

#### ❖ DELIVERY FORM

The test item should be accompanied by a delivery form detailing:

Manufacturer's name or sponsor's name  
Date of despatch  
Number of containers or items, type, amount of contents  
Identity of test item  
Batch number(s)  
Identity of person responsible for despatch  
Name of carrier

#### ❖ CERTIFICATES

Certificates of analysis, stability (with storage conditions) and MSDS (material safety data sheets) should follow test item.

#### ❖ COMMERCIAL INVOICE

To facilitate the sending of your products and to minimise customs problem and delay, prepare a commercial invoice including :

*"Non-Hazardous material – for research use only. Not for sale. No commercial value."*

#### ❖ LABELLING

Each test material container should be clearly labelled with sufficient information to identify it and allow the testing facility to confirm its contents.

Ideally, labels should contain the following information:

Test item name  
Batch number  
Expiry date  
Storage conditions  
Container number  
Tare weight  
Initial gross weight

### RELATED REQUIREMENTS

#### ❖ OECD Environmental Health and Safety Publications

The Role and Responsibilities of the Sponsor in the Application of the Principles of GLP

Advisory Document of the Panel on GLP Series on Principles of Good Laboratory Practice and Compliance Monitoring No. 11

#### Provision of chemical safety information:

The sponsor should inform the test facility of any known potential risks of the test item to human health or the environment as well as any protective measures which should be taken by test facility staff.

#### Characterisation of the test item:

The revised OECD Principles of GLP include several requirements related to the characterisation of the test item. These requirements call for careful identification of the test item and description of its characteristics. This characterisation is carried out either by the contracted test facility or by the sponsor. If the characterisation is indeed conducted by the sponsor, this fact should be explicitly mentioned in the final report. Sponsors should be aware that

failure to conduct characterisation in accordance with GLP case could lead to rejection of a study by a regulatory authority in some Member countries.

If characterisation data are not disclosed by the sponsor to the contracted test facility, this fact should also be explicitly mentioned in the final report.

❖ Directive 2004/10/EC of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of GLP and the verification of their applications for tests on chemical substances :

For each study, the identity, including batch number, purity, composition, concentrations, or other characteristics to appropriately define each batch of the test or reference items should be known.

The stability of test and reference items under storage and test conditions should be known for all studies.