



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

June 28, 1991

MEMORANDUM

SUBJECT: Interpretation of the Good Laboratory Practice (GLP)
Regulation

GLP Regulations Advisory No. 32

FROM: David L. Dull, Director
Laboratory Data Integrity Assurance Division

TO: GLP Inspectors

Please find attached an interpretation of the GLP regulations as issued by the Policy & Grants Division of the Office of Compliance Monitoring. This interpretation is official policy in the GLP program and should be followed by all GLP inspectors.

For further information, please contact Francisca E. Liem at FTS 398-8333 (703) 308-8333.

Attachment

cc: C. Musgrove



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PESTICIDES AND TOXIC
SUBSTANCES

Dear

This is in response to your letter of February 27, 1991. In that letter you described an oncogenicity study, sponsored by the N currently being conducted at the X. As you have indicated, the study will require an anticipated 24 fifty-five gallon drums of isopropanol. The Good Laboratory Practices (GLP) regulations (40 CFR §792.1 et seq) require, among other things, that each storage container for a test, control, or reference substance be assigned to a particular substance for the duration of the study (40 CFR §792 105(c))

EPA believes that the provision for the assignment of storage containers for the duration of a study is a logical and necessary provision of the GLP regulations. In most cases this requirement provides accountability of test material in a manner which poses no unusual burden. However, due to the limited storage facilities, and the highly volatile and flammable nature of the substance in question (isopropanol), this GLP requirement may present an unusual burden to the N, as well as a potentially hazardous situation.

In granting previous exemptions to this provision of the GLP regulations, EPA has established stringent record keeping requirements as an alternate method of accounting for the storage containers in lieu of actual storage for the duration of the study. For the purposes of exemption from the assignment requirements for this study, EPA will require that the following documentation be retained for the duration of the study: 1) purchase and shipping receipts for all isopropanol storage containers received at the N (certified copies dated and signed by responsible persons will be considered adequate); and 2) records of the final destination of the storage containers such as receipts from the recycler or reclaimer (against dated and signed certified copies will be adequate).

Additionally, this exemption from the assignment requirements for the above study is conditional on the following:

- 1) for this study, a statement shall be included with the statement of compliance or noncompliance required at 40

CFR Section 792 12(b) explaining that this exception to the Good Laboratory Practices regulations is in accordance with the requirements provided in this letter;

- 2) an inventory shall be prepared-of all empty containers before disposal, including sufficient information to uniquely identify containers This inventory Shall be maintained in an up-to-date manner, recording all shipments of empty containers and their disposal This record shall be maintained for the duration of the study;
- 3) identification of the locations of the facilities where test material is stored, where empty containers are stored prior to disposal or recycling, where records of shipment of containers are maintained, and where the test substance is used in the study (i.e., testing facility). Within two weeks of receipt of this letter, the location of each of these facilities shall be reported to:

David L. Dull, Director
Laboratory Data Integrity Assurance Division
Office of Compliance Monitoring (EN-342)
Office of Pesticides and Toxic Substances
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460

Should these conditions not be fully met, the provisions of 40 CFR S 792 105(c) shall apply

In addition, is reminded that storage, disposal or recycling of containers must be done in a manner pursuant to all applicable Federal, State, County or local laws.

Sincerely yours,

/s/ John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring (EN-342)

cc David Dull
Scott Garrison (LE-134P)

Dear:

This is in response to your letter dated April 28, 1991. In that letter, you repeated a request for exemption from one of the requirements of the Toxic Substance Control Act Good Laboratory Practices regulations (GLPs) for study being conducted at the N. The letter containing your initial request was dated February 27, 1991. Our response to that inquiry was issued May 16, 1991.

Your April 28 letter raises one question regarding your request. In that letter, which you said was to correct your

February letter, you changed the citation of the regulation from which you have requested an exemption. In the first letter you cited the TSCA GLP provision (40 CFR §792.105(c)). Your second letter, however, cites that same requirement for the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) GLPs (40 CFR §160.105(c)). As you mentioned TSCA in both of your letters, I assume that you are seeking a TSCA exemption, and the second (FIFRA) citation was incorrect. Please contact me at (202) 382-7825 if there is any further confusion in this matter or if you have not received our original response.

Sincerely yours,

/s/ John J. Neylan III, Director
Policy and Grants Division
Office of Compliance Monitoring

cc: David L. Dull