



IMPORTANT NOTICE This Material Safety Data Sheet (MSDS) is prepared by CSL Limited in accordance with the Australian National Occupational Health & Safety Commission National Code of Practice for the Preparation of Material Safety Data Sheets [NOHSC:2011(2003)]. The information contained herein must not be altered or deleted. Additional information may be appended to the MSDS, but it must be marked clearly to indicate that it is not part of the original.

1. IDENTIFICATION OF THE MATERIAL AND SUPPLIER

Product Name Modavigil[®]

Other Names Not applicable

Manufacturer's Product Code 80750005 (10 tablet pack); 80750004 (30 tablet pack); 80750002 (60 tablet pack); 80750003 (90 tablet pack)

Use Modavigil[®] is indicated to improve wakefulness in patients with excessive sleepiness.

Supplier Name CSL Limited (ABN 99 051 588 348)

Address 45 Poplar Road, Parkville, Victoria 3052, Australia

Telephone +61 03 9389 1911

Emergency Telephone 03 9389 1984 (24hr)

2. HAZARDS IDENTIFICATION

Not classified as hazardous according to the criteria of SWA
Not classified as a dangerous good by the criteria of the ADG Code

3. COMPOSITION/INFORMATION ON INGREDIENTS

<i>Chemical Name:</i>	<i>CAS number:</i>	<i>Proportion:</i>
Modafinil	68693-11-8	<45%
Lactose	63-42-3	<45%
Other non-hazardous ingredients	-	up to 100%

4. FIRST AID MEASURES

Eye Wash eye thoroughly with running water for at least 15 minutes and seek medical attention in event of irritation.

Swallowed Seek immediate medical attention.

Skin Wash affected area with water.

Inhaled Seek immediate medical attention.

Advice To Doctor Management of overdose is primarily symptomatic, as no specific antidote to the toxic effects of modafinil overdose has been identified. Overdoses should be managed empirically, with supportive care, including cardiovascular monitoring.

5. FIRE FIGHTING MEASURES

Fire/Explosion Hazard Toxic gases may be emitted from fires involving this product, therefore self-contained breathing apparatus and full protective equipment are recommended for fire fighters.

Fire Extinguishing Media No restriction.

Hazchem Code None allocated.

6. ACCIDENTAL RELEASE MEASURES

Minor Spills

- Wear protective gloves and safety glasses.
- Clean up spill immediately.
- Take care to avoid inhaling dust during clean up.
- If dust is present wear a minimum P1 filter grade dust mask.
- Place spilled material in clean, dry, sealed container for disposal.
- Wash area with copious amounts of water.

Major Spills

- Wear protective gloves and safety glasses.
- Clean up spill immediately.
- Take care to avoid creating excessive dust during clean up.
- If dust is present wear a minimum P1 filter grade dust mask.
- Do not allow material to enter sewage system or surface/ground water.
- Place spilled material in clean, dry, sealed container for disposal.
- Wash area with copious amounts of water.

7. HANDLING AND STORAGE

- Store capsules below 25°C in dry conditions.
- Store as per Schedule 4 pharmaceutical.
- Avoid crushing tablets.
- Always wash hands with soap and water after handling.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Standards No exposure limits set by NOHSC or ACGIH

Engineering Controls None under normal operating conditions.

Personal Protection No special equipment needed when handling unbroken tablets. Otherwise, for potentially moderate exposure or if dust from tablets is present:

- Protective gloves
- Safety Glasses
- Dust mask (minimum P1 filter grade)

The local concentration of material, quantity and conditions of use determine the type of personal protective equipment required. For further information, consult your Occupational Health and Safety Adviser.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance	White, round-shaped tablets with smooth convex sides.
Odour	Odourless
pH	Not determined
Boiling Point/Melting Point	Not determined
Vapour Pressure	Not determined
Vapour Density	Not determined
Specific Gravity	Not determined
Flashpoint	Not determined
Autoignition Temperature	Not determined
Flammability Limits	Not determined
Solubility in Water	Miscible

10. STABILITY AND REACTIVITY

Reactivity	Not known to be incompatible with other materials.
Stability	Stable under anticipated storage and handling conditions (refer section 7).
Decomposition Products	None known.

11. TOXICOLOGICAL INFORMATION

Eye	May cause mild irritation.
Swallowed	Will increase wakefulness. Machinery should not be operated until modafinil has been shown not to produce functional impairment, any drug affecting the central nervous system may alter judgement, thinking or motor skills. Overdose: A small number of individuals have each taken Modavigil [®] at doses of 1000mg/day (2.5 times the maximum recommended daily dose of 400mg) or more. The adverse experiences observed were limited, expected and non-life threatening, and the patients recovered fully by the following day. The adverse experiences included excitation or agitation, insomnia and slight or moderate elevations in haemodynamic parameters. No specific organ toxicities were observed. Other observed high dose effects in clinical studies have included anxiety, irritability, aggressiveness, confusion, nervousness, tremor, palpitations, sleep disturbances, nausea, diarrhoea and decreased prothrombin time.
Skin	No acute health effects known.
Inhaled	Not an expected route of exposure unless dust is present. May cause irritation of respiratory tract. See Acute Health Effects: Swallowed.
Chronic Health Effects	No chronic health effects known.

12. ECOLOGICAL INFORMATION

- No data available.
- For good environmental practice avoid discharge to waterways.

13. DISPOSAL CONSIDERATIONS

- In accordance with state land and waste management authority.
- Disposal of this material should only be undertaken by a licensed chemical disposal company.

14. TRANSPORT INFORMATION

UN Number	None allocated
DG Class	None allocated
Subsidiary Risk	None allocated
Packing Group	None allocated
Hazchem Code	None allocated

15. REGULATORY INFORMATION

Poisons Schedule Number Schedule 4 (S4) – Prescription only medicine

16. OTHER INFORMATION

Last Revised 6 August 2012

Reason for Revision 5 Yearly Review

Abbreviations

SWA	-	Safe Work Australia
ACGIH	-	American Conference of Governmental Industrial Hygienists
ADG Code	-	Australian Dangerous Goods Code
UN Number	-	United Nations Number
DG Class	-	Dangerous Goods Class
CAS Number	-	Chemical Abstract Service Number

Contact Point

Company Contact:	+61 3 9389 1984 (24hr)
Australian Poisons Information Centre, 24 hour service:	13 11 26
Australian Police, Fire Brigade or Ambulance:	000

New Zealand Poisons Information Centre, 24 hour service:	(03) 4747 000
New Zealand Police, Fire Brigade or Ambulance:	111

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