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*).

1.1	Name of test item (used in report; must match declaration on vessel)				
1.2	Batch/lot number (must match declaration on vessel)				
1.3	CAS number		☐	unknown	
			☐	not available	
1.4	Composition/chemical name (IUPAC if mono constituent; no CAS needed; If more components available, please click here)		Concentration		unit
	1.		1.		
	2.		2.		
	3.		3.		
	4.		4.		
1.5	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		
1.6	Expiry date (e.g. 31. Dec. 2030)				
1.7	Stability (stable under storage conditions)	☐	yes	☐	no
1.8	Colour/Appearance (e.g. white powder, yellow granules, red liquid, clear, turbid, …)				
1.9	Purity of batch (e.g. 100 % water)				
		☐	not applicable, mixture		
		☐	not applicable, UVCB		
		☐	not applicable, medical device		
1.10	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 Groupon Good Laboratory Practice on the Management, Characterisation and Use of Test Items (2018)

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1b. Optional test item data

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

1.11	Production date of batch (e.g. 31. Dec. 2030)				
1.12	EC number			☐	unknown
1.13	Molecular formula			☐	unknown
1.14	Molecular weight		g/mol	☐	unknown
1.15	Categorization	UVCB ☐ polymer ☐	nano material ☐	none ☐	
1.16	Melting point (range)		°C	☐	unknown
1.17	Density		g/cm³ at 20 °C	☐	unknown
1.18	Bulk density			☐	unknown
1.19	Tap density			☐	unknown
1.20	Vapour pressure		hPa at °C	☐	unknown

1.21	Solubility (If other solvents available, please click here)				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	☐	☐	☐	☐	☐	☐	☐	☐	☐

1.22	Explosive properties	☐ yes ☐ no ☐ unknown
1.23	Content $C_{org.}$	% ☐ not available
1.24	Quality System (under which the characterization above was performed)	☐ GLP ☐ not available ☐ others
1.25	Surface activity/Surface active agent (for BCOP, OECD 437)	☐ yes ☐ no If yes, please tick one: ☐ surfactant ☐ mixture (< 5 % surfactant) ☐ mixture (> 5 % surfactant)
1.26	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
1.27	pH-value	

2. Obligatory information regarding organisational matter

2.1	Notification/Registration (for US EPA registration please fill in "EPA")	☐ REACH ☐ agrochemical ☐ biocidal product ☐ pharmaceutical product ☐ others
2.2	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)
2.3	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 pm@laus.group	

Substance Data Sheet

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

3.1	Class of dangerous goods (ADR)			
3.2	Hazardous properties (explosive, flammable, self-reactive)		☐	unknown
3.3	Toxicological data		☐	unknown
3.4	Precautions		☐	unknown
3.5	Proposed route of disposal		☐	unknown
3.6	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 **Word®** file to	☐	Monitor
	☐	Sponsor
Printed final report required	☐	yes
	☐	no (pdf file only)
Printed final report should be sent to either (only one)	☐	Monitor
	☐	Sponsor
e-mail 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.

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6. Obligatory sponsor and monitor information

6.1	**Sponsor**	
	Name of company	
	Division/Contact Person/Title	
	Street	
	Postal code	
	City	
	Country	
	Telephone	
	E-mail	
6.2	**Monitor**	
	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 (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).
Client is responsible for consistent content of available documents.
Changes of test item specifications to a later date, may be subject to costs.

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Additional test item information

To be filled out *only* if necessary (see also 1.4, 1.19 and 2.3)

additional 1.4	Composition / Chemical name		Concentration		unit
	5.		5.		
	6.		6.		
	7.		7.		
	8.		8.		
	9.		9.		
	10.		10.		
	11.		11.		

additional 1.21	Solubility				Stability				
	< 0.1 g/L	0.1 - 1 g/L	> 1 g/L	unknown	4 h	24 h	48 h	96 h	unknown
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
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	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐
	☐	☐	☐	☐	☐	☐	☐	☐	☐

additional 2.3	**Return test item to sponsor's address**	
	Name of company	
	Division/Contact Person/Title	
	Street	
	Postal code	
	City	
	Country	
	Telephone	
	E-mail	