

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® NIVOLUMAB (Opdivo®) ELISA | Document Code | SDS-0210 |
| Catalog Number/Code | NIV-FD-OPD | Revision No /Date | 04-17.07.2023 |

1. Identification of the substance/preparation and of the company/undertaking**1.1. Product identifier**

Product name: SHIKARI® NIVOLUMAB (Opdivo®) ELISA

Catalog number/code: NIV-FD-OPD

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

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

Kit content

| Name | Label Reference |
|--|----------------------------|
| Microtiter plate | MICROTITER PLATE |
| Standard A-E | STANDARD A-E |
| 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.
Gazi Universitesi Golbasi Yerleskesi
Teknoplaza Binasi C Blok 10/50C-47
06830 Golbasi/Ankara/TURKEY
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 67/548/EEC and 1999/45/EC, Regulation (EC) No 1907/2006 and Regulation (EC) No 1272/2008.

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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 substances 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% |

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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 |

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| | |
|----------------------------------|--|
| | 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.

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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 |
|-----|----------------|--|
| | | |

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| | | | |
|------------|--------------|-------------------------------|-----------------------|
| 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 | | |

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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 |

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| 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.

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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, soot, 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.

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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

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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 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 |

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| | |
|-----------|---|
| 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. |

Revision Summary

| Revision No | Revision Date | Explanation |
|-------------|---------------|--|
| 01 | 01.11.2019 | New documentation |
| 02 | 07.09.2022 | Manufacturer's address has been changed The document code has been changed |
| 03 | 30.12.2022 | Sections 2, 9, 11 and 12 have been revised The document code has been changed |
| 04 | 17.07.2023 | Company logo has been changed |