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

Date	Data points containing amendments or additions [1]	Document identifier or version number

[1]Note how the amendments or additions are represented (italics/colour etc)

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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. Anyhow 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 MKH 6561 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 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.

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 MKH 6561 70 WG to support Attribut SG70.

Table CP 7.1-1: Acute toxicological data obtained with MKH 6561 70 WG

Parameter [Reference]	Species	Result mg/kg or mg/m³ or effect	Classification	Comment
Acute oral toxicity [CP 7.1.1/01, [redacted] 1998]	Rat	LD_{50} > 2000 mg/kg 2500 mg/kg (LD_{50} cut-off value according to the interpretation of OECD 423)	EU classification: none CLP classification: none	For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)
Acute dermal toxicity [CP 7.1.2/01, [redacted] 1998]	Rat	>2000 mg/kg	EU classification: none CLP classification: none	For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)
Acute inhalation toxicity; 4-hour, nose-only [CP 7.1.3/01, [redacted], J., 1998]	Rat	>4995 mg/m³ (maximum technically attainable concentration)	EU classification: none CLP classification: none	For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)
Skin irritation [CP 7.1.4/01, [redacted], J., 1998]	Rabbit	Not irritating	EU classification: none CLP classification: none	For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)
Eye irritation [CP 7.1.5/01, [redacted], J., 1998]	Rabbit	Not irritating	EU classification: none CLP classification: none	For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)
Skin sensitisation; Buehler test [CP 7.1.6/01, [redacted], G., 1999]	Guinea pig	Not sensitising	EU classification: none CLP classification: none	For details refer to Dossier P-010244-01 (SANCO dossier of former representative formulation ATTRIBUT 70WG)
Skin sensitisation; Maximization test [CP 7.1.6/02, [redacted]., 2003]	**Guinea pig**	**Not sensitising**	**EU classification: none** **CLP classification: none**	**For details refer to CP 7.1.6/02**

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).

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 sensitiser 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; [redacted], 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
Guidelines:	**OECD - Guideline for Testing of Chemicals No.423 - "Acute Oral Toxicity - Acute Toxic Class Method"; adopted: 22th March 1996; Annex VB, Part B.l tris (Acute toxicity [oral] - Acute Toxic Class Method); Directive 67/548/EEC amended by Directive 96/54/EC**
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 LD_{50} 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 LD_{50} cut-off value was considered to be 2500 mg/kg body weight.

The study result triggers the following classification/labelling:
- EU Directive 2001/59/EC: none
- 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; [redacted], 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
Guidelines:	**OECD-Guideline for Testing of Chemicals; Section 4: Health Effects No. 402, "Acute Dermal Toxicity", adopted: 24February, 1987 (Third Addendum to the 1981 OECD Guidelines for Testing of Chemicals, OECD Publication Service, Paris 1987), the Pesticide Assessment Guidelines, Subdivision F, Hazard Evaluation: Humans and Domestic Animals, Series 81-2 Acute Dermal Toxicity Study (Revised Edition, November, 1984**
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 LD_{50} value of MKH 6561 WG 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:
- EU Directive 2001/59/EC: none
- 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.

Report:	KCP 7.1.3 /01; [redacted] J.;1998;M-005538-02
Title:	MKH 6561 70 WG 05780/0031 (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**

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 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:
- EU Directive 2001/59/EC: none
- 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.

Report:	KCP 7.1.4 /01; [redacted], J.;1998;M-005540-02; Amended: 1999-01-19
Title:	Acute skin irritation test (patch test) of MKH 6561 70 WG 05780/0031 in rabbits
Report No:	R7171A
Document No:	M-005540-02-1
Guidelines:	**OECD No. 404; EC L 383 A: Acute toxicity (skin irritation) B.4.**
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).

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

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

Report:	KCP 7.1.5 /01; [redacted], J.;1998;M-005541-02; Amended: 1999-01-19
Title:	Acute eye irritation study of MKH 6561 70 WG 05780/0031 by instillation into the conjunctival sac of rabbits
Report No:	R7172A
Document No:	M-005541-02-1
Guidelines:	**OECD No. 405; EC L 383 A: Acute toxicity (eye irritation) B.5**
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).

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:
- EU Directive 2001/59/EC: none
- 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.

Report:	KCP 7.1.6 /01; [redacted], G.;1999;M-010860-01
Title:	MKH 6561 70 WG 05780/0031 - Study for the skin sensitization effect in guinea pigs (Buehler Patch Test)
Report No:	28701
Document No:	M-010860-01-1
Guidelines:	n.a.
Deviations:	n.a.
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).

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 propoxycarbazone-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 (22nd 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.

Report:	[redacted]u; [redacted];2003;M-105950-01
Title:	MKH 6561 70 WG - Study for the skin sensitization effect in guinea pigs (guinea pig maximization test according to Magnusson and Kligman)
Report No:	AT00451
Document No:	M-105950-01-1
Guidelines:	**OECD 406;EC B.6 (1996);OPPTS 870.2600**
Deviations:	None
GLP/GEP:	**yes**

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 a 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.
- Regulation (EC) No 1272/2008 (CLP): 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 Crl:HA
Source:	[redacted], 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 ([redacted]), *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 ([redacted], 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 Crl: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.
Three 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

	Test item group (20 animals)					Control group (10 animals)				
	Test item patch			Control patch		Test item patch			Control patch	
Hours	**48**	**72**	**Total**	**48**	**72**	**48**	**72**	**Total**	**48**	**72**
1st challenge 6%	6	4	6	0	0	0	0	0	0	0
2nd challenge 6%	3	1	3	0	0	0	0	0	0	0

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:
- EU Directive 2001/59/EC: none
- 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 is 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

Crop	F/G	Max. kg a.s./ha	kg product/ ha	Water volume L/ha	Method of application	Max. no of appl.	Interval
Cereals	F	0.07	0.1	150	Tractor-mounted boom sprayer	1	-

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").

- Revised UK-POEM Model, as available on:
  http://www.pesticides.gov.uk/Resources/CRD/Migrated-Resources/Documents/U/UK_POEM_07.xls
  [Estimation of Exposure and Absorption of Pesticides by Spray Operators, Scientific subcommittee on Pesticides and British Agrochemical association Joint Medical Panel Report (UK MAFF), 1986 and the Predictive Operator Exposure Model (POEM) V 1.0, (UK MAFF), 1992. ("UK model")].

The estimations were compared to following data:

End-Point	Active substance: propoxycarbazone-sodium
AOEL	0.3 mg/kg bw/day
Dermal penetration	Concentrate: 25% (default value) Spray dilutions: 75% (default value)

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

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

Model data	Level of PPE	Total absorbed dose (mg/kg bw/day)	% of AOEL
Tractor-mounted boom sprayer application outdoors to low crops Application rate: 0.1 kg/ha product (0.070 kg propoxycarbazone-sodium/ha)			
UK POEM • 50 ha/day, 6 h/day • 150 L/ha • 60 kg operator	no PPE	0.328	109.3
	Gloves during mixing/loading	0.246	82.0
German Model • 20 ha/day • 70 kg operator	no PPE	0.0408	13.6

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 SG70 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 SG70 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 7.2-3Table 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

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Attribut SG 70**		Active substance	**propoxycarbazone-sodium**	
Formulation type	WG or SG		a.s. concentration	**700**	mg/g
Dermal absorption from product	**25**	%	Dermal absorption from spray	**75**	%
PPE during mix/loading	None		PPE during application	None	
Dose	**0.1**	kg product/ha	Work rate/day	**50**	ha
Application volume	**150**	l/ha	Duration of spraying	**6**	h

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	spray/ha				
Volume of surface contamination	10	ml/h				
Distribution	Hands		Trunk		Legs	
	65%		10%		25%	
Clothing	None		Permeable		Permeable	
Penetration	100%		5%		25%	
Dermal exposure	6.5		0.05		0.375	ml/h
Duration of exposure	6	h				
Total dermal exposure to spray	41.55	ml/day				
Concentration of a.s. in spray soluti	0.466666667	mg/ml				
Dermal exposure to a.s.	19.39	mg/day				

INHALATION EXPOSURE DURING SPRAYING

Inhalation exposure to spray	0.01	m3/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

	Mix/load		Application	
Dermal exposure to a.s.	20.02	mg/day	19.39	mg/day
Percent absorbed	25	%	75	%
Absorbed dose (dermal route)	5.005	mg/day	14.5425	mg/day
Inhalation exposure to a.s.	0.1253	mg/day	0.028	mg/day
Absorbed dose	5.1303	mg/day	14.5705	mg/day

PREDICTED EXPOSURE

Total absorbed dose	19.7008	mg/day
Operator body weight	60	kg
Operator exposure	0.328	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)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles				
Product	**Attribut SG 70**		Active substance		**propoxycarbazone-sodium**
Formulation type	WG		a.s. concentration		**700** g/kg
Dermal absorption from product	**25** %		Dermal absorption from spray		**75** %
RPE during mix/loading	None		RPE during application		None
PPE during mix/loading	None				
PPE during application: Head	None	Hands	None	Body	None
Dose	**0.1** kg product/ha		Work rate/day		**20** ha

DERMAL EXPOSURE DURING MIXING AND LOADING		
Hand contamination/kg a.s.	2	mg/kg a.s.
Hand contamination/day	2.8	mg/day
Protective clothing	none	
Transmission to skin	100	%
Dermal exposure to a.s.	2.8	mg/day
INHALATION EXPOSURE DURING MIXING AND LOADING		
Inhalation exposure/kg a.s.	0.008	mg/kg a.s.
Inhalation exposure/day	0.0112	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0112	mg/day

DERMAL EXPOSURE DURING SPRAY APPLICATION

Application technique: Tractor-mounted/trailed boom sprayer/hydraulic nozzles

	Head	Hands	Rest of body	
Dermal contamination/kg a.s.	0.06	0.38	1.6	
Dermal contamination/day	0.084	0.532	2.24	
Protective clothing	none	none	none	
Transmission to skin	100	100	100	%
Total dermal exposure to a.s.	2.856	mg/day		

INHALATION EXPOSURE DURING SPRAYING		
Inhalation exposure/kg a.s.	0.001	mg/kg a.s.
Inhalation exposure/day	0.0014	mg/day
RPE	none	
Transmission through RPE	100	%
Inhalation exposure to a.s.	0.0014	mg/day

ABSORBED DOSE

	Mix/load		Application		
Dermal exposure to a.s.	2.8	mg/day	2.856	mg/day	
Percent absorbed	25	%	75	%	
Absorbed dose (dermal route)	0.7	mg/day	2.142	mg/day	
Inhalation exposure to a.s.	0.0112	mg/day	0.0014	mg/day	
Total systemic exposure	0.7112	mg/day	2.1434	mg/day	

PREDICTED EXPOSURE		
Total systemic exposure	2.8546	mg/day
Operator body weight	70	kg
Operator exposure	0.0408	mg/kg bw/day
AOEL	0.3	mg/kg bw/day
% of AOEL	**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

THE UK PREDICTIVE OPERATOR EXPOSURE MODEL (POEM) WITH GERMAN MODEL MIX/LOAD DATA (75th PERCENTILE)

Application method	Tractor-mounted/trailed boom sprayer: hydraulic nozzles			
Product	**Attribut SG 70**	Active substance	**propoxycarbazone-sodium**	
Formulation type	WG or SG	a.s. concentration	**700**	mg/g
Dermal absorption from product	**25** %	Dermal absorption from spray	**75**	%
PPE during mix/loading	Gloves	PPE during application	None	
Dose	**0.1** kg product/ha	Work rate/day	**50**	ha
Application volume	**150** l/ha	Duration of spraying	**6**	h

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	Gloves	
Transmission to skin	1	%
Dermal exposure to a.s.	0.2002	mg/day

INHALATION EXPOSURE DURING MIXING AND LOADING

Inhalation exposure/kg a.s.	0.0358	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	spray/ha		
Volume of surface contamination	10	ml/l		
Distribution	Hands	Trunk	Legs	
	65%	10%	25%	
Clothing	None	Permeable	Permeable	
Penetration	100%	5%	15%	
Dermal exposure	6.5	0.05	0.375	ml/h
Duration of exposure	6	h		
Total dermal exposure to spray	41.55	ml/day		
Concentration of a.s. in spray soln	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

	Mix/load		Application		
Dermal exposure to a.s.	0.2002	mg/day	19.39	mg/day	
Percent absorbed	25	%	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	0.17535	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 SG70 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

	Propoxycarbazone-sodium (AOEL = 0.3 mg/kg bw/day)	
	Bystander	
	Adult	Child
Dermal exposure (mg/kg bw/day)	0.0002538	0.0001980
Inhalation exposure (mg/kg bw/day)	0.0000003	0.0000007
Total systemic exposure (mg/kg bw/day)	**0.0002541**	**0.0001987**
% of AOEL	**0.08%**	**0.07%**
	Resident	
	Adult	Child
Dermal exposure (mg/kg bw/day)	0.0000185	0.0000245
Inhalation exposure (mg/kg bw/day)	-	-
Oral exposure (hand-to-mouth transfer)	-	0.0000006
Oral exposure (object-to-mouth transfer)	-	0.0000002
Total systemic exposure (mg/kg bw/day)	**0.0000185**	**0.0000253**
% of AOEL	**0.01%**	**0.01%**

CONCLUSION

It is concluded that there is no undue risk to any bystander and resident after accidental short-term exposure to Attribut SG70.

[1] Martin S. *et al*. Guidance for exposure and risk evaluation for bystanders and residents exposed to plant protection products during and after application, J. Verbr. Lebensm., Vol 3, No. 3, p. 272-281, August 2008.

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 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: 5 minutes
Exposed body surface are:
- Adult: 1 m^2
- Child: 0.21 m^2

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:

Intended use(s):	cereals		**Drift (D):**	0.29	% (FCTM, 10 m)
Application rate (AR):	0.07	kg a.s./ha	**Exposed Body Surface Area (BSA):**	1	m² (adults)
				0.21	m² (children)
Body weight (BW):	60	kg/person (adults)	**Specific Inhalation Exposure (I^*_A):**	0.001	mg/kg a.s. (6 hours, adults)
	16.15	kg/person (children)		0.00057	mg/kg a.s. (6 hours, children)
Dermal absorption (DA):	75.00	% ('worst case')	**Area Treated (A):**	20	ha/d (based on Field Crops, Tractor Mounted (FCTM))
Inhalation absorption (IA):	100	%	**Exposure duration (T):**	5	min
AOEL:	0.3	mg/kg bw/d			

Bystander exposure towards propoxycarbazone-sodium					
Adults			**Children**		
Bystander: Dermal exposure after application in cereals (via spray drift)					
SDE_B = (AR x D x BSA x DA) / BW			SDE_B = (AR x D x BSA x DA) / BW		
(7 x 0.29% x 1 x 75%) / 60			(7 x 0.29% x 0.21 x 75%) / 16.15		
External exposure	0.0203	mg/person	External exposure	0.004263	mg/person
External exposure	0.00033833	mg/kg bw/d	External exposure	0.00026396	mg/kg bw/d
Absorbed dose:	**0.0002538**	**mg/kg bw/d**	**Absorbed dose:**	**0.0001980**	**mg/kg bw/d**
Bystander: Inhalation exposure after application in cereals					
SIE_B = (I^*_A x AR x A x T x IA) / BW			SIE_B = (I^*_A x AR x A x T x IA) / BW		
(0.001 / 360 x 0.07 x 20 x 5 x 100%) / 60			(0,00057 / 360 x 0.07 x 20 x 5 x 100%) / 16.15		
External exposure	1.9444E-05	mg/person	External exposure	1.1175E-05	mg/person
External exposure	3.2407E-07	mg/kg bw/d	External exposure	6.9195E-07	mg/kg bw/d
Absorbed dose:	**0.0000003**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000007**	**mg/kg bw/d**
Total systemic exposure: $SE_B = SDE_B + SIE_B$			Total systemic exposure: $SE_B = SDE_B + SIE_B$		
Total systemic exposure (absorbed dose)	0.01524444	mg/person	Total systemic exposure (absorbed dose)	0.00320842	mg/person
Total systemic exposure (absorbed dose)	**0.0002541**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0001987**	**mg/kg bw/d**
% of AOEL:	**0.08**	**%**	**% of AOEL:**	**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 SG70 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 CP 7.2-8: Estimated resident exposure to propoxycarbazone-sodium

Input parameters considered for the estimation of resident exposure:

Intended use(s):	cereals		**Drift (D):**	0.29	% (FCTM, 10 m)
Application rate (AR):	0.07	kg a.s./ha	**Transfer coefficient (TC):**	7300	cm^2/h (adults)
				2600	cm^2/h (children)
Number of applications (NA):	1		**Turf Transferable Residues (TTR):**	5	%
Body weight (BW):	60	kg/person (adults)	**Exposure Duration (H):**	2	h
	16.15	kg/person (children)	**Airborne Concentration of Vapour (ACV):**	none	
Dermal absorption (DA):	75.00	% ('worst case')	**Inhalation Rate (IR):**	16.57	m^3/d (adults),
Inhalation absorption (IA):	100	%		8.31	m^3/d (children)
Oral absorption (OA)	25	%	**Saliva Extraction Factor (SE):**	50%	
AOEL	0.3	mg/kg bw/d	**Surface Area of Hands (SA):**	20	cm
			Frequency of Hand to Mouth (Freq):	20	events/h
			Dislodgeable foliar residues (DFR):	20	%
			Ingestion Rate for Mouthing of Grass/Day (IgR):	25	cm^2/d

Resident exposure towards propoxycarbazone-sodium					
Adults			**Children**		
Residents: Dermal exposure after application in cereals (via deposits caused by spray drift)					
$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$			$SDE_R = (AR \times NA \times D \times TTR \times TC \times H \times DA) / BW$		
(0.0007 x 1 x 0.29% x 5% x 7300 x 2 x 75%) / 60			(0.0007 x 1 x 0.29% x 5% x 2600 x 2 x 75%) / 16.15		
External exposure	0.0014819	mg/person	External exposure	0.0005278	mg/person
External exposure	2.4698E-05	mg/kg bw/d	External exposure	3.2681E-05	mg/kg bw/d
Absorbed dose:	**0.0000185**	**mg/kg bw/d**	**Absorbed dose:**	**0.0000245**	**mg/kg bw/d**
Residents: Inhalation exposure to vapour					
$SIE_R = (AC_V \times IR \times IA) / BW$			$SIE_R = (AC_V \times IR \times IA) / BW$		
(0 x 16.57 x 100%) / 60			(0 x 8.31 x 100%) / 16.15		
External exposure		mg/person	External exposure		mg/person
External exposure		mg/kg bw/d	External exposure		mg/kg bw/d
Absorbed dose:		**none**	**Absorbed dose:**		**none**
			Residents: Oral exposure (hand-to-mouth transfer)		
			$SOE_H = (AR \times NA \times D \times TTR \times SE \times SA \times Freq \times H \times OA) /$		
			(0.0007 x 1 x 0.29% x 5% x 50% x 20 x 20 x 2 x 25%) / 16.15		
			External exposure	0.0000406	mg/person
			External exposure	2.5139E-06	mg/kg bw/d
			Absorbed dose	**0.0000006**	**mg/kg bw/d**
			Residents: Oral exposure (object-to-mouth transfer)		
			$SOE_O = (AR \times NA \times D \times DFR \times IgR \times OA) / BW$		
			(0.0007 x 1 x 0.29% x 20% x 25 x 25%) / 16.15		
			External exposure	0.00001015	mg/person
			External exposure	6.2848E-07	mg/kg bw/d
			Absorbed dose	**0.0000002**	**mg/kg bw/d**
Total systemic exposure: $SE_R = SDE_R + SIE_R$			Total systemic exposure: $SE_R = SDE_R + SIE_R + SOE_H + SOE_O$		
Total systemic exposure (absorbed dose)	0.0011143	mg/person	Total systemic exposure (absorbed dose)	0.00040854	mg/person
Total systemic exposure (absorbed dose)	**0.0000185**	**mg/kg bw/d**	**Total systemic exposure** (absorbed dose)	**0.0000253**	**mg/kg bw/d**
% of AOEL:	**0.01**	**%**	**% of AOEL:**	**0.01**	**%**

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 in cereals treated with the highest recommended one-time application rate of 0.1 kg product/ha (i.e. 0.07 kg propoxycarbazone-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 propoxycarbazone-sodium (no PPE)

Scenario	AOEL [mg/kg bw/day]	Exposure parameter[1]	
		Absorbed dose [mg/kg bw/day]	% of AOEL
Inspection/scouting	0.3	0.013125	4.4%

[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 calculated worker exposure:
D = DFR x TC x WR x AR x P

D = Dermal exposure
DFR = Dislodgeable foliar residues (µg as/cm²)
TC = Transfer Coefficient (cm²/person/h)
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

Input parameters considered for the estimation of worker 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		
Without PPE		
Worker (re-entry): Systemic dermal exposure after application in cereals		
SDE_W = (DFR x TC x WR x AR x NA x DA) / BW		
(3 x 2500 x 2 x 0.07 x 1 x 75%) / 60		
External dermal exposure	1.05	mg/person
External dermal exposure	0.02	mg/kg bw/d
Total systemic exposure	0.79	mg/person
Total systemic exposure	**0.013125**	**mg/kg bw/d**
% of AOEL	**4.4**	**%**

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 CP 7.3-1: Dermal absorption end-points for the risk assessment

End-Point	Active substance: propoxycarbazone-sodium
Dermal penetration	Concentrate: 25% (default value) Spray dilutions: 75% (default value)

CP 7.4 Available toxicological data relating to co-formulants

CONFIDENTIAL information - data provided separately (Document J)

[2] EFSA Panel on Plant Protection Products and their Residues (PPR); Guidance on Dermal Absorption. EFSA Journal 2012;10(4):2665. [30 pp.] doi:10.2903/j.efsa.2012.2665