Registration Human Safety Review PM: Tavano TOX Reviewer: Engler

EPA #	Date	Product Name	Use Classification	Toxic Catego
34292-1	Apr.23 76	Dow corning Q9 5700 (amendement)		

RECOMMENDATION: TB objects to the registration of the amended label (use on socks). 1. The active ingredient must be tested for its teratogenic potential. 2. we request a review by CB indicating the possible exposure of man resulting from wearing treated garmets (leaching?); based on this review we will be able to determine whether or not other studies will be required.
Note: The basic acute studies for the product would not qualify for registration of the label (studies on technical are not available). We were however informed that only those requirements pertaining to the ammendment should be treated as a "new" registration. We concur with this since it is a logical approach . We also request a clarification as to why only 0.03 ml material was used in the human patch test(this appears to be a very small amount, could this be an error in reporting?)

		TECH	FORMULATION	USE DILUTION	DATA ACCEP ABL
Acute Oral (Rat)	LD_{50}		12.3 g/kg		ok

Toxic signs: none reported

Comments:

Acute Dermal (Rabbit)	LD_{50}		> 8.0 g/kg		ok

Toxic signs: slight erythemas and edemas

Comments:

Acute Inhalation ( )	LC_{50}				

Toxic signs:

Comments: not done, not needed

Primary Eye Irritation (Rabbit) Draize score:		>70	//////////	ok

Comments: Draize score estimate by reviewer, since other scoring technique was used. Corneal damage severe and not reversible after 7 days. A 2% solution showed no effect after 48 hours. A 10% solution showed slight corneal changes up to 7 days but eyes were normal after 10 days.

Primary Skin Irritation (Rabbit) Draize score:		<3	//////////	ok

Comments: Draize score estimated by reviewer since other scoring techique was used

Other Studies: See reverse side:

E for OEP 4/27/76

1/2

1. Human Patch test: 50 humans were exposed to a 2% solution ; 9 applications and one challenge application after 2 weeks. 1/50 reacted with slight erythema and 1/50 with slighte erythema and edema.

2. 28 day rabbit patch test. Treated fabric (0.5% use dilution and 5% = 10x use dil.) was applied to the skin of rabbits. No adverse effects were noted; the animals were also examined for gross and histopathological changes.

3. Human wear test with treated socks (32 days and 3 months). The socks used were treated with 0.35%. The subjects received several pairs of socks, one sock of each pair was treated the other served as control. no effects were noted.