REVIEW OF ENSYSTEX DATA MATRIX SUBMITTED 7/30/08 for #82957-L

matrix ~~9/24~~/08, rev. 9/25/08 5:05 pm
19

yellow = questions
blue = conditionally required (CR) for non-food. might drop out if delete food handling use
shaded row = deleted from 8/21/08 version; not in 10/07 40CFR158

guideline #	guideline name	gdln required?	Ensystex cited	study ok?	gdln satisfied?	other studies for gdln	food handling toler used	EPA also requires	Ensystex gdln satisfied ?	comments
Product Chemistry Data Requirements										
830.1550	Product Identity and Composition	R	46925201 47268001		Y	-			Y	
830.1600	Description of Materials Used to Produce the Product	R	46925201 47268001		Y	-			Y	
830.1620	Description of Production Process	R	46925201 47268001		Y	-			Y	
830.1650	Description of Formulation Process	-			na	-			na	
830.1670	Discussion of Formation of Impurities	R	46925201 47268001		Y	-			Y	
830.1700	Preliminary Analysis	R	46925201 47275501		Y	-			Y	
830.1750	Certified Limits	R	46925201 47268001		Y	-			Y	
830.1800	Enforcement Analytical Method	R	46925201 47275501		Y	-			Y	
830.6302	Color	R	46925202 46925203 47268003		Y	-			Y	
830.6303	Physical State	R	46925202 46925203 47268003		Y	-			Y	
830.6304	Odor	R	46925202 46925203 47268003		Y	-			Y	

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830.6313	Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	R	46925202 46925203 47268003		Y	-			Y	
830.6314	Oxidation/Reduction: Chemical Incompatibility	-			na	-			na	
830.6315	Flammability	-			na	-			na	
830.6316	Explodability	-			na	-			na	
830.6317	Storage Stability	R	none			-			cond. data gap	En: not for tech EPA: yes; typical data gap
830.6319	Miscibility	-			na	-			na	
830.6320	Corrosion Characteristics	R	none			-			cond. data gap	En: not for tech EPA: yes; typical data gap
830.6321	Dielectric Breakdown Voltage	-			na	-			na	
830.7000	pH	R	46925202 46925203 47268003		Y	-			Y	
830.7050	UV/Visible Absorption	R	46925202 46925203 47268003		Y	-			Y	
830.7100	Viscosity	-			na	-			na	
830.7200	Melting Point/Melting Range	R	46925202 46925203 47268003		Y	-			Y	
830.7220	Boiling Point/Boiling Range	-			na	-			na	
830.7300	Density/Relative Density/Bulk Density	R	46925202 46925203 47268003		Y	-			Y	
830.7370	Dissociation Constants in Water	R	46925202 46925203 47268003		Y	-			Y	

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830.7550	Partition Coefficient (n-octanol/water), Shake Flask Method	R	46925202 46925203 47268003		Y	-			Y	
830.7560	Partition Coefficient (n-octanol/water), Generator Column Method	-			na	-			?	En: see 830.7550 EPA: note needed?
830.7570	Partition Coefficient (n-octanol/water), Estimation by Liquid Chromatography	-			na	-			?	En: see 830.7550 EPA: note needed?
830.7840	Water Solubility: Column Elution Method; Shake Flask Method	R	46925202 ~~46925203~~ ok 47268003	y gdln #	Y	-			Y	EPA: 46925203 not this gdln
830.7860	Water Solubility, Generator Column Method	-			na	-			-	
830.7950	Vapor Pressure	R	waiver request			-			Y	
Ecotoxicity Data Requirements										
850.2100 (71-1(a))	Acute Avian Oral Toxicity: Quail or Duck	R	00129879 (AC250672)	y	y				Y	
850.2200 (71-2(a))	Acute Avian Dietary Toxicity: Quail	R	00129880 (AC250673)	y	y				Y	
850.2200 (71-2(b))	Acute Avian Dietary Toxicity: Duck	R	00129520 (AC250761)	y	y					
850.2400 (71-3)	Wild Mammal Toxicity	-							na	
850.2300 (71-4(a))	Avian Reproductive Toxicity: Quail	R	40318601						?	En: no quail, cite duck EPA: need cite?
850.2300 (71-4(b))	Avian Reproductive Toxicity: Duck	R	40318601	y	y				Y	
850.1075 (72-1(a),(b))	Fish Toxicity: Bluegill	R	00088782 (AC246358)	y	y				Y	EPA: need 850.1045, .1055? any in-b.b.? or see EFED rev.

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850.1075 (72-1(c),(d))	Fish Toxicity: Trout	R	00088780 (AC246358)	y	y					
850.1010 (72-2(a)(b))	Freshwater Invertebrate Toxicity	R	00088784 (AC246358) 00153540 (AC74005)	y y	y y				Y	
850.1075 (72-3(a))	Estuarine/Marine Fish Toxicity	R	00150910 (AC259623)	y	y	40856304 40856305			Y	
850.1025 (72-3(b))	Estuarine/Marine Mollusk Toxicity	R	00159158 (AC252115)	y	y				Y	
850.1035 (72-3(c))	Estuarine/Marine Shrimp Toxicity	R	00150565 (AC259623) 40856304 40856305	y	y				Y	
850.1400 (72-4(a))	Early Life Stage: Fish	R	40069609	y	y	40069609			Y	
850.1300 (72-4(b))	Early Life Stage: Aquatic Invertebrate	R	00153570 (AC259364)	y	y	~~40856506~~ error: should be 40856306			Y	
850.1350	Aquatic Invertebrate Life Cycle (Saltwarer)	CR	40856306	y	y	~~40856506~~ error: should be 40856306			Y	
850.1500 (72-5)	Life Cycle Fish	-							-	
Toxicity Data Requirements										
870.1100 (81-1)	Acute Oral Toxicity: Rat	R	46925205		Y			~~46945403~~ ~~46945404~~	Y	
870.1200 (81-2)	Acute Dermal Toxicity: Rat	R	46925205		Y				Y	
870.1300 (81-3)	Acute Inhalation Toxicity: Rat	R	46925206		Y				Y	
870.2400 (81-4)	Primary Eye Irritation: Rabbit	R	46925207		Y				Y	
870.2500 (81-5)	Primary Dermal Irritation	R	46925208		Y				Y	

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870.2600 (81-6)	Dermal Sensitization	R	46925209		Y				Y	
870.3050 (N/A)	Repeated Dose 28-Day Oral Toxicity Study in Rodents	???							?	
870.3100 (82-1(a))	90-Day Oral Toxicity in Rodents [also see .6300]	R NF=cr	46959201	y	y			46959201 00131081 in new RA	?	EPA: 001x unacc/nongdln; why use?
870.3150 (82-1(b))	90-Day Oral Toxicity in Non-Rodents	R NF=cr	00131082 00164152	y	y		00131082	00131082 00164152 in new RA	Y	
870.3200 (82-2)	21-Day Dermal Toxicity	R NF=cr							?	En: EPA allowed waiver
870.3250 (82-3)	90-Day Dermal Toxicity	R							?	En: only R if exposed to skin; na for tech
870.3465 (82-4)	90-Day Inhalation Toxicity	-				46921501 prelim 5 day 46921502 final 30 day			-	En: only R if exposed to inhale; na for tech, gel, granular EPA: bridged gdln from oral tox; what about 2006 46921502? - 30 day, not 90
870.3550 (N/A)	Reproduction/Development Toxicity Screening Test	???								En: note to see .3700 EPA: note needed?

CD-1 mouse - no barrier (like
CF-1 mouse -

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870.3700 (83-3)	Prenatal Development Toxicity Studies	R	00130819 (AC 249152) 00153124 (AC 073303)			44173801 44179901	AC 249152 44179901 (not -801) cited all	~~44173801~~ 44179901RA ~~45608602~~ see 84-2 other 44160501RA 265564 RA 40912701RA 073759RA 073761RA 00096446RA 40713406RA	N	En: delta 8,9 (plant photodegradate) EPA: need for non-food (lawn)? HED said need -901 for all F/NF, correct? EPA: do we need cite all red? probably need 44179901
870.3800 (83-4)	Reproduction and Fertility Effects	R	00164151 (AC265576) 40713404	y	y		00164151 40713404 00096450 00096451		Y	En: NF = na EPA: note 000xs are unac/nongdl
870.4100 (83-1(a))	Chronic Toxicity Rat	R NF=cr	40069601 40069602 40375511 40375512 40517801						?	EPA: cite needed? ok
870.4100 (83-1(b))	Chronic Toxicity Dog	R NF=cr	40375510	y	y		40375510		Y	En: dog no longer required ~~EPA: need cite?~~ ok
870.4200 (83-2(a))	Carcinogenicity Rat	R NF=cr	40069601 40069602 40375511 40375512 40517801	y	y				Y	
870.4200 (83-2(b))	Carcinogenicity Mouse	R NF=cr	~~40517802~~ 40069601 40069602 40375511 40375512 40517801	y	y				Y	

What?

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870.4300 (83-5)	Combined Chronic Toxicity/Carcinogenicity	????	40069601 40069602 40375511 40375512 40517801	y	y		40069601 40375511 40517801 40069602 40375512	40069601 40375511 40517801 40069602 40375512	?	EPA: gdln gone? cite needed? OK
870.5100 (84-2(a))	Bacterial Reverse Mutation Test	R	00139573 (AC 252113) 00164016 (AC 265568) 00164017 (AC 265569) 00164018 (AC 265570) 40713402 40713405			45608602	AC 246894 #? AC 265568 AC 265569 40713402 40713405		Y	EN: NF = na EPA: 246894 wrong # EPA: 45608602 not in RA
870.5140 (84-2(a))	Gene Mutation in *Aspergillus nidulans*	???								
870.5195 (84-4)	Mouse Biochemical Specific Locus Test	???								
870.5200 (84-4)	Mouse Visible Specific Locus Test	???								
870.5250 (84-4)	Gene Mutation in *Neurospora crassa*	???								
870.5275 (84-4)	Sex-linked Recessive Lethal Test in *Drosophila melanogaster*	???								

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870.5300 (84-2(b))	*In vitro*Mammalian Cell Gene Mutation Test	R	00139573 (AC 252113) 00164016 (AC 265568) 00164017 (AC 265569) 00164018 (AC 265570) 40713402 40713405				265570		Y	EPA: 45608602 needed? not in RA
870.5375 (84-2(b))	*In vitro*Mammalian Chromosome Aberration Test	R				45608602			Y	En: NF = na
870.5380 (84-2(b))	Mammalian Spermatogonial Chromosome Aberration Test	???								
870.5385 (84-2(b))	Mammalian Bone Marrow Chromosome Aberration Test	R	00139573 (AC 252113) 00164016 (AC 265568) 00164017 (AC 265569) 00164018 (AC 265570) 40713402 40713405						Y	
870.5395 (84-4)	Mammalian Erythrocyte Micronucleus Test	R							Y	En: NF = na
870.5450 (84-4)	Rodent Dominant Lethal Assay	???								
870.5460 (84-4)	Rodent Heritable Translocation Assays	???								
870.5500 (84-2(b))	Bacterial DNA Damage or Repair Tests	???								
870.5550 (84-4)	Unscheduled DNA Synthesis in Mammalian Cells in Culture	???					1983 MRID unavail in RA		?	EPA: gdln gone; citation needed?

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870.5575 (84-4)	Mitotic Gene Conversation in *Saccharomyces cerevisiae*	???								
870.5900 (84-4)	*In vitro*Sister Chromatid Exchange Assay	???								
870.5915 (84-4)	*In vivo*Sister Chromatid Exchange Assay									
870.6100 (81-7 and 82-5)	Acute and 28-Day Delayed Neurotoxicity of Organophosphorus Substances	-							Y	En: not OP; na ?previously OP, now all? - no, only OP
870.6200 (81-8 and 82-7)	Neurotoxicity Screening Battery	R	44996501 46959201 46959202 46959203			44996501		44996501 46959201 46959202 46959203	Y	
870.6300 (83-6)	Developmental Neurotoxicity Study [also see .3100]	R	~~46727403~~ 46727402 47116201 47241801			46727402 46727403 46786801		46727402 46727403 46786801 47116201 47241801	N	
870.6500	Schedule-Controlled Operant Behavior	???								
870.6850	Peripheral Nerve Function	???								
870.6855	Neurophysiology; Sensory Evoked Potentials	???								
870.7200	Companion Animal Safety	-							-	
870.7485 (85-1?)	Metabolism and Pharmacokinetics	R NF=cr	00145888 (AC73761) 00145907 (AC73761)			42851523 42851524		42851523 42851524	Y	En: 428s are ema, not aver EPA: correct? - yes
870.7600 (85-2)	Dermal Penetration	CR?	00164161 (AC 265590)				AC 265590		Y	En: NF = na

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870.7800	Immunotoxicity	R							data gap	EPA: needed? yes; data gap for all
870.8355	Combined Chronic Toxicity/Carcinogenicity Testing of Respirable Fibrous Particles	???								
Plant Protection Data Requirements										
850.4100 (122-1(a))	Tier 1: Seed Germination and Seedling Emergence	cr								
850.4150 (122-1(b))	Tier 1: Vegetative Vigor	cr								
850.4400 (122-2)	Tier 1: Aquatic Plant Growth	R	00088788 (AC246358) 00088787 (AC246358)	y y	y				Y	EPA: need 850.5400?
Reentry Exposure Data Requirements										EPA: need 875.1100-1700?
875.2100 (132-1a)	Foliar Residue Dissipation	R - ep	00164163 (AC265591) 40443011						y?	TEP
875.2400 (133-3)	Dermal Passive Dosimetry Exposure	R - ep	44972201 45262901 45262902 45663701 45663703			none			y?	

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875.2500 (133-4)	Inhalation Passive Dosimetry Exposure	R - ep	44972201 45262901 45262902 45663701 45663703						y?	
Nontarget Insect Data Requirements					y? = could not id MRID in copy of review					
850.3020 (141-1)	Acute Contact Toxicity: Honey Bee	R	00159161 (AC252115)	y	y?				Y	
Environmental Fate Data Requirements										
835.2120 (161-1)	Hydrolysis	R	00159163 (AC252115)	y? MRID is collection; satisfies EUP	y?				Y	
835.2240 (161-2)	Photodegradation in Water	R	00159163 (AC252115)	y?	y?				Y	
835.2410 (161-3)	Photodegradation in Soil	R	00159163 (AC252115)	y?	y?				Y	
835-2370 (161-4)	Photodegradation in Air	cr				45500501		~~45500501~~	-	EPA: need cite? - no, plastic runoff study
835.4100 (162-1)	Aerobic Soil Metabolism	R	00159163 (AC252115)	y?	y?				Y	
835.4200 (162-2)	Anaerobic Soil Metabolism	R	00159163 (AC252115)	y?	y?				Y	
835.4300 (162-3)	Anaerobic Aquatic Metabolism	R	00159163 (AC252115)						Y	
835.4400 (162-4)	Aerobic Aquatic Metabolism	R	00159163 (AC252115)						Y	

check EFED rev. need? ORDER — correct coding ema not aver

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835.1230, 835.1240 (163-1)	Leaching and Adsorption/Desorption	R	40856301 00159163 (AC 252115)	y y?	y y?	42851526		42851526?	?	En: 2 old acceptable & enough EPA: correct? EPA: 428x aver or ema? - aver
835.6100 (164-1)	Soil Field Dissipation Study	R-ep	00161179 (AC072437) 00153569 (AC 259365) 42627601 45906202	? n	? n	42627601 42900002 45906202		42627601 42900002 45906202	?	En: 429x soil dissip for ag crop EPA: 42900002 needed only if food? others enough?
835.6200 (164-2)	Aquatic Sediment Field Dissipation Study	-							-	
835.6300 (164-3)	Forest Field Dissipation Study	-							-	
164-5	Long Term Field Dissipation Study	cr								EPA: gdln cite needed?
165-1	Confined Crop Rotation Study									
165-3	Accumulation –Irrigated Crops									
850.1710 (165-4)	Accumulation in Fish	cr	00159163 (AC252115)	y?	y?				Y	
835.7100 (166-1)	Small-Scale Prospective Groundwater Study	-							-	
835.7100 (166-2)	Small-Scale Retrospective Groundwater Study-	-							-	
Residue Chemistry Data Requirements										
860.1100 (171-2)	Chemical Identity	R	own						Y	
860.1200 (171-3)	Directions for Use	R	see label						Y	
860.1300 (171-4(a))	Nature of the Residue: Plants	-							-	

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860.1300 (171-4(b))	Nature of the Residue: Livestock	-							-	
860.1340 (171-4(c)) - Plants	Residue Analytical Methods: Plants	cr	44878101 44933401 44933402 44933403				44878101 44933401 44933402 44933403		Y	
860.1340 (171-4(d))	Residue Analytical Methods: Animal	-							-	
860.1380 (171-4(e))	Storage Stability	R	44878101 44933401 44933402 44933403						Y	
860.1400 (171-4(f,g,h))	Magnitude of Residue: Water, Fish, and Irrigated Crops	-							-	
860.1460 (171-4(i))	Magnitude of Residue: Food Handling Establishments	R	44878101 44933401 44933402 44933403				44878101 44933401 44933402 44933403		Y	
860.1480 (171-4(j))	Magnitude of Residue: Meat/Milk/Poultry/Eggs	-							-	
860.1500 (171-4(k))	Magnitude of Residue in Plants -	-							-	
860.1520 (171-4(l))	Magnitude of Residue in Processed Food/Feed	-							-	
---	post application from crack/crevice	used in RA	EN will cite 44147801 under what gdln?				44655901 44147801	44655901 44147801	N	En:44655901 = 42332501 but unacceptable EPA: need cite?
---	Maternal and Pup Exposure Following Dietary and Gavage Dosing in the Rat	used in RA?						46727401	?	En: submitted as 6a2, not gdln EPA: need cite?

~~44665901~~

not a #

~~42332501~~ Barnes study

need both

whitmire memo 1995

Mark Dapen

did we use it HED

WBL 3/10/01