

Amiloxate Docket No. 2003N-0233  
Neo Helopan® E 1000: Safety and Efficacy

Euro Pharmaceuticals Pty Ltd.

**Submissions by Interested Parties for:**

**Amiloxate Docket No. 2003N-0233**

**Substantiation of Safety and Efficacy**

Submitted by:  
Euro Pharmaceuticals Pty Ltd  
21-31 Malcolm Road  
Braeside Victoria Australia 3195  
Phone: (0)3-9587-1088  
Fax: 61-3-9580-7647

Contact Person:  
Dr Jane Oppenheim  
Scientific Director

COMMERCIAL-IN-CONFIDENCE

**Amiloxate Docket No. 2003N-0003**  
**Neo Heliopan® E 1000: Safety and Efficacy**

*Ego Pharmaceuticals Pty Ltd.*

Ego Pharmaceuticals Pty Ltd first purchased NeoHeliopan® E 1000 in Jun 1995. From June 1995 until August 2003, a total of 3.2 tonne of NeoHeliopan® E 1000 has been purchased.

Ego Pharmaceuticals Pty Ltd has used NeoHeliopan® E 1000 in two Sunscreen products, SunSense Toddler Milk and SunSense Clear Gel. The SunSense Toddler Milk is an emulsion with SPF 30+ and 40 minutes water resistance, while the SunSense Clear Gel is an anhydrous gel, SPF 30+, with 40 minutes water resistance.

See Appendix 1 for copies of the labels for these two Sunscreens. The labels are not routinely approved by the Therapeutic Goods Administration (TGA), but must be in accordance with the regulations for labeling of listable products in Australia. Assurances are given by the sponsor that the labels comply to the current Therapeutic Goods Order (TGO). If a product fails to comply with the regulations the TGA has the authority to order a product recall.

**Table 1. Summary Data for Products Containing NeoHeliopan ® E 1000**

	<b>SunSense Toddler Milk</b>	<b>SunSense Clear Gel</b>
<b>Launch date</b>	June 1995 (formulation superceded May 2001)	June 2000
<b>Total units sold to date</b>	649,000 (June 1995 – May 2001)	94,260
<b>% NeoHeliopan® E 1000</b>	3.5%	5.0%
<b>Other UV actives</b>		
Octyl methoxycinnimate	3.5%	8.0%
Benzophenone-3	1.5%	5.0%
4-methylbenzylidene camphor	---	4.0%
Butyl methoxdibenzoylmethane	---	2.5%
Titanium dioxide	3.2%	---

*Ego Pharmaceuticals Pty Ltd.*

---

**1. Animal Safety Data**

**a. Neo Heliopan® E 1000 alone**

No data held by Ego Pharmaceuticals Pty Ltd

**b. Neo Heliopan® E 1000 formulated into a sunscreen**

No data held by Ego Pharmaceuticals Pty Ltd

**2. Human Safety Data**

**a. Neo Heliopan® E 1000 alone**

No data held by Ego Pharmaceuticals Pty Ltd

**b. Neo Heliopan® E 1000 formulated into a sunscreen**

**SunSense Toddler Milk**

No data held by Ego Pharmaceuticals Pty Ltd

**SunSense Clear Gel**

No data held by Ego Pharmaceuticals Pty Ltd

**c. Documented side effects**

Ego Pharmaceuticals Pty Ltd keeps a database of all customer complaints and comments regarding all our products. Since the SunSense Toddler Milk and SunSense Clear Gel formulations using NeoHeliopan® E 1000 were launched no adverse affects have been attributed to NeoHeliopan® E 1000.

In summary, for SunSense Toddler Milk, 649,000 units were sold between June 1995 and May 2001, with a total of 48 customer complaints being received (see table 2 below). Seventeen of these complaints related to skin reactions/sensitivity. Of the 17 complaints, we have not been able to positively conclude that any were actual skin reaction/sensitivity to the SunSense Toddler Milk, as no photos, Doctors reports or data has been provide to us in addition to the initial complaints by the customers.

For SunSense Clear Gel, 94,260 units have been sold since May 2000, with a total of 17 Customer complaints being received (see table 3 below). Eleven of these complaints related to skin reactions/sensitivity. Of the 11 complaints, we have not

*Ego Pharmaceuticals Pty Ltd.*

---

been able to positively conclude that any were actual skin reaction/sensitivity to the SunSense Clear Gel, as no photos, Doctors reports or data has been provide to us in addition to the initial complaints by the customers.

Reporting of adverse events for therapeutic products is a voluntary undertaking of the sponsor. A description of how adverse effects are monitored for therapeutic products can be obtained from the Therapeutic Goods Administration (TGA) website [www.health.gov.au/tga](http://www.health.gov.au/tga).

**3. *In Vitro* Safety Data**

**a. Neo Heliopan® E 1000 alone**

No data held by Ego Pharmaceuticals Pty Ltd

**b. Neo Heliopan ® E 1000 formulated into a sunscreen  
SunSense Toddler Milk**

i. *In Vitro* Eye irritation using the EYETEX method.

**RESULT:** Non-irritant to minimal irritant.

(Appendix 2)

ii. *In Vitro* Dermal irritation using the SKINTEX method.

**RESULT:** Minimal irritant.

(Appendix 3)

**SunSense Clear Gel**

No data held by Ego Pharmaceuticals Pty Ltd

**Amiloxate Docket No. 2003N-0233**  
**Neo Heliopan® E 1000: Safety and Efficacy**

*Ego Pharmaceuticals Pty Ltd.*

**Table 2: Tabulated Customer Complaints relating to SunSense Toddler Milk (Neo Heliopan® E 1000 @ 3.5%w/w)**

<b>Date of Complaint</b>	<b>Ego Ref. No.</b>	<b>Complaint Type</b>	<b>Product returned for investigation</b>	<b>Product investigation result</b>	<b>Adverse drug reaction</b>
January 1999	99/7	Ineffective product	Yes	Normal	Unsubstantiated
January 1999	99/13	Ineffective product	No	Inconclusive	Unsubstantiated
February 1999	99/35	Odour and mold present	Yes	Defective	N/A
February 1999	99/53	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
March 1999	99/57	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
March 1999	99/63	Skin reaction/sensitivity	No	Inconclusive	Unsubstantiated
March 1999	99/77	Odour present	Yes	Normal	N/A
April 1999	99/99	Skin reaction/sensitivity	No	Inconclusive	Unsubstantiated
May 1999	99/149	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
June 1999	99/164	Odour and mold present	Yes	Defective	N/A
June 1999	99/167	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
September 1999	99/220	Odour and mold present	Yes	Defective	N/A
October 1999	99/279	Faulty packaging	Yes	Inconclusive	N/A
October 1999	99/282	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
November 1999	99/316	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
October 1999	99/317	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated

**Amiloxate Docket No. 2003N-0233**  
**Neo Heliopan® E 1000: Safety and Efficacy**

*Ego Pharmaceuticals Pty Ltd.*

<b>Date of Complaint</b>	<b>Ego Ref. No.</b>	<b>Complaint Type</b>	<b>Product returned for investigation</b>	<b>Product investigation result</b>	<b>Adverse drug reaction</b>
November 1999	99/225	Faulty packaging	Yes	Defective	N/A
November 1999	99/318	Odour present	Yes	Defective	N/A
November 2000	99/337	Faulty packaging	Yes	Defective	N/A
December 1999	99/347	Odour present	Yes	Defective	N/A
December 2000	99/371	Odour present/faulty packaging	Yes	Defective	N/A
January 2000	00/026	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
January 2000	00/034	Odour present	Yes	Defective	N/A
January 2000	00/039	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
January 2000	00/069	Faulty packaging	Yes	Defective	N/A
February 2000	00/066	Odour present	Yes	Defective	N/A
March 2000	00/091	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
April 2000	00/111	Odour present	Yes	Defective	N/A
April 2000	00/119	Odour present	Yes	Normal	N/A
April 2000	00/130	Odour present	Yes	Defective	N/A
May 2000	00/143	Faulty packaging	Yes	Normal	N/A
June 2000	00/162	Faulty packaging	Yes	Defective	N/A
October 2000	00/278	Odour present	Yes	Defective	N/A

**Amiloxate Docket No. 2003N-0233**  
 Neo Heliopan® E 1000: Safety and Efficacy

*Ego Pharmaceuticals Pty Ltd.*

Date of Complaint	Ego Ref. No.	Complaint Type	Product returned for investigation	Product investigation result	Adverse drug reaction
October 2000	00/279	Odour present	Yes	Defective	N/A
October 2000	00/286	Odour present	Yes	Normal	N/A
November 2000	00/317	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
November 2000	00/318	Ineffective product	Yes	Normal	Unsubstantiated
October 2000	00/323	Odour present	Yes	Normal	N/A
December 2000	00/338	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
December 2000	00/349	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
January 2001	00/361	Faulty packaging	Yes	Defective	N/A
December 2000	00/351	Odour and mold present	Yes	Defective	N/A
January 2001	00/359	Skin reaction/sensitivity	No	Inconclusive	Unsubstantiated
January 2001	01/011	Odour present	Yes	Inconclusive	N/A
February 2001	01/024	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
February 2001	01/052	Odour present	Yes	Defective	N/A
March 2001	01/058	Faulty packaging	Yes	Defective	N/A
May 2001	01/117	Odour present	Yes	Defective	N/A

**Amilorate Docket No. 2003N-0233**  
**Neo Heliopan® E 1000: Safety and Efficacy**

*Ego Pharmaceuticals Pty Ltd.*

**Table 3: Tabulated Customer Complaints relating to SunSense Clear Gel (Neo Heliopan® E 1000 @5%w/w)**

Date of Complaint	Ego Ref. No.	Complaint Type	Product returned for investigation	Product investigation result	Adverse drug reaction
October 2000	1433	Staining of clothing	Yes	Normal	NA
June 2001	1968	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
June 2001	1724	Skin reaction/sensitivity	No	Inconclusive	Unsubstantiated
June 2001	1726	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
September 2001	1805	Other Product was tacky and pilled on the skin	No	Inconclusive	NA
January 2002	1925	Skin reaction/sensitivity	No	Inconclusive	NA
February 2002	1968	Skin reaction/sensitivity	No	Inconclusive	NA
February 2002	1978	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
April 2002	2036	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
May 2002	2066	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
June 2002	2095	Other Product softened nail polish and balled on application	No	Inconclusive	NA
September 2002	2200	Other Lumps in product	No	Inconclusive	NA
October 2002	2256	Other Bloated packaging	Yes	Normal	NA
November 2002	2396	Ineffective product	Yes	Normal	Unsubstantiated

**Amiloxate Docket No. 2003N-0233**  
Neo Heliopan® E 1000: Safety and Efficacy

*Ego Pharmaceuticals Pty Ltd.*

<b>Date of Complaint</b>	<b>Ego Ref. No.</b>	<b>Complaint Type</b>	<b>Product returned for investigation</b>	<b>Product investigation result</b>	<b>Adverse drug reaction</b>
February 2003	2623	Skin reaction/sensitivity	Yes	Normal	Unsubstantiated
February 2003	2694	Skin reaction/sensitivity	No	Inconclusive	NA
July 2003	3079	Skin reaction/sensitivity	Investigation pending		

*Ego Pharmaceuticals Pty Ltd.*

---

**4. Efficacy Data**

**a. SPF**

**SunSense Toddler Milk**

Tested according to Australian Standard/New Zealand Standard 2604:1993.

**RESULT:** Static SPF 68.04

(Appendix 4)

**SunSense Clear Gel**

All SPF results on the marketed formulation were obtained after 40 minutes immersion (see section 4c), no static SPF data was obtained on the marketed formulation.

**b. UVA**

**SunSense Toddler Milk**

i. Tested according to Australian Standard/New Zealand Standard 2604:1993.

**RESULT:** Pass

(Appendix 5)

ii. Tested according to *The Guide to Practical Measurements of UVA/UVB Ratios* published by the Boots Company.

**RESULT:** UVA Ratio of 0.36, 1 Star

(Appendix 6)

**SunSense Clear Gel**

i. Tested according to Australian Standard/New Zealand Standard 2604:1998, Appendix C3, Method I.

**RESULT:** Pass

(Appendix 7)

ii. Labsphere SPF Analyzer / Diffey SPF Analyzer Method

**RESULT:** UVA Ratio of 0.8, 4 Stars

Critical Wavelength 382nm, Maximum protection

(Appendix 8)

Ego Pharmaceuticals Pty Ltd.

---

**c. Water Resistance**

**SunSense Toddler Milk**

Tested according to Australian Standard/New Zealand Standard 2610, Part 2 – 1983 private spas.

**RESULT:** After 40 minutes immersion the Water Resistance SPF value obtained was 30.06.

(Appendix 4)

**SunSense Clear Gel**

Tested according to Australian Standard/New Zealand Standard 2604:1998

**RESULT:** After 40 minutes immersion the Water Resistance SPF value obtained was 32.

(Appendix 9)

**5. Other useful information**

**a. Number of years of use of Neo Heliopan® E 1000**

Ego Pharmaceuticals Pty Ltd has been using Neo Heliopan® E 1000 commercially for 8 years.

**b. Number of different formulations using Neo Heliopan® E 1000**

Ego Pharmaceuticals Pty Ltd has utilized Neo Heliopan® E 1000 in two formulations, SunSense Toddler Milk and SunSense Clear Gel.

**c. Different percentages of Neo Heliopan® E 1000 in formulations**

Ego Pharmaceuticals Pty Ltd uses Neo Heliopan® E 1000 at the following levels:

**SunSense Toddler Milk:** 3.5% w/w

**SunSense Clear Gel:** 5.0% w/w

**d. Any serious adverse reactions to your formulation containing Neo Heliopan® E 1000**

Ego Pharmaceuticals Pty Ltd is not aware of any serious adverse reactions having occurred as a result of the use of Neo Heliopan® E 1000, either on its own or in the products SunSense Toddler Milk and SunSense Clear Gel.