MDS GLP STUDY INITIATION QUESTIONNAIRE (Form Q-L)

NOTE: This form provides information about the test article and information on the scope of work to be performed with the test article A Material Safety Data Sheet {MSDS) is requested if available

1. INFORMATION ON TEST ARTICLE

Test Article Name:_____ Lot/Batch Number:_____ Expiration date:_____

Physical description:_____
(Such as physical state, viscosity, characteristics, appearance, and color)

Net Quantity Submitted:_____

Storage Temperature:
- ☐ambient_____
- ☐2-80C_____
- ☐ -5 to -300C_____
- ☐ -600C or lower_____
- ☐Other:_____

Additional Storage Info:
- ☐protect from light
- ☐protect from moisture
- ☐store under nitrogen
- ☐store under argon
- ☐Other

Additional Characteristics:
- Molecular weight:_____
- Purity:_____
- Strength:_____
- Solubility:_____
- Other:_____
- Stability:_____
- Volatility:_____
- pH:_____

2. ADJUSTMENT FOR PURITY: Should concentrations be adjusted for purity/active ingredient? ☐Yes ☐No

If yes, what correction factor should be used?

3. HAZARD INFORMATION ON TEST ARTICLE

To comply with California and US regulations for the proper management and shipment of hazardous chemicals, we request the MSDS and the following information before we initiate testing. If you wish to maintain secrecy of the test article identity during testing, this information may be provided sealed to our Health and Safety Department, which will not disclose the identity to laboratory personnel.

Chemical Identity (or chemical class):_____

LD_{50} (Specify species, vehicle and route):_____

Precautions in handling or disposal:_____

US DOT Hazardous Material? ☐Yes ☐No If Yes, proper US DOT shipping name:_____

US EPA Hazardous Waste? ☐Yes ☐No If Yes, US EPA Waste Number:_____

Material Safety Data Sheet (MSDS) provided with study initiation paperwork: ☐Yes ☐No

4. ADMINISTRATIVE SUMMARY

MDS assay name or protocol number:_____

Sponsor purchase order number:_____
(provided by Sponsor prior to test initiation)

5. SPONSOR AND AUTHORIZED REPRESENTATIVE INFORMATION

The GLP Regulations require that the Master Schedule identify the Sponsor and the Study Director. Infrequently, the actual Sponsor is not the company submitting the work to MDS and the Study Director may be someone other than a MDS scientist. The following questions will help identify these unique situations.

Is this work contracted for a Sponsor other than the one listed in Section 2 of the protocol? 0 Yes 0 No
Is this work part of another protocol signed by a non-MDS Study Director? ☐Yes ☐No
If either is Yes, provide information on the company sponsoring this work and/or the Study Director.

Information on Sponsoring Company

Company Name:_____

Address:_____

Information on Non-MDS Study Director

Name: _____

Title: _____

Phone: _____

FAX: _____

Email:_____

If you choose to not provide MDS with the information on the Sponsoring Company or the Non-MDS Study Director, please check here:☐

MDS STUDY INITIATION QUESTIONNAIRE – p. 2

NOTE: This form provides essential information to help MDS accurately perform toxicology testing for studies performed under the Good Laboratory Practice (GLP) Regulations.

1. **REGULATORY SUBMISSION:**
Will the report be submitted to a regulatory agency? ☐Yes ☐No
If yes, check which one(s):

☐El US EPA (FIFRA)	☐El US FDA	☐Canada
☐El US I- PA (TSCA)	☐El EU	☐Other
☐El US EPA (California)	☐El Japan	

2. DRAFT REPORT:
Do you want a draft report? ☐Yes ☐No
If yes, draft reports will be sent to the Authorized Representative unless an alternate address is noted below.

3. ANIMAL USAGE:
Does this study unnecessarily duplicate any previous animal study? ☐Yes ☐No

4. TEST ARTICLE DISPOSITION: Instruction for disposing of unused test article.
Test article will be disposed of by a mutually agreed upon method and time after acceptance of final report by Sponsor. The default method of disposal will be by high temperature incineration by licensed hazardous waste contractor. For test article returns, test article will be returned to the Authorized Representative unless an alternate address is noted below. For returns, please identify the method to return unused test article (international shipments higher):

☐Return to Sponsor by UPS/Ambient temperature ($25)
☐Return to Sponsor by Overnight/Ambient Temperature ($50)
☐Return to Sponsor by Overnight/Cool packs ($75)
☐Return to Sponsor by Overnight/Dry ice ($100)
☐MDS to dispose of (no charge)
☐Other disposal instruction (extra charge may apply) _____

5. DOSING ANALYSIS:
Do you want samples of the dosing preparations analyzed? ☐Yes ☐No
If yes, please complete the attached Dosing Preparation Analysis form.

6. MICROSCOPE SLIDE DISPOSITION:
Dispose of microscope slides upon finalization of report: ☐Yes ☐No
Note: this applies only to studies that use microscope slides, including cytogenetics, micronucleus, and UDS assays. If No, slides will he returned to the Authorized Representative unless an alternate address is noted below.

7. MAILING OF INVOICE:
Should the invoice be sent to the Authorized Representative? ☐Yes ☐No
If No, provide the alternate billing address in below.

8. ALTERNATE ADDRESS:
All material that needs to be sent (including reports, unused test article, microscope slides and invoices) will be sent to the Authorized Representative at the Sponsor's address identified in Section 2 of the study protocol unless noted below or otherwise indicated in the study protocol. If an alternate shipping address is to be used, please provide the information and special instructions below:

☐Reports ☐Test article ☐Slides ☐Billing

Name_____
Title_____
Company_____
Address_____
Phone: _____
FAX:_____
Email:_____

☐Reports ☐Test article ☐Slides ☐Billing

Name_____
Title_____
Company_____
Address_____
Phone: _____
FAX:_____
Email:_____

GOOD LABORATORY PRACTICE QUESTIONNAIRE

NOTE: To be in compliance with the FDA, EPA, and OECD Good Laboratory Practice (GLP) Regulations, MDS must make statements concerning the characterization and stability of test and control articles. The following questions will help ensure collection of the correct information to maintain full compliance with the various GLP Regulations and to ensure the accuracy of the Quality Assurance Compliance Statement in the final report. Please contact us should you have any questions.

1. **TEST ARTICLE CHARACTERIZATION**
   Has the test article been characterized with regard to identity, strength, purity, composition or other characteristics? ☐ Yes ☐ No
   If Yes, a copy of this report is requested prior to initiation of the study and for inclusion as an appendix to the study report. Will such a report be supplied to MDS? ☐ Yes ☐ No ☐ Not Applicable

2. TEST ARTICLE STABILITY
   Has the test article been characterized with regard to stability? ☐ Yes ☐ No
   If Yes, a copy of this report is requested prior to initiation of the study and for inclusion as an appendix to the study report. Will such a report be supplied to MDS? ☐ Yes ☐ No ☐ Not Applicable

3. TEST ARTICLE DOSING PREPARATION UNIFORMITY OR CONCENTRATION
   Will the test article dosing preparations be characterized with regard to uniformity (as applicable) or concentration? ☐ Yes ☐ No
   If Yes, a copy of this report is requested for inclusion as an appendix to the study report. ☐ Yes ☐ No
   Will such a report be supplied to MDS? ☐ Yes ☐ No ☐ Not Applicable
   If performed, will this work be done according to GLP regulations? ☐ Yes ☐ No ☐ Not Applicable

4. TEST ARTICLE DOSING PREPARATION STABILITY
   Will the test article dosing preparations be characterized with regard to stability? ☐ Yes ☐ No
   If Yes, a copy of this report is requested for inclusion as an appendix to the study report.

   Will such a report be supplied to MDS? ☐ Yes ☐ No ☐ Not Applicable

   If performed, will this work be done according to GLP regulations? ☐ Yes ☐ No ☐ Not Applicable

   Your dated signature below attests to the completeness and accuracy of the information that you have provided.

   Signature of Authorized Representative_____ Date_____

   Printed Name of Authorized Representative_____