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MEMORANDUM

SUBJECT: Metam Sodium (Sodium Methyldithiocarbamate) Reregistration (Case No. 2390, Chemical No. 039003): The Metam Sodium Task Force (10/6/92) Response to the Phase 4 DCI Concerning "Test Substance" for Product Chemistry 61, 62, and 63 Series. (no MRID No.; CBRS # 10885; DP BARCODE: D184538).

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The Metam-Sodium Task Force, in correspondence dated 10/6/92, has cited definitions at 40 CFR §158.153 and has concluded that since the chemical composition of the TGAI, MP, and EP of each respective Task Force member are identical, data generated using the EP as test substance (to be generated by each Task Force Company) can fulfill data requirements concerning

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Series 61 and 62 data. Additionally, the Metam Sodium Task Force indicates that both EPA and the Task Force have been confused and/or unclear about the "Test Substance" used to conduct the 63 series studies.

In the case of this List B Chemical, we note that CBRS is only responsible for **generic data** (61-2, 61-3, 62-1, and 63-2 to 63-13) requirements which make use of the TGAI as test substance to support registration of EPs and/or MPs. The Registration Division/RSB has purview of product specific data,i.e. data reflecting use of the EP or MP as test substance.

CBRS Response/Recommendation:

The footnotes to the Product Chemistry portion of the Phase 4 Review (C. Olinger and S. Funk, CBRS, 5/13/91) remain applicable- at least to ICI's registrations. We will clarify rationale for the Phase 4 DCI requirements below.

The Metam Sodium Task Force has correctly concluded that, if indeed the TGAI, MP, and EP have identical compositions, there is, in effect, only a single test substance. However, this applies only to product specific data requirements, i.e. where the MP and/or EP must serve as test substance. In the case of generic data requirements (i.e. where the TGAI or PAI must serve as the test substance) there are two possible scenarios: (i) if the TGAI, MP, and EP are identical, of high purity, and do not contain any intentionally added inerts, diluents, and/or processing solvents then, as above, there is basically only one test substance and any one can serve that purpose and (ii) if the MP and EP are different from the TGAI, and/or if they contain intentionally-added inerts, diluents, and/or processing solvents, then the TGAI (or an isolated TGAI-equivalent) must serve as the generic test substance.

Because Series 63 generic requirements apply to the properties of the active ingredient itself, a TGAI, TGAI-equivalent, or PAI must be isolated, whether or not this is done commercially. Series 61 and 62 requirements are TGAI/ manufacturing process/registrant specific and, to reflect what actually occurs commercially, a TGAI-equivalent should not be isolated, but rather the most concentrated form of the ai prior

to the intentional addition of any inerts, if applicable, should be used (in the case of 62-1, preliminary analysis, correction should be made for dilution of the ai and impurities if a relatively pure TGAI is not commercially isolated).

One benefit to consortia lies in the potential for using a single TGAI or isolated TGAI-equivalent (or a blend of all TGAIs/ TGAI-equivalents) as test substance to satisfy Series 63 generic data requirements. To permit approval of this, the Consortium members must demonstrate similarity in purity/composition. For those properties where the PAI is required or optional (63-8 thru 63-11), obviously only one PAI need be isolated and tested. The Agency, on a case-by-case basis, may not permit data translation from one TGAI/ TGAI-equivalent to another (or a blend of all consortium members ai's) in the case of certain properties that could be influenced by differences in composition, depending on the comparison of 62-1, preliminary analysis, data from each consortium member.

cc: Methyldithiocarbamate (metam sodium) S.F., R.F., List B file, F. Toghrol, and F. Chow (HED/CCB).
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