4%</td>
</tr>
</tbody>
</table>

1 Unprotected worker wearing shoes, socks, long-sleeved shirt, and long trousers

CONCLUSION
It is concluded that there is no unacceptable risk anticipated for the worker wearing adequate work clothing (but no PPE), when re-entering crops treated with Attribut SG70.

CP 7.2.3.1 Estimation of worker exposure
Exposure of workers when performing re-entry activities is calculated considering the approach proposed by EUROPOEM II.

The following formula is used to calculate worker exposure:

\[
D = DFR \times TC \times WR \times AR \times P
\]

D = Dermal exposure
DFR = Dislodgeable foliar residues (µg as/cm²)
TC = Transfer Coefficient (cm²/person/hr)
WR = Work rate (hours/day)
AR = Application rate (kg as/ha)
P = Protection factor for PPE

Consideration on DFR
According to EUROPOEM II the default Dislodgeable Foliar Residues (DFR) value of 3 µg/cm² per kg a.s./ha will be used in this assessment.
Consideration on Transfer Coefficient (TC)
It has to be noted that no specific TC for re-entry activities performed in cereals is available from EUROPOEM II. Therefore, as surrogate value it is proposed with this evaluation to use the TC of 2500 cm²/h established for harvesting vegetables (reach and pick scenario).

Consideration on personal protective equipment (PPE)
Exposure calculations will consider the unprotected worker.

Further assumptions:
- Worker body weight: 60 kg
- Max. dose rate: 0.1 kg/ha Attribut SG70 (0.07 kg/ha propoxycarbazone-sodium)
- Dermal absorption: 75% for the in-use dilution
- Work duration: 2 hours/day
- No. of applications per season: 1

The results are summarized in Table CP 7.2-9 in Section CP 7.2.3 above. Detailed calculations are provided in Table CP 7.2-10.

**Table CP 7.2-10: Estimated worker exposure to propoxycarbazone-sodium**

**Estimation of worker (re-entry) exposure**

| Intended use(s): | cereals | Dislodgeable foliar residues (DFR): | 3 µg/cm²/kg a.s. | Application rate (AR): | 0.07 kg a.s./ha | Transfer coefficient (TC): | 2500 cm²/person/h | Number of applications (NA): | 1 | Work rate per day (WR): | 2 h/d | Body weight (BW): | 60 kg/person | Dermal absorption (DA): | 75% ('worst case') | AOEL | 0.3 mg/kg bw/d |
|----------------|---------|-------------------------------------|------------------|-----------------------|----------------|----------------------------|------------------|---------------------------|---|------------------|--------|----------------|-----------------|------------------|----------------|---------|

**Worker exposure towards propoxycarbazone-sodium**

<table>
<thead>
<tr>
<th>Without PPE</th>
<th>Worker (re-entry): Systemic dermal exposure after application in cereals</th>
</tr>
</thead>
<tbody>
<tr>
<td>SDEW = (DFR x TC x WR x AR x NA x DA) / BW</td>
<td></td>
</tr>
<tr>
<td>(3 x 2500 x 2 x 0.07 x 1 x 75%) / 60</td>
<td></td>
</tr>
<tr>
<td>External dermal exposure</td>
<td>1.04 mg/person</td>
</tr>
<tr>
<td>External dermal exposure</td>
<td>0.92 mg/kg bw/d</td>
</tr>
<tr>
<td>Total systemic exposure</td>
<td>0.79 mg/person</td>
</tr>
<tr>
<td>Total systemic exposure</td>
<td>0.013125 mg/kg bw/d</td>
</tr>
<tr>
<td>% of AOEL</td>
<td>4.4%</td>
</tr>
</tbody>
</table>

**CP 7.2.3.2 Measurement of worker exposure**
Since the exposure estimate carried out indicated that the AOEL will not be exceeded under practical conditions of use if no PPE is worn, a study to provide a measure of worker exposure is not deemed necessary.
CP 7.3  Dermal absorption

No in vitro or in vivo dermal absorption study has been conducted with Attribut SG70. Therefore, according to EFSA Guidance on Dermal Absorption\(^2\) the default values of dermal absorption are considered applicable for the risk assessment of Attribut SG70.

According to the guidance, a default dermal absorption value of 25% is applied for the concentrate, containing active substance > 5% (700 g/kg of propoxycarbazone-sodium in Attribut SG70), and 75% is applied for the in-use dilution containing active substance < 5%.

The percentage absorptions used in the operator exposure assessment are in Table CP 7.3-1.

<table>
<thead>
<tr>
<th>End-Point</th>
<th>Active substance: propoxycarbazone-sodium</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal penetration</td>
<td>Concentrate: 25% (default value)</td>
</tr>
<tr>
<td></td>
<td>Spray dilutions: 75% (default value)</td>
</tr>
</tbody>
</table>

CP 7.4  Available toxicological data relating to co-formulants

CONFIDENTIAL information - data provided separately (Document J)

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