SURROUND® WP CROP PROTECTANT

DOCUMENT M-CP, Section 7

TOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Annex to EU Regulation 284/2013

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Version history[1]

Date	Data points containing amendments or additions and brief description	Document identifier and version number
28/02/2019	Revised version following RMS comments	MCP-S7_2019-02-28
28/02/2018	Applicant's initial dossier	MCP-S7_2018-02-28

[1] It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4 How to revise an Assessment Report

Table of Contents

CP 7 TOXICOLOGICAL STUDIES ON THE PLANT PROTECTION PRODUCT

Introduction

This document contains new summaries of studies and information which were not available at the time of the first Annex I inclusion of aluminium silicate (kaolin), and were therefore not evaluated during the first EU review. To facilitate discrimination between new and original study information, the original information is written in grey shaded text. Studies submitted by the notifier for the first Annex I inclusion are contained in the Monograph, its Addenda and in the original dossier.

CP 7.1 Acute Toxicity

CP 7.1.1 Oral toxicity

Report:	KCP 7.1.1/01, [redacted] 1997 a
Title:	Satintone® 5HB, Lot #10146 "Calcined Kaolin" - Acute Oral Toxicity Limit Test
Report No:	4903
Guidelines:	40 CFR 158, Guideline #81-1 – FIFRA
GLP:	Yes

Executive Summary

In an acute oral toxicity test, Satintone® 5HB, as manufactured, 100% Kaolin clay, was administered as a 36% w/w suspension in distilled water (5000 mg/kg bw) by oral gavage to five male and five female Sprague-Dawley albino rats. The test animals were observed for 14 days following administration of the test substance.

Oral LD_{50}:	Males	=	> 5000 mg/kg bw
	Females	=	> 5000 mg/kg bw
	Combined	=	> 5000 mg/kg bw

Test material is not toxic to rats following exposure by the oral route. No clinical signs were observed, and all rats appeared active and healthy throughout the study. There were no signs of gross toxicity, adverse pharmacological effects or abnormal behaviour. Gross necropsy findings at terminal sacrifice were generally unremarkable. Apart from red lung discolouration consistent with euthanasia by CO_2 inhalation, all tissues and organs appeared normal.

On the basis of this study, test material does not warrant classification as harmful or toxic when administered orally.

I MATERIALS AND METHODS

A. MATERIALS

1. Test Material:	Satintone ® 5HB
Description:	White powder
Lot/Batch #:	10146
Purity:	Not stated
Stability of test component:	Stable
2. Vehicle and/or positive control:	distilled water
3. Test animals –	
Species:	Rat
Strain:	Sprague-Dawley derived, albino
Age:	Young adults, male and female
Weight at dosing:	202 – 221g males, 165 – 180 g females
Source:	Ace Animals, Inc. Boyertown, PA
Acclimation:	7 days
Diet:	Purina Rodent Chow (#5012) *ad libitum*
Water:	Filtered tap water, *ad libitum*
Housing:	Animals were individually housed in stainless steel suspended cages
Environmental conditions –	
Temperature:	20-23ºC
Humidity:	Not specified
Air changes:	Not specified
Photoperiod:	12-hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates: 17-31 December 1996

2. Animal assignment and treatment

Animals were fasted for approximately 19 hours prior to selection. Ten (five males, five females) healthy rats were selected for test. Individual doses were calculated, and a dose of 5000 mg/kg bw was administered to each rat via a stainless-steel ball-tipped gavage needle attached to an appropriate syringe. Test substance was administered as a 36% suspension in distilled water.

Animals were observed for signs of gross toxicity and behaviour changes at 1 and 3 hours post dosing and at least once daily thereafter for 14 days. Bodyweights were recorded at day 0 (prior to dosing) and again at day 7 and 14. At day 14, surviving animals were sacrificed and all animals were necropsied and examined for gross pathological changes.

3. Statistics

The data did not warrant statistical analysis.

II. RESULTS AND DISCUSSIONS

A. MORTALITY

Details are provided in table 7.1.1-1. No mortality occurred at 5000 mg/kg bw, the only dose level tested

Table 7.1.1-1. Doses, mortality / animals treated

Dose (mg/kg bw)	Males	Females	Combined
5000	0/5	0/5	0/10

Oral LD_{50}: Males = > 5000 mg/kg bw
Females = > 5000 mg/kg bw
Combined = > 5000 mg/kg bw

B. CLINICAL OBSERVATIONS

All animals appeared active and healthy throughout the study.

C. BODYWEIGHT

All animals had gained bodyweight 7 and 14 days following dosing.

D. NECROPSY

Gross necropsy findings at termination sacrifice were generally unremarkable. Apart from red discolouration consistent with euthanasia by CO_2 inhalation, all tissues and organs appeared normal

E. DEFICIENCIES

None

III. CONCLUSIONS

The acute oral LD_{50} for Satintone® 5HB 100% Kaolin clay is greater than 5000 mg/kg bw for male and female rats. The preparation does not warrant classification as being toxic or harmful on the basis of its acute oral toxicity

Current Conclusion

This GLP study, conducted to internationally recognised guidelines remains supportive of Surround® WP Crop Protectant with respect to acute oral toxicity.

The results have been reinterpreted and based upon the outcome of the study, no classification is warranted according to (EC) 1272/2008.

Report:	KCP 7.1. 1/02, [redacted] 1997 b

Title:	M-96-018, Lot #08145 - Acute Oral Toxicity Limit Test.
Report No:	5003
Guidelines:	40 CFR 158, Guideline #81-1 – FIFRA
GLP:	Yes

Executive Summary

In an acute oral toxicity test, M-96-018, as manufactured, 98.8% Kaolin clay, was administered as a 30% w/w suspension in corn oil (5000 mg/kg bw) by oral gavage to five male and five female Sprague-Dawley albino rats. Due to the volume of the dose (15.22 ml/kg), the test material was administered in two approximately equal portions, two hours apart .The test animals were observed for 14 days following administration of the test substance.

Oral LD_{50}:	Males	=	> 5000 mg/kg bw
	Females	=	> 5000 mg/kg bw
	Combined	=	> 5000 mg/kg bw

Test material is not toxic to rats following exposure by the oral route. No clinical signs were observed, and all rats appeared active and healthy throughout the study. There were no signs of gross toxicity, adverse pharmacological effects or abnormal behaviour. Gross necropsy findings at terminal sacrifice were generally unremarkable. Apart from red lung discolouration consistent with euthanasia by CO_2 inhalation, all tissues and organs appeared normal.
On the basis of this study, test material does not warrant classification as harmful or toxic when administered orally.

I MATERIALS AND METHODS

A. MATERIALS

1. Test Material: M-96-018
   - Description: White powder
   - Lot/Batch #: 08145
   - Purity: Not stated
   - Stability of test component: Stable

2. Vehicle and/or positive control: Corn oil

3. Test animals –
   - Species: Rat
   - Strain: Sprague-Dawley derived, albino
   - Age: Young adults, male and female
   - Weight at dosing: 175-215 g males, 168-173 g females
   - Source: Ace Animals, Inc. Boyertown, PA
   - Acclimation: 7 days
   - Diet: Purina Rodent Chow (#5012) *ad libitum*
   - Water: Filtered tap water, *ad libitum*

Housing:	Animals were individually housed in stainless steel suspended cages

Environmental conditions –

Temperature:	20-22ºC
Humidity:	Not specified
Air changes:	Not specified
Photoperiod:	12-hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates: 4-18 February 1997

2. Animal assignment and treatment

Animals were fasted for approximately 20 hours prior to selection. Ten (five males, five females) healthy rats were selected for test. Individual doses were calculated, and a dose of 5000 mg/kg bw was administered to each rat via a stainless-steel ball-tipped gavage needle attached to an appropriate syringe. Test substance was administered as a 30% suspension in corn oil. Due to the high volume of test suspension to be administered (15.22 ml/kg), each animal's dose was divided into two approximately equal portions and administered two hours apart.
Animals were observed for signs of gross toxicity and behaviour changes at 1, 2, 3 and 4 hours post dosing and at least once daily thereafter for 14 days. Bodyweights were recorded at day 0 (prior to dosing) and again at day 7 and 14. At day 14, surviving animals were sacrificed and all animals were necropsied and examined for gross pathological changes.

3. Statistics

The data did not warrant statistical analysis.

II. RESULTS AND DISCUSSIONS

A. MORTALITY

Details are provided in table 7.1.1-2. No mortality occurred at 5000 mg/kg bw, the only dose level tested

Table 7.1.1-2. Doses, mortality / animals treated

Dose (mg/kg bw)	Males	Females	Combined
5000	0/5	0/5	0/10

Oral LD_{50}:	Males	=	> 5000 mg/kg bw
	Females	=	> 5000 mg/kg bw
	Combined	=	> 5000 mg/kg bw

B. CLINICAL OBSERVATIONS

All animals appeared active and healthy throughout the study.

C. BODYWEIGHT

All animals had gained bodyweight 7 and 14 days following dosing.

D. NECROPSY

Gross necropsy findings at termination sacrifice were generally unremarkable. Apart from red discolouration consistent with euthanasia by CO_2 inhalation, all tissues and organs appeared normal

E. DEFICIENCIES

None

III. CONCLUSIONS

The acute oral LD_{50} for M-96-018 is greater than 5000 mg/kg bw for male and female rats. The preparation does not warrant classification as being toxic or harmful on the basis of its acute oral toxicity

CP 7.1.2 Dermal toxicity

Report:	KCP 7.1.2/01, [redacted] 1997
Title:	Satintone® 5HB, Lot #10146 Acute Dermal Toxicity
Report No:	4904
Guidelines:	40 CFR 158, Guideline #81-2 – FIFRA
GLP:	Yes

Executive Summary

In an acute dermal toxicity test, Satintone® 5HB, as manufactured, 100% Kaolin clay, was moistened to a dry paste with distilled water, administered to the closely clipped dorsum of five male and five female Sprague-Dawley albino rats at a dose level of 5000 mg/kg bw, and was covered with an occlusive dressing for 24 hours.

Dermal LD_{50}:	Males	=	> 5000 mg/kg bw
	Females	=	> 5000 mg/kg bw
	Combined	=	> 5000 mg/kg bw

Test material is not toxic to rats following exposure by the dermal route. No clinical signs were observed, and all rats appeared active and healthy throughout the study. There were no signs of gross toxicity, adverse pharmacological effects or abnormal behaviour. Gross necropsy findings at terminal sacrifice were generally unremarkable. Apart from red lung discolouration consistent with euthanasia by CO_2 inhalation, all tissues and organs appeared normal.

On the basis of this study, test material does not warrant classification as harmful or toxic when administered topically.

I MATERIALS AND METHODS

A. MATERIALS

1. Test Material:	Satintone® 5HB
Description:	White powder
Lot/Batch #:	10146
Purity:	Not stated
Stability of test component:	Stable
2. Vehicle and/or positive control:	distilled water
3. Test animals –	
Species:	Rat
Strain:	Sprague-Dawley derived, albino
Age:	Young adults, male and female
Weight at dosing:	232-240g males, 216-238g females
Source:	Ace Animals, Inc. Boyertown, PA
Acclimation:	20 days
Diet:	Purina Rodent Chow (#5012) *ad libitum*
Water:	Filtered tap water, *ad libitum*
Housing:	Animals were individually housed in stainless steel suspended cages
Environmental conditions –	
Temperature:	20-22ºC
Humidity:	Not specified
Air changes:	Not specified
Photoperiod:	12-hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates:	30 December 1996 – 13 January 1997

2. Animal assignment and treatment

On the day prior to application, a group of animals was prepared by clipping the dorsal area and the trunk. After clipping and prior to application, the animals were examined for health, weighed (initial) and the skin checked for any abnormalities. Ten (five males, five females) healthy rats were selected for test.
The test substance was moistened to a dry paste by preparing a 50% w/w mixture with distilled water. 5000 mg/kg bw of the paste was applied to a dose area representing approximately 10% of body surface, and maintained for 24 hours with a semi-occlusive bandage.
Animals were observed for signs of gross toxicity and behaviour changes at 1 and 3 hours post dosing and at least once daily thereafter for 14 days. Bodyweights were recorded at day 0 (prior

to dosing) and again at day 7 and 14. At day 14, surviving animals were sacrificed and all animals were necropsied and examined for gross pathological changes.

3. Statistics

The data did not warrant statistical analysis.

II. RESULTS AND DISCUSSIONS

A. MORTALITY

Details are provided in table 7.1.2-1. No mortality occurred at 5000 mg/kg bw, the only dose level tested

Table 7.1.2-1. Doses, mortality / animals treated

Dose (mg/kg bw)	Males	Females	Combined
5000	0/5	0/5	0/10

Dermal LD_{50}: Males = > 5000 mg/kg bw
Females = > 5000 mg/kg bw
Combined = > 5000 mg/kg bw

B. CLINICAL OBSERVATIONS

All animals appeared active and healthy throughout the study.

C. BODYWEIGHT

All animals had gained bodyweight 7 and 14 days following dosing.

D. NECROPSY

Gross necropsy findings at termination sacrifice were generally unremarkable. Apart from red discolouration consistent with euthanasia by CO_2 inhalation, all tissues and organs appeared normal

E. DEFICIENCIES

None

III. CONCLUSIONS

The acute dermal LD_{50} for Satintone® 5HB 100% Kaolin clay is greater than 5000 mg/kg bw for male and female rats. The preparation does not warrant classification as being toxic or harmful on the basis of its acute oral toxicity.

Current Conclusion

This GLP study, conducted to internationally recognised guidelines remain supportive of Surround® WP Crop Protectant with respect to acute dermal toxicity.

The results have been reinterpreted and based upon the outcome of the study, no classification is warranted according to (EC) 1272/2008.

CP 7.1.3 Inhalation toxicity

Report:	KCP 7.1.3/01, [redacted] 1997 a
Title:	M-97-009, Lot #09255 "Calcined Kaolin"- Acute Inhalation Toxicity Limit Test.
Report No:	5405
Guidelines:	40 CFR 158, Guideline #81-3 – FIFRA
GLP:	Yes

Executive Summary

In an acute inhalation toxicity test, M-97-009, as manufactured, 100% Kaolin clay, was administered as an aerosol suspension (concentration 2.07 mg/l, maximal attainable concentration) for 4 hours and 9 minutes to five male and five female Sprague-Dawley albino rats. The test animals were observed for 14 days following administration of the test substance.

Inhalation LD_{50}:	Males	=	> 2.07 mg/l
	Females	=	> 2.07 mg/l
	Combined	=	> 2.07 mg/l

Test material is not toxic to rats following inhalation exposure. During the initial 2.5 hours of exposure, animals exhibited nasal and ocular discharge, irregular respiration, hunched posture. All rats recovered from these symptoms within 17 hours and appeared active and healthy during the reminder of the study. There were no signs of gross toxicity, adverse pharmacological effects or abnormal behaviour. Gross necropsy findings at terminal sacrifice were generally unremarkable. Apart from red lung discolouration consistent with euthanasia by CO_2 inhalation, all tissues and organs appeared normal. On the basis of this study, test material does not warrant classification as toxic or harmful by inhalation.

I MATERIALS AND METHODS

A. MATERIALS

1. Test Material:	M-97-009
Description:	White powder
Lot/Batch #:	09255

Purity:	Not stated
Stability of test component:	Stable

2. Vehicle and/or positive control: None

3. Test animals –

Species:	Rat
Strain:	Sprague-Dawley derived, albino
Age:	Young adults, male and female
Weight at dosing:	226-238g males, 197-211g females
Source:	Ace Animals, Inc. Boyertown, PA
Acclimation:	10 days
Diet:	Purina Rodent Chow (#5012) *ad libitum*
Water:	Filtered tap water, *ad libitum*
Housing:	Animals were individually housed in stainless steel suspended cages

Environmental conditions –

Temperature:	16-24ºC
Humidity:	Not specified
Air changes:	Not specified
Photoperiod:	12 hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates: 25 July – 8 August 1997

2. Animal assignment and treatment

Ten (five males, five females) healthy rats were selected for test. Animals were observed for signs of gross toxicity and behaviour changes before exposure, at least every 30 minutes during the first 2.5 hours during exposure, upon removal from the chamber and at least once daily thereafter for 14 days. Bodyweights were recorded at day 0 (prior to dosing) and again at day 7 and 14. At day 14, surviving animals were sacrificed and all animals were necropsied and examined for gross pathological changes.

3. Generation of the test atmosphere / chamber description

A rectangular whole-body Perspex chamber with a volume of 100 l operated under slight negative pressure was used. Test material was ground in a ball mill for 24 hours to achieve a mass median aerodynamic diameter of 2.5 µm. Chamber concentrations were determined by collecting samples on pre-weighed Whatman GF/B filter papers, measuring the mass of sample collected and dividing by the total volume of air sampled. The test atmosphere concentration was 2.07 mg/l

4. Statistics

The data did not warrant statistical analysis.

II. RESULTS AND DISCUSSIONS

A. MORTALITY

Details are provided in table 7.1.3-1. No mortality occurred at 2.07 mg/l, the only concentration level tested

Table 7.1.3-1. Doses, mortality / animals treated

Dose (mg/l)	Males	Females	Combined
2.07	0/5	0/5	0/10

Oral LD_{50}: Males = > 2.07 mg/l
Females = > 2.07 mg/l
Combined = > 2.07 mg/l

B. CLINICAL OBSERVATIONS

During exposure, animals exhibited ocular and nasal discharge, irregular respiration and hunched posture.
All animals appeared active and healthy throughout the study.

C. BODYWEIGHT

All animals survived exposure, gained bodyweight over the 14-day observation period.

D. NECROPSY

Gross necropsy findings at terminal sacrifice revealed red foci on the surface of the lungs of one female. Apart from red lung discolouration consistent with CO_2 inhalation, all other tissues and organs appeared normal.

E. DEFICIENCIES

None

III. CONCLUSIONS

The median lethal chamber concentration for four hours exposure (LC_{50}, 4 hour) for M-97-009, Lot #09255, 100% calcined Kaolin is greater than 2.07 mg per litre of air. The preparation does not warrant classification as being toxic or harmful on the basis of its acute inhalation toxicity.

Report:	KCP 7.1.3/02, [redacted] 1997 b
Title:	M-96-018 - Acute Inhalation Toxicity Limit Test.
Report No:	5424
Guidelines:	40 CFR 158, Guideline #81-3 – FIFRA
GLP:	Yes

Executive Summary

In an acute inhalation toxicity test, M-96-018, as manufactured, 98.8% Kaolin clay, was administered as an aerosol suspension (concentration 2.18 mg/l, maximal attainable concentration) for 4 hours to five male and five female Sprague-Dawley albino rats. The test animals were observed for 14 days following administration of the test substance.

Inhalation LC_{50}:	Males	=	> 2.18 mg/l
	Females	=	> 2.18 mg/l
	Combined	=	> 2.18 mg/l

Test material is not toxic to rats following inhalation exposure. During the initial 1 hour of exposure, animals exhibited nasal and ocular discharge, hypoactivity, hunched posture. All rats recovered from these symptoms within 17 hours and appeared active and healthy during the reminder of the study. There were no signs of gross toxicity, adverse pharmacological effects or abnormal behaviour. Gross necropsy findings at terminal sacrifice were generally unremarkable. Apart from red lung discolouration consistent with euthanasia by CO_2 inhalation, all tissues and organs appeared normal.
On the basis of this study, test material does not warrant classification as toxic or harmful by inhalation.

I MATERIALS AND METHODS

A. MATERIALS

1. Test Material:	M-96-018
Description:	White powder
Lot/Batch #:	Not stated
Purity:	98.8% kaolin
	1.2% siloxane
Stability of test component:	Stable

2. Vehicle and/or positive control:	None

3. Test animals –	
Species:	Rat
Strain:	Sprague-Dawley derived, albino
Age:	Young adults, male and female
Weight at dosing:	214-244g males, 185-203g females
Source:	Ace Animals, Inc. Boyertown, PA
Acclimation:	9 days
Diet:	Purina Rodent Chow (#5012) *ad libitum*
Water:	Filtered tap water, *ad libitum*
Housing:	Animals were individually housed in stainless steel suspended cages

Environmental conditions –

Temperature:	17-22ºC
Humidity:	Not specified
Air changes:	Not specified
Photoperiod:	12-hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates: 31 July – 14 August 1997

2. Animal assignment and treatment

Ten (five males, five females) healthy rats were selected for test. Animals were observed for signs of gross toxicity and behaviour changes before exposure, at least every 30 minutes during the first hour during exposure, upon removal from the chamber and at least once daily thereafter for 14 days. Bodyweights were recorded at day 0 (prior to dosing) and again at day 7 and 14. At day 14, surviving animals were sacrificed and all animals were necropsied and examined for gross pathological changes.

3. Generation of the test atmosphere / chamber description

A rectangular whole-body Perspex chamber with a volume of 100 l operated under slight negative pressure was used. Test material was ground in a ball mill for 24 hours to achieve a mass median aerodynamic diameter of 2.0 µm. Chamber concentrations were determined by collecting samples on pre-weighed Whatman GF/B filter papers, measuring the mass of sample collected and dividing by the total volume of air sampled. The test atmosphere concentration was 2.18 mg/l

4. Statistics

The data did not warrant statistical analysis.

II. RESULTS AND DISCUSSIONS

A. MORTALITY

Details are provided in table 7.1.3-2. No mortality occurred at 2.18 mg/l, the only concentration level tested

Table 7.1.3-2. Doses, mortality / animals treated

Dose (mg/l)	Males	Females	Combined
2.18	0/5	0/5	0/10

Oral LC_{50}:	Males	=	> 2.18 mg/l
	Females	=	> 2.18 mg/l
	Combined	=	> 2.18 mg/l

B. CLINICAL OBSERVATIONS

During exposure, animals exhibited ocular and nasal discharge, hypoactivity and hunched posture. All animals appeared active and healthy throughout the study.

C. BODYWEIGHT

All animals survived exposure, gained bodyweight over the 14-day observation period.

D. NECROPSY

Gross necropsy findings at terminal sacrifice were generally unremarkable. Apart from red lung discolouration consistent with CO_2 inhalation, all other tissues and organs appeared normal.

E. DEFICIENCIES

None

III. CONCLUSIONS

The median lethal chamber concentration for four hours exposure (LC_{50}, 4 hour) for M-96-018, 98.8% calcined Kaolin is greater than 2.18 mg per litre of air. The preparation does not warrant classification as being toxic or harmful on the basis of its acute inhalation toxicity

Current Conclusion

These GLP studies, conducted to internationally recognised guidelines remain supportive of Surround® WP Crop Protectant with respect to acute inhalation toxicity.

The results have been reinterpreted and based upon the outcome of the study, no classification is warranted according to (EC) 1272/2008.

CP 7.1.4 Skin irritation

Report:	KCP 7.1.4/01, [redacted] 1997
Title:	M-96-018, lot #08145 – Primary Skin Irritation.
Report No:	4906
Guidelines:	40 CFR 158, Guideline #81-5 – FIFRA
GLP:	Yes

Executive Summary

In a primary skin irritation test, M-96-018, as manufactured, 98.8% Kaolin clay, was administered as a dry paste to the skin of six healthy rabbits for 4 hours. The test animals were observed at

approximately 1, 24, 48 and 72 hours following administration of the test substance. Irritation was scored according to Draize *et al*[1].

All animals appeared active and healthy throughout the study. There were no signs of gross toxicity, adverse pharmacologic effects or abnormal behaviour. No dermal irritation was noted at any treated site throughout the study. On the basis of this study, test material does not warrant classification as irritating to skin.

I MATERIALS AND METHODS

A. MATERIALS

1. Test Material:	M-96-018
Description:	White powder
Lot/Batch #:	08145
Purity:	98.8% kaolin
Stability of test component:	Stable
2. Vehicle and/or positive control:	Distilled water
3. Test animals –	
Species:	Rabbit
Strain:	New Zealand, albino
Age:	Adults, male and female
Weight at dosing:	Not stated
Source:	Davidson's Mill Farm, South Brunswick, NJ
Acclimation:	13 days
Diet:	Pelleted Purina Rabbit Chow (#5326)
Water:	Filtered tap water, *ad libitum*
Housing:	Animals were individually housed in stainless steel suspended cages
Environmental conditions –	
Temperature:	17.5-18.5ºC
Humidity:	Not specified
Air changes:	Not specified
Photoperiod:	12-hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates:	19-22 December 1996
2. Animal assignment and treatment	

[1] Draize, J.H., Woodward, G. and Calvery, H.O. Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. *J. Pharmacol. Exp. Ther.* 1944; 82:377-390

Test substance was moistened to a dry pasted and 0.5 g was applied to the clipped dorsum of six New Zealand albino rabbits (three males and three females). The test substance was kept in place with the aid of an occlusive bandage for four hours. After four hours, the bandage was removed and residual test substance was removed using water and a clean towel.

3. Statistics

The data did not warrant statistical analysis.

II. RESULTS AND DISCUSSIONS

A. FINDINGS

Details are provided in table 7.1.4-1. No irritation was observed in any of the treated animals

Table 7.1.4-1 Irritation indices following application of M-96-018 to the skin of New Zealand rabbits

Animal Number and sex	Type of Response	Score After Removal of Dressings			
		1 Hour	24 Hours	48 Hours	72 Hours
1102 M	Erythema	0	0	0	0
	Oedema	0	0	0	0
1103 F	Erythema	0	0	0	0
	Oedema	0	0	0	0
1104 M	Erythema	0	0	0	0
	Oedema	0	0	0	0
1105 F	Erythema	0	0	0	0
	Oedema	0	0	0	0
1106 M	Erythema	0	0	0	0
	Oedema	0	0	0	0
1107 F	Erythema	0	0	0	0
	Oedema	0	0	0	0

All scores at each of the reading times (24, 48 and 72 hours) for an effect are used for calculating respective mean values.

Mean scores over 24, 48 and 72 hours for the six rabbits were:

Erythema : 0.0
Oedema : 0.0

III. CONCLUSIONS

On the basis of this study, M-96-018 – Kaolin clay, Lot #08145 is classified as non-irritating to the skin.

Current Conclusion

This GLP study, conducted to internationally recognised guidelines remains supportive of Surround® WP Crop Protectant with respect to skin irritation.

The results have been reinterpreted and based upon the outcome of the study, no classification is warranted according to (EC) 1272/2008.

CP 7.1.5 Eye irritation

Report:	KCP 7.1.5/01, [redacted] 2000
Title:	Surround® WP Crop Protectant - Primary Eye Irritation Study in Rabbits.
Report No:	9914
Guidelines:	Health Effects Test Guidelines, OPPTS 870.2400 (1998)
GLP:	Yes

Executive Summary

In a primary eye irritation test, Surround® WP Crop Protectant, as manufactured, 95% Kaolin clay (0.1 ml, approx. 0.04 to 0.05 g) was instilled in the right conjunctival sac of 3 healthy rabbits (one male, two females). The other eye served as control. Eye irritation was scored according to Draize *et al*[2] at 1, 24, 48 and 72 hours post instillation.
All animals appeared active and healthy throughout the study. Apart from the eye irritation noted below, there were no signs of gross toxicity, adverse pharmacologic effects or abnormal behaviour. No corneal opacity or iritis was noted during the study. One hour after test substance instillation, all treated eyes exhibited conjunctivitis. The incidence and severity of irritation decreased thereafter. All eyes were free from irritation by 24 and 72 hours respectively.

On the basis of this test, test substance is not irritating to eyes.

I MATERIALS AND METHODS

A. MATERIALS

1. Test Material: Surround® WP Crop Protectant
   Description: White powder
   Lot/Batch #: 02140
   Purity: 95% kaolin
   Stability of test component: Stable

2. Vehicle and/or positive control: none

3. Test animals –

[2] Draize, J.H., Woodward, G. and Calvery, H.O. Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. *J. Pharmacol. Exp. Ther.* 1944; 82:377-390

Species:	Rabbit
Strain:	New Zealand, albino
Age:	Adults, male and female
Weight at dosing:	Not stated
Source:	Davidson's Mill Farm, South Brunswick, NJ
Acclimation:	14 days
Diet:	Pelleted Purina Rabbit Chow (#5326)
Water:	Filtered tap water, *ad libitum*
Housing:	Animals were individually housed in stainless steel suspended cages

Environmental conditions –

Temperature:	21-23ºC
Humidity:	Not specified
Air changes:	Not specified
Photoperiod:	12-hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates: 17-20 November 2000

2. Animal assignment and treatment

Prior to instillation, both eyes of potential test animals were examined using a fluorescein dye procedure. Only healthy animals without pre-existing ocular lesions were selected for the study. 0.1 ml (approximately 0.04 to 0.05g) of the test substance was instilled in the conjunctival sac of the right eye of each rabbit. The eyelids were then gently held together for about one second. The contralateral eye served as control.
Scoring took place 1, 24, 48 and 72 hours after instillation. The fluorescein dye procedure was used at 24 hours to verify the absence of corneal damage.

3. Statistics

The data did not warrant statistical analysis.

II. RESULTS AND DISCUSSIONS

A. FINDINGS

Details are provided in table 7.1.5-1.

Table 7.1.5-1 Incidence, severity and reversibility of irritation

Time Post Instillation	Incidence of Irritation		
	Corneal Opacity	Iritis	Conjunctivitis
1 hour	0/3	0/3	3/3
24 hours	0/3	0/3	2/3

48 hours	0/3	0/3	0/3
72 hours	0/3	0/3	0/3

FINDINGS

Reddening of the conjunctiva was observed in all rabbits one-hour post instillation. After 24 hours, the incidence of irritation in all three rabbits was below the level required for classification of the substance as irritating to the eyes. All rabbits had fully recovered by 48 hours.
No corneal damage or iritis was observed at any time during the observation period.

Individual scores in are provided in table 7.1.5-2

Table 7.1.5-2 Individual scores

Rabbit No / Sex	Region of eye		One hour	24 h	48 h	72 h
3239	Cornea		0	0[1]	0	0
Female	Iris		0	0	0	0
	Conjunctivae	Redness	1	1	0	0
		Chemosis	1	0	0	0
		Discharge	1	1	0	0
3240	Cornea		0	0[1]	0	0
Male	Iris		0	0	0	0
	Conjunctivae	Redness	1	0	0	0
		Chemosis	0	0	0	0
		Discharge	1	0	0	0
3241	Cornea		0	0[1]	0	0
Female	Iris		0	0	0	0
	Conjunctivae	Redness	1	0	0	0
		Chemosis	0	0	0	0
		Discharge	1	1	0	0

1: 2% fluorescein sodium used to verify the absence of corneal opacity

All scores at each reading time (24, 48 and 72 hours) and for an effect are used for calculating the respective mean values.

For each rabbit, the mean scores over 24, 48 and 72 hours were:

Chemosis	:	0.00	0.00	0.00
Redness of the conjunctive	:	0.33	0.00	0.00
Iris lesions	:	0.00	0.00	0.00
Corneal opacity	:	0.00	0.00	0.00

III. CONCLUSIONS

Based on this test, Surround® WP Crop Protectant, is not classified as irritating to the eye.

Report:	KCP 7.1.5/02, [redacted] 1997
Title:	M-96-018, lot #08145 – Primary Eye Irritation
Report No:	4905
Guidelines:	40 CFR 158, Guideline #81-4 – FIFRA
GLP:	Yes

Executive Summary

In a primary eye irritation test, M-96-018, as manufactured, 98.8% Kaolin clay (0.1 ml, approx. 0.04 to 0.05 g) was instilled in the right conjunctival sac of nine healthy rabbits. The other eye served as control. Test substance was rinsed off the eye of three out of the nine rabbits with physiological saline. Eye irritation was scored according to Draize *et al*[3] at 1, 24, 48 and 72 hours post instillation.
All animals appeared active and healthy throughout the study. Apart from the eye irritation noted below, there were no signs of gross toxicity, adverse pharmacologic effects or abnormal behaviour. No corneal opacity or iritis was noted during the study. One hour after test substance instillation, all treated eyes (rinsed and unrinsed) exhibited conjunctivitis. The incidence and severity of irritation decreased thereafter. All rinsed and unrinsed eyes were free from irritation by 24 and 72 hours respectively.

On the basis of this test, test substance is not irritating to eyes.

I MATERIALS AND METHODS

A. MATERIALS

1. Test Material:	M-96-018
Description:	White powder
Lot/Batch #:	08145
Purity:	not stated
Stability of test component:	Stable
2. Vehicle and/or positive control:	none
3. Test animals –	
Species:	Rabbit
Strain:	New Zealand, albino
Age:	Adults, female
Weight at dosing:	Not stated
Source:	Davidson's Mill Farm, South Brunswick, NJ
Acclimation:	19 days
Diet:	Pelleted Purina Rabbit Chow (#5326)

[3] Draize, J.H., Woodward, G. and Calvery, H.O. Methods for the study of irritation and toxicity of substances applied topically to the skin and mucous membranes. *J. Pharmacol. Exp. Ther.* 1944; 82:377-390

Water:	Filtered tap water, *ad libitum*
Housing:	Animals were individually housed in stainless steel suspended cages

Environmental conditions –

Temperature:	19.5-22ºC (67-72ºF)
Humidity:	Not specified
Air changes:	Not specified
Photoperiod:	12-hour light/dark cycle

B. STUDY DESIGN AND METHODS

1. In life dates: 23-26 December 1996

2. Animal assignment and treatment

Prior to instillation, both eyes of potential test animals were examined using a fluorescein dye procedure. Only healthy animals without pre-existing ocular lesions were selected for the study.

0.1 ml (approximately 0.04 to 0.05g) of the test substance was instilled in the conjunctival sac of the right eye of each rabbit. The eyelids were then gently held together for about one second. The contralateral eye served as control.

In three test animals, the test eye was rinsed with physiological saline (0.9% NaCl) approximately 20-30 seconds after instillation. The test eye of the six remaining test animals remained unrinsed.

Scoring took place 1, 24, 48 and 72 hours after instillation. The fluorescein dye procedure was used at 24 hours to verify the absence of corneal damage.

3. Statistics

The data did not warrant statistical analysis.

II. RESULTS AND DISCUSSIONS

A. FINDINGS

Details are provided in table 7.1.5-3.

Table 7.1.5-3 Incidence, severity and reversibility of irritation

Time Post Instillation	Incidence of Irritation					
	Unrinsed			Rinsed		
	Corneal Opacity	Iritis	Conjunctivitis	Corneal Opacity	Iritis	Conjunctivitis
1 hour	0/6	0/6	6/6	0/3	0/3	3/3
24 hours	0/6	0/6	5/6	0/3	0/3	0/3
48 hours	0/6	0/6	2/6	0/3	0/3	0/3
72 hours	0/6	0/6	0/6	0/3	0/3	0/3

FINDINGS – UNRINSED EYES ONLY

Reddening of the conjunctiva was observed in all rabbits one-hour post instillation. After 24 hours, the incidence of irritation in all six rabbits was below the level required for classification of the substance as irritating to the eyes, and by 48 hours, only two rabbits showed slight signs of irritation. All rabbits had fully recovered by 72 hours.

No corneal damage or iritis was observed at any time during the observation period.

Individual scores in unrinsed eyes are provided in table 7.1.5-4

Table 7.1.5-4 Individual scores – Unrinsed eye only

Rabbit No / Sex	Region of eye		1 h	24 h	48 h	72 h
1124	Cornea		0	0[1]	0	0
Female	Iris		0	0	0	0
	Conjunctivae	Redness	3	2	1	0
		Chemosis	1	1	0	0
		Discharge	1	1	0	0
1125	Cornea		0	0[1]	0	0
Female	Iris		0	0	0	0
	Conjunctivae	Redness	2	1	0	0
		Chemosis	0	0	0	0
		Discharge	1	0	0	0
1126	Cornea		0	0[1]	0	0
Female	Iris		0	0	0	0
	Conjunctivae	Redness	2	1	0	0
		Chemosis	1	0	0	0
		Discharge	2	0	0	0
1127	Cornea		0	0[1]	0	0
Female	Iris		0	0	0	0
	Conjunctivae	Redness	2	0	0	0
		Chemosis	1	0	0	0
		Discharge	2	0	0	0
1128	Cornea		0	0[1]	0	0
Female	Iris		0	0	0	0
	Conjunctivae	Redness	3	2	1	0
		Chemosis	1	0	0	0
		Discharge	1	0	0	0
1129	Cornea		0	0[1]	0	0
Female	Iris		0	0	0	0
	Conjunctivae	Redness	2	1	0	0
		Chemosis	0	0	0	0
		Discharge	2	0	0	0

1: 2% fluorescein sodium used to verify the absence of corneal opacity

All scores at each reading time (24, 48 and 72 hours) and for an effect are used for calculating the respective mean values. The mean scores for the six animals over 24, 48 and 72 hours were:

Chemosis	:	0.06
Redness of the conjunctive	:	0.50
Iris lesions	:	0.00
Corneal opacity	:	0.00

III. CONCLUSIONS

On the basis of this test, M-96-018 – Kaolin clay, Lot #08145 does not warrant classification as irritating to the eye.

Current Conclusions

These GLP studies, conducted to internationally recognised guidelines continue to be supportive of Surround® WP Crop Protectant with respect to eye irritation.

The results have been reinterpreted and based upon the outcome of the studies, and considering both the tiered evaluation described by ECHA (2017)[4] and lack of evidence from human exposure, Surround® WP Crop Protectant, is classified as non-irritating to the eye (EC) 1272/2008.

CP 7.1.6 Skin sensitization

Report:	KCP 7.1.6/01, [redacted], 2017
Title:	Assessment of sensitising properties on albino guinea pigs. Maximisation test according to Magnusson and Kligman.
Report No:	SMK-PH-17/0024
Guidelines:	OECD Test Guideline No. 406; Method B.6 of Council Regulation No. 440/2008.
GLP:	Yes

Executive summary

The aim of the study was to evaluate the possible sensitising potential of aluminium silicate after intradermal and topical administration to guinea pigs. The induction phase (intradermal injection at 10% and topical application at 40%) was conducted using 10 guinea pigs and a 10-day rest phase. The challenge phase conducted under occlusive dressing for 24 hours, consisted of a single topical application of the test item diluted at 40% and 20% in distilled water. In the treated group (treatment dose of 20%), no macroscopic cutaneous reactions attributable to skin sensitisation were noted after the challenge phase. In the concurrent control group, no

[4] ECHA (2017). Guidance on the Application of the CLP Criteria. Version 5.0 – July 2017

macroscopic cutaneous intolerance reactions were recorded after the challenge phase. In the treated group (treatment dose of 40%), no macroscopic cutaneous reactions attributable to skin sensitisation were noted after the challenge phase. In the concurrent control group, no macroscopic cutaneous intolerance reactions were recorded after the challenge phase. In conclusion, under the experimental conditions of this study, aluminium silicate does not have the potential to induce skin sensitisation.

I. MATERIALS AND METHODS

A. MATERIALS

1. **Test material:** Aluminium silicate (Calcined Kaolin)
   Description: White powder
   Batch No.: 61014E
   Purity: 99%

B. STUDY DESIGN AND METHODS

1. **Test animals:** **A**lbino guinea pigs (Dunkin-Hartley strain)
   Age: 3 to 4 weeks old
   Source: Envigo (Kreuzelweg 53, 5961 NM HORST - The Netherlands)
   Acclimation: Minimum 5 days
   Diet: 50 % (w/v) aqueous sucrose solution, *ad libitum*
2. **Dose preparation:** The test item was used freshly prepared in physiological saline for the intradermal injections and in distilled water for the topical applications.
3. **Animal housing:** The animals were housed in groups of 3 (maximum) in polycarbonate containers, the flooring of which was covered with dust-free cuttings and the top fitted with a stainless-steel lid with a feeding device and drinking bottle of 500 mL. Drinking water (tap water from public distribution system) and food were supplied *ad libitum.*
4. **Environmental conditions:**

   Temperature: 19 to 25 °C
   Relative humidity: 30 to 70%
   Photoperiod: 12 hours light (07.00 to 19.00) and 12 hours dark

5. **Preparation of animals**

Before study, animals were identified individually by marking with picric acid and by means of a numbered ring on the edge of one ear. The animals were specifically shorn before each test item application:

- inter-scapular zone for the induction phase

- dorso-lumbar zone for the challenge phase

At least 3 hours before the first reading (challenge phase) they were shorn a second time in the dorso-lumbar zone. The animals were weighed at the beginning of the test, after the second induction and at the end of the test.

6. Preliminary studies:

Determination by intradermal injection of the Maximal Non-Necrotising Concentration (MNNC)

This was conducted for the purpose of defining an MNNC of the test item which, on intradermal injection during the induction phase, does not risk causing too great a lesion (non-necrotising concentration). Two animals received a volume of 0.1 mL of the test item, on both sides of the spine, at 4 concentrations: 20%, 10%, 5% and 2% (diluted in physiological saline). A macroscopic evaluation of the cutaneous reactions was conducted 24 hours after the injections to determine the MNNC.

Determination by topical application of the Pre-Maximal Non-Irritant Concentration (Pre-MNIC)

This allowed the evaluation of the irritancy potential of the test item and defined whether an application of sodium lauryl sulfate would be needed during the topical induction phase. The test item was applied on the dorso-lumbar zone of two guinea pigs (shorn beforehand), with occlusive dressing for 24 hours, at 4 different concentrations: 40%, 30%, 20% and 10% (diluted in distilled water). After the removal of the occlusive dressing, the treated areas were rinsed with distilled water. A macroscopic evaluation of the cutaneous reactions was conducted 24 hours after removal of the dressing to determine the pre-MNIC.

Determination by topical application of the Maximal Non-Irritant Concentration (MNIC)

This was carried out to determine the MNIC of the test item to ensure there was no risk of an irritant effect during the challenge phase. Three guinea pigs were treated according to the same treatment as animals from GROUP 1 (control) for the induction phase (i.e. physiological saline and distilled water). During the challenge phase, the animals were treated with the test item placed onto the selected treatment sites and covered with an occlusive dressing for a period of 24 hours at 4 different concentrations: 40%, 30%, 20% and 10% (diluted in distilled water). After removal of the occlusive dressing, the treated areas were rinsed with distilled water. A macroscopic evaluation of the cutaneous reactions was conducted 24 and 48 hours after removal of the occlusive dressing to determine the MNIC.

7. Main study:

GROUP 1 (negative control): 5 female guinea pigs

GROUP 2 (treated): 10 female guinea pigs

Induction phase

1st Intradermal Induction:

Day 0

After shearing the scapular zone, three pairs of intradermal (ID) injections of 0.1 mL were performed on the scapular zone in such a way to ensure that each pair was placed on either side of the spine as follows:

GROUP 1 (control):

- 2 ID: Freund's Complete Adjuvant diluted at 50 % in physiological saline
- 2 ID: physiological saline
- 2 ID: a mixture with equal volumes of Freund's Complete Adjuvant at 50% and physiological saline

GROUP 2 (Treated):

- 2 ID: Freund's Complete Adjuvant diluted at 50 % in physiological saline
- 2 ID: test item at 10% in physiological saline
- 2 ID: a test mixture in equal volumes Freund's Complete Adjuvant at 50% and the test item at 20% in physiological saline

2nd Topical Induction:

Day 7

The scapular zone of all the animals in each group (shorn beforehand), was brushed with a solution of sodium lauryl sulfate at 10% in thick Vaseline®, to create local irritation.

Day 8

A topical application under occlusive dressing (25mm x 25mm non-woven swab of 4-layer gauze) in contact with the skin by means of 50 mm wide hypoallergenic adhesive tape for 48 hours was performed on the injection sites of each animal as follows:

GROUP 1 (control): 0.5 mL of distilled water

GROUP 2 (treated): 0.5 mL of the test item at 40% in distilled water

Day 10

The treated areas were rinsed with distilled water after the removal of the semi-occlusive dressing.

Rest phase

The animals of both groups were left for 10 days.

Challenge phase

Day 21

The experimental procedure of this phase was identical for both groups GROUP 1 (Control) and GROUP 2 (Treated). To the previously shorn dorso-lumbar zones, a 24-hour application, under occlusive dressing, was performed as follows:

- 1 sample cup containing the test item diluted at 40% (MNIC)
- 1 sample cup containing the test item diluted at 20% in distilled water (½ MNIC).

Day 22

The treated areas were rinsed with distilled water after the removal of the semi-occlusive dressing.

Day 23

1st reading time – 24 hours after the patch removal.

Day 24

2nd reading time – 48 hours after the patch removal.

7. Interpretation of results:

According to the scoring, the test item would be regarded as a skin sensitiser if 30% or more of the test animals show a sensitisation response. With regards to the current EU-based classification systems, the following classification and labelling requirements would be necessary for the test if it were concluded to be a skin sensitiser:

- In accordance with the Regulation (EC) No 1272/2008, the test item would be classified in Category 1. The signal word "Warning" and hazard statement H317 "May cause an allergic skin reaction" would be required.
- In accordance with the Regulation (EC) No. 286/2011, the test item would be classified in sub-category 1A or 1B as described below:

	Criteria
Sub-category 1A	≥ 30 % responding at ≤ 0.1 % intradermal induction dose or ≥ 60 % responding at > 0.1 % to ≤ 1 % intradermal induction dose
Sub-category 1B	≥ 30 % to < 60 % responding at > 0.1 % to ≤ 1 % intradermal induction dose or ≥ 30 % responding at > 1 % intradermal induction dose

II. RESULTS AND DISCUSSION

Preliminary studies

MNNC determination

24 hours after the injections, slight necrosis to moderate erythema was observed at the tested concentration of 20%. Moderate to discrete erythema was noted at the tested concentrations of 10%, 5% and 2% in all animals. Consequently, the first induction of Group 2 was performed (by intradermal injection) at the maximal non-necrotising concentration of 10% (see below).

Table 7.1.6-1 Macroscopic evaluation of cutaneous reactions

Injection	Animal No.	CONCENTRATIONS			
		20%#	10%	5%	2%
Intradermal injection	C8869	SINe	2	1	1
	C8870	2	2	1	1

#: Maximum concentration administrable by intradermal route

SINe: Slight necrosis

Grading scale
0....No visible change
1....Discrete or patchy erythema
2....Moderate and confluent erythema
3....Intense erythema and swelling

Maximal Non-Necrotising Concentration	10%

Pre MNIC determination

24 hours after the removal of the occlusive dressings, no cutaneous reactions were noted irrespective of the concentration tested. In view of these results, the concentration selected was 40% for the 2nd induction of Group 2 and the MNIC determination began at a concentration of 40%.

MNIC determination

24 and 48 hours after removal of the occlusive dressings, no cutaneous reactions were noted irrespective of the concentration tested. In view of these results, the concentrations selected were 40% (MNIC) and 20% (½ MNIC).

Main study

Induction phase Group 1

No cutaneous reaction was noted during the induction phase.

Induction phase Group 2

24 hours after the first induction, moderate erythema was noted in all animals (10/10). Discrete erythema associated with dryness of the skin was noted in all animals (10/10) 24 hours after the second induction.

Challenge phase Groups 1 & 2

The overall results of the challenge phase with the test item (readings at 24 and 48 hours) are presented below. In the treated group (treatment dose of 20%), no macroscopic cutaneous reactions attributable to skin sensitisation were noted after the challenge phase. In the concurrent control group, no macroscopic cutaneous intolerance reactions were recorded after the challenge phase. In the treated group (treatment dose of 40%), no macroscopic cutaneous reactions attributable to skin sensitisation were noted after the challenge phase. In the concurrent control group, no macroscopic cutaneous intolerance reactions were recorded after the challenge phase.

Table 7.1.6-2

Macroscopic evaluation of cutaneous reactions (readings at 24 and 48 hours)

Groups	Timepoint	Concentration	INCIDENCE				% of positive responses ≥1	% of animals sensitized #
			0	1	2	3		
Group 1 (Control)	24 h	40%	5	0	0	0	0%	N/A
	48 h	40%	5	0	0	0	0%	N/A
	24 h	20%	5	0	0	0	0%	N/A
	48 h	20%	5	0	0	0	0%	N/A
Group 2 (Treated)	24 h	40%	10	0	0	0	0%	0%
	48 h	40%	10	0	0	0	0%	0%
	24 h	20%	10	0	0	0	0%	0%
	48 h	20%	10	0	0	0	0%	0%

N/A: Not applicable

Grading scale
0.....No visible change
1.....Discrete or patchy erythema
2.....Moderate and confluent erythema
3.....Intense erythema and swelling

#A comparison of the intensities and persistence of reactions at the test item challenge sites in the test and control animals permits identification of sensitization reactions. If the test item at the maximum non-irritant concentration produces reactions in test group animals at the 24 or 48-hour readings, these reactions are attributed to skin sensitization. This pre-supposes that no similar reactions were observed in the test item challenge sites of any of the control group animals. If irritation is observed in the control group animals, only reactions in the test group animals that exceed the most severe reaction seen in the control group animals are attributed to skin sensitization. The number of test group animals showing skin reactions greater than the most severe reaction observed in the control group animals is expressed as a percentage of test group animals.

Body-weight measurements

No abnormality in bodyweight gain was recorded in either of the groups.

Mortality

There was no mortality during the study.

III. CONCLUSION

Under the experimental conditions of this study, aluminium silicate did not have the potential to induce skin sensitisation. No classification is warranted according to (EC) 1272/2008.

CP 7.1.7 Summary of Acute Toxicity

Parameter	Species	Result	Reference
Acute Oral LD_{50}	Rat	> 5000mg/kg	[redacted] (1997a)
Acute Oral LD_{50}	Rat	> 5000mg/kg	[redacted] (1997b)

Acute Dermal LD_{50}	Rat	> 5000mg/kg	[redacted] (1997)
Acute Inhalation LC_{50}	Rat	> 2.07 mg/l	[redacted] (1997a)
Acute Inhalation LC_{50}	Rat	> 2.18 mg/l	[redacted] (1997b)
Acute Skin Irritation	Rabbit	Non irritant	[redacted] (1997)
Acute Eye Irritation	Rabbit	Non irritant	[redacted] (1997)
Acute Eye Irritation	Rabbit	Non irritant	[redacted] (2000)
Skin sensitisation	Guinea pig	non-sensitising	[redacted] (2017)

Surround® WP Crop Protectant is nontoxic via the oral, dermal or inhalation route to rats.

Surround® WP Crop Protectant is not a dermal irritant nor is it a skin sensitiser.

Transient eye irritation was observed in the eye irritation studies; however, signs of irritation were below the classification threshold within 24 hours and reversible within 48 hours without signs of eye damage. Such findings indicate that Surround® WP Crop Protectant should not be classified as slightly irritant to eyes.

CP 7.1.8 Supplementary studies on the plant protection product

There is no requirement to submit any supplementary studies for Surround® WP Crop Protectant.

CP 7.1.9 Supplementary studies for combinations of plant protection product

It is not intended that Surround® WP Crop Protectant will be applied in combination with any other plant protection product(s) and therefore supplementary studies are not required.

CP 7.2 Data on Exposure

Table 7.2-1 Product information and toxicological reference values used for exposure assessment

Product name and code	SURROUND® WP CROP PROTECTANT
Formulation type	Wettable powder (WP)
Category	Insecticide
Active substance(s) (incl. content)	Aluminium silicate 950 g/kg
AOEL systemic	Based on its physical-chemical properties aluminium silicate does not hydrolyse in the digestive tract (regardless of pH) or in the skin and oral and dermal absorption are considered negligible. Therefore aluminium silicate is expected to be of low concern by the oral and dermal route of administration. Via the inhalation route, a potential for pneumoconiosis has been described for chronic inhalation of respirable aluminium silicate dust in occupational settings. The use of the workplace exposure limit (WEL)-time weighted average (TWA) of 2 mg/m^3 (8 hours; 1.25 m^3/hour; equivalent to ~~36.6~~ 20 mg/day) established for aluminium silicate for occupational settings is considered adequate in the absence of an adequate operator exposure level (AOEL) although this probably represents a conservative exposure estimate for an agricultural setting. A tolerated dose of ~~36.6~~ 20 mg/kg/day is equivalent to ~~0.61~~ 0.33 mg/kg bw/day (for a 60-kg person). Aluminium silicate is not acutely toxic and no acute AOEL (AAOEL) has to be defined.
Inhalation absorption	100%
Oral absorption	Negligible, based on its physico-chemical properties
Dermal absorption	Negligible, based on its physico-chemical properties

CP 7.2.1 Selection of critical use(s) and justification

The critical GAP used for the exposure assessment of the plant protection product is shown in Table 7.2.1-1 hereafter.

Table 7.2.1-1 Critical use and overall conclusion of exposure assessment

1	2	3	4	5	6	7	8	9	10			
Use-No.*	Crops and situation (e.g. growth stage of crop)	F, Fn, Fpn G, Gn, Gpn or I**	Application		Application rate		PHI (d)	Remarks: (e.g. safener/synergist (L/ha)) critical gap for operator, worker, resident or bystander exposure based on [Exposure model]	Acceptability of exposure assessment			
			Method / Kind (incl. application technique***	Max. number (min. interval between applications) a) per use b) per crop/ season	Max. application rate kg as/ha a) a.s. 1 b) a.s. 2	Water L/ha min / max			Operator	Worker	Residents	Bystander
1	Grapes	G	HCTM HCHH	a) 4 (7) b) 4 (7)	28.5	500 / 1000	0	[Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products; EFSA Journal 2014;12(10):3874]				

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

** F: professional field use, Fn: non-professional field use, Fpn: professional and non-professional field use, G: professional greenhouse use, Gn: non-professional greenhouse use, Gpn: professional and non-professional greenhouse use, I: indoor application

*** e.g. LC: low crops, HC: high crop, TM: tractor-mounted, HH: hand-held

Explanation for column 10 "Acceptability of exposure assessment"

A	Exposure acceptable without PPE / risk mitigation measures
R	Further refinement and / or risk mitigation measures required
N	Exposure not acceptable / evaluation not possible

Justification

The cGAP has been based upon a consideration of the maximum use rate (kg a.s/ha) and the minimum water volume (i.e. spray volume). Manual hand-held applications are covered by the tractor-mounted applications.

CP 7.2.2 Operator exposure

CP 7.2.2.1 Estimation of operator exposure

A summary of the exposure models used for estimation of operator exposure to the active substance aluminium silicate during application of SURROUND® WP CROP PROTECTANT according to the critical use is presented in Table 7.2.2.1-1. The outcomes of the estimations are presented in Table 7.2.2.1-2. Detailed calculations are in Appendix 1.

Table 7.2.2.1-1: Exposure models for intended uses

Critical use(s)	Grapes (max. 28.5 kg a.s./ha)
Model(s)	EFSA guidance document: "Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products". EFSA Journal 2014;12(10):3874[55 pp.].

Table 7.2.2.1-2: Estimated operator exposure

		Aluminium silicate	
Model data	**Level of PPE**	**Total absorbed dose (mg/kg/day)**	**% of tolerated dose**
Grapes – HCTM			
Application rate		28.5 kg a.s./ha	
EFSA calculator (AOEM; 75th percentile) Body weight: 60 kg	No PPE	0.221	~~36~~ 67
Grapes – HCHH (manual-hand held)			
Application rate		28.5 kg a.s./ha	
EFSA calculator (AOEM; 75th percentile) Body weight: 60 kg	No PPE	0.217	66
Grapes – HCTM (manual knapsack)			
Application rate		28.5 kg a.s./ha	
EFSA calculator (AOEM; 75th percentile) Body weight: 60 kg	No PPE	0.0297	9.0

No PPE: bare hands; the default clothing is work wear: arms, body and legs covered.

CP 7.2.2.2 Measurement of operator exposure

Since the operator exposure estimations carried out indicated that the tolerated dose will not be exceeded under conditions of intended uses and consideration of the above mentioned personal protective equipment (PPE), a study to provide measurements of operator exposure was not necessary and was therefore not performed.

CP 7.2.3 Bystander and resident exposure

CP 7.2.3.1 Estimation of bystander and resident exposure

Table 7.2.3.1-1 shows the exposure model used for estimation of resident and bystander exposure to aluminium silicate. The outcome of the estimation is presented in Table 7.2.3.1-2. Detailed calculations are in Appendix 1.

Table 7.2.3.1-1: Exposure models for intended uses

Critical use(s)	Grapes (max. 28.5 kg a.s./ha)
Model	EFSA guidance document: "Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products". EFSA Journal 2014;12(10):3874[55 pp.].

Table 7.2.3.1-2: Estimated resident exposure

		Aluminium silicate	
Model data		**Total absorbed dose (mg/kg bw/day)**	**% of the tolerated dose**
Tractor mounted air assisted spray application outdoors Buffer zone: 5 m Drift reduction technology: No DT_{50}: 30 days DFR: 3 µg/cm^2/kg a.s./ha Interval between treatments: 7 days			
Number of applications and application rate		4 applications, 28.5 kg a.s./ha	
Resident child Body weight: 10 kg	Drift (75th perc.)	0.00937	~~1.5~~ 2.8
	Vapour (75th perc.)	0.00107	~~0.18~~ 0.32
	Deposits (75th perc.)	-	-
	Re-entry (75th perc.)	-	-
	Sum (mean)	**0.00865**	**~~1.4~~ 2.6**
Resident adult Body weight: 60 kg	Drift (75th perc.)	0.00200	~~0.33~~ 0.60
	Vapour (75th perc.)	0.000230	~~0.038~~ 0.070
	Deposits (75th perc.)	-	-
	Re-entry (75th perc.)	-	-
	Sum (mean)	**0.00185**	**~~0.30~~ 0.56**

Pending development of a harmonised approach to the setting of an acute non-dietary reference dose, it is not considered appropriate to undertake acute non-dietary exposure assessments (i.e. those that might be incurred in a single day) using the upper estimates of exposure (i.e. 95th percentile values) as stated in the guidance. Until a method has been described for deriving the Acute Acceptable Operator Exposure Level (AAOEL), this will not be included in the risk assessment. For bystanders, this means that the risk of exposure to substances with the potential for acute effects is not calculated; the risk of long-term exposure to substances for bystanders is included in the assessment of risks for residents.

CP 7.2.3.2 Measurement of bystander and resident exposure

Since the resident and bystander exposure estimations carried out indicated that the tolerated dose for aluminium silicate will not be exceeded under conditions of intended uses and considering above mentioned risk mitigation measures, a study to provide measurements of resident/bystander exposure was not necessary and was therefore not performed.

CP 7.2.4 Worker exposure

Worker exposure can happen during vine hand harvesting. However, during such outdoor task, no inhalation exposure is expected and then the risk to workers is considered negligible.

An estimation or measurement of worker exposure is not deemed necessary.

CP 7.3 Dermal Absorption

Surround® WP Crop Protectant contains 95% kaolin. There is no demonstrable dermal absorption and kaolin is recognised as an inert mineral. The acute dermal LD_{50} is > 5000 mg/kg bw, clearly demonstrating no dermal toxicity and strongly suggesting that very little if any dermal penetration occurs. The EPA Biopesticides Fact Sheet on Kaolin[5] (100104) describes this material as:

"Exposure to kaolin is not expected to pose any health risks to people, including children and other sensitive populations. Kaolin has been extensively tested, and no evidence of toxicity to humans was detected. Human exposure occurs primarily through numerous non-pesticidal uses of kaolin. For example, the Food and Drug Administration (FDA) has approved kaolin as a packaging ingredient for dry foods, and as an anti-caking agent in foods. Toiletries such as toothpaste and antiperspirants contain kaolin, as do various cosmetics. In addition to being an active pesticide ingredient itself, kaolin is also an inert ingredient in other pesticide products. FDA has granted kaolin GRAS status (Generally Recognized as Safe) when used in human food."

Furthermore, Becker *et al* (2013)[6], in a safety assessment, that included kaolin, concluded that:

"Although no data were available on dermal penetration, the Panel considered that the charge properties and the large molecular weight of these clay-like ingredients would preclude significant dermal penetration. Because they are chemically inert, no metabolites are expected that would penetrate the skin."

In support of this the WHO (2005)[7] concluded that:

"There are no studies on the possible adverse effects of clay minerals upon direct skin contact; however, both bentonite and kaolin are used extensively in cosmetics, and the absence of reports of adverse effects indicates that these clays pose no important health hazards via the dermal route."

Overall the view that predominates is that aluminium silicate is unlikely to have significant dermal penetration in humans as clearly demonstrated by no toxicity or adverse effects after direct skin application.

[5] https://www3.epa.gov/pesticides/chem_search/reg_actions/registration/fs_PC-100104_01-Jun-99.pdf
[6] Becker, LC et al (2013). Safety Assessment of Ammonium Hectorites as Used in Cosmetics. International Journal of Toxicology 32(Supplement 4).
[7] WHO (2005). Bentonite, kaolin, and selected clay minerals. Environmental health criteria; 231

The EFSA (2017)[8] guidance document on dermal absorption suggests that in the absence of data that default values of 10% (concentrate) od 50% (dilution) could be used. However, for such an inert, inorganic, insoluble (either in water or organic solvents) material these defaults can be considered as overly conservative. The Monograph (2008) for aluminium silicate suggested that a value of 10% could be used, and indeed this value was used to calculate exposure in the UK POEM and German models for operator exposure. However, in the peer review of the pesticide risk assessment of the active substance aluminium silicate (SURROUND® WP)[9] (EFSA, 2012), dermal absorption was described as negligible. Furthermore, the RMS France, in their risk management report[10] on a WP formulation of kaolin (1000g/kg), concluded that *"Moreover, dermal penetration of aluminium silicate is negligible because of its physical-chemical properties."*

The conclusions from the EFSA and the RMS France, clearly indicate that even a dermal absorption value of 0% is appropriate.

CP 7.3.1 Justification for proposed values

The proposed values reflect the original EFSA conclusions[9]. Results of existing studies have been reinterpreted and based upon the outcome of the analysis no change in classification is required according to Regulation (EC) 1272/2008. Moreover, results of the new study provided ([redacted], 2017) confirm that status:

Summary (Annex IIA, point 5.10)	Value	Study	Safety factor
ADI ‡	No data available – not required	-	-
AOEL (mg/kg bw/day) ‡	No suitable data available to set an AOEL. Inhalation exposure limit (IEL) of 36.6 mg/day derived from the WEL-TWA value of 2 mg/m^3 (8 hours) based on a potential for pneumoconiosis after chronic inhalation exposure.	-	-
ARfD ‡	No data available – not required	-	-
Dermal absorption ‡ (Annex IIIA, point 7.3)	Negligible based on its physico-chemical properties		

[8] EFSA (2017). Guidance on dermal absorption. EFSA Journal 2017;15(6):4873.
[9] EFSA Journal 2012;10(2):2517
[10] REGISTRATION REPORT (2016). Part A, Risk Management, Sokalciarbo WP, Active Substance: aluminium silicate, 1000 g/kg. Zonal Rapporteur Member State: France. Date: 2016-12-13

CP 7.4 Available Toxicological Data Relating to Co-Formulants

CONFIDENTIAL information - data provided separately (Document J).

Appendix 1 Exposure calculations

A 1.1 Operator exposure calculations (KCP 7.2.2.1)

A 1.1.1 Calculations for aluminium silicate

The following tables are taken directly from the EFSA exposure calculator, which is associated with the EFSA "Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products". EFSA Journal 2014;12(10):3874[55 pp.].

As dermal absorption is considered to be negligible, absorption percentages in the EFSA calculator were filled as 0% for the concentrate and diluted product.

Table A 1: Estimation of operator exposure towards aluminium silicate (SURROUND® WP CROP PROTECTANT) according to EFSA guidance – grapes – vehicle-mounted

Operator exposure for SURROUND WP CROP PROTECTANT outdoor spray applications

Application rate of active substance	28.5 kg a.s./ha	*i_AppRate*
Assumed area treated	10 ha/day	*d_AreaTreated*
Amount of active substance applied	285 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0.00%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0.00%	*i_AbsorInuse*
Formulation type	Wettable powder, soluble powder	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Vehicle-mounted	
Season	not relevant	

	Exposure values	µg exposure/day mixed and loaded		Reference	Comment
		75th centile	95th centile		
Mixing and loading	Hands	1874663	7217517	AOEM	
	Body	4402548	1476497	AOEM	
	Head	35548	56699	AOEM	
	Protected hands (gloves)	35705	574572	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	160439	567107	AOEM	
	Protected head (hood and face shield)	571	3210	AOEM	
	Inhalation	11676	5595	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied		Reference	Comment
		75th centile	95th centile		
Application	Hands	379195	1777481	AOEM	No data available for a drift reduction scenario
	Body	2511336	14653618	AOEM	
	Head	330031	2025559	AOEM	
	Protected hands (gloves)	10028	262039	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	32765	64039	AOEM	
	Inhalation	1557	23562	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

	Without RPE/PPE
Longer term	
Total systemic exposure from mixing, loading and application (mg a.s./day)	13.2
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.221
% of RVNAS	67%

Table A 2: Estimation of operator exposure towards aluminium silicate (SURROUND® WP CROP PROTECTANT) according to EFSA guidance – grapes – manual-hand held

Operator exposure for SURROUND WP CROP PROTECTANT outdoor spray applications

Application rate of active substance	28.5 kg a.s./ha	*i_AppRate*
Assumed area treated	4 ha/day	*d_AreaTreated*
Amount of active substance applied	114 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0.00%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0.00%	*i_AbsorInuse*
Formulation type	Wettable powder, soluble powder	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Hand held	
Season	not relevant	

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	925928	3536141	AOEM	
	Body	2311959	1131389	AOEM	
	Head	14219	22680	AOEM	
	Protected hands (gloves)	19666	229829	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	71218	226843	AOEM	
	Protected head (hood and face shield)	228	1284	AOEM	
	Inhalation	8889	5474	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	142833	329650	AOEM	No data available for a drift reduction scenario
	Body	128990	186850	AOEM	
	Head	698	3875	AOEM	
	Protected hands (gloves)	2725	14152	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	4126	3071	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE
Longer term	
Total systemic exposure from mixing, loading and application (mg a.s./day)	13.0
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.217
% of RVNAS	66%

Table A 3: Estimation of operator exposure towards aluminium silicate (SURROUND® WP CROP PROTECTANT) according to EFSA guidance – grapes – manual-knapsack

Operator exposure for SURROUND WP CROP PROTECTANT outdoor spray applications

Application rate of active substance	28.5 kg a.s./ha	*i_AppRate*
Assumed area treated	1 ha/day	*d_AreaTreated*
Amount of active substance applied	28.5 kg a.s./day	*i_AmoutAS*
Dermal absorption of the product	0.00%	*i_AbsorpProduct*
Dermal absorption of in-use dilution	0.00%	*i_Absorinuse*
Formulation type	Wettable powder, soluble powder	
Indoor or Outdoor application	Outdoor	
Application method	Upward spraying	
Application equipment	Manual-Knapsack	
Season	not relevant	

	Exposure values	µg exposure/day mixed and loaded 75th centile	95th centile	Reference	Comment
Mixing and loading	Hands	180405	484158	AOEM	
	Body	15257	52953	AOEM	
	Head	95	209	AOEM	
	Protected hands (gloves)	342	3116	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	475	1957	AOEM	
	Protected head (hood and face shield)	95	209	AOEM	
	Inhalation	475	494	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Water soluble bag	No		1	

	Exposure values	µg exposure/day applied 75th centile	95th centile	Reference	Comment
Application	Hands	44807	114147	AOEM	No data available for a drift reduction scenario
	Body	103830	184441	AOEM	
	Head	447	2461	AOEM	
	Protected hands (gloves)	681	3538	AOEM	
	Protected body (workwear or protective garment and sturdy footwear)	1033	1938	AOEM	
	Inhalation	1304	1344	AOEM	
	Protective Equipment	Select for inclusion		Penetration factor	Inhalation Protection factor
	Gloves	No			
	Clothing	Work wear - arms, body and legs covered		Incl. in AOEM model	
	Head and respiratory PPE	None		1	1
	Closed cab	No		vehicle mounted upward spraying only	

1. Total

	Without RPE/PPE
Longer term	
Total systemic exposure from mixing, loading and application (mg a.s./day)	1.78
Total systemic exposure from mixing, loading and application per kg body weight (mg/kg bw/day)	0.0297
% of RVNAS	9.0%

A 1.2 Resident and bystander exposure calculations (KCP 7.2.3.1)

A 1.2.1 Calculations for Aluminium silicate

Estimation of bystander and residential exposure towards aluminium silicate (SURROUND® WP CROP PROTECTANT) has been calculated using the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products". EFSA Journal 2014;12(10):3874[55 pp.].

Among the initial four pathways of exposure, only spray drift (at the time of application) and vapour (which may occur after the PPP has been applied) are considered. Exposure to surface deposits and entry into treated crops are not retained as they do not happen via the inhalation route.

Pending development of a harmonised approach to the setting of an acute non-dietary reference dose, it is not considered appropriate to undertake acute non-dietary exposure assessments (i.e. those that might be incurred in a single day) using the upper estimates of exposure (i.e. 95th percentile values) as stated in the guidance. Until a method has been described for deriving the Acute Acceptable Operator Exposure Level (AAOEL), this will not be included in the risk assessment. For bystanders, this means that the risk of exposure to substances with the potential for acute effects is not calculated; the risk of long-term exposure to substances for bystanders is included in the assessment of risks for residents.
Aluminium silicate is not acutely toxic.

The following tables are taken directly from the EFSA exposure calculator which is associated with the EFSA Guidance document.

Table A 4: **Estimation of resident exposure towards aluminium silicate (SURROUND® WP CROP PROTECTANT) according to EFSA guidance**

Resident exposure for SURROUND WP CROP PROTECTANT			
Croptype	Grapes		
Application method	Upward spraying		
Application equipment	Vehicle-mounted		i_AppEquip
Formulation type	Wettable powder, soluble powder		i_FormVal
Buffer strip	5	m	i_Buffer
Application rate of the product	28.5	kg a.s./ha	i_AppRate
Concentration of active substance (in-use dilution for liquid applications)	57	g a.s./l	d_ConcAS
Dermal absorption of product	0.00%		i_AbsorpProduct
Dermal absorption of in-use dilution	0.00%		i_AbsorpInuse
Oral absorption	0.00%		i_AbsorpOralInuse
Dislodgeable foliar residue (i_AppRate*i_DFR)	85.5	µg a.s./cm²	d_DFR
Vapour pressure of in-use dilution	low volatile substances having a vapour pressure of <5*10-3Pa	Pa	i_Volat
Concentration in air	0.001	mg/m³	d_AirCon
Resident dermal spray drift exposure 75th percentile - adult	5.63	ml spray dilution/person	
Resident dermal spray drift exposure 75th percentile - child	1.689	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - adult	0.00210	ml spray dilution/person	
Resident inhal. spray drift exposure 75th percentile - child	0.00164	ml spray dilution/person	
Resident dermal spray drift exposure mean - adult	3.68	ml spray dilution/person	
Resident dermal spray drift exposure mean - child	1.11	ml spray dilution/person	
Resident inhal. spray drift exposure mean - adult	0.00170	ml spray dilution/person	
Resident inhal. spray drift exposure mean - child	0.00133	ml spray dilution/person	
Exposure duration dermal	2	hours	d_ReExpDur
Exposure duration inhalation	24	hours	d_ReExpDurInhal
Exposure duration entry into treated crops	0.25	hours	d_ExpDurTreatCrop
Light clothing adjustment factor	18.0%		d_ClothAF
Breathing rate adult	0.23	m³/day/kg	d_BreathRAd
Breathing rate child (1-3 year old)	1.07	m³/day/kg	d_BreathRCh
Drift percentage on surface (75th percentile)	3.07%		
Drift percentage on surface (mean)	2.32%		
Turf transferable residues percentage	5.00%		d_Turf
Transfer coeff. of surface deposits-adult	7300	cm²/hour	d_ReTCAd
Transfer coeff. of surface deposits-child (1-3 year old)	2600	cm²/hour	d_ReTCCh
Saliva extraction percentage	50.00%		d_SalExt
Surface area of hands mouthed	20	cm²	d_AreaHM
Frequency of hand to mouth activity	9.5	events/hour	d_ReFreqHM
Ingestion rate for mouthing of grass per day	25	cm²	d_MouthGrass
Dislodgeable residues percentage transferability for object to mouth	20.00%		d_DRP
Transfer coefficient for entry into treated crops (75th percentile) - ad	7500	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (75th percentile) - ch	2250	cm²/h	d_TcEntryCh
Transfer coefficient for entry into treated crops (mean) - adult	5980	cm²/h	d_TcEntryAd
Transfer coefficient for entry into treated crops (mean) - child	1794	cm²/h	d_TcEntryCh

1. Total

1.1 1-3 year old child

	Spray drift (75th percentile)	Vapour (75th percentile)	Surface deposits (75th percentile)	Entry into treated crops (75th percentile)	All pathways (mean)
Total systemic exposure (mg a.s./day)	**0.0937**	**0.0107**	-	-	**0.0865**
Total systemic exposure per kg body weight (mg/kg bw/day)	**0.00937**	**0.00107**	-	-	**0.00865**
% of RVNAS	~~**1.5%**~~ **2.8%**	~~**0.18%**~~ **0.32%**	-	-	~~**1.4%**~~ **2.6%**

1.2 Adult

	Spray drift	Vapour	Surface deposits	Entry into treated crops	All pathways (mean)
Total systemic exposure (mg a.s./day)	0.120	0.0138	-	-	0.111
Total systemic exposure per kg body weight (mg/kg bw/day)	0.00200	0.000230	-	-	0.00185
% of RVNAS	~~0.33%~~ 0.60%	~~0.038%~~ 0.070%	-	-	~~0.30%~~ 0.56%