

Data requirement for pesticide registration in Japan 2021

(1) ADI-set: Usual chemical pesticide is required full studies of toxicological studies and crop residue studies to establish ADI ARfD and MRLs.

(2) No ADI set for safe products is required no toxicological studies to establish ADI ARfD and MRLs, such as extract from food crops.

(3) For non food/feed crops, only limited toxicological studies are required from acute toxicity, subacute toxicity and teratology studies.

In detail, check below table. If you want to know registration possibility of your product, please feel free to ask us, we will check it at limited cost.

	Documents	Necessity			Test guideline (OECD)	GLP Y/N
		(1)ADI-set	(2) No ADI-set for safe products	(3) for non food/feed crops		
1. TGAI studies						
1	application form	Y	Y	Y	-	-
2	Quality check list of Test reports	Y	Y	Y	-	-
3	A list of study reports /literatures	Y	Y	Y	-	-
Manufacturing information						
4	Specification of TGAI	Y	Y	Y	-	-
5	Manufacturing method of TGAI	Y	Y	Y	-	-
6	Impurities and reason of impurities	Y	Y	Y	-	-
7	Five batch analysis report	Y	Y	Y	JMAFF	Y
8	Analysis of dioxine	Y	Y	Y	JMAFF	N
9	Batch analysis for toxicological studies	Y	Y	Y	JMAFF	Y
10	upper or lower limit of TGAI content	Y	Y	Y	-	-
11	Equivalency of TGAI	Y	Y	Y	-	-
Physical chemical properties of AI standard						
* note that tes substance is not TGAI, but AI.						
12	Melting point	Y	Report/lietrature	Y	102	Y
13	Boiling point	Y	Report/lietrature	Y	103	Y
14	density	Y	Report/lietrature	Y	109	Y
15	vapour pressure	Y	Report/lietrature	Y	104	Y
16	Appearance (color, shape)	Y	Report/lietrature	Y	JMAFF	N
17	Odor	Y	Report/lietrature	Y	JMAFF	N

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		(1)ADI-set	(2) No ADI-set for safe products	(3) for non food/feed crops		
18	Spectrum (UV-visible absorption (UV))	Y	Report/lietrature	Y	101	Y
19	(Infrared absorption (IR))	Y	Report/lietrature	Y	101	Y
20	(Nuclear magnetic resonance (NMR))	Y	Report/lietrature	Y	101	Y
21	(Mass spectrometry (MS))	Y	Report/lietrature	Y	101	Y
22	Water solubility	Y	Report/lietrature	Y	105	Y
23	Solubility in organic solvents	Y	Report/lietrature	Y	105/CIP AC181	Y
24	n-octanol / water partition coefficient	Y	Report/lietrature	Y	107/117 /123	Y
25	Hydrolysis	Y	Report/lietrature	Y	111	Y
26	photodegradation in water	Y	Report/lietrature	Y	316	Y
27	Dissociation constant	Y	Report/lietrature	Y	112	Y
28	Thermal stability	Y	Report/lietrature	Y	113	Y
Analytical method						
29	crops	Y	N	N	-	Y
30	livestock	Y	N	N	-	Y
31	residue in soil	Y	N	Y	-	Y
32	residue in water	Y	N	Y	-	Y
33	analysis of TGAI	Y	Y	Y	-	Y
Toxicological studies(TGAI)						
34	animal metabolism	Y	N	Y	417	Y
Acute toxicity studies						
35	Acute oral	Y	N	Y	420, 423, 425	Y
36	Acute dermal	Y	N	Y	402	Y
37	Acute inhalation	Y	N	Y	403, 433, 436	Y
38	skin sensitization	Y	N	Y	406,429, 442A-E	Y
Subacute toxicity studies						
39	90 days dietary (rat)	Y	N	Y	408,429	Y
40	90 days dietary (dog)	Y	N	N	408,429	Y
41	90 days inhalation	C	N	C	413	Y
42	21days dermal	C	N	C	410	Y
Gene toxicity						

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43	reverse mutation test	Y	C	Y	471	Y
44	chromosome abberation	Y	N	Y	473,487	Y
45	micronucleus test	Y	N	Y	474	Y
46	Genemutation test(in vivo)	C	N	C	488,489	Y
	Long term studies					
47	combined(chronic and carcinogenicity)	Y	N	N	452	Y
48	carcinogenicity	Y	N	N	451,453	Y
	Reproduction					
49	Reproduction	Y	N	N	416	Y
50	teratogenicity(rat)	Y	N	Y	414	Y
51	teratogenicity(rabbit)	Y	N	Y	414	Y
	Neurotoxicity					
52	acute neurotoxicity	C	N	N	424	Y
53	acute delayed neurotoxicity	C	N	N	418	Y
54	28-day repeated administration delayed neurotoxicity	C	N	N	419	Y
55	repeated dose oral neurotoxicity	C	N	N	424	Y
56	developmental neurotoxicity study	C	N	N	426	Y
57	detoxification	C	N	N	JMAFF	Y
	Residue					
58	Plant metbolism	Y	N	N	501	Y
59	Crop residue	Y	N	N	509	Y
60	Metabolism in livestock	C	N	N	503	Y
61	Residue in livestock	C	N	N	505	Y
62	Storage stability of residue sample	Y	N	N	-	Y
63	Residue in succeeding crops	C	N	N	JMAFF	Y
64	Bioaccumulation	C	N	C	305	Y
	Environmental fate					
	Fate in soil					

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65	Aerobic paddy field	C	N	N	JMAFF/307	Y
66	Aerobic soil	Y	N	Y	JMAFF/307	Y
67	Anaerobic soil	C	N	C	JMAFF/307	Y
68	Soil residue	Y	N	Y	JMAFF	N
69	Soil adsorption	Y	N	Y	106	Y
	Fate in water					
70	Hydrolysis	Y	N	Y	111	Y
71	Photolysis	Y	N	Y	316	Y
Test results regarding derivation of predicted environmental concentration						
72	(1)Test on water polluting properties	C	N	C	JMAFF	N
73	(2) Test on agricultural chemical concentration measurement in paddy water of model paddy	C	N	C	JMAFF	N
74	(3) Test on agricultural chemical concentration measurement in paddy water of actual paddy	C	N	C	JMAFF	N
75	(4) Test on surface soil runoff in model field	C	N	C	JMAFF	N
76	(5) Drift test	C	N	C	JMAFF	N
77	(6) Monitoring test on agricultural chemical concentration in the rivers	C	N	C	JMAFF	N
Environmental toxicity						
	Avian toxicity					
78	Acute oral toxicity	Y	Y	Y	223/EP A850.21 00	Y
	Fish toxicity test					
79	(1) Fish acute toxicity test	Y	Y	Y	203	Y

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80	(3)Test on effects of coexistent organic substances on fish acute toxicity	C	C	C	JMAFF	Y
Aquatic invertebrate						
82	Daphnia spp acute immobilization test	Y	Y	Y	202	Y
83	Daphnia (adult daphnids) acute immobilization test	C	C	C	JMAFF	Y
84	Chironomid larva acute toxicity	C	C	C	235	Y
85	Freshwater shrimp or Amphipoda acute toxicity test	C	C	C	JMAFF	Y
86	Daphnia reproduction	C	C	C	211	Y
87	Algae growth inhibition test	Y	Y	Y	201	Y
Toxicity on beneficial organisms other than aquatic animals						
88	Bee	Y	Y	Y	213/214	N
2. Formulation studies						
89	Check list of documents	Y	Y	Y	-	-
Manufacturing information						
90	Manufacturing information	Y	Y	Y	-	-
Physical chemical properties						
91	Appearance(color and physical state)	Y	Y	Y	JMAFF	N
92	Physical chemical properties	Y	Y	Y	JMAFF	N
93	Stability of product	Y	Y	Y	JMAFF	N
94	Stability of diluted solution	Y	Y	Y	JMAFF	N
95	Storage stability	Y	Y	Y	JMAFF	N
Analytical method						
96	Formulation sample analysis summary	Y	Y	Y	JMAFF	-

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97	Formulation sample analysis report	Y	Y	Y	JMAFF	N
Toxicity studies						
98	Acute oral toxicity	Y	Y	Y	420, 423, 425	Y
99	Acute dermal toxicity studies	Y	Y	Y	402	Y
100	Acute inhalation studies	C	C	C	403, 433, 436	Y
101	Dermal irritation	Y	Y	Y	404, 430, 431, 435, 439	Y
102	Eye irritation	Y	Y	Y	405, various	Y
103	Skin sensitization	Y	Y	Y	406, various	Y
Aquatic toxicity						
105	Acute fish toxicity	C	C	C	203	Y
106	Daphnia immobility test	C	C	C	202	Y
107	Algal growth inhibition test	C	C	C	201	Y

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