Dr. GAURAV DAHIYA, IAS **MEMBER SECRETARY** SEIAA (GUJARAT)



STATE LEVEL ENVIRONMENT IMPACT ASSESSMENT AUTHORITY **GUJARAT**

Government of Gujarat

No. SEIAA/GUJ/EC/5(f)/ 407/2016

Date: 19 7 JUN 2016

ByRPAD

Time Limit

Sub: Environment Clearance to M/s. Nira Life Sciences Pvt. Ltd. for setting up of the proposed manufacturing unit of Synthetic organic chemicals at Plot no:6-9, GIDC-Bamanbore, Ta.: Chotila, Dist.: Surendranagar In Category 5(f) of Schedule annexed with EIA Notification dated 14/09/2006.

Dear Sir,

This has reference to your application along with Form-I dated 29/10/2013 submitted to SEIAA, seeking Environmental Clearance under Environment Impact Assessment Notification, 2006 and EIA Report/ additional information / documents submitted vide letter dated 21/03/2015, 15/10/2015 and 25/03/2016 to the SEAC.

The proposal is for Environmental Clearance to M/s. Nira Life Sciences Pvt. Ltd. for setting up of the proposed manufacturing unit of Synthetic organic chemicals at Plot no:6-9, GIDC-Bamanbore, Ta.: Chotila, Dist.: Surendranagar . It is an existing unit for manufacturing following proposed products, which falls in the category - 5(f) of the schedule of the EIA Notification-2006:

Sr. no.	Name of the Products	Capacity (MT/Month)
1	Closantel	5.0
2	Gabapentinn	
3	Itopride Hydrochloride	
4	Nitazoxanide	
5	Pregabalin	
6	Rafoxanide	
7	Valproic acid	25.0
8	Niclosamide	
9	Mefenamic acid	
10	Tinidazole	
11	Ofloxamine	
12	Oxyclozanide	

The project activity is covered in 5(f) and is of 'B' Category. Since, the proposed project is located in notified industrial estate, public consultation is not required as per paragraph 7(i) (III) (i) (b) of the Environment Impact Assessment Notification-2006.

The SEAC, Gujarat vide their letter dated 01/06/2016 had recommended to the SEIAA, Gujarat, to grant the Environment Clearance for the above-mentioned project based on its meeting held on 13/04/2016. The proposal was considered by SEIAA, Gujarat in its meeting held on 13/06/2016 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:

1 SPECIFIC CONDITION:

1. Unit shall manufacture only one product at a time.

Entire quantity of Wastes/By-products (1) HCI – 25 % [27.29 MT/Month], NaHSO₃ – 25% Solution [38.94 MT/Month], HF - 20% [7.67 MT/Month], (NH4)2SO4 - 30% solution [24.44 MT/Month] & Potassium Acetate [6.31 MT/Month] shall be sell out to the actual end users who are authorized to receive the respective By-products/Wastes.

Above mentioned items/ wastes qualifying the Hazardous and other Wastes (Management and Transboundary Movement) Rules, 2016 and its amendment time to time shall only be sold after obtaining prior permission from CPCB/SPCB/PCC.

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- 4. The above mentioned By-product/hazardous wastes shall be sold only to the potential users who are authorized by the competent authority (MoEF/CPCB/SPCB etc.)
- 5. The unit shall submit the list of authorized end users of above mentioned by-products/hazardous wastes along with MoU signed with them at least two months in advance prior to commencement of production. In absence of potential buyers of these items, the unit shall restrict the production of respective item.
- 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 completely. Solvent recovery system with adequate reflux condensers shall be provided for controlling escape of low boiling solvents (VOCs).

A. 2 WATER:

- Total water consumption after proposed expansion shall not exceed 18.350 KL/day.
- Unit shall recycle MEE Condensate (6.4 KL/day) as Boiler feed water. Hence, actual fresh water requirement for the proposed project shall not exceed 11.95 KL/day, which shall be sourced from GIDC water supply. No ground water shall be tapped for the project requirements.
- The water meter shall be installed and records of daily and monthly water consumption shall be maintained.
- 10. Total waste water generation shall not exceed 6.5 KL/day, which shall be treated in proposed Primary treatment plant followed by Multiple Effect Evaporator (MEE) system.
- 11. The unit shall provide adequate effluent treatment plant (ETP) followed by Multiple Effect Evaporator (MEE) system for treatment of industrial effluent and it shall be operated regularly and efficiently so as to achieve Zero liquid discharge.
- 12. MEE condensate (6.4 KL/day) shall be reused for utility section.
- 13. A separate electric meter shall be placed for the ETP & Evaporation system. Proper logbook of ETP & MEE operations also showing chemicals consumed, treated water reused, power consumed etc. shall be maintained and furnished to the
- 14. Regular performance evaluation of the ETP & MEE shall be undertaken every year to check its adequacy, through credible institutes like L.D. College of Engineering, NPC or such other institutes of similar repute, and its records shall be
- 15. 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 Govt. /

A. 3 AIR:

- 16. Bio-Coal to the tune of 1 MT/day shall be used for Steam Boiler (Cap. 1 TPH).
- 17. Diesel (10 ltrs/hr) shall be used as a fuel for stand-by DG set (62.5 KVA)
- 18. Multi Cyclone dust collector and bag filter shall be provided with Boiler (1 TPH) as APCM.
- 19. Acoustic enclosure shall be provided to the DG sets to mitigate the noise pollution.
- 20. Stack of adequate height shall be provided as per the GPCB/CPCB/MoEF&CC norms for flue gas emission.
- 21. Flue gas emission from the Boiler, DG set and gaseous emissions shall conform to the standards prescribed by the GPCB/CPCB/MoEF&CC. At no time, emission level should go beyond the stipulated standards.
- 22. Unit shall provide water scrubber followed by alkali scrubber as APCM for control of HCl, SO2 and HF.
- 23. The air pollution control systems shall be operated efficiently and effectively to achieve the norms prescribed by the GPCB/CPCB/MoEF&CC at vent / stack outlets.
- 24. Fugitive emissions of VOC's must be regularly monitored. Sensors for detecting VOC's shall be provided at strategic locations. Leak Detection and Repair (LDAR) programme shall be implemented to control VOC emissions.
- 25. For control of fugitive emission, VOCs, following steps shall be followed:
 - Closed handling and charging system shall be provided for chemicals.
 - Reflux condenser shall be provided over Reactors.
 - Pumps shall be provided with mechanical seals to prevent leakages.
 - System of leak detection and repair (LDAR) of pump/pipeline based on preventive maintenance.
- 26. The fugitive emission in the work zone environment shall be monitored. The emission shall conform to the standards prescribed by the concerned authorities from time to time (e.g. Directors of Industrial Safety & Health). Following indicative guidelines shall also be followed to reduce the fugitive emission.
 - All transfer points shall be fully enclosed.
 - Internal roads shall be either concreted or asphalted or paved properly to reduce the fugitive emission during vehicular movement.
 - Air borne dust shall be controlled with water sprinklers at suitable locations in the plant.
 - A green belt shall be developed all around the plant boundary and also along the roads to mitigate fugitive & transport dust emission.
- All the vessels used in the manufacturing process shall be closed to reduce the fugitive emission.
- $\frac{1}{2}$ 8. 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.
- Begular monitoring of ground level concentration of SO2, NOx, PM10, PM2.5, HCl, HF, HC and VOC shall be carried out in the impact zone and its records shall be maintained. Ambient air quality levels shall not exceed the standards

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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.

- 30. Solvent management shall be carried out as follows:
 - Reactor shall be connected to adequate condenser system to condensate solvent vapors and reduce solvent losses.
 - Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
 - The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% solvent recovery.
 - Solvents shall be stored in a separate space specified with all safety measures.
 - Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
 - Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.

A. 4 SOLID / HAZARDOUS WASTE:

- 31. The company shall strictly comply with the rules and regulations with regards to handling and disposal of Hazardous waste in accordance with the Hazardous and Other Wastes (Management and Transboundary Movement) Rules 2016, as may be amended from time to time. Authorization of the GPCB must be obtained for collection / treatment / storage / disposal of hazardous wastes.
- 32. Hazardous wastes shall be dried, packed and stored in separate designated hazardous waste storage facility with pucca bottom and leachate collection facility, before its disposal.
- 33. ETP waste & Evaporation residue shall be disposed off at the Common TSDF site.
- 34. Process waste & Carbon waste shall be disposed off at the TSDF site or CHWIF depending on its characteristics and as per CPCB guidelines.
- 35. Discarded barrels / containers / bags / liners shall be either reused or returned back to suppliers or sold only to the authorized vendors after decontamination.
- 36. Used oil shall be sold only to the registered recyclers.
- 37. The unit shall obtain necessary permission from the nearby TSDF site and CHWIF.
- 38. Vehicles used for transportation of hazardous waste shall be in accordance with the provisions under the Motor Vehicle
 Act, 1988, and rules made there under.
- 39. All possible efforts shall be made for Co-Processing of the Hazardous waste prior to disposal into TSDF/CHWIF.

A. 5 SAFETY:

- 40. The company shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended.
- 41. The project authorities shall strictly comply with the provisions made in Manufacture, Storage and Import of Hazardous Chemicals Rules 1989, as amended in 2000 and the Public Liability Insurance Act for handling of hazardous chemicals etc. Necessary approvals from the Chief Controller of Explosives and concerned Govt. Authorities shall be obtained before commissioning of the project. Requisite On-site and Off-site Disaster Management Plans have to be prepared and implemented.
- 42. Storage of flammable chemicals shall be sufficiently away from the production area.
- 43. Sufficient no. of fire extinguishers shall be provided near the plant and storage area.
- 44. All necessary precautionary measures shall be taken to avoid any kind of accident during storage and handling of toxic / hazardous chemicals.
- 45. All the toxic/hazardous chemicals shall be stored in optimum quantity and all necessary permissions in this regard shall be obtained before commencing the expansion activities.
- 46. The project management shall ensure to comply with all the environment protection measures, risk mitigation measures and safeguards mentioned in the Risk Assessment repot.
- 47. Only flame proof electrical fittings shall be provided in the plant premises.
- 48. Storage of hazardous chemicals shall be minimized and it shall be in multiple small capacity tanks / containers instead of one single large capacity tank / containers.
- 49. All the storage tanks shall be fitted with appropriate controls to avoid any leakages. Bund/dyke walls shall be provided for storage tanks for Hazardous Chemicals.
- 50. Handling and charging of the chemicals shall be done in closed manner by pumping or by vacuum transfer so that minimal human exposure occurs.
- 51. Tie up shall be done with nearby health care unit / doctor for seeking immediate medical attention in the case of emergency.
- 52. Personal Protective Equipments shall be provided to workers and its usage shall be ensured and supervised.
- 53. First Aid Box and required Antidotes for the chemicals used in the unit shall be made readily available in adequate quantity.
- 54. Training shall be imparted to all the workers on safety and health aspects of chemicals handling.
- 65. Occupational health surveillance of the workers shall be done and its records shall be maintained. Pre-employment and

MEANING CHENTARY

State Level Enviries registrat Pollution Control Board, "Paryavaran Bhavan" Sector-10 A, Gandhinagar-382010 Page 3 of 5 Impact Assessment Authority Phone No.:- (079) 232-32152,232-41514 Fax No.:- (079) 232-22784

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- periodical medical examination for all the workers shall be undertaken as per the Factories Act & Rules.
- 56. Transportation of hazardous chemicals shall be done as per the provisions of the Motor Vehicle Act & Rules.
- 57. The company shall implement all preventive and mitigation measures suggested in the Risk Assessment Report.
- 58. Necessary permissions from various statutory authorities like PESO, Factory Inspectorate and others shall be obtained prior to commissioning of the project.

A. 6 NOISE:

59. 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 confirm to the standards prescribed under The Environment (Protection) Act, 1986 & Rules.

A. 7 CLEANER PRODUCTION AND WASTE MINIMISATION:

- 60. The unit shall undertake the Cleaner Production 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.
- 61. The company shall undertake various waste minimization measures including :
 - a) Metering and control of quantities of active ingredients to minimize waste.
 - b) Reuse of by-products from the process as raw materials or as raw materials substitutes.
 - c) Use of automated and close filling to minimize spillages.
 - d) Use of close feed system into batch reactors.
 - Venting equipment through vapour recovery system. e)
 - Use of high pressure hoses for cleaning to reduce wastewater generation. f)
 - g) Recycling of washes to subsequent batches.
 - h) Recycling of steam condensate
 - Sweeping / mopping of floor instead of floor washing to avoid effluent generation. i)
 - Regular preventive maintenance for avoiding leakage, spillage etc.

A. 8 GREEN BELT AND OTHER PLANTATION:

62. 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:

- 63. 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.
- 64. All the recommendations / commitments made in the EIA report of the project prepared by M/s: Bhagwati Enviro Care Pvt. Ltd., Ahmedabad and submitted vide letter no. NIL dated 21/03/2015 shall be implemented in letter and spirit.
- 65. The project authorities must strictly adhere to the stipulations made by the Gujarat Pollution Control Board (GPCB), State Government and any statutory authority.
- 66. During material transfer, spillages shall be avoided and garland drain be constructed to avoid mixing of accidental spillages with domestic wastewater or storm water.
- 67. Pucca flooring / impervious layer shall be provided in the work areas, chemical storage areas and chemical handling areas to minimize soil contamination.
- 68. Leakages from the pipes, pumps, shall be minimal and if occurs, shall be arrested promptly.
- 69. 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.
- 70. 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 and Other Wastes (Management and Transboundary Movement) Rules 2016 and the Public Liability Insurance Act, 1991 along with their amendments and rules.
- 71. The company shall undertake socio-economic developmental / community welfare activities as per the CSR Rules 2014.
- 72. The project proponent shall comply all the conditions mentioned in "The Companies (Corporate Social Responsibility Policy) Rules, 2014" and its amendments from time to time in a letter and spirit.
- 73. The project management shall ensure that unit complies with all the environment protection measures, risk mitigation measures and safeguards recommended in the EMP report and Risk Assessment study report as well as proposed by project proponent.
- 74. 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.
- 75. 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/

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- 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.
- 76. 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.
- 77. 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.
- 78. 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.
- 79. The project authorities shall also adhere to the stipulations made by the Gujarat Pollution Control Board.
- 80. The SEIAA may revoke or suspend the clearance, if implementation of any of the above conditions is not found satisfactory.
- 81. 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.
- 82. 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.
- 83. This environmental clearance is valid for seven years from the date of issue.
- 84. 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 singerel

(Dr. GAURAV DAHIYA, IAS) Member Secretary

Issued to:

Mr. Vishal K Shankhavara M/s. Nira Life Sciences Pvt. Ltd. 21, Brahmaniya Para, Nr. Radhika Print, Pedak Road, Rajkot-360003.

Copy to:-

- 1. The Secretary, SEAC, C/O. G.P.C.B. Gandhinagar 382010.
- 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

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