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Description: SPFEN,AZ,LOZ, FLURBIPROFEN

Status: Published

Revision Reason: New Aust R & FG code for Orange SugarFree.

Issue Date: 11 Feb 2010

PSDS

PSDS

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1. PRODUCT and COMPANY IDENTIFICATION

Product Name **Strepfen Intensive Lozenges**

Other Names **Strepfen Lozenge with Flurbiprofen**

Product Code(s) 0215849 Orange Sugar Free
 3443078 Honey & Lemon

Recommended Use Relief of pain, swelling and inflammation associated with severe sore throats.

Supplier

AUSTRALIA

COMPANY: Reckitt Benckiser (Australia) Pty Limited
ABN: 17 003 274 655
ADDRESS: 44 Wharf Road
 West Ryde NSW 2114
TELEPHONE: (02) 9857 2000

AFTER HOURS EMERGENCY TELEPHONE
(5pm to 8am EST Australia): (02) 9857 2444

NEW ZEALAND

COMPANY: Reckitt Benckiser (New Zealand) Limited
ADDRESS: Lincoln Manor
 289 Lincoln Road
 Henderson Auckland 1231
TELEPHONE: (09) 839 0200

Poisons Centre Information

AUSTRALIA 13 1126
NEW ZEALAND 0800 764 766 or 0800 POISON

2. HAZARD(S) IDENTIFICATION

regulations.

7. HANDLING AND STORAGE

Handling No special treatment required.
Storage Store at ambient temperatures away from oxidising materials.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Exposure Standards
Australia & New Zealand No exposure standards have been set for any of the ingredients in this product.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance Circular
Colour Honey & Lemon : Pale yellow - brown
Orange Sugar free : Pale orange
Average weight 2.5 - 2.7 g/lozenge
Flurbiprofen content 8.1 - 9.4 mg/lozenge
Relative Density Not applicable
pH Not applicable
Flashpoint Not applicable
Solubility in water Dissolves slowly

10. STABILITY AND REACTIVITY

Stability/Reactivity Not applicable
Conditions to Avoid Not applicable
Materials to Avoid Not applicable
Hazardous Decomposition Products None

11. TOXICOLOGY INFORMATION

Product Toxicity The toxicity of this product has not been determined.
No hazard expected.
Component Toxicity The hazard identifications in Section 2 were derived from the known effects of the individual ingredients and their concentrations in the product.

12. ECOLOGICAL INFORMATION

Product Ecotoxicity The ecotoxicity of this product has not been determined.
No hazard expected.
Component Ecotoxicity Based on component ecotoxicity data the product is not an environmental hazard.

13. DISPOSAL CONSIDERATIONS

Disposal Method Product should be treated according to the instructions given under sections 6,7 and 8 above.

Dispose of according to Local, State and Federal regulations. Contact relevant authority for details.

14. TRANSPORT INFORMATION

Road Transport Regulations (ADG 6 Aust.)

UN number: None allocated
Proper shipping name: None allocated
DG class: Not a DG
Subsidiary risk: None allocated
Packing group: None allocated
Hazchem code: None allocated

Maritime Transport Regulations (IMDG)

UN number: None allocated
Proper shipping name: None allocated
DG class: Not a DG
Subsidiary risk: None allocated
Packing group: None allocated
Marine Pollutant: Not a Marine Pollutant

Air Transport Regulations (IATA)

UN number: None allocated
Proper shipping name: None allocated
DG class: Not a DG
Subsidiary risk: None allocated
Packing group: None allocated

15. REGULATORY INFORMATION

This product is regulated as a medicine in the UK and complies with all the requirements of the Medicines Act.

AUSTRALIA Regulatory Status

This product has been approved by TGA Australia, approval no.:
Orange Sugar free - AUST R 157020
Honey & Lemon - AUST R 133376.

Hazardous Substances Regulation Not hazardous

Risk Phrase(s) None

Environmental Risk Phrase None

Safety Phrase(s) S2 Keep out of the reach of children.

SUSDP S2 Pharmacy Medicine

NEW ZEALAND Regulatory Status

This product has been approved by Medsafe New Zealand.
Orange Sugar free - TT50-6033/1
Honey & Lemon - TT50-7578

Approved Handler Not required

Tracking Not required

16. OTHER INFORMATION

CONTACT POINT

AUSTRALIA and NEW ZEALAND

Regulatory, Safety & Environmental Services

From outside Australia Ph: (61) (2) 9857 2000
From within Australia Ph: (02) 9857 2000

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KEY/LEGEND

NOHSC = National Occupational Health and Safety Commission (Australia)
ADG = Australian Code for the Transport of Dangerous Goods by Road and Rail
DG = Dangerous Goods
IMDG = International Maritime Dangerous Goods
IATA = International Air Transport Association
TGA = Therapeutic Goods Administration (Australia)

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