SAFETY DATA SHEET

Acetyl Methionine Formulation

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 Product identifier

Trade name : Acetyl Methionine Formulation

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

Use of the Substance/Mixture : Veterinary product

1.3 Details of the supplier of the safety data sheet

Company : MSD
20 Spartan Road
1619 Spartan, South Africa

Telephone : +27119239300

E-mail address of person responsible for the SDS : EHSDATASTEWARD@msd.com

1.4 Emergency telephone number

+1-908-423-6000

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Classification (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

2.2 Label elements

Labelling (REGULATION (EC) No 1272/2008)
Not a hazardous substance or mixture.

Additional Labelling
EUH210 Safety data sheet available on request.

2.3 Other hazards

None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures

Components

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>EC-No.</th>
<th>Index-No.</th>
<th>Classification</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
</table>

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SECTION 4: First aid measures

4.1 Description of first aid measures

Protection of first-aiders: No special precautions are necessary for first aid responders.

If inhaled: If inhaled, remove to fresh air. Get medical attention if symptoms occur.

In case of skin contact: Wash with water and soap as a precaution. Get medical attention if symptoms occur.

In case of eye contact: Flush eyes with water as a precaution. Get medical attention if irritation develops and persists.

If swallowed: If swallowed, DO NOT induce vomiting. Get medical attention if symptoms occur. Rinse mouth thoroughly with water.

4.2 Most important symptoms and effects, both acute and delayed

None known.

4.3 Indication of any immediate medical attention and special treatment needed

Treatment: Treat symptomatically and supportively.

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media: Water spray
Alcohol-resistant foam
Carbon dioxide (CO2)
Dry chemical

Unsuitable extinguishing media: None known.
5.2 Special hazards arising from the substance or mixture

Specific hazards during firefighting: Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides, Nitrogen oxides (NOx), Sulphur oxides, Chlorine compounds.

5.3 Advice for firefighters

Special protective equipment for firefighters: Wear self-contained breathing apparatus for firefighting if necessary. Use personal protective equipment.

Specific extinguishing methods: Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. Use water spray to cool unopened containers. Remove undamaged containers from fire area if it is safe to do so. Evacuate area.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Personal precautions: Follow safe handling advice (see section 7) and personal protective equipment recommendations (see section 8).

6.2 Environmental precautions

Environmental precautions: Avoid release to the environment. Prevent further leakage or spillage if safe to do so. Prevent spreading over a wide area (e.g. by containment or oil barriers). Retain and dispose of contaminated wash water. Local authorities should be advised if significant spillages cannot be contained.

6.3 Methods and material for containment and cleaning up

Methods for cleaning up: Soak up with inert absorbent material. For large spills, provide dyking or other appropriate containment to keep material from spreading. If dyked material can be pumped, store recovered material in appropriate container. Clean up remaining materials from spill with suitable absorbent. Local or national regulations may apply to releases and disposal of this material, as well as those materials and items employed in the cleanup of releases. You will need to determine which regulations are applicable. Sections 13 and 15 of this SDS provide information regarding certain local or national requirements.

6.4 Reference to other sections

See sections: 7, 8, 11, 12 and 13.
SECTION 7: Handling and storage

7.1 Precautions for safe handling

Technical measures: See Engineering measures under EXPOSURE CONTROLS/PERSONAL PROTECTION section.

Local/Total ventilation: Use only with adequate ventilation.

Advice on safe handling: Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment. Take care to prevent spills, waste and minimize release to the environment.

Hygiene measures: If exposure to chemical is likely during typical use, provide eye flushing systems and safety showers close to the working place. When using do not eat, drink or smoke. Wash contaminated clothing before re-use. The effective operation of a facility should include review of engineering controls, proper personal protective equipment, appropriate degowning and decontamination procedures, industrial hygiene monitoring, medical surveillance and the use of administrative controls.

7.2 Conditions for safe storage, including any incompatibilities

Requirements for storage areas and containers: Keep in properly labelled containers. Store in accordance with the particular national regulations.

Advice on common storage: Do not store with the following product types: Strong oxidizing agents.

7.3 Specific end use(s)

Specific use(s): No data available

SECTION 8: Exposure controls/personal protection

8.1 Control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>N-Acetyl-DL-methionine</td>
<td>1115-47-5</td>
<td>TWA</td>
<td>2000 µg/m³ (OEB 1)</td>
<td>Internal</td>
</tr>
<tr>
<td>Pyridoxine hydrochloride</td>
<td>58-56-0</td>
<td>TWA</td>
<td>OEB 3 (&gt;= 10 &lt; 100 µg/m³)</td>
<td>Internal</td>
</tr>
</tbody>
</table>

Derived No Effect Level (DNEL) according to Regulation (EC) No. 1907/2006:

<table>
<thead>
<tr>
<th>Substance name</th>
<th>End Use</th>
<th>Exposure routes</th>
<th>Potential health effects</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>nicotinamide</td>
<td>Workers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>43.75 mg/m³</td>
</tr>
<tr>
<td></td>
<td>Workers</td>
<td>Skin contact</td>
<td>Long-term systemic effects</td>
<td>12.5 mg/kg bw/day</td>
</tr>
<tr>
<td></td>
<td>Consumers</td>
<td>Inhalation</td>
<td>Long-term systemic effects</td>
<td>21.88 mg/m³</td>
</tr>
</tbody>
</table>
8.2 Exposure controls

**Engineering measures**

Use appropriate engineering controls and manufacturing technologies to control airborne concentrations (e.g., drip-less quick connections). All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
Containment technologies suitable for controlling compounds are required to control at source and to prevent migration of the compound to uncontrolled areas (e.g., open-face containment devices).
Minimize open handling.

**Personal protective equipment**

**Eye protection**: Wear safety glasses with side shields or goggles. If the work environment or activity involves dusty conditions, mists or aerosols, wear the appropriate goggles. Wear a faceshield or other full face protection if there is a potential for direct contact to the face with dusts, mists, or aerosols.

**Hand protection**

**Material**: Chemical-resistant gloves

**Remarks**: Consider double gloving.

**Skin and body protection**: Work uniform or laboratory coat. Additional body garments should be used based upon the task being performed (e.g., sleevelets, apron, gauntlets, disposable suits) to avoid exposed skin surfaces. Use appropriate degowning techniques to remove potentially contaminated clothing.

**Respiratory protection**: If adequate local exhaust ventilation is not available or exposure assessment demonstrates exposures outside the recommended guidelines, use respiratory protection.

**Filter type**: Combined particulates and organic vapour type (A-P)

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**SECTION 9: Physical and chemical properties**

**9.1 Information on basic physical and chemical properties**

**Appearance**: liquid

**Colour**: Colorless to pale yellow

**Odour**: characteristic

**Odour Threshold**: No data available

**pH**: 3,30 - 4,30

**Melting point/freezing point**: No data available

**Initial boiling point and boiling range**: 99 °C

**Flash point**: No data available

**Evaporation rate**: No data available

**Flammability (solid, gas)**: Not applicable

**Upper explosion limit / Upper flammability limit**: No data available

**Lower explosion limit / Lower flammability limit**: No data available

**Vapour pressure**: No data available
Relative vapour density : 1.03 - 1.09
Relative density : No data available
Density : No data available
Solubility(ies)
  Water solubility : soluble
Partition coefficient: n-octanol/water : Not applicable
Auto-ignition temperature : No data available
Decomposition temperature : No data available
Viscosity
  Viscosity, kinematic : No data available
Explosive properties : Not explosive
Oxidizing properties : The substance or mixture is not classified as oxidizing.

9.2 Other information
  Flammability (liquids) : No data available
  Molecular weight : No data available
  Particle size : Not applicable

SECTION 10: Stability and reactivity

10.1 Reactivity
  Not classified as a reactivity hazard.

10.2 Chemical stability
  Stable under normal conditions.

10.3 Possibility of hazardous reactions
  Hazardous reactions : Can react with strong oxidizing agents.

10.4 Conditions to avoid
  Conditions to avoid : None known.

10.5 Incompatible materials
  Materials to avoid : Oxidizing agents

10.6 Hazardous decomposition products
  No hazardous decomposition products are known.
SECTION 11: Toxicological information

11.1 Information on toxicological effects

Information on likely routes of exposure:
- Inhalation
- Skin contact
- Ingestion
- Eye contact

Acute toxicity

Not classified based on available information.

Product:

- Acute oral toxicity:
  - Acute toxicity estimate: > 2,000 mg/kg
  - Method: Calculation method

- Acute inhalation toxicity:
  - Acute toxicity estimate: > 5 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: Calculation method

Components:

Nicotinamide:

- Acute oral toxicity:
  - LD50 (Rat): > 2,500 mg/kg
  - Method: OECD Test Guideline 423
  - Assessment: The substance or mixture has no acute oral toxicity

- Acute inhalation toxicity:
  - LC50 (Rat): > 3.8 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: OECD Test Guideline 436
  - Assessment: The substance or mixture has no acute inhalation toxicity
  - Remarks: Based on data from similar materials

- Acute dermal toxicity:
  - LD50 (Rabbit): > 2,000 mg/kg
  - Method: OECD Test Guideline 402
  - Assessment: The substance or mixture has no acute dermal toxicity

Caffeine:

- Acute oral toxicity:
  - LD50 (Rat): 367.7 mg/kg

- Acute inhalation toxicity:
  - LC50 (Rat): 4.94 mg/l
  - Exposure time: 4 h
  - Test atmosphere: dust/mist
  - Method: OECD Test Guideline 403

- Acute dermal toxicity:
  - LD50 (Rat): > 2,000 mg/kg
  - Assessment: The substance or mixture has no acute dermal toxicity
Pyridoxine hydrochloride:
Acute oral toxicity: LD50 (Rat): 4.000 mg/kg

N-Acetyl-DL-methionine:
Acute oral toxicity: LD50 (Rat): > 5.000 mg/kg
Remarks: Based on data from similar materials

Acute inhalation toxicity: LC50 (Rat): > 5,25 mg/l
Exposure time: 4 h
Test atmosphere: dust/mist
Method: OECD Test Guideline 403
Remarks: Based on data from similar materials

Skin corrosion/irritation
Not classified based on available information.

Components:
nicotinamide:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Caffeine:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation

Pyridoxine hydrochloride:
Species: Rabbit
Result: No skin irritation

N-Acetyl-DL-methionine:
Species: Rabbit
Method: OECD Test Guideline 404
Result: No skin irritation
Remarks: Based on data from similar materials

Serious eye damage/eye irritation
Not classified based on available information.

Components:
nicotinamide:
Species: Rabbit
Method: OECD Test Guideline 405
Result: Irritation to eyes, reversing within 7 days

Caffeine:
Species: Rabbit
Method: OECD Test Guideline 405
Result: No eye irritation

Pyridoxine hydrochloride:
Species: Rabbit
Result: No eye irritation

Respiratory or skin sensitisation

Skin sensitisation
Not classified based on available information.

Respiratory sensitisation
Not classified based on available information.

Components:

nicotinamide:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

Caffeine:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Method: OECD Test Guideline 429
Result: negative

Pyridoxine hydrochloride:
Test Type: Maximisation Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative

N-Acetyl-DL-methionine:
Test Type: Buehler Test
Exposure routes: Skin contact
Species: Guinea pig
Method: OECD Test Guideline 406
Result: negative
Remarks: Based on data from similar materials

Germ cell mutagenicity
Not classified based on available information.

Components:

nicotinamide:
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Chromosome aberration test in vitro</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
<td>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</td>
<td>Test Type: Bacterial reverse mutation assay (AMES)</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
</tr>
<tr>
<td></td>
<td>Result: negative</td>
<td>Application Route: Intraperitoneal injection</td>
<td>Result: negative</td>
<td>Application Route: Ingestion</td>
<td>Result: negative</td>
<td>Application Route: Ingestion</td>
<td>Result: negative</td>
<td>Application Route: Ingestion</td>
<td>Result: equivocal</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Species: Mouse</td>
<td>Result: negative</td>
<td></td>
<td>Result: negative</td>
<td></td>
<td>Result: equivocal</td>
<td></td>
<td></td>
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<tr>
<td>Germ cell mutagenicity- Assessment</td>
<td></td>
<td>Result: negative</td>
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<td></td>
<td>Weight of evidence does not support classification as a germ cell mutagen.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</td>
<td>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</td>
<td>Test Type: Mammalian erythrocyte micronucleus test (in vivo cytogenetic assay)</td>
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<tr>
<td></td>
<td></td>
<td>Species: Rat</td>
<td>Test Type: Mutagenicity (in vivo mammalian bone-marrow cytogenetic test, chromosomal analysis)</td>
<td>Species: Mouse</td>
<td>Application Route: Ingestion</td>
<td>Species: Mouse</td>
<td>Application Route: Ingestion</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td>Application Route: Intraperitoneal injection</td>
<td>Result: negative</td>
<td>Result: negative</td>
<td>Result: negative</td>
<td>Result: equivocal</td>
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</tbody>
</table>
cytogenetic assay)
Species: Mouse
Application Route: Intraperitoneal injection
Result: negative
Remarks: Based on data from similar materials

Carcinogenicity
Not classified based on available information.

Components:

Caffeine:
Species: Rat
Application Route: Ingestion
Exposure time: 104 weeks
Result: negative

Reproductive toxicity
Not classified based on available information.

Components:
	nicotinamide:
Effects on foetal development: Test Type: Embryo-foetal development
Species: Rabbit
Application Route: Ingestion
Method: OECD Test Guideline 414
Result: negative

Caffeine:
Effects on fertility: Test Type: Fertility
Species: Mouse
Application Route: Ingestion
Result: negative

Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

Pyridoxine hydrochloride:
Effects on foetal development: Test Type: Embryo-foetal development
Species: Rat
Application Route: Ingestion
Result: negative

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Not classified based on available information.
Repeated dose toxicity

Components:

**nicotinamide:**

- **Species:** Rat
- **NOAEL:** 215 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 28 Days
- **Method:** OECD Test Guideline 407

**Caffeine:**

- **Species:** Mouse
- **NOAEL:** >= 167.4 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days

**N-Acetyl-DL-methionine:**

- **Species:** Rat
- **NOAEL:** > 100 mg/kg
- **Application Route:** Ingestion
- **Exposure time:** 90 Days
- **Method:** OECD Test Guideline 408
- **Remarks:** Based on data from similar materials

Aspiration toxicity

Not classified based on available information.

SECTION 12: Ecological information

12.1 Toxicity

Components:

**nicotinamide:**

- **Toxicity to fish:** LC50 (Poecilia reticulata (guppy)): > 1.000 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203

- **Toxicity to daphnia and other aquatic invertebrates:** EC50 (Daphnia magna (Water flea)): > 1.000 mg/l
  Exposure time: 24 h
  Method: OECD Test Guideline 202

- **Toxicity to algae/aquatic plants:** EC50 (Desmodesmus subspicatus (green algae)): > 1.000 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

  NOEC (Desmodesmus subspicatus (green algae)): 560 mg/l
  Exposure time: 72 h
  Method: OECD Test Guideline 201

- **Toxicity to microorganisms:** NOEC (Pseudomonas putida): 4.235 mg/l
Caffeine:
- **Toxicity to fish**: LC50 (Leuciscus idus (Golden orfe)): 87 mg/l
  - Exposure time: 96 h
  - Method: DIN 38412
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): 182 mg/l
  - Exposure time: 48 h
  - Method: DIN 38412
- **Toxicity to algae/aquatic plants**: EC50 (Scenedesmus subspicatus): > 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - NOEC (Scenedesmus subspicatus): 6.25 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
- **Toxicity to microorganisms**: EC50 (Pseudomonas putida): 3.490 mg/l
  - Exposure time: 17 h
  - Method: DIN 38412 Part 8

Pyridoxine hydrochloride:
- **Toxicity to fish**: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  - Exposure time: 96 h
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h

N-Acetyl-DL-methionine:
- **Toxicity to fish**: LC50 (Danio rerio (zebra fish)): > 100 mg/l
  - Exposure time: 96 h
  - Method: OECD Test Guideline 203
  - Remarks: Based on data from similar materials
- **Toxicity to daphnia and other aquatic invertebrates**: EC50 (Daphnia magna (Water flea)): > 100 mg/l
  - Exposure time: 48 h
  - Method: OECD Test Guideline 202
  - Remarks: Based on data from similar materials
- **Toxicity to algae/aquatic plants**: ErC50 (Pseudokirchneriella subcapitata (green algae)): > 100 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials
  - NOEC (Pseudokirchneriella subcapitata (green algae)): > 1 mg/l
  - Exposure time: 72 h
  - Method: OECD Test Guideline 201
  - Remarks: Based on data from similar materials
12.2 Persistence and degradability

Components:

nicotinamide:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 95%
Exposure time: 28 d
Method: OECD Test Guideline 301E

Caffeine:
Biodegradability: Result: Readily biodegradable.
Biodegradation: > 90%
Exposure time: 28 d
Method: OECD Test Guideline 301A

Pyridoxine hydrochloride:
Biodegradability: Result: Readily biodegradable.
Biodegradation: 94%
Exposure time: 28 d
Method: OECD Test Guideline 301E

N-Acetyl-DL-methionine:
Biodegradability: Result: Readily biodegradable.
Remarks: Based on data from similar materials

12.3 Bioaccumulative potential

Components:

nicotinamide:
Partition coefficient: n-octanol/water
: log Pow: -0,38

Caffeine:
Partition coefficient: n-octanol/water
: log Pow: -0,091

Pyridoxine hydrochloride:
Partition coefficient: n-octanol/water
: log Pow: 4,32

N-Acetyl-DL-methionine:
Partition coefficient: n-octanol/water
: log Pow: -0,313
Remarks: Calculation

12.4 Mobility in soil
No data available

12.5 Results of PBT and vPvB assessment
Not relevant
SECTION 13: Disposal considerations

13.1 Waste treatment methods
Product: Dispose of in accordance with local regulations. According to the European Waste Catalogue, Waste Codes are not product specific, but application specific. Waste codes should be assigned by the user, preferably in discussion with the waste disposal authorities.
Contaminated packaging: Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.

SECTION 14: Transport information

14.1 UN number
Not regulated as a dangerous good

14.2 UN proper shipping name
Not regulated as a dangerous good

14.3 Transport hazard class(es)
Not regulated as a dangerous good

14.4 Packing group
Not regulated as a dangerous good

14.5 Environmental hazards
Not regulated as a dangerous good

14.6 Special precautions for user
Not applicable

14.7 Transport in bulk according to Annex II of Marpol and the IBC Code
Remarks: Not applicable for product as supplied.

SECTION 15: Regulatory information

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
The components of this product are reported in the following inventories:
AICS: not determined
DSL: not determined
IECSC: not determined

15.2 Chemical safety assessment
A Chemical Safety Assessment has not been carried out.
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SAFETY DATA SHEET
Acetyl Methionine Formulation

SECTION 16: Other information

Other information: Items where changes have been made to the previous version are highlighted in the body of this document by two vertical lines.

Full text of H-statements

H302: Harmful if swallowed.
H319: Causes serious eye irritation.
H332: Harmful if inhaled.

Full text of other abbreviations

Acute Tox.: Acute toxicity
Eye Irrit.: Eye irritation

Further information

SAFETY DATA SHEET

Acetyl Methionine Formulation

Version 3.0  Revision Date: 10.10.2020  SDS Number: 5357346-00003  Date of last issue: 11.02.2020  Date of first issue: 17.12.2019

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ZA / EN