FINAL REGISTRATION REPORT

Part B

Section 7

Metabolism and Residues

Detailed summary of the risk assessment

Product code: M-100SC-OR2-C

Product name(s): Juzan Extra 100 SC

Chemical active substance:

Mesotrione, 100 g/L

Central Zone

Zonal Rapporteur Member State: Poland

CORE ASSESSMENT

(authorization)

Applicant: CIECH Sarzyna S.A.

Submission date: 05/2022

MS Finalisation date: 12/2022; 05/2023

Katarzyna Czaja

Elektronicznie podpisany przez Katarzyna Czaja
Data: 2023.05.18 17:26:54 +02'00'

Barbara Gworek

Elektronicznie podpisany przez Barbara Gworek
Data: 2023.05.19 13:30:09 +02'00'

Version history

When	What
May 2022	First submission for the product authorisation
12/2022	zRMS assessment
05/2023	The final version of RR after commenting period

Table of Contents

7 Metabolism and residue data (KCA section 6)

7.1 Summary and zRMS Conclusion

Storage stability

The stability of residues during storage of samples was reviewed during the Annex I inclusion process and no further data is required.

Mesotrione is considered to be stable under freezer storage at -18ºC±5ºC for at least 42 months in maize grain and 31 months in maize forage. Frozen storage stability at -18ºC±5ºC of MNBA in maize grain and forage was demonstrated for at least 42 months.

Metabolism in plants and animals

Metabolism in plants and livestock data was provided during the EU review of mesotrione.

Plant residue definition for monitoring Mesotrione (cereals and pulses/oilseeds only) - EFSA journal 2016;14(3):4419, Reg. (EU) 2017/626

Plant residue definition for risk assessment:

Food commodities: Mesotrione (cereals and pulses/oilseeds only)

Feed commodities: Mesotrione and AMBA (including its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional. - EFSA journal 2016;14(3):4419

Magnitude of residues in plants

Proposed GAP for maize is within the EU GAP (SANTE/11654/2016, 23 March 2017).

Sufficient unprotected data were submitted and evaluated in DAR and RAR, and considered enough to support the intended use in maize in NEU. Unprotected data are accepted in RAR.

According to SANTE/2019/12752, extrapolation from immature maize to sweet corn is possible. The residue trials conducted in maize could also be used to support the intended GAP use of sweet corn (taken before BBCH 85).

An exceedance of the current MRL of 0.01 mg/kg for mesotrione on maize and sweet corn as laid down in Reg. (EC) No 396/2005 is not expected.

Magnitude of residues in livestock

No new data were submitted in the framework of this application and no required.

Animals are not exposed to residues via feed above the trigger value (0.004 mg/kg). Therefore livestock feeding studies are not required.

Dietary burden calculation with regard to AMBA conjugates residues in maize forage, fodder and total residues in maize grain from the metabolism data were tentatively estimated by EFSA (*EFSA Journal 2016;14(3):4419*).

EFSA (2016): *This assessment has to be reconsidered pending the outcome of data gap set for clarification of the genotoxic potential of AMBA and of its toxicological profile.*

According to the *EFSA Supporting publication 2018:EN-1527*, genotoxic potential of AMBA is considered clarified:

EFSA: we agree with the RMS conclusion that the micronucleus test gave sufficient evidence of lack of genotoxic (clastogenic and aneugenic) potential of the metabolite AMBA since bone marrow exposure was demonstrated after 2 dosing with the substance with 24 h interval and measurement of AMBA in whole blood. We agree with the RMS that the confirmatory data requirement (1) has been fulfilled. It is however noted that the data gap identified in the EFSA conclusion (EFSA, 2016) regarding the relative

toxicity of the metabolite compared with mesotrione has not been addressed.

The dietary burden recalculation performed by zRMS has been added.

Magnitude of residues in processed commodities

As residues of Mesotrione are not expected in treated crops, there is no need to investigate the effect of industrial and/or household processing. Specific processing factors for enforcement of processed commodities are therefore not proposed.

Magnitude of residues in representative succeeding crops

No new data were submitted in the framework of this application and no required.

Field rotational crop study are not triggered considering the very low TRRs in rotational crops after a bare soil application at ca. 1N rate. No mitigation measures for rotational crops are necessary.

Other / special studies

Studies are not required. Maize is not a melliferous crop foraged by bees.

Estimation of exposure through diet and other means

The proposed uses of mesotrione in the formulation Juzan Extra 100 SC do not represent unacceptable acute and chronic risks for the consumer. Calculations are accepted.

7.1.1 Critical GAP(s) and overall conclusion

Selection of critical uses and justification

The critical GAPs with respect to consumer intake and risk assessment for the preparation M-100SC-OR2-C are presented in Table 7.1-1. They have been selected from the individual GAPs in the zone/EU for maize. A list of all intended uses within the zone/EU is given in Part B, Section 0.

Overall conclusion

The data available are considered sufficient for risk assessment. An exceedance of the current MRL of 0.01 mg/kg for mesotrione as laid down in Reg. (EU) 396/2005 is not expected.

The chronic and the short-term intakes of mesotrione residues are unlikely to present a public health concern.
As far as consumer health protection is concerned, zRMS agrees with the authorization of the intended use(s).

According to available data, no specific mitigation measures should apply.

Data gaps

Data gaps should be listed in the summary to give an overview (especially for cMS).

None

Table 7.1-1: Acceptability of critical GAPs (and respective fall-back GAPs, if applicable)

1	2	3	4	5	6	7		8				9			10	11
GAP number (see part B.0)*	**Crop and/ or situation ****	**Zone**	**Product code**	**F, Fn, Fpn G, Gn, Gpn or I*****	**Pests or Group of pests controlled**	**Formulation**		**Application**				**Application rate per treatment**			**PHI (days)**	**Conclusion**
						Type	**Conc. of as**	**method kind**	**growth stage & season**	**number min max**	**interval between applications (min)**	**g as/hL min max**	**water L/ha min max**	**g as/ha min max**		
1	Maize 0500030	N-EU	M-100SC-OR2-C	F	Monotyledonous weeds(TTDMS); Dicotyledonous weeds (TTDSS)	SC	100 g/L	spraying	BBCH 12 - 18	1	n.a.	37.5 - 75	200-400	150	n.a.	A
2	Sugar maize (ZEAMS); Popcorn (ZEAME); 0234000	N-EU	M-100SC-OR2-C	F	Monotyledonous weeds(TTDMS); Dicotyledonous weeds (TTDSS)	SC	100 g/L	spraying	BBCH 12 - 18	1	n.a.	37.5 - 75	200-400	150	n.a.	A

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

** Use also code numbers according to Annex I of Regulation (EU) No 396/2005

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

Explanation for Column 11 “Conclusion”

A	Exposure acceptable without risk mitigation measures, safe use
R	Further refinement and/or risk mitigation measures required
N	Exposure not acceptable, no safe use

7.1.2 Summary of the evaluation

The preparation M-100SC-OR2-C is composed of mesotrione.

Table 7.1-2: Toxicological reference values for the dietary risk assessment of mesotrione

Reference value	Source	Year	Value	Study relied upon	Safety factor
Mesotrione					
ADI	EFSA Journal 2016;14(3):4419, Peer review of the pesticide risk assessment of the active substance mesotrione	2016	0.01	mouse multigeneration	200
ARfD	EFSA Journal 2016;14(3):4419, Peer review of the pesticide risk assessment of the active substance mesotrione	2016	0.02	mouse multigeneration	100

7.1.2.1 Summary for mesotrione

Table 7.1-3: Summary for mesotrione

Use-No.*	Crop	Plant metabolism covered?	Sufficient residue trials?	PHI sufficiently supported?	Sample storage covered by stability data?	MRL compliance	Chronic risk for consumers identified?	Acute risk for consumers identified?
1	Maize	Yes	Yes (9)	Not relevant (PHI covered by the time between the last application and har-vest)	Yes	Yes	No	No
2	Sugar maize; Popcorn	Yes	Yes (extrapolated from maize)	Not relevant (PHI covered by the time between the last application and har-vest)	Yes	Yes	No	No

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

As residues of mesotrione do not exceed the trigger values defined in Reg (EU) No 283/2013, there is no need to investigate the effect of industrial and/or household processing.

Number of trials available for maize, sugar maize and popcorn fulfils the requirements for central Europe.

The proposed uses of mesotrione in the formulation Juzan Extra 100 SC do not represent unacceptable acute and chronic risks for the consumer.

7.1.2.2 Summary for M-100SC-OR2-C

Table 7.1-4: Information on M-100SC-OR2-C (KCA 6.8)

Crop	PHI for M-100SC-OR2-C proposed by applicant	PHI/ Withholding period* sufficiently supported for	PHI for M-100SC-OR2-C proposed by zRMS	zRMS Comments (if different PHI proposed)
		Mesotrione		
Maize	F	NR		
Sugar maize; Popcorn	F	NR		

NR: not relevant
* Purpose of withholding period to be specified
** F: PHI is defined by the application stage at last treatment (time elapsing between last treatment and harvest of the crop).

Table 7.1-5: Waiting periods before planting succeeding crops

Waiting period before planting succeeding crops		Overall waiting period proposed by zRMS for M-100SC-OR2-C
Crop group	Led by mesotrione	
NR	NR	

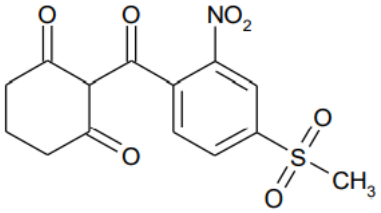
NR: not relevant

Assessment

7.2 Maize

General data on mesotrione are summarized in the table below

Table 7.2-1: General information on mesotrione

Active substance (ISO Common Name)	Mesotrione
IUPAC	2-(4-mesyl-2-nitrobenzoyl) cyclohexane -1,3-dione
Chemical structure	
Molecular formula	$C_{14}H_{13}NO_7S$
Molar mass	339.3 g/mol
Chemical group	Triketone
Mode of action (if available)	Selective, absorbed by roots and translocated. Bleaching: inhibition of 4-hydroxyphenyl-pyruvate-dioxygenase.
Systemic	Yes
Company (ies)	Syngenta*
Rapporteur Member State (RMS)	UK
Approval status	Approved Date of (01/06/2017) and reference to decision (Commission Implementing Regulation (EU) 2017/725 of 24 April 2017)
Restriction	N/A
Review Report	SANTE/11654/2016, 23 March 2017
Current MRL regulation	COMMISSION REGULATION (EU) 2017/626 of 31 March 2017
Peer review of MRLs according to Article 12 of Reg No 396/2005 EC performed	Yes
EFSA Journal : Conclusion on the peer review	Yes**
EFSA Journal: conclusion on article 12	Yes** EFSA Journal 2015;13(1):3976
Current MRL applications on intended uses	None

* Notifier in the EU process to whom the a.s. belong(s)
** If yes: EFSA, 2016 and 2015 - see list of references

7.2.1 Stability of Residues (KCA 6.1)

7.2.1.1 Stability of residues during storage of samples

Available data

No new data submitted in the framework of this application.

Table 7.2-2: Summary of stability data achieved at ≤ - 18°C (unless stated otherwise)

Matrix	Characteristics of the matrix	Acceptable Maximum Storage duration	Reference
Data relied on in EU			
Plant products			
Maize grain	Dry commodities	17 months	RMS, 1999 Wiebe, L.A., 1997, RR 97-042B INT
Maize forage	High water content	18 months	RMS, 1999 Wiebe, L.A., 1997, RR 97-042B INT

Conclusion on stability of residues during storage

Storage stability of mesotrione and MNBA was demonstrated for a period of 18 months at -18 °C in commodities with high water content (maize forage) and for a period of 17 months in dry commodities (maize grain) (United Kingdom, 1999).
Taking above into consideration additional studies on storage stability are not regarded as necessary.

7.2.1.2 Stability of residues in sample extracts (KCA 6.1)

Additional data on the stability of the analytes in the extract when stored < 7 °C for up to 7 days for maize seed and 12 days for maize whole plant were also provided in DAR for mesotrione and show no significant change after this period.

7.2.2 Nature of residues in plants, livestock and processed commodities

7.2.2.1 Nature of residue in primary crops (KCA 6.2.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-3: Summary of plant metabolism studies

Crop Group	Crop	Label position	Application and sampling details					Reference
			Method, F or G (a)	Rate (kg a.s./ha)	No	Sampling (DAT)	Remarks	
EU data								

Cereals	Maize	[cyclohexane-2-14C] ZA1296 [phenyl-U-14C] ZA1296	F	280–307 g a.s./ha (pre-emergence)	1	Forage: 27 Fodder: 154 Grain: 154		RMS, 1999 Wei Y and Dohn D.R (1997), Report Number . RR 96-026B,
				161–164 g a.s./ha (post-emergence)	1	Forage: 28 Fodder: 125 Grain: 125		Tarr J.B and van Neste L (1997), Report Number RR 96-007B,

Summary of plant metabolism studies reported in the EU

Plant metabolism was studied in maize (pre- and post-emergence) with mesotrione labelled on cyclohexane-2-14C and phenyl-U-14C. The metabolic pattern of mesotrione was found to be quantitatively different in conventional crops (maize) compared to genetically modified soya bean. In maize, parent mesotrione was hardly recovered (3% TRR in maize forage only) whilst the most pertinent metabolites identified in the feed items were MNBA (up to 20% TRR in maize forage leaves) and AMBA, free and conjugated (13% and 28% TRR respectively in maize forage leaves and fodder). The unextracted radioactivity was further characterized as carbohydrates (maize) incorporated into the natural constituents of the plant. The metabolism of mesotrione in maize proceeds by oxidation of the parent molecule to 4/5-hydroxy mesotrione and to MNBA with subsequent reduction to AMBA and its conjugates observed in conventional maize.

Conclusion on metabolism in primary crops

Taking above into consideration additional studies on metabolism in primary crops are not regarded as necessary.

7.2.2.2 Nature of residue in rotational crops (KCA 6.6.1)

Available data

No new data submitted in the framework of this application.

Table 7.2-4: Summary of metabolism studies in rotational crops

Crop group	Crop	Label position	Application and sampling details					Reference
			Method, F or G *	Rate (kg a.s./ha)	Sowing intervals (DAT)	Harvest Intervals (DAT)	Remarks	
EU data								
Leafy vegetables	Broad leaves Endive	[phenyl-U-14C] ZA 1296	G	164 g a.s./ha	120 300	78	-	RMS, 1999 Spillner, C. et al, 1997
Root and tuber vegetables	Radish					56		
Cereals	Wheat					22 57 134		

* Outdoor/field application (F) or glasshouse/protected/indoor application (G)

Summary of plant metabolism studies reported in the EU

The metabolism of mesotrione in rotational crops was found to be similar to the primary crops.

Conclusion on metabolism in rotational crops

Taking above into consideration additional studies on metabolism in rotational crops are not regarded as necessary.

7.2.2.3 Nature of residues in processed commodities (KCA 6.5.1)

Available data

No new data submitted in the framework of this application.

Summary of nature of residues in processed commodities reported in the EU

Based on results from residue trials conducted to date, no mesotrione residues are expected at or above the limit of detection. It is therefore unlikely that mesotrione residues will be detected in processed fractions such. Therefore, no study has been conducted regarding the effects of industrial processing and household preparation on the nature and magnitude of mesotrione residues.

Conclusion on nature of residues in processed commodities

Juzan Extra 100 SC is applied early in the season to maize. The levels of mesotrione residues in maize grain at the time of harvest were below the limit of quantification in all residues trials conducted.
Taking above into consideration additional studies of residues in processed commodities are not regarded as necessary.

7.2.2.4 Conclusion on the nature of residues in commodities of plant origin (KCA 6.7.1)

Table 7.2-5: Summary of the nature of residues in commodities of plant origin

Endpoints	
Plant groups covered	Cereals (Maize)
Rotational crops covered	Root/tuber crops Leafy crops Cereal (small grain)
Metabolism in rotational crops similar to metabolism in primary crops?	Yes
Processed commodities	Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain < 0.01 mg/kg).
Residue pattern in processed commodities similar to pattern in raw commodities?	Hydrolysis studies addressing the nature of the residues in processed commodities are not triggered (mesotrione residue levels in maize grain < 0.01 mg/kg).
Plant residue definition for monitoring	Mesotrione (cereals and pulses/oilseeds only)*
Plant residue definition for risk assessment	Food commodities: Mesotrione (cereals and pulses/oilseeds only) Feed commodities: Mesotrione and AMBA (including

	its conjugates) (Cereals, pulses and oilseeds only – Conventional crops) – Provisional.**
Conversion factor from enforcement to RA	Not applicable

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX).
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.2.2.5 Nature of residues in livestock (KCA 6.2.2-6.2.5)

Available data

No new data submitted in the framework of this application.

Table 7.2-6: Summary of animal metabolism studies

Group	Species	Label position	No of animal	Application details		Sample details		Reference
				Rate (mg/kg bw/d)	Duration (days)	Commodity	Time of sampling	
EU data								
Lactating ruminants	Cow	[phenyl-U- 14C] labelled AMBA	1	0.4	7	Milk	daily	RMS, 1999
						Urine and faeces	daily	
						Tissues	at sacrifice	

Summary of animal metabolism studies reported in the EU

A ruminant metabolism study was however conducted with phenyl-U-14C AMBA. The total residues were below 0.01 mg/kg in all matrices except in kidney (0.053 mg/kg) and fat (0.018 mg/kg) with AMBA being the predominant compound that accounted for 79% TRR and 62% TRR, respectively.

Conclusion on metabolism in livestock

All metabolism data are active substance data and were evaluated in the EU review of mesotrione and additional studies are not regarded as necessary.
Mesotrione product is applied early in the season to maize. The levels of mesotrione residues in maize grain at the time of harvest were below the limit of determination used in all residues trials conducted and therefore under normal agricultural circumstances it is unlikely that mesotrione residues will be found in animal tissues. The plant protection product is to be used in crops whose parts or products, also after processing, are fed to poultry but the intake is not expected to exceed 0,004 mg/kg bw/day therefore metabolism studies on livestock are not required.

7.2.2.6 Conclusion on the nature of residues in commodities of animal origin (KCA 6.7.1)

Table 7.2-7: Summary on the nature of residues in commodities of animal origin

	Endpoints
Animals covered	Lactating goats/cows

Time needed to reach a plateau concentration	5 days in milk
Animal residue definition for monitoring	Not required for the representative use (provisional)
Animal residue definition for risk assessment	Not required for the representative use (provisional)
Conversion factor	Not applicable
Metabolism in rat and ruminant similar	Yes
Fat soluble residue	AMBA residues in muscle (<0.01 mg/kg) and in fat free muscle (0.003-0.018 mg/kg). AMBA is not expected to be fat soluble.

* A more recent proposal by EFSA may be provided as additional information (EFSA RO XXXX)
** If no EFSA proposal is available, a proposal should be made by the applicant/zRMS.

7.2.3 Magnitude of residues in plants (KCA 6.3)

7.2.3.1 Summary of European data and new data supporting the intended uses

New studies on the magnitude of residue have been submitted by the applicant in the framework of this application. These studies are summarized in the Table below. The detailed assessment of these studies is presented in Appendix 2.

Table 7.2-8: Summary of EU reported and new data supporting the intended uses of M-100SC-OR2-C and conformity to existing MRL

Commodity	Source	Residue zone (N-EU, S-EU, EU, outside EU)	Evaluation GAP Residue levels (mg/kg) E = according to enforcement residue definition RA = according to risk assessment residue definition	STMR (mg/kg)	HR (mg/kg)	Unrounded OECD calculator MRL (mg/kg)	Current EU MRL (mg/kg) *	MRL compliance
Maize grain	RMS, 1999	N-EU	Trials GAP: 1 x 0.15 – 0.2 kg as/ha, BBCH 16-18, outdoor 9 x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	Trials GAP: 1 x 0.15 – 0.2 kg as/ha, BBCH 16-18, outdoor 9 x <0.01	0.01	0.01	0.01	0.01	Yes
Sugar maize; Popcorn (extrapolated from maize)	RMS, 1999	N-EU	Trials GAP: 1 x 0.15 – 0.2 kg as/ha, BBCH 16-18, outdoor 9 x <0.01	N/A				
	Overall supporting data for cGAP	N-EU	Trials GAP: 1 x 0.15 – 0.2 kg as/ha, BBCH 16-18, outdoor 9 x <0.01	0.01	0.01	0.01	0.01	Yes

* Source of EU MRL: COMMISSION REGULATION (EU) 2017/626 of 31

NR – not relevant

Maize

Maize is a major crop in Northern Europe (EU guideline SANTE/2019/12752). A minimum eight trials are necessary to cover Norther Europe. Nine residue trials on maize were reviewed during the Annex I inclusion process of mesotrione (see DAR,1999). The trials were performed in Northern European region over two growing seasons 1995-1996. Grain, cob, forage, silage residues were determined to be below the limit of quantification (LOQ) of the analytical method 0.01 mg/kg in all trials. Therefore number of trials carried out of maize fulfils the requirements for northern Europe. For more details about trials evaluated in the DAR please refer to the table below:

Country/year	Application rate kg a.s./ha	No of treat-ments	Growth stage	Portion analyses	Residues		PHI
					ZA 1296	MNBA	
Ile de France North France 1995 Barnes, J.P et al., 1997a DP 59806	0.15	1	6-8 leaves (16-18 BBCH)	immature	4.58	0.15	0
				immature	<0.01	<0.01	14
				forage	<0.01	<0.01	63
				silage	<0.01	<0.01	80
				grain	<0.01	<0.01	120
				grain+cob	<0.01	<0.01	120
				grain+cob+husk	<0.01	<0.01	120
Normandy North France 1996 Barnes, J.P et al., 1997b DP 59808	0.20	1	6-8 leaves (16-18 BBCH)	immature	20.0	0.10	0
				immature	<0.01	<0.01	14
				forage	<0.01	<0.01	56
				silage	<0.01	<0.01	90
				grain	<0.01	<0.01	119
				grain+cob	<0.01	<0.01	119
				grain+cob+husk	<0.01	<0.01	119
Sleswig- Hol-stein Germany 1995 Barnes, J.P et al., 1997c DP 59810	0.15	1	7 leaves (17 BBCH)	immature	9.23	0.08	0
				immature	<0.01	<0.01	13
				forage	<0.01	<0.01	32
				silage	<0.01	<0.01	68
				grain	<0.01	<0.01	78
				grain+cob	<0.01	<0.01	78
				grain+cob+husk	<0.01	<0.01	78
Bavaria Germany 1995 Barnes, J.P et al., 1997c DP 59810	0.15	1	7 leaves (17 BBCH)	immature	10.31	0.08	0
				immature	<0.01	<0.01	14
				forage	<0.01	<0.01	32
				silage	<0.01	<0.01	73
				grain	<0.01	<0.01	114
				grain+cob	<0.01	<0.01	114
				grain+cob+husk	<0.01	<0.01	114
Bavaria Germany 1995 Barnes, J.P et al., 1997c DP 59810	0.15	1	6-7 leaves (16-17 BBCH)	immature	11.56	0.08	0
				immature	<0.01	<0.01	14
				forage	<0.01	<0.01	32
				silage	<0.01	<0.01	78
				grain	<0.01	<0.01	114
				grain+cob	<0.01	<0.01	114
				grain+cob+husk	<0.01	<0.01	114
Saxe- Anhalt Germany 1995 Barnes, J.P et al., 1997c DP 59810	0.15	1	6-7 leaves (16-17 BBCH)	immature	5.98	0.20	0
				immature	<0.01	<0.01	14
				forage	<0.01	<0.01	32
				silage	<0.01	<0.01	78
				grain	<0.01	<0.01	114
				grain+cob	<0.01	<0.01	114
				grain+cob+husk	<0.01	<0.01	114

Sleswig- Holstein Germany 1996 Barnes, J.P et al., 1997d DP 59812	0.20	1	6 leaves (16 BBCH)	immature	23.2	0.10	0
				immature	<0.01	<0.01	14
				forage	<0.01	<0.01	44
				silage	<0.01	<0.01	86
				grain	<0.01	<0.01	109
				grain+cob	<0.01	<0.01	109
				grain+cob+husk	<0.01	<0.01	109
Bavaria Germany 1996 Barnes, J.P et al., 1997d DP 59812	0.20	1	7 leaves (17 BBCH)	immature	10.9	0.10	0
				immature	<0.01	<0.01	14
				forage	<0.01	<0.01	35
				silage	<0.01	<0.01	110
				grain	<0.01	<0.01	135
				grain+cob	<0.01	<0.01	135
				grain+cob+husk	<0.01	<0.01	135
Saxe- Anhalt Germany 1996 Barnes, J.P et al., 1997d DP 59812	0.20	1	8 leaves (18 BBCH)	immature	9.21	0.08	0
				immature	<0.01	<0.01	14
				forage	<0.01	<0.01	36
				silage	<0.01	<0.01	88
				grain	<0.01	<0.01	126
				grain+cob	<0.01	<0.01	126
				grain+cob+husk	<0.01	<0.01	126

The stage of development of the crop at the time of application is within the range of intended use i.e. before forming the edible part of the crop. The application rates for the trials presented in DAR are similar or slightly above than the maximum recommended rate of Juzan Extra 100 SC (150 g a.s./ha). However it should be considered as a worst case. Moreover residue trials show that residues are below the limit of quantification. Since the objective is not new MRL setting but only MRL compliance, it is considered that all the trials are relevant to support registration of Juzan Extra 100 SC.

Sugar maize; Popcorn
Sugar maize; Popcorn are minor crops in Northern Europe (EU guideline SANTE/2019/12752). A minimum eight trials are necessary to cover Norther Europe. For Juzan Extra 100 SC no new trials were conducted because of possibility of extrapolation the results from maize trials. Available maize trials are presented in DAR and are summarizes above. Therefore number of trials fulfils the requirements for northern Europe.

7.2.3.2 Conclusion on the magnitude of residues in plants

According to the available data, the intended uses on maize, Sugar maize; Popcorn are considered acceptable, for outdoor use.

According to appendix D of EU guidelines, extrapolation to Sugar maize; Popcorn is possible with 4 trials on maize, which is the case here.
The data submitted show that no exceedance of the MRL will occur.
The uses are considered acceptable.

7.2.4 Magnitude of residues in livestock

7.2.4.1 Dietary burden calculation

Table 7.2-9: Input values for the dietary burden calculation (considering the uses under consideration)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Mesotrione				
Corn field grain	0.01	STMR	0.01	STMR
Corn pop grain	0.01	STMR	0.01	STMR
Corn, filed, milled by pdts	0.01 x 1	STMR x PF	0.01 x 1	STMR x PF
Corn filed, hominy meal	0.01 x 1	STMR x PF	0.01 x 1	STMR x PF
Corn filed, gluten feed	0.01 x 1	STMR x PF	0.01 x 1	STMR x PF
Corn filed, gluten meal	0.01 x 1	STMR x PF	0.01 x 1	STMR x PF

Table 7.2-10: Results of the dietary burden calculation

Animal species	Median dietary burden (mg/kg bw/d)	Maximum dietary burden (mg/kg bw/d)	Highest contributing commodity	Max dietary burden (mg/kg DM)	Trigger exceeded (Y/N)
Dairy cattle*	0	0	Corn, field gluten feed	0.02	N
Ram/ewe	0	0	Corn, field gluten feed	0.01	N
Lamb	0.001	0	Corn, field gluten feed	0.01	N
Finishing swine*	0	0	Corn, field gluten feed	0.01	N
Layer poultry*	0.001	0.001	Corn, field milled bypdts	0.01	N
Turkey	0.001	0.001	Corn, field milled bypdts	0.01	N

* These categories correspond to those (formerly) assessed at EU level.

zRMS

Input values for the dietary burden calculation (EFSA Journal 2016;14(3):4419)

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Risk assessment residue definition: mesotrione				
Maize grain	0.01	Median residue	0.01	Median residue
Maize fodder	0.01	Median residue	0.01	Median residue
Maize forage	0.01	Median residue	0.01	Median residue
Risk assessment residue definition: AMBA (including its conjugates)				
Maize grain	0.014		0.014	Total residues from the

Feed Commodity	Median dietary burden		Maximum dietary burden	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
				metabolism data.
Maize fodder	0.301 (provisional)		0.301 (provisional)	Maximum residue levels of total AMBA (including its conjugates) recovered from the metabolism data. Pending clarification of the genotoxic potential of AMBA and of its toxicological profile GAP-compliant residue trials for the determination of AMBA conjugates residues in maize fodder, forage may be needed and the livestock dietary burden to be revised accordingly.
Maize forage	0.043 (provisional)		0.043 (provisional)	

EFSA Animal_model_2017

Risk assessment residue definition: mesotrione

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,001	0,001	0,04	0,04	Dairy cattle	Corn, field	gluten feed	No
Cattle (dairy only)	0,001	0,001	0,03	0,03	Dairy cattle	Corn, field	gluten feed	No
Sheep (all diets)	0,001	0,001	0,02	0,02	Lamb	Corn, field	gluten feed	No
Sheep (ewe only)	0,001	0,001	0,02	0,02	Ram/Ewe	Corn, field	gluten feed	No
Swine (all diets)	0,001	0,001	0,02	0,02	Swine (finishing)	Corn, field	gluten feed	No
Poultry (all diets)	0,002	0,002	0,02	0,02	Poultry layer	Corn, field	hominy meal	No
Poultry (layer only)	0,002	0,002	0,02	0,02	Poultry layer	Corn, field	hominy meal	No

Risk assessment residue definition: AMBA and its conjugates

Relevant groups	Dietary burden expressed in				Most critical diet (a)	Most critical commodity (b)		Trigger exceeded (Yes/No)
	mg/kg bw per day		mg/kg DM					0.004
	Median	Maximum	Median	Maximum				mg/kg bw
Cattle (all diets)	0,004	0,004	0,12	0,12	Dairy cattle	Corn, field	stover	No
Cattle (dairy only)	0,004	0,004	0,10	0,10	Dairy cattle	Corn, field	stover	No
Sheep (all diets)	0,001	0,001	0,03	0,03	Lamb	Corn, field	gluten feed	No
Sheep (ewe only)	0,001	0,001	0,03	0,03	Ram/Ewe	Corn, field	gluten feed	No
Swine (all diets)	0,002	0,002	0,10	0,10	Swine (breeding)	Corn, field	stover	No
Poultry (all diets)	0,003	0,003	0,04	0,04	Poultry layer	Corn, field	forage/silage	No
Poultry (layer only)	0,003	0,003	0,04	0,04	Poultry layer	Corn, field	forage/silage	No

7.2.4.2 Livestock feeding studies (KCA 6.4.1-6.4.3)

Available data

No new data were submitted in the framework of this application.

Animals are not exposed to residues via feed above the trigger value established in Reg. (EC) No 1107/2009, above 0.004 mg/kg. Therefore livestock feeding studies are not required.

7.2.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation) (KCA 6.5.2-6.5.3)

No further studies has been performed. Mesotrione residue levels in maize grain are below 0.01 mg/kg. Therefore magnitude of residues in processed commodities are not requires.

7.2.6 Magnitude of residues in representative succeeding crops

The crops under consideration can be grown in rotation.

Considering available data dealing with nature of residues (see 7.2.2.2), no study dealing with magnitude of residues in succeeding crops is needed.

Magnitude of residues trials for rotational crops are not required as the available rotational metabolism data demonstrates that significant residues of mesotrione (greater than 0.01 mg/kg) are not expected in following crops as a result of the proposed use on maize.

7.2.7 Other / special studies (KCA6.10, 6.10.1)

The available data for the active substance sufficiently address aspects of the residue situation that might arise from the use of M-100SC-OR2-C. Therefore, other special studies are not needed.

7.2.8 Estimation of exposure through diet and other means (KCA 6.9)

Toxicological reference values relevant for dietary risk assessment are reported in the summary of the evaluation (see 7.1.2).

7.2.8.1 Input values for the consumer risk assessment

Table 7.2-11: Input values for the consumer risk assessment

Commodity	Chronic risk assessment		Acute risk assessment	
	Input value (mg/kg)	Comment	Input value (mg/kg)	Comment
Mesotrione				
Maize	0.01	MRL	0.01	MRL
Sweet corn/Popcorn	0.01	MRL	0.01	MRL
Other commodities	various	MRL	-	-

7.2.8.2 Conclusion on consumer risk assessment

Extensive calculation sheets are presented in Appendix 3.

Table 7.2-12: Consumer risk assessment

TMDI (% ADI) according to EFSA PRIMo rev 3.1	12 % (based on NL toddler)
IEDI (% ADI) according to EFSA PRIMo rev 3.1	TMDI does not exceed ADI, therefore IEDI calculation is not required.
IESTI (% ARfD) according to EFSA PRIMo rev 3.1*	Unprocessed commodities: Sweet corn:2 % (Children) Sweet corn:0.8 % (Adults) Processed commodities: Maize/oil:1% (Children) Maize/oil:0.6 % (Adults)
NTMDI (% ADI) **	Not applicable
NEDI (% ADI)**	Not applicable
NESTI (% ARfD) **	Not applicable

* include raw and processed commodities if both values are required for PRIMo
** if national model is available

The proposed uses of mesotrione in the formulation Juzan Extra 100 SC do not represent unacceptable acute and chronic risks for the consumer.

7.3 Combined exposure and risk assessment

Not relevant. The product contains only one active substance.

7.4 References

EFSA Journal 2016;14(3):4419, Peer review of the pesticide risk assessment of the active substance mesotrione

EFSA Journal 2015;13(1):3976, Reasoned opinion on the review of the existing maximum residue levels (MRLs) for mesotrione according to Article 12 of Regulation (EC) No 396/2005

Appendix 1 Lists of data considered in support of the evaluation

Tables considered not relevant can be deleted as appropriate.

MS to blacken authors of vertebrate studies in the version made available to third parties/public.

List of data submitted by the applicant and relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
-	-	-	-	-	-

List of data submitted or referred to by the applicant and relied on, but already evaluated at EU peer review

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.1	Wiebe, L.A.	1997	ZA 1296: Stability of ZA 1296 and the Metabolite MNBA in Frozen Crops (Interim Report). Zeneca Report No:RR 97-042B INT GLP, Not published	N	SYN
KCA 6.2.1/01	Wei Y et al	1997	[Cyclohexane-2-14C]ZA 1296: Nature of the Residues in Corn (Zea mays). Zeneca Agrochemicals Report : RR 96-026B	N	SYN
KCA 6.2.1/02	Tarr, J.B. et al	1997	[Phenyl-U-14C]ZA 1296: nature of the residues in corn	N	SYN
KCA 6.6.1	Spillner, C. et al	1997	[Cyclohexane-2-14C]ZA 1296: confined accumulation studies on rotational crops – low rate	N	SYN

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner
KCA 6.3/01	Barnes J.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1995 (WRC-96-114) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 96-078B GLP, not published Syngenta File No ZA1296/0409	N	SYN
KCA 6.3/02	Barnes J., Atger J., Wiebe L., Miller M.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in France During 1996 (Postemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-045B GLP, not published Syngenta File No ZA1296/0421	N	SYN
KCA 6.3/03	Miller M., Griehl T., Wiebe L., Elvira D.	1998	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Preemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-063B GLP, not published Syngenta File No ZA1296/0418	N	SYN
KCA 6.3/04	Barnes J., Chamier O., Wiebe L., Miller M.	1997	ZA1296: Residue Levels in Maize from Trials Carried out in Germany During 1996 (Postemergence) Zeneca Agrochemicals, Jealott's Hill, United Kingdom , RR 97-048B GLP, not published Syngenta File No ZA1296/0414	N	SYN

The following tables are to be completed by MS.

List of data submitted by the applicant and not relied on

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

List of data relied on and not submitted by the applicant but necessary for evaluation

Data point	Author(s)	Year	Title Company Report No. Source (where different from company) GLP or GEP status Published or not	Vertebrate study Y/N	Owner

Appendix 2 Detailed evaluation of the additional studies relied upon

A 2.1 Mesotrione

A 2.1.1 Stability of residues

No new or additional studies have been submitted

A 2.1.2 Nature of residues in plants, livestock and processed commodities

No new or additional studies have been submitted

A 2.1.3 Magnitude of residues in plants

No new or additional studies have been submitted

A 2.1.4 Magnitude of residues in livestock

No new or additional studies have been submitted

A 2.1.5 Magnitude of residues in processed commodities (Industrial Processing and/or Household Preparation)

No new or additional studies have been submitted

A 2.1.6 Magnitude of residues in representative succeeding crops

No new or additional studies have been submitted

A 2.1.7 Other/Special Studies

No new or additional studies have been submitted

Appendix 3 Pesticide Residue Intake Model (PRIMo)

A 3.1 TMDI calculations

No of diets exceeding the ADI : ---

	Calculated exposure (% of ADI)	MS Diet	Expsoure (µg/kg bw per day)	Highest contributor to MS diet (in % of ADI)	Commodity / group of commodities	2nd contributor to MS diet (in % of ADI)	Commodity / group of commodities	3rd contributor to MS diet (in % of ADI)	Commodity / group of commodities	Exposure resulting from MRLs set at the LOQ (in % of ADI)	Exposure resulting from commodities not under assessment (in % of ADI)
TMDI/NEDI/IEDI calculation (based on average food consumption)	12%	NL toddler	1,24	6%	Milk: Cattle	1%	Apples	0,7%	Maize/corn	12%	
	7%	NL child	0,67	2%	Milk: Cattle	0,8%	Sugar beet roots	0,6%	Apples	7%	
	6%	DE child	0,64	2%	Milk: Cattle	1%	Apples	0,4%	Wheat	6%	
	6%	UK infant	0,61	4%	Milk: Cattle	0,3%	Potatoes	0,3%	Wheat	6%	
	6%	FR toddler 2 3 yr	0,56	3%	Milk: Cattle	0,3%	Apples	0,3%	Wheat	6%	
	6%	FR child 3 15 yr	0,55	2%	Milk: Cattle	0,5%	Wheat	0,4%	Sugar beet roots	6%	
	5%	GEMS/Food G11	0,49	1%	Soyabeans	0,8%	Milk: Cattle	0,4%	Potatoes	4%	
	4%	UK toddler	0,45	2%	Milk: Cattle	0,4%	Wheat	0,3%	Potatoes	4%	
	4%	GEMS/Food G10	0,43	1,0%	Soyabeans	0,5%	Milk: Cattle	0,4%	Wheat	3%	
	4%	GEMS/Food G07	0,42	0,6%	Milk: Cattle	0,5%	Soyabeans	0,4%	Wheat	4%	
	4%	GEMS/Food G08	0,42	0,6%	Soyabeans	0,6%	Milk: Cattle	0,4%	Wheat	4%	
	4%	GEMS/Food G15	0,42	0,7%	Milk: Cattle	0,5%	Soyabeans	0,5%	Wheat	4%	
	4%	DK child	0,41	1%	Milk: Cattle	0,6%	Rye	0,4%	Wheat	4%	
	4%	GEMS/Food G06	0,41	0,7%	Wheat	0,4%	Soyabeans	0,4%	Tomatoes	4%	
	4%	RO general	0,38	1%	Milk: Cattle	0,5%	Wheat	0,4%	Potatoes	4%	
	4%	ES child	0,38	1%	Milk: Cattle	0,4%	Wheat	0,3%	Cocoa beans	4%	
	4%	SE general	0,37	1%	Milk: Cattle	0,4%	Bovine: Muscle/meat	0,4%	Potatoes	4%	
	4%	DE women 14-50 yr	0,37	1%	Milk: Cattle	0,5%	Sugar beet roots	0,3%	Apples	4%	
	4%	DE general	0,36	1%	Milk: Cattle	0,4%	Sugar beet roots	0,2%	Apples	4%	
	4%	FI adult	0,35	3%	Coffee beans	0,1%	Potatoes	0,1%	Rye	4%	
	3%	IE adult	0,33	0,4%	Milk: Cattle	0,4%	Sweet potatoes	0,2%	Wheat	3%	
	3%	NL general	0,30	0,8%	Milk: Cattle	0,3%	Sugar beet roots	0,2%	Potatoes	3%	
	3%	FR infant	0,29	2%	Milk: Cattle	0,2%	Potatoes	0,2%	Apples	3%	
	2%	FR adult	0,22	0,4%	Milk: Cattle	0,2%	Wine grapes	0,2%	Wheat	2%	
	2%	PT general	0,21	0,5%	Potatoes	0,4%	Wheat	0,2%	Wine grapes	2%	
	2%	ES adult	0,21	0,5%	Milk: Cattle	0,2%	Wheat	0,1%	Oranges	2%	
	2%	FI 3 yr	0,18	0,5%	Potatoes	0,1%	Bananas	0,1%	Wheat	2%	
	2%	IT toddler	0,16	0,7%	Wheat	0,2%	Other cereals	0,1%	Tomatoes	2%	
	2%	DK adult	0,16	0,5%	Milk: Cattle	0,1%	Potatoes	0,1%	Wheat	2%	
	2%	LT adult	0,16	0,4%	Milk: Cattle	0,3%	Potatoes	0,2%	Apples	2%	
	1%	UK vegetarian	0,15	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	1%	
	1%	FI 6 yr	0,14	0,4%	Potatoes	0,1%	Cocoa beans	0,1%	Wheat	1%	
	1%	UK adult	0,14	0,3%	Milk: Cattle	0,2%	Wheat	0,1%	Potatoes	1%	
	1%	IT adult	0,12	0,4%	Wheat	0,1%	Tomatoes	0,1%	Apples	1%	
	1,0%	PL general	0,10	0,3%	Potatoes	0,2%	Apples	0,1%	Tomatoes	1,0%	
	0,8%	IE child	0,08	0,4%	Milk: Cattle	0,1%	Wheat	0,1%	Potatoes	0,8%	

Conclusion:
The estimated long-term dietary intake (TMDI/NEDI/IEDI) was below the ADI.
The long-term intake of residues of Mesotrione is unlikely to present a public health concern.
DISCLAIMER: Dietary data from the UK were included in PRIMO when the UK was a member of the European Union.

A 3.2 IEDI calculations

TMDI does not exceed ADI, therefore IEDI calculation is not required.

A 3.3 IESTI calculations - Raw commodities

Show results of IESTI calculation only for crops with GAPs under assessment

Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
2%	Sweet corn	0,01 / 0,01	0,43
0,3%	Maize/corn	0,01 / 0,01	0,07
0,2%	Sorghum	0,01 / 0,01	0,03
0,07%	Common millet/proso	0,01 / 0,01	0,01

Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,8%	Sweet corn	0,01 / 0,01	0,16
0,1%	Maize/corn	0,01 / 0,01	0,02
0,05%	Common millet/proso millet	0,01 / 0,01	0,01
0,02%	Sorghum	0,01 / 0,01	0,00

IESTI new
Results for children
No. of commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,9%	Sweet corn	0,01 / 0,01	0,19
0,3%	Maize/corn	0,01 / 0,01	0,07
0,2%	Sorghum	0,01 / 0,01	0,03
0,07%	Common millet/proso	0,01 / 0,01	0,01

IESTI new
Results for adults
No. of commodities for which ARfD/ADI is exceeded (IESTI new): --

IESTI new

Highest % of ARfD/ADI	Commodities	MRL / input for RA (mg/kg)	Expo (µg/kg
0,6%	Sweet corn	0,01 / 0,01	0,1
0,1%	Maize/corn	0,01 / 0,01	0,0
0,05%	Common millet/proso millet	0,01 / 0,01	0,0
0,02%	Sorghum	0,01 / 0,01	0,0

A 3.4 IESTI calculations - Processed commodities

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Maize / oil	0,01 / 0,25	0,23
0,3%	Millet / boiled	0,01 / 0	0,05
0,1%	Maize / processed (not spe·	0,01 / 0,01	0,02
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Expand/collapse list

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI): ---

IESTI

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
0,6%	Maize / oil	0,01 / 0,25	0,13
0,1%	Millet / boiled	0,01 / 0	0,02
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Results for children
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Exposure (µg/kg bw)
1%	Maize / oil	0,01 / 0,25	0,23
0,3%	Millet / boiled	0,01 / 0	0,05
0,1%	Maize / processed (not	0,01 / 0,01	0,02
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!
#LICZBA!	#LICZBA!	#LICZBA!	#LICZBA!

Results for adults
No of processed commodities for which ARfD/ADI is exceeded (IESTI new): ---

IESTI new

Highest % of ARfD/ADI	Processed commodities	MRL / input for RA (mg/kg)	Expos (µg/kg
0,6%	Maize / oil	0,01 / 0,25	0,1
0,1%	Millet / boiled	0,01 / 0	0,0
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI
#LICZBA!	#LICZBA!	#LICZBA!	#LICZI

Conclusion:
No exceedance of the toxicological reference value was identified for any unprocessed commodity.
A short term intake of residues of Mesotrione is unlikely to present a public health risk.
For processed commodities, no exceedance of the ARfD/ADI was identified.