



State Level Environment Impact Assessment Authority (SEIAA)

Andhra Pradesh

Ministry of Environment, Forests & Climate Change

Government of India

D.No.33-26-14 D/2, Near Sunrise Hospital, Pushpa Hotel Centre,
Chalamavari Street, Kasturibaipet, Vijayawada

REGD.POST WITH ACK.DUE

Order No. SEIAA/AP/KRI/IND/07/2017/354 -

Dt:17.05.2018

Sub: SEIAA, A.P. – M/s. Dinakara Life Sciences Pvt Ltd. (Formerly known as Khem Krazy Labs Pvt. Ltd.) at Plot No: 80 to 85, Industrial Park Jaggaiahpet, Krishna District -Environmental Clearance - Expansion- Issued - Reg.

- I. This has reference to your EC application submitted through online on 04.07.2017 and EIA report submitted on 14.03.2018, seeking Environmental Clearance for manufacturing of **Bulk Drug & Bulk Drug Intermediates** in the name of **M/s. Dinakara Life Sciences Pvt Ltd. (Formerly known as Khem Krazy Labs Pvt. Ltd.) at Plot No: 80 to 85, Industrial Park Jaggaiahpet, Krishna District**. The total area of the site is 6699 Sq.m. The total cost of the project is Rs.4.60 Crores and the production capacity of the project is as following:

List of Existing Products and Quantities:

S. No.	Name of The Product	Quantity
1.	2-(2-(3(s)-(3-(2-(7-Chloro-2 quinolinyl) ethenyl) Phenyl)-3- hydroxy propyl) phenyl)2-proponal	0.24 Tons/Annum
2.	2-Bromo butane	12.0 Tons /Annum
3.	4-Chloro-1-hydroxy butane sulphonic acid sodium salt (CBA)	6.0 Tons/Annum
4.	4-Hydrozino-N-Methyl benzene methanesulphonamide Hydro chloride	6.0 Tons/Annum
5.	1-(mercapto methyl) cyclopropane acetic acid	0.12 Tons/Annum
Total		24.36 Tons/annum

Products and Quantities after expansion:

S. No.	Products Name	CAS Number	Capacity TPM
1	Bupropion Hydrochloride	31677-93-7	2
2	Clopidogrel Bisulphate	135046-48-9	3

3	2,4-Difluoro-2-(1h- 1,2,4-Triazole-1-Yl) Acetophenone (DFTA)	86404-63-9	10
4	Fluconazole	86386-73-4	4
5	Itraconazole	84625-61-6	3
6	Ketoconazole	65277-42-1	3
7	Levocetirizine Di hydrochloride	130018-77-8	1
8	Minoxidil	38304-91-5	1
9	Ziprasidone Hydrochloride	138982-67-9	2
10	Irbesartan	138402-11-6	3
11	Telmisartan	144701-48-4	3
12	Carisoprodol	78-44-4	3
13	Simvastatin	79902-63-9	3
14	Quetiapine Fumarate	111974-72-2	3
15	Rivaroxaban	366789-02-8	1
16	Memantine HCl	41100-52-1	1
17	Cinacalcet Hydrochloride	364782-34-3	1
	Total (Worst combination of any 4 Products with production capacity of 20 TPM at any given point of time)		20 TPM (240 TPA)
Note: Industry proposes to manufacture either Drug (Mentioned above Drugs) or Drug intermediates of particular Drug, without increasing the product production capacity of 20 TPM.			

The proposal has been examined and processed in accordance with EIA Notification, 2006 and its amendments thereof. The State Level Expert Appraisal Committee (SEAC) examined the application in its meetings held on **07.04.2018**. The representative of the project proponent and their Consultant M/s. Rightsource Industrial Solutions Pvt. Ltd., have attended the meeting and presented their case. The committee noted that the TOR was issued on 14.08.2017 and final EIA report submitted on 14.03.2018 with TOR & additional compliance reports, for the proposed expansion of Bulk Drugs Intermediates unit. This unit is located in the notified industrial area i.e., IDA, Jaggaiahpet (V)& (M), Krishna District. The proposed project falls under Item 5(f) of the schedule of the EIA Notification 2006- Synthetic organic chemicals industry (dyes & dye intermediates & bulk drug and intermediates) and the exemption of public consultation, as provided for under Para 7(i) III. Stage (3)(i)(b) of EIA Notification, 2006. The Committee after detailed discussions recommended for issue the **Environmental Clearance (EC)** to the proposed expansion of Bulk Drugs & Bulk drug Intermediates from 2,030 kg/month to 20,000 kg/month, by stipulating the standard conditions and other condition that industry shall install appropriate pollution control system to achieve Zero Liquid Discharge (ZLD). The State Level Environment Impact Assessment Authority (SEIAA), in its meeting held on **24.04.2018** examined the proposal and the recommendations of SEAC and decided to issue Environmental Clearance to the project as recommended by the earlier SEAC. The SEIAA, A.P hereby **accords prior Environmental Clearance to the project** as mentioned at Para no. I

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under the provisions of the EIA Notification 2006 and its subsequent amendments issued under Environment (Protection) Act, 1986 subject to implementation of the following specific and general conditions:

A. Special Conditions:

- i. The industry shall install appropriate pollution control system to achieve Zero Liquid Discharge (ZLD).
- ii. The industry shall segregate effluents into different streams i.e. High COD and Low TDS, Low COD and High TDS, Low COD and Low TDS.
- iii. The industry shall develop waste factors for different streams of effluents and solid waste.
- iv. The industry shall provide two stage scrubbing system to control process emissions.
- v. The industry shall provide solvent recovery system.
- vi. The industry shall provide hazardous waste container (drums) cleaning/washing system.
- vii. The industry shall provide mass flow meter to measure quantity of steam consumed for MEE system.
- viii. The industry shall provide magnetic tamper proof flow meters to measure quantity of different streams of effluents generated and routed through the treatment systems.
- ix. The industry shall provide steam stripping system to handle volatile matter in the effluents.
- x. The industry shall send hazardous waste to the authorized cement industries/ TSDF/ authorized recyclers by properly maintaining the system.

B Specific Conditions:

a) Air pollution:

- I. The emissions from the coal fired Boiler of capacity 2.0 TPH (Existing) & proposed 1.0 TPH Boiler, shall be routed through multi cone cyclones followed by a stack of height 30 m. The concentration of particulates in the emission shall not exceed 115 mg/Nm^3 . Sampling Port with removable dummy of not less than 15cm diameter in the stack at a distance of 8 times the diameter of the stack from the nearest constraint such as bends etc., shall be provided to monitor stack emissions. Adequate stack height shall be provided for existing D.G. Sets 1 x 125 KVA & proposed D.G. Set 1 x 280 KVA as per CPCB norms.
- II. The process emissions containing HCl and NH_3 shall be routed through two stages scrubber system. Scrubbed liquid shall be treated and reused or subjected to MEE.
- III. Necessary measures shall be taken to control odour as far as possible. Sub coolers for brine circulation shall be installed to reduce solvent evaporation losses into the atmosphere. All the solvent storage tanks shall be connected to vent condensers with chilled water circulation to minimize the solvent loss. The proponent shall install VOC meter in the plant to monitor continuously the VOC emissions with recording facility.

- IV. The solvents shall be recovered by installing fractional distillation columns. The recovered solvents shall be reused in the process or sold to recyclers authorized by APPCB. The volatile vapours generated during process shall be routed through condensers and the condensate shall be reused in the plant.
- V. The area of the greenbelt shall not be less than 33% of the total area of the site. Greenbelt with tall growing trees shall be developed along the boundary of the site.
- VI. Raw materials shall be transported in covered trucks. Raw materials shall be stored under sheds. All the belt conveyors shall be covered with G.I. sheets. Appropriate dust suppression system shall be provided all around the stockpiles and conveyor system. All the roads in the plant area shall be asphalted / concreted and water shall be sprinkled to suppress the dust.
- VII. Fugitive emissions from storage tanks will be avoided by providing air condensers.
- VIII. Ambient air quality including ambient noise levels must not exceed the standards stipulated under Notification dt. 16.11.2009 issued by the MOEF&CC,GOI. Monitoring of ambient air quality and stack emissions shall be carried out regularly in consultation with APPCB. Data on ambient air quality should be regularly submitted to the Ministry including its Regional Office located at Chennai and the State Pollution Control Board/ Central Pollution Control Board once in six months.

b) Water Pollution:

- i The total water requirement after expansion shall not exceed 76.72 KLD. Quantity of water used for Process is 17.22 KLD, washings -2 KLD, Boiler Makeup -17.50 KLD, cooling tower - 31 KLD, Scrubbing System-3 KLD, Domestic purposes - 3 KLD & for Development of greenbelt - 3 KLD.
- ii The total waste water generated is 30.79 KLD. Out of that, 18.79 KLD (HTDS - 11.03 KLD & LTDS - 7.76 KLD) is from Process; 2 KLD (LTDS) is from washings; 2.5 KLD (LTDS) is from Boiler blow down; 4 KLD (LTDS) is from cooling towers blow down; 1 KLD (HTDS) is from Scrubbing system; 2.5 KLD (LTDS) is from Domestic section. Total quantity of HTDS effluent is 12.03 KLD and LTDS effluent is 18.76 KLD.
- iii Zero discharge concepts shall be adopted. High COD & Low TDS shall be sent to incinerator, Low COD & Low TDS shall be sent to conventional ETP and the Low COD & High TDS effluents are routed through Stripper with scrubber followed by MEE and rejects of MEE shall be sent to ATFD. The condensate of the MEE shall be sent to RO. The permeate from the RO plant shall be re-used in the plant and rejects to MEE. The domestic waste water shall be disposed into the septic tank followed by soak pit.
- iv The proponent shall provide separate storm water drains and harvest the rainwater from the rooftops to recharge the ground water.

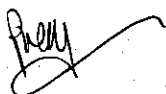


c) Solid Waste :

- i. Hazardous waste generated from the industry such as organic residue, salts, spent solvents waste oils, used oils etc., shall be disposed as per the Hazardous and other Wastes (Management and Tran boundary movement) Rules, 2016 and its amendments thereof.
- ii. The Inorganic Solid Waste-112 kg/day is to be disposed to TSDF; Organic residues-327 kg/day is to be disposed to TSDF/Authorised Cement Industry; MEE Salts-800 kg/day is to be disposed to TSDF; Organic evaporative liquid (from MEE Stripper) – 300 kg/day is to be disposed to Authorized Cement Industries; Spent Carbon-49 kg/day is to be sent to TSDF/Authorized Cement Industry; Solvent distillation residue – 467 kg/day; ETP Sludge-100 kg/day is to be disposed to TSDF, Boiler Ash-4200 kg/day is to be disposed to brick manufacturers; Detoxified Container-150 Nos/Month is to be disposed to traders after Detoxification; Waste Oil & Grease-200 Ltrs/Annum is to be disposed to Authorized recycler. Used Lead acid Batteries-4 Nos/Annum is to be returned to manufacturer/dealer on buy back basis for new batteries.

B. General Conditions:

- i. **This order is valid for a period of 7 years.**
- ii. "Consent for Establishment" shall be obtained from Andhra Pradesh Pollution Control Board under Air and Water Act before the start of any activity / construction work at site.
- iii. Provision shall be made for the housing of the construction labour within the site with all necessary infrastructure and facilities such as safe drinking water, fuel for cooking, mobile toilets, mobile STP, medical health care, crèche etc., The housing may be in the form of temporary structures to be removed after the completion of the project. The safe disposal of wastewater and solid wastes generated during the construction phase should be ensured.
- iv. No change in the process technology and scope of working should be made without prior approval of the SEIAA, A.P. No further expansion or modifications in the plant shall be carried out without prior approval of the SEIAA, AP/ MOEF&CC, GoI, New Delhi, as applicable.
- v. The proponent shall submit half-yearly compliance reports in respect of the terms and conditions stipulated in this order in hard and soft copies to the SEIAA on 1st June and 1st December of each calendar year.
- vi. Four ambient air quality-monitoring stations should be established in the core zone as well as in the buffer zone for RSPM, SPM, PM₁₀, PM_{2.5}, SO₂, NO_x, Ammonia, VOCs monitoring. Location of the stations should be decided based on the meteorological data, topographical features and environmentally and ecologically sensitive targets and frequency of monitoring should be undertaken in consultation with the State Pollution Control Board.



- vii. Data on ambient air quality (RPM, SPM, PM₁₀, PM_{2.5}, SO₂, NO_x, Ammonia, VOCs) should be regularly submitted to the Ministry including its Regional Office located at Bangalore and the State Pollution Control Board/ Central Pollution Control Board once in six months.
- viii. Personnel working in dusty areas should wear protective respiratory devices and they should also be provided with adequate training and information on safety and health aspects.
- ix. Occupational health surveillance program of the workers should be undertaken periodically to observe any contraindications due to exposure to dust and take corrective measures, if needed.
- x. A separate environmental management cell with suitable qualified personnel should be set-up under the control of a Senior Executive, who will report directly to the Head of the Organization.
- xi. The funds earmarked for environmental protection measures (**Capital cost of Rs.57 lakhs & Recurring cost of Rs.17 Lakhs/annum**) should be kept in separate account and should not be diverted for other purpose. Year wise expenditure should be reported to the SEIAA, Ministry and its Regional Office located at Bangalore.
- xii. The Regional Office of MOEF&CC located at Chennai monitor compliance of the stipulated conditions. The project authorities should extend full cooperation to the officer(s) of the Regional Office by furnishing the requisite data/information/monitoring reports.
- xiii. The project proponent shall submit the copies of the environmental clearance to the Heads of local bodies, Panchayats and Municipal Bodies in addition to the relevant offices of the Government who in turn has to display the same for 30 days from the date of receipt.
- xiv. The project authorities should advertise at least in two local newspapers widely circulated, one of which shall be in the vernacular language of the locality concerned, within 7 days of the issue of the clearance letter informing that the project has been accorded environmental clearance and a copy of the clearance letter is available with the State Pollution Control Board and SEIAA, A.P. This order shall be displayed in the website of the project proponent.
- xv. The SEIAA or any other competent authority may alter/modify the above conditions or stipulate any further condition in the interest of environment protection.
- xvi. 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.
- xvii. The company shall undertake eco-development measures including community welfare measures in the project area.
- xviii. The proponent shall obtain all other mandatory clearances from respective departments.



- xix. Concealing the factual data or 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.
- xx. The SEIAA may revoke or suspend the order, if implementation of any of the above conditions is not satisfactory. The SEIAA reserves the right to alter/modify the above conditions or stipulate any further condition in the interest of environment protection.
- xxi. The above conditions will be enforced inter-alia, under the provisions of the Water (Prevention & Control of Pollution) Act, 1974, the Air (Prevention & Control of Pollution) Act, 1981, the Environment (Protection) Act, 1986 and the Public Liability Insurance Act, 1991 along with their amendments and rules.

Sd/-
**MEMBER SECRETARY,
SEIAA, A.P.**

Sd/-
**MEMBER,
SEIAA, A.P.**

Sd/-
**CHAIRMAN,
SEIAA, A.P.**


To

M/s. Dinakara Life Sciences Pvt Ltd,
Sri D. Nageswara Rao, Director,
Plot No.237, Kalyani Nagar,
S.R.Nagar, Hyderabad- 500038.
Ph.No.9951530245

Copy to:

1. The Chairman, SEAC, A.P. for kind information.
2. The Member Secretary, APPCB for kind information.
3. The EE, RO: Vijayawada, APPCB for information.
4. The Regional Officer, MOEF&CC, GOI, Chennai for kind information.
5. The Secretary, MOEF&CC, GOI New Delhi for kind information.
6. Monitoring cell, MoEF&CC, GOI, New Delhi for kind information.

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SENIOR ENVIRONMENTAL ENGINEER (EC)

