Triplicate

INDIAN DRUGS RESEARCH LABORATORY. PUNE
561-B, Shivajinagar, Pune-411 005. Phone : 55018

of

The Indian Drugs Research Association, Pune

(Department of Chemical Testing and Toxicology)

REPORT OF ANALYSIS

Form - 39

No. (Rule 150-E (f)) Date : 1.7.1988.

Name of the sample SANOSIL SUPER.

Batch No. (Senders) -

[Details of Raw Material/Final Products as obtained from manufacturers]

(a) Original Manufacturer :- -

(b) Supplier's name :- -

(c) Original Mfgr's Batch No. :- -

(d) Total quantity -

Name of the sender M/S. SANOSIL CHEMICA (INDIA) PVT.LTD.

Licence No. -

Reference NIL.

Quantity received -

Date of Receipt 10.6.1988.

Date of Manufacture NIL

Date of Expiry NIL.

Results of analysis with protocols of tests applied :

Sample collected by Self/Senders

Results of Bacterial tests carried out :-

a) Total Bacterial count :		25 PPM	50 PPM
1.Control (River water)	-	32,433	32,433
2.After 15 minutes	-	450	39
3.After 30 minutes	-	160	8
4.After 60 minutes	-	61	NIL
5.After240 minutes	-	12	NIL
6.After 24 hours	-	NIL	NIL
b) E.Coli Count.		25 PPM	50 PPM
1.Control(st D.W.+E.Coli)	-	217	204
2.After 15 minutes	-	113	69
3.After 30 minutes	-	37	NIL
4.After 60 minutes	-	21	NIL
5.After240 minutes	-	3	NIL
6.After 24 hours	-	NIL	NIL

c) Total suspended solids = - 120 mg/L.

d) pH - 7.29

Analysed by - V.P.R.

Report

In the opinion of the undersigned sample referred to above is / is not of standard quality in the Drugs & Cosmetics Act 1940 & rules thereunder as it conforms to / does not conform to

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REPORT OF ANALYSIS

Form - 39

No. (Rule 150-E (f)) Date : 2.7.88.

Name of the sample Senosil - super - 25.

Batch No. (Senders) GMS-50

Name of the sender Senosil Chemicals (India)Pvt.Ltd.

[Details of Raw Material/Final Products as obtained from manufacturers]

(a) Original Manufacturer :-

(b) Supplier's name :-

(c) Original Mfgr's Batch No. :-

(d) Total quantity

Licence No.

Reference

Quantity received

Date of Receipt 10.6.88.

Date of Manufacture

Date of Expiry

Results of Analysis with protocols of tests applied :

Sample collected by Self/Senders

Acute oral Toxicity.

Animals used - Mice (5 male + 5 female) 10 for each dose.

Source of animals - INDIAN DRUG RESEARCH LABORATORY

Body weight - 20 - 25 gms.

No.of doses - 5.(1.586 gms/kg.-- 8.032 gms/kg.)

Observation period - Seven days.

Results - With the various doses tried, ranging from 1.586gms/kg to 8.032 gms/kg. There was no mortatity after 24 hours. LD 50 ex exceeds 8.032 Gms/kg.

The animals were normal.

Analysed by - S.M.M.

Report The work was carried out as per report of the subcommitte on pesticide Toxicology submitted by Dr.B.B.Gaitonde(1978) P.P.73.

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REPORT OF ANALYSIS

Form - 39

No. (Rule 150-E (f)) Date : 2.7.88.

Name of the sample Sanofil super-25.

Batch No. (Senders) G.N.S.-50.

[Details of Raw Material/Final Products as obtained from manufacturers]

(a) Original Manufacturer :-

(b) Supplier's name :-

(c) Original Mfgr's Batch No. :-

(d) Total quantity

Name of the sender Sanofil Chemicals (India) Pvt. Ltd.

Licence No.

Reference

Quantity received

Date of Receipt 10.6.88.

Date of Manufacture

Date of Expiry

Sample collected by Self/Senders

Results of Analysis with protocols of tests applied :

Permary skin ~~irritation~~ irritation test in Rabbits.
(DARIZE'S METHOD)

Report --

Animals used - 6 Rabbits (3 male + 3 female)

Source of animals - Indian Drug Research Association Laboratory, Shivajinagar, Pune-5.

Body weight - 2.5 - 3 kg.

Dose - 0.5 ml applied on the shaved area on both sides of back.

Observation period - 120 hours.

Reaction - Erythema and rsehar formation - Nil.

Score - 0

Edema formation - Nil-

Score - 0

Remarks - No erythema or eschar formation observed at 24 hr and 48 hours. The site of application was practically normal.

Analysed by - S.M.M.

Report The work was carried out as per report of the subcommittee on pesticide Toxicity submitted by Dr.B.B.Gaitone(1978)PP 73.

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REPORT OF ANALYSIS

Form - 39

No. (Rule 150-E (f)) Date : 2.7.88.

Name of the sample Sanosil - super 25.

Batch No. (Senders) GHS-50. Name of the sender Sanosil Chemicals (India) Pvt. Ltd.

[Details of Raw Material/Final Products as obtained from manufacturers]

(a) Original Manufacturer :-

(b) Supplier's name :-

(c) Original Mfgr's Batch No. :-

(d) Total quantity

Licence No.

Reference

Quantity received

Date of Receipt 10.6.88.

Date of Manufacture

Date of Expiry

Sample collected by Self/Senders

Results of Analysis with protocols of tests applied :

Acute dermal Toxicity in rats.

Animals used - 10 Rats.(5 ♂ male + 5 female) for each dose.

Source of animals - B.J.Medical College, Pune-1.

Body weight - 100 - 150 gm.

No.Of doses - Three(3) 3.34 gm/kg--- 10.02 gm/kg.

Observation period - 15 days.

Results -

No mortatity was observed with the various doses used ranging from 3.34 gm/kg to 10.02 gm/kg after 24 hours. Dermal LD 50 exceeds 10.02 gm/kg. The animals were normal within the observation period of 15 days.

Analysed by :- S.M.Mujumdar.

Report The work was carried out as per report of the subcommittee on pesticide Toxicology submitted by Dr.B.B.Gaitonde(1978)PP73.

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(Rule 150-E (f)) Date : 2.7.88.

Name of the sample Sanosil Super-25.

Batch No. (Senders) G.K.S. 50.	Name of the sender Sanosil Chemicals (India) Pvt. Ltd.
[Details of Raw Material/Final Products as obtained from manufacturers]	Licence No.
	Reference
(a) Original Manufacturer :-	Quantity received
(b) Supplier's name :-	Date of Receipt 10.6.88.
(c) Original Mfgr's Batch No. :-	Date of Manufacture
(d) Total quantity	Date of Expiry
Results of Analysis with protocols of tests applied :	Sample collected by Self/Senders

Micous membrane irritation test in rabbits.

Animals used - 6 Rabbits. (3 Male + 3 Female)

Source of animals - Indian Drug Research Laboratory, Pune-411005.

Body weight :- 1.5 - 2.2 kg.

Dose - 0.1 ml instilted in eye.

Observation period :- 15 days.

Observations :- Immediately on application to the micous membrane of the eye, irritation and watering of the eye which lasted for 4 hours. Redness, inflammation and slight oedema was observed after 24 hours, Redness was observed at 48,72 hours and there after upto 11 days. Then aftered words the the eye was ~~practically normal~~ practically normal.

Analysed by - S.M.M.

Report The work was carried out as per report of the subcommitte on perticide toxicology by Dr.B.B.Gaitonde(1978)P.P.73.

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