

Interoffice
Communication

TO: Distribution

TGG: JCL: BHT: MJH: AJO: RF

XF: 591

FROM: T. G. Grumbles
DATE: January 17, 1990

SUBJ: TSCA ALCOHOL REREGISTRATION CONSORTIUM MEETING OF JANUARY

15.

VISTA

The subject meeting was attended by representatives from Cochran, Drexel, Fair Products, Coastal Chemical, Uniroyal, Ethyl, and Vista. Helena, P & G, and Henkel were not present. P & G and Henkel had indicated that they would technically support the effort but would not attend the meeting. No one had heard from Helena so it is not clear what they plan to do. Below are highlights of the meeting.

1. A consortium will be formed to develop the data needed to reregister 8 and 10 alcohols at least. Cochran expressed a desire to obtain a reregistration that would cover a C₆-C₁₂ range. Most others present felt this would be difficult but Cochran can use the 8 and 10 data developed in any way they wish.
2. An 810 blend will probably be used for testing and an attempt made to demonstrate that this data adequately represents both.
3. Gene Cochran was elected chairman and Hurley Hathaway (Cochran) and Louis Haefele (Drexel) will function as the technical committee.
4. Uniroyal is still undecided as to whether they will join the consortium or not. They may claim a formulators exemption and "pay the price" in the future if they wish to use consortium data.
5. The consortium signed our document reserving our data use right, however this was done outside the meeting with no open discussion on the matter.
6. The consortium asked that we not cancel our registration but transfer it to the consortium, or if the consortium is not yet a legal entity, a consortium member (probably Coastal) who would transfer it to the consortium of a later date. They wish this to happen just in case they need a technical (active ingredient) as well as a formulated product registration. In effect, they would then reregister our "labels" as well. I don't fully understand their concern but told them we could do that if I can figure out how to do it and meet our January 24th filing deadline.

Regardless, we would provide them with the use of any of our original data they need to support reregistration.

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7. Louis Haefele reviewed his assessment of the data needs with the group. This is attached for your reading pleasure. Bottom line is a cost ranging from 350,000 to 1,500,000 depending how persuasive we are on the "conditionally required" tests arguments.

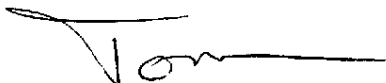
Also, some interesting issues were discussed. Some test requirements are determined by the results of an octanol/water partition coefficient. Obviously, octanol is very soluble in octanol and tests results would be indicative of the need for more testing.

Another similar problem is the testing requirement for vegetative vigour or growth inhibition. TSCA alcohols are growth inhibitors by design and will "flunk" these tests.

We (they) will make technical arguments against the applicability of these test and hope reason prevails.

8. In summary, Vista will be asked for the following:
- a. Transfer registrations to Consortium vs. a voluntary cancellation
 - b. Alcohol samples
 - c. Physical and chemical measurements on the samples and possibly the blend to be tested.
 - d. Use (without compensation) of existing registration data if needed.
 - e. General technical assistance such as reviewing toxicology testing results.

I did make the point that we were depending on the consortium to do the reregistration well and successfully because we were all at risk if they didn't. I think the members have the experience to do this and along with our technical help they can.



T. G. Grumbles

dlj

Attachment

cc: M. Sweet, R. Swantkowski, M. Clark, P. Hitchcock

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Total Cost

350,000 - 2 million (Best guess is 1.2 - 1.5 million)

if all
waivers
successful

if no
waivers
work

1/15/90
Prepared by Lou Hatley

In case - non-food

DATA REQUIREMENTS				compliance	This data Req't applies to my chemical		How I will comply with this data requirement										Time permitted for submission to EPA (in Years)	cost
Guideline Reference Number	Title of Study	non-food crop	Conditions Under Which it Applies		YES	NO	1	2	3	4	5	6	7	8	9			
61-1	Chemical Identity	R		M	X					X					1			
61-2(a)	Begin. mat. & mfg. proc.	R		M	X					X					1			
61-2(b)	Discussion of Impurities	R		M	X					X					1			
62-1	Preliminary Analysis	CR	These data apply to all Manufacturing- use Products(MPs)	M	X					X					1			
62-2	Certification of limits	R		M	X					X					1			
62-3	Analytical Method	R		M	X					X					1			
63-2	Color	R		M	X					X					1			
63-3	Physical State	R		M	X					X					1			
63-4	Odor	R		M	X					X					1			
63-5	Melting Point	R				X									1			
63-6	Boiling Point	R		M	X					X					1			
63-7	Density	R		M	X					X					1			
63-8	Solubility	R		M	X					X					1			
63-9	Vapor Pressure	R		M	X					X					1			
63-10	Dissociation Constant	R		M	X					X					1			
63-11	Oct/Water partition Coef.	CR	These data apply if the Technical is organic and non-polar.	W		X						X			1			

W = try for waiver
M = manufacturer (us) supplied
C = consortium

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DATA REQUIREMENTS				compliance	This data Req't applies to my chemical		How I will comply with this data requirement									Time permitted for submission to EPA (in Years)	COST
Guideline Reference Number	Title of Study	non-food crop	Conditions Under Which it Applies		YES	NO	1	2	3	4	5	6	7	8	9		
63-12	pH	CR	These data apply if the test substance is dispersible with water.	M	X					X						1	
63-13	Stability	R		M	X					X						1	
63-14	Oxidizing/Reducing Action	CR	These data apply if the product contains oxidizing or reducing			X										1	
63-15	Flammability	CR	These data apply if the product contains combustible liquids.	M	X					X						1	
63-16	Explosibility	R				X										1	
63-17	Storage stability	R		M	X					X						2	
63-18	Viscosity	CR	These data apply if the product is a liquid.	M	X					X						1	
63-19	Miscibility	CR	emulsifiable liquid and is to be diluted with petroleum solvents			X										1	
63-20	Corrosion characteristics	R		M	X					X						2	
63-21	Dielectric breakdown volt	CR	liquid to be used around electrical equipment.			X										1	
71-1(a)	Acute avian oral quail/duck	R		C	X		?	?								1	3,200
71-1(b)	Acute avian oral quail/duck-TE	CR	products formulated as granulars, pellets and baits			X										1	
71-2(a)	Acute avian diet. quail	R		C			?	?								1	2,800
71-2(b)	Acute avian diet. duck	R		C			?	?								1	2,800
71-3	Wild mammal toxicity	CR	predicide or rodenticide. results of lower tier studies			X										1	
71-4(a)	Avian repro. quail	CR	if one or more of the criteria are met	W		X							X			2	(48,000)

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DATA REQUIREMENTS				compliance	This data Req't applies to my chemical		How I will comply with this data requirement									Time permitted for submission to EPA (in Years)	cost
Guideline Reference Number	Title of Study	non-food crop	Conditions Under Which it Applies		YES	NO	1	2	3	4	5	6	7	8	9		
71-4(b)	Avian repro. duck	CR	if one or more of the criteria are met	W		X							X			2	(55,000)
71-5(a)	Simulated field study	CR	depending on the results of lower tier studies			X										3	
71-5(b)	Actual field study	CR	depending on the results of lower tier studies			X										3	
72-1(a)	Fish toxicity bluegill	R		C	X		?	?								1	1,800
72-1(b)	Fish toxicity bluegill - TEP	CR	end-use product which meets conditions			X										1	
72-1(c)	Fish toxicity rainbow trout	R		C	X		?	?								1	1,800
72-1(d)	Fish toxicity rainbow trout - TEP	CR	end-use product which meets conditions.			X										1	
72-2(a)	Invertebrate toxicity	R		C						X						1	6,000
72-2(b)	Invertebrate toxicity - TEP	CR	end-use product which meets conditions:			X										1	
72-3(a)	Fatu/mari tox. fish	CR	if the pesticide is expected to enter this environment in significant concentrations because of its expected use or mobility pattern.	W		X							X			1	(6,500)
72-3(b)	Fatu/mari tox. mollusk	CR		W		X							X			1	(6,500)
72-3(c)	Fatu/mari tox. shrimp	CR	To assist the registrant in determining whether the pesticide may enter estuarine and marine environments in significant concentrations, the following sites are those that EPA considers may be associated with estuarine and marine habitats	W		X							X			1	(6,500)
72-3(d)	Fatu/mari tox. fish - TEP	CR				X										1	
72-3(e)	Fatu/mari tox. mollusk - TEP	CR				X										1	
72-3(f)	Fatu/mari tox. shrimp - TEP	CR				X										1	
72-4(a)	Early life stage fish	CR	pesticide is applied to water			X										1	

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DATA REQUIREMENTS				compliance	This data Req't applies to my chemical		How I will comply with this data requirement										Time permitted for submission to EPA (in Years)	cost
Guideline Reference Number	Title of Study	non-food crop	Conditions Under Which it Applies		YES	NO	1	2	3	4	5	6	7	8	9			
72-4(b)	Life cycle invertebrate	CR	pesticide is applied to water		X										1			
72-5	Life cycle fish	CR	pesticide is applied directly to water		X										2			
72-6	Aquatic org. accumulation	CR	likely to occur in aquatic environments		X										1			
72-7(a)	Simul. field-aquatic orgs.	CR	depending on the results of lower tier studies		X										3			
72-7(b)	Actual field-aquatic orgs.	CR	depending on the results of lower tier studies		X										3			
81-1	Acute oral tox. rat	R		C	X		?	?							2	1,000		
81-2	Acute dermal tox. rabbit/rat	R		C	X		?	?							2	1,000		
81-3	Acute inhal. tox rat	R		C	X		?	?							2	2,500		
81-4	Primary eye irritation-rabbit	R		C	X		?	?							1	500		
81-5	Primary dermal irritation	R		C	X		?	?							1	500		
81-6	Dermal sensitization	R		C	X					5					1	2,500		
81-7	Acute delayed neurotox hen	CR	organophosphate,		X										2			
82-1(a)	90-day feeding-rodent	CR	the intended use is expected to result in human exposure	W	X							X			2	(50,000)		
82-1(b)	90-day feeding-norrodent	CR	the intended use is expected to result in human exposure	W	X							X			2	(90,000)		
82-2	21-day dermal-rabbit/rat	CR	if a subchronic 90-day dermal study (82-3) is not required.	W	X							X			2	(20,000)		
82-3	90-day dermal-rodent	CR	dermal exposure is the primary route of exposure.		X										2			

09601000 VVV

DATA REQUIREMENTS				compliance	This data Req't applies to my chemical		How I will comply with this data requirement									Time permitted for sub-mission to EPA (in Years)	cost
Guideline Reference Number	Title of Study	non-food crop	Conditions Under Which it Applies		YES	NO	1	2	3	4	5	6	7	8	9		
82-4	90-day Inhal. - rat	CR	A test with duration of 21 days if pesticide is used on tobacco.	C	X					X						2	50,000
82-5(a)	90-day neurotox - hen	CR	studies showed neuropathy or neurotoxicity.			X										2	
82-5(b)	90-day neurotox - mammal	CR	test showed neuropathy or neurotoxicity.			X										2	
83-1(a)	Chronic tox - rodent	CR	repeated human exposure to the product over a significant	W		X							X			4	500,000
83-1(b)	Chronic tox - non-rodent	CR	portion of the human life-span	W		X							X			4	600,000
83-2(a)	Oncogenicity - rat	CR	exposure over a portion of the human life-span	W		X							X			4	
83-2(b)	Oncogenicity - mouse	CR	which is significant	W		X							X			4	500,000
83-3(a)	Teratogenicity - rat	CR	For non-food uses, testing in one species is required.		X											2	40,000
83-3(b)	Teratogenicity - rabbit	CR				X											2
83-4	2-generation repro. - rat	CR	human exposure over a portion of the human life span	W		X							X			4	100,000
84-2(a)	Gene mutation - Ames	R		C	X						X					1	1,500
84-2(b)	Struct. chrom. aberration	R		C	X						X					1	6,500
84-4	Other genotoxic effects	R		C	X						X					1	10,000
85-1	General metabolism	CR	applies if chronic feeding or oncogenicity studies apply	W		X							X			2	(80,000
85-2	Dermal penetration	CR	applies for chemicals having a serious toxic effect			X										2	
86-1	Domestic animal safety	CR	as determined by EPA.			X										2	

~30,000

VVV 000010961

DATA REQUIREMENTS					This data Req'mt applies to my chemical		How I will comply with this data requirement									Time permitted for submission to EPA (in Years)	
Guideline Reference Number	Title of Study	non-food crop	Conditions Under Which it Applies		YES	NO	1	2	3	4	5	6	7	8	9		
122-1(a)	Seed germ/seedling emerg	R		C	X					X					1	8,500	
122-1(b)	Vegetative vigor	R		C	X					X					1	9,000	
122-2	Aquatic plant growth	R		C	X					X					1	6,000	
123-1(a)	Seed germ/seedling emerg	CR	previous tier			X									1		
123-1(b)	Vegetative vigor	CR	previous tier			X									1		
123-2	Aquatic plant growth	CR	previous tier			X									1		
124-1	Terrestrial field	CR	previous tier			X									2		
124-2	Aquatic field	CR	previous tier			X									2		
132-1(a)	Foliar residue dissipation	CR	Use conditions of end-use product			X									2		
132-1(b)	Soil residue dissipation	CR	Use conditions of end-use product			X									2		
133-3	Dermal passive dosimetry expo	CR	Use conditions of end-use product			X									2		
133-4	Inhal. passive dosimetry expo	CR	Use conditions of end-use product			X									2		
141-1	Honey bee acute contact	CR	If the end-use will result in exposure of honey bees.		X										1	1,000	
141-2	Honey bee residue on foliage	CR	previous tier			X									1		
141-5	Field test for pollinators	CR	previous tier			X									2		
160-5	Chemical identity	R	as required in 61-1	C	X					X					1		

VV 000010962

plus costs
to Radio Label
(C-14)

DATA REQUIREMENTS				compliance	This data Req't applies to my chemical		How I will comply with this data requirement									Time permitted for submission to EPA (in Years)	cost
Guideline Reference Number	Title of Study	non-food crop	Conditions Under Which it Applies		YES	NO	1	2	3	4	5	6	7	8	9		
161-1	Hydrolysis	R		C	X					X						1	10,000
161-2	Photodegradation-water	R		C	X					X						1	15,000
161-3	Photodegradation-soil	R		C	X					X						1	15,000
161-4	Photodegradation-air	CR	The vapor pressure of the technical is > 10 ⁻⁴ torr.	C	X					X						1	25,000
162-1	Aerobic soil metabolism	R		C	X					X						2	25,000
162-2	Anaerobic soil metabolism	R		C	X					X						2	30,000
162-3	Anaerobic aquatic metab.	R				X										2	
162-4	Aerobic aquatic metab.					X										2	
163-1	Leach/adsorp/desorption	R		C	X					X						1	20,000
163-2	Volatility - lab					X										1	
163-3	Volatility - field					X										1	
164-1	Terrestrial field dissipation	R		C	X					X						2	30,000
164-2	Aquatic field dissipation					X										2	
164-3	Forest field dissipation					X										2	
164-5	Long term soil dissipation	CR	material has not dissipated within one year			X										4	
165-1	Confined rotational crop	R		C	X					X						2	20,000

VVV 000010963

OK w/ Allen Nielsen

Radioisotopes

DATA REQUIREMENTS				compliance	This data Req't applies to my chemical	How I will comply with this data requirement										Time permitted for submission to EPA (in Years)	cost	
Guideline Reference Number	Title of Study	non-fond crop	Conditions Under Which it Applies			YES	NO	1	2	3	4	5	6	7	8			9
165-2	Field rotational crop	CR	determined by the results of the confined rotational crop study		X											3		
165-3	Accumulation - Irrig crop				X											3		
165-4	Bioaccumulation in fish	CR	unless the octanol/ water partition coefficient is less than 1000,	W	X							X				1	30,000	
165-5	Bioaccum - aquatic non-target	CR	depending on the outcome of accumulation studies in fish		X											1		
166-1	Grd water-small prospect	CR	pesticide or the major degradates demonstrate persistence		X											4		
166-2	Grd water-sm. retrospect	CR	pesticide residues demonstrate persistence and mobility		X											4		
166-3	Grd water-lrg retrospect	CR	This study may apply		X											4		
201-1	Droplet size spectrum	CR	Conditionally Required - These studies apply unless it can be demonstrated that a detrimental effect will not occur under reasonable conditions of use.		X											1		
202-1	Drift field evaluation	CR				X											2	
171-2	Chemical Identity	R		X	X											1		
171-3	Directions for use	R		X	X											1		
171-5	Reduction of residues															2		
171-4(a)	Nature of residue - plants															2		
171-4(b)	Nature of residue - livestock															2		
171-4(c)	Res. analyt. method - plant															2		
171-4(d)	Res. analyt. method - animal															2		

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