

Liberté Égalité Fraternité





WEBINAR: METAPATH

How to complete MSS composers for pesticides metabolism studies

Metabolism in rotational crop studies



Wednesday 31 March

Time	Торіс
9h35 – 10h30	Livestock MSS composer
10H30 – 10h45	Coffee break
10h45 - 11h30	Rotational crops MSS
11h30 – 12h	Q&A session and Conclusion





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B.7.9 Resi	dues in succeeding cro	ops (Annex IIA 6.6)
References:	For the FIRST CR	OP only :
ADD DEL	I. General inform	nations / II. Material and Methods / IV. Conclusions & VI.
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Guidelines:	OPPTS 860.1850 ECC 96/68 E	C Annex 1, Section
		III. Results and Discussion V. Appendix
GLP:	yes 👻	
Acceptability:	The study is 🔹 conside	red scientifically acceptable.

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	-			other depending on the rotational crops tested in the st	udy
	/=	Testing	Laboratory: Charle	ver Laboratories, Tranent, Scotland, UK	
		Company St	udv Number: Duro		
			Identifiers:		
Test Mat	erial:	Currente anti-		In comparison with plant MSS composer, same manner to fulfill "Ger	neral Info" section
Identifie	rs:				
Guideline	s:	OPPTS 860, 1850 EC OECD Guideline 502	Metabolism in Rotatio	crops (January 2007)	
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		I. General info
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Wheat (rotation)/ cereal grai	in Lettuce (rotation)/leafy vegetable Beet (rotation)/ root ve ils and Methods III. Results and Discussion IV. Conclusions	petable Soil (rotation) V. Appendix VI. Attachments
B.7.9 Residue References:	es in succe	Same manner to fill "General Info" section than Plants MSS
ADD DEL Citation #1	Author(s): Date: Study Title: Confined rotational grop stu Reference Type: IIA, 6.6.2/01 Testing Laboratory: Charles River Laboratories, Company Study Number Identifiers:	2009 * Pages: ty using [1
Test Material: Identifiers: Guidelines:	OPPTS 860. 1850 ECC 96/68 EC Annex 1, Section 6.6 (1996) OECC Guideline 502 Metabolism in Rotational Crops (January 20	EDIT 107)
GLP:	yes *	
Acceptability:	The study is * considered scientifically acceptable.	
BACKGROUND INFORMATION		
EXECUTIVE SUMMARY		



I. General info

Same manner to fill "General Info" section than Plants MSS

Crop 1 Crop 2		
I. General Info	II. Materials and Methods III. Results and Discussion IV. Conclusions V. Appendix VI. Attachments	
B.7.1	Metabolism, distribution and expression of residues in plants (Annex IIA 6.2.1)	

Product Type:	Pesticide function : Free text + Limited number of characters	 1
Product Use:	Intended Crops : Free text + Limited number of characters	

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II. Materials and Methods

I. General Info. II. Mitterials and Methods					
III. RESults and Discussion TV. Conclusion	ns V. Appendix VI. Attachments				
A. Materials a Study Design considered Name 3-bromo-1-(3-chloro-2-pyridiny)-N-[4-cya	ano-2-methyl-6-[(me				
CAS no. 736994-63-1					
Other synonyms (i applicable)					
Molecular Formula C19H14BrCIN6O2					
Analytical Purity Impurities					
Physical State					
Expiration Date					
Lot/Batch #					
Radiolabeled Test Material		Come money to fill		eastion then Diants MCC	
ADD DEL		Same manner to fill	Materials and methods	section than Plants wiss	
ICvano-14Cl-c Radicchemical purity: 99.0 %					
[Pyrazole carbonyl] Specific activity as received: 0/63 MBq/mg					
[Cyano-14C] #3 [Pyrazole carbonyl Specific activity of dose: units					
Q Q #					
5 mm					
	Q				
	ci N				
<u>Structure:</u>	_1				
Table PhysChem Physicochemical Properties.					
Parameter Notes		Value	Units	Reference	
pH		[217-224]	70		
Density					
Water solubility (20°C)		12.33 * 0.61	ppm	(
Vapour pressure at 20°C		5.133 * 10-15	Pa		
Dissociation constant (pKa) At 20%	c	8.80 * 1.38		5	
Dissociation constant (pKa) At 20% Octanol/water partition coefficient Log(Kow) At 22%	c	8.80 * 1.38 1.97 ± 0.01		аралана (р. 1997) Спорта с страна (р. 1997) Спорта с страна (р. 1997)	
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II. Materials and Methods

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A. Materials Study Design	inner to fill "Waterials and methods" section than Plants WISS
B STUDY DESIGN	
Everymental Conditions	
	Free-text field: briefly describe the experimental conditions
Table B.7.9-3. Use Pattern Information.	
Parameter	Value
Chemical name	
Application method	In bare sol
Number of applications	1
Timing of applications	
PBI	30, 120 and 365 days
Camping .	
KAC samples of forage, hay, straw, and grain of spring wheat; foliage and roots of red beets; and whole is follower taken at the times of couring and grain maturity and separated into 0 to 15 cm and 15 to 30	ettuce were harvested from paia 🖌 Free-text field: briefly describe how samples were taken, parts sampled, how samples were handled af
Sou cores were taken at the times of sowing and crop maturity and separated into 0 to 15 cm and 15 to 50	harvesting (shipment, storage, etc.), and any preparation that was done prior to extraction
Extraction and Analysis	
-Flowchart of the extraction and fractionation schemes #1-	
	Attach Clear View
Fromichart of the extraction and tractionation schemes #2	Attach Clear View
- Flowchart of the extraction and fractionation schemes #3	

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II. Materials and Methods

I. General Info II. Materials and Methods III. Results and Discu	ission IV. Conclusions V. Appendix VI. Attachments	
A. Materials B. Study Design		
Sampling		
- Flowchart of the extraction and fractionation schemes #1		
	Attach Clear View	Attach Clear View
- Flowchart of the extraction and fractionation schemes #2	↑	
		Attach Clear View
Flowchart of the extraction and fractionation schemes #3 Attach. cle	ar or view flowchart of the extraction and fractionation scheme	s
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Extraction and Analysis		
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Identification and Characterization		
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III. Results and discussion

Wheat (rotation)/ cereal grain Lettuce (rotation)/ leafy vegetable Beet (rotation)/ root vegetable Soil (rotation)	One tab for each rotational crop tested	
I. General Info II. Materials and Methods III. Results and Discussion IV. Conclusions V. Appendix VI. Attachmen	nts	
A. Total Radioactive Residues B. Extraction, Characterization, and Distribution of Residues C. Storage Stability of R	Residues D. Identity of Residues in Rotational Crop E. Proposed Metabolic Pathway	
5 SUBTABS tive Residues		
Extraction efficiency of radioactive residues from plant metabolism study using residue enforcement	nt method	

WARNING/REMEMBER:

For the rotational crops tested informed in II. Material and Methods (wheat/cereal grain, Lettuce/leafy, Beet/Root vegetable or other depending on those tested in the study)

General information and study design are the same for all the tested crops but single results have to be informed in this III. Results and Discussion tab

RÉPUBLIQUE III. Results and discussion FRANÇAISE Liberté Égalité Fraternité anses Just click on the other tab to fill results for other rotational crop testeds Wheat (rotation)/ cereal grain .ettuce (rotation)/leafy vegetable Beet (rotation)/root vegetable Soil (rotation) III. Results and Discussion IV. Conclusions V. Appendix VI. Attachments 1. General Into 11. Materials and Method A. Total Radioactive Residues Extraction, Characterization, and Distribution of Residues C. Storage Stability of Residues D. Identity of Residues in Rotational Crop E. Proposed Metabolic Pathway Same manner to fill this section than Plants MSS A. Total Radioactive Residues Please refer to the 1st Day presentation for basic functions : add a row (matrices), change rows and Extraction efficiency of radioactive residues from plant metabol columns names Overall extraction efficiency (%) Recovered equivalents (mg/kg) Enforcement method Extraction method used in study 100 Fill in table if extraction efficiency data available Quantitation Human food commodities: TRRs in crops grown in soil treated with both labels ranged from <0.01 to 0.06 mg/kg for wheat grain Animal feed commodities: The TRRs in wheat commodities harvested from the 30, 120, and 365 day sowings into soil treated with both labels ranged between 0.09 to 0.31 mg/kg for early forage, 0.31 to 1.62 mg/kg for hay, and 0.27 to 0.97 mg/kg for straw Fill in text Informations on the methods for determining TRR values Table B.7.9-4. TRRs in Matrices. Cyano-14C [Pyrazole carbonyl-14(Matrix Timing and Application Preharvest Interval (days) PBI % TRR ppm % TRR ppm 30 Human food commoditie (grain) 0.056 0.054 Human food commoditie 120 0.004 0.008 365 Human food commodities (grain) 0.014 0.018 30 0.313 Animal feed commodities (forage) 0.287 Animal feed commodities (forage) 120 0.129 0.103 In rows : Fill the matrice names corresponding to the rotational crop tested and the different Plant Back Fill in table for TRR's in various matrices Intervals (PBI)



III. Results and discussion

/heat (rotation)/ cereal grain	Lettuce (rotation)/leafy	vegetable Beet (rotatio	on)/root vegetable Soil (rotation)									
. General Info II. Ma <mark>terials</mark>	and Methods III. Result	s and Discussion IV. Co	nclusions V. Appendix	VI. Attachments									
A. Total Radioactive Residues	B. Extraction, Charac	terization, and Distribution	of Residues C. Storage	Stability of Residues D.	Identity of Residues in F	otational Crop E. Prop	osed Metabolic Pathway						
B. Extraction, C	haracterization	, and Distributi	on of Residues		Prefilled: Se	parate tab fo	r each radiolab	el					
[Cyana]	Durazela carbanul	1	ware 1401 #2 Durazala	contrary 1401 #4		•							
	no [Pyrazole carbonyl-1Cyano-14C] #3 [Pyrazole carbonyl-14C] #4 in this example there are two labels but 4 tabs (grain 2 PRIs/ Forage 3 PR												
Characterization of residu	aracterization of residue 30, 120 or 365 days after soil treatment. e grain extracts from the 120 DAT [14C]-cyantraniliprole treatment contained negligible amounts of radioactivity (0.004 mg etg												
The grain extracts from t													
losses of first during prep	osses of TRR during preparation of samples and analysis by HPLC were calculated and considered having no impact on the values												
In wheat forage, the une	In wheat forage, the unextracted residues accounted for <0.03 molec and 10 %TRP. Extraction was therefore deemed sufficient. The losses of TRP during organization of samples and analysis by HPLC were calculated and considered having no impact on the values. In samples from												
Free text for d	lescription of i	results (footno	otes, abreviatio	ons)					-				
Metabolite Fraction		1			-		Forage -	· 120 DAT	Forage ·	- 365 DAT			
	%TRR	ppm	%TRR	ppm	%TRR	ppm	%TRR	ppm	%TRR	ppm			
TRR		0.056		0.014		0.313		0.129		0.128			
Extracted residues	85.9	0.048	56.5	0.008	92.4	0.289	90.2	0.113	91.5	0.117			
Extract 1	23.5	0.013	32.7	0.005	64.7	0.202	69.3	0.089	64.1	0.082			
Extract 2	14.2	0.008	23.8	0.003	21.4	0.067	20.9	0.027	22.8	0.029			
Extract 3					6.4	0.020		NC		NC			
Extract 4:	26.5	This tak our	n mariaaa tha a	where other	restariastion	مرجع والمعتقا والمعاد	n of the TDD o	mong the		0.004			
Organic fraction	16.6	inis tab sur	nmarises the e	extraction, cha	racterisation	and distributio	on of the TRR a	mong the					
Aqueous fraction	8.0	differents n	natrices										
Gel fraction	1.9	0.001											
Extract 5	10.6	0.006		NC		NC		NC	1.2	0.002			
Extract 6	11.1	0.006		NC									
Unextracted residues	14.1	0.008	43.6	0.006	7.6	0.024	9.8	0.013	8.5	0.011			
Extracted residues after processing	91.5	0.05	56.5	0.008	84.4	0.263	95.3	0.122	86.5	0.111			
Loss during processing	-5.6	-0.003		<0.01	8.1	0.026	-5.1	-0.006	5.1	0.006			



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III. Results and discussion

/heat (rotation)/ cereal grain Lettuce (rotation)/ leafy vegetable Beet (rotation)/ root vegetable Soil (rotation)									
I. General Info II. Materials and Methods III. Results and Discussion IV. Conclusions V. Appendix VI. Attachments									
A. Total Radioactive Residues	B. Extracti	ion, Characterization, and Di	stribution of Residues	C. Storage Stability of Residues	D. Identity of Residues in Rotational Crop E. Proposed Metabolic Pathway				

C. Storage Stability of Residues

14C-Residues in crop samples were extracted and initial analysis conducted by HPLC within 4 weeks of harvest. After a period of storage (64 to 73 weeks at -20°C) milled tissue from selected crops sown 30 cyantraniliprole), beet foliage, and hay ([PC-14C]-cyantraniliprole) were analysed.

The composition of the residue from wheat grain was similar to the original residue after prolonged storage, with cyantraniliprole being the major component, and metabolites IN-J9Z38, and IN-MLA84 bein

Free-text field: describe storage conditions, discuss whether the petitioner demonstrated that residues are stable during storage.

Table B.7.2.1-8. Sum	mary of Storage Cond	itions.	
Matrix (RAC or Extract)	Storage Temperature °C	Actual Storage Duration (Days or Months)	Interval of Demonstrated Storage Stability [specify crop/matrix if different] (Days or Months)

Tab to summarize storage stability data in study and demonstrated storage stability

eat (rotation)/ cereid grain [Lettuce (rotation)// leafy vegetable [Beet (rotation)// root vegetable Sol (rotation) Results and Discussion V. Appendix Total Radioactive Residues B. Extraction, Characterization, and Distribution of Residues C. Storage Stability of Residue [D. Identity of Residues in Rotational Crop E. Prop. D. Identity of Residues in Rotational Crop [Cyano-14C] #3 [Pyrazole carbonyl-14C] #4 Nature of residue 30 or 120 days after soil treatment. The majority of the extracted radioactivity from lettuce planted 30 and 120 days after soil treatment was identified as [D. 01 to 0.08 mg/kg, 39.6 to 69.1% TRR). Of more than 0.01 mg/kg. No undentified component individually accounted for more than 0.01 mg/kg. Table B.7.9-7. Summary of Characterization and Identification of Radioactive Residues in Rotational Crop Matrices Following Application Compound 30 PBT a 120 PBT a 120 PBT a Matrix 3 Ph-3C238 3.7 0.005 1.6 0.001 [Ph-3C238 3.7 0.005 1.6 0.001 [Ph-3C238 3.7 0.005 1.2 0.001 [Ph-3C238 3.7 0.005 [Ph-3C238 [Ph-3C238 3.7 0.005 [Ph-3C238	ion) Dility of Residues D. Identity of Residues in Rotational Crop E. Proposed Metabolic Path onyl-14C] #4 entified as
Results and Discussion V. Appendix Total Radioactive Residues B. Extraction, Characterization, and Distribution of Residues C. Storage Stability of Residue D. Identity of Residues in Rotational Crop E. Prop. D. Cleancity of Residues in Rotational Crop [Pyrazole carbonyl-14C] [Cyano-14C] #3 [Pyrazole carbonyl-14C] #4 Nature of residue 30 or 120 days after soil treatment. The majority of the extracted radioactivity from lettuce planted 30 and 120 days after soil treatment was identified as	bility of Residue D. Identity of Residues in Rotational Crop E. Proposed Metabolic Patt onyl-14C] #4 entified asD.0.1 to 0.08 mg/kg, 39.6 to 69.1% TRR). Other lettuce metabolic sidues in Rotational Crop Matrices Following Application of [Cyano-14C Matrix 3
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IV. Conclusions

Vheat (rotation)/ cereal grain	Lettuce (rotation)/leafy vegetable	Beet (rotation)/ root v	egetable Soi	(rotation)
I. General Info II. Materials	and Methods III. Results and Discu	ssion IV. Conclusions	V. Appendix	VI. Attachments

Same manner to fill "Conclusion" section than Plants MSS

CONCLUSIONS

In human food commodities, TRRs in crops grown in soil treated with both labels ranged from <0.01 to 0.06 mg/kg for wheat grain, 0.01 to 0.03 mg/kg for red beet roots and 0.02 to 0.11 mg/kg for lettuce. In animal feed commodities the TRR into soil treated with both labels ranged between 0.09 to 0.31 mg/kg for early forage, 0.31 to 1.62 mg/kg for hay, and 0.27 to 0.97 mg/kg for straw. TRRs in red beet foliage sampled from the 30 and 120 day sowings into treated soil ranged from the TRR in the upper 15 cm of soil collected 30 DAT with [CN-¹⁴C] and [PC-¹⁴C] and [PC-¹⁴

Soil residues at 493 DAT (wheat maturity from 365 sowing) did not decline significantly from those at 30 DAT. Since this soil had received two wheat sowings this indicated that total radioactivity in soil remained similar throughout the study. Concentrations of total radioactivity in soil from the lower 15 to 30 cm horizon were <0.01 mg/kg.

REFERENCES

Chaples, S., Confined rotational crop study using [146] DBY USING Chapter Laboratories, Tranent, Scotland, UK, study "D. D. Laboratories, and other study and the study of the

Free-text field: cite references for other metabolism studies (if applicable); if available, include the EPA MRID# and PMRA# of both the study and the review.



V. Appendix

'heat (r	otation)/ cereal grain	Lettuce (rot	ation)/leafy veget	able Beet (rotation	n)/ root veget	able Soil (rotatio	n)									
II. Resi	ults and Discussion	Appendix				Y	-	-	-							
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Cy_	ettuce_30_PBI		In bare soil	450 g ai/ha	1			30 da	ay Foliage			Citation #1		[Cyano-14C]-MTP_W	/-2! Lettuce (rotation)/lea	fy Sandy loam soil
Cy_	lettuce_120_PBI		In bare soil	450 g ai/ha	1			120	Foliage			Citation #1		[Cyano-14C]-MTP_W	/-2! Lettuce (rotation)/lea	fy Sandy loam soil
Cy	lettuce_b_30_PBI		In bare soil	450 g ai/ha	1			30	Foliage			Citation #1		[Pyrazole carbonyl-1	4C] Lettuce (rotation)/lea	fy Sandy loam soil
Cy_	lettuce_b_120_PBI		In bare soil	450 g ai/ha	1			120	Foliage			Citation #1		[Pyrazole carbonyl-1	4C] Lettuce (rotation)/lea	fy Sandy loam soil
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2	IN-J9238	Sumn	narize of all	identified a	nd/or de	etected con	npounds f	rom r	netabo	lism study and	relations	hips between	compound	s.		
3	IN-NBC94	Each l	<mark>ine represe</mark>	nts a compo	und.											
+	IN-MLA84	ALWA	YS begin wi	ith parent co	ompoun	d and carry	<mark>on with</mark> n	netab	olites.							
	IN-N/869					t- D M	G-1-(C)			100)-4110(
	IN-MYX98		3-Brom	0-1-(3-chioro	o-2-pyric	inyi)-N	Cc1cc(C#	N)CC((C(=O)I	VCO)C1IVC(=	1					
/	IN-HGW87		N-[2-(A	minocarbon	уі)-4-суа	ino-6	CC1CC(C#	N)CC((C(N)=0	D)CINC(=0)	ь					
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Wheat (rotation)/ cereal grain Lettuce (rotation)/ leafy vegetable Beet (rotation)/ root vegetable Soil (rotation)

III. Results and Discussion V. Appendix

Appendix 1 Appendix 1 filled thanks to append	ndix 1 editor	
Bre Application Method Application Rate Number of Applications Joan In bare soil 450 g ai/ha 1 Ioan In bare soil 450 g ai/ha Ioan	Test#*	 → Matrices should be named briefly but unambiguously so that they can be easily distinguished 1. first letters of the labelling (mandatory) 2. portion analysed (mandatory) 3. dose applied (optional) 4. PHI (optional) → Every information separated from the next with an underscore (_)
30 days * Application Method Application Rate In bare soil 450 g ai/ha	Number	ightarrow number of plants by radiolabelled test material
Number of Applications 1 * Matrix Foliage *	Plants: PHI* Rotational Crops: PBI*	/!\ The value must be separated from the unit by a space otherwise the information will not appear once the MSS xml file imported into MetaPath.
Experimental Descriptor	Application Method	
Citation Radiolabeled Test Material Citation #1 * • [Cyano-14C] Test Crop (from Table 1) Image: Component of the co	Application Rate*	/!\ The dose rate must be separated from the unit by a space otherwise the information will not appear once the MSS xml file imported into MetaPath.
"Lettuce (rotation)/ leafy vegetable"*Lettuce (Lac Soil Type (from Table 2) "Sandy loam soil", "6.2 (in water)", "1 [*] /4 (OC)", 70, 1!	Number of Applications*	Value

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V. Appendix

Wheat (rotation)/ cereal grain Lettuce (rotation)/ leafy vegetable Beet (rotation)/ root vegetable Soil (rotation)

III. Results and Discussion V. Appendix

Appe	endix 1	Арре	endix 1 filled t	hanks to apper	ndix 1 editor								
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Append Test# Cy_lett	lix1 Edit # tuce_30d	or *		×	Matrix*	120 10	iliage			Claun #1	i Lyano 1 Kuj Cyano an	in Lettuce (Totalion)) fear	n soil
Numb	er	thed	PBI 30 days *		Remarks				\rightarrow free-t	ext field. To expla	ain terms and abb	reviations	
Numb	e soil e soil er of App c	plications	Application Rate	tions	Citation*				→ select radiolab	t corresponding c elled test materia	itation (according al or the administe	to the ered dose)	
Exper	• * rimental D	escriptor			Radiolabele	d Test	Mat	terial*	\rightarrow select	t corresponding r	adiolabelled test ı	naterial	
Rema	ırks				Test Crop (fr	om Ta	ble	1)*	\rightarrow select	t corresponding t	est crop		
Citat Citati	ion on #1 Crop (fror	* • [m Table 1)—	Radiolabeled Test Cyano-14C]-	Material i₩▼	Soil type (fro	om Tal	ble 2	2)*	\rightarrow select	t corresponding s	oil type		
Soil T	uce (rotat ype (from	ion)/leafy v Table 2)	egetable *Lettuc	e (Lac 🔻									
Sand	iy loam so	Submit	vater)","17 (OC)" Cancel	./0,1! •	Click on Submi created r	it to va natrice	lidat e	te					

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Appendix 2	Appendix 2 filled thanks to		v. Appendix
ID Common Name /	Code Chemical Name SMILES	Common Name/Code	common name / company experimental name
Common Name / C		Chemical Name	common name (company experimental name) Do not write down the full chemical name of the molecules
Parent(s) 2 : IN-J9Z38 (Cd 3 : IN-JCZ38 (Cd	C)NC)CINC(=O)C1=CC(Br)=NN1C1C(C)	Parents	Describe relationship(s) between compounds by ticking the box(es) that correspond(s) to compound(s) from which the metabolite can be generated. Relationships specified for all metabolites, except parent compound. <i>N.B.: The metabolic pathway is built based on the information encoded in this</i> <i>field.</i>
4 : IN-MLA84 (C	c1cc(C#N)cc2c1N=C(C1=CC(Br)=NN1c1c(C)cc c1cc(C#N)cc(C(=O)NCO)c1NC(=O)C1=CC(Br)=	Treatment Groups	Tick the box(es) that correspond(s) to matrix(ces) in which the compound has been identified.
CI Solution Consec Solution Consec Solution Consec Solution Consec Consection Consec	reated compound	Expertise	If no issue drawing the compound , select " None " Select " Expertly specified " and " Assumed by author(s) " for <u>compounds that</u> <u>were not identified in the study</u> but are assumed intermediates between identified metabolites. In case of uncertainties while drawing a compound (e.g.: position of a chemical group not clearly determined), select " Expertly specified " and specify in the " Decision " field which assumptions were made when drawing the compound (e.g.: Unknown site of conjugation)



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Appendix 3					
	Cy_lettuce	Cy_lettuce	Py_lettuce_	Py_lettuce_	
	linked	linked	linked	linked	
IN-J9Z38	linked	linked	linked		
IN-JCZ38	linked	linked			
IN-MLA84	linked	linked	linked	linked	
IN-MYX98	linked	linked		linked	

V. Appendix

This table is <u>filled in automatically</u> using the information available in Appendix 1 and 2.

You can link and unlink matrices and compounds by right-clicking in the cells. This can also be done by scrolling **but it is very sensitive**.

Recommendation: we strongly recommend updating this table using the "Treatment group" fields of Appendix 2.



MSS Crop composer

Live filling