

# **Insecticides don't Kill Lice**

**- but formulations of  
insecticides do!**

John Staton  
Technical Consultancy Services

# MEC - Therapeutic Goods Administration -2003

"There is little information in the literature regarding the effect of formulation on product efficacy. What evidence there is suggests that efficacy is formulation dependant ... and should be supported by clinical data on the formulation intended for marketing".

# MEC - Therapeutic Goods Administration -2003

"In-vitro data is not considered  
suitable in most cases".

Performance criteria to be assessed in selection of the final formulation of the insecticide.

*Efficacy Properties - in vivo*

Kill efficacy

Ovicidal activity

Clore and Longyear- 1993 - 7 Pediculicides  
 Compared for efficacy - 5 containing Pyrethrin  
 0.3%.

No. of Subs reinfection 7 days	6	3	8	14	8
No. of Subs reinfection 14 days	2	4	2	6	5
Infested throughout	1	1	2	5	3

Clore and Longyear- 1993 - 7 Pediculicides  
Compared for efficacy - 5 containing Pyrethrin 0.3%.

Student - Newman - Keuls Mean Rank	76	158	94	119	125	
---------------------------------------	----	-----	----	-----	-----	--

“Efficacy varied by 48% between  
highest and lowest”

## Cordero and Zaias - Two Pyrethrin-Piperonyl Butoxide formulations

Efficacy	Adults	Ovicidal
Shampoo	100%	29%
Lotion	85%	20%

- In same concentrations
- Infestation levels were balanced
- 20 subjects in each arm
- Contact time not given.

# Pitman et al - Two Pyrethrin- Piperonyl Butoxide formulations

Efficacy	Lice	Ovicidal
Shampoo	100%	50%
Lotion	100%	25%

- In same concentrations
- Infestation levels were balanced
- 20 subjects in each arm
- Contact time not given.

# Armoni et al 5 formulas with various actives

No Not Lice Free	Day 1	Day 10
Carbaryl Lotion	0	1
Carbaryl Shampoo	4	16

- 250 Subjects
- Carabryl - a lotion and a shampoo
- Both from the same company

## Armoni et al 5 formulas with various actives

The authors concluded that lotions were more efficacious than shampoos, due their residual properties.

They went as far as to say that

"We would discourage the uses of any kind of shampoo as it is immediately diluted..."

# Barker. S. 2004

No Not Lice Free	Day 1
Lotion	63%
Shampoo	38%

40 subjects in each arm

Both formulations with the same actives

Significance at 95% conf level

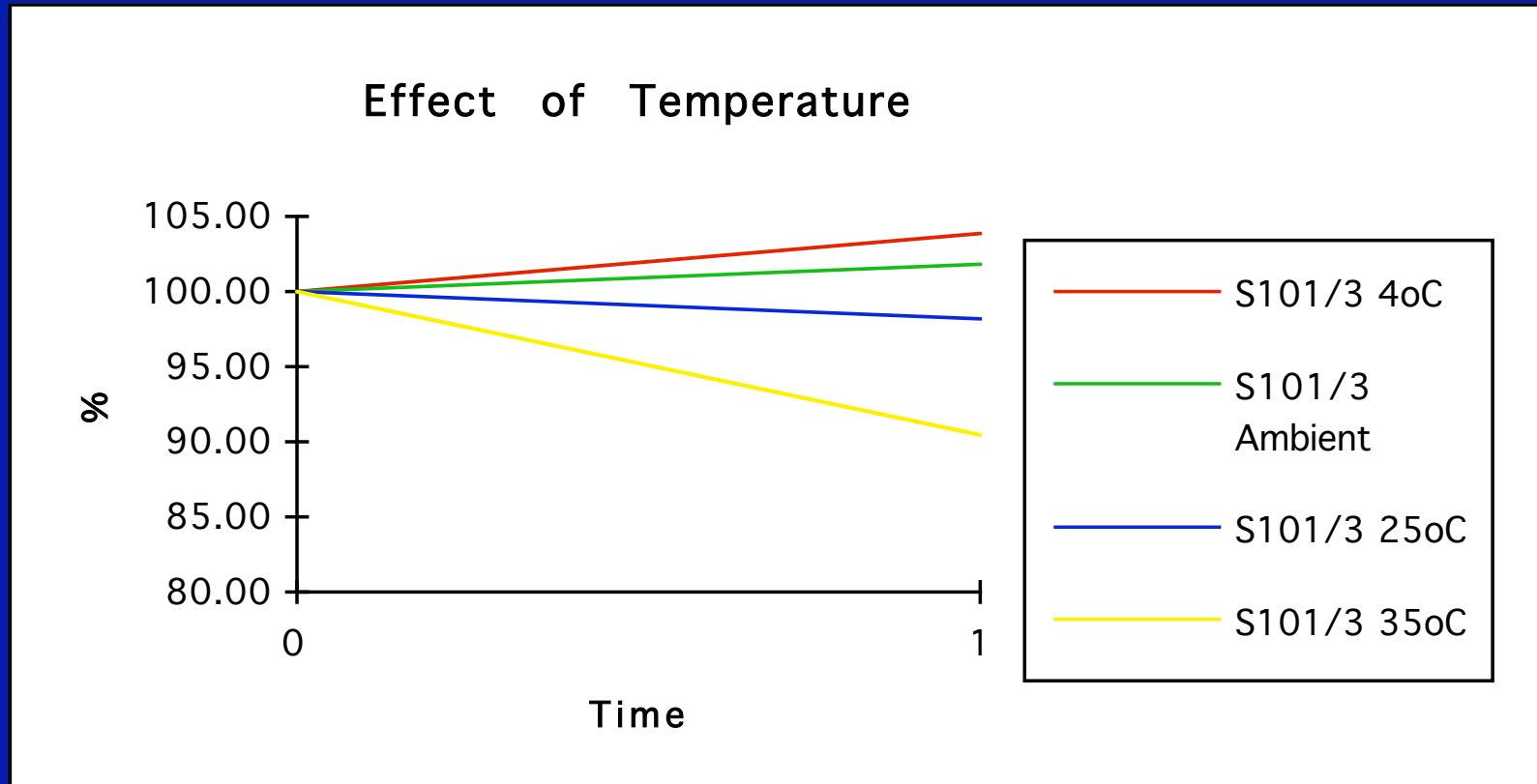
# Additional Criteria to be assessed in selection of the final formulation of the insecticide.

Stability - chemical, physical and  
microbiological

# Stability Issues for Actives

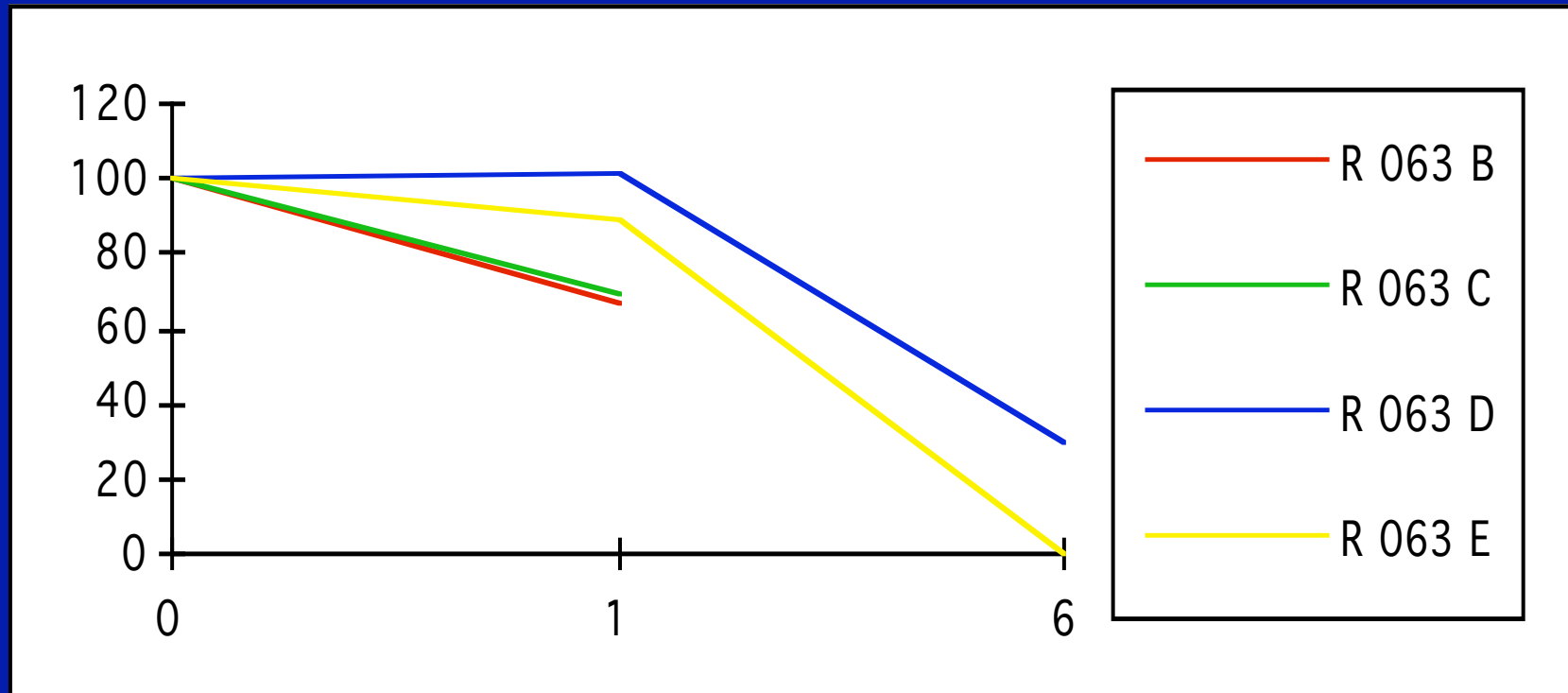
- Malathion - hydrolysis - heat sensitive
- Pyrethroids - heat sensitive -precipitate
- Permethrin - reasonable stability
- Herbal Extracts - very little data - difficult to quantify the active
- Essential Oils - volatile - citral oxidation - p-cymene hydrolysis

# Heat Stability of Malathion



1 month Storage (10% loss at 35oC)

# Heat Stability of Malathion



Aqueous Formulation  
6 month Storage (100% loss at 40oC)

# Microbiological Integrity

Preservative Efficacy Testing

Toxicity of Actives is high

# Additional Criteria to be assessed in selection of the final formulation of the insecticide.

Stability - chemical, physical and  
microbiological

Physical Properties - volatility - permeability

# Evaporation properties % loss

Essential Oil	35oC 1 hr	40oC 1 hr	
<i>Eucalyptus radiata</i>	20	41	
<i>Callitrus glaucophyla</i>	2	2	
<i>Melaleuca linarifolia</i>	16	30	
<i>Melaleuca bracteata</i>	4	6	
<i>Eremophilla mitchellii</i>	26	28	
<i>Backhousia anisata</i>	2	4	

Rates vary from 0 to 50% over 1 hr at 40oC.

# Additional Criteria to be assessed in selection of the final formulation of the insecticide.

Stability - chemical, physical and  
microbiological

Physical Properties - volatility - permeability

**Subjective Properties**

**- cosmetic acceptability**

# IMPACT OF FORMULATION ON SKIN IRRITATION

Miller et al compared phenothrin lotions containing 70% and 100% isopropanol as the base.

- 56 subjects
- Acceptability parameters were subjectively assessed
- Smell
- Stinging on the scalp
- Speed of Drying
- Cosmetic Acceptability

# Summary

Criteria to be assessed in selection of the final formulation of the insecticide.

# Summary

Criteria to be assessed in selection of the final formulation of the insecticide.

Efficacy

# Summary

Criteria to be assessed in selection of the final formulation of the insecticide.

Efficacy

Stability

# Summary

Criteria to be assessed in selection of the final formulation of the insecticide.

Efficacy

Stability

Physical

# Summary

Criteria to be assessed in selection of the final formulation of the insecticide.

Efficacy

Stability

Physical

Subjective

# Summary

Criteria to be assessed in selection of the final formulation of the insecticide.

Efficacy

Stability

Physical

Subjective

Safety

# MEC - Therapeutic Goods Administration -2003

"Where the formulation of a product is substantially similar to the formulation of a previously evaluated product, data showing in-vitro equivalence to the original product MAY be acceptable."

End

T<sub>cs</sub>