

SAFETY DATA SHEET

1 IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

Product identifier

PB2452 (MEDI2452), 100 mg/mL

Details of the supplier of the safety data sheet: PhaseBio Pharmaceuticals, Inc.
One Great Valley Parkway, Suite 30
Malvern, PA 19335
PHONE (610) 981-6500

CAS No.: Not applicable

Use: Fragment (Fab) of monoclonal antibody for investigational use

2 HAZARDS IDENTIFICATION

Caution - This material has not been fully tested and is for research and development purposes only. The toxicology and physical hazards of this material are still under investigation. This product may have pharmacological effects. Exposure to mist by inhalation may cause an allergic reaction in rare cases.

3 COMPOSITION/INFORMATION ON INGREDIENTS

Mixture:

Component	%	CAS No.		
PB2452 (MEDI2452)	1 - 10	-		
	Hazard class [#]	Category	Hazard Statements [#]	
	-	-	-	
Component	%	CAS No.		
Sucrose	1 - 10	57-50-1		
	Hazard class [#]	Category	Hazard Statements [#]	
	-	-	-	

Refer to Section 16 'Other Information'

4 FIRST AID MEASURES

Description of first aid measures

Inhalation: Remove patient from exposure, keep warm and at rest. Obtain medical attention if ill effects occur.

Skin Contact:	Wash skin with soap and water.
Eye Contact:	Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects remain.
Ingestion:	Provided the patient is conscious, wash out mouth with water and give 200-300 ml of water to drink. Do NOT induce vomiting as a First-Aid measure. Obtain medical attention if ill effects occur.

Most important symptoms and effects, both acute and delayed

Refer to sections 2 and 11

Indication of any immediate medical attention and special treatment needed

Symptomatic treatment and supportive therapy as indicated. Emergency medical treatment advice varies within different countries. For further information consult the Local National Poisons Information Services.

5 FIRE FIGHTING MEASURES

Extinguishing Media (suitable):	Use suitable extinguishing media for the surrounding fire.
Extinguishing Media (unsuitable):	-
Special hazards arising from the substance or mixture:	Low fire hazard.
Special protective actions for fire-fighters:	A self-contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6 ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures:	Ensure suitable personal protection during removal of spillages. See Section 8.
Environmental Precautions:	Prevent entry into drains unless inactivated or denatured.
Methods and material for containment and cleaning up:	Absorb spillages onto sand, earth or any suitable adsorbent material. Transfer to a container for disposal. Wash the spillage area clean with water and detergent.

7 HANDLING AND STORAGE

Precautions for safe handling	Avoid contact with skin and eyes.
Conditions for safe storage, including any incompatibilities	Keep containers properly sealed when not in use.
Storage temperature:	Drug Product: 2 to 8°C or -70 to -90°C (dependent on label instructions) Drug Substance: -70 to -90°C
Specific end use(s)	Not applicable, refer to Section 1

8 EXPOSURE CONTROLS/PERSONAL PROTECTION

Control parameters

Occupational Exposure Limit Value

Ingredients	Value	Control Parameters	Comments
Sucrose	10 mg/m ³	TWA	TLV

Exposure Controls

Use appropriate controls (e.g. containment, ventilation) as specified in the workplace risk assessment to ensure that the defined occupational exposure limit is not exceeded. The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment.

Prevent entry into drains unless inactivated or denatured.

Occupational exposure controls

Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

Respiratory protection

As necessary, use NIOSH approved respiratory protection device consistent with the work place risk assessment. Consult a qualified safety and health professional for additional guidance, as needed.

Skin protection

Wear appropriate protective clothing and gloves.

Eye protection

Use safety glasses to protect against direct contact with the liquid if the risk assessment does not support the selection of other protection.

9 PHYSICAL AND CHEMICAL PROPERTIES

Information on basic physical and chemical properties

Appearance:	Drug Product: Brown to yellow color, Clear to opalescent liquid. Free from or practically free from visible particles or Lyophilized powder; White to off-white, uniform, dry cake, free from visible extraneous particles Drug Substance: Brown to yellow color, Clear to opalescent liquid. Free from or practically free from visible particles.
Odor:	No information available.
Odor threshold:	No information available.

pH:	6
Melting point/freezing point:	No information available.
Initial boiling point and boiling range:	No information available.
Flash point:	No information available.
Evaporation point:	No information available.
Evaporation rate:	No information available.
Flammability (solid, gas):	No information available.
Upper/lower flammability or explosive limits:	No information available.
Vapor pressure:	No information available.
Vapor density:	No information available.
Relative density:	No information available.
Solubility(ies):	No information available.
Partition coefficient: N-octanol/water;	No information available.
Auto-ignition temperature:	No information available.
Decomposition temperature:	No information available.
Viscosity:	No information available.

Other Information

Molecular weight:	47.4 kDa approx.
Molecular formula:	C2095 N560 O674 S12 H3240
Isoelectric point:	8.8

10 STABILITY AND REACTIVITY

Reactivity:	No known reactivity hazard under normal conditions.
Chemical stability:	Stable under normal conditions.
Possibility of hazardous reactions:	None known.
Conditions to avoid:	No conditions producing hazardous situations known.
Incompatible materials:	None known.
Hazardous decomposition products:	No hazardous decomposition products are known.

11 TOXICOLOGICAL INFORMATION

The toxicology of this material is still under investigation. This product may have pharmacological effects.

Inhalation:	No information available.
Skin Contact:	Unlikely to be corrosive to the skin.
Eye Contact:	Unlikely to be a severe irritant to the eye.
Ingestion:	Unlikely to be toxic if swallowed.

Single exposure

Specific Target Organ Toxicity (STOT): Rat – no organ weight and/or organ weight ratio changes and no macroscopic or microscopic findings of doses up to 2000 mg/kg which was considered to be the No Observed Adverse Effect Level (NOAEL), with systemic exposures for MEDI2452 (PB2452) of up to: Cmax: 18500 µg/mL, AUC(0-∞): 23100 µg/mL*h (males and females combined).

Repeated exposure

No information available.

Tissue Cross-Reactivity

The objective of this study was to determine the potential cross reactivity of fluoresceinated PB2452 (MEDI2452) with cryosections of human tissues. MEDI2452-FITC did not stain any tissue elements in any of the human tissues examined. No staining seen in the following tissues (three samples each tissue from three donors):

Adrenal	Heart	Salivary Gland
Bladder (urinary)	Kidney (glomerulus, tubule)	Skin
Blood Cells		Spinal Cord
Blood Vessels (endothelium)	Liver	Spleen
Bone Marrow	Lung	Striated Muscle (skeletal)
Brain – cerebellum	Lymph Node	Testis
Brain – cerebrum (cerebral cortex)	Ovary	Thymus
Breast	Pancreas	Thyroid
Colon (large intestine)	Parathyroid	Tonsil
Eye	Peripheral Nerve	Ureter
Fallopian Tube	Pituitary	Uterus – cervix
Gastrointestinal (GI) Tract	Placenta	Uterus – endometrium
	Prostate	

Sensitization: Exposure to mist by inhalation may cause an allergic reaction in rare cases.

Carcinogenicity: Not expected to be carcinogenic.

Mutagenicity: Not expected to be genotoxic.

Large protein molecules are not expected to cross the nuclear or mitochondrial membrane.

Reproductive toxicity: No information available.

12 ECOLOGICAL INFORMATION

Ecotoxicity: Unlikely to be toxic to aquatic organisms.

Effect on Effluent Treatment: No information available.

Persistence and degradability: Expected to be biodegradable.

Bioaccumulative potential: Unlikely to be bioaccumulative.

Mobility in soil: No information available.

Other adverse effects: No information available.

13 DISPOSAL CONSIDERATIONS

Waste treatment methods: Disposal should be in accordance with local, state or national legislation. Waste, even small quantities, should never be poured down drains, sewers or water courses. Normal waste disposal is via incineration operated by an accredited disposal contractor.

Contaminated Packaging: Empty container will retain residue. Observe all hazard precautions.

14 TRANSPORT INFORMATION

Not Restricted for Transport

15 REGULATORY INFORMATION

Safety, health and environmental regulations/legislation specific for the substance or mixture

TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation when manufactured, processed or distributed in commerce for use as a drug. CERCLA and SARA Regulations (40 CFR 302,355,370 and 372): This product does not contain any chemicals subject to applicable reporting requirements. Other Determined Regulations: California Proposition 65: This product does not contain a listed chemical. Discarded product is not considered a "hazardous waste" under RCRA, 40 CFR 261.

This Safety Data Sheet was prepared in accordance with Hazard Communication Standard (HCS) (29 CFR 1910.1200(g))

16 OTHER INFORMATION

TSE Risk Assessment

A transmissible spongiform encephalopathy (TSE) risk evaluation was conducted for material of biological origin used in strain generation, cell bank manufacture, seed expansion and the manufacture of MEDI2452 (PB2452) Drug Substance. There are no materials of animal origin used in the manufacture of MEDI2452 (PB2452). Based upon the information obtained from the suppliers, the risk of transmission of TSE from materials used in the production of MEDI2452 (PB2452) is extremely low.

Glossary

COM:	In-house occupational exposure limit
LTEL:	Long-term exposure limit (8-hour TWA (time-weighted average))
STEL:	Short-term exposure limit (15-minute TWA (time-weighted average))
TLV:	Threshold Limit Value (ACGIH)
TLV-C:	Threshold Limit Value - Ceiling limit (ACGIH)
HYG:	An in-house analytical method for occupational exposure monitoring is available
Sk:	Can be absorbed through skin, thus contributing to systemic effects
Sen:	Capable of causing respiratory sensitization

This Glossary is applicable to Substances for which Hazardous Ingredients/Occupational Exposure Limits are assigned.

The information contained herein is based on data considered accurate and is offered solely for information, consideration and investigation. Company extends no warranties, makes no representations and assumes no responsibility as to the accuracy, completeness or suitability of this data for any third-party use. The data on this Safety Data Sheet relates only to this product and does

not relate to use with any other material or in any process. All chemical products should only be used by, or under the direction of, technically qualified personnel who are aware of the hazards involved and the necessity for reasonable care in handling. Hazard communication regulations require that employees must be trained on how to use a Safety Data Sheet as a source of hazard information.

Revision History

Version	Issue Date
.00	20Mar2018
.01	20Mar2020