SAFETY DATA SHEET

According Regulation EC No. 1907/2006 (REACH)
Commission Regulation (EU) 2020/878
Regulation EC No. 1272/2008 (CLP)
Commission Regulation EU No. 453/2010

Product Name	SHIKARI® USTEKINUMAB (Stelara®) SPECIFIC ELISA	**Document Code**	SDS-0314
Catalog Number/Code	UST-SPEC-UST	**Revision No /Date**	02-01.10.2025

1. Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product name: SHIKARI® USTEKINUMAB (Stelara®) SPECIFIC ELISA

Catalog number/code: UST-SPEC-UST

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

Enzyme immunoassay for the specific and quantitative determination of free Ustekinumab (Stelara®) in serum and plasma

Kit content

Name	Label Reference
Microtiter plate	MICROTITER PLATE
Standard A-F	STANDARD A-F
Low level control – High level control	CONTROL LOW – CONTROL HIGH
Assay buffer	ASSAY BUFFER
Horse radish peroxidase conjugated probe	CONJUGATE
TMB substrate solution	SUBSTRATE SOLUTION
TMB stop solution	STOP SOLUTION
Wash buffer	WASH BUFFER
Adhesive foil	FOIL

1.3. Details of the supplier of the safety data sheet

Manufacturer: *Matriks Biotechnology CO., LTD.*
Universiteler Mah. 1596. Cad.
Hacettepe Teknokent 6. Ar-Ge Binasi
C Blok 1. Kat No:19 Beytepe 06800
Cankaya/ANKARA/Türkiye
Tel: +90 312 485 42 94
Fax: +90 312 485 11 87
info@matriksbiotek.com

1.4. Emergency telephone number: +90 312 485 42 94

2. Hazards identification

General classification of the mixture: the mixture is not classified as hazardous in compliance with Directive 67/548IEEC and 1999/45IEC, 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.

Results of ED assessment: The subsrances in the mixture do not meet the ED criteria according to Regulations (EC) 2017/2100 and (EC)2018/605.

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	Hydrochloric Acid (HCL) Index No. 017-002-01-X
CAS No (EC No)	7647-01-0(231-595-7)
Containing Conc. (%)	<5,0* (Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1272/2008/EC)
Classification according to regulation (EC) No 1272/2008 (CLP) (related to the concentrated form)	
Hazard Class and Category Codes(s)	Skin Corr. 1B STOT SE 3
Hazard Statement Code(s)	H314, H335
Pictogram, Signal Word Code(s)	GHS05, GHS07, Dgr
Specific Conc. Limits, M-factors	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%
Directive 67/548/EEC	C; R34-37: C≥25%

	Xi; R36/37/38: 10%≤C<25%

3.2. Mixtures

Standards, Controls, Assay Buffer	
Ingredient	Sodium Azide Index no. 011-004-00-7
CAS No (EC No)	26628-22-8 (247-852-1)
Containing Conc. (%)	<0,001 % (Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1272/2008/EC)
Classification according to regulation (EC) No 1272/2008 (CLP) (related to the concentrated form)	
Hazard Class and Category Codes(s)	Acute Tox. 2 (oral) Acute Tox. 1 (dermal) STOT RE 2 Acute Aquatic 1 Aquatic Chronic 1
Hazard Statement Code(s)	H300, H310, H373, H400, H410
Pictogram, Signal Word Code(s)	GHS06, GHS08, GHS09
Specific Conc. Limits, M-factors	M-Factor-Aquatic Acute:1
Directive 67/548/EEC	R23/24/25-36/37/38-50/53

Conjugate	
Ingredient	Proclin 150 Index no. 613-167-00-5 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).
CAS No (EC No)	55965-84-9
Containing Conc. (%)	<0,0015% (Dilution is not classified as hazardous according to the European Regulation 67/548/EEC and 1272/2008/EC)
Classification according to regulation (EC) No 1272/2008 (CLP) (related to the concentrated form)	
Hazard Class and Category Codes(s)	Acute Tox. 3

	Skin Corr. 1B Skin Sens. 1 Acute Aquatic 1 Aquatic Chronic 1
Hazard Statement Code(s)	H301, H311, H314, H317, H331, H400, H410
Pictogram, Signal Word Code(s)	GHS05, GHS07, GHS09
Specific Conc. Limits, M-factors	≥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
Directive 67/548/EEC	T; N R:23/24/25-34-35-50/53 S: (2-)26-28-36/37/39-45-60-61

4. First-aid measures

4.1. Description of first aid measures

General advice: 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 accurate 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. Fire-fighting 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 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).

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, bunded areas. Keep away from direct sunlight and heat sources. Recommended storage temperature: 10-30°C (shipment), 2-8°C (long term storage). 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 uses

For EU diagnostic product.
For the rest of the world “Research use only”.

8. Exposure controls/personel 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	
		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

9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

COMPONENT	PHYSICAL STATE	ODOR	pH
Microtiter plate	Solid, white	Odorless	Not applicable
Standards and controls	Liquid, colorless	Odorless	7,4 ± 0,05
Conjugate	Liquid, red	Odorless	7,4 ± 0,05
Assay buffer	Liquid, blue	Odorless	7,4 ± 0,05
Substrate solution	Liquid, colorless	Odorless	3,6 – 3,8
Stop solution	Liquid, colorless	Odorless	<1
Wash buffer	Liquid, colorless	Odorless	7,4 ± 0,05

For All Components	
Odor threshold	No data available
Melting point/freezing point	No data available
Initial boiling point and range	No data available
Flash point	No data available
Evaporation rate	No data available
Flammability (solid, gas)	No data available
Upper/lower flammability or explosive limits	No data available
Vapour pressure	No data available
Vapour density	No data available
Relative density	No data available
Solubility(ies)	Fully miscible
Partition coefficient: n-octanol water	No data available
Auto-ignition temperature	Product is not self-igniting
Decomposition temperature	No data available
Viscosity	No data available
Explosive properties	Product does not present an explosion hazard
Oxidizing properties	No data available
Particle characteristics	No data available
Mechanical sensitivity	No data available
Acid/Alkaline reserve	No data available
Conductivity	No data available
Redox Potential	No data available

9.2. Other information

No other information available.

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

11.1.1. 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.

11.1.2. 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

11.1.3. 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

11.1.4. Respiratory or skin sensitization

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

11.1.5. Germ cell mutagenicity

Based on available data, the classification criteria are not met. Compounds have no potential for mutagenic activity.

11.1.6. Carcinogenicity

Based on available data, the classification criteria are not met. Compounds have no potential for carcinogenic activity.

11.1.7. Reproductive toxicity

Based on available data, the classification criteria are not met. Compounds have no potential for reproductive toxicity.

11.1.8. STOT-single exposure

Based on available data, the classification criteria are not met

11.1.9. STOT-repeated exposure

Based on available data, the classification criteria are not met.

11.1.10. Aspiration hazard

Based on available data, the classification criteria are not met.

11.1.11. Endocrine Disrupters

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. Endocrine disruptors

No data available.

12.7. 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

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 prepared according to;
REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/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

16.1. "H code" and "R Phrases" used in this document

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

16.2. "P statements" and "S Phrases" used in this document

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.

SAFETY DATA SHEET

According Regulation EC No. 1907/2006 (REACH)
Commission Regulation (EU) 2020/878
Regulation EC No. 1272/2008 (CLP)
Commission Regulation EU No. 453/2010

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Revision Summary

Revision No	Revision Date	Explanation
01	21.09.2023	New documentation
02	01.10.2025	The company address has been changed.