SAFETY DATA SHEET

Sulfamethoxazole / Trimethoprim Formulation

Section 1: Identification

Product name : Sulfamethoxazole / Trimethoprim Formulation

Manufacturer or supplier's details

Company : MSD
Address : 33 Whakatiki Street - Private Bag 908
Upper Hutt - New Zealand
Telephone : +1-908-740-4000
Emergency telephone number : +1-908-423-6000
E-mail address : EHSDATASTEWARD@msd.com

Recommended use of the chemical and restrictions on use

Recommended use : Veterinary product

Section 2: Hazard identification

GHS Classification

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Skin corrosion/irritation</td>
<td>Sub-category 1A</td>
</tr>
<tr>
<td>Serious eye damage/eye irritation</td>
<td>Category 1</td>
</tr>
<tr>
<td>Reproductive toxicity</td>
<td>Category 2</td>
</tr>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Category 2 (Bone marrow)</td>
</tr>
</tbody>
</table>

GHS label elements

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
<th>![Pictograms]</th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal word</td>
<td>Danger</td>
</tr>
<tr>
<td>Hazard statements</td>
<td>H314 Causes severe skin burns and eye damage.</td>
</tr>
<tr>
<td></td>
<td>H361d Suspected of damaging the unborn child.</td>
</tr>
<tr>
<td></td>
<td>H373 May cause damage to organs (Bone marrow)</td>
</tr>
<tr>
<td></td>
<td>through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>Precautionary statements</td>
<td>Prevention:</td>
</tr>
<tr>
<td></td>
<td>P201 Obtain special instructions before use.</td>
</tr>
<tr>
<td></td>
<td>P202 Do not handle until all safety precautions have been read and understood.</td>
</tr>
<tr>
<td></td>
<td>P260 Do not breathe mist or vapours.</td>
</tr>
<tr>
<td></td>
<td>P264 Wash skin thoroughly after handling.</td>
</tr>
</tbody>
</table>
P280 Wear protective gloves/ protective clothing/ eye protection/ face protection.

Response:
P301 + P330 + P310 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting. Immediately call a POISON CENTER/ doctor.
P303 + P361 + P353 + P310 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water or shower. Immediately call a POISON CENTER/ doctor.
P304 + P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P305 + P351 + P338 + P310 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/ doctor.
P308 + P313 IF exposed or concerned: Get medical advice/ attention.
P363 Wash contaminated clothing before reuse.

Storage:
P405 Store locked up.

Disposal:
P501 Dispose of contents/ container to an approved waste disposal plant.

Other hazards which do not result in classification
Corrosive to the respiratory tract.

Section 3: Composition/information on ingredients

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mixture</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chemical name</th>
<th>CAS-No.</th>
<th>Concentration (% w/w)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole</td>
<td>723-46-6</td>
<td>&gt;= 30 - &lt; 60</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>&gt;= 3 - &lt; 10</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>&gt;= 5 - &lt; 10</td>
</tr>
</tbody>
</table>

Section 4: First-aid measures

General advice : In the case of accident or if you feel unwell, seek medical advice immediately. When symptoms persist or in all cases of doubt seek medical advice.

If inhaled : If inhaled, remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Get medical attention immediately.

In case of skin contact : In case of contact, immediately flush skin with plenty of water for at least 15 minutes while removing contaminated clothing and shoes.
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Get medical attention immediately. Wash clothing before reuse. Thoroughly clean shoes before reuse.

In case of eye contact: In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. If easy to do, remove contact lens, if worn. Get medical attention immediately.

If swallowed: If swallowed, DO NOT induce vomiting. If vomiting occurs have person lean forward. Call a physician or poison control centre immediately. Rinse mouth thoroughly with water. Never give anything by mouth to an unconscious person.

Most important symptoms and effects, both acute and delayed: Causes serious eye damage. Suspected of damaging the unborn child. May cause damage to organs through prolonged or repeated exposure. Corrosive to the respiratory tract. Causes severe burns. Causes digestive tract burns.

Protection of first-aiders: First Aid responders should pay attention to self-protection, and use the recommended personal protective equipment when the potential for exposure exists (see section 8).

Notes to physician: Treat symptomatically and supportively.

Section 5: Fire-fighting measures

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

Unsuitable extinguishing media: None known.

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

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)
Sulphur oxides
Metal oxides

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.

Special protective equipment for firefighters: In the event of fire, wear self-contained breathing apparatus. Use personal protective equipment.

Hazchem Code: 2R

Section 6: Accidental release measures

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

Methods and materials for containment and 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.

Section 7: Handling and storage

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

Local/Total ventilation:
If sufficient ventilation is unavailable, use with local exhaust ventilation.

Advice on safe handling:
Do not get on skin or clothing.
Do not breathe mist or vapours.
Do not swallow.
Do not get in eyes.
Wash skin thoroughly after handling.
Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
Keep container tightly closed.
Do not eat, drink or smoke when using this product.
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.

Conditions for safe storage:
Keep in properly labelled containers.
Store locked up.
Keep tightly closed.
Store in accordance with the particular national regulations.

Materials to avoid:
Do not store with the following product types:
Self-reactive substances and mixtures
Organic peroxides
Oxidizing agents
Explosives

Section 8: Exposure controls/personal protection

Components with workplace control parameters

<table>
<thead>
<tr>
<th>Components</th>
<th>CAS-No.</th>
<th>Value type (Form of exposure)</th>
<th>Control parameters / Permissible concentration</th>
<th>Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sulfamethoxazole</td>
<td>723-46-6</td>
<td>TWA</td>
<td>OEB 2 (&gt;= 100 &lt; 1000 µg/m3)</td>
<td>Internal</td>
</tr>
<tr>
<td>Trimethoprim</td>
<td>738-70-5</td>
<td>TWA</td>
<td>400 µg/m³ (OEB 2)</td>
<td>Internal</td>
</tr>
<tr>
<td>Sodium hydroxide</td>
<td>1310-73-2</td>
<td>WES-Ceiling</td>
<td>2 mg/m³</td>
<td>NZ OEL</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>C</td>
<td>ACGIH</td>
</tr>
</tbody>
</table>

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. Laboratory operations do not require special containment.

Personal protective equipment

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

Filter type: Particulates type
Material: Chemical-resistant gloves

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.

Skin and body protection:
Work uniform or laboratory coat.

Section 9: Physical and chemical properties

Appearance: suspension
Colour: white to off-white
Odour: No data available
Odour Threshold: No data available
pH: 9.5 - 12.5
Melting point/freezing point : No data available
Initial boiling point and boiling range : No data available
Flash point : No data available
Evaporation rate : No data available
Flammability (solid, gas) : Not applicable
Flammability (liquids) : No data available
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 : No data available
Relative density : No data available
Density : 1.179 g/cm³
Solubility(ies)
Water solubility : No data available
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.
Molecular weight : No data available
Particle size : Not applicable

Section 10: Stability and reactivity
Reactivity : Not classified as a reactivity hazard.
Chemical stability : Stable under normal conditions.
Possibility of hazardous reac- : Can react with strong oxidizing agents.
Section 11: Toxicological information

Exposure routes:
- 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

Components:

Sulfamethoxazole:
- Acute oral toxicity: LD50 (Mouse): 2,300 mg/kg

Trimethoprim:
- Acute oral toxicity: LD50 (Rat): 1,500 - 5,300 mg/kg
  LD50 (Mouse): 1,910 - 7,000 mg/kg
- Acute toxicity (other routes of administration):
  LD50 (Rat): 400 - 500 mg/kg
  Application Route: Intraperitoneal
  LD50 (Dog): 90 mg/kg
  Application Route: Intravenous
  LD50 (Mouse): 132 mg/kg
  Application Route: Intravenous

Sodium hydroxide:
- Acute inhalation toxicity: Assessment: Corrosive to the respiratory tract.

Skin corrosion/irritation
Causes severe burns.

Components:

Sulfamethoxazole:
- Species: Rabbit
- Result: No skin irritation

Sodium hydroxide:
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Result: Corrosive after 3 minutes or less of exposure

Serious eye damage/eye irritation
Causes serious eye damage.

Components:

Sodium hydroxide:
Result: Irreversible effects on the eye
Remarks: Based on skin corrosivity.

Respiratory or skin sensitisation
Skin sensitisation
Not classified based on available information.
Respiratory sensitisation
Not classified based on available information.

Components:

Sulfamethoxazole:
Test Type: Magnusson-Kligman-Test
Exposure routes: Skin contact
Species: Guinea pig
Result: negative

Trimethoprim:
Test Type: Maximisation Test
Exposure routes: Dermal
Species: Guinea pig
Result: Not a skin sensitizer.

Sodium hydroxide:
Test Type: Human repeat insult patch test (HRIPT)
Exposure routes: Skin contact
Result: negative

Chronic toxicity
Germ cell mutagenicity
Not classified based on available information.

Components:

Sulfamethoxazole:
Genotoxicity in vitro:
Test Type: Bacterial reverse mutation assay (AMES)
Result: negative
Test Type: Chromosome aberration test in vitro
Result: negative
Genotoxicity in vivo:
Test Type: Mutagenicity (in vivo mammalian bone-marrow
Trimethoprim:

Genotoxicity in vitro: Test Type: Bacterial reverse mutation assay (AMES)
Result: negative

Test Type: Chromosomal aberration
Result: negative

Test Type: In vitro mammalian cell gene mutation test
Result: negative

Test Type: DNA damage and repair, unscheduled DNA synthesis in mammalian cells (in vitro)
Result: negative

Genotoxicity in vivo: Test Type: Micronucleus test
Species: Rat
Result: negative

Test Type: Chromosomal aberration
Species: Humans
Result: negative

Carcinogenicity
Not classified based on available information.

Components:

Sulfamethoxazole:
Species: Mouse
Application Route: Ingestion
Exposure time: 26 weeks
Result: negative

Reproductive toxicity
Suspected of damaging the unborn child.

Components:

Trimethoprim:

Effects on fertility: Test Type: Fertility
Species: Rat
Application Route: Oral
Fertility: NOAEL: 70 mg/kg body weight
Result: No effects on fertility

Effects on foetal development: Test Type: Development
Species: Rat
Application Route: Oral
Developmental Toxicity: LOAEL: 70 mg/kg body weight
Result: Effects on newborn
### Remarks:

Maternal toxicity observed.

- **Test Type:** Development  
- **Species:** Rat  
- **Application Route:** Oral  
- **Developmental Toxicity:** LOAEL: 70 mg/kg body weight  
- **Result:** Embryotoxic effects.  
- **Remarks:** Maternal toxicity observed.

- **Test Type:** Development  
  - **Species:** Rat  
  - **Application Route:** Oral  
  - **Developmental Toxicity:** LOAEL: 15 mg/kg body weight  
  - **Result:** Embryotoxic effects, Teratogenic effects

- **Test Type:** Development  
  - **Species:** Hamster  
  - **Application Route:** Oral  
  - **Developmental Toxicity:** LOAEL: 1.7 mg/kg body weight  
  - **Result:** Embryotoxic effects, No teratogenic effects

- **Test Type:** Development  
  - **Species:** Rabbit  
  - **Application Route:** Oral  
  - **Developmental Toxicity:** LOAEL: 100 mg/kg body weight  
  - **Result:** Embryotoxic effects, No teratogenic effects

### Reproductive toxicity - Assessment

Suspected of damaging the unborn child.

#### STOT - single exposure

Corrosive to the respiratory tract.

#### STOT - repeated exposure

May cause damage to organs (Bone marrow) through prolonged or repeated exposure.

### Components:

**Trimethoprim:**

- **Target Organs**
  - **Assessment:** Bone marrow  
  - **Causes damage to organs through prolonged or repeated exposure.**

### Repeated dose toxicity

#### Components:

**Trimethoprim:**

- **Species:** Rat  
- **NOAEL:** 100 mg/kg  
- **LOAEL:** 300 mg/kg  
- **Application Route:** Oral  
- **Exposure time:** 6 Months  
- **Target Organs:** Bone marrow, Liver, Pituitary gland, Thyroid

- **Species:** Rat
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Sulfamethoxazole / Trimethoprim Formulation

Version: 3.0
Revision Date: 27.08.2021
SDS Number: 6289829-00006
Date of last issue: 09.04.2021
Date of first issue: 25.08.2020

LOAEL: 300 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Bone marrow

Species: Dog
NOAEL: 2.5 mg/kg
LOAEL: 45 mg/kg
Application Route: Oral
Exposure time: 3 Months
Target Organs: Blood, Thyroid

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:
Trimethoprim:

Ingestion:
Target Organs: Bone marrow
Symptoms: Abdominal pain, Nausea, Vomiting, skin rash, Dizziness, Headache, mental depression, confusion

Section 12: Ecological information

Ecotoxicity

Components:

Sulfamethoxazole:

Toxicity to fish:
LC50 (Oryzias latipes (Japanese medaka)): 562.5 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates:
EC50 (Ceriodaphnia dubia (water flea)): 0.21 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants:
EC50 (Synechococcus leopoliensis (blue-green algae)): 0.0268 mg/l
Exposure time: 96 h
NOEC (Synechococcus leopoliensis (blue-green algae)): 0.0059 mg/l
Exposure time: 96 h

Toxicity to fish (Chronic toxicity):
NOEC (Danio rerio (zebra fish)): 0.533 mg/l
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):
NOEC (Daphnia magna (Water flea)): 0.01 mg/l
Exposure time: 30 d

Toxicity to microorganisms:
NOEC (activated sludge): 3.76 mg/l
Method: OECD Test Guideline 301D
Trimethoprim:

Toxicity to fish: LC50 (Pimephales promelas (fathead minnow)): 100 mg/l
Exposure time: 96 h

Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna Straus): 92 mg/l
Exposure time: 48 h

Toxicity to algae/aquatic plants: EC50 (Pseudokirchneriella subcapitata (microalgae)): 80.3 mg/l
Exposure time: 72 h

NOEC (Pseudokirchneriella subcapitata (green algae)): 16 mg/l
Exposure time: 72 h

EC50 (Anabaena flos-aquae): 253 mg/l
Exposure time: 72 h

EC10 (Anabaena flos-aquae): 26 mg/l
Exposure time: 72 h

Toxicity to fish (Chronic toxicity): NOEC (Zebrafish): 0.157 mg/l
Exposure time: 21 d

Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity): NOEC (Daphnia magna (Water flea)): 6 mg/l
Exposure time: 21 d

Persistence and degradability

Components:

Sulfamethoxazole:

Biodegradability: Result: Not readily biodegradable.
Biodegradation: 0 %
Exposure time: 28 d
Method: OECD Test Guideline 301D

Bioaccumulative potential

Components:

Sulfamethoxazole:

Bioaccumulation: Species: Cyprinus carpio (Carp)
Bioconcentration factor (BCF): < 120

Partition coefficient: n-octanol/water: log Pow: 0.89

Trimethoprim:

Partition coefficient: n-octanol/water: log Pow: 0.91

Mobility in soil
No data available
Section 13: Disposal considerations

Disposal methods

<table>
<thead>
<tr>
<th>Waste from residues</th>
<th>Contaminated packaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dispose of in accordance with local regulations.</td>
<td>Empty containers should be taken to an approved waste handling site for recycling or disposal. If not otherwise specified: Dispose of as unused product.</td>
</tr>
</tbody>
</table>

Section 14: Transport information

International Regulations

**UNRTDG**
UN number : UN 1824  
Proper shipping name : SODIUM HYDROXIDE SOLUTION  
Class : 8  
Packing group : II  
Labels : 8

**IATA-DGR**
UN/ID No. : UN 1824  
Proper shipping name : Sodium hydroxide solution  
Class : 8  
Packing group : II  
Labels : Corrosive  
Packing instruction (cargo aircraft) : 855  
Packing instruction (passenger aircraft) : 851

**IMDG-Code**
UN number : UN 1824  
Proper shipping name : SODIUM HYDROXIDE SOLUTION  
(Sulfamethoxazole)  
Class : 8  
Packing group : II  
Labels : 8  
EmS Code : F-A, S-B  
Marine pollutant : yes

Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code  
Not applicable for product as supplied.

National Regulations

**NZS 5433**
UN number : UN 1824  
Proper shipping name : SODIUM HYDROXIDE SOLUTION  
Class : 8  
Packing group : II  
Labels : 8  
Hazchem Code : 2R
Special precautions for user

The transport classification(s) provided herein are for informational purposes only, and solely based upon the properties of the unpackaged material as it is described within this Safety Data Sheet. Transportation classifications may vary by mode of transportation, package sizes, and variations in regional or country regulations.

Section 15: Regulatory information

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

HSN0 Approval Number
HSR100425 Pharmaceutical Active Ingredients Group Standard 2017

HSW Controls
Certified handler certificate not required.
Tracking hazardous substance not required.
Refer to the Health and Safety at Work (Hazardous Substances) Regulations 2017, for further information.

The components of this product are reported in the following inventories:

<table>
<thead>
<tr>
<th>Inventory</th>
<th>Not Determined</th>
</tr>
</thead>
<tbody>
<tr>
<td>DSL</td>
<td>not determined</td>
</tr>
<tr>
<td>AICS</td>
<td>not determined</td>
</tr>
<tr>
<td>IECSC</td>
<td>not determined</td>
</tr>
</tbody>
</table>

Section 16: Other information

Further information


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

Date format: dd.mm/yyyy

Full text of other abbreviations

ACGIH / C: Ceiling limit
NZ OEL / WES-Ceiling: Workplace Exposure Standard - Ceiling

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
NZ OEL: New Zealand. Workplace Exposure Standards for Atmospheric Contaminants

AIIC - Australian Inventory of Industrial Chemicals; ANTT - National Agency for Transport by Land of Brazil; ASTM - American Society for the Testing of Materials; bw - Body weight; CMR - Carcinogen, Mutagen or Reproductive Toxicant; DIN - Standard of the German Institute for Standardisation; DSL - Domestic Substances List (Canada); ECx - Concentration associated with x% response; ELx - Loading rate associated with x% response; EmS - Emergency Schedule;
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<table>
<thead>
<tr>
<th>Version</th>
<th>Revision Date:</th>
<th>SDS Number:</th>
<th>Date of last issue:</th>
<th>Date of first issue:</th>
</tr>
</thead>
<tbody>
<tr>
<td>3.0</td>
<td>27.08.2021</td>
<td>6289829-00006</td>
<td>09.04.2021</td>
<td>25.08.2020</td>
</tr>
</tbody>
</table>

The information provided in this Safety Data Sheet is correct to the best of our knowledge, information and belief at the date of its publication. The information is designed only as a guidance for safe handling, use, processing, storage, transportation, disposal and release and shall not be considered a warranty or quality specification of any type. The information provided relates only to the specific material identified at the top of this SDS and may not be valid when the SDS material is used in combination with any other materials or in any process, unless specified in the text. Material users should review the information and recommendations in the specific context of their intended manner of handling, use, processing and storage, including an assessment of the appropriateness of the SDS material in the user’s end product, if applicable.

NZ / EN