



No. SEIAA/GUJ/EC/5(f)/1145/2015

Date: 30-03-2015

Time Limit

Sub: Environment Clearance for M/s. Fermenta Biotech Ltd for expansion in unit located at Plot No: Z/109 B & Z/109 C, Dahej SEZ, Taluka: Vagra, Dist : Bharuch..... In Category 5 (f) of Schedule annexed with EIA Notification dated 14/9/2006.

Dear Sir,

This has reference to your application along with Form-I submitted on dated 29/07/2012 seeking Environmental Clearance under Environment Impact Assessment Notification, 2006 and EIA report submitted on dated 03/07/2013 and additional information / documents submitted vide letter dated 14/08/2014 to the SEAC.

The proposal is for Environmental Clearance for **Fermenta Biotech Ltd for expansion in unit located at Plot No: Z/109 B & Z/109 C, Dahej SEZ, Taluka: Vagra, Dist : Bharuch.** It is an existing bulk drug manufacturing unit and environmental clearance was granted for Manufacturing of Active Pharma Ingredients (API), their intermediates and formulations/pre-formulations vide office order dated SEIAA/GUJ/EC/5(f)/30/2010 dated 21/12/2010. The unit now proposes to carry out backward integration in manufacturing of one of their Bulk Drugs, Vitamin D3 by manufacturing of its raw material – Cholesterol, as well as introduce another Bulk Drug – Isoxsuprine HCl. They have also proposed to reduce production quantity of few products and to discontinue one of the Bulk Drug. The list of products along with existing and proposed production capacities is as under, which falls in the category - 5(f) of the schedule of the EIA Notification-2006:

S. No.	Products	Existing Capacity (MT/annum)	Proposed Capacity (MT/annum)	Proposed Change
Products by Chemical Synthesis Route				
1	7-Dehydrocholesterol (7-DHC)	50	40	Decrease to 80 %
2	Vitamin D3 Resin	50	40	Decrease to 80 %
3	Vitamin D3 Crystalline	4	4	No change
4	Phenyramidol HCl	60	60	No change
5	Phenyl Glycine Methyl Ester	30	0	Discontinue
6	Polymer Beads	25	25	No change
7	Cholesterol	--	80	New raw material
8	Isoxsuprine HCl	--	6	New bulk drug
Co-products of Cholesterol				
a	Lanosterol	--	80	New co-product
b	Lanolin Alcohol	--	350	New co-product
c	Lanoline Fatty Acid	--	700	New co-product
Products by Fermentation Route				
1.	Penicillin G Amidase Biocatalyst (PGAB, NPGA)	25	25	No change
Formulations/Pre Formulations				
A	Vitamin D3 CWD	80	80	No change
B	Vitamin D3 resin in oil (1 MIU/2MIU) Food grade	2	2	No change
C	Vitamin D3 resin in oil (2MIU/5MIU/15MIU) Feed grade	30	30	No change
D	Vitamin D3 feed premix powder (0.5MIU/gm) and (0.2 MIU/gm)	5000	5000	No change
E	Silicon Powder	50	50	No change

The project activity is covered in 5(f) and is of 'B' Category. Since, As the unit is located in SEZ Dahej, public consultation was not carried out as per paragraph 7(i) III (i) (b) of the EIA Notification-2006

The SEAC, Gujarat had recommended to the SEIAA, Gujarat, to grant the Environment Clearance for the above-mentioned project. The proposal was considered by SEIAA, Gujarat in its meeting held on 20.03.2015 at Gandhinagar. After careful consideration, the SEIAA hereby accords Environmental Clearance to above project under the provisions of EIA Notification dated 14th September, 2006 subject to the compliance of the following conditions.

A. CONDITIONS :

A. 1 SPECIFIC CONDITION

Spent solvents shall be recovered by in-house distillation in such a manner that recovery shall not be less than 95 percent and recovered solvent shall be reused in the process as far as possible. If need arises, excess solvent shall be sold to only such distillation units having valid consent & authorization from the GPCB

A.2. WATER:

2. Fresh water requirement after proposed expansion shall not exceed 598 KLPD. Fresh water shall be met only with water supply system managed by Dahej SEZ Ltd. The water meter shall be installed and records of daily and monthly water consumption shall be maintained. No ground water shall be tapped for the project requirements in any case.
3. Industrial effluent generated from manufacturing process and other utilities after proposed expansion shall not exceed 337 KLPD from which 66 KLPD wastewater generated from cooling tower shall be utilized for gardening [61 KLPD] and flushing [5 KLPD].
4. Industrial effluent 280 KLPD shall be treated in Effluent Treatment Plant and after achieving permissible norms it shall be discharged in to existing common deep sea effluent disposal line of GIDC.
5. Domestic wastewater generation shall not exceed 12 KL/day after proposed expansion and it shall be treated along with industrial effluent.
6. The unit shall provide metering facility at the inlet and outlet of the Effluent Treatment Plant and maintain the records of the same.
7. A proper logbook of the ETP operation, effluent discharge quality and quantity, power consumption, chemical consumption etc. shall be maintained and shall be furnished to the GPCB from time to time.
8. The unit shall join and participate financially and technically for any common environmental facility / infrastructure as and when the same is taken up either by the GIDC or GPCB or any such authority created for this purpose by the Government / GIDC.

A. 3 AIR :

9. There shall be no additional fuel consumption for the proposed expansion.
10. There shall be no process gas emission from the for the proposed expansion.
11. Existing Air Pollution Control Systems shall be operated regularly and efficiently to control the pollutant concentration below the GPCB norms at the stack outlets.
12. Flue gas emissions and process emissions shall conform to the standards prescribed by the GPCB. At no time, the emission levels shall go beyond the stipulated standards.
13. An arrangement shall also be done for reflecting the online monitoring results on the company's server, which can be accessed by the GPCB on real time basis.
14. Existing scrubbing system shall be operated regularly & efficiently for control of process emission of HCl & SO₂ and scrubbing water will be sent to ETP for further treatment.
15. The alkali scrubber shall be installed for scrubbing HCl or any traces emitted from proposed activity and the scrubbing water shall be sent to ETP.
16. All the vessels used in the manufacturing process shall be close to reduce the fugitive emission.
17. The unit shall undertake measures for solvent recovery and adequate reflux condensers and chilled brine secondary condensers shall be provided for controlling escape of low boiling solvents. Solvent recovery shall not be less than 95 percent in any case.
18. Measures shall be taken to reduce the process vapors emissions as far as possible. Use of toxic solvents shall be minimum. All venting equipment shall have vapour recovery system.
19. The fugitive emission in the work zone environment shall be monitored. The emission shall strictly conform to the standards prescribed by the concerned authorities from time to time (e.g. Directors of Industrial Safety & Health).

20. Regular monitoring of ground level concentration of SO₂, NO_x, Acid Mist, PM₁₀ and PM_{2.5} shall be carried out in the impact zone and its records shall be maintained. Ambient air quality levels shall not exceed the standards stipulated by the GPCB. If at any stage these levels are found to exceed the prescribed limits, necessary additional control measures shall be taken immediately. The location of the stations and frequency of monitoring shall be decided in consultation with the GPCB.

A. 4 SOLID / HAZARDOUS WASTE:

21. The company shall strictly comply with the rules and regulations with regards to handling and disposal of Hazardous waste in accordance with the Hazardous Waste (Management, Handling and Transboundary Movement) Rules 2008, as may be amended from time to time. Authorization of the GPCB must be obtained for collection / treatment / storage / disposal of hazardous wastes.
22. The hazardous wastes shall be stored in separate designated hazardous waste storage facility with pucca bottom and leachate collection facility, before its disposal.
23. Spent carbon, ETP sludge and chemical containing residue shall be disposed off at the nearest TSDF. The unit shall obtain membership of the common facility.
24. Resin waste shall be sent to the nearest Common Hazardous Waste Incineration Facility (CHWIF). The unit shall obtain membership of the nearest CHWIF for disposal of resin waste.
25. Discarded containers/drums/bags/liners shall be either reused or sold to the authorized recyclers after its decontamination.
26. Used oil shall be sold only to the registered recyclers.

A. 4 SAFETY:

26. The project management shall strictly comply with the provisions made in the Factories Act, 1948 as well as Manufacture, Storage and Impact of Hazardous Chemicals Rules 1989 as amended in 2000 for handling of hazardous chemicals.
27. Necessary approvals from PESO and concerned Govt. Authorities (If any) shall be obtained before commissioning of the project.
28. All necessary precautionary measures shall be taken to avoid any kind of accident during storage and handling of hazardous chemicals; especially solvents and chlorine.
29. Proper ventilation shall be provided in the work area.
30. Storage and use of hazardous chemicals shall be minimized to the extent possible.
31. Hazardous materials storage shall be at an isolated designated location, bund/dyke walls shall be provided for storage tanks for Hazardous Chemicals.
32. Storage of hazardous chemicals shall be in multiple small capacity tanks / containers instead of one single large capacity tank to reduce the risk.
33. All the storage tanks shall be fitted with appropriate controls to avoid any leakages. Close handling system for chemicals shall be provided.
34. Personal Protective Equipments shall be provided to workers and its usage shall be ensured and supervised.
35. First Aid Box and required Antidotes for the chemicals used in the unit shall be made readily available in adequate quantity at all the times.
36. Necessary tie up with the nearby doctor qualified for occupational health shall be made to ensure that the medical treatment is given within the shortest possible time in case of any adverse condition.
37. Training shall be given to all workers on safety and health aspects of handling chemicals.
38. Occupational health surveillance of the workers shall be carried out on a regular basis and records shall be maintained as per the Factories Act and Rules.
39. The project management shall prepare a detailed Disaster Management Plan (DMP) for the project as per the guidelines from Directorate of Industrial Safety and Health.
40. All Transportation of Hazardous Chemicals shall be as per the Motor Vehicle Act & Rules.
41. All transporting routes within the factory premise shall have paved roads to minimize splashes and spillages.

A. 5 NOISE:

42. The overall noise level in and around the plant area shall be kept well within the standards by providing noise control measures including engineering controls like acoustic insulation hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise level shall conform to the standards prescribed under The Environment (Protection) Act, 1986 & Rules.

A. 6 CLEANER PRODUCTION AND WASTE MINIMISATION:

43. The unit shall undertake the Cleaner Production (CP) Assessment study through a reputed institute / organization and shall form a CP team in the company. The recommendations thereof along with the compliance shall be furnished to the GPCB.
44. The company shall undertake various waste minimization measures including :
 - a) Metering and control of quantities of active ingredients to minimize waste.
 - b) Use of automated and enclosed filling to minimize spillage.
 - c) Use of close feed system into batch reactors.
 - d) Regular preventive maintenance for avoiding leakage, spillage etc.
 - e) Dry cleaning / mopping of floor instead of floor washing.
 - f) Regular preventive maintenance for avoiding leakage, spillage etc.

A. 7 GREEN BELT AND OTHER PLANTATION:

45. The unit shall develop green belt within premises as per the CPCB guidelines. However, if the adequate land is not available within the premises, the unit shall take up adequate plantation on road sides and suitable open areas in GIDC estate or any other open areas in consultation with the GIDC / GPCB and submit an action plan of plantation for next three years to the GPCB.

B. OTHER CONDITIONS:

46. All the recommendation / commitments made in the EIA report shall be implemented
47. In the event of failure of any pollution control system adopted by the unit, the unit shall be safely closed down and shall not be restarted until the desired efficiency of the control equipment has been achieved.
48. During material transfer, spillages shall be avoided and garland drain be constructed to avoid mixing of accidental spillages with domestic wastewater or storm water.
49. Pucca flooring / impervious layer shall be provided in the work areas, chemical storage areas and chemical handling areas to minimize soil contamination.
50. Leakages from the pipes, pumps, shall be minimal and if occurs, shall be arrested promptly.
51. The project proponent shall also comply with any additional condition that may be imposed by the SEAC or the SEIAA or any other competent authority for the purpose of the environmental protection and management.
52. No further expansion or modifications in the plant likely to cause environmental impacts shall be carried out without obtaining prior Environment Clearance from the concerned authority.
53. The above conditions will be enforced, inter-alia under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986, Hazardous Wastes (Management, Handling and Transboundary Movement) Rules, 2008 and the Public Liability Insurance Act, 1991 along with their amendments and rules.
54. The project authorities shall earmark adequate funds to implement the conditions stipulated by SEIAA as well as GPCB along with the implementation schedule for all the conditions stipulated herein. The funds so provided shall not be diverted for any other purpose.
55. The applicant shall inform the public that the project has been accorded environmental clearance by the SEIAA and that the copies of the clearance letter are available with the GPCB and may also be seen at the Website of SEIAA/ SEAC/ GPCB. This shall be advertised within seven days from the date of the clearance letter, in at least two local newspapers that are widely circulated in the region, one of which shall be in the Gujarati language and the other in English. A copy each of the same shall be forwarded to the concerned Regional Office of the Ministry.
56. The company shall undertake socio-economic developmental / community welfare activities in consultation with the District Development Officer / District Collector.
57. Project proponent shall implement the action plan for beneficiation of the farmers and other commitments made in their submission vide letter dated 17/11/2014.
58. It shall be mandatory for the project management to submit half-yearly compliance report in respect of the stipulated prior environmental clearance terms and conditions in hard and soft copies to the regulatory authority concerned, on 1st June and 1st December of each calendar year.
59. Concealing factual data or submission of false/fabricated data and failure to comply with any of the conditions mentioned above may result in withdrawal of this clearance and attract action under the provisions of Environment (Protection) Act, 1986.
60. The project authorities shall also adhere to the stipulations made by the Gujarat Pollution Control Board.
61. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not found satisfactory.

62. The company in a time bound manner shall implement these conditions. The SEIAA reserves the right to stipulate additional conditions, if the same is found necessary.
63. The project authorities shall inform the GPCB, Regional Office of MoEF and SEIAA about the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.
64. This environmental clearance is valid for five years from the date of issue.
65. Any appeal against this environmental clearance shall lie with the National Green Tribunal, if preferred, within a period of 30 days as prescribed under Section 16 of the National Green Tribunal Act, 2010.

With regards,
Yours sincerely,

Sd/-
(N.K. PATEL)
Member Secretary

Issued to:
Shri Rajendra Gaitonde
Fermenta Biotech Ltd
Dil Complex, Ghodbander Road,
Thane (West), Maharashtra – 400 610

Copy to:-

1. The Secretary, SEAC, C/O. G.P.C.B. Gandhinagar - 382010.
2. The Chairman, Central Pollution Control Board , Parivesh Bhavan, CBD -cum-Office Complex, East Arjun Nagar, New Delhi-110032
3. The Chief Conservator of Forests (Central), Ministry of Environment & Forests, Regional Office (WZ), E-5, Arera Colony, Link Road-3, Bhopal-462016, MP
4. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi-110003.
5. The Member Secretary, Gujarat Pollution Control Board, Paryavaran Bhavan, Sector-10 A, Gandhinagar-382010
6. Select File

Sd/-
(N.K. PATEL)
Member Secretary