MATERIAL SAFETY DATA SHEET

1. PRODUCT AND COMPANY IDENTIFICATION

Name
'DIPRIVAN' 1 % & 2 %

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ASTRAZENECA PTY LTD
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NSW 2113
AUSTRALIA
+61 2 9978 3500

Emergency Telephone:
+44 (0) 1235 239 670

SafetyDataSheets.AlderleyPark@astrazeneca.com

2. COMPOSITION/INFORMATION ON INGREDIENTS

CAS No. : Not applicable
Use: intravenous anaesthetic

HAZARDOUS INGREDIENT(S) % CAS No.
Propofol 1 - 2 2078-54-8
Glycerol 2,25 56-81-5

3. HAZARDS IDENTIFICATION

Form: ampoules/vials, pre-filled syringe
Color: white emulsion

As a result of the physical presentation of the product, the risk to health in the normal handling of the product is expected to be low. Exposure to solutions from broken vials may cause adverse health effects.
4. FIRST AID MEASURES

Inhalation : Remove patient from exposure. Obtain medical attention if ill effects occur.
Skin Contact : Wash skin with soap and water. If symptoms (irritation or blistering) occur, obtain medical attention.
Eye Contact : Irrigate with eyewash solution or clean water, holding the eyelids apart, for at least 10 minutes. Obtain medical attention if ill effects remain.
Ingestion : Wash out mouth with water and give 200-300ml of water to drink. Obtain medical attention if ill effects occur. Do NOT induce vomiting as a First-Aid measure.

Note to Physicians
Symptomatic treatment and supportive therapy as indicated. For further detail consult the prescribing information.

5. FIRE FIGHTING MEASURES

If involved in a fire, it may burn and emit noxious and toxic fumes.

Extinguishing Media (suitable) : water spray, foam, dry chemical or CO2.
Extinguishing Media (unsuitable) : -
Fire Fighting Protective Equipment : A self contained breathing apparatus and suitable protective clothing should be worn in fire conditions.

6. ACCIDENTAL RELEASE MEASURES

Personal Precautions : Ensure suitable personal protection during removal of spillages. See Section 8. Ensure adequate ventilation. Take care to avoid needles and broken containers.
Environmental Precautions : Prevent entry into drains, sewers or watercourses.
Clean Up Methods : Clear up spillages. Transfer spilled vials to a suitable container for disposal. Wash the spillage area clean with water and detergent.

7. HANDLING AND STORAGE

Handling : No special precautions are necessary when handling packed product. In case of accident, avoid contact with skin and eyes.
Storage : Do not freeze.

Page 2 of 6
23.03.2012
Revision : 2
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls: The specific controls will depend on local circumstances and should be based on the risk assessment. Appropriate controls to reduce exposure may include engineering controls, for example ventilation, procedural controls and the use of personal protection equipment. Prevent entry into drains, sewers or watercourses.

**Occupational Exposure Limits**

**HAZARDOUS INGREDIENT(S)**

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<tr>
<th></th>
<th>TWA</th>
<th>STEL/CEILING(C)</th>
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<tbody>
<tr>
<td>Propofol</td>
<td>0,1 ppm</td>
<td>0,73 mg/m³</td>
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<td>COM, HYG</td>
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This is an in-house standard for the active ingredient during manufacture.

**Propofol**

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<tbody>
<tr>
<td>Glycerol</td>
<td>10 mg/m³</td>
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<td>TLV</td>
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Personal Precautions: Decisions about whether the use of personal protective equipment (PPE) is appropriate as part of the control strategy should be based on the workplace risk assessment and should take account of local legislative requirements for selection and use. There are multiple factors that will affect the specific requirements such as amount and concentration of the material, duration of exposure, frequency of exposure, external environmental conditions, the task, the user etc.

The information below should not be used in isolation and should be considered in the context of the workplace risk assessment on a case by case basis.

**Respirators**

NIOSH/MSHA approved respiratory protection device consistent with the workplace risk assessment.

**Protective Clothing**

Use impervious clothing to protect against direct contact with the product if the risk assessment does not support the selection of other protection. Use chemical protective gloves with a permeation time greater than the activity duration. Take note of the information given by the PPE producer/supplier concerning permeability and breakthrough times and special workplace conditions.

**Eye Protection**

Use safety glasses to protect against direct contact with the substance if the risk assessment does not support the
selection of other protection.

Other Protective Equipment : Eyewash station in work area.

9. PHYSICAL AND CHEMICAL PROPERTIES

Form : ampoules/vials, pre-filled syringe
Color : white emulsion
Solubility (Water) : very slightly soluble

10. STABILITY AND REACTIVITY

Stability : Stable under normal conditions.
Hazardous Reactions : None known.
Hazardous Decomposition Product(s) : None known

11. TOXICOLOGICAL INFORMATION

As a result of the physical presentation of the product, the risk to health is expected to be very low under normal conditions of handling and use. The following health hazard assessment is based on a consideration of the composition of this product.

Inhalation : The vapour has anaesthetic properties and when inhaled may cause sedation, lowering of heart rate and blood pressure, headache, dizziness and vomiting.

Skin Contact : May cause skin irritation.

Eye Contact : May cause eye irritation.

Ingestion : May cause effects as described under inhalation.

Long Term Exposure : Short term tests have shown that it is unlikely to be a carcinogenic hazard to man., Studies in animals have shown that repeated doses produce no adverse reproductive effects.

12. ECOLOGICAL INFORMATION

This environmental hazard assessment is based on information available on the components of the formulation.

Ecotoxicity : The active ingredient is very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment.
LC50 Bluegill Sunfish 96 H (flow through) 0,62 mg/l
The formulation is harmful to aquatic organisms and may cause long-term adverse effects in the environment.

Degradability : The active ingredient shows no evidence for biodegradability
in water.

**Bioaccumulation**

The active ingredient has high potential for bioaccumulation.

**Effect on Effluent Treatment**

The active ingredient was not shown to be biodegradable under anaerobic conditions.

### 13. DISPOSAL CONSIDERATIONS

**Chemical Disposal/**

Disposal should be in accordance with local, state or national legislation.

**Disposal Method**

Disposal of waste material via high-temperature incineration is recommended.

**Contaminated Packaging**

Empty container will retain residue. Observe all hazard precautions.

### 14. TRANSPORT INFORMATION

NOT RESTRICTED FOR TRANSPORT

### 15. REGULATORY INFORMATION

TSCA (Toxic Substances Control Act) Regulations, 40 CFR 710: This product is a drug and is exempt from TSCA regulation when manufactured, processed or distributed in commerce for use as a drug. CERCLA and SARA Regulations (40 CFR 302, 355, 370 and 372): This product does not contain any chemicals subject to applicable reporting requirements. Other Determined Regulations: California Proposition 65: This product does not contain a listed chemical. Discarded product is not considered a "hazardous waste" under RCRA, 40 CFR 261.

### 16. OTHER INFORMATION

The following sections contain revisions or new statements:
Minor changes: 1, 3, 5, 7, 8

This Material Safety Data Sheet was prepared in accordance with ANSI Z400.1/Z129.1-2010

GLOSSARY

COM : In-house occupational exposure limit
TLV : Threshold Limit Value (ACGIH)
TLV-C : Threshold Limit Value – Ceiling Limit (ACGIH)
HYG : An in-house analytical method for occupational exposure monitoring is available.
Sk : Can be absorbed through skin, thus contributing to systemic effects
Sen : Capable of causing respiratory sensitisation

This Glossary is applicable to substances for which Occupational Exposure Limits are assigned. Not all of the Glossary items may have been used in this Data Sheet.

The information herein is given in good faith but no warranty, expressed or implied, is made.