



MATERIAL SAFETY DATA SHEET

According Regulation EC No. 1907/2006 (REACH)

Regulation EC No. 1272/2008 (CLP)

Commission Regulation EU No. 453/2010

Trade Name	SHIKARI® Q-PEM ELISA
Reference Number	TR-PEMv1

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

1.1. Product Identifier

Trade Name: SHIKARI® Q-PEM ELISA

Reference Number: TR-PEMv1

1.2. Relevant identified uses of the substance or mixture and uses advised against

Enzyme immunoassay for the quantitative determination of free pembrolizumab in serum and plasma.

Kit Content (name and label reference)

Microtiter Plate	MTP
Standard A-E	STND A-E
High Level Control - Low Level Control	HIGH LEVEL CNTRL – LOW LEVEL CNTRL
Assay Buffer	ASSAY BUF
Horse radish peroxidase-Conjugated Probe	HRP-CONJ
TMB Substrate Solution	TMB SUBS
TMB Stop Solution	TMB STOP
Wash Buffer	WASH BUF
Adhesive Foil	FOIL

1.3. Details of the supplier of the safety data sheet

Manufacturer/Supplier:

Matriks Biyoteknoloji Sanayii ve Ticaret LTD. ŞTİ.

Gazi Üniversitesi Gölbaşı Yerleşkesi Teknoplaza Binası

B Blok Zemin Kat BZ17 06830 – Gölbaşı/Ankara/TÜRKİYE

Phone: +90 312 485 42 94

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E-mail: info@matriksbiotek.com

Website: www.matriksbiotek.com

1.4. Emergency telephone number

+90 312 485 42 94 (During opening time: 09:00 – 18:00)



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2. HAZARDS IDENTIFICATION

General classification of the mixture: the mixture is not classified as hazardous in compliance with Directive 67/548IEEC and 1999/45IEEC, Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008.

2.1. Classification of the substance or mixture

Classification in accordance with 1272/2008IEC (CLP/GHS): not classified as hazardous

Classification in accordance with 67/548IEEC and 1999/45IEC (DPD): not classified as hazardous

2.2. Label elements

This product is not under labelling according to Regulation (EC) n. 1272/2008

2.3. Other hazards

Results of PBT and vPvB assessment: The substances in the mixture do not meet the PBT/vPvB criteria according to REACH (content < 0.1 % w/w), annex XIII; the substances in the mixture are not included in the Candidate List of SVHC.

Note: This product is intended for laboratory use by professional uses only. Use appropriate personal protective equipment while working with the reagents provided.

3. COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substances

Stop Solution							
Ingredient	CAS No (EC No)	Containing Conc. (%)	Classification according to regulation (EC) No 1272/2008(CLP) (related to the concentrated form)		Pictogram, Signal Word Code(s)	Specific Conc. Limits, M-factors	Dir. 67/548/EEC
			Hazard Class and Category Codes(s)	Hazard Statement Code(s)			
Hydrochloric Acid (HCL) Index No. 017-002-01-X	7647-01-0 (231-595-7)	< 5.0 %*	Skin Corr. 1B STOT SE 3	H314 H335	GHS05 GHS07 Dgr	Skin Corr. 1B; H314: C≥25% Skin Irrit. 2; H315: 10%≤C<25 % Eye Irrit. 2, H319: 10%≤C<25 % STOT SE 3; H355: C≥10%	C; R34-37: C≥25% Xi; R36/37/38: 10%≤C<25%

* Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1272/2008/EC



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3.2. Mixtures

Standards and Controls, Assay Buffer							
Ingredient	CAS No (EC No)	Containing Conc. (%)	Classification according to regulation (EC) No 1272/2008(CLP) (related to the concentrated form)		Pictogram, Signal Word Code(s)	Specific Conc. Limits, M-factors	Dir. 67/548/EEC
			Hazard Class and Category Codes(s)	Hazard Statement Code(s)			
Sodium Azide Index no. 011-004-00-7	26628-22-8 (247-852-1)	<0,001 %	Acute Tox. 2 (oral) Acute Tox. 1 (dermal) STOT RE 2 Acute Aquatic 1 Aquatic Chronic 1	H300 H310 H373 H400 H410	GHS06 GHS08 GHS09	M-Factor- Aquatic Acute:1	R23/24/25- 36/37/38- 50/53

*Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1272/2008/EC

Horse radish peroxidase-Conjugated Probe							
Ingredient	CAS No (EC No)	Containing Conc. (%)	Classification according to regulation (EC) No 1272/2008(CLP) (related to the concentrated form)		Pictogram, Signal Word Code(s)	Specific Conc. Limits, M-factors	Dir. 67/548/EEC
			Hazard Class and Category Codes(s)	Hazard Statement Code(s)			
Proclin 150 Index no. 613-167-00-5	55965-84-9	<0,0015%*	Acute Tox. 3 Skin Corr. 1B Skin Sens. 1 Acute Aquatic 1 Aquatic Chronic 1	H301 H311 H314 H317 H331 H400 H410	GHS05 GHS07 GHS09	>= 0,6%: Skin Corr. 1B, H314; 0,06 - < 0,6 %: Skin Irrit. 2, H315; 0,06 - < 0,6 %: Eye Irrit. 2, H319; >= 0,0015 %: Skin Sens. 1, H317; M-Factor - Aquatic Acute: 10	T; N R:23/24/25- 34-35- 50/53 S: (2-)26- 28- 36/37/39- 45-60-61
Proclin 150 is a mixture of substances of the components, 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H -isothiazol-3-one (3:1).							

*Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1272/2008/EC



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4. FIRST AID MEASURES

4.1. Description of first aid measures

- General advise: No special measures required. Consult physician in case of complaints.
- If inhaled: Supply fresh air.
- In case of skin contact: Immediately flush skin with plenty of water. Cold water may be used. Remove contaminated clothing and shoes.
- In case of eye contact: Check for and remove any contact lenses. Immediately flush eyes with plenty of water for at least 15 minutes. Cold water may be used.
- If swallowed: Rinse mouth with plenty of water.

4.2. Most important symptoms and effects, both acute and delayed

There are no hazards under normal use conditions. Direct contact with eyes may cause slight and temporary irritation. Swallowing of larger amounts may lead to stomachache, vomiting or diarrhea.

4.3. Indication of any immediate medical attention and special treatment needed

No specific therapy known. Use supportive and symptomatic treatment.

5. FIREFIGHTING MEASURES

5.1. Extinguishing media

- Suitable extinguishing media: Water spray, alcohol resistant foam, dry-powder, carbon dioxide
- Unsuitable extinguishing media: Direct water stream

5.2. Special hazards arising from the substance or mixture

To the best of our knowledge, no special hazards can be defined.

5.3. Advice for fire-fighters

No data available.

6. ACCIDENTAL RELEASE MEASURES

6.1. Personal precautions, protective equipment and emergency procedures

Wear appropriate protective gloves and clothes.

6.2. Environmental precautions

- Dilute with plenty of water.
- Do not allow to enter sewers/surface or ground water.

6.3. Methods and materials for containment and cleaning up

Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).



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6.4. Reference to other sections

For personal protection see section 8.

For disposal see section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Use all reagents in accordance with the relevant package insert provided with the product.

Do not smoke, eat, drink or apply cosmetics in areas where kit reagents are handled.

Wear disposable latex gloves when handling reagents.

Never pipet by mouth and avoid contact of reagents and specimens with skin and mucous membranes.

Handling should be done in accordance with the procedures defined by an appropriate national biohazard safety guideline or regulation.

Use all reagents in accordance with the relevant package insert provided with the product.

7.2. Conditions for safe storage, including any incompatibilities

Store in tightly closed original packages or appropriately labeled alternate vessels. Store in dry, banded areas.

Keep away from direct sunlight and heat sources. Recommended storage temperature: 2 - 8°C. Protect from freezing. Keep away from food and drinks. Keep away from acids and heavy metals. Keep out of the reach of children.

7.3. Specific end use(s)

For EU diagnostic product.

For the rest of the world 'RESEARCH USE ONLY'

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control parameters

Indicative occupational exposure limit ES (2000/39IEC, Directive 2006/15IEC and Directive 2009/161IEC):

CAS	Substance name	Indicative occupational exposure limit	
26628-22-8	Sodium Azide	OEL mean (time-weighted 8 h):	0.1 mg.m ³
		OEL short term (LS min):	0.3
		Notation: skin	

National work-place occupational exposure limits (only selected lands are displayed):

CAS	Substance name	Occupational exposure limits	
26628-22-8	Sodium Azide	Turkey	
		PEL:	0.1 mg.m ³
		NPEL-P:	0.3 mg.m ³
		D - absorb through skin	
		I - irritating to mucosa (eye, airways) and skin	



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		Government Regulation no. 361/2007 Coll.	
		Slovakia	
		NPEL mean:	0.1 mg.m ³
		NPEL short-term:	0.3 mg.m ³
		Note K: absorbed through skin	
		Regulation 300/2007 Coll. (SK), Appendix 1	
		Germany	
		AGW – time weighted mean:	0.2 mg.m ³
		Short –term factor:	2 (I)
		1RGS-900	
		United Kingdom	
		TWA:	0.1 mg.m ³
		STEL:	0.3 mg.m ³
		France	
		TWA:	0.1 mg.m ³
		STEL:	0.3 mg.m ³

Other recommended values: not set

CAS	Substance name	OEL - equivalents
-	-	-

Indicative biological limits (Turkey, 432/2003 Coll.): not set

Substance	Evaluated as	Limit values
-	-	-

DNEL: not available for the mixture.

PNEC: not available for the mixture.

8.2. Exposure controls

General hygiene directives should be considered.

Keep away from food stuffs and beverages. Wash hands before breaks and at the end of the working day.

Personal protective equipment:

Respiratory protection:	Not required.
Skin protection:	Protective gloves of nitrile or nature latex, satisfying the norm DIN EN 455
Eye/Face protection:	Safety glasses with side shields confirming to EN 166 (EN), NIOSH (US)
Body protection:	Impenetrable protective clothing



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9. PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on basic physical and chemical properties

COMPONENT	(a) APPEARANCE	(b) ODOR	(c) pH
Standards and Controls	Liquid, colorless	Odorless	7.4 ± 0.05
Horse radish peroxidase-Conjugated Probe	Liquid, red	Odorless	7.4 ± 0.05
Microtiter Plate	Solid, white	Odorless	Not applicable
Assay Buffer	Liquid, blue	Odorless	7.4 ± 0.05
TMB Substrate Solution	Liquid, colorless	Odorless	3.6 – 3.8
TMB Stop Solution	Liquid, colorless	Odorless	<1
Wash Buffer	Liquid, colorless	Odorless	7.4 ± 0.05

For All Components	
(c) Odor threshold	No data available
(e) Melting point/freezing point	No data available
(f) Initial boiling point and range	No data available
(g) Flash point	No data available
(h) Evaporation rate	No data available
(i) Flammability (solid, gas)	No data available
(j) Upper/lower flammability or explosive limits	No data available
(k) Vapour pressure	No data available
(l) Vapour density	No data available
(m) Relative density	No data available
(n) Solubility(ies)	Fully miscible
(o) Partition coefficient: n-octanol water	No data available
(p) Auto-ignition temperature	Product is not selfigniting
(q) Decomposition temperature	No data available
(r) Viscosity	No data available
(s) Explosive properties	Product does not present an explosion hazard
(t) Oxidising properties	No data available

9.2. Other information

No other information available.



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10. STABILITY AND REACTIVITY

10.1. Reactivity

Not reactive under normal conditions of storage and manipulation. Sodium azide has been reported to form lead or copper azide in laboratory plumbing (heavy metals) which may explode on percussion. Treatment of sodium azide with strong acids gives hydrazoic acid, which is also extremely toxic.

10.2. Chemical stability

Mixture is chemically stable under normal conditions of storage and manipulation. Overheating may cause thermal decomposition.

10.3. Possibility of hazardous reactions

Sodium azide has been reported to form lead or copper azide in laboratory plumbing (heavy metals) which may explode on percussion.

10.4. Conditions to avoid

Stable under normal conditions. Keep away from direct sunlight and heat sources. Do not mix with strong acids and heavy metals.

10.5. Incompatible materials

Strong acids, heavy metals, halogenated hydrocarbons.

10.6. Hazardous decomposition products

Material does not decompose at ambient temperatures. Incomplete combustion and thermolysis may produce toxic, irritating and flammable decomposition products (such as carbon monoxide, carbon dioxide, sooth, aldehydes and other products of organic compounds decomposition, sulfur / nitrogen oxides).

11. TOXICOLOGICAL INFORMATION

11.1. Information on toxicological effects

a) Acute toxicity:

Based on available data, the classification criteria are not met. Based on composition, the mixture has low acute toxicity and no adverse effects for human health are expected under applicable conditions of exposure sodium azide.

b) Skin corrosion/irritation:

Based on available data, the classification criteria are not met. Prolonged or repeated skin contact may cause mild irritation and dermatitis (skin inflammation). However, these effects do not required classification.

c) Serious eye damage/irritation:

Based on available data, the classification criteria are not met. Direct contact with eyes may cause slight and temporary irritation. However, these effects do not required classification.

d) Respiratory or skin sensitization:

Based on available data, the classification criteria are not met. Compounds have no sensitization effects.



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- e) Germ cell mutagenicity:
Based on available data, the classification criteria are not met. Compounds have no potential for mutagenic activity.
- f) Carcinogenicity:
Based on available data, the classification criteria are not met. Compounds have no potential for carcinogenic activity.
- g) Reproductive toxicity:
Based on available data, the classification criteria are not met. Compounds have no potential for reproductive toxicity.
- h) STOT-single exposure:
Based on available data, the classification criteria are not met.
- i) STOT-repeated exposure:
Based on available data, the classification criteria are not met.
- j) Aspiration hazard:
Based on available data, the classification criteria are not met.

12. ECOLOGICAL INFORMATION

12.1. Toxicity: No data available.

12.2. Persistence and degradability: No data available.

12.3. Bio accumulative potential: No data available.

12.4. Mobility in soil: No data available.

12.5. Results of PBT and vPvB assessment: The substances in the mixture do not meet the PBT/vPvB criteria according to REACH, annex XIII (content < 0,1 % w/w); the substances in the mixture are not included in the Candidate List of SVHC.

12.6. Other adverse effects: No data available.

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Product:

Waste should be disposed of in accordance with federal, state and local environmental control regulations. Must not be composed together with household garbage.

Uncleaned packaging:

Waste should be disposed of in accordance with federal, state and local environmental control regulations. Must not be composed together with household garbage.

General notes:

Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.



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14. TRANSPORT INFORMATION

The mixture is not classified as dangerous for transport according to ADR/RID/IMDG/ICAO/IATA/DGR

14.1. UN number: None

14.2. Un proper shipping name: None

14.3. Transport hazard class(es): None

14.4. Packing group: None

14.5. Environmental hazards: None

14.6. Special precautions for user: Not applicable.

14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code: Not applicable.

15. REGULATORY INFORMATION

This Safety Data Sheet is according to:

1907/2008/EC Registration, evaluation and authorization of chemicals regulation (REACH)

1272/2008/EC Classification, labelling and packaging regulation (CLP, globally harmonized system GHS) replaces 67/548/EEC and 1999/45/EC, amending 1907/2006/EC 453/2010/EC Compilation of safety data sheets regulation (SDS), amending 1907/2006/EC

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

No data available.

15.2. Chemical safety assessment

No data available.

16. OTHER INFORMATION

"H code" and "R Phrases" used in this Safety Data Sheet

H301	Toxic if swallowed.
H311	Toxic in contact with skin.
H314	Causes severe skin burns and eye damage.
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Cause serious eye irritation.
H331	Toxic if inhaled.
H335	May cause respiratory irritation.
H400	Very toxic to aquatic life.
H410	Very toxic to aquatic life with long lasting effects.
R23/24/25	Toxic by inhalation, in contact with skin and if swallowed.
R34	Causes burns.
R37	Irritating to respiratory system.
R36/37/38	Irritating to eyes, respiratory system and skin.
R43	May cause sensitisation by skin contact.



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R50/53 Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

“P statements” and “S Phrases” used in this Safety Data Sheet

- S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- S28 After contact with skin, wash immediately with plenty of (to be specified by the manufacturer).
- S36/37 Wear suitable protective clothing and gloves.
- S39 Wear eye/face protection.
- S45 In case of accident or if you feel unwell seek medical advice immediately (show the label where possible).
- S60 This material and its container must be disposed of as hazardous waste.
- S61 Avoid release to the environment. Refer to special instructions/safety data sheet.