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│     CBRS TRANSMITTAL SHEET FOR PHASE 4 REVIEWS         │
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Transmitted to HED on __8/31/90__   DEB No. 6974

Case name: __Methanearsonic acid and salts__

Chemical Name(s): ___Disodium methanearsonate (DSMA)___

Data submitter(s): __Vineland Chemical Company__

CRM:__Betty Crompton__   Phone #:_308-8067_

Issues/flags:

This action contains a request for a   DATA WAIVER   ( )
                                       TIME EXTENSION   ( )
                                       ALTERED/DELETED USE ( )

Other: LUIS output dated 2/16/91 and product labels were used as
         sources of use information.

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│   Branch: CBRS, Phase 4 Review Team                    │
│                                                        │
│   Reviewed by: _Christine L. Olinger_ CLO_ Date:_3-26-91_│
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3/26/91

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│   Approvals:                                           │
│                                                        │
│   Section Head:_Andrew R. Rathman___  Date:_3/27/91_   │
│                                                        │
│   Branch Approval:_Edward Zager___  Date:_3/28/91_     │
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cc: CLOlinger, List B File, Circ., B. Grim (EFED), C. Furlow
     (FOD/PIB), RF

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│                    Response, by Guideline                         │
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Guideline #: __171-3__   Description:_Directions for Use_____
Is requirement applicable? (Y/N): _Y_
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: _N/A_

Discussion: Product labels require several modifications as
                 outlined below under "Data Gap".

Data Gap: All product labels with cotton as a use site must
                 prohibit feeding treated foliage to livestock. For
                 citrus and non-bearing orchard crop use, a restriction
                 prohibiting livestock grazing in treated orchards must
                 be on the label. A pre-harvest interval for bearing
                 citrus uses should be added to the label. All product
                 labels with cotton and/or citrus as a use site should
                 state "No more than three applications of MSMA or DMSA
                 may be made per growing season". All product labels
                 should specify a maximum number of applications and a
                 retreatment interval. These parameters must reflect
                 those used in the crop field trials.

Guideline #: _171-4(a)_   Description:_Nature of residue - plants_
Is requirement applicable? (Y/N): _Y_
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: _N/A_

Discussion: Registrant has committed to conduct the study. CBRS
                 accepts translation of monosodium methanearsonate
                 (MSMA) data to DSMA since the use patterns and
                 chemistry are very similar.

Data Gap: The registrant must provide two new plant metabolism
                 studies. Monosodium methanearsonate labelled in a
                 non-labile part of the molecule should be applied to
                 cotton and a citrus fruit reflecting the currently
                 registered use. The specific activity and/or
                 application rate should be high enough to allow for
                 adequate identification of the metabolites/
                 degradates. The plant material from the metabolism
                 study should be tested using the data collection
                 method(s) and enforcement analytical method(s).

Guideline #: _171-4(b)_   Description:_Nature of residue - animals_
Is requirement applicable? (Y/N): _Y_
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: _N/A_

Discussion: Registrant has committed to conduct the study. CBRS
                 accepts translation of monosodium methanearsonate
                 (MSMA) data to DSMA since the use patterns and

Data Gap:
chemistry are very similar.
The registrant must provide poultry and ruminant metabolism studies. Monosodium methanearsonate labelled in a non-labile part of the molecule should be fed to the livestock for a minimum of three days. Orally treated test animals must be sacrificed within 24 hours of the final dose. The dose administered and the specific activity should be high enough to allow for adequate identification of the metabolites/ degradates. The tissues from the metabolism study should be tested using the data collection method(s) and enforcement analytical method(s).

Guideline #: _171-4(c)_ Description: Res. analyt. method - plant
Is requirement applicable? (Y/N): _Y_
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: _N/A_

Discussion: Registrant has committed to conduct the study. CBRS accepts translation of monosodium methanearsonate (MSMA) data to DSMA since the use patterns and chemistry are very similar. Multi-residue method testing will not be required since recovery of monosodium methanearsonate through any of the protocols is unlikely.

Data Gap: The registrant must submit data collection and regulatory analytical method(s) for the determination of monosodium methanearsonate in/on plant matrices. If new metabolites (which require regulation) are found in the new plant metabolism studies, then analytical method(s) must be developed for them as well. Any regulatory methods submitted will require an independent method validation as described in PR Notice 88-5 (July 15, 1988).

Guideline #: _171-4(d)_ Description: Res. anal. method - animals
Is requirement applicable? (Y/N): _Y_
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: _N/A_

Discussion: Registrant has committed to conduct the study. CBRS accepts translation of monosodium methanearsonate (MSMA) data to DSMA since the use patterns and chemistry are very similar. Multi-residue method testing will not be required since recovery of monosodium methanearsonate through any of the protocols is unlikely.

Data Gap: The registrant must submit data collection and regulatory analytical method(s) for the determination of monosodium methanearsonate in/on animal commodities. If new metabolites (which require regulation) are found in the new animal metabolism

studies, then analytical method(s) must be developed
for them as well. Any regulatory methods submitted
will require an independent method validation as
described in PR Notice 88-5 (July 15, 1988).

Guideline #: _171-4(e)_ Description:_Storage stability_____
Is requirement applicable? (Y/N): _Y_
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: _N/A_

Discussion: Registrant has committed to conduct the study. CBRS
                 accepts translation of monosodium methanearsonate
                 (MSMA) data to DSMA since the use patterns and
                 chemistry are very similar.

Data Gap: Storage stability studies must be conducted on all
                 crops and processed products for which a field trial
                 and/or processing study has been (or will be)
                 conducted, as well as representative livestock
                 commodities. Use of field-weathered samples is
                 strongly recommended. Storage conditions must reflect
                 the storage conditions of the treated samples (from
                 the field trial and processing studies) with respect
                 to temperature, length of storage, containers,
                 lighting, etc. If there are any metabolites and/or
                 degradates included in the tolerance expressions, then
                 they must be tested as well. The chosen intervals
                 must allow for unforeseen delays in sample storage.

Guideline #: _171-4(f)_ Description:_Mag. res. - potable water_
Guideline #: _171-4(g)_ Description:_Magnitude residue - fish_
Guideline #: _171-4(h)_ Description:_Mag. res. - irrigated crop_
Guideline #: _171-4(i)_ Description:_Mag. res. - food handling_
Are requirements applicable? (Y/N): _N_

Guideline #: _171-4(j)_ Description:_Mag. meat/milk/poultry/eggs_
Is requirement applicable? (Y/N): _Y_
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: _N/A_

Discussion: Registrant has committed to conduct the study. CBRS
                 accepts translation of monosodium methanearsonate
                 (MSMA) data to DSMA since the use patterns and
                 chemistry are very similar.

Data Gap: Monosodium methanearsonate must be fed to dairy cattle
                 and poultry for a minimum of 28 days or until residues
                 plateau in the milk or eggs, whichever is longer.
                 Following oral treatment, test animals should be
                 sacrificed within 24 hours of the final dose. Feeding
                 levels should be determined based on the latest crop
                 residue data generated or to be generated. Animals

should be fed at levels of 1X, 3X, and 10X the maximum
dietary burden. When determining the feeding levels
the registrant should consider the maximum crop
residue levels possible and the dietary burden based
on Table II Subdivision O - Residue Chemistry
Guidelines.

Guideline #: _171-4(k/l)_ Description:_Cotton field trials/process_
Are requirements applicable? (Y/N): _Y_
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: _N/A_
Discussion: Registrant has committed to conduct the study. CBRS
                accepts translation of monosodium methanearsonate
                (MSMA) data to DSMA since the use patterns and
                chemistry are very similar.
Data Gap: Data depicting residues of monosodium methanearsonate
                and the regulated metabolites in/on cotton must be
                submitted. A representative aqueous formulation must
                be applied at the maximum label rate, the maximum
                number of applications, the minimum retreatment
                interval, and the minimum PHI. These parameters are
                specified in Table 1. The use of aerial and ground
                equipment must be represented in separate tests. The
                states in which the tests must be conducted are also
                listed in Table 1.

                A processing study must be conducted for cottonseed.
                Cottonseed bearing detectable residues of the parent
                and the regulated metabolites should be processed into
                meal, hulls, soapstock, crude oil, and refined oil to
                determine the residue concentration or reduction
                factor(s). If the cottonseed is treated at
                exaggerated rates equivalent to at least the maximum
                theoretical concentration factor due to processing and
                no detectable residues are found on the RAC, then
                processing studies are not required.

Guideline #: _171-4(k/l)_ Description:_Citrus field trials/process_
Are requirements applicable? (Y/N): _Y_
Does the summary/available information indicate that the MRID is a
candidate for Phase 5 review?: _N/A_
Discussion: Registrant has not addressed this use site. CBRS
                accepts translation of monosodium methanearsonate
                (MSMA) data to DSMA since the use patterns and
                chemistry are very similar.
Data Gap: Data depicting residues of monosodium methanearsonate
                and the regulated metabolites in/on lemons, oranges,
                and grapefruit must be submitted. A representative
                aqueous formulation must be applied at the maximum
                label rate, the maximum number of applications, the

minimum retreatment interval, and the minimum PHI. These parameters are listed in Table 1. The use of aerial and ground equipment must be represented in separate tests. The states in which the tests must be conducted are also listed in Table 1.

A processing study must be conducted for a representative citrus fruit. The commodity bearing detectable residues of the parent and the regulated metabolites should be processed into dried pulp, oil, molasses, and juice to determine the residue concentration or reduction factor(s). If the commodity is treated at exaggerated rates equivalent to at least the maximum theoretical concentration factor due to processing and no detectable residues are found on the RAC, then processing studies are not required.

Guideline #: 171-4(k/1) Description: Crop field trials/process
Commodity: Non-bearing Orchard Crops
Is requirement applicable? (Y/N): N - see discussion
Does the summary/available information indicate that the MRID is a candidate for Phase 5 review?: N/A
Discussion: Registrant has not addressed this use site. Residue data are not needed if product labels are modified as described below.
Data Gap: Product labels with non-bearing orchard crops as use sites must be modified to include the following statement: "Treated crop may not be harvested within one year of application."

ADDITIONAL COMMENTS:
The registrant is advised to consult the Subdivision O Residue Chemistry Guidelines, the Standard Evaluation Procedures, the Data Reporting Guidelines, and the Phase 3 Technical Guidance concerning conduct of residue chemistry studies. If the registrant has additional concerns they are advised to submit a protocol for CBRS review.

Table 1. Test Parameters for Crop Field Trials

Crop	States[1]	Appl. Rate lb a.i./A	Timing	Equip. A, G, C[2]	Max. No. of Appl.	Retreatment Interval, days	PHI, days
Cotton	TX, CA, AZ, MS, LA	2.0	1)pre-plant or post-plant to cracking; broadcast application	G,A			
		1.0	2)post-e 3-6" or 1st squares; broadcast application	G,A	3	7-21	NS[3]
		2.0	3)post-e 3" to 1st bloom, directed application	G			
Orange	FL, CA		NS				
Lemon	CA, AZ	4.0		G	3	NS	NS[4]
Grapefruit	CA, FL, TX						

[1]If a slash appears between states then either site may be chosen.

[2]A = aerial, G = ground, C = chemigation.

[3]NS = Not specified on product labels.

[4]PHI has not been specified on label. Labels should be amended to reflect PHIs from crop field trials.

PRODUCT CHEMISTRY

Case Name: Methanearsonic acid and salts
Chemical Name(s):   Disodium methanearsonate (DSMA)
Registrant: Vineland Chemical Company

Guideline Number	Is requirement applicable?	Does summary or available information indicate MRID is a candidate for Phase 5 review?	Are additional data required?	MRID Number
61-1	Y	N/A	Y*	N/A
61-2(a)	Y	N/A	Y*	N/A
61-2(b)	Y	N/A	Y*	N/A
62-1	Y	N/A	Y*	N/A
62-2	Y	N/A	Y*	N/A
62-3	Y	N/A	Y*	N/A
63-2	Y	Y	N	41602501
63-3	Y	Y	N	41602501
63-4	Y	Y	N	41602501
63-5	Y	N[b]	Y[b]	U[b]
63-6	N	N/A	N/A	N/A
63-7	Y	N[b]	Y[b]	U[b]
63-8	Y	Y	N	41602502
63-9	Y	N/A	Y*	N/A
63-10	Y	N/A	Y*	N/A
63-11	Y[c]	N/A	Y[c]	N/A
63-12	Y	N/A	Y*	N/A
63-13	Y	N/A	Y*	N/A

Key: Y=yes; N=no; I=a decision cannot be made at this time;   S=fully satisfies requirement;
P=partially; N/A=not applicable; U=unsatisfactory.

Note to CRM: Decisions on Physical/Chemical Characteristics (63 Series) are based on data submitted by CCI on behalf of Task Force 3. Based on correspondence submitted with the Phase 3 package (letter from Les Shockey, APC Holdings, to U.S. EPA, 6/20/90) CBRS cannot determine if Vineland Chemical Company and APC Holdings are members in good standing of the Task Force. Despite this fact CBRS based their response for Vineland Chemical on the Task Force data (with the exception of 63-11 which was specifically cited in the registrant's response). If SRRD later determines that this registrant may not cite these data, then the 63 series requirements should be considered data gaps.

*Registrant has committed to conduct the study. The registrant is advised that a solid form of the TGAI or PAI must be used for physical/chemical testing.

[b]CBRS cannot determine adequacy of study since test method was not reported.

[c]The registrant has committed to providing documentation that the active ingredient is polar, which would preclude the need for partition coefficient data.