SPONSOR: 160 DELTA WEST LIMITED (WA)

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P R O D U C T D E T A I L S
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A6 Product number: NRTG 48012 10805

A7 Product name:
Sodium Citrate Mixture 8.8%

* *

A8 Application:
(please indicate)
|✓| I apply for registration of the drug(s) described in this application.

|__| I apply for listing of the drug(s) described in this application.

IF THIS PRODUCT IS EXEMPT FROM THE PROVISIONS OF THE ACT OR HAS BEEN CEASED PLEASE INDICATE IN THE APPROPRIATE BOX BELOW. NO FURTHER ACTION IS REQUIRED FOR THIS PRODUCT ON THIS FORM.

Exempt |__| Ceased |__|

DELTA WEST SODIUM CITRATE 8.8% oral liquid sachet

A9 Registration/Listing Name: ~~SODIUM CITRATE MIXTURE 8.8 (0.311) 30 mL~~

A10 Category of Therapeutic Good:
(Tick only one box)
Is this Therapeutic Good a

drug only? |✓|

drug-device combination? #|__|

drug supplied as a component of a therapeutic device kit, tray or pack? #|__|

medicated or formulated device? *|__|

device only? *|__|

| OFFICE USE ONLY |
| Drug Device |
| Defn Y (N) N |
| Data Y |
| ADG code ..... |

- Please complete a Supplement for Therapeutic Devices

* - Please complete an Application for Registration/Listing of Currently Supplied Therapeutic Devices

SPONSOR: 160 DELTA WEST LIMITED (WA)

A11 PRINCIPAL MANUFACTURER DETAILS

Manufacturer's business name: DELTA WEST LIMITED
15 BRODIE HALL DRIVE,
TECHNOLOGY PARK
BENTLEY W.A. 6102

- If blank please give the name of the manufacturer here and either complete an Enterprise Details form for the manufacturer or give the manufacturer's enterprise identification code below.

Manufacturer's Enterprise Identification Code: 160..
Manufacturer Address details:

State: Postcode:
Country:

A12 ALTERNATIVE PRINCIPAL MANUFACTURERS

Is there another alternative principal manufacturer? Yes |__| No |

If yes, print the name below and either complete an Enterprise Details form for the manufacturer or give the manufacturer's enterprise identification code.

.....

.....

STATUS RE

CHARGE LEVEL RL

COMMENT CODE NRTGNC

SPONSOR: 160 DELTA WEST LIMITED (WA)

DRUG DETAILS

A13 Existing supply details: Import Permit(s) or Licence number(s) issued by the Department of Community Services and Health for the importation of these goods (if applicable)

N.A. ....

....

A14 Date first supplied in Australia by Sponsor: (dd/mm/yy) .../.../.1985

OFFICE USE ONLY

Date

01/01/85

DD MM YY

A15 Is this product supplied as a Commonwealth Pharmaceutical Benefit?

Yes |__| No |✓|

A16 Pack size and Poison Schedule: Pack/container sizes in which this product is supplied

A17 SUSDP Schedule No. for this pack size (if not scheduled write 'N')

1	30 mL	N
2		
3		
4		
5		

A18 COMPOSITE PACKS

If this product is a composite pack and the details of each drug component or formulation are NOT given in the following pages, please 'tick' yes and attach details:

Yes |__|

SPONSOR: 160 DELTA WEST LIMITED (WA)

COMPONENT/FORMULATION DETAILS

A19 Dosage Form: ~~MIXTURE, UNSPECIFIED~~ ORAL LIQUID, solution

A20 Route(s) of administration:
ORAL

A21 Visual identification of dosage form:
CLEAR, COLOURLESS SOLUTION, FREE FROM VISIBLE IMPURITIES.

OFFICE USE ONL
Container Code
SACHT

A22 Type of container: ...SACHET.....

A23 Sterility: Is this product or any of its components supplied sterile? Yes |☑| No |__|

If yes, how is it sterilised -

steam |☑|ST| ethylene oxide |__|EO| filtration |__|FT|

gamma irradiation |__|GR| dry heat |__|DH| other |__|__|

If other, please specify

.....

A24 Source of material:
Was material of human or other animal origin used in the manufacture and/or formulation of these goods ?

Yes |__| No |☑| Not applicable |__|

If yes, type of animal origin:

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SPONSOR: 160 DELTA WEST LIMITED (WA)

FORMULATION DETAILS

A25 Active Ingredients

✓SODIUM CITRATE
88 mg/mL

A26 Excipients

✓SUCROSE

✓SODIUM METHYL HYDROXYBENZOATE

~~PROPYLENE GLYCOL~~

✓ water ~~for injections~~ PURIFIED

A27 Product Descriptive Material:

Product labels, packaging or other explanatory material attached to this page - where this material includes information on indications:

Container Label	☑ CL	Primary pack label	☑ PP
Package insert	☐ IN	Promotional material	☐ PM
Approved product information	☐ PI		
Other (describe) _____	☐		

NO MATERIAL ATTACHED - the above information has been supplied since 1 January 1990 and should be transferred from the NRTG ☐ TR