SCHEDULE 1

PRINCIPLES OF GOOD LABORATORY PRACTICE (BASED ON ANNEX 2 TO THE DECISION OF 12TH MAY 1981 OF THE COUNCIL OF THE OECD ON THE MUTUAL ACCEPTANCE OF DATA FOR THE EVALUATION OF CHEMICAL PRODUCTS)

PART IX

REPORTING OF SAFETY STUDY RESULTS

General

23.—(1) A final report should be prepared for the safety study.

(2) The use of the International System of Units (SI) is recommended.

(3) The final report should be signed and dated by the study director.

(4) If reports of principal scientists from co-operating disciplines are included in the final report, they should sign and date them.

(5) Corrections and additions to a final report should be in the form of an amendment. The amendment should clearly specify the reason for the corrections or additions and should be signed and dated by the study director and by the principal scientist from each discipline involved.

Content of the final report

24. The final report should include, but not be limited to, the following information—

(a) Identification of the test and reference substance

(i) a descriptive title,

(ii) identification of the test substance by code or name (IUPAC, CAS number, etc.),

(iii) identification of the reference substance by chemical name,

(iv) characterisation of the test substance including purity, stability and homogeneity;

(b) Information concerning the laboratory

(i) name and address,

(ii) name of the study director,

(iii) name of other principal personnel having contributed reports to the final report;

(c) Dates

dates on which the safety study was initiated and completed;

(d) Statement

a quality assurance statement certifying the dates inspections were made and the dates any findings were reported to management and to the study director;

(e) Description of materials and test methods

(i) description of methods and materials used,

(ii) reference to OECD test guidelines or other test guidelines;

(f) Results

(i) a summary of results,

(ii) all information and data required in the study plan,

(iii) a presentation of the results, including calculations and statistical methods,

(iv) an evaluation and discussion of the results and, where appropriate, conclusions;

(g) Storage

The location where all samples, specimens, raw data and the final report are to be stored.