

## **FINAL REPORT**

**STAPHYT study No. ChR-14-16340**

**DETERMINATION OF OPERATOR DERMAL EXPOSURE  
AND PROTECTIVE FACTORS PROVIDED BY PERSONAL PROTECTIVE  
EQUIPMENT AND WORKING COVERALL DURING MIXING/LOADING,  
FOLIAR APPLICATION AND SPRAYER CLEANING IN VINEYARDS**

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**Distribution of the report:**

1 original for STAPHYT archives  
1 electronic copy for the Sponsor representative

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## STATEMENT OF GLP COMPLIANCE

The study described in this report was performed in compliance with:

- ⇒ REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
- ⇒ OECD Series on Testing and Assessment No. 9 "Guidance document on the conduct of studies of occupational exposure to pesticides during agricultural application", Paris 1997.
- ⇒ EU pesticide residue legislation: Guidance Documents on Residue Analytical SANCO/3029/99 rev.4, 11 July 2000.
- ⇒ GLP Guidelines:
  - OECD Series on Principles of GLP and Compliance Monitoring No. 1 (revised) "OECD Principles on Good Laboratory Practice", Paris 1998.
  - OECD Series on Principles of GLP and Compliance Monitoring No. 6 (revised) "The application of GLP-Principles to Field Studies", Paris 1999.
  - OECD Series on Principles of GLP and Compliance Monitoring No. 13; "The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site", Paris 2002.
- ⇒ Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances..
- ⇒ In France: Article D523-8 du code de l'environnement du 16 octobre 2007 et son Annexe II – Principes de l'OCDE de Bonnes Pratiques de Laboratoire (BPL).

The national requirements are based on the OECD Principles of Good Laboratory Practice, which are accepted by regulatory authorities throughout the European Community, the United States of America (EPA and FDA) and Japan (MHW, MAFF and METI) on the basis of intergovernmental agreements.

This report is an accurate description of the procedures and practices employed during the study and a correct and faithful presentation of the findings.

The exceptions (non GLP data) are all data given by the farmers (pesticide history, cultural practices...), products used for application (no GLP certificate of analysis), weather data for operator 11, GPS references and photographs.

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STUDY DIRECTOR

---

Date

# STAPHYT GLP CERTIFICATE



Liberté - Égalité - Fraternité  
RÉPUBLIQUE FRANÇAISE

## GROUPE INTERMINISTÉRIEL DES PRODUITS CHIMIQUES

CERTIFICAT DE CONFORMITÉ AUX BONNES PRATIQUES DE LABORATOIRE  
SELON LES DIRECTIVES 2004/9/CE ET 2004/10/CE

CERTIFICATE OF COMPLIANCE WITH GOOD LABORATORY PRACTICES ACCORDING  
TO DIRECTIVES 2004/9/CE AND 2004/10/CE

Certificat n°: 2013/9

Société ou organisme : STAPHYT - 23 rue de Moeuvres - 62860 INCHY EN ARTOIS  
Company :

Installation d'essais : STAPHYT - 23 rue de Moeuvres - 62860 INCHY EN ARTOIS  
Test facilities :

Vu les articles D.523-8 et suivants du code de l'environnement relatifs au groupe interministériel des produits chimiques,

*Having regard to the articles D.523-8 and onwards relating to the interministerial group of chemical products (GIPC),*

Vu les résultats de l'inspection périodique réalisée par le Comité français d'accréditation (COFRAC) - Section Laboratoires - le : 27 et 28 novembre 2012

*Having regard to the results of the periodic inspection realised by the French Committee of accreditation (COFRAC) - Laboratory Section - on the : 27 and 28 November 2012*

Vu l'avis du GIPC en date du : 7 mars 2013  
*Having regard to the GIPC's opinion dated : 7 March 2013*

La conformité aux principes des BPL de l'installation précitée est reconnue dans les domaines suivants :  
*Compliance with the principles of GLP is recognized for the facility above in the following areas:*

- 5 - études portant sur le comportement dans l'eau, dans le sol et dans l'air ; bioaccumulation  
*(studies on behaviour in water, soil and air; bioaccumulation)*
- 6 - études portant sur les résidus *(residue studies)*
- 7 - études portant sur les effets, sur les mécosystèmes et les écosystèmes naturels  
*(studies on effects on mesocosms and natural ecosystems)*
- 9 - autres études à préciser *(others studies to specify)* :  
exposition opérateurs - transformation agro-alimentaire  
*operators exposure - food processing studies*

Fait à Ivry, le - 8 MARS 2013  
Le Président,

  
Jean-Marc GROGNET

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Secrétariat général du GIPC - DGCS- SI - 67, rue Barbès - 94201 Ivry-sur-Seine CEDEX  
Téléphone : 01 79 84 96 10 -  
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MINISTÈRE DU REDRESSEMENT  
PRODUCTIF

## QUALITY ASSURANCE STATEMENT

I, undersigned, \_\_\_\_\_ (Lead QA), hereby declare that the study ChR-14-16340 was inspected in accordance with the Good Laboratory Practice principles and confirm that this report reflects the raw data.

STAPHYT Quality Assurance Unit audited the Study Plan, field activities, raw data of the field phase, the Final Report and STAPHYT facility.

STAPHYT Quality Assurance Unit checked GLP organisations in order to ensure this organisation fulfils STAPHYT requirements by regards to multi-site organisation of the study.

Findings were reported to the Study Director and to STAPHYT Management. The dates on which inspections were made and the dates on which the findings were reported are given in the table below.

Analytical laboratory Quality Assurance Unit inspected the analytical phase plan, the activities (Process audits), the raw data and the report of the analytical phase. The statement of Quality Assurance Unit is included in the report of the analytical phase (see Appendix "Analytical phase report").

		Date of QA inspection reported to or signed by:			
Type of inspection	Inspection date	Study Director	Test facility manager	Field principal investigator	Lead QA
Draft Study Plan	15/07/2013	15/07/2013	15/07/2013	NR	15/07/2013
Study Plan	19/07/2013	19/07/2013	19/07/2013	NR	19/07/2013
Critical phase (sampling)	08/08/2013	22/08/2013	22/08/2013	22/08/2013	22/08/2013
Raw data (1 <sup>st</sup> inspection)	14/01/2014	14/01/2014	14/01/2014	14/01/2014	14/01/2014
Raw data (last inspection)	12/03/2014	12/03/2014	12/03/2014	12/03/2014	12/03/2014
Draft Final Report	05-06/02/2014	06/02/2014	06/02/2014	NR	06/02/2014
Final Report	13/03/2014	13/03/2014	13/03/2014	NR	13/03/2014
STAPHYT SE34 Facility and records	26/03/2013	13/05/2013	13/05/2013	13/05/2013	13/05/2013
STAPHYT SE37 Facility and records	13-14/03/2012	15/05/2012	27/03/2012	15/05/2012	28/03/2012
Eurofins Agrosience Services Chem SAS (Questionnaire)	09/12/2013	11/12/2013	11/12/2013	11/12/2013	11/12/2013

Date

LEAD QUALITY ASSURANCE

## ORGANISATIONS AND PERSONNEL INVOLVED IN THE STUDY

**SPONSOR** : ANSES  
27-31, avenue du General Leclerc  
94701 Maisons-Alfort Cedex - France

SPONSOR REPRESENTATIVE AND : ANSES  
SPONSOR MONITOR

TEST FACILITY AND FIELD STAFF : STAPHYT  
23 rue de Moeuvres  
62860 Inchy-en-Artois - France

TEST FACILITY MANAGER : STAPHYT  
La Paluzette, Route des Mas  
34590 Marsillargues - France

STUDY DIRECTOR

PRINCIPAL INVESTIGATOR FOR FIELD  
PHASE

**LEAD QA AND QA FOR FIELD PHASE** :

**STAPHYT**  
**La Paluzette, Route des Mas**  
**34590 Marsillargues – France**

## FIELD MONITORS



<u>FIELD AND TRAVEL FORTIFICATION</u>	:	_____
<u>OFFICER</u>	:	STAPHYT La Paluzette, Route des Mas 34590 Marsillargues - France
<u>ANALYTICAL TEST SITE</u>	:	Eurofins Agrosience Services Chem SAS 75 chemin de Sommières 30310 Vergèze - France
<u>TEST SITE MANAGER</u>	:	_____
<u>PRINCIPAL INVESTIGATOR FOR</u>	:	_____
<u>ANALYTICAL PHASE</u>	:	Eurofins Agrosience Services Chem SAS
<u>DEPUTY PRINCIPAL INVESTIGATOR FOR</u>	:	_____
<u>ANALYTICAL PHASE</u>	:	Eurofins Agrosience Services Chem SAS
<u>ANALYTICAL TEST SITE QA</u>	:	_____
	:	Eurofins Agrosience Services Chem SAS

This is to confirm that the personnel listed above conducted their responsibilities and all procedures in accordance with the Study Plan and followed relevant SOP's during the study described.

## ABBREVIATIONS AND SYMBOLS

ADE :	actual dermal exposure
AHE :	actual hand exposure
Appl. :	application
a.s. :	active substance
A.M. :	arithmetic mean
ASD :	arithmetic standard deviation
BLD :	below limit of detection
BLQ :	below limit of quantification
Clean.:	cleaning phase
CV :	coefficient of variation (i.e. ASD/A.M.) expressed as a percentage
G.M. :	geometric mean
GPS :	Global Positioning System
GSD :	geometric standard deviation
LOD :	limit of detection
LOQ :	limit of quantification
Min. :	minimum
Max. :	maximum
M/L :	mixing/loading
No. :	number
Op. :	operator
PDE :	potential dermal exposure
PHE :	potential hand exposure
RSD :	relative standard deviation

## GENERAL INFORMATION

- **Objectives of the study**

The study was conducted with a spinosad-based formulation applied for treatment of various crops including vineyards to generate exposure data for professional operators in agriculture and to determine protection factors provided by personal protective equipment and working coverall under representative conditions.

This was achieved by determination of dermal exposure (using passive dosimetry) to spinosad during mixing/loading, application and sprayer cleaning (in most cases) in vineyards.

- **Study Schedule**

Activity	Date
Study Initiation	July 19, 2013
Amendment 1 approval by Study Director	July 26, 2013
Field phase part	August 9 to 20, 2013
Analytical experimental part	September 6 to October 25, 2013

- **Archiving**

The study data file, i.e. the final report and any amendment, the original of the study plan and amendment, all field study raw data, will be archived at STAPHYT, Inchy-en-Artois, France for at least 10 years, after which time no study specific archived material will be disposed of without prior written consent of the sponsor.

The analytical raw data generated by the analytical test site will be archived for at least 15 years at Eurofins ADME Bioanalyses, Codognan, France.

At the end of the retention period, the sponsor will be asked whether these documents should be discarded, retained for an additional period, or transferred to the archives of the sponsor.

## SUMMARY

This report describes the results of a study carried out in France in August 2013 to assess operator exposure likely to arise under the specific proposed conditions of use in France. This was achieved by determination of dermal exposure (using passive dosimetry) to spinosad during mixing/loading, application and sprayer cleaning (in most cases) in vineyards. The protection factors afforded by personal protective equipment and working coverall were studied under those representative conditions.

Application of a suspension concentrate spinosad-based formulation was performed using a vehicle-mounted/trailed broadcast air-assisted sprayer.

Study involved fifteen male farmers or farm employees in thirteen vine growing farms located in the South of France: in Pyrenees Orientales (Department 66), in Herault (Department 34) and in Aude (Department 11).

The main tasks performed by the operators were mixing/loading and application. Ten operators also cleaned the application equipment at the end of the working day.

The product was used at ca. 50 g/ha, under a volume of 96 to 213 L/ha. The main mixing/loading and application parameters (A.M., Min. and Max.) are summarised hereafter:

Mean concentration of a.s. in the spray:	0.377 g/L (from 0.240 to 0.747 g/L)
Mean duration of one M/L phase:	11 min/phase (from 2 to 21 min)
Mean volume of spray applied :	1605 L/applicator (from 880 to 3200 L)
Mean amount of a.s. applied:	581 g/applicator (from 288 to 1200 g)
Mean application rate:	144 L/ha (from 96 to 213 L/ha)
Mean duration of application (incl. cleaning):	294 min (from 178 to 442 min)
Mean duration of cleaning:	20 min (from 4 to 46 min)
Mean treated surface area:	11 ha (from 6 to 24 ha)

Dermal exposure was measured by analysis of the residues collected on the clothing (whole-body dosimetry method). Washing procedures were also performed to monitor the exposure of hands and face/neck.

Inhalation exposure was not monitored as it was out of the scope of the study and considered to be a minor source of exposure when compared to dermal exposure under the conditions of the study.

The body dosimeters consisted of:

- An outer layer of clothes:
  - o a water-repellent polyester/cotton (65/35) coverall 280 g/m<sup>2</sup>;
  - o a Category III Type 3 Partial Body gown worn over the above polyester/cotton coverall during the mixing/loading phase or during the cleaning phase. Two distinct gowns were worn during mixing/loading and cleaning.
- An inner layer of clothes: a full-length cotton undergarment (covering arms, legs and torso) worn below the polyester/cotton coverall.

The others dosimeters and samples allowed the measurement of the residue levels separately during mixing/loading and application. They were:

- Protective nitrile gloves satisfying the EN 374-3 Standard (to measure potential hand exposure);
- Hand washes (to measure actual hand exposure);
- Face/neck wipes (to measure head exposure).

The sampling was performed according to specific Standard Operating Procedures. Spinosad residues were determined by liquid chromatography with MS/MS detection (LC-MS/MS) according to analytical methods developed and validated at Eurofins Agrosience Services Chem SAS using spiked samples. The mean field recoveries were within the limit of acceptance (70 – 120%) and the relative standard deviation (RSD) was below 20% at each fortification level for all matrices.

The potential dermal exposure (PDE) was mainly collected by the gown worn during the mixing/loading phase (36% of PDE), followed by the coverall (24.9%) and the gown worn during the cleaning phase (15.4%).

The gloves and hand washes respectively collected ca. 21% and 1.9% of the potential dermal exposure (A.M.). Glove/hand exposure during application and cleaning (if any) was higher than during mixing/loading. Actual hand exposure represented 85% of total actual dermal exposure (A.M.).

The results obtained during the study are summarized hereafter.

**Rates of Exposure:**

Type of exposure	Exposure (µg/day)					
	Potential dermal without hands *	Actual dermal without hands **	Potential hand #	Actual hand ##	Potential dermal \$	Actual dermal \$\$
A.M.	6 428	32.5	2 039	153	8 467	186
ASD	6 486	46.7	2 036	177	7 442	187
G.M.	3 891	11.9	1 309	104	5 570	133
GSD	2.9	5.4	2.8	2.3	2.7	2.2
Min.	994	0.650	227	37.3	1 358	39.4
50 <sup>th</sup> centile	3 532	18.5	1 167	89.6	5 452	96.8
75 <sup>th</sup> centile	9 741	46.6	2 852	102	12 306	198
95 <sup>th</sup> centile	18 211	100	5 092	523	21 828	577
Max.	20 167	183	8 129	665	23 381	694
No. replicates	15	15	15	15	15	15

\*: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes

\*\*: underwear + all face/neck wipes

#: gloves + hand washes

##: hand washes

\$: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes + gloves + hand washes

\$\$: underwear + all face/neck wipes + hand washes

Type of exposure	Exposure (µg/kg a.s. applied)					
	Potential dermal without hands *	Actual dermal without hands **	Potential hand #	Actual hand ##	Potential dermal \$	Actual dermal \$\$
A.M.	11 855	62.4	4 180	286	16 035	348
ASD	12 152	84.4	5 695	340	14 407	354
G.M.	7 096	21.7	2 387	189	10 157	242
GSD	3.2	5.6	3.0	2.4	2.8	2.4
Min.	1 827	1.35	473	31.1	2 358	51.3
50 <sup>th</sup> centile	5 640	20.2	3 034	169	8 261	202
75 <sup>th</sup> centile	19 066	83.2	3 925	236	26 722	447
95 <sup>th</sup> centile	32 675	209	11 732	814	38 179	888
Max.	41 358	305	23 522	1 386	44 965	1 445
No. replicates	15	15	15	15	15	15

\*: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes

\*\*: underwear + all face/neck wipes

#: gloves + hand washes

##: hand washes

\$: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes + gloves + hand washes

\$\$: underwear + all face/neck wipes + hand washes

Type of exposure	Exposure ( $\mu\text{g/kg bw}$ )					
	Potential dermal without hands *	Actual dermal without hands **	Potential hand #	Actual hand ##	Potential dermal \$	Actual dermal \$\$
A.M.	89.3	0.489	28.6	1.93	118	2.42
ASD	94.7	0.833	30.9	2.03	111	2.27
G.M.	51.5	0.157	17.3	1.37	73.7	1.75
GSD	3.1	5.7	3.0	2.2	2.9	2.2
Min.	10.5	0.00722	3.06	0.497	13.6	0.563
50 <sup>th</sup> centile	51.2	0.247	14.8	1.19	73.7	1.33
75 <sup>th</sup> centile	136	0.671	36.9	1.68	178	2.74
95 <sup>th</sup> centile	255	1.51	84.1	6.02	301	6.64
Max.	316	3.33	120	7.82	385	8.16
No. replicates	15	15	15	15	15	15

\*: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes

\*\* : underwear + all face/neck wipes

#: gloves + hand washes

##: hand washes

\$: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes + gloves + hand washes

\$\$: underwear + all face/neck wipes + hand washes

The individual protection equipment the operators were wearing during the study included a pair of nitrile gloves satisfying EN-374-3 Standard and a category III Type 3 Partial Body gown. That equipment was not worn all the working day long and then no transfer factor was calculated via them. Actually, gloves were not worn during application except if maintenance/repair of the application equipment was necessary and no gown was worn during application.

The body was protected by a water-repellent polyester/cotton coverall (corresponding to usual work clothes) which was worn over the whole working day. The body protection afforded by the coverall was 98.5% (75<sup>th</sup> percentile) and 94.9% (95<sup>th</sup> percentile). When considering the combined protection afforded by this coverall and a gown (when recommended during the mixing/loading phase and possible cleaning phase) the protection level increased to 99.5% (75<sup>th</sup> percentile) and 98.7% (95<sup>th</sup> percentile).

Transfer via gloves was calculated only for operators 5, 6 and 10 during mixing/loading (0.37%, 0.24% and 0.41%, respectively). Actually, there were no other operators who used a pair of gloves once only and for whom indirect contamination could be excluded. Calculation of a protective factor for gloves was considered irrelevant under the conditions of the study even if the afforded protection was obvious.

## 1. INTRODUCTION

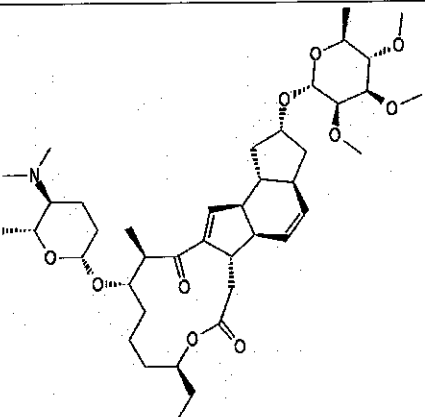
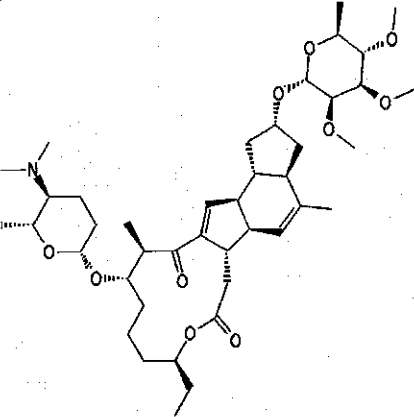
The objective of this study was to determine dermal exposure (using passive dosimetry) of operators to spinosad during mixing/loading, application of SUCCESS 4 and sprayer cleaning (in most cases). This formulation is an insecticide suspension concentrate formulation containing 480 g spinosad/L which is applied in vineyards using airblast sprayer equipment.

The study was conducted in France in August 2013 to generate data for professional operators in agriculture and to determine protection factors provided by personal protective equipment and working coverall under representative conditions.

## 2. MATERIALS

### 2.1 TEST ITEM

Test item name :	<b>SUCCESS 4</b>
Active substance common name (ISO):	<b>Spinosad</b>
Active substance chemical name (IUPAC):	Spinosyn A and Spinosyn D
CAS No.:	168316-95-8 (mixture)

Spinosyn A	Spinosyn D
	

### 2.2 REFERENCE ITEM

Reference item name:	<b>Mixture of Spinosyn A and Spinosyn D</b>
Provider :	CiL
Batch number :	91029
Purity :	94 %
Expiry date :	26 Nov 2013

The reference item was used for the analytical phase.



### 2.3 TEST FORMULATION

Test formulation name:	SUCCESS 4 or MUSDO 4
Main uses:	Insecticide
Formulation type:	SC
Batch numbers:	There were several batch numbers (registered in the study raw data) as the products were obtained from local suppliers
Test item:	Spinosad
Common name (ISO)	Spinosad, a mixture of 50-95% spinosyn A and 5-50% spinosyn D
Nominal content (g/L):	480

Information pertaining to the identity, characteristics, and storage of test and reference items and test formulation used during the conduct of the study are kept in the raw data. Information related to the reference (analytical standard) item is given in Appendix D (Analytical report). This information is under the responsibility of the manufacturer.

No certificate of analysis is available for each of the commercial batches of SUCCESS 4 / MUSDO 4 used in the field or in the analytical test site. Those commercial batches have to meet the specification requirements for the formulation and then the nominal content is considered. For analytical purposes, the content of the test item (formulation which was used diluted for field fortification of all the matrices) was measured against a calibration curve (built using specimens prepared from the reference item).

A copy of the SUCCESS 4 Safety Data Sheet and of the SUCCESS 4 and MUSDO 4 product labels are included in the study raw data. Label safety requirements were explained to the operators.

### 2.4 TEST SYSTEM

The test system included the persons and the passive dosimetry equipment they were wearing, i.e. operators preparing and applying the formulation SUCCESS 4 and eventually cleaning the application equipment.

Conditions and practices of preparation, application and cleaning were representative of usually encountered conditions during professional insecticide applications in vineyards using an airblast sprayer.

### **3. METHODS**

#### **3.1. FIELD PHASE**

##### **3.1.1. Operators**

Fifteen male operators who were either farmer or farm employees were monitored in the study. All operators acted as mixer/loader and applicator and ten among them acted also as cleaner (of the application equipment).

Before the start of the study the purpose and procedures were fully explained to each operator both orally and signing on a consent form. They were told that they were under no obligation to participate and could withdraw at any time. The consent forms were signed by each subject and counter signed by the field principal investigator.

Each operator was monitored throughout a typical working day. In order to maintain confidentiality in the final report, a unique identity number was allocated to each operator.

Observations were recorded throughout the period of time when the operators perform their tasks. Any specific occurrences that could have affected exposure were noted on the observation forms. Photographic records were taken to document operator tasks being performed during monitoring.

##### **3.1.2. Exposure monitoring techniques**

Dermal exposure to spinosad was measured by operators wearing standardised whole-body dosimeters. The specifications of the dosimeters used in the study are documented in the study raw data and a summary is presented in Table 4.

The body dosimeters consisted of:

- Outer layer of clothes:
  - o a water-repellent polyester/cotton (65/35) coverall 280 g/m<sup>2</sup>;
  - o a Category III Type 3 Partial Body gown worn over the above polyester/cotton coverall during the mixing/loading phase or during the cleaning phase. Two distinct gowns were worn during mixing/loading and cleaning.
- Inner layer of clothes: a full-length cotton undergarment (covering arms, legs and torso) worn below the polyester/cotton coverall.

The others dosimeters and samples allowed the measurement of the residue levels separately during mixing/loading and application. They were:

- Protective nitrile gloves satisfying the EN 374-3 Standard (to measure potential hand exposure);
- Hand washes (to measure actual hand exposure);

- Face/neck wipes (to measure head exposure).

The shoes operators were wearing during their work were work shoes, sports shoes, mountain shoes, leather boots...; only one operator (No. 4) wore wellies (over the coverall legs) during the cleaning phase. The bottom legs of the undergarment were then always placed just below the bottom legs of the polyester/cotton coverall.

The dosimeters acted as collection media for the test substance. They were worn throughout the period of monitoring and were removed at the end of each phase (when necessary, e.g. for gown or gloves), with the possible assistance of a member of the monitoring team. Generally, except for the first taking on of the gown (when the field monitor supplied some help), the operator took off the gown alone. When he had to use the same gown again (in case of a second mixing/loading phase), the operator handled it without help. The gown used during mixing/loading was stored close to the site where this task was done or in the field monitor car (in a bag); details are kept in the raw data and reported when necessary. There was no real break during the monitoring period (no lunch) and then no need for intermediate and inner cloth taking off before the end of the working day.

At the end of the monitoring period, the **body dosimeters** were sectioned in 2 parts (gown) or 3 parts (coverall and undergarment).

**Hand exposure** was assessed by the **hand wash procedure**. Operators washed their hands in an appropriate detergent solution (0.01% dioctyl sulfosuccinate sodium solution

Hands were washed just prior to beginning the work activity; this hand wash was discarded. Hand washes were conducted at times when the operator would have normally washed his hands for reasons such as eating, using the toilet, etc... and at the end of each working phase (after each mixing/loading phase, after each application phase and each cleaning phase of the sprayer).

**Protective gloves** were worn by all operators during mixing/loading, maintenance/repair activities during application and during cleaning at the end of the working day (if any). One pair (at least) was dedicated to the mixing/loading task and one pair (at least) was be dedicated to the application and/or cleaning tasks.

Exposure of the **head** was assessed by **face/neck wipes** (2 gauze pads each moistened with 4 mL of the same detergent solution as this used for hand wash).

The operators were allowed to wear a headgear. This was carefully noted and reported in the field observations (Table 8).

The sectioned clothes, face/neck wipes, gloves and hand wash specimens were placed in temporary frozen storage as soon as possible for shipment to the analytical facility. Specimens were maintained in frozen storage until analysis.

### 3.1.3. Sampling, storage and shipping

#### 3.1.3.1 Sampling procedure

[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]
[REDACTED]	[REDACTED]	[REDACTED]

### 3.1.3.2. Storage and shipping

The specimen storage and transport conditions were deep frozen in a deep freezer (at approximately  $\leq -18^{\circ}\text{C}$ ) in the field test site and at the analytical test site or in dry ice (e.g. for shipment from field test site to the analytical test site). The temperature in the deep freezer was monitored at regular intervals and noted in the raw data during the freezer storage.

### 3.1.4. Field fortifications

#### 3.1.4.1. Field fortification solutions

Fortification solutions prepared from the test item were used to fortify the coverall, gown and underwear materials, protective gloves, hand wash solutions and face/neck wipes. The fortification stock solutions were prepared under the supervision of the Analytical Principal Investigator and shipped to the Field Principal Investigator for field recovery evaluation. A reserve sample of each solution was maintained at the analytical laboratory.

Fortification solutions were stored in a fridge (target 4°C, between 0 and 9°C). Min/max temperatures were recorded during storage. The actual storage details are recorded in the analytical raw data. Preparation of all stock and serially diluted solutions are also

documented in the analytical raw data. The stability of the field fortification solutions was checked by the analytical laboratory.

### 3.1.4.2. Field fortification

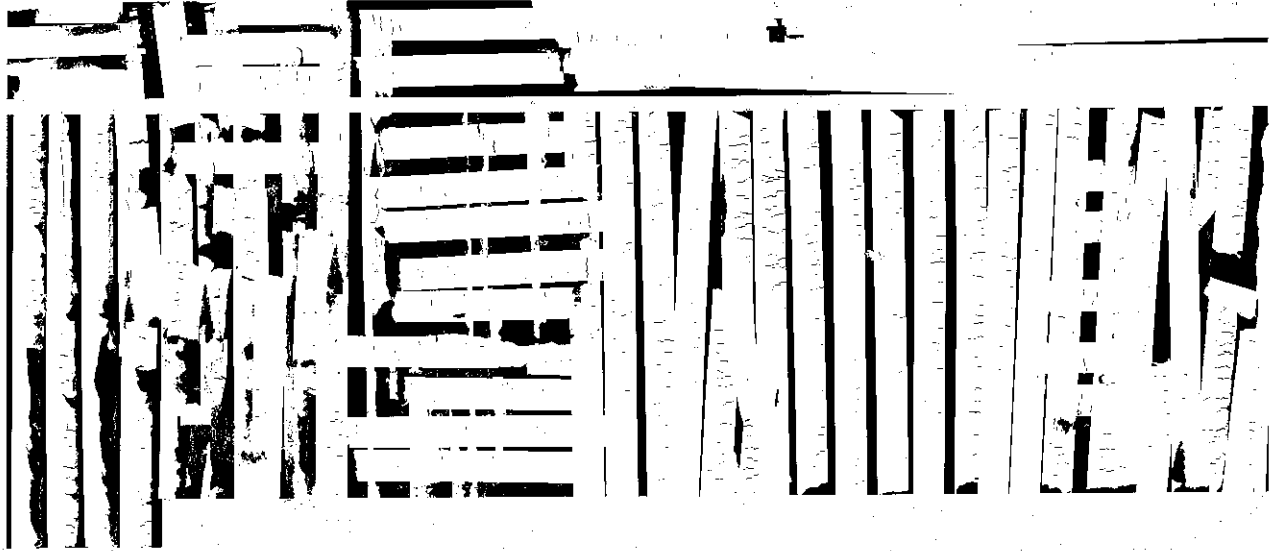
On each day of operator monitoring, field fortification specimens of each matrix to be sampled were performed to show the stability of the active substance on specimens under field, storage and transit conditions.

**Table B: Limits of quantification for each matrix**

$\mu\text{g}/\text{specimen}$	Coverall (Polyester/cotton)	Gown	Undergarment (Cotton)	Gloves (nitrile)	Face/neck wipes	Hand wash
				(1 pair)	(2 gauze pads)	(1000 mL)
spinosad	5	5	0.5	10	0.25	0.5

The fortified whole-body dosimeter specimens were kept at ambient conditions for the full exposure monitoring period at a location that did not allow contamination. Pieces of coverall, gown and protective gloves were left uncovered during exposure to ambient conditions. Undergarment specimens were covered with a single layer of coverall material during exposure to ambient conditions.

Face/neck wipe specimens and hand wash specimens were fortified at any time during the exposure monitoring period. Then the hand wash bottles were closed and the face/neck wipe specimens were wrapped in aluminium foil and kept under ambient conditions for approximately four hours after fortification. Then, they were stored frozen.



Packaging, storage and shipment of the field fortified specimens were the same as for the field operator specimens.

### 3.2. ANALYTICAL PHASE

The objectives of the analytical phase of this study were:

- To determine residual concentrations of spinosad in specimens of the matrices fortified with known concentrations of spinosad and to establish their stability under field, storage and transit conditions: *field fortifications*.
- To determine residual concentrations of spinosad in specimens of poly/cotton coveralls, gowns, inner dosimeters, and protective gloves and to determine residual concentrations in face wipes and hand wash solutions: *operator samples*.

#### 3.2.1. Specimen handling

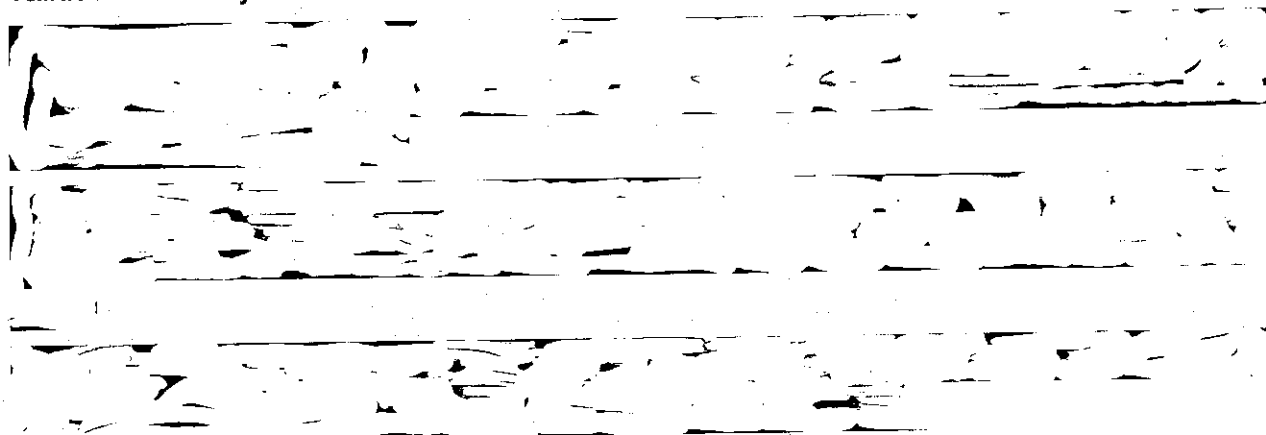
Specimens arrived at the analytical laboratory in good conditions.

Details of the chain of custody records for specimens are kept in the raw data.

All samples generated from the field phase of the study were stored frozen (ca. -18°C) on receipt at the Eurofins Agrosience Services Chem SAS analytical laboratory.

### 3.2.2. Analytical method

All specimens were analysed using the Eurofins Agrosience Services Chem SAS method validated in study S13-03456 for all matrices.



Finally, spinosad residues present in the extracts were quantified by LC-MS/MS.

### 3.3. CALCULATIONS

#### 3.3.1. Exposure calculations

- *Potential dermal exposure (PDE) excluding hands* is the sum of exposure on whole-body dosimeters (polyester/cotton coverall, gowns and undergarment) and face/neck washes over all the work phases.
- *Actual dermal exposure (ADE) excluding hands* is the sum of exposure on undergarment and face/neck washes over all the work phases.
- *Potential hand exposure (PHE)* is the sum of exposure on protective gloves and hand washes. It can be calculated over all the work phases but also separately during mixing/loading and application (and cleaning if any).
- *Actual hand exposure (AHE)* is the exposure as determined by hand wash. It can be calculated over all the work phases but also separately during mixing/loading and application.

The graphs presented in section 4 – Results (i.e. exposure distribution), represent graphically the exposure found in/on the different dosimeters.

Transfer (TF) via clothes and protective equipment:

$$\text{TF coverall (\%)} = \frac{(\text{residues undergarment } (\mu\text{g}))}{(\text{residues undergarment } (\mu\text{g}) + \text{residues coverall } (\mu\text{g}))}$$

$$\text{TF coverall \& gown (\%)} = \frac{(\text{residues undergarment } (\mu\text{g}))}{(\text{residues undergarment } (\mu\text{g}) + \text{residues coverall } (\mu\text{g}) + \text{residues gown } (\mu\text{g}))}$$



$\text{TF gloves (\%)} = \frac{(\text{residues hand washes } (\mu\text{g}))}{(\text{residues gloves } (\mu\text{g}) + \text{residues hand washes } (\mu\text{g}))}$
---

Average transfer factor is the arithmetic mean of individual transfer factors.

The exposure expressed as  $\mu\text{g}/\text{specimen}$  corresponds to the exposure occurring over the day for a given task.

The BLQ and BLD values were replaced respectively by  $\frac{1}{2}$  LOQ and  $\frac{1}{2}$  LOD for calculations.

The results obtained for operator's specimens were corrected by the mean recoveries obtained for the respective mean field spiked specimens if  $<95\%$ . For exposure values between two fortification levels, the correction was done with the nearest recovery value on both sides of a limit defined as the geometric mean of the two fortification levels. When the mean field recoveries were higher or equal to  $95\%$ , no correction was done. BLQ/BLD values were not corrected for field recoveries.

### 3.3.2. Statistical methods

Results were presented with arithmetic and geometric means (A.M. and G.M.), standard deviations (ASD and GSD), Min., Max. and 50th, 75th, 95th percentiles. All were calculated by means of Excel 2010 functions.

Geometric standard deviation (GSD) was calculated using several Excel 2010 functions. GSD is a unit less value and, as such, allows the comparison of the dispersion of several distributions and to evaluate the effect of different types of normalisation on the decrease of dispersion.

For laboratory and field fortification recoveries, the overall means, arithmetic standard deviations, minimum, maximum and Coefficients of Variation (CV) were calculated for each matrix and fortification level.

## 4. RESULTS

### 4.1. FIELD PHASE

#### 4.1.1. Operators

*Details on operators are given in Table 1.*

The operators involved in the study were male farmers or farm employees who were experienced in mixing/loading and application in vineyards.

The bodyweight of the operators was between 55 and 100 kg (arithmetic mean = 76 kg). Their height ranged from 163 to 187 cm and their age was in the range 22-71 years.

The last application of a spinosad-based formulation was variable: operators 1, 3, 5 and 15 had treated on the day before, operators 2, 7 to 14 had treated at least 3 weeks before and the remaining operators had treated 3 days (Op. 4) or one week (Op. 6) before the monitoring day.

*Note: the application equipment of operator 9 had been used by another person for a spinosad-based formulation treatment on the day before.*

#### 4.1.2. Study location

*Details of the locations are recorded in the study raw data and summarized in Table 2.*

Study took place with thirteen vine growing farms located in the South of France: in Pyrenees Orientales (Department 66), in Herault (Department 34) and in Aude (Department 11).

#### 4.1.3. Environmental monitoring

*Full details are given in Table 3.*

Air temperature and relative humidity were monitored at approximately two to four hour intervals at each site during each day of treatment, except on the site where operator 11 was monitored. Actually, there were more operators monitored on this day than initially planned and there was not enough weather monitoring equipment available for each one. Public weather conditions were then obtained from Lezignan station which was 8 km from the treated fields.

The air temperature ranged from 16.5 to 35.8°C. The relative humidity ranged from 21 to 80% over all sites. The lowest temperature and the highest relative humidity were respectively registered for operator 2 on the 12<sup>th</sup> of August 2013 at 06:57 a.m. and for operator 10 on the 20<sup>th</sup> of August 2013 at 07:24 a.m.

On several occasions, a wind speed higher than 3 m/sec was registered during field monitoring. During those summer days in this region, the wind is usually blowing. The farmers often have no other choice than working nevertheless. Actually the development stage of the butterfly to treat is decision leading. On each day and each site, the farmer (or farm employee) who had been recruited was the only one to decide if he would treat or not. All operators who experienced wind chose to treat when the field team asked them if it was relevant. The wind speed was sometimes also registered in the row at the vine level (e.g. operators 7, 9 ...) where it was lower than on the vineyard border. Spray drift might

have occurred but as the main objective of the study was to evaluate protective factors, it is not considered to have impaired the study results. Treatment efficacy and environmental secondary effects were not the purpose of the study.

#### **4.1.4. Description of the monitored tasks**

Two main tasks were defined: mixing/loading and application. In addition, 10 operators cleaned the application equipment at the end of the working day. This cleaning could be a quick rinse of the inside of the tank (dilution in the field and then rinse in the farm) as e.g. for operator 1 to a cleaning of the inside/outside of the tank, outside of the tractor, using a brush/broom and a cleaning agent as e.g. for operator 4. Details are given in Table 8 (Field observations).

#### **4.1.5. Mixing/loading parameters**

*Details on mixing/loading parameters are presented in Table 6.*

Operators either did one mix/load (Op. 5, 6, 10 and 12) or two mix/loads.

Mean amount of a.s. mixed: 578 g/operator (from 288 to 1200 g)

Mean concentration of a.s. in the spray: 0.377 g/L (from 0.240 to 0.747 g/L)

Mean duration of one M/L phase: 11 min/phase (from 2 to 21 min)

#### **4.1.6. Application parameters and application rates**

*Details on application parameters are presented in Table 7.*

The total duration of application included the time spent to clean the application for all operators except those (Op. 2, 7, 8, 11 and 15) who did no cleaning. There was no break for lunch as all operators started early in the morning and stopped the working day not later than early in the afternoon. When it was necessary to have a short break, the operator took advantage of a working phase change, after hand wash and face/neck wipes were sampled. Only operator 6 had a break during application; a specific hand wash was then done on this occasion (no face/neck wipe was considered to be necessary).

The application parameters (A.M., Min. and Max.) are summarised hereafter.

Volume of spray applied :	1605 L/operator (from 880 to 3200 L)
Amount of a.s. applied:	581 g/operator (from 288 to 1200 g)
Application rate:	144 L/ha (from 96 to 213 L/ha)
Duration of application (incl. cleaning):	294 min (from 178 to 442 min)
Duration of cleaning:	20 min (from 4 to 46 min)
Treated surface area:	11 ha (from 6 to 24 ha)

Operators 5, 8 and 10 were exposed during less than 4 hours during the application phase (see Deviation 7). The surface area each of them had to treat on this day was not wide (6 to 10 ha) but had been accepted as representative of small farms. On the basis of the objectives of the study (transfer factor determination through clothes and protective equipment) and of the normalising factors (amount of handled active substance or bodyweight), the consequence of an actual application time shorter than 4 hours was negligible.

Three operators applied an amount of active substance which was different than this they mixed/loaded: Op. 8 (- 60 g, i.e. - 8%), Op. 9 (+ 140 g, i.e. + 21%) and Op. 15 (- 45 g, i.e. - 9%). In spite of those differences, the amount of a.s. handled which was considered for normalisation of the residues levels in  $\mu\text{g/kg}$  a.s. was only this applied because it was considered as more representative for a working day.

The application rate was always in the low part (96 to 213 L/ha) of the target range (100 to 1000 L/ha) which had been planned to avoid any exclusion. The rate of 96 L/ha is close enough to 100 L/ha to consider it as acceptable.

#### 4.1.7. Equipment

*Some details on application equipment are presented in Table 5.*

The study covered the major types of vehicle-mounted/trailed broadcast air-assisted sprayers. Most of them (9/15) had the sprayer at the back of the tank.

The tank capacity per equipment ranged from 800 to 2000 L. All vehicles except three (Op. 9, 10 and 15) had a cabin which was closed with filters and the air conditioning was on during the application phase. The tractor of operator 10 had a simple canopy.

The sprayers were sometimes observed to be dirty (mainly blue colour from copper). No cleaning of the equipment had been requested before (or at the start) of the monitoring day. There was no visible leak at the beginning of the monitoring day.

#### **4.1.8. Field observations**

*Details of field observations are given in Table 8.*

Observations were made throughout the day on each operator who was monitored, on his work practices and hygiene standards. The time was noted for the duration of each operation.

No accidents were reported.

Some incidents were observed:

- Operator 11 experienced repeated breaks of a metal rod supporting the sprayer and while trying to repair it first he took off a hose and a spray mixture jet reached his left knee. The coverall and the full long underwear were sampled and replaced by a new set of clothes before he continued the working day. The application gloves were changed too. The legs of the two coveralls and of the two pairs of pants were analysed separately to get an idea of the influence of the incident on exposure and transfer at the leg level.
- Operator 15 stored the empty formulation container in the top tank basket. During application the label stuck on the bottle disintegrated and blocked the way to the nozzles. The operator had to clean them carefully.

Other operators were considered to work according to usual practices.

#### **4.2. ANALYTICAL RESULTS**

The analytical phase report "Determination of operator dermal exposure and protective factors provided by personal protective equipment and working coverall during mixing/loading, foliar application and sprayer cleaning in vineyards" is presented in Appendix D.

##### **4.2.1. Field recoveries**

According to the study plan, analyses were done on the field spiked specimens including one untreated sample, one spiked sample (low level) and one spiked sample (high level) per matrix and per day of monitoring. Field spiked specimens were prepared on 4 days.

As residue levels measured with the first set of field spiked specimen was lower than 70% at the high fortification level on the polyester/cotton coverall for Day 4, the second and third sets for the fortified samples were also analysed for this matrix at the high level on this day. The residue levels measured for sets 2 and 3 were higher than 70% (close to 100%). The recovery result for set 1 (36%) was excluded from further calculations with field recoveries residue levels.

A summary of the results is presented in the following table.

**Table C: Field recoveries – Summary**

	Fortification level (µg/specimen)	n	Mean	ASD	CV	Min.	Max.
<b>Gown</b>	5	4	<b>97</b>	3	3%	94	101
	2500	4	<b>104</b>	3	3%	101	108
<b>Polyester/cotton coverall</b>	5	4	<b>87</b>	7	9%	77	94
	2500	5	<b>97</b>	4	4%	93	104
<b>Undergarment</b>	0.5	4	<b>103</b>	3	3%	100	106
	250	4	<b>103</b>	2	2%	102	107
<b>Protective gloves</b>	10	4	<b>107</b>	2	2%	105	109
	5000	4	<b>110</b>	3	3%	106	114
<b>Hand wash</b>	0.5	4	<b>113</b>	3	2%	110	115
	250	4	<b>111</b>	2	2%	109	114
<b>Face-neck wipe</b>	0.25	4	<b>83</b>	1	1%	82	84
	125	4	<b>105</b>	4	4%	101	109

All mean recoveries per fortification level were in the range of 83 to 113% with a CV (coefficient of variation) lower than 20%.

Correction of operator's residue levels had to be made when recoveries were <95%, i.e. on the following matrices:

- Polyester/cotton coveralls using 87% for correction when the measured residue level was lower than 111.8 µg/specimen; and
- Face/neck wipes using 83% for correction when the measured residue level was lower than 5.59 µg/specimen.

#### 4.2.2. Travel quality controls

As field recoveries were acceptable for all matrices, travel recovery samples were not analysed.

#### 4.2.3. Field specimens

The specimens taken on the 15 monitored operators were analysed. Coverall and inner clothes were worn during the whole working day while gloves and gowns were worn during specific tasks (mixing/loading, maintenance/repair during application and/or cleaning). Hand washes and face/neck wipes were conducted separately by task.

As a consequence, total potential and actual dermal exposures could only be calculated over the whole working day while hand and face/neck exposures could be evaluated per task.

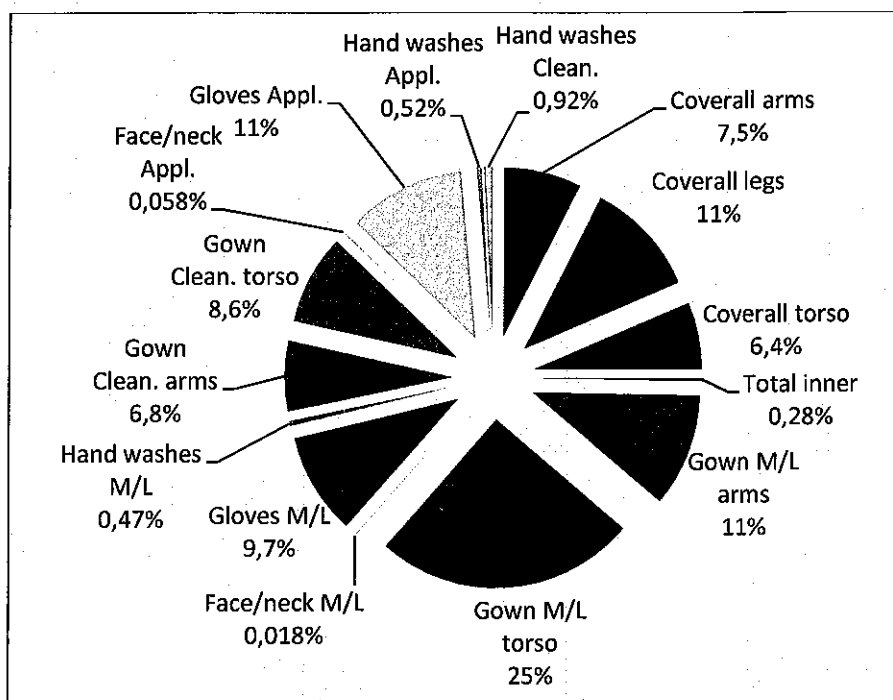
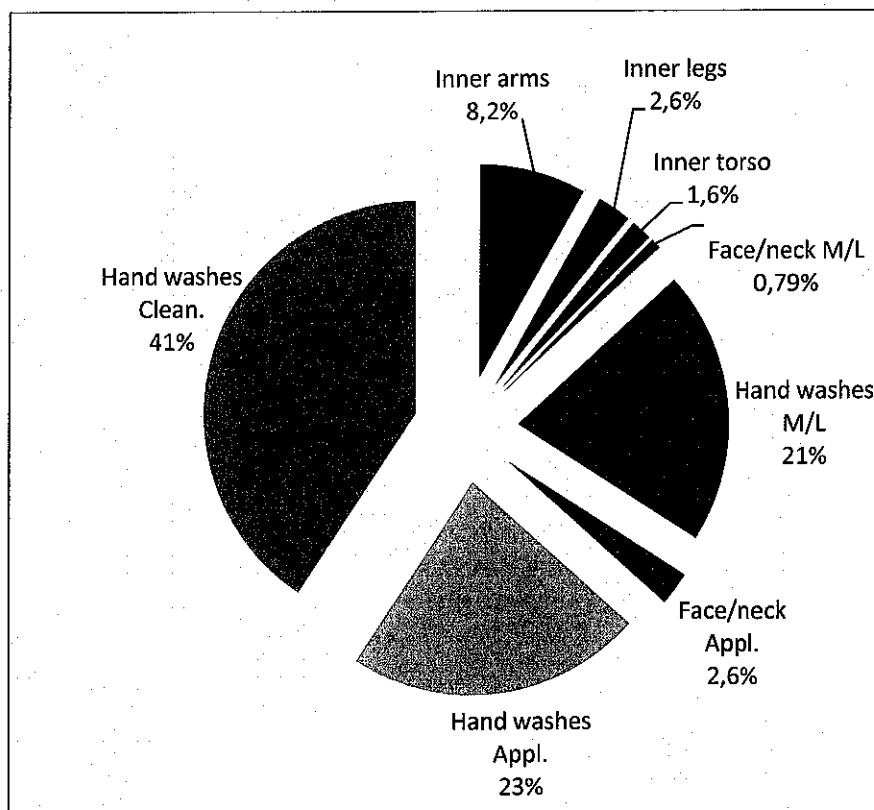
*Individual results of the analyses for operator specimens are summarized in Tables 9 to 11.*

Normalisation of the residue levels in  $\mu\text{g}/\text{kg}$  a.s. applied or in  $\mu\text{g}/\text{kg}$  bw did not decrease the geometric standard deviations calculated for potential or actual exposures which meant that the homogeneity of the results was not improved by those normalisations. As a consequence, the results in  $\mu\text{g}/\text{day}$  were considered hereafter for further discussion.







**Figure A: Distribution of potential dermal exposure (arithmetic mean) in µg/day****Figure B: Distribution of actual dermal exposure (arithmetic mean) in µg/day**

Tables D, E and F present the results in µg/day, µg/kg a.s. applied and µg/kg bw/day, respectively, for all operators.

**Table D: Summary of operator exposure (µg/day)**

Type of exposure	Exposure (µg/day)					
	Potential dermal without hands *	Actual dermal without hands **	Potential hand #	Actual hand ##	Potential dermal \$	Actual dermal \$\$
A.M.	6 428	32.5	2 039	153	8 467	186
ASD	6 486	46.7	2 036	177	7 442	187
G.M.	3 891	11.9	1 309	104	5 570	133
GSD	2.9	5.4	2.8	2.3	2.7	2.2
Min.	994	0.650	227	37.3	1 358	39.4
50 <sup>th</sup> centile	3 532	18.5	1 167	89.6	5 452	96.8
75 <sup>th</sup> centile	9 741	46.6	2 852	102	12 306	198
95 <sup>th</sup> centile	18 211	100	5 092	523	21 828	577
Max.	20 167	183	8 129	665	23 381	694
No. replicates	15	15	15	15	15	15

\*: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes

\*\*: underwear + all face/neck wipes

#: gloves + hand washes

##: hand washes

\$: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes + gloves + hand washes

\$\$: underwear + all face/neck wipes + hand washes

**Table E: Summary of operator exposure (µg/kg a.s. applied)**

Type of exposure	Exposure (µg/kg a.s. applied)					
	Potential dermal without hands *	Actual dermal without hands **	Potential hand #	Actual hand ##	Potential dermal \$	Actual dermal \$\$
A.M.	11 855	62.4	4 180	286	16 035	348
ASD	12 152	84.4	5 695	340	14 407	354
G.M.	7 096	21.7	2 387	189	10 157	242
GSD	3.2	5.6	3.0	2.4	2.8	2.4
Min.	1 827	1.35	473	31.1	2 358	51.3
50 <sup>th</sup> centile	5 640	20.2	3 034	169	8 261	202
75 <sup>th</sup> centile	19 066	83.2	3 925	236	26 722	447
95 <sup>th</sup> centile	32 675	209	11 732	814	38 179	888
Max.	41 358	305	23 522	1 386	44 965	1 445
No. replicates	15	15	15	15	15	15

\*: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes

\*\*: underwear + all face/neck wipes

#: gloves + hand washes

##: hand washes

\$: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes + gloves + hand washes

\$\$: underwear + all face/neck wipes + hand washes

**Table F: Summary of operator exposure ( $\mu\text{g/kg bw}$ )**

Type of exposure	Exposure ( $\mu\text{g/kg bw}$ )					
	Potential dermal without hands *	Actual dermal without hands **	Potential hand #	Actual hand ##	Potential dermal \$	Actual dermal \$\$
A.M.	89.3	0.489	28.6	1.93	118	2.42
ASD	94.7	0.833	30.9	2.03	111	2.27
G.M.	51.5	0.157	17.3	1.37	73.7	1.75
GSD	3.1	5.7	3.0	2.2	2.9	2.2
Min.	10.5	0.00722	3.06	0.497	13.6	0.563
50 <sup>th</sup> centile	51.2	0.247	14.8	1.19	73.7	1.33
75 <sup>th</sup> centile	136	0.671	36.9	1.68	178	2.74
95 <sup>th</sup> centile	255	1.51	84.1	6.02	301	6.64
Max.	316	3.33	120	7.82	385	8.16
No. replicates	15	15	15	15	15	15

\*: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes

\*\*: underwear + all face/neck wipes

#: gloves + hand washes

##: hand washes

\$: gown M/L + gown Clean. + polyester/cotton coverall + underwear + all face/neck wipes + gloves + hand washes

\$\$: underwear + all face/neck wipes + hand washes

## 5. DISCUSSION – CONCLUSION

The field phase of this study was conducted in August 2013 in various vine growing farms in the South of France. Each operator mixed/loaded a liquid formulation in a tank (no pre-mix) and applied the spray-mix using a vehicle-mounted/trailed broadcast air-assisted sprayer. Ten operators among fifteen also cleaned the application equipment at the end of the working day.

All operators were considered to work according to representative practices, even if a few incidents occurred.

The individual protection equipment the operators were wearing during the study included a pair of nitrile gloves satisfying EN 374-3 Standard and a category III Type 3 Partial Body gown. That equipment was not worn all the working day long and then no transfer factor was calculated via them. Actually, gloves were not worn during application except if maintenance/repair of the application equipment was necessary and no gown was worn during application.

The body was protected by a water-repellent polyester/cotton coverall (corresponding to usual work clothes) which was worn over the whole working day. The body protection afforded by the coverall was 98.5% (75th percentile) and 94.9% (95<sup>th</sup> percentile). When considering the combined protection afforded by this coverall and a gown (when recommended) the protection level increased to 99.5% (75<sup>th</sup> percentile) and 98.7% (95<sup>th</sup> percentile).

The potential dermal exposure was mainly collected by the gown worn during the mixing/loading phase (36% of PDE), followed by the coverall (24.9%) and the gown worn during the cleaning phase (15.4%).

The gloves collected 20.7% of the potential dermal exposure (A.M.). Glove exposure during application and cleaning (if any) was higher than during mixing/loading. Actual hand exposure represented 85% of total actual dermal exposure (A.M.).

Transfer via gloves was calculated only for operators 5, 6 and 10 during mixing/loading (0.37%, 0.24% and 0.41%, respectively). Actually, there were no other operators who used a pair of gloves once only and for whom indirect contamination could be excluded.

The overall face/neck exposure represented 0.076% of PDE and 3.39% of ADE.

## TABLES

TABLE 1: INFORMATION ON OPERATORS

Operator Number	Date of trial	Sex	Age (years)	Height (cm)	Weight (kg)	Experience (years)	Application equipment cleaning
1	09/08/2013	M	50	174	75	32	yes
2	12/08/2013	M	55	187	90	30	no
3	12/08/2013	M	48	170	73	10	yes
4	13/08/2013	M	58	172	68	15	yes
5	13/08/2013	M	65	170	85	25	yes
6	13/08/2013	M	29	179	70	4	yes
7	13/08/2013	M	49	170	75	30	no
8	13/08/2013	M	51	171	74	30	no
9	09/08/2013	M	47	170	88	30	yes
10	20/08/2013	M	71	175	70	30	yes
11	13/08/2013	M	22	163	55	5	no
12	20/08/2013	M	29	180	100	10	yes
13	20/08/2013	M	45	175	73	25	yes
14	20/08/2013	M	43	175	73	5	yes
15	12/08/2013	M	36	177	75	11	no
Arithmetic mean			47	174	76	19	
Minimum			22	163	55	4	
Maximum			71	187	100	32	

TABLE 2: SITE DETAILS

Operator No.	Site location
1	██████████ - Pyrenees Orientales - France
2	██████████ - Pyrenees Orientales - France
3	██████████ - Pyrenees Orientales - France
4	██████████ - Herault - France
5	██████████ - Herault - France
6	██████████ - Herault - France
7	██████████ - Herault - France
8	██████████ - Herault - France
9	██████████ - Pyrenees Orientales - France
10	██████████ - Aude - France
11	██████████ - Aude - France
12	██████████ - Aude - France
13	██████████ - Aude - France
14	██████████ - Aude - France
15	██████████ - Pyrénées Orientales - France

TABLE 3: ENVIRONMENTAL CONDITIONS

Operator No.	Date	Time	Temperature (°C)	Relative humidity (%)	Wind speed – Mean-Max (m/sec)	Wind direction (From)
1	09/08/2013	05:45	20.1	69	4.5 - 6.3	N
		07:45	20.4	67	5.4 - 9.8	N
		07:52	-	-	0.6 - 2.3	N
		09:36	23.9	54	4.5 - 8.8	N
		09:38	-	-	0.9 - 2.0	N
		11:39	27.0	42	5.3 - 9.0	N
		11:42	-	-	1.2 - 3.3	N
2	12/08/2013	06:57	16.5	73	0.0 - 0.4	-
		07:34	25.0	45	0.0 - 0.3	-
		09:06	29.5	40	0.4 - 1.1	-
		11:00	30.0	29	1.2 - 2.2	-
		11:26	34.0	22	1.5 - 4.7	E
3	12/08/2013	06:06	21.7	57	0.0 - 0.7	-
		08:04	21.3	59	0.9 - 1.7	N
		10:05	30.9	38	2.1 - 3.1	S
		11:08	29.0	37	2.3 - 4.1	S
4	13/08/2013	06:54	21.8	68	0 - 0.4	-
		08:22	22.7	70	0 - 0.5	-
5 & 6	13/08/2013	07:02	21.9	54	0 - 0	-
		08:04	25.0	42	0 - 0.4	-
		09:45	26.2	40	0.7 - 1.1	SW
		10:28	27.3	40	2.4 - 4.4	SW
7	13/08/2013	07:10	24.7	58	2.6 - 4.4	N
					vine: 0.9 - 1.5	N
		08:56	27.3	55	4.5 - 11.8	N
					vine: 0.8 - 4.4	N
		10:59	35.8	48	0.4 - 1.9	N
8	13/08/2013	07:13	27.1 *	59	0.7 - 2.3	S
		07:50	24.0	64	0.3 - 1.5	NW
		11:28	28.9	49	1.4 - 2.6	SW

- not recorded

\* this temperature seems to be odd (too high) when compared to the next temperature recorded for operator 8 or to the temperature recorded for operators 4, 5, 6, 7 and 11 at a roughly similar hour on the same day. It may be considered with caution.



**Table 3 (continued): Environmental conditions**

Operator No.	Date	Time	Temperature (°C)	Relative humidity (%)	Wind speed – Mean-Max (m/sec)	Wind direction (From)
9	09/08/2013	05:15	21.1	64	2.4 - 6.2	N
		06:26	21.2	65	3.3 - 8.4	N
					vine: 1.5 - 3.8	N
		08:00	24.8	53	2.2 - 4.1	N
					vine: 0.9 - 1.8	N
10	20/08/2013	09:20	27.8	44	2.7 - 6.5	N
					vine: 1.0 - 1.6	N
11	13/08/2013	07:24	17.6	80	2.4 - 2.6	W
		08:43	21.1	63	2.1 - 3.2	W
		09:12	24.0	52	1.8 - 3.5	W
12	20/08/2013	06:00	22.3	73	10.1 #	W
		08:00	21.7	78	9.8 #	W
		10:00	22.1	70	9.2 #	W
		12:00	26.4	52	10.4 #	W
		06:26	17.8	65	5.2 - 9.8	W
		06:32	-	-	vine: 2.5 - 5.5	W
13	20/08/2013	07:52	18.2	63	2.6 - 4.3	W
		07:57	-	-	vine: 2.3 - 4.6	W
		09:28	22.0	48	1.3 - 3.7	W
		09:30	-	-	vine: 2.0 - 3.3	W
13	20/08/2013	04:39	20.0	74	3.3 - 4.0	N
					vine: 1.9 - 2.2	N
		06:37	17.8	77	1.5 - 2.9	N
		08:38	21.3	69	3.3 - 9.2	N
					vine: 1.5 - 2.5	N
		10:39	25.5	44	3.0 - 4.8	N
					vine: 1.6 - 3.2	NW

- not recorded

# wind speed data measured at 10 m from the ground in Lezignan station (8 km from the first field treated by operator 11). When considering an adequate surface roughness (0.2 to 0.4) for vineyards, the wind speed which can be calculated at vine level is reduced (from 2.6 to 4.3 m/sec at 1 m).

**Table 3 (continued): Environmental conditions**

Operator No.	Date	Time	Temperature (°C)	Relative humidity (%)	Wind speed – Mean-Max (m/sec)	Wind direction (From)
14	20/08/2013	06:09	21.0	73	2.2 - 3.3	NW
		07:44	19.8	70	1.1 - 4.5	NW
		08:44	21.0	61	0.5 - 1.5	NW
		09:45	20.9	67	2.6 - 4.4	NW
		11:02	25.0	45	2.1 - 4.1	NW
		12:05	28.3	30	2.7 - 5.9	NW
		13:06	29.7	28	3.1 - 5.9	NW
		14:28	35.6	21	2.3 - 4.5	NW
15	12/08/2013	06:58	20.9	72	0 - 0	-
		08:48	24.8	56	0.1 - 1.4	SW
		11:24	34.8	29	2.4 - 6.0	SE

- not applicable

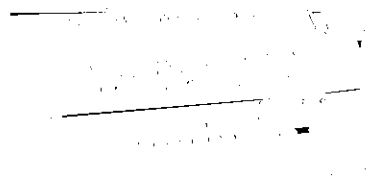
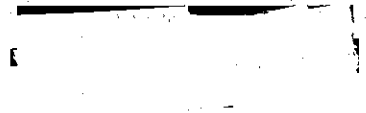

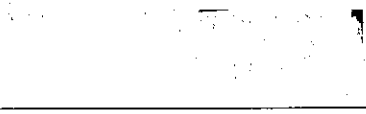
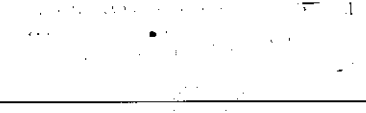
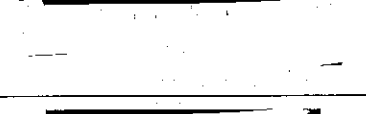
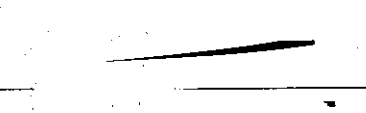
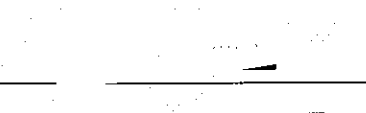

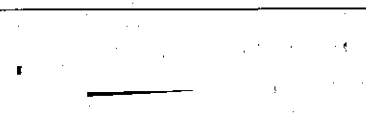

TABLE 4: DOSIMETERS

MATRIX	BRAND NAME (SUPPLIER)	FABRIC TYPE
Polyester/cotton overall	[REDACTED] #	water repellent 65% polyester / 35% cotton; 280 g/m <sup>2</sup>
Chemical protective gown	[REDACTED]	Cat. III Type 3 Partial Body
Underwear dosimeter	Long-sleeved T-shirt and long johns [REDACTED] \$	[REDACTED] 100% white cotton.
Protective Gloves	[REDACTED]	[REDACTED] nitrile); length 330 mm Cat. III, EN-374-3
Hand wash solution	dioctyl sulfosuccinate [REDACTED] diluted in [REDACTED] water	[REDACTED]
Face/ neck wipes	[REDACTED]	100 % cotton gauze pads, 10 x 10 cm, 16 folds, 13 threads [REDACTED]

# pre-washed three times at 60 °C with soap.

\$ pre-washed once at 95°C with soap.

**TABLE 5: APPLICATION EQUIPMENT DETAILS**

Operator No.	Sprayer type	Tank capacity (L)	Cab details	Observation
1		2000	Closed, filters, air conditioned	Not very clean equipment; rear sprayer
2		800	Closed, filters, air conditioned	Clean; sprayer at the back of the tank
3		800	Closed, filters, air conditioned	Clean; sprayer at the back of the tank
4		800	Closed, filters, air conditioned	Clean; sprayer at the front of the tank (between tractor and tank)
5		1500	Closed, filters, air conditioned	Copper coloured; sprayer at the back of the tank
6		1500	Closed, filters, air conditioned	Dirty; sprayer at the back of the tank
7		1000	Closed, filters, air conditioned	Dirty; sprayer at the back of the tank
8		1000	Closed, filters, air conditioned	Clean; sprayer at the front of the tank (between tractor and tank)
9		1600 (two 800L tanks)	No cabin	Dirty, spraying in the row (nozzles placed close to the ground); operator seated on the top of the vehicle
10		1000	No cabin; canopy	Clean; sprayer at the front of the tank (between tractor and tank)
11		1000	Closed, filters, air conditioned	Dirty; sprayer at the back of the tank

**Table 5 (continued): Application equipment details**

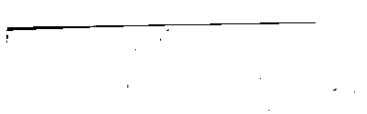
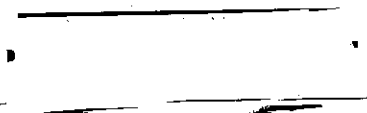
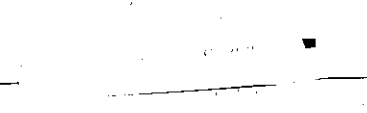
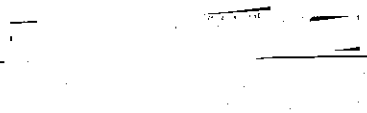
Operator No.	Sprayer type	Tank capacity (L)	Cab details	Observation
12		1500	Closed, filters, air conditioned	Dirty; sprayer at the back of the tank
13		1000	Closed, filters, air conditioned	Clean; sprayer at the front of the tank
14		1000	Closed, filters, air conditioned	Dirty; sprayer at the front of the tank
15		800	No cabin	Dirty; sprayer at the back of the tank

TABLE 6: MIXING/LOADING PARAMETERS

Operator No.	M/L No.	Volume of formulation handled (L)	Volume of water used (L)	Amount a.s. handled (g)	Concentration a.s. in spray (g/L)	Duration of mixing/loading (min)
1	1	1.8	1800	864	0.480	14
	2	0.7	450	336	0.747	10
2	1	0.5	800	240	0.300	13
	2	0.5	800	240	0.300	10
3	1	0.8	800	384	0.480	21
	2	0.2	200	96	0.480	8
4	1	0.7	840	336	0.400	14
	2	0.02	40	9.6	0.240	6
5	1	1.0	1500	480	0.320	18
6	1	1.0	1500	480	0.320	10
7	1	0.8	800	384	0.480	12
	2	0.7	700	336	0.480	18
8	1	1.0	1000	480	0.480	13
	2	0.5	600	240	0.400	17
9	1 *	0.6	1100	288	0.262	5
	2	0.8	1600	384	0.240	2
10	1	0.6	1000	288	0.288	4
11	1	1.0	1000	480	0.480	7
	2	0.25	250	120	0.480	15
12	1	1.2	1500	576	0.384	8
13	1	0.6	1000	288	0.288	20
	2	0.6	1000	288	0.288	2
14	1	0.6	1000	288	0.288	7
	2	0.6	1000	288	0.288	6
15	1	0.5	800	240	0.300	10
	2	0.5	800	240	0.300	6

a.s.: active substance; nominal content in the formulation = 480 g spinosad/L

a.s. handled (g) = formulation volume handled (L) x spinosad content (g/L)

\* the tank already contained 500 L of spinosad spray mixture (left from the previous day).

All operators used 500 mL formulation bottles except operators 5 and 6 who shared a 2 L container, operators 11 and 12. Operator 14 started with a 2 L bottle (0.8 L remaining from Op 12). He finished with a 0.5 L bottle.

TABLE 7: APPLICATION PARAMETERS

Operator No.	Appli. No.	Spray vol. applied (L)	Concentration a.s. in spray (g/L)	Amount a.s. handled (g)	Surface area treated (ha)	Application rate (L/ha)	Total duration of application (min)	Duration of cleaning included in total duration of application \$ (min)
1	1	1550	0.480	744	23.5	96	356	20 #
	2 *	700	0.652	456				
2	1	800	0.300	240	10	160	353	no cleaning
	2	800	0.300	240		160		
3	1	750	0.480	360	10	100	333	21
	2	250	0.480	120				
4	1	840	0.400	336	7	126	270	46
	2	40	0.240	9.6				
5	1	1500	0.320	480	10	150	236	4
6	1	1500	0.320	480	10	150	240	15
7	1	800	0.480	384	15	100	256	no cleaning
	2	700	0.480	336				
8	1	1000	0.480	480	9.5	153	230	no cleaning
	2	450	0.400	180				
9	1	1600	0.262	419	15	213	272	29
	2	1600	0.245	392				
10	1	1000	0.288	288	6	167	178	7
11	1	1250	0.480	600	11.5	109	291	no cleaning
	2							
12	1	1500	0.384	576	12	125	245	35
13	1	1000	0.288	288	11.5	174	407	20
	2	1000	0.288	288				
14	1	1000	0.288	288	12	167	442	4
	2	1000	0.288	288				
15	1	800	0.300	240	9	161	296	no cleaning
	2	650	0.300	195				

a.s.: active substance; nominal content in the formulation = 480 g spinosad/L  
a.s. handled (g) = formulation volume handled (L) x spinosad content (g/L)

\* 450 L spray mix (containing 0.747 g spinosad/L) + 250 L spray mix remaining in the tank at the end of the first application phase (containing 0.480 g spinosad/L)

\$ does not include the rinse done in the field (when exists)

# estimated value

TABLE 8: FIELD OBSERVATIONS

Operator No.	Observation
1	<p>Individual equipment: water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); shoes up-to-ankle.</p> <hr/> <p>The last application of a spinosad-based formulation was done on the day before.</p> <ul style="list-style-type: none"> <li> <b>Mixing/loading:</b>            There were two tanks on the self-propelled vehicle which were filled through the same manhole. Two mixing/loading phases were done.            Operator 1 used to shake each formulation container before opening it. The stuck cap was difficult to remove and he used his thumb for this. Containers were rinsed using the tank content; he plunged each container inside the tank (one of his hands/forearms may have been in contact with the content of the spray tank).            During the first tank mix, a tank overflow happened during 5 seconds.            Fuel tank filling was done using own gloves.         </li> <li> <b>Application:</b>            The cabin was closed during the spraying except during one round trip when the cabin door was kept open.            When he went out of the cabin to check the content of the tanks, he put the gloves on when standing on the ground and put them off before coming back into the cabin; he touched the banister with bare hands.            On one occasion he wore one glove to check one nozzle; he put the glove off with the other bare hand.            The tank was empty at the end of spraying phase.         </li> <li> <b>Cleaning:</b>            Cleaning of the tank was started in vineyard, using 50 L water (from a clean water tank). Then at the farm using 100L water. The outside of the vehicle/tank was not cleaned.         </li> </ul> <p><i>Whitish marks on the coverall arms.</i>  <i>Rust coloured marks on the mixing/loading gown torso.</i>  <i>Marks on the cleaning gown arms and clear brown marks on the cleaning gown torso.</i></p>



Table 8 (continued): Field observations

Operator No.	Observation
2	<p><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown during mixing/loading; protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair); leather boat shoes worn without socks. Sun glasses often worn during application.</p>
	<p>The last application of a spinosad-based formulation was done one month before.</p> <ul style="list-style-type: none"> <li>• <b>Mixing/loading:</b> He did two mixing/loading phases. Each time he used 500 mL of product and added ca. 800 L of water. At the end of the first application phase, less than 10 L was left in the tank. After pouring of the formulation into the tank he rinsed once the empty formulation container. During the second loading, a tank overflow happened and then a liquid/foam stream was observed over the sides of the tank.</li> <li>• <b>Application:</b> The content of the first tank was applied over 5 ha. The content of the second one was also applied over 5 ha. On journeys between the M/L site and the vineyard or between two fields, some overflow was observed. On many occasions, he had to go out from the cabin in order to proceed on the sprayer; each time he was wearing gloves. However he did not always took off the gloves to drive the tractor. On several occasions when he tested the smooth working of the sprayer, he left open the cabin door. Moreover, sometimes, he stood outside of the cabin while the spraying was on-going. Due to the mountainous area where he was working, it was sometimes impossible for the monitor to keep the operator in view. At the end of the second application phase, the operator did an automatic rinsing of the inside of the tank in the field. He did not rinse the tank outside.</li> </ul>
	<p><i>No remark at undressing.</i></p>

**Table 8 (continued): Field observations**

Operator No.	Observation
3	<p><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); leather shoes up to ankle level (mountain shoes).</p> <hr/> <p>The last application of a spinosad-based formulation was done on the day before. The operator had a shower before the day of monitoring.</p> <ul style="list-style-type: none"> <li>• <b>Mixing-loading:</b> Although the bottle cap is aimed to help tearing the stuck cap, the bottle was difficult to open, and the operator needed to remove this stuck cap using a finger (gloves still worn). When the volume of the whole bottle was needed, the content of the bottle was poured directly into the tank then rinsed on three successive occasions using water. Each time the rinsing water was poured into the tank. When only a part of the bottle content was needed, the operator measured the requested volume using a graduated plastic jug. This jug content was then poured into the tank, and rinsed as described above. To reach the tap of water delivery system, the operator needed to use a key which was hung around his neck. Once, he forgot to remove it before putting the gown on and then he had to catch it with the gloves on: some contamination of the neck might have occurred. After mixing-loading, the gloves were put into a plastic bag and kept in the tractor cabin.</li> <li>• <b>Application:</b> There was no maintenance activity required during application. Nothing remarkable occurred during application.</li> <li>• <b>Cleaning:</b> Once application was finished, rinsing of the tank and the nozzles was done at the mixing/loading site. While rinsing water was sprayed through the nozzles, the operator went close to them (without any cap on his head). Face/neck wipes were passed over the head at the end of cleaning.</li> </ul> <hr/> <p><i>Mud spots on the coverall legs.</i></p>

Table 8 (continued): Field observations

Operator No.	Observation
4	<p data-bbox="328 338 1447 495"><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); sports shoes. Cap, eyeglasses, noise-cancelling earmuffs. Wore wellies during cleaning.</p> <hr/> <p data-bbox="328 524 1283 557">The last application of a spinosad-based formulation was done three days before.</p> <ul style="list-style-type: none"> <li data-bbox="376 591 624 624">• <b>Mixing-loading:</b>            Water was taken from a private water delivery, with a shower head at the end of the hose; therefore there was a low pressure and some splashes occurred during formulation container rinsing. Although the bottle cap is aimed to help tearing the stuck cap, the bottle was difficult to open, and the operator needed to remove this stuck cap using a finger (gloves still worn). When the volume of the whole bottle was needed, the content of the bottle was poured directly into the tank then rinsed on three successive occasions using water. Each time the rinsing water was poured into the tank. When only a part of the bottle content was needed, the operator measured the requested volume using a graduated plastic jug. This jug content was then poured into the tank, and rinsed as described above.            Other products were added in the tank: Pyrevert®, ChampFloAmpli® and a home-made mixture of natural extracts.            During mixing-loading, the gown laces untied themselves.            After mixing-loading, the gloves were put into a plastic bag and kept in the cabin.</li> <li data-bbox="376 1055 580 1088">• <b>Application:</b>            The operator had to maintain nozzles from time to time during application. To do that, he wore protective gloves. He also had to add fuel into the tractor.            In one plot, application was performed without the upper nozzles because vines were young and not high enough.            Some negligible raindrops were observed during application.</li> <li data-bbox="376 1272 544 1305">• <b>Cleaning:</b>            Once the last application was finished, rinsing of tank and nozzles was done over a small plot near the rinsing area. Rinsing of tank and cabin outsides was done over a rinsing area different from the mixing-loading area. The operator was wearing a pair of wellies (over the coverall legs). Water was delivered at a low pressure. The operator used a small brush. A cleaning agent (diluted Primaflash®) was sprayed over the tank using a manual trigger sprayer. Filters were plugged in some extent by the copper product. The operator had some copper product on his gloves and on his face (as he scratched his nose). From time to time, operator scrubbed the tank with hands (gloves on).            Gloves and gown were taken off, but the operator had to restart the tractor engine. He also wiped a piece of the tractor engine using a cloth. The nozzles were emptied over the rinsing area; the operator rapidly added some water on his hands before the last hand wash.</li> </ul> <hr/> <p data-bbox="328 1671 932 1704"><i>Some mud spots on a mixing-loading gown sleeve.</i></p> <p data-bbox="328 1704 1171 1738"><i>Oil and copper product spots on gloves and on a cleaning gown sleeve.</i></p>

**Table 8 (continued): Field observations**

Operator No.	Observation
5	Individual equipment: water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); sports low-cut shoes. Eyeglasses often worn while application.
	The last application of a spinosad-based formulation was done on the day before.
	<ul style="list-style-type: none"> <li>• <b>Mixing/loading:</b> He started by water filling and then he measured 1 L of formulation from a 2 L container and poured the product into the tank. Then he washed the measuring jug above the tank. He also added the content of four containers of a sulfur-based product. He stopped water filling, closed the tank and moved the tractor to another water filling area. He finished water filling into the tank up to 1500 L.</li> <li>• <b>Application:</b> The application was done on ca. 10 ha. He was applying over 2 rows at a time.</li> <li>• <b>Cleaning:</b> At the end of application, he rinsed the tank by applying water over the vine rows and came back to the farm. He washed the filters using compressed air.</li> </ul>
	<i>Spots on the inner torso. The outer legs were dirty.</i>

Table 8 (continued): Field observations

Operator No.	Observation
6	<p><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); trainers lower than ankle level.</p> <hr/> <p>The last application of a spinosad-based formulation was done on the week before.</p> <ul style="list-style-type: none"> <li> <b>Mixing/loading:</b>            One mixing/loading phase was done.            The spinosad formulation (1 L from a 2 L container from which Op 5 had already used 1 L) was poured first in the tank. The spinosad container was rinsed using water from a tap located inside the farm. This tap and the sink below were very dirty. The container was closed, shaken and the rinsing was poured in the mix tank.            Then a sulphur-based formulation (4 L/ha) was added in the tank. Four 10 L container was put on its side on the border of the tank manhole and its content flew quite rapidly without control. As a consequence, spatters occurred outside of the tank, which was thereafter rinsed with the hose used to finish water tank filling.         </li> <li> <b>Application:</b>            During application, there was a break (to urinate, eat 2 biscuits and phone). A hand wash was collected before. While discussing, Op 6 touched his face with hands on several occasions. When he opened the tank to check the volume left, he wore gloves.            He used to stop spraying and re-start spraying when out of the rows while turning back. The tank was empty at the end of spraying phase.         </li> <li> <b>Cleaning:</b>            There was no water in the clean water tank and no dilution/rinsing could be done in the field. At the farm, over a graded area, the inside and outside of the tank and the outside of the tractor were rinsed using a hose. The emptying of the bottom of the tank was over the graded area and the operator walked in the puddles (diluted spray).         </li> </ul> <hr/> <p><i>Yellow marks on the coverall lower legs and on the mixing/loading gown torso and arms.</i></p>

Table 8 (continued): Field observations

Operator No.	Observation
7	<p data-bbox="336 344 1457 465"><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown during mixing/loading; protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair); leather shoes up to ankle level (work shoes).</p> <hr/> <p data-bbox="336 499 1406 528">The last application of a spinosad-based formulation was done earlier than 3 weeks before.</p> <ul style="list-style-type: none"> <li data-bbox="384 562 628 591">• <b>Mixing/loading:</b>  First mixing-loading: The tank was already full of water when the field monitor arrived in the farm. After dressing, the operator poured the content of a Pyrivert® bottle directly into the tank before pouring the spinosad formulation. One spinosad bottle was poured directly into the tank. The relevant amount was measured from a second bottle using a graduated jug and then poured directly into the tank. The measuring jug was rinsed with water from a clean water tank.  Second mixing-loading: Filling up with gasoil was done wearing personal gloves. After dressing for mixing/loading (dedicated gown and gloves), the tank was filled with water. After the manhole opening, the spinosad bottles were poured directly into the tank. The bottles were rinsed in the tank using the spray mix; the operator's left arm was inside the tank. Spinosad bottles containing the rinsing mixture were shaken and poured into the tank. Cuproxat® was also added into the tank.</li> <li data-bbox="384 965 587 994">• <b>Application:</b>  Nothing remarkable occurred during the first application. For the second application the nozzles were adjusted with gloves on.  The application gloves were stored in the cabin during the first application phase and in a coverall pocket during the second application phase.</li> </ul> <hr/> <p data-bbox="336 1151 1171 1180"><i>Inner dosimeter legs: brown marks. Outer dosimeter arms: white marks</i></p> <p data-bbox="336 1180 1457 1240"><i>Outer dosimeter legs: brown marks in the bottom (dust). Outer dosimeter torso: white and brown marks. Gown M/L arms: greenish mark. Gown M/L torso: greenish and brown marks</i></p>

**Table 8 (continued): Field observations**

Operator No.	Observation
8	<p><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown during mixing/loading; protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair); safety low-cut shoes worn. Eyeglasses often worn mainly while mixing/loading.</p>
	<p>The last application of a spinosad-based formulation was done earlier than 3 weeks before.</p>
	<p>• <b>Mixing/loading:</b></p> <p>For the first mixing/loading, the operator used 1 L of product with 1000L of water (700L already loaded on the day before). For the second mixing/loading he used 500 mL for a loading of 600L water.</p> <p>The empty formulation container was rinsed three times. For the second M/L, there was no rinsing need because the product container was not empty.</p> <p>After the first M/L he did not rinse his gloves; after the second one, he did.</p> <p>During the two M/L phases he briefly entered the tractor cabin still wearing the M/L clothes (including gloves) after he handled the product.</p> <p>During the second M/L, the operator spilled some concentrate formulation over one glove finger. A few minutes later, he handled his eyeglasses and he briefly wiped his face with his gloves on.</p> <p>• <b>Application:</b></p> <p>The operator stored the application gloves on the left side of the tractor seat in the cabin.</p> <p>During the end of the first application phase, the operator stopped the tractor in the row, put his gloves on, went down to check the remaining volume in tank and then he continued spraying. As he was in the row, there might be contact with the treated foliage.</p> <p>At the end of application, there was 150L left in the tank.</p>
	<p><i>Several marks were observed on the coverall legs.</i></p>

Table 8 (continued): Field observations

Operator No.	Observation
9	<p><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); leather shoes up to ankle level (mountain shoes).</p> <p>The last application of a spinosad-based formulation was done 3 weeks before. The application equipment was used by another operator on the day before.</p> <ul style="list-style-type: none"> <li> <b>Mixing/loading:</b>            First mixing-loading: the tank already contained 500 L of spinosad spray mixture (left from the previous day). Water filling of the tank was done before dressing. After dressing with the study clothes, the content of the spinosad bottle was poured directly into the tank. The bottle was rinsed inside the tank. The left hand was splashed with product. A graduated jug was used to measure 100 mL in addition. The measuring jug was rinsed with water done using a hose.            Note: as the operator had to use stairs to reach the manhole, the M/L gown was not practical (too long).            Second mixing-loading: with the gown and gloves on, tank filling with water was done using a hose. The bottles were shaken, open and poured directly in the tank. The bottle was rinsed using the hose. The operator put one finger inside the spinosad bottle to mix the rinsing mixture. The water pipe was inside the tank in contact with the mixture during filling completion.            After mixing-loading and gloves rinsing, the gloves were taken off: left glove with the right glove on and right glove was taken off with the bare left hand.         </li> <li> <b>Application:</b>            At the end of each row, the operator stopped spraying, folded the booms, turned, unfolded the booms and restarted spraying.            During the second application, the operator went downstairs to check the spray tank level. At the end of the second application phase the operator put hands inside the coverall pockets and smoked. The application gloves were stored close to the driver seat (no cabin).         </li> <li> <b>Cleaning:</b>            The two tanks were rinsed using a hose. The tanks were emptied. The tractor was cleaned using the hose. The nozzle back filters and other pieces of the tank were taken down and rinsed using the hose. The booms were unfolded and the left nozzles switched on. The operator came in the fog done by the left nozzles to handle the back and the right nozzles. The operator scratched his forehead with his left hand. The booms were finally folded and the tanks closed. The equipment was driven to its storage place.         </li> </ul> <p><i>Outer dosimeter legs: mud marks and dust</i>  <i>Gown M/L arms: right arms white marks, left arms brown marks</i>  <i>Gown M/L torso: brown marks at the bottom</i>  <i>Gown cleaning arms: soil marks left arms</i>  <i>Gown cleaning torso: brown marks at the bottom</i></p>



**Table 8 (continued): Field observations**

Operator No.	Observation
10	<p><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); sports low-cut shoes without socks; eyeglasses.</p> <p>He was wearing a dust mask and gloves during application.</p>
	<p>The last application of a spinosad-based formulation was done earlier than 3 weeks before.</p>
	<ul style="list-style-type: none"> <li>• <b>Mixing/loading:</b> The operator started water filling and mixing. He poured one bottle (500 mL) into the tank and rinsed the bottle using a hose then he measured 100 mL of product from another bottle and poured the product into the tank. The measuring jug was rinsed in the tank. Tank filling was completed at about 1000 L.</li> <li>• <b>Application:</b> The application was done in several small fields. He needed to adjust the sprayer on several occasions, including maintenance of nozzles. He wiped his face with the protected hand. At the end of application, he came back to the farm. The tank was empty.</li> </ul>
	<ul style="list-style-type: none"> <li>• <b>Cleaning:</b> He emptied the bottom tank and rinsed it using tap water; the rinse flew below the tank. Then he filled part of the tank using water and started the sprayer to rinse it. He stood close to the tractor during this phase. He rinsed the outside of the tank and sprayer using a hose.</li> </ul> <p><i>The coverall legs were dirty. Some colored drops on the cleaning gown.</i></p>

Table 8 (continued): Field observations

Operator No.	Observation
11	<p><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown during mixing/loading; protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair); leather shoes up to ankle level (working shoes). Change of underwear and coverall just before the second M/L phase. Cap worn all along the monitoring period.</p> <hr/> <p>The last application of a spinosad-based formulation was done earlier than 3 weeks before.</p> <ul style="list-style-type: none"> <li>• <b>Mixing/loading:</b> Mixing/loading was conducted below a shed with a narrow space around the sprayer. His clothes were in contact with the sprayer while walking along. During measurement of the required volume of formulation using a graduated jug, one finger touched the formulation (gloves on).</li> <li>• <b>Application:</b> A pair of nitrile gloves was placed in the tractor cabin, available for possible use during application. From the beginning of application (6:22), the wind was already blowing (ca. 20 km/h in open space). After less than 10 minutes of application, a small tube (conducting the spray mix to a nozzle) was disconnected. The operator got out of the cabin with gloves on and fixed the tube. Some drops of mixture fell on the coverall and even more on the cap. When getting back inside the cabin, he removed the gloves in a secure way (without rinsing them) and placed them in a plastic bag. He drank water in the cabin. While driving, the coverall zip was opened. The zip was closed up before he got out of the cabin. After almost two hours of application, a metal rod supporting the sprayer appeared to be broken.  The operator tried to replace it (with gloves on) and waited for a colleague to decide for maintenance. When he was trying to fix broken part, he removed a hose and a spray mixture jet reached his left knee. He climbed over the tank; his clothes touched the contaminated tank. He drove back to the workshop and fixed the broken part using a welding torch, helped by one colleague. When the fixing was completed, hands wash and face neck wipes were taken and inner dosimeters and polyester/cotton coverall were changed to new clothes before the second mixing/loading.  After 10 minutes of spraying during the second application phase, he stopped because of some rain. He cleaned some nozzles during this stop. Ten minutes later, the weld appeared to be broken again. Since he was bare hands, he avoided to touch the sprayer and held it instead with his coverall right forearm. He started application again for 20 minutes before the break was full. He had to stop and drove back to the workshop for a new weld. His gloves were very dirty because of the cleaning of the nozzles. He never removed them during the repair. Spraying started again after a stop to urinate (no hand wash was done) in the field. The wind was blowing stronger than before but spray drift remained limited. The tank was empty at the end of application.</li> </ul> <hr/> <p><i>Outer leg (first coverall): Left leg was soaked. Outer arms (second coverall) were dirty with white marks. Outer torso (second coverall) was also marked with white spots. Application gloves (the first pair and particularly the second pair worn during the second application phase) were heavily dirty with white marks.</i></p>

Table 8 (continued): Field observations

Operator No.	Observation
12	<p data-bbox="331 344 1458 501"><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); sports shoes. Eyeglasses.</p> <hr/> <p data-bbox="331 533 1398 562">The last application of a spinosad-based formulation was done earlier than 3 weeks before.</p> <ul style="list-style-type: none"> <li data-bbox="379 593 624 622">• <b>Mixing-loading:</b>            Water to fill the tank was taken from a hose. When the full content of a bottle was needed, the bottle was poured directly into the tank and then rinsed three successive times. Each time the rinsing water was poured into the tank. When only a part of bottle content was needed, the operator measured the requested volume using a graduated plastic jug. The jug was then poured into the tank, and rinsed three successive times (each time the rinsing water was poured into the tank). The operator added a copper product (SCOUBI HI BIO WG®) into the tank.            After undressing (gown and gloves) and hand and face/neck washing, the operator had to repair the pump and to unblock tank filters because the products had precipitated at the bottom of the tank. He put on the gown and gloves already worn during mixing-loading. There was some spray mixture allowed to flow down. Some droplets of spray mixture were observed while the operator was unblocking the filters. Some contamination of the operator may have occurred. After undressing (gown and gloves) new hand wash and face/neck wipe specimens were taken. After mixing-loading, the gloves were put into a plastic bag and kept inside the cabin.</li> <li data-bbox="379 1086 580 1115">• <b>Application:</b>            The operator had to maintain a fuse wire on the sprayer during application. For that he did not wear gloves. He was kneeling on small platform just outside the cabin door. Contamination of hands and legs might have occurred. The ladder to reach the cabin was designed in a way that the operator needed to grip a bar with one hand to enter the cabin. This outside bar was probably contaminated by the spray mixture. The gloves were stored inside the cabin (not very clean) when not worn during application.</li> <li data-bbox="379 1332 544 1361">• <b>Cleaning:</b>            Once application was finished, rinsing of the nozzles was done on a separate plot. Rinsing of filters, tank and cabin exteriors was done on the same area as mixing-loading was. The cabin exterior was cleaned using a broom and water.</li> </ul> <hr/> <p data-bbox="331 1489 842 1518"><i>Mud and product spots on the coverall legs.</i></p> <p data-bbox="331 1520 1458 1581"><i>Product spots on mixing/loading gown torso. Some splashes on the cleaning gown torso and arms.</i></p>

Table 8 (continued): Field observations

Operator No.	Observation
13	<p><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); leather shoes up to ankle level (work shoes). Eyeglasses worn from 09:30 to 11:30 (end of second application phase).</p> <hr/> <p>The last application of a spinosad-based formulation was done earlier than 3 weeks before.</p> <ul style="list-style-type: none"> <li> <b>Mixing-loading:</b>            After dressing and before the mixing-loading started, the operator sprayed gasoil over the tractor and the tank to protect them.            First mixing-loading: The operator poured 5 kg of FONGURAN OH® (copper formulation) before pouring the spinosad formulation. The content of a spinosad bottle was poured directly into the tank and then rinsed over the tank manhole with the water from a hose. A measuring jug was used to measure the required complement volume. It was rinsed as the bottle was. The gloves and probably the forearms touched the spray mixture during rinsing.            Second mixing-loading: the tank was filled with water from a public hose. Then the operator drove to the farm shed to fill up the tractor with diesel fuel. He was still wearing the mixing-loading gloves for this water and diesel fuel fillings. After equipment (gloves and gown) for the mixing/loading, the same operations as those done during the first mixing/loading were repeated except that the formulation container and jug rinse was done first using water from a hose and second using water from the clean water tank. At the end of the phase, the operator started to wash his hands below tap water before the study monitor stopped him, to wash them as planned (including collection).            The gloves were put in a plastic bag and kept with the mixing-loading gown in the study monitor car.         </li> <li> <b>Application:</b>            During application the operator checked the tank volume and nozzle pressure and then washed the application gloves with water from the clean water tank. Once he adjusted the nozzles (gloves on) and then washed them again.            The application gloves were stored in the tool box outside of the tractor.         </li> <li> <b>Cleaning:</b>            After dressing with new gown, the application gloves and a pair of wellies (no more work shoes), the operator rinsed the filters, switched on the nozzles and emptied the tank. The nozzle filters were stripped down and rinsed using a hose. The gloves were rinsed and taken off and put inside the cabin. The application equipment was moved to wash the outside (tractor and sprayer) using water under pressure (gloves on).         </li> </ul> <hr/> <p><i>Inner dosimeter arms: little brown spot &lt; 2 cm². Coverall legs: greenish mark on the thigh and hip. Coverall torso: greenish mark on the chest. Cleaning gown arms: brown mark wrist.</i></p>

**Table 8 (continued): Field observations**

Operator No.	Observation
14	<p>Individual equipment: water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown (one during mixing/loading; one during cleaning); protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair and cleaning); leather shoes up to ankle level (work shoes). A cap and sunglasses.</p> <hr/> <p>The last application of a spinosad-based formulation was done earlier than 3 weeks before.</p> <ul style="list-style-type: none"> <li> <b>Mixing-loading:</b>  Mixing/loading was done outside a shed with space all around the sprayer.  The operator wiped some foam from the tank mixture on the water hose with his gloves (traces of copper). Thereafter he filled the clean water tank with water and then rinsed the gloves with water from the clean water tank before taking them off.  Near the shed, he filled up the tractor with diesel fuel (gloves on) and rinsed the empty containers. </li> <li> <b>Application:</b>  A pair of nitrile gloves was placed inside the tractor cabin, available for possible use during the application phase.  The operator went out of the cabin with gloves on and checked the tank filter. Then he rinsed his gloves before removing them and placed them inside the tractor cabin.  He replaced an air deflector without rinsing his gloves after.  The checked again the tank filter. Some tank mixture fell on his gloves (apparently none on the overall). Before coming back in the cabin, he rinsed the gloves (before taking them off) and forearms.  On some occasions when he went out of the cabin in a row, the operator was in contact with the treated crop.  He checked the mixture volume and rinsed the gloves. </li> <li> <b>Cleaning:</b>  Cleaning the tractor and sprayer: The operator wore gloves to do a first rinse of the spraying equipment in the field using water from the clean water tank. Then, back to the shed, he rinsed the whole equipment: moving screen wipes and brushing the tractor using a broom after wetting it. </li> </ul> <hr/> <p>Coverall legs: Soil spots on the bottom part.  Inner legs: dirty with soil marks on the bottom.  Mixing/loading gown torso marked with product spots.</p>

Table 8 (continued): Field observations

Operator No.	Observation
15	<p><u>Individual equipment:</u> water-repellent polyester/cotton (65/35) coverall and full-length cotton undergarment covering full length of arms and legs; category III Type 3 Partial Body gown during mixing/loading; protective nitrile gloves (one pair during mixing/loading; one pair during application maintenance/repair); leather boots like a guardian with a zip up to ankle level. A straw hat and noise cancelling headphone; eyeglasses. From 09:51 he wore a tee-shirt around his head to protect it and the back of the neck from sunshine.</p> <hr/> <p>The last application of a spinosad-based formulation was done on the day before.</p> <ul style="list-style-type: none"> <li> <b>Mixing-loading:</b>  First mixing-loading: the tank was filled with water from a public hose support. At the same time, the content of the bottle was poured directly into the tank. The bottle was rinsed in the tank mixture; the operator right lower arm touched the mixture. The bottle was rinsed a second time with water from the tank tap. Overflow of the tank was observed with splashes on the bottom legs. The empty formulation bottle was stored in the top tank basket.  Second mixing-loading: identical as the first mixing/loading.  After mixing-loading and the gloves washing, the operator took the gloves off: the right hand touched the outside of the gloves. The gloves were put inside a plastic bag and kept in the field monitor car with the mixing-loading gown. </li> <li> <b>Application:</b>  The application gloves were stored in the right pocket of the coverall.  At the beginning of application the operator adjusted the nozzles once with bare hands. For the next adjustments (6) of the nozzles the operator wore protective gloves. The operator drank water on five occasions. The water bottle was stored on the tractor without protection (no cabin). The operator scratched his neck and nose with the right hand.  During the second application phase, a nozzle supply problem happened: the label wrapping the empty bottles stored in the top tank basket was in the way of the nozzles. Then the operator took the filter off to clean it (twice) and rinsed the nozzles using the water of the clean water tank. At the end of the application, the booms were manually folded (gloves on). </li> </ul> <hr/> <p><i>Coverall arms: brown marks.</i>  <i>Coverall legs: white marks on the front and brown marks at the bottom.</i>  <i>Coverall torso: white marks on the front.</i></p>

TABLE 9: INDIVIDUAL RESULTS FOR OPERATORS (µG/DAY)

MATRIX		ACTIVE INGREDIENT FINDINGS (µg/day) corrected for field recoveries when required														
		Operator No.														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Body weight (kg)		75	90	73	68	85	70	75	74	88	70	55	100	73	73	75
Amount a.s. applied (kg)		1.20	0.480	0.480	0.346	0.480	0.480	0.720	0.660	0.811	0.288	0.600	0.576	0.576	0.576	0.435
Coverall	Arms	151	48.4	48.4	65.0	288	13.9	213	416	651	2 729	3 555	117	319	43.6	1 400
	Legs	362	50.4	183	202	250	152	519	144	2 376	2 567	3 849	257	128	595	3 282
	Torso	122	13.6	118	122	124	7.98	134	345	1 017	2 858	2 285	104	55.9	36.0	1 282
	Total	635	112	350	389	662	174	866	905	4 044	8 153	9 689	478	503	675	5 964
Undergarment	Arms	15.2	0.250	3.06	1.59	18.1	0.250	0.0750	0.89	2.21	27.2	122	2.23	48.6	1.74	6.46
	Legs	2.54	0.0750	0.520	1.09	0.940	0.250	0.250	0.250	19.3	5.66	41.6	0.500	0.250	1.67	4.96
	Torso	2.36	0.0750	0.630	0.510	5.40	0.0750	0.650	0.250	20.8	6.50	8.62	0.0750	0.0750	0.250	2.46
	Total	20.1	0.400	4.21	3.19	24.4	0.575	0.98	1.39	42.2	39.4	172	2.81	49.0	3.66	13.9
Face/neck wipes – M/L		2.36	0.125	1.87	0.125	0.125	0.0375	1.71	3.43	6.67	1.07	4.94	0.0375	0.325	0.125	1.04
Gloves – M/L		694	360	852	661	418	105	2 460	1 421	1 788	366	1 980	50.3	1131	106	645
Hand washes – M/L		8.38	40.7	47.3	39.5	1.55	0.250	45.8	39.6	45.6	1.50	42.3	40.5	40.3	57.4	182
Gown – M/L	Arms	402	840	227	527	236	48.7	1 637	1 503	2 946	411	1 482	13.4	3 067	359	884
	Torso/legs	1673	1 754	301	356	209	216	12 417	793	7 880	228	6 018	39.6	853	571	705
	Total	2 075	2 594	528	882	445	264	14 054	2 296	10 825	639	7 500	53.0	3 920	929	1 589
Face/neck wipes – Application		0.795	0.125	1.18	41.5	3.98	0.0375	0.904	1.00	9.85	7.92	6.25	0.373	0.627	0.125	3.61
Face/neck wipes – M/L & Application		1.08	#	#	#	#	#	#	#	5.95	#	#	#	#	#	#
Gloves – Application		322	173	79.5	7 370	84.1	83.8	256	742	964	633	1 705	164	530	117	2 026
Hand washes – Application		10.0	43.1	42.3	59.1	68.3	37.8	37.2	44.3	76.9	29.9	62.5	45.6	43.0	39.3	52.0
Hand washes – M/L & Application		12.0	#	#	#	#	#	#	#	300	#	#	#	#	#	#
Hand washes – Cleaning		6.90	\$	\$	\$	595	0.746	\$	\$	38.9	8.18	\$	5.70	3.78	0.910	\$
Gown – Cleaning	Arms	212	α	49.5	1 372	68.5	595	α	α	2 108	1 017	α	174	420	30.5	α
	Torso/legs	894	α	59.3	844	14.3	145	α	α	3 125	2 054	α	344	167	42.2	α
	Total	1 107	α	109	2 216	82.7	741	α	α	5 233	3 071	α	518	586	72.7	α

# not applicable; was linked to the fact that the first face/neck wipes and the first hand wash collected the first M/L and the first application phases for operators 1 and 9 (see Deviation 4)

α no cleaning phase

\$ there was either no cleaning of the application equipment or the hand wash combined application and cleaning

Table 9 (continued): Individual results for Operators ( $\mu\text{g/day}$ )

MATRIX	ACTIVE INGREDIENT FINDINGS ( $\mu\text{g/day}$ ) corrected for field recoveries when required														
	Operator No.														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Body weight (kg)	75	90	73	68	85	70	75	74	88	70	55	100	73	73	75
Amount a.s. applied (kg)	1.20	0.480	0.480	0.346	0.480	0.480	0.720	0.660	0.811	0.288	0.600	0.576	0.576	0.576	0.435
Potential dermal exposure excluding hands	3 842	2 707	994	3 532	1 219	1 179	14 924	3 206	20 167	11 911	17 372	1 052	5 060	1 680	7 571
Potential hand exposure	1 053	618	1 021	8 129	1 167	227	2 799	2 246	3 214	1 039	3 790	306	1 747	320	2 905
<b>Potential dermal exposure</b>	<b>4 895</b>	<b>3 325</b>	<b>2 015</b>	<b>11 661</b>	<b>2 386</b>	<b>1 407</b>	<b>17 723</b>	<b>5 452</b>	<b>23 381</b>	<b>12 950</b>	<b>21 162</b>	<b>1 358</b>	<b>6 807</b>	<b>2 000</b>	<b>10 477</b>
Actual dermal exposure excluding hands	24.3	0.650	7.26	44.8	28.5	0.650	3.59	5.82	64.7	48.4	183	3.22	49.9	3.91	18.5
Actual hand exposure	37.3	83.8	89.6	98.6	665	38.8	83.1	83.9	462	39.6	105	91.8	87.1	97.6	234
<b>Actual dermal exposure</b>	<b>61.6</b>	<b>84.5</b>	<b>96.8</b>	<b>143</b>	<b>694</b>	<b>39.4</b>	<b>86.6</b>	<b>89.7</b>	<b>526</b>	<b>87.9</b>	<b>288</b>	<b>95.0</b>	<b>137</b>	<b>101</b>	<b>253</b>
% transfer via coverall	Arms	9.1	0.51	5.9	2.4	5.9	1.8	0.035	0.21	0.34	0.99	3.3	1.9	3.8	0.46
	Legs	0.70	0.15	0.28	0.54	0.37	0.16	0.048	0.17	0.80	0.22	1.1	0.19	0.28	0.15
	Torso	1.9	0.55	0.53	0.42	4.2	0.93	0.48	0.072	2.0	0.23	0.38	0.072	0.13	0.19
	<b>Total</b>	<b>3.1</b>	<b>0.35</b>	<b>1.2</b>	<b>0.81</b>	<b>3.6</b>	<b>0.33</b>	<b>0.11</b>	<b>0.15</b>	<b>1.0</b>	<b>0.48</b>	<b>1.7</b>	<b>0.58</b>	<b>0.54</b>	<b>0.23</b>
% transfer via coverall and gown worn during mixing/loading and cleaning (when any)	Arms	1.9	0.028	0.93	0.081	3.0	0.038	0.0041	0.046	0.039	0.65	2.4	0.73	1.3	0.28
	Legs / torso	0.16	0.0082	0.17	0.10	1.0	0.062	0.0069	0.039	0.28	0.16	0.41	0.077	0.027	0.15
	<b>Total</b>	<b>0.52</b>	<b>0.015</b>	<b>0.42</b>	<b>0.091</b>	<b>2.0</b>	<b>0.049</b>	<b>0.0065</b>	<b>0.043</b>	<b>0.21</b>	<b>0.33</b>	<b>1.0</b>	<b>0.27</b>	<b>0.97</b>	<b>0.22</b>
	<b>Total</b>	<b>0.52</b>	<b>0.015</b>	<b>0.42</b>	<b>0.091</b>	<b>2.0</b>	<b>0.049</b>	<b>0.0065</b>	<b>0.043</b>	<b>0.21</b>	<b>0.33</b>	<b>1.0</b>	<b>0.27</b>	<b>0.97</b>	<b>0.22</b>



TABLE 10: INDIVIDUAL RESULTS FOR OPERATORS (µg/KG A.S. APPLIED)

MATRIX		ACTIVE INGREDIENT FINDINGS (µg/kg a.s. applied) corrected for field recoveries when required														
		Operator No.														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Body weight (kg)		75	90	73	68	85	70	75	74	88	70	55	100	73	73	75
	Amount a.s. applied (kg)	1.20	0.480	0.480	0.346	0.480	0.480	0.720	0.660	0.811	0.288	0.600	0.576	0.576	0.576	0.435
Coverall	Arms	126	101	101	188	601	28.9	296	631	803	9 474	5 926	203	554	75.7	3 219
	Legs	302	105	382	584	522	317	721	218	2 929	8 912	6 415	445	223	1 033	7 544
	Torso	101	28.2	247	353	258	16.6	186	523	1 254	9 922	3 808	181	97.1	62.5	2 947
	Total	529	234	729	1 125	1 380	362	1 203	1 371	4 986	28 308	16 148	830	873	1 171	13 710
Undergarment	Arms	12.6	0.521	6.38	4.60	37.6	0.521	0.104	1.35	2.73	94.5	203	3.87	84.4	3.02	14.9
	Legs	2.12	0.156	1.08	3.15	1.96	0.521	0.347	0.379	23.8	19.7	69.3	0.868	0.434	2.90	11.4
	Torso	1.97	0.156	1.31	1.48	11.3	0.156	0.903	0.379	25.6	22.6	14.4	0.130	0.130	0.434	5.66
	Total	16.7	0.833	8.8	9.2	50.9	1.20	1.35	2.11	52.1	137	286	4.87	85.0	6.35	31.9
Face/neck wipes – M/L		1.97	0.260	3.89	0.362	0.260	0.0781	2.38	5.20	8.22	3.72	8.23	0.0651	0.565	0.217	2.38
Gloves – M/L		578	751	1 775	1 912	870	218	3 416	2 152	2 205	1 272	3 301	87.4	1 963	183	1 482
Hand washes – M/L		6.98	84.9	98.5	114	3.23	0.521	63.7	60.0	56.2	5.21	70.5	70.3	70.0	99.6	419
Gown – M/L	Arms	335	1 749	473	1 524	491	102	2 273	2 277	3 632	1 428	2 469	23.3	5 325	623	2 033
	Torso/legs	1 394	3 655	627	1 029	436	449	17 246	1 201	9 716	792	10 031	68.8	1 481	991	1 620
	Total	1 729	5 405	1 100	2 553	927	551	19 520	3 478	13 348	2 220	12 500	92.1	6 806	1 613	3 653
Face/neck wipes – Application		0.663	0.260	2.46	120	8.28	0.0781	1.26	1.52	12.1	27.5	10.4	0.648	1.09	0.217	8.31
Face/neck wipes – M/L & Application		0.904	#	#	#	#	#	#	#	7.34	#	#	#	#	#	#
Gloves – Application		268	361	166	21 325	175	175	356	1124	1 188	2 198	2 842	285	920	202	4 657
Hand washes – Application		8.36	89.8	88.1	171	142	78.7	51.7	67.1	94.8	104	104	79.2	74.7	68.2	120
Hand washes – M/L & Application		10.0	#	#	#	#	#	#	#	370	#	#	#	#	#	#
Hand washes – Cleaning		5.75	\$	\$	\$	1 240	1.55	\$	\$	47.9	28.4	\$	9.90	6.56	1.58	\$
Gown – Cleaning	Arms	177	□	103	3 971	143	1 240	□	□	2 599	3 530	□	303	729	53.0	□
	Torso/legs	745	□	124	2 441	29.7	302	□	□	3 854	7 132	□	597	289	73.2	□
	Total	922	□	227	6 412	172	1 543	□	□	6 453	10 662	□	900	1 018	126	□

# not applicable; was linked to the fact that the first face/neck wipes and the first hand wash collected the first M/L and the first application phases for operators 1 and 9 (see Deviation 4)

□ no cleaning phase

\$ there was either no cleaning of the application equipment or the hand wash combined application and cleaning

Table 10 (continued): Individual results for Operators ( $\mu\text{g/kg}$  a.s. applied)

MATRIX	ACTIVE INGREDIENT FINDINGS ( $\mu\text{g/kg}$ a.s. applied) corrected for field recoveries when required														
	Operator No.														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Body weight (kg)	75	90	73	68	85	70	75	74	88	70	55	100	73	73	75
Amount a.s. applied (kg)	1.20	0.480	0.480	0.346	0.480	0.480	0.720	0.660	0.811	0.288	0.600	0.576	0.576	0.576	0.435
Potential dermal exposure excluding hands	3 201	5 640	2 071	10 220	2 539	2 457	20 727	4 858	24 867	41 358	28 953	1 827	8 784	2 917	17 406
Potential hand exposure	878	1 287	2 127	23 522	2 431	473	3 887	3 403	3 963	3 608	6 317	531	3 034	555	6 679
Potential dermal exposure	4 079	6 927	4 199	33 742	4 970	2 930	24 615	8 261	28 830	44 965	35 270	2 358	11 818	3 472	24 084
Actual dermal exposure excluding hands	20.2	1.35	15.1	130	59.4	1.35	4.99	8.82	79.8	168	305	5.58	86.6	6.79	42.6
Actual hand exposure	31.1	175	187	285	1 386	80.8	115	127	569	137	175	159	151	169	539
Actual dermal exposure	51.3	176	202	415	1 445	82.1	120	136	649	305	480	165	238	176	582

TABLE 11: INDIVIDUAL RESULTS FOR OPERATORS ( $\mu\text{G/KG BODYWEIGHT}$ )

MATRIX		ACTIVE INGREDIENT FINDINGS ( $\mu\text{g/kg bw}$ ) corrected for field recoveries when required														
		Operator No.														
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Body weight (kg)		75	90	73	68	85	70	75	74	88	70	55	100	73	73	75
Amount a.s. applied (kg)		1.20	0.480	0.480	0.346	0.480	0.480	0.720	0.660	0.811	0.288	0.600	0.576	0.576	0.576	0.435
Coverall	Arms	2.02	0.538	0.663	0.955	3.39	0.198	2.84	5.62	7.40	39.0	64.6	1.17	4.37	0.597	18.7
	Legs	4.83	0.560	2.51	2.97	2.95	2.17	6.92	1.94	27.0	36.7	70.0	2.57	1.76	8.15	43.8
	Torso	1.62	0.151	1.62	1.80	1.45	0.114	1.78	4.66	11.6	40.8	41.5	1.04	0.766	0.493	17.1
Total		8.47	1.25	4.80	5.72	7.79	2.48	11.5	12.2	46.0	116	176	4.78	6.89	9.24	79.5
Undergarment	Arms	0.202	0.00278	0.0419	0.0234	0.213	0.00357	0.00100	0.0120	0.0251	0.389	2.21	0.0223	0.666	0.0238	0.0861
	Legs	0.0339	0.000833	0.00712	0.0160	0.0111	0.00357	0.00333	0.00338	0.219	0.0809	0.755	0.00500	0.00342	0.0229	0.0661
	Torso	0.0315	0.000833	0.00863	0.00750	0.0635	0.00107	0.00867	0.00338	0.236	0.0929	0.157	0.000750	0.00103	0.00342	0.0328
Total		0.267	0.00444	0.0577	0.0469	0.287	0.00821	0.0130	0.0188	0.480	0.563	3.12	0.0281	0.671	0.0501	0.185
Face/neck wipes - M/L		0.0315	0.00139	0.0256	0.00184	0.00147	0.000536	0.0228	0.0464	0.0758	0.0153	0.0898	0.000375	0.00446	0.00171	0.0138
Gloves - M/L		9.25	4.01	11.7	9.72	4.91	1.49	32.8	19.2	20.3	5.23	36.0	0.503	15.5	1.45	8.60
Hand washes - M/L	Arms	0.112	0.453	0.648	0.580	0.0182	0.00357	0.611	0.535	0.518	0.0214	0.769	0.405	0.552	0.786	2.43
	Torso/legs	5.36	9.33	3.11	7.74	2.77	0.696	21.8	20.3	33.5	5.87	26.9	0.134	42.0	4.91	11.8
	Total	22.3	19.5	4.12	5.23	2.46	3.08	166	10.7	89.5	3.26	109	0.396	11.7	7.82	9.40
Gown - M/L		27.7	28.8	7.23	13.0	5.24	3.78	187	31.0	123	9.13	136	0.530	53.7	12.7	21.2
Face/neck wipes - Application		0.0106	0.00139	0.0162	0.610	0.0468	0.000536	0.0120	0.0135	0.112	0.113	0.114	0.00373	0.00858	0.00171	0.0482
Face/neck wipes-M/L & Appl.		0.0145	#	#	#	#	#	#	#	0.0676	#	#	#	#	#	#
Gloves - Application		4.30	1.93	1.09	108	0.990	1.20	3.42	10.0	10.9	9.04	31.0	1.64	7.26	1.60	27.0
Hand washes - Application		0.134	0.479	0.580	0.870	0.803	0.540	0.496	0.598	0.874	0.427	1.14	0.456	0.590	0.538	0.694
Hand washes-M/L & Appl.		0.160	#	#	#	#	#	#	#	3.41	#	#	#	#	#	#
Hand washes - Cleaning		0.0920	\$	\$	\$	7.00	0.0107	\$	\$	0.442	0.117	\$	0.0570	0.0518	0.0125	\$
Gown - Cleaning	Arms	2.83	¤	0.679	20.2	0.805	8.51	¤	¤	24.0	14.5	¤	1.74	5.75	0.418	¤
	Torso/legs	11.9	¤	0.813	12.4	0.168	2.07	¤	¤	35.5	29.3	¤	3.44	2.28	0.577	¤
	Total	14.8	¤	1.49	32.6	0.973	10.6	¤	¤	59.5	43.9	¤	5.18	8.03	0.996	¤

# not applicable; was linked to the fact that the first face/neck wipes and the first hand wash collected the first M/L and the first application phases for operators 1 and 9 (see Deviation 4)

¤ no cleaning phase

\$ there was either no cleaning of the application equipment or the hand wash combined application and cleaning

Table 11 (continued): Individual results for Operators ( $\mu\text{g}/\text{kg}$  bodyweight)

MATRIX	ACTIVE INGREDIENT FINDINGS ( $\mu\text{g}/\text{kg}$ bw) corrected for field recoveries when required														
	Operator No.														
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15
Body weight (kg)	75	90	73	68	85	70	75	74	88	70	55	100	73	73	75
Amount a.s. applied (kg)	1.20	0.480	0.480	0.346	0.480	0.480	0.720	0.660	0.811	0.288	0.600	0.576	0.576	0.576	0.435
Potential dermal exposure excluding hands	51.2	30.1	13.6	51.9	14.3	16.8	199	43.3	229	170	316	10.5	69.3	23.0	101
Potential hand exposure	14.0	6.86	14.0	120	13.7	3.25	37.3	30.4	36.5	14.8	68.9	3.06	23.9	4.38	38.7
Potential dermal exposure	65.3	36.9	27.6	171	28.1	20.1	236	73.7	266	185	385	13.6	93.2	27.4	140
Actual dermal exposure excluding hands	0.324	0.00722	0.0994	0.659	0.335	0.00929	0.0479	0.0787	0.735	0.691	3.33	0.0322	0.684	0.0536	0.247
Actual hand exposure	0.497	0.931	1.23	1.45	7.82	0.554	1.11	1.13	5.25	0.565	1.91	0.918	1.19	1.34	3.13
Actual dermal exposure	0.821	0.939	1.33	2.11	8.16	0.563	1.16	1.21	5.98	1.26	5.23	0.950	1.88	1.39	3.37