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ಕರ್ನಾಟಕ ರಾಜ್ಯ ಮಾಲಿನ್ಯ ನಿಯಂತ್ರಣ ಮಂಡಳಿ

Karnataka State Pollution Control Board

“ಪರಿಸರ ಭವನ”, 1 ರಿಂದ 5ನೇ ಮಹಡಿಗಳು, ನಂ. 49, ಚರ್ಚ್ ಸ್ಟ್ರೀಟ್, ಬೆಂಗಳೂರು - 560 001, ಕರ್ನಾಟಕ, ಭಾರತ
“Parisara Bhavana”, 1st to 5th Floor, # 49, Church Street, Bengaluru - 560 001, Karnataka, INDIA

NO;PCB/407/17CAT/HPI/2017-18 6448

DATED:
28 FEB 2018

KARNATAKA STATE POLLUTION CONTROL BOARD

PROCEEDINGS OF THE 1st TECHNICAL COMMITTEE MEETING
CONSTITUTED AS PER MINISTRY OF ENVIRONMENT, FOREST &
CLIMATE CHANGE NOTIFICATION, HELD ON 12.1.2018 IN THE BOARD
MEETING HALL, 3RD FLOOR, “PARISARA BHAVANA”, CHURCH STREET,
BANGALORE - 560001.

Presiding Officer:

1.	Sri. Lakshman, Hon'ble, Chairman, Karnataka State pollution Control Board.	Chairman
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Invitee:

1.	Sri. G.V. Ranga Rao, Member Secretary, Karnataka State pollution Control Board.	Invitee
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Members Present:

1.	Sri. B.G. Mohan Krishna, Chief Environmental Officer-1, KSPCB, Bengaluru.	Member
2.	Sri. K.M. Nagaraj, Senior Environmental Officer, KSPCB, Zonal Office, Bellary.	Member
3.	Sri. S. Suresh, Regional Director, Central Pollution Control Board, Bengaluru.	Member
4.	Dr. G.Srinikethan, Professor, Chemical Engineering, NITK, Surathkal, Dakshina Kannada District,	Expert
5.	Dr. Channabasavaraju .K.P Professor, Pharmaceutical Chemistry, Government College of Pharmacy, Bengaluru-560027,	Expert

6	Sri. R. Padmanabhan, Environmental Officer, Pharma, 17 Category, KSPCB, Bengaluru.	Convener
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Members Absent:

1.	Dr. J.Narayana, Professor, Department of Post Graduate Studies and Research in Environmental sciences, Kuvempu University, Jnana Sayadri, Shankaraghatta-577451, Shivamogga District.	Expert
2.	Prof. K.R.Prabhu Department of Organic Chemistry, Indian Institute of Science, Bengaluru-560012	Expert

Hon'ble Chairman welcomed all the members, experts of the committee and briefed the action taken with regards to the Empanelment of Environmental auditors keeping in view of the MOEF Notification dated:23.11.2016. Chief Environmental Officer explained the process involved in empanelling auditors as per the provisions of Notification and ratification obtained in the 216th Board Meeting held on 22.12.2017. Further the Members were apprised regarding the two applications received by the Board which required to be discussed in the committee. Since this committee is meeting for the 1st time for scrutiny, the CEO requested for formulating proper procedures in order to present the details before the committee. The details submitted by the industries have been circulated through soft copies for all members of the committee in advance. Keeping in view of the above, Hon'ble Chairman initiated the discussions on the two applications and following are the details of the discussions:

A. M/s.Seutic Labs Pvt Limited, Plot NO. 4P2, KIADB Industrial Area, Humnabad, Bidar District.

This unit is a specialty pharmaceutical company engaged in development, manufacture and marketing of quality finished dosages in domestic and international markets. It focus on commercializing unique generic products and pioneering synergistic combination products in the therapeutic areas of

- Antic-malarial, Cardiovascular,
- Dermatology, Male erectile dysfunction,
- Musculoskeletal and Ophthalmology.

This unit was initially established in the name of M/S. Vasista life Science (p) Limited and later taken over by the management of M/s. Seutic labs (p)Limited. This unit has obtained EC from the SEIAA vide order NO:SEIAA:28:IND:2010 dated: 3.10.2010 for the following products:

Group-I

SL.No	Name of the Product	Production (in MT/Month)
1	Atorvastatin Calcium	2.00
2	Gabapentin	2.50
3	Aripiprazole	2.00
4	Oxyclozamide	1.5
	Total	8.00

Group-II

1	Valcyeclovir	1.00
2	Levo-cetirizine dil HCL	1.50
3	Voriconazole	1.50
4	Montelukast Sodium	1.00
5	Fenoterol HBr	1.50
6	Tramadol HCL	1.50
	Total	8.00

Group-III

1.	Topiramate	3.00
2	Efavirenz	2.00
3	Ritonavir	1.00
4	Lopinavir	1.00
5	Gemeitabine HCL	1.00
	Total	8.00

Group-IV

1	Omeprazole	2.50
2	Pantoprazole Sodium	2.00
3	Rabeprazole Sodium	1.50
4.	Telmisaratan	2.00
	Total	8.00

Intermediates:

1.	Isopropyl—P-Dithio galacto PvranosidedPTG)	0.20
2.	PNPP	0.50
3.	5-Acetylthiophene Carboxylic acid	2- 0.50
4.	Phenylbromic acid	0.20
5.	X-Gal	0.20
6.	Benzophenonamine	0.90
7.	2 Nitro 4-Bromo 6-Methyl Aniline	0.20
8.	4-Nitro Indole	0.20
9.	n-Butyl Imidazole	0.20
10.	Sodium Phenoxide	0.20
11.	B Pinene	0.20
12.	Diphenyl Propioniyrile	0.20

13.	Benzyl Magnesium Chloride	2.00
14.	Ethyl Magnesium Chloride	5.00
15.	Methyl Magnesium Chloride	5.00
16.	Phenyl Magnesium Chloride	5.00
17.	1,3- Aceto Dicarboxylate	0.5
	Total	21.20

The industry which is manufacturing 19 API's with installed capacity of 32 T/Month and 17 No's intermediates with a capacity of 21.2 T/M proposes to change the product mix for the manufacture of 33 No's of API's with an installed capacity of 35.2 T/M and 23 No's of intermediates with an install capacity of 18 T/M.

As per details submitted , the production will be on an campaign basis and any one group from the following table will be produced at a time

Products Application- API's (Active Pharmaceutical Ingredients)

Sl. No.	Name of the product	Application
1	Atorvastatin Calcium	Anti-inflammatory
2	Gabapentin	Anticonvulsant
3	Aripiprazole	<u>Atypical antipsychotic</u>
4	Valacyclovir	Antiviral
5	Voriconazole	Antifungal agent
6	Montelukast Sodium	Antiallergic/ asthma
7	Fenoterol HBr	β_2 adrenoreceptor agonist
8	Tramadol HCL	Analgesic
9	Topiramate	Anti-epileptic
10	Efavirenz	Antiretroviral therapy
11	Ritonavir	HIV protease inhibitor
12	Lopinavir	Antiviral
13	Gemeitabine HCL	Antitumor activity
14	Omeprazole	Proton pump inhibitor
15	Pantoprazole Sodium	Proton pump inhibitor
16	Rabeprazole Sodium	Anti ulcerative
17	Telmisartan	Angiotensin receptor blocker
18	Posaconazole	Antifungal
19	Azelaic Acid	Treatment of skin pigmentation
20	Atovaquone	Antiprotozoal
21	Entecavir	Antiviral
22	Bupropion Hydrochloride	Used to treat depression
23	Carvedilol	Antihypertensive
24	Cilostazol	<u>Phosphodiesterase inhibitor</u>
25	Ezetamibe	Anti-hyperlipidemic
26	Lornoxicam	Anti-inflammatory and analgesic
27	Etoricoxib	Anti-inflammatory drug

28	Linezolid	Antibiotic
29	Sitagliptin Phosphate Monohydrate	Antidiabetic drug
30	Fluconazole	Antifungal drug
31	Olmesartan Medoxomil	Hypertension
32	Sertaconazole Nitrate	Antifungal
33	Adapalene	Antibiotics

Products Application- Intermediates

Sl. No.	Name of the intermediates	Code	Application
1	5-methyl-1-(propan-2-yl)-4-(4-(propan-2-yloxy) benzyl)-1H- pyrazol-3-yl-β-D-glucopyranoside	REMO	Antihyperglycemic
2	1,7-Hepta carboxylic acid	TOPAZ	Postinflammatory hyperpigmentation
3	(Z)-4-(4-hydroxy-1,2-diphenylbut-1-en-1-yl)phenol	ROSE	Dyspareunia
4	3-(bromomethyl)-7-chlorobenzo[b]thiophene	STAR	Antifungal
5	1-(6-methyl pyridin -3yl)2-[4-methyl sulphonyl] phenyl ethanone	TRT	Anti-inflammatory
6	(2-chloro-3-(dimethylamino)allylidene)-N-methylmethanaminium hexafluorophosphate	ZEN	Specific inhibitor of COX-2
7	6-fluorochroman-2-carboxylic acid	NEBO	Hypertension
8	ethyl 3-(2-(((4-carbamimidoylphenyl)amino)methyl)-1-methyl-N-(pyridin-2-yl)-1H-benzo[d]imidazole-6-carboxamido)propanoate	DART	Anticoagulant
9	(2S)-4-oxo-2-(3-thiazolidinyl carbonyl)-1-pyrrolidine carboxylic acid tert-butyl ester	JET	Anti-diabetic drugs
10	1-(3-Methyl-1-phenyl-1H-Pyrazol-5-yl) Piperazine	MSP	Antidiabetic
11	[(2-bromoethoxy)methyl]benzene	ASP	Dyspareunia
12	9-(4-bromobutyl)-9H-fluorene-9-carboxylic acid	LTD	Hypercholesterolemia
13	Isopropyl- P- Dithiogalacto Pyranosided PTG	-	Antiseptics

14	PNPP	-	Protein phosphatases & Kinases, RNA cloning
15	5-Acetylthiophene 2- Carboxylic acid	-	Used in the preparation of various 2,5-disubstituted thiophenes
16	Phenylbromic acid	-	Used in <u>organic synthesis</u>
17	X-Gal	-	β -galactosidase
18	2 Nitro 4- Bromo 6- Methyl Aniline	-	
19	4- Nitro Indole	-	Protein kinase inhibitors
20	n- Butyl Imidazole	-	Used in the synthesis of a heterocyclic mesomeric betaine
21	Sodium Phenoxide	-	Antiseptic
22	B-Pinene	-	Anti-depressant
23	Diphenyl Propioniyrole	-	

API's production will be on campaign basis, any of one group from the following table will be produced at a time.

Sl. No	Name of The Product	Qty (TPM)
Group-I		
1	Atorvastatin Calcium	0.50
2	Gabapentin	1.00
3	Etoricoxib	4.50
4	Valacyclovir	0.25
5	Voriconazole	0.50
6	Montelukast Sodium	0.50
7	Fenoterol HBr	0.25
8	Tramadol HCL	0.25
9	Adapalene	0.25
	Total Qty	8.00
Group- II		
10	Topiramate	0.25
11	Efavirenz	0.25
12	Ritonavir	0.25
13	Lopinavir	0.25
14	Gemeitabine HCL	0.50
15	Omeprazole	2.50
16	Pantoprazole Sodium	2.00
17	Rabeprazole Sodium	1.00
18	Linezolid	1.00
	Total Qty	8.00
Group- III		

19	Telmisartan	2.15
20	Posaconazole	0.25
21	Azelaic acid	2.00
22	Atovaquone	1.50
23	Bupropion hydrochloride	2.50
24	Carvedilol	0.25
25	Cilostazol	0.50
26	Aripiprazole	0.25
	Total Qty	9.40
Group- IV		
27	Ezetamibe	1.50
28	Lornoxicam	1.00
29	Sitagliptin phosphate monohydrate	1.50
30	Fluconazole	2.00
31	Olmесartan medoxomil	2.00
32	Sertaconazole nitrate	1.50
33	Entecavir	0.30
	Total Qty	9.80

Total Production capacity for API's is - 35.20 TPM

The details submitted before the committee was not in accordance with the format stipulated in the MOef &CC Notification dated: 23.11.2016 which required individual production details of each product which includes raw material details, manufacturing process of each products with chemical reactions, Mass balance of each product. Further the water aspects, effluent generation, flue gas emission, process emissions Hazardous waste generation product wise shall have to be separately submitted in the format:

HAZARDOUS WASTE GENERATION:

1. Proposal for reduction/recovery/reuse/recycle/sale of waste, if any.
2. Proposal for effluent recovery of solvents(with technical details)
3. Membership of Common Secured Landfill Site(if any)
4. Membership of Common hazardous waste incineration facility(if any)

DETAILS OF COMPLIANCE:

1. Status of environment clearance conditions compliance and its validity.
2. Status of consent and its validity:
3. Notice of directions/Closure Orders issued by the KSPCB during last 2 years.
4. Status of submission of Environment Audit report for previous audit period(If applicable)
5. EMS adequacy certificate from environmental auditor:
6. "No Increase in Pollution Load" certificates from environmental auditor:-

ADDITIONAL INFORMATION IMPORTANT FOR APPRISAL OF THE PROPOSAL:

1. Product wise Separate Sheet, showing the existing and proposed change in Air pollutants(eg.,Kg/Hr or Kg/day) Water pollutants(eg Kg/day) and Hazardous waste generation(Kg/Month or MT/Month) along with respective proposed control measures suggested, must be shown in tabular form, Along with the details of total change in pollution load(Water, Air, Haz, Waste)
2. Separate colored Layout plans for existing and proposed plant machineries must be provided.
3. Details of MSDC of all the Raw Materials & Products must be shown.
4. Copy of valid consents must be produced.
5. Comparative statement showing ARs of W/W & stacks samplings must be shown with prescribed permissible limits of respective pollutants.
 - a) List of raw materials with quantities must be product wise, in tabular form.
 - b) Chemicals reactions giving each step of the process must be given.
 - c) Mass balance for each reactant has to be given.
 - d) Separate sheet showing the details of product wise consumption and waste water generation (from existing & proposed) must be shown in tabular form.
 - e) Undertaking for no change in machinery and plant layout.
 - f) Hazardous chemicals storage facility.
 - g) Product wise effluent quantity & their load.

The committee after presentation made by the auditors and the F/A's committee concluded that the detailed submitted is not as per the prescribed format and insufficient.

The committee advised the proponents and the auditors to re-submit entire data in the prescribed format along with pollution load calculation for each product, each of exiting product as well as for each of the proposed product in the prescribed format for taking action on the matter.

B. M/S. Shree Renuka Sugars Limited, Athani Unit, Sy.No.R.S.No.377, Burlatti Village, Athani Tq, Belgavi.

M/s Shree Renuka Sugars Limited, located at the above said location, is an existing industry and engaged in Sugarcane crushing of 10,000 TCD, Power generation using Co-generation plant of 68 MW and Molasses based distillery of 300 KLPD.

The industry proposed to take up production of rectified spirit using molasses and grains either 100% or in combination and have submitted proposal to the Board seeking issue of " No increase in Pollution Load Certificate " in accordance with the Ministry of Environment and Forest & Climate Change No. S.O.3518(E) Dated: 23.11.2016. Representatives of the industry along with accredited auditors have given detailed presentation before the Technical Advisory Committee, constituted under the said Notification.

The industry has obtained Environmental Clearance from Ministry of Environment and Forest vide Order dated: 20.08.2014 and consent of the Board upto 30.06.2021 for the following activities;

- a) Sugarcane crushing – 10,000 TCD.
- b) Power generation using Co-gen plant – 68 MW

c) Distillery – 300 KLPD(100% Molasses based)

During presentation , it was informed that, the distillery has been established with 2 independent distillation lines each of 150 KLPD capacity and can be operated independently depending on availability of Molasses. Due to non- availability of Molasses on continuous basis, industry proposes to take up production RS using Grain based route or combination of grain and molasses based distillation. The only need for taking up grain based distillation is instillation of grain cleaning and digestion/ saccharification system. Industry contended that, if only grain based distillery is operated, spent lees and slop is generated. Spent lees is treated in Condensate Polishing Unit and reused. Slop is dried and converted to distillery dried grain with soluble solids (DDGS) due to which, the pollution load will be well within the existing load as per EC issued.

The committee after detailed deliberation observed that, the industry has to submit the required details in the format prescribed in MOEF & CC Notification dated: 23.11.2016. The committee also felt that, there is a requirement for assessment of pollution load of the existing operation taking into account of Water, Air as well as Solid Waste parameters and assessment of the pollution load when the distillery is operated either fully using grain based operation or combination of grain and molasses based distillation.

Accordingly, the Committee advised the representative of the industry and the auditors to submit the above details with necessary technical calculations in the prescribed format provided in the MOEF & CC Notification for taking further action.

The committee also decided that the proponents shall submit application directly to the Head Office, Bangalore. The applications received shall be forwarded to jurisdictional Regional Office for inspection of the industry/projects and to get the report in this regard.

The meeting concluded with vote of thanks.

Sd/-
Chairman
Technical Committee
Karnataka State Pollution Control Board

To,

1. **M/s.Seutic Labs Pvt Limited,**
Plot NO. 4P2, KIADB Industrial Area,
Humnabad,
Bidar District.
2. **M/S. Shree Renuka Sugars Limited,**
Atani Unit, Sy.No.R.S.No.377,
Burlatti Village, Athani Tq,
Belgavi.

Copy Submitted to:

1. PA to Chairman for information and brought to the notice of Chairman..
2. PA to Member Secretary for information and to place before Member Secretary for perusal.

1. The Chief Environmental Officer-1. KSPCB - Member of the Committee.
2. Shri. K.M. Nagaraju, Senior Environmental Officer - Member of the Committee.
3. Regional Director, CPCB, Bangalore - Member of the Committee.
4. Dr. G.Srinikethan, Professor, Chemical Engineering, NITK, Surathkal, Dakshina Kannada District- Member of the Committee.
5. Prof. K.R.Prabhu, Department of Organic Chemistry, India Institute of Science, Bengaluru-560012- Member of the Committee.
6. Dr. Channabasavaraju .K.P Professor, Pharmaceutical Chemistry, Government College of Pharmacy, Bengaluru-560027 - Member of the Committee.
7. E-Governance Cell for information and upload the proceedings in Board Web site.
8. ~~Case file.~~


**CHIEF ENVIRONMENTAL OFFICER
KSPCB,BANGALORE.** 

