

## Substance Data Sheet

### 1a. Obligatory test item data

The ordered studies can only be initiated, after all GLP and study relevant test item specifications have been received and cleared. If the obligatory information is not filled in, it will be indicated as a GLP deviation in the study plan and final report. Name, batch and storage conditions must match exactly with the certificate of analysis and the labels on the container used for shipment. Failure to comply may be regarded as an exclusion in GLP compliance by regulatory authorities (OECD 19\*).

<b>1.1</b>	Name of test item (used in report; must match declaration on vessel)			
<b>1.2</b>	Batch/lot number (must match declaration on vessel)			
<b>1.3</b>	CAS number		unknown	
			not available	
<b>1.4</b>	Composition/chemical name (IUPAC if mono constituent; no CAS needed; If more components available, please click <a href="#">here</a> )		Concentration	unit
		1.	1.	
		2.	2.	
		3.	3.	
		4.	4.	
<b>1.5</b>	Storage conditions (Standard: kept in dry and dark storage conditions)		room temperature (20 ± 5 °C)	
			fridge (2 - 8 °C)	
			freezer (-25 - -15 °C)	
			keep under inert gas	
			other	
<b>1.6</b>	Expiry date (e.g. 31. Dec. 2030)			
<b>1.7</b>	Stability (stable under storage conditions)	yes		no
<b>1.8</b>	Colour/Appearance (e.g. white powder, yellow granules, red liquid, clear, turbid, ...)			
<b>1.9</b>	Purity of batch (e.g. 100 % water)		not applicable, mixture	
			not applicable, UVCB	
			not applicable, medical device	
<b>1.10</b>	Homogeneous (general visual aspect)	yes		no
		if no, specify procedure of homogenization before use:		

\* OECD Series on principles of Good Laboratory Practice and Compliance Monitoring, Number 19; Advisory Document of the Working Group on Good Laboratory Practice on the Management, Characterisation and Use of Test Items (2018)

## Substance Data Sheet

### 1b. Optional test item data

Please include information if available as it may be study specifically relevant.

<b>1.11</b>	Production date of batch (e.g. 31. Dec. 2030)												
<b>1.12</b>	EC number												
<b>1.13</b>	Molecular formula												
<b>1.14</b>	Molecular weight						g/mol						
<b>1.15</b>	Categorization	UVCB		polymer		nano material		none					
<b>1.16</b>	Melting point (range)						°C						
<b>1.17</b>	Density						g/cm <sup>3</sup> at 20 °C						
<b>1.18</b>	Bulk density												
<b>1.19</b>	Tap density												
<b>1.20</b>	Vapour pressure						hPa at		°C				
<b>1.21</b>	Solubility (If other solvents available, please click <a href="#">here</a> )					Stability							
	< 0.1 g/L	0.1 - 1 g/L	> 1 g/L	unknown	4 h	24 h	48 h	96 h	unknown				
	Water												
	Ethanol												
	Acetone												
	Acetonitrile												
	DMSO												
	Methanol												
<b>1.22</b>	Explosive properties						yes		no		unknown		
<b>1.23</b>	Content C <sub>org</sub> .						%		not available				
<b>1.24</b>	Quality System (under which the characterization above was performed)						GLP						
							not available						
							others						
<b>1.25</b>	Surface activity/Surface active agent (for BCOP, OECD 437)					yes		no					
					If yes, please tick one:								
						surfactant			mixture (< 5 % surfactant)			mixture (> 5 % surfactant)	
<b>1.26</b>	LogKow/Partition coeff. Octanol-Water (for h-CLAT, OECD 442E)				if no data is available or stated, extra costs may occur due to experimental determination by LAUS GmbH								
<b>1.27</b>	pH-value												

### 2. Obligatory information regarding organisational matter

<b>2.1</b>	Notification/Registration (for US EPA registration please fill in "EPA")		REACH
			agrochemical
			biocidal product
			pharmaceutical product
			EFSA notification
			others
<b>2.2</b>	Archiving - following procedure should apply (documents will be destroyed after 15 years in GLP archive at LAUS GmbH, if nothing is filled in here)		shipment to sponsor (at sponsor's cost)
			destruction (free of charge)
<b>2.3</b>	Remaining quantities of test item will be disposed of after project conclusion. If quantities are to be returned, please contact project management at beginning of project at <a href="mailto:pm@laus.group">pm@laus.group</a>		

## Substance Data Sheet

### 3. Safety data (only for new substances, others: provide safety data sheet)

<b>3.1</b>	Class of dangerous goods (ADR)			
<b>3.2</b>	Hazardous properties (explosive, flammable, self-reactive)			unknown
<b>3.3</b>	Toxicological data			unknown
<b>3.4</b>	Precautions			unknown
<b>3.5</b>	Proposed route of disposal			unknown
<b>3.6</b>	Hazard classification (for new substances and if SDS is not available)			none

### 4. Further information

Document	enclosed			will be handed in			not available		
Analytical method									
Safety data sheet									
Structural formula									
Certificate of analysis/Analytical report									
Certificate of analysis should be attached to final report(s)?			yes			no			
Further documents enclosed									
Further documents to be attached to final report(s)									

### 5. Obligatory information on organizational matter

Draft (study plan, report) for comments/approval send as <b>Word®</b> file to		Monitor
		Sponsor
<b>Printed</b> final report required		yes
		no (pdf file only)
<b>Printed</b> final report should be sent to either (only one)		Monitor
		Sponsor
<b>e-mail</b> communication should be sent to (e.g. drafts, pdf files of final report in case only pdf is required)	direct:	
	cc:	
Financial information should be sent to (e.g. Quotation, Confirmation of order, Invoice)	direct:	

A paper version of the study plan will not be issued. After finalization of the study plan, one signed hardcopy will be archived at LAUS GmbH. You will receive the pdf scan via e-mail for your records. If an additional printed paper version of the study plan is required, extra costs will be charged.

## Substance Data Sheet

### 6. Obligatory sponsor and monitor information

<b>6.1</b>	<b>Sponsor</b>	
	Name of company	
	Division/Contact Person/Title	
	Street	
	Postal code	
	City	
	Country	
	Telephone	
E-mail		
<b>6.2</b>	<b>Monitor</b>	
	Contact Person / Title	
	Telephone	
	E-mail	
	if company of sponsor and monitor differ, please state further obligatory information:	
	Name of company	
	Division	
	Street	
	Postal Code	
	City	
	Country	

For studies which are performed at other laboratories (e.g. acute oral toxicity), we authorize LAUS GmbH to monitor the respective studies

We herewith confirm that the test item:

is a representative and homogenous sample of the product to be tested and that the statements in this document correspond with its properties

For the Sponsor/Monitor:

\_\_\_\_\_  
Name

\_\_\_\_\_  
Date

Please save pdf file electronically after data input and send it back to [info@laus.group](mailto:info@laus.group) (incompletion will lead to delayed study performance, as the study plan cannot be written before completion of this data sheet)

Substance data sheet only to be filled in once. All following wishes for change of test item specifications after arrival of test item at LAUS, need to be communicated directly to project management (via e-mail [pm@laus.group](mailto:pm@laus.group)).

Client is responsible for consistent content of available documents.

Changes of test item specifications to a later date, may be subject to costs.

