# SAFETY DATA SHEET
## Desogestrel Formulation

<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>5.6</td>
<td>23.03.2020</td>
<td>21953-00018</td>
<td>13.09.2019</td>
<td>15.10.2014</td>
</tr>
</tbody>
</table>

## SECTION 1. PRODUCT AND COMPANY IDENTIFICATION

<table>
<thead>
<tr>
<th>Product name</th>
<th>Desogestrel Formulation</th>
</tr>
</thead>
</table>

### Manufacturer or supplier’s details

<table>
<thead>
<tr>
<th>Company</th>
<th>MSD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Address</td>
<td>26 Talavera Road, Talavera Corp Centre, Macquarie Park, New South Wales, 2113 Australia</td>
</tr>
<tr>
<td>Telephone</td>
<td>(61)-02-8988-8000</td>
</tr>
<tr>
<td>Emergency telephone number</td>
<td>(61)-02-8988-8000</td>
</tr>
<tr>
<td>E-mail address</td>
<td><a href="mailto:EHSDATASTEWARD@msd.com">EHSDATASTEWARD@msd.com</a></td>
</tr>
<tr>
<td>Telefax</td>
<td>908-735-1496</td>
</tr>
</tbody>
</table>

### Recommended use of the chemical and restrictions on use

**Recommended use**: Pharmaceutical

## SECTION 2. HAZARDS IDENTIFICATION

### GHS Classification

<table>
<thead>
<tr>
<th>Reproductive toxicity</th>
<th>Category 1B</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specific target organ toxicity - repeated exposure</td>
<td>Category 1 (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate)</td>
</tr>
</tbody>
</table>

### GHS label elements

<table>
<thead>
<tr>
<th>Hazard pictograms</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Signal word</td>
<td>Danger</td>
</tr>
<tr>
<td>Hazard statements</td>
<td>H360Fd May damage fertility. Suspected of damaging the unborn child. H372 Causes damage to organs (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) through prolonged or repeated exposure.</td>
</tr>
<tr>
<td>Precautionary statements</td>
<td>Prevention:</td>
</tr>
<tr>
<td>P201</td>
<td>Obtain special instructions before use.</td>
</tr>
<tr>
<td>P202</td>
<td>Do not handle until all safety precautions have been read and understood.</td>
</tr>
<tr>
<td>P260</td>
<td>Do not breathe dust.</td>
</tr>
<tr>
<td>P264</td>
<td>Wash skin thoroughly after handling.</td>
</tr>
<tr>
<td>P270</td>
<td>Do not eat, drink or smoke when using this product.</td>
</tr>
</tbody>
</table>
P281 Use personal protective equipment as required.

Response:
P308 + P313 IF exposed or concerned: Get medical advice/attention.

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
Dust contact with the eyes can lead to mechanical irritation.
Contact with dust can cause mechanical irritation or drying of the skin.
May form explosive dust-air mixture during processing, handling or other means.

SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Substance / Mixture</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mixture</td>
<td></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>Titanium dioxide</td>
<td>13463-67-7</td>
<td>&lt; 1</td>
</tr>
<tr>
<td>Desogestrel</td>
<td>54024-22-5</td>
<td>&gt;= 0.01 -&lt; 0.3</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.
Get medical attention.

In case of skin contact
In case of contact, immediately flush skin with soap and plenty of water.
Remove contaminated clothing and shoes.
Get medical attention.
Wash clothing before reuse.
Thoroughly clean shoes before reuse.

In case of eye contact
If in eyes, rinse well with water.
Get medical attention if irritation develops and persists.

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

Most important symptoms and effects, both acute and delayed
May damage fertility. Suspected of damaging the unborn child.
Causes damage to organs through prolonged or repeated exposure.
Contact with dust can cause mechanical irritation or drying of the skin.
Dust contact with the eyes can lead to mechanical irritation.
SECTION 5. FIREFIGHTING MEASURES

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.

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

Unsuitable extinguishing media: None known.

Specific hazards during firefighting: Avoid generating dust; fine dust dispersed in air in sufficient concentrations, and in the presence of an ignition source is a potential dust explosion hazard. Exposure to combustion products may be a hazard to health.

Hazardous combustion products: Carbon oxides
Nitrogen oxides (NOx)

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: 2Z

SECTION 6. ACCIDENTAL RELEASE MEASURES

Personal precautions, protective equipment and emergency procedures: Use personal protective equipment. Follow safe handling advice and personal protective equipment recommendations.

Environmental precautions: Discharge into the environment must be avoided. Prevent further leakage or spillage if safe to do so. 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: Sweep up or vacuum up spillage and collect in suitable container for disposal. Avoid dispersal of dust in the air (i.e., clearing dust surfaces with compressed air). Dust deposits should not be allowed to accumulate on surfaces, as these may form an explosive mixture if they are released into the atmosphere in sufficient concentration. 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

SDS Number: 21953-00018
Date of last issue: 13.09.2019
Date of first issue: 15.10.2014
certain local or national requirements.

SECTION 7. HANDLING AND STORAGE

Technical measures: Static electricity may accumulate and ignite suspended dust causing an explosion. Provide adequate precautions, such as electrical grounding and bonding, or inert atmospheres.

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 dust.
- Do not swallow.
- Avoid contact with eyes.
- Handle in accordance with good industrial hygiene and safety practice, based on the results of the workplace exposure assessment.
- Keep container tightly closed.
- Minimize dust generation and accumulation.
- Keep container closed when not in use.
- Keep away from heat and sources of ignition.
- Take precautionary measures against static discharges.
- 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:
  - Strong oxidizing agents

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>Titanium dioxide</td>
<td>13463-67-7</td>
<td>TWA</td>
<td>10 mg/m3</td>
<td>AU OEL</td>
</tr>
</tbody>
</table>

Further information: This value is for inhalable dust containing no asbestos and < 1% crystalline silica.

<table>
<thead>
<tr>
<th>TWA</th>
<th>10 mg/m3</th>
<th>ACGIH</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Titanium dioxide)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Desogestrel Formulation

Engineering measures: Use closed processing systems or containment technologies to control at source (e.g., glove boxes/isolators) and to prevent leakage of compounds into the workplace.
All engineering controls should be implemented by facility design and operated in accordance with GMP principles to protect products, workers, and the environment.
No open handling permitted.
 Totally enclosed processes and materials transport systems are required.
Operations require the use of appropriate containment technology designed to prevent leakage of compounds into the workplace.

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
Hand protection: Chemical-resistant gloves
Remarks: Consider double gloving.
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. 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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance: powder
Colour: white
Odour: No data available
Odour Threshold: No data available
pH: No data available
Melting point/freezing point: No data available
Initial boiling point and boiling: No data available
range

Flash point : Not applicable

Evaporation rate : Not applicable

Flammability (solid, gas) : May form explosive dust-air mixture during processing, handling or other means.

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 : Not applicable

Relative vapour density : Not applicable

Relative density : No data available

Density : No data available

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 : Not applicable

Explosive properties : Not explosive

Oxidizing properties : The substance or mixture is not classified as oxidizing.

Particle size : No data available

SECTION 10. STABILITY AND REACTIVITY

Reactivity : Not classified as a reactivity hazard.

Chemical stability : Stable under normal conditions.

Possibility of hazardous reactions
  May form explosive dust-air mixture during processing, handling or other means.
  Can react with strong oxidizing agents.

Conditions to avoid : Heat, flames and sparks.
  Avoid dust formation.
Incompatible materials: Oxidizing agents
Hazardous decomposition products: No hazardous decomposition products are known.

SECTION 11. TOXICOLOGICAL INFORMATION

<table>
<thead>
<tr>
<th>Exposure routes</th>
<th>Acute toxicity</th>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inhalation</td>
<td>Not classified based on available information.</td>
<td><strong>Titanium dioxide:</strong></td>
</tr>
<tr>
<td>Skin contact</td>
<td></td>
<td>Acute oral toxicity: LD50 (Rat): &gt; 5,000 mg/kg</td>
</tr>
<tr>
<td>Ingestion</td>
<td></td>
<td>Acute inhalation toxicity: LC50 (Rat): &gt; 6.82 mg/l Exposure time: 4 h Test atmosphere: dust/mist Assessment: The substance or mixture has no acute inhalation toxicity</td>
</tr>
<tr>
<td>Eye contact</td>
<td></td>
<td>Desogestrel: Acute oral toxicity: LD50 (Rat, male and female): &gt; 2,000 mg/kg LD50 (Mouse, male and female): &gt; 2,000 mg/kg</td>
</tr>
</tbody>
</table>

Skin corrosion/irritation: Not classified based on available information.

**Components:**

**Titanium dioxide:**
- Species: Rabbit
- Result: No skin irritation

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

**Components:**

**Titanium dioxide:**
- 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:
Titanium dioxide:
Test Type: Local lymph node assay (LLNA)
Exposure routes: Skin contact
Species: Mouse
Result: negative

Chronic toxicity

Germ cell mutagenicity
Not classified based on available information.

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

Genotoxicity in vivo: Test Type: In vivo micronucleus test
Species: Mouse
Result: negative

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

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

Carcinogenicity
Not classified based on available information.

Components:
Titanium dioxide:
Species: Rat
Application Route: inhalation (dust/mist/fume)
Exposure time: 2 Years
Method: OECD Test Guideline 453
Result: positive
Remarks: The mechanism or mode of action may not be relevant in humans.

Carcinogenicity - Assessment: Limited evidence of carcinogenicity in inhalation studies with animals.
Desogestrel Formulation

Desogestrel:
Species: Rat
Application Route: Oral
Exposure time: 104 weeks
Result: negative

Species: Mouse
Application Route: Oral
Exposure time: 81 weeks
Result: negative

Reproductive toxicity
May damage fertility. Suspected of damaging the unborn child.

Components:

Desogestrel:
Effects on fertility:
Test Type: Fertility/early embryonic development
Species: Rabbit, female
Fertility: LOAEL Parent: 2 mg/kg body weight
Result: Effects on fertility

Test Type: Fertility/early embryonic development
Species: Rat, female
Fertility: NOAEL Parent: 0.5 mg/kg body weight
Result: No effects on fertility

Effects on foetal development:
Test Type: Embryo-foetal development
Species: Rabbit, female
Application Route: Oral
Developmental Toxicity: NOAEL F1: 1 mg/kg body weight
Result: Embryotoxic effects and adverse effects on the offspring were detected., No teratogenic effects

Test Type: Embryo-foetal development
Species: Rat, female
Application Route: Oral
Embryo-foetal toxicity: LOAEC Parent: 0.125 mg/kg body weight
Result: No teratogenic effects

Reproductive toxicity - Assessment
Clear evidence of adverse effects on sexual function and fertility, based on animal experiments., Some evidence of adverse effects on development, based on animal experiments.

STOT - single exposure
Not classified based on available information.

STOT - repeated exposure
Causes damage to organs (Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate) through prolonged or repeated exposure.
Desogestrel Formulation

Components:

Desogestrel:
Target Organs: Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate
Assessment: Causes damage to organs through prolonged or repeated exposure.

Repeated dose toxicity

Components:

Titanium dioxide:
Species: Rat
NOAEL: 24,000 mg/kg
Application Route: Ingestion
Exposure time: 28 Days

Species: Rat
NOAEL: 10 mg/m3
Application Route: Inhalation (dust/mist/fume)
Exposure time: 2 yr

Desogestrel:
Species: Rat, female
LOAEL: 0.00625 mg/kg
Application Route: Oral
Exposure time: 26 Weeks
Target Organs: Pituitary gland, Uterus (including cervix), Ovary, Mammary gland

Species: Rat
LOAEL: 0.005 mg/kg
Application Route: Oral
Exposure time: 52 Weeks
Target Organs: Pituitary gland, Uterus (including cervix), Ovary, Mammary gland

Species: Dog
LOAEL: 0.005 mg/kg
Application Route: Oral
Exposure time: 52 Weeks
Target Organs: Pituitary gland, Uterus (including cervix), Ovary, Mammary gland, Prostate

Aspiration toxicity
Not classified based on available information.

Experience with human exposure

Components:

Desogestrel:
Ingestion: Symptoms: Headache, changes in libido, Dizziness, Nausea,
Vomiting, Diarrhoea, water retention, sodium retention, Gastrointestinal discomfort, mental depression, amenorhea, insomnia, impaired glucose tolerance, pulmonary embolism

Target Organs: Uterus (including cervix)
Target Organs: Mammary gland

SECTION 12. ECOLOGICAL INFORMATION

Ecotoxicity

**Components:**

**Titanium dioxide:**
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): > 100 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 100 mg/l
  Exposure time: 48 h
- Toxicity to algae/aquatic plants: EC50 (Skeletonema costatum (marine diatom)): > 10,000 mg/l
  Exposure time: 72 h
- Toxicity to microorganisms: EC50: > 1,000 mg/l
  Exposure time: 3 h
  Method: OECD Test Guideline 209

**Desogestrel:**
- Toxicity to fish: LC50 (Oncorhynchus mykiss (rainbow trout)): 4 mg/l
  Exposure time: 96 h
  Method: FDA 4.11
  Remarks: Based on data from similar materials
  LC50 (Lepomis macrochirus (Bluegill sunfish)): 1.3 mg/l
  Exposure time: 96 h
  Method: OECD Test Guideline 203
  Remarks: No toxicity at the limit of solubility
  Based on data from similar materials
- Toxicity to daphnia and other aquatic invertebrates: EC50 (Daphnia magna (Water flea)): > 3.9 mg/l
  Exposure time: 48 h
  Method: OECD Test Guideline 202
  Remarks: No toxicity at the limit of solubility
  Based on data from similar materials
- Toxicity to fish (Chronic toxicity): NOEC (Pimephales promelas (fathead minnow)): 0.059 mg/l
  Exposure time: 32 d
  Method: OECD Test Guideline 210
  Remarks: Based on data from similar materials
  NOEC (Oryzias latipes (Japanese medaka)): 0.0000027 mg/l
  Exposure time: 183 d
  Remarks: Based on data from similar materials
Toxicity to daphnia and other aquatic invertebrates (Chronic toxicity):

- NOEC (Daphnia magna (Water flea)): 1.2 mg/l
- Exposure time: 21 d
- Remarks: Based on data from similar materials

Toxicity to microorganisms:

- EC50: > 1,000 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Method: OECD Test Guideline 209
- Remarks: Based on data from similar materials

- NOEC: 70.8 mg/l
- Exposure time: 3 h
- Test Type: Respiration inhibition
- Remarks: Based on data from similar materials

Persistence and degradability

Components:

Desogestrel:
- Stability in water: Hydrolysis: < 10 % (5 d)
- Remarks: Based on data from similar materials

Bioaccumulative potential

Components:

Desogestrel:
- Bioaccumulation: Species: Lepomis macrochirus (Bluegill sunfish)
- Bioconcentration factor (BCF): 128
- Remarks: Based on data from similar materials
- Partition coefficient: n-octanol/water: log Pow: 3.5

Mobility in soil

Components:

Desogestrel:
- Distribution among environmental compartments: log Koc: 2.84

Other adverse effects
No data available

SECTION 13. DISPOSAL CONSIDERATIONS

Disposal methods

Waste from residues: Dispose of in accordance with local regulations.
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

International Regulations

**UNRTDG**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Desogestrel)
- Class: 9
- Packing group: III
- Labels: 9

**IATA-DGR**
- UN/ID No.: UN 3077
- Proper shipping name: Environmentally hazardous substance, solid, n.o.s. (Desogestrel)
- Class: 9
- Packing group: III
- Labels: Miscellaneous, 956
- Packing instruction (cargo aircraft): 956
- Packing instruction (passenger aircraft): 956
- Environmentally hazardous: yes

**IMDG-Code**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Desogestrel)
- Class: 9
- Subsidiary risk: ENVIRONM.
- Packing group: III
- Labels: 9 (ENVIRONM.)
- EmS Code: F-A, S-F
- 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**

**ADG**
- UN number: UN 3077
- Proper shipping name: ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (Desogestrel)
- Class: 9
- Packing group: III
- Labels: 9
- Hazchem Code: 2Z

**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.
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

Prohibition/Licensing Requirements: There is no applicable prohibition or notification/licensing requirements, including for carcinogens under Commonwealth, State or Territory legislation.

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

AICS: not determined

DSL: not determined

IECSC: not determined

SECTION 16. OTHER INFORMATION

Further information

Revision Date: 23.03.2020

Date format: dd.mm.yyyy

Full text of other abbreviations

ACGIH: USA. ACGIH Threshold Limit Values (TLV)
AU OEL: Australia. Workplace Exposure Standards for Airborne Contaminants.

ACGIH / TWA: 8-hour, time-weighted average
AU OEL / TWA: Exposure standard - time weighted average

AICS - Australian Inventory of Chemical Substances; 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; ENCS - Existing and New Chemical Substances (Japan); ErCx - Concentration associated with x% growth rate response; ERG - Emergency Response Guide; GHS - Globally Harmonized System; GLP - Good Laboratory Practice; IARC - International Agency for Research on Cancer; IATA - International Air Transport Association; IBC - International Code for the Construction and Equipment of Ships carrying Dangerous Chemicals in Bulk; IC50 - Half maximal inhibitory concentration; ICAO - International Civil Aviation Organization; IECSC - Inventory of Existing Chemical Substances in China; IMDG - International Maritime Dangerous Goods; IMO - International...
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AU / EN