PHASE FOUR REVIEW

(**NOTE:** This only contains additions and changes from the phase 2 response.)

Pesticide: Mineral oil includes paraffin oil from 063503 (Tox. Chem # 632A)

Transmitted to HED on 5/27/94 Chemical#/Case#: 063502/819001
Tox. Chem #: 580
Sponsor: Sun Refining and Marketing Co.

CRM: Bonnie Adler Phone#: 308-8523

Branch: Toxicology I, Section 2 Reviewer: Paul Chin, PhD 9/15/94
Completed: 9/15/94
~~Division Director's~~ Concurrence: Karl P. Baetcke 9/15/94
BRANCH CHIEF:

EXECUTIVE SUMMARY:

The Toxicology Branch I has reviewed summaries of several studies submitted for phase four review. Based on preliminary assessment of the summaries of the studies, TB has determined that each study is tentatively acceptable/not acceptable for review as indicated below under the appropriate guideline numbers. This phase four review for mineral oil includes paraffin oil.

TB has also reviewed the document entitled "Horticultural Spray Oil (Mineral Oil) Testing Strategy" submitted by the Horticultural Spray Oils Task Force. In this document, the Task Force is asking EPA if any additional required testing could be conducted on one representative oil. TB has no objection for the Task Force in conducting toxicity testing on one representative oil because of the similar acute toxicities of the mineral oils from three different manufacturers demonstrated in the earlier submissions on mineral oils (HED Doc. Nos. 10809, 10810, and 10813). In addition, the horticultural spray oils have similar physical and chemical properties because common processes are involved in their manufacturing of the horticultural spray oils as documented in this document.

Response, by Guideline

Guideline #: 81-1 Description: Acute oral/rat
MRID No.(original/summary): 41368815/93030014 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-1 Description: Acute oral/rat
MRID No.(original/summary): 41368811/93030013 Study # N/A

Discussion/Recommendation:
This summary contains only data for one test material [Neutral Oil 20], although 4 test materials [Neutral Oil 20, Neutral Oil 40, Neutral Oil 110, and Bright Stock 32] were tested in this study.

Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review for Neutral Oil 20 only. The registrant should submit the results of the other studies.

Guideline #: 81-1 Description: Acute oral/rat
MRID No.(original/summary): 00117149/93030011 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-1 Description: Acute oral/rat
MRID No.(original/summary): 41368801/93030012 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-2 Description: Acute dermal/rabbit
MRID No.(original/summary): 41368811/93030013 Study # N/A

Discussion/Recommendation:
This summary contains only data for one test material [Neutral Oil 20], although 4 test materials [Neutral Oil 20, Neutral Oil 40, Neutral Oil 110, and Bright Stock 32] were tested in this study.
Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review for Neutral Oil 20 only. The registrant should submit the results of the other studies.

Guideline #: 81-2 Description: Acute dermal/rabbit
MRID No.(original/summary): 41368816/93030017 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-2 Description: Acute dermal/rabbit
MRID No.(original/summary): 41368802/93030016 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of

the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-2 Description: Acute dermal/rabbit
MRID No. (original/summary): 41368826/93030018 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-2 Description: Acute dermal/rabbit
MRID No. (original/summary): 00117150/93030015 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-3 Description: Acute inhalation/rat
MRID No. (original/summary): 41368803/93030019 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-3 Description: Acute inhalation/rat
MRID No. (original/summary): 41368827/93030021 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-3 Description: Acute inhalation/rat
MRID No. (original/summary): 41368817/93030020 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-4 Description: Primary eye irritation/rabbit
MRID No. (original/summary): 41368811/93030013 Study # N/A

Discussion/Recommendation:
This summary contains only data for one test material [Neutral Oil 20], although 4 test materials [Neutral Oil 20, Neutral Oil 40, Neutral Oil 110, and Bright Stock 32] were tested in this study.
Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review for Neutral Oil 20 only. The registrant should submit the results of the other studies.

Guideline #: 81-4 Description: Primary eye irritation/rabbit
MRID No.(original/summary): 40270806/93026019;93023008 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-4 Description: Primary eye irritation/rabbit
MRID No.(original/summary): 41368804/93030024 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-4 Description: Primary eye irritation/rabbit
MRID No.(original/summary): 41368818/93030025 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-4 Description: Primary eye irritation/rabbit
MRID No.(original/summary): 00116423/93030022 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-4 Description: Primary eye irritation/rabbit
MRID No.(original/summary): 00124331/93030023 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-5 Description: Primary dermal irritation/rabbit
MRID No.(original/summary): 41368811/93030013 Study # N/A

Discussion/Recommendation:
This summary contains only applicable data for one test material [Neutral Oil 20], although 4 test materials [Neutral Oil 20, Neutral Oil 40, Neutral Oil 110, and Bright Stock 32] were tested in this study.
Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review for Neutral Oil 20 only. The registrant should submit the results of the other studies.

Guideline #: 81-5 Description: Primary dermal irritation/rabbit
MRID No.(original/summary): 40270807/93026009 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-5 Description: Primary dermal irritation/rabbit
MRID No.(original/summary): 41368819/93030028 Study # N/A
Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.
Guideline #: 81-5 Description: Primary dermal irritation/rabbit
MRID No.(original/summary): 41368828/93026029 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-5 Description: Primary dermal irritation/rabbit
MRID No.(original/summary): 00116422/93026026 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-5 Description: Primary dermal irritation/rabbit
MRID No.(original/summary): 41368805/93030027 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-6 Description: Dermal sensitization/Guinea Pig
MRID No.(original/summary): 41368820/93030031 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

Guideline #: 81-6
Description: Dermal sensitization/Guinea Pig
MRID No.(original/summary): 41368812/93030030 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review.

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Guideline #: 82-2 Description: 21 Day dermal/rodent/rabbit
MRID No.(original/summary): 41368806/93030032 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, this study does not meet guideline 82-2 acceptance criteria because 2 test groups and 1 control group consisting of 3 animals/sex/group were used for the study. Also, animals were dosed for 5 days/week for 2 weeks instead of 3 weeks.
However, this study with MRID No. 41368829 (with a similar treatment regime and with a similar test material) is tentatively acceptable for review.

Guideline #: 82-2 Description: 21 Day dermal/rodent/rabbit
MRID No.(original/summary): 41368829/93030035 Study # N/A

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, this study does not meet guideline 82-2 acceptance criteria because 2 test groups and 1 control group consisting of 3 animals/sex/group were used for the study. Also, animals were dosed for 5 days/week for 2 weeks instead of 3 weeks.
However, this study with MRID No. 41368806 (with a similar treatment regime and with a similar test material) is tentatively acceptable for review.

Guideline #: 82-2 Description: 21 Day dermal/rodent/rat
MRID No.(original/summary): 41368821/93030033 Study # N/A

Discussion/Recommendation: The study summarized is a five-day long repeated dose dermal toxicity study in rats. Based on preliminary assessment of the summary of the study, this study does not meet guideline 82-2 acceptance criteria because 2 test groups were used, the duration of this study was five days, and no hematology or clinical chemistry was evaluated.

However, this study with MRID No. 41368822 (with a similar treatment regime and with a same test material, Light Neutral Oil) is tentatively acceptable for review.

Guideline #: 82-2 Description: 21 Day dermal/rodent/mouse
MRID No.(original/summary): 41368822/93030034 Study # N/A

Discussion/Recommendation: The study summarized is a four-week long repeated dose dermal toxicity study in mice. The frequency of dosing was 3 times per week and a total of 12 applications were administered over four weeks. An acceptance criteria is not available for a repeated dose dermal toxicity in mice. However, based on preliminary assessment of the summary of the study, this study does not meet guideline 82-2

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acceptance criteria because the frequency of dosing was 3 times per week and 2 test groups were used. In addition, no hematology or clinical chemistry was evaluated.

However, this study with MRID No. 41368821 (with a similar treatment regime and with a same test material, Light Neutral Oil) is tentatively acceptable for review.

Guideline #: 82-4
Description: Subchronic Inhalation Toxicity in the Rat
MRID No.(original/summary): 41368807/93030036 Study # N/A

Discussion/Recommendation: The study summarized is a 9-day inhalation exposure, not a 90-day subchronic study. Based on preliminary assessment of the summary of the study, this study does not meet guideline 82-4 acceptance criteria because the duration of this study was 9 days instead of 90 days.

However, this study with MRID No. 41368823 (with a similar treatment regime and with a similar test material, Light Neutral Oil) is tentatively acceptable for review.

Guideline #: 82-4
Description: Subchronic Inhalation Toxicity in the Rat
MRID No.(original/summary): 41368823/93030037 Study # N/A

Discussion/Recommendation: The study summarized is a 5-day inhalation exposure, not a 90-day subchronic study. Based on preliminary assessment of the summary of the study, this study does not meet guideline 82-4 acceptance criteria because the duration of this study was 5 days instead of 90 days.

However, this study with MRID No. 41368823 (with a similar treatment regime and with a similar test material, Orchard Spray 70) is tentatively acceptable for review.

Guideline #: 82-4
Description: Subchronic Inhalation Toxicity in the Rat
MRID No.(original/summary): 41368824/93030038 Study # N/A

Discussion/Recommendation: The study summarized is a 4-week inhalation exposure, not a 90-day subchronic study. Based on preliminary assessment of the summary of the study, this study does not meet guideline 82-4 acceptance criteria because the duration of this study was 4 weeks instead of 90 days.

However, this study with MRID No. 41368823 (with a similar treatment regime and with a same test material, Light Neutral Oil) is tentatively acceptable for review.

Guideline #: 84-2
Description: Mutagenicity (Gene mutation)
MRID 40270811 (Summary MRID 93026012), Study #

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, this study does not meet guideline 84-2 acceptance criteria because this study used only one strain (Salmonella typhimurium strain TA98) instead of minimum of 4 strains (TA98, TA100, TA1535, and TA1537) as required under Criterion # 1 of Test Specific Requirements.

Guideline #: 84-2
Description: Mutagenicity (Gene mutation)
MRID 40270812 (Summary MRID 93026013), Study #

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, this study does not meet guideline 84-2 acceptance criteria because this study used only one strain (Salmonella typhimurium strain TA98) instead of minimum of 4 strains (TA98, TA100, TA1535, and TA1537) as required under Criterion # 1 of Test Specific Requirements.

Guideline #: 84-2
Description: Mutagenicity (Gene mutation)
MRID 41368808 (Summary MRID 93030039), Study #

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review. Test substance is Orchard Spray 70.

Guideline #: 84-2
Description: Mutagenicity (Gene mutation)
MRID 41368813 (Summary MRID 93030040/93030048), Study #

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, this study does not meet guideline 84-2 acceptance criteria because this study used only one strain (Salmonella typhimurium strain TA100) instead of minimum of 4 strains (TA98, TA100, TA1535, and TA1537) as required under Criterion # 1 of Test Specific Requirements.

Guideline #: 84-2
Description: Mutagenicity (Gene mutation)
MRID 41368814 (Summary MRID 93030041/93030049), Study #

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review. Test substances are four Hydrocracked Lube Oil stocks and three RPM Lube Oil stocks.

Guideline #: 84-2
Description: Mutagenicity (Gene mutation)
MRID 41368825 (Summary MRID 93030042), Study #

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review. Test substance is Light Neutral Oil.

Guideline #: 84-2
Description: Mutagenicity (micronucleus)
MRID 41368809 (Summary MRID 93030043), Study #

Discussion/Recommendation: This study is a range-finding test for the micronucleus test described below (MRID 41368810 (Summary MRID 93030044). Therefore, this study should be reviewed with the MRID 41368810.

Guideline #: 84-2
Description: Mutagenicity (micronucleus)
MRID 41368810 (Summary MRID 93030044), Study #

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review. This study should be reviewed with a range-finding test (MRID 41368810) for the micronucleus test.

Guideline #: 84-2
Description: Mutagenicity (micronucleus)
MRID 41368830 (Summary MRID 93030045), Study #

Discussion/Recommendation: This study is a range-finding test for the micronucleus test described below (MRID 41368831 (Summary MRID 93030046). Therefore, this study should be reviewed with the MRID 41368831.

Guideline #: 84-2
Description: Mutagenicity (micronucleus)
MRID 41368831 (Summary MRID 93030046), Study #

Discussion/Recommendation: Based on preliminary assessment of the summary of the study, it is tentatively acceptable for review. This study should be reviewed with a range-finding test (MRID 41368830) for the micronucleus test.

In addition to the studies listed above, the registrant submitted three study reports without MRID numbers. Based on preliminary assessment of these reports, they are not acceptable for review because these studies as stated by the registrant were not intended to support the pesticide registration. Three study reports

submitted were as follows:

1. Evaluation of the skin irritating and sensitizing propensities of Sun 8601507 (Sun R & M ARD Auto Lab) in humans (April 17, 1987)

2. Subacute dermal (3 weeks) toxicity study API 78-10 Paraffinic Oil (150 SUS/100°F) in rabbits (Feb. 9, 1981)

3. Lifetime dermal carcinogenesis bioassay of selected petroleum streams in mice (Jan. 15, 1988)

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