

Data requirement for pesticide registration in Japan of 1 April 2019

	Documents	Necessity			Test guideline (OECD)	GLP Y/N
		(1)ADI-set	(2) No ADI-set for safe products	(3) for non food/feed crops ex.turf		
<b>1. TGAI studies</b>						
1	application form	○	○	○	-	-
2	Quality check list of Test reports	○	○	○	-	-
3	A list of study reports /literatures	○	○	○	-	-
<b>Manufacturing information</b>						
4	Specification of TGAI	○	○	○	-	N
5	Manufacturing method of TGAI	○	○	○	-	N
6	Impurities and reason of impurities	○	○	○	-	N
7	Five batch analysis report	○	○	○	JMAFF	Y
8	Analysis of dioxine	○	○	○	-	N
9	Batch analysis for toxicological studies	○	○	○	JMAFF	Y
10	upper or lower limit of TGAI content	○	○	○	-	N
11	Equivalency of TGAI	○	○	○	-	N
<b>Physical chemical properties of AI standard</b>						
<b>* note that tes substance is not TGAI, but AI.</b>						
12	Melting point	○	○	○	102	Y
13	Boiling point	○	○	○	103	Y
14	density	○	○	○	109	Y
15	vapour pressure	○	○	○	104	Y
16	Appearance (color, shape)	○	○	○	-	N
17	Odor	○	○	○	-	N
18	Spectrum (UV-visible absorption (UV))	○	○	○	101	Y
19	(Infrared absorption (IR))	○	○	○	101	Y
20	(Nuclear magnetic resonance (NMR))	○	○	○	101	Y
21	(Mass spectrometry (MS))	○	○	○	101	Y
22	Water solubility	○	○	○	105	Y
23	Solubility in organic solvents	○	○	○	105/CIP AC181	Y

24	n-octanol / water partition coefficient	○	○	○	107/117 /123	Y
25	Hydrolysis	○	○	○	111	Y
26	photodegradation in water	○	○	○	316	Y
27	Dissociation constant	○	○	○	112	Y
28	Thermal stability	○	○	○	113	Y
<b>Analytical method</b>						
29	crops	○	×	×	-	Y
30	livestock	○	×	×	-	Y
31	residue in soil	○	×	○	-	Y
32	residue in water	○	×	○	-	Y
33	analysis of TGAI	○	○	○	-	Y
<b>Toxicological studies(TGAI)</b>						
34	animal metabolism	○	×	○	417	Y
<b>Acute toxicity studies</b>						
35	Acute oral	○	×	○	420, 423, 425	Y
36	Acute dermal	○	×	○	402	Y
37	Acute inhalation	○	×	○	403, 433, 436	Y
38	skin sensitization	○	×	○	406,429, 442A-E	Y
<b>Subacute toxicity studies</b>						
39	90 days dietary (rat)	○	×	○	408,429	Y
40	90 days dietary (dog)	○	×	×	408,429	Y
41	90 days inhalation	△	×	△	413	Y
42	21days dermal	△	×	△	410	Y
<b>Gene toxicity</b>						
43	reverse mutation test	○	○	○	471	Y
44	chromosome abberation	○	×	○	473,487	Y
45	micronucleus test	○	×	○	474	Y
46	Genemutation test(in vivo)	△	×	△	488,489	Y
<b>Long term studies</b>						
47	combined(chronic and carcinogenicity)	○	×	×	452	Y
48	carcinogenicity	○	×	×	451,453	Y
<b>Reproduction</b>						
49	Reproduction	○	×	×	416	Y
50	teratogenicity(rat)	○	×	○	414	Y

51	teratogenicity(rabbit)	○	×	○	414	Y
Neurotoxicity						
52	acute neurotoxicity	△	×	×	424	Y
53	acute delayed neurotoxicity	△	×	×	418	Y
54	28-day repeated administration delayed neurotoxicity	△	×	×	419	Y
55	repeated dose oral neurotoxicity	△	×	×	424	Y
56	developmental neurotoxicity study	△	×	×	426	Y
57	detoxification	△	×	×	JMAFF	Y
Residue						
58	Plant metabolism	○	×	×	501	Y
59	Crop residue	○	×	×	509	Y
60	Metabolism in livestock	△	×	×	503	Y
61	Residue in livestock	△	×	×	505	Y
62	Storage stability of residue sample	○	×	×	-	Y
63	Residue in succeeding crops	△	×	×	JMAFF	Y
64	Bioaccumulation	△	×	△	305	Y
Environmental fate						
Fate in soil						
65	Aerobic paddy field	△	×	×	JMAFF/ 307	Y
66	Aerobic soil	○	×	○	JMAFF/ 307	Y
67	Anaerobic soil	△	×	△	JMAFF/ 307	Y
68	Soil residue	○	×	○	JMAFF	N
69	Soil adsorption	○	×	○	106	Y
Fate in water						
70	Hydrolysis	○	×	○	111	Y
71	Photolysis	○	×	○	316	Y
Test results regarding derivation of predicted environmental concentration						
72	(1)Test on water polluting properties	△	×	△	JMAFF	N

73	(2) Test on agricultural chemical concentration measurement in paddy water of model paddy	△	×	△	JMAFF	N
74	(3) Test on agricultural chemical concentration measurement in paddy water of actual paddy	△	×	△	JMAFF	N
75	(4) Test on surface soil runoff in model field	△	×	△	JMAFF	N
76	(5) Drift test	△	×	△	JMAFF	N
77	(6) Monitoring test on agricultural chemical concentration in the rivers	△	×	△	JMAFF	N
<b>Environmental toxicity</b>						
	Avian toxicity					
78	Acute oral toxicity	○	○	○	223/EP A850.21 00	Y
	Fish toxicity test					
79	(1) Fish acute toxicity test	○	○	○	203	Y
80	(3) Test on effects of coexistent organic substances on fish acute toxicity	△	△	△	JMAFF	Y
	Aquatic invertebrate					
82	Daphnia spp acute immobilization test	○	○	○	202	Y
83	Daphnia (adult daphnids) acute immobilization test	△	△	△	JMAFF	Y
84	Chironomid larva acute toxicity	△	△	△	235	Y
85	Freshwater shrimp or Amphipoda acute toxicity test	△	△	△	JMAFF	Y
86	Daphnia reproduction	△	△	△	211	Y
87	Algae growth inhibition test	○	○	○	201	Y
<b>Toxicity on beneficial organisms other than aquatic animals</b>						
88	Bee	○	○	○	213/214	N

<b>2. Formulation studies</b>						
89	Check list of documents	○	○	○	-	-
<b>Manufacturing information</b>						
90	Manufacturing information	○	○	○	-	-
<b>Physical chemical properties</b>						
91	Appearance(color and physical state)	○	○	○	JMAFF	N
92	Physical chemical properties	○	○	○	JMAFF	N
93	Stability of product	○	○	○	JMAFF	N
94	Stability of diluted solution	○	○	○	JMAFF	N
95	Storage stability	○	○	○	JMAFF	N
<b>Analytical method</b>						
96	Formulation sample analysis summary	○	○	○	JMAFF	-
97	Formulation sample analysis report	○	○	○	JMAFF	N
<b>Toxicity studies</b>						
98	Acute oral toxicity	○	○	○	420, 423, 425	Y
99	Acute dermal toxicity studies	○	○	○	402	Y
100	Acute inhalation studies	△	△	△	403, 433, 436	Y
101	Dermal irritation	○	○	○	404, 430, 431, 435, 439	Y
102	Eye irritation	○	○	○	405, various	Y
103	Skin sensitization	○	○	○	406, various	Y
<b>Aquatic toxicity</b>						
105	Acute fish toxicity	△	△	△	203	Y
106	Daphnia immobility test	△	△	△	202	Y
107	Algal growth inhibition test	△	△	△	201	Y

Toxicity to non-target organisms						
108	Toxicity to silk worm	△	△	△	JMAFF	N
Efficacy and phytotoxicity trials						
109	Efficacy and phytotoxicity trials	○	○	○	JMAFF	N
110	Mode of action	○	○	○	-	-
111	Residual odor in tea	△	△	△	JMAFF	N
112	Tabaco taste test	△	△	△	JMAFF	N