Annex to:

EFSA (European Food Safety Authority), 2022. Statement concerning the review of the approval of the active substance ipconazole. EFSA Journal 2022;20(2):7133, 12 pp. doi:10.2903/j.efsa.2022.7133

Annex A – Assessment of the field studies submitted for non-dietary negligible exposure of ipconazole

A.1. Operator

Study reference:

Determination of operator dermal and inhalation exposure to ipconazole during maize seed treatment with Rancona 450 FS (F2243AA) in a French facility, 2020

[redacted] 2021-03-26, PP164-00009, Doc. N°:575-002.

Methodology:

The submitted study presented the following **limitations**, agreed by RMS and EFSA:

- limited number of operators: 7 (for 8 half-day working shifts) while at least 10 are recommended in the available guidance (OECD, 1997). Consequently, the individual operator exposure estimates are provided instead of a statistical estimate. It is noted that test subjects 3 and 7 were not practically involved in any seed treatment task as they were forklift drivers, thus cannot be considered strictly as operators.

- the operators in the study wore normal workwear, high visibility waistcoats and gloves, further personal protective equipment (PPE) such as safety caps, face masks and safety googles were used but residues levels were not monitored on these PPEs. Therefore it will be considered that potential dermal exposure of the face has not been measured and face/neck wipes values will correspond to the actual dermal exposure of the face with use of protective mask.

[redacted]

- the treated seed type was maize while the critical representative use of ipconazole is on barley. The impact of this difference on the exposure estimates cannot be quantified but is not expected to be significant.

- the applied formulation type was FS while the representative formulation type is ME. The impact of this difference on the exposure estimates cannot be quantified and remains an uncertainty.

The study parameters were compared to the **critical representative use** on barley, as supported in the EU peer review assessment (EFSA, 2013a,b) (see Table 1).

Table 1: Comparison of the study parameters with the critical representative use

	Study	Representative use
Formulation name	RANCONA 450 FS	Rancona 15ME
Formulation type	flowable concentrate for seed treatment (FS)	micro-emulsion (ME)
Active substance (g/L)	452	15
Application rate (g. a.s./ 100 kg seed)	8.21	2
Seed type	maize	barley
Mass of seed handled/day	7234.5 kg seed (morning shift) (2) 9100 kg seed (afternoon shift) (2)	75 tonnes (1)
Amount of ipconazole handled (kg/day)	593.95 g (morning shift) 747.11 g (afternoon shift)	1500 g/day (3)

(1) Based on ipconazole peer review (EFSA, 2013a,b) it is assumed that a static treatment plant with a low level of automation can achieve a throughput of 75 tonnes of seed per day.

(2) Calculated based on the information provided in the study that 7234.5 kg seed were filled in the bags during the morning shift and 9100 kg seed were filled during the afternoon shift.

(3) Maximum daily application rate based on a seed loading of 20 g ipconazole/tonne of seed and a throughput of 75 tonnes of treated seed/day.

For the exposure results from the study to be in line with the amount of ipconazole handled per day from the critical representative use, the values for individual operators were scaled up by a factor of 2.53 (morning shift operators) and 2.01 (afternoon shift operators) (see Table 5 below). It is noted that the RMS proposed to scale on a timely basis by a factor of 1.6, extrapolating the overall study duration in the trial of 5h to a full working day of 8h but could also agree with the EFSA's approach.

Results:

Table 2: Ipconazole residues on operator dosimeters (µg/dosimeter)

Operator No.		**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Mean flow rate of pump (L/min)		1.022	1.02	1.023	1.021	1.021	1.023	1.02	1.022
Mass (g) of a.s. handled/day		593.95	593.95	593.95	593.95	747.11	747.11	747.11	747.11
Body weight (kg)		106	81	70	71	59	76	75	71
Cotton undergarment dosimeter *= inner clothing*	Arms	0.419	9.450	0.439	13.400	1.060	0.350 (5)	0.850	7.860
	Legs	1.080	5.650	0.991	13.600	0.673	2.340	1.190	5.900
	Torso	1.000(5)	1.740	1.040	37.200	1.000 (5)	1.000 (5)	1.220	10.600
Polyester/Cotton coverall, outer dosimeter #1 *= outer clothing*	Arms	3.550	80.700	4.630	1842.000	40.300	4.240	2.800 (5)	106.000
	Legs	6.000 (5)	53.800	15.600	7952.000	105.000	23.300	26.200	93.800
	Torso	10.800 (5)	50.700	10.800 (5)	1335.000	31.600	10.800 (5)	10.800 (5)	121.000
Polyester Hi-vis waistcoat, Outer dosimeter #4	Total (torso)	13.500	163.000	10.800 (5)	1523.000	107.000	10.800 (5)	10.800 (5)	90.400
Hand wash solution	Slurry prep.	---	---	---	8.630	---	---	---	---
	Calibration	---	---	---	3.511 (2)	---	---	---	8.200
	Other tasks	0	2.557 (2)	0	---	0.568 (1,5)	0	0	---
Protective gloves	Slurry	---	---	---	16887.	---	---	---	---

	prep.				500 (2)				
	Calibration	---	---	---	11037.500 (2)	---	---	---	4187.500 (2)
	Other tasks	0	35.395 (1)	13.158 (1,5)	---	61.579 (1)	13.158 (1,5)	13.158 (1,5)	---
Face/neck wipes	Slurry prep & calibration	---	---	---	0.137	---	---	---	0.240
	Other tasks	0	0.414	0	---	0.100	---	0	---
XAD-2 OVS tube	Slurry prep.	---	---	---	0.0463 (3)	---	---	---	---
	Calibration	---	---	---	0.0202 (3)	---	---	---	0.0059 (4)
	Other tasks	0.0333 (3)	0.4506 (3)	0.0052 (4)	---	0.0547 (3)	0.0178 (3)	0.0064 (4)	---
	Sum of tubes	0.0333	0.4506	0.0052	0.0666	0.0547	0.0178	0.0064	0.0059

Data correction was performed when the relevant mean field recovery was <95%:

(1) corrected for field recovery 76%

(2) corrected for field recovery 88%

(3) corrected for field recovery 87%

(4) corrected for field recovery 92%

(5) Values below LOQ were reported at the LOQ, values below the LOD were considered nul (no exposure)

Based on the exposure values from the dosimeters, the exposure values per person were calculated and are presented in Table 3.

Table 3: Individual exposure values (µg/person)

Operator No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Body PDE (1)	36.349	365.040	44.300	12716.200	286.633	52.830	53.860	435.560
Body ADE (2)	2.499	16.840	2.470	64.200	2.733	3.690	3.260	24.360
Body ADEc (3)	1.817	18.252	2.215	635.810	14.332	2.642	2.693	21.778
Hand PDE (4)	0.000	37.952	13.158	27937.141	62.147	13.158	13.158	4195.700
Hand ADE (5)	0.000	2.557	0.000	12.141	0.568	0.000	0.000	8.200
PIE (6)	0.678	9.188	0.106	1.356	1.115	0.362	0.130	0.121
AIE (7)	0.068	0.919	0.011	0.136	0.111	0.036	0.013	0.012
Face ADE (8)	0.000	0.414	0.000	0.137	0.100	0.000	0.000	0.240

(1) **Body PDE** = potential dermal exposure of the body, excluding face and hands (corresponding to the sum of inner + outer clothing + polyester Hi-vis waistcoat in the study)

(2) **Body ADE** = actual dermal exposure of the body, excluding face and hands, assuming the use of workwear (corresponding to inner clothing in the study)

(3) **Body ADEc** = actual dermal exposure of the body, excluding face and hands, assuming the use of certified protective coveralls instead of working clothing (with application of a 95% protection factor to the Body PDE (EFSA, 2014))

(4) **Hand PDE** = potential dermal exposure of the hands (corresponding to the sum of hand washings and gloves in the study)

(5) **Hand ADE** = actual dermal exposure of the hands, with use of protective gloves (corresponding to hand washings in the study)

(6) **PIE** = potential exposure by inhalation, calculated for a standard breathing rate of 20.8 L/min and based on the mean flow rate of the pump for each operator

(7) **AIE** = actual exposure by inhalation, assuming the use of FFP2 face mask (with application of a 90% protection factor to the PIE (EFSA, 2014))

(8) **Face ADE** = actual dermal exposure of the face (corresponding to the sum of the face/neck wipes in the study, and considering that the operators were wearing safety caps, face masks and googles during their activities)

As next step, the systemic exposure values were calculated, assuming the dermal absorption value of 5% for ipconazole and the actual body weight of each operator, as presented in Table 4.

Table 4: Systemic exposure values (µg/kg bw)

Operator No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Total PSE (1)	0.024	0.362	0.043	28.648	0.315	0.048	0.046	3.263
Total ASE ww+FFP2 (2)	0.002	0.045	0.011	19.721	0.057	0.012	0.011	2.972
Total ASE ww+gl+FFP2 (3)	0.002	0.024	0.002	0.056	0.005	0.003	0.002	0.023
Total ASE cc+gl+FFP2 (4)	0.001	0.024	0.002	0.458	0.015	0.002	0.002	0.021

(1) **Total PSE** = Total potential systemic exposure, without use of PPE/RPE (corresponding to Body PDE + Hand PDE + Face ADE + PIE)
(2) **Total ASE ww+FFP2** = Total actual systemic exposure, with use of normal workwear and FFP2 (corresponding to Body ADE + Hand PDE + Face ADE + AIE)
(3) **Total ASE ww+gl+FFP2** = Total actual systemic exposure, with use of normal workwear, single use splash resistant gloves and FFP2 face mask (corresponding to Body ADE + Hand ADE + Face ADE + AIE)
(4) **Total ASE cc+gl+FFP2** = Total actual systemic exposure, with use of certified protective coveralls (instead of workwear), single use splash resistant gloves and FFP2 face mask (corresponding to Body PDE assuming 95% protection by certified coveralls + Hand ADE + Face ADE + AIE)

In order to align the exposure results from the study with the amount of ipconazole handled per day from the critical representative use, the exposure values for individual operators were scaled up by a factor of 2.53 and 2.01 (see Table 1) and are presented in Table 5.

Table 5: Scaled systemic exposure estimates (µg/kg bw) assuming 1500 g a.s. is handled/day

Operator No.	**1**	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Scaling factor	2.53	2.53	2.53	2.53	2.01	2.01	2.01	2.01
Total PSE (1)	0.060	0.917	0.108	72.480	0.632	0.097	0.093	6.559
Total ASE ww+FFP2 (2)	0.005	0.115	0.029	49.895	0.114	0.023	0.022	5.974
Total ASE ww+gl+FFP2 (3)	0.005	0.060	0.005	0.141	0.010	0.006	0.005	0.047
Total ASE cc+gl+FFP2 (4)	0.004	0.062	0.004	1.160	0.029	0.004	0.004	0.043

(1) **Total PSE** = Total potential systemic exposure, without use of PPE/RPE (corresponding to Body PDE + Hand PDE + Face ADE + PIE)
(2) **Total ASE ww** = Total actual systemic exposure, with use of normal workwear (corresponding to Body ADE + Hand PDE + Face PDE + PIE)
(3) **Total ASE ww+gl+FFP2** = Total actual systemic exposure, with use of normal workwear, single use splash resistant gloves and FFP2 face mask (corresponding to Body ADE + Hand ADE + Face ADE + AIE)
(4) **Total ASE cc+gl+FFP2** = Total actual systemic exposure, with use of certified protective coveralls (instead of workwear), single use splash resistant gloves and FFP2 face mask (corresponding to Body PDE assuming 95% protection by certified coveralls + Hand ADE + Face ADE + AIE)

The final results in % of (A)AOEL can be found in Table 1 in the Statement.

[redacted]

[redacted]

Table 6: SeedTropex estimates for equipment cleaning and seed bagging tasks

Exposure estimates for bagging	**mg/person per day**	**mg/kg bw per day****
Potential inhalation exposure during bagging	0.0432#	0.001
Inhalation exposure during bagging assuming FFP2	0.00432*	0.000
Actual dermal exposure during bagging using coveralls	5.58#	0.005
Total exposure during bagging, with coveralls and FFP2		0.005
Exposure estimates for equipment cleaning		
Actual dermal exposure during cleaning using coveralls and gloves	1.2505#	0.001
Potential inhalation exposure during cleaning	0.24#	0.004
Inhalation exposure during cleaning assuming FFP2	0.024*	0.000
Total exposure during cleaning, with coveralls, gloves and FFP2		0.001

Value as calculated during the peer review of the representative product when the product is applied undiluted at an application rate of 2.0 g a.s./100 kg seed.

* Exposure calculated by applying a 90% protection factor (EFSA, 2014) to the potential inhalation exposure data as predicted by the model.

** Based on a default body weight of 60kg and a dermal absorption of 5% (as agreed during the peer review).

A.2. Worker

Study reference:

Determination of worker and bystander dermal and inhalation exposure to ipconazole during seed loading and drilling maize seed treated with Rancona 450 FS (F2243AA) in the UK in 2020.

[redacted]2021-03-26, PP164-00009, Doc. N°: 575-003.

Methodology:

The submitted study presented the following **limitations**:

- limited number of workers: 2 while at least 10 are recommended in the available guidance (OECD, 1997). Consequently, the individual exposure estimates are provided for each worker instead of a statistical estimate.

- the drilling machinery was a pneumatic-type device: according to the available guidance (European Commission, 2012), vacuum pneumatic machines must be equipped with devices ensuring dust deflection to soil, in order to limit the dust drift. It is unclear if the machinery used in this study was equipped with such deflectors.

- the workers used tractors with closed cabins: inhalation exposure is expected to occur mainly during loading and emptying of the seed hoppers, rather than during drilling. Therefore, FFP2 was considered as an applicable PPE.

- limited work duration and quantity of seed drilled (due to poor weather conditions): it is considered that the main study parameter to be aligned with the representative use is the amount of ipconazole handled by each worker during the working day. Even though a small part of the total amount of loaded seed has been effectively drilled (and therefore the exposure during drilling might be underestimated), it is noted that the additional activity of emptying the hoppers at the end of the day

is expected to increase significantly the level of exposure compared to drilling with closed cabins. Accordingly, the values for individual workers were scaled up by a factor of 11 (for worker 1) and 12 (for worker 2) on the basis of the total amount of ipconazole contained in the seed loaded by each worker (see Tables 7 and 11). It is noted that the RMS proposed to scale on a timely basis by a factor of 1.9 and 4.4, extrapolating the overall study duration in the trial to a full working day of 8h, and considered that the scaling factors proposed by EFSA may be extreme worst-case.

- the 2 workers drilled the seed on the same field: on one hand the worker 2 could have been exposed to the previous sown treated seeds, which could be more easily dislodged due to the wet condition of the soil; on the other hand a lower dust formation would be expected in wet conditions.

- the treated seed type was maize while the critical representative use of ipconazole is on barley. The impact of this difference cannot be quantified but is not expected to be significant.

- the applied formulation type was FS while the representative formulation type is ME

The study parameters were compared to the **critical representative use** on barley, as supported in the EU peer review assessment (EFSA, 2013a,b) (see Table 7).

Table 7: Comparison of the study parameters with the critical representative use

	Study (W1 – W2)		**Representative use**
Formulation name	RANCONA 450 FS		Rancona 15ME
Formulation type	flowable concentrate for seed treatment (FS)		micro-emulsion (ME)
Active substance (AS) (g/L)	452		15
Amount of ipconazole on treated seed (g a.s./ ton seed)	70.5 (actual)		20
Seed type	maize		barley
Amount of seed loaded (kg)	135	120	
Amount of seed drilled (kg)	50.75	7.25	
Amount of seed recovered (kg)	84.25	112.75	
Duration of loading (min)	9	11	
Duration of drilling (h)	3h36	1h06	
Seeding/drilling area (ha/day)	0.38	0.21	15 (1)
Seeding rate (kg seed/ha)	133.55	34.5	350
Application rate during sowing (g a.s./ha)	9.42 (2)	2.43 (2)	7 (3)
Amount of a.s. handled (g/day)	9.52 (4)	8.46 (4)	7x15 = 105 (5)
Scaling factors (6)	11	12	na

(1) It is assumed that a realistic average work rate for sowing/drilling seed is 15 ha/day.
(2) The application rate during sowing is based on the amount of ipconazole on treated seed multiplied by the seeding rate (kg seed/ha).
(3) The application rate for the representative use during sowing is based on the amount of ipconazole on treated seed multiplied by the seeding rate.
(4) The amount of active substance handled per day is based on the amount of ipconazole on treated seed multiplied by the total amount of seed loaded.
(5) The amount of active substance handled per day during the representative use is based on the application rate during sowing multiplied by the average work rate for sowing/drilling (15 ha/day).
(6) The scaling factors will be used for extrapolating the measured exposure values to the amount of a.s. handled per day for the representative use.

Results:

Table 8: Ipconazole residues on worker dosimeters (µg/dosimeter)

WORKER No.		Worker 1	Worker 2
Inner body dosimeter [1]	Arms	6.96	23.17
	Legs	2.77	11.24
	Torso	4.15	21.34
Outer body dosimeter [2]	Arms	227	475
	Legs	209	546
	Torso	309	443
Hand wash solution		19.5	65.3
Protective gloves [3] [4]		3107	2852
Face/neck wipes [5]		1.38	2.04
XAD-2 OVS tube [6]		0.444	2.15
Pump mean flow (L/min)		0.991	0.996

Data correction was performed when the relevant mean field recovery was <95%:
[1] Corrected for field recovery 82%
[2] Corrected for field recovery 93%
[3] Corrected for field recovery 87% when residue level < geom mean
[4] Corrected for field recovery 89% when residue level > geom mean
[5] Corrected for field recovery 92%
[6] Corrected for field recovery 88%

Based on the exposure values from the dosimeters, the exposure values per person were calculated and are presented in Table 9.

Table 9: Individual exposure values (µg/person)

WORKER No.	Worker 1	Worker 2
PDE (unprotected) [1]	3886.76	4439.09
ADE (protected body) [2]	3141.76	2975.09
ADE (protected hand/body) [3]	34.76	123.09
PIE (no RPE) [4]	9.319	44.9
AIE (RPE) [5]	0.93	4.49

[1] **PDE (unprotected)** = potential dermal exposure of unprotected body, including face and hands (corresponding to the stum of outer dosimeter + inner dosimeter + hand wash + gloves + face/neck wipes)
[2] **ADE (protected body)** = actual dermal exposure of the protected body, including face and hands (corresponding to the sum of inner dosimeter + hand wash + gloves + face/neck wipes)
[3] **ADE (protected hand/body)** = actual dermal exposure of the protected body and hands, including face (corresponding to the sum of inner dosimeter + hand wash + face/neck wipes)
[4] **PIE (no RPE)** = potential exposure by inhalation, calculated for a standard breathing rate of 20.8 L/min and based on the mean flow rate of the pump for each worker.
[5] **AIE (RPE)** = actual exposure by inhalation, assuming the use of FFP2 face mask (with application of a 90% protection factor to the PIE (EFSA, 2014)).

As next step, the systemic exposure values were calculated, assuming the dermal absorption value of 5% for ipconazole and the actual body weight of each worker, as presented in Table 10.

Table 10: Systemic exposure values (mg/kg bw)

WORKER No.	Worker 1	Worker 2
Body weight (kg)	85	46
Total PSE [(1)]	0.00239	0.00580
Total ASE (working clothing) [(2)]	0.00196	0.00421
Total ASE (working clothing + gloves) [(3)]	0.00013	0.00111
Total ASE (working clothing + gloves + FFP2) [(4)]	0.000031	0.00023

[(1)] **Total PSE** = Total potential systemic exposure, without use of PPE/RPE (corresponding to PDE + PIE)
[(2)] **Total ASE (working clothing)** = Total actual systemic exposure, with use of working clothing (corresponding to ADE (protected body) + PIE)
[(3)] **Total ASE (working clothing + gloves)** = Total actual systemic exposure, with use of working clothing and gloves (corresponding to ADE (protected hand/body) + PIE)
[(4)] **Total ASE (working clothing + gloves + FFP2)** = Total actual systemic exposure, with use of working clothing, gloves and FFP2 face mask (corresponding to ADE (protected hand/body) + AIE (RPE))

In order to align the exposure results from the study with the amount of ipconazole handled per day from the critical representative use (as mentioned above), the exposure values for individual workers were scaled up to 11 and 12 fold (see Table 7) and are presented in Table 11.

Table 11: Scaled systemic exposure estimates (mg/kg bw) assuming 105 g a.s./ha

WORKER No.	Worker 1	Worker 2
Scaling factor	11	12
Total PSE [(1)]	0.026	0.070
Total ASE (working clothing) [(2)]	0.022	0.051
Total ASE (working clothing + gloves) [(3)]	0.001	0.013
Total ASE (working clothing + gloves + FFP2) [(4)]	< 0.001	0.003

[(1)] **Total PSE** = Total potential systemic exposure, without use of PPE/RPE (corresponding to PDE + PIE)
[(2)] **Total ASE (working clothing)** = Total actual systemic exposure, with use of working clothing (corresponding to ADE (protected body) + PIE)
[(3)] **Total ASE (working clothing + gloves)** = Total actual systemic exposure, with use of working clothing and gloves (corresponding to ADE (protected hand/body) + PIE)
[(4)] **Total ASE (working clothing + gloves + FFP2)** = Total actual systemic exposure, with use of working clothing, gloves and FFP2 face mask (corresponding to ADE (protected hand/body) + AIE (RPE))

A.3. Bystander and resident

Study reference (same study as for workers)

Determination of worker and bystander dermal and inhalation exposure to ipconazole during seed loading and drilling maize seed treated with Rancona 450 FS (F2243AA) in the UK in 2020.

[redacted] 2021-03-26, PP164-00009, Doc. N°:575-003.

Methodology:

The submitted study presented some **limitations**:

- limited number of mannequins: three for adults and three for children, while at least 10 are recommended in the available guidance (OECD, 1997). Consequently, the individual exposure estimates are provided for each mannequin instead of a statistical estimate.

- lack of data on the limits of quantifications (LOQ) for the different dosimeters:

  - LOQ for the child dosimeters: not provided in the study for each specimen analysed, thus the LOQ for the adult dosimeters was used instead;
  - LOQ for head: as no specimen LOQ was provided in the study, LOQ for head is based on the adult head surface area.

- no external dermal dosimeters were included in the study, thus a 50% protection from light clothing covering only torso (EFSA, 2014) was assumed. Applicant and RMS followed the same approach.

- the treated seed type was maize while the critical representative use of ipconazole is on barley.

- the applied formulation type was FS while the representative formulation type is ME

The study parameters were compared to the **critical representative use** on barley, as supported in the EU peer review assessment (EFSA, 2013a,b) (see Table 7).

Table 12: Comparison of the study parameters with the critical representative use

	Study (W1)	**Representative use**
Formulation name	RANCONA 450 FS	Rancona 15ME
Formulation type	flowable concentrate for seed treatment (FS)	micro-emulsion (ME)
Active substance (AS) (g/L)	452	15
Amount of ipconazole on treated seed (g a.s./ ton seed)	70.5 (actual)	20
Seed type	maize	barley
Amount of seed loaded (kg)	135	
Amount of seed drilled (kg)	50.75	
Amount of seed recovered (kg)	84.25	
Seeding/drilling area (ha/day)	3.8	15 (1)
Seeding rate (kg seed/ha)	133.55	350
Application rate during sowing (g a.s./ha)	9.42 (2)	7 (3)

(1) It is assumed that a realistic average work rate for sowing/drilling seed is 15 ha/day.
(2) The application rate during sowing is based on the amount of ipconazole on treated seed multiplied by the seeding rate (kg seed/ha).
(3) The application rate for the representative use during sowing is based on the amount of ipconazole on treated seed multiplied by the seeding rate.

Results:

a) Exposure to dust drift (dermal + inhalation):

Ipconazole residues found in the all dosimeters were below the LOQ except for the residues found in the XAD-2 OVS tubes. For the exposure calculations presented, values below LOQ were reported at the LOQ.

Table 13: Measured exposure values (µg/dosimeter) assuming all residues (except for inhalation tubes) were found at the LOQ.

Mannequin No		Adult 1	Adult 3	Adult 5	Child 2	Child 4	Child 6
Inner body dosimeter [1]	Arms	0,35	0,35	0,35	0,35	0,35	0,35
	Legs	0,5	0,5	0,5	0,5	0,5	0,5
	Torso	1	1	1	1	1	1
Head (M) [2]		0,111	0,111	0,111	0,111	0,111	0,111
XAD-2 OVS tube		0,001	0,001	0,00162	0,001	0,00135	0,00104
Pump mean flow (L/min)		0,996	1,008	1,01	1,001	0,998	1,005

[1] No LOQs reported in the study for the child mannequin specimens, thus corresponding LOQs reported for the adult mannequins were used as a worst-case scenario.

[2] Calculated based on the LOQ of 0.01 µg/100 cm² and the adult head default surface area of 1 110 cm^2 (EFSA, 2014)

Table 14: Individual exposure values (µg/person)

Mannequin No	Adult 1	Adult 3	Adult 5	Child 2	Child 4	Child 6
ADE [1]	2,072	2,072	2,072	2,072	2,072	2,072
PIE ADULT BYSTANDER [2]	0,040	0,040	0,064			
PIE CHILD BYSTANDER [2]				0,032	0,043	0,033
PIE ADULT RESIDENT [2]	0,010	0,009	0,015			
PIE CHILD RESIDENT [2]				0,007	0,010	0,008

[1] **ADE** = actual dermal exposure, calculated by applying 50% reduction on torso exposure to account for light clothing (EFSA, 2014).

[2] **PIE** = potential inhalation exposure, calculated using default inhalation rates as reported in EFSA, 2014.

As final step, the systemic exposure values were calculated, assuming light clothing, a dermal absorption value of 5%, default body weight values (10 kg child, 60 kg adult) and default inhalation rates (EFSA, 2014). The results are presented in table 15.

Table 15: Systemic exposure values (µg/kg bw per day)

Mannequin No	Adult 1	Adult 3	Adult 5	Child 2	Child 4	Child 6
Adult bystander	0,002	0,002	0,003			
Child bystander				0,014	0,015	0,014
Adult resident	0,002	0,002	0,002			
Child resident				0,011	0,011	0,011

b) Child exposure to surface deposits:

Exposure to surface deposits for children aged less than three years (worst case scenario compared to adults) is calculated using the following equations (EFSA, 2014):

(1) Dermal exposure + (2) hand to mouth transfer + (3) object to mouth transfer

(1) Dermal exposure: $SER_D = (AR \times D \times TTR \times TC \times H \times DA)/BW$

(2) Hand to mouth transfer: $SOE_H = (AR \times D \times TTR \times SE \times SA \times Freq \times H \times OA)/BW$

(3) Object to mouth transfer: $SOE_O = (AR \times D \times DRP \times IgR \times OA)/BW$

where:

SER_D = systemic exposure of residents via the dermal route (mg/kg bw per day)

TC = transfer coefficient (cm^2/h) (default values of 2600 cm^2/h for children)

H = exposure duration of 2 hours

DA = dermal absorption (5 %)

BW = body weight (10 kg)

SOE_H = systemic oral exposure via the hand to mouth route (mg/kg bw per day)

AR = application rate (mg/cm^2)

D = drift (%)

TTR = 1% turf transferable residues

SE = saliva extraction factor 50 %

SA = surface area of hands (cm^2) (the assumption used here is that 20 cm^2 of skin area is contacted each time a child puts a hand in his or her mouth (US EPA, 2001))

Freq = frequency of hand to mouth (9.5 events per hour)

OA = oral absorption (100 %)

SOE_O = systemic oral exposure via the object to mouth route (mg/kg bw per day)

DPR = dislodgeable residues percentage (%) (a default value of 20 % transferability for object to mouth assessments is recommended by US EPA, 2001)

IgR = ingestion rate for mouthing of grass/day equal to 25 cm^2 of grass/day

For child exposure to ipconazole surface deposits originating from dust drift, the measured residues deposited in the Petri dishes at the feet of the adult mannequins in the study are used in the different equations as outcome of the (AR x D). In total 3 Petri dishes were used, and residues were found below the limit of detection for two of them and at 0.01 µg/100 cm² in the other one. This corresponds to surface deposits of 10^{-7} mg/cm^2.

(1) Dermal exposure:

$SER_D = (10^{-7} \times 1\% \times 2600 \times 2 \times 5\%)/10 = 0.26 \times 10^{-7}$ mg a.s./kg bw per day

(2) Hand to mouth transfer:

$SOE_H = (10^{-7} \times 1\% \times 50\% \times 20 \times 9.5 \times 2 \times 100\%)/10 = 9.50 \times 10^{-9}$ mg a.s./kg bw per day

(3) Object to mouth transfer:

$SOE_O = (10^{-7} \times 20\% \times 25 \times 100)/10 = 50 \times 10^{-7}$ mg a.s./kg bw per day

The total exposure from surface deposits for children aged less than three years (worst case scenario compared to adults) is calculated to be equal to:

$(0.26 \times 10^{-7}) + (9.50 \times 10^{-9}) + (50 \times 10^{-7}) = 50.35 \times 10^{-7}$ mg a.s./kg bw per day which equals to < 1% of the A(AOEL).

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