



भारत सरकार  
पर्यावरण एवं वन मंत्रालय  
Government of India  
Ministry of Environment & Forests  
(IA Division)

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F. No. J-11011/1159/2007-IA-II(I)

Dated : June 10, 2008

To,

The General Manager  
M/s Divi's Laboratories Ltd. Unit-1  
Lingojigudem (V), Choutuppal (M)  
Nalgonda District,  
Andhra Pradesh – 508 252

**Subject : Expansion of Bulk drug unit (Change in Product Mix) at Mandal Choutuppal, District Nalgonda, Andhra Pradesh by M/s Divi's Laboratories Ltd, Unit-1 – Environmental Clearance regd.**

Sir,

This has reference to your letter no. nil dated 27.10.2007 along with application in Form – 1, pre-feasibility report and subsequent communication dated 11<sup>th</sup> February, 2008 seeking environmental clearance for the above project under the Environment Impact Assessment Notification, 2006.

2.0 The Ministry of Environment and Forests has examined the proposal for expansion of Bulk drug unit along with the change in the product mix in the existing plant premises by M/s Divi's Laboratories Limited, Unit -1 in District Nalgonda in Andhra Pradesh. The expansion will be carried out in the existing plant premises for which an area of 500 acres has been acquired. It is noted that presently the unit is manufacturing 16 products with production capacity of 497.5 MTPA. It is proposed to manufacture 60 products with production capacity of 2235.67 MTPA. At any time a maximum of 16 products out of 60 proposed products will be manufactured of which 6 are dedicated and 10 on campaign basis. A list of products along with the production capacity to be manufactured are given at annexure.

3.0. It is noted that water requirement will be 1200 m<sup>3</sup>/d of which 480 m<sup>3</sup>/d will be met from the ground water source as makeup water and 720 from the treated waste water. Permission for drawal of ground water has been obtained on 02.02.2005 from the State Government authority. About 1080 m<sup>3</sup>/d of effluent will be generated. The low TDS and domestic effluent will be treated in ETP and RO. The treated waste water will be used for green belt development. High TDS wastewater will be evaporated in multi-effect evaporators (MEE) and condensate will be reused for cooling purpose etc. The rejects from RO Plant will be treated in MEE and salts will be sent to TSDF. Cyclones, dust collectors and bag filters will be provided to control particulate emissions. Process emissions in the form of HCl, NH<sub>3</sub> and SO<sub>2</sub> will be scrubbed with scrubber. Vent condensers will be provided to solvent storage tanks to trap the vapours. Incinerator is provided with scrubber and stack of 40 m for proper dispersion of emissions. It is proposed to install 16 TPH FBC Boiler.

4.0. The Semi solid waste generated will be incinerated in incinerator and incinerator ash will be disposed off in TSD. Residual wastes from process or utilities will be either sent to SLF or incinerated. Spent solvents will be recovered. Process residues and distillation bottom residue will be sent to incinerator. Spent carbon, forced evaporation salts, ETP sludge, incineration ash will be sent to TSD. Sewage and ETP sludge will be sent to TSD at Dundigal. All the hazardous materials will be incinerated or sent to secured land fill for disposal. Coal ash will be provided to brick manufacturers. Spent solvent will be recovered within the plant premises. Mixed spent solvent and spent acids will be provided to the recyclers. A new incinerator as per the CPCB norms will be installed during expansion of the project. Cost of expansion project is Rs. 15.0 Crore.

5.0. The synthetic organic chemicals manufacturing units are listed at serial no. 5(f) of schedule of EIA Notification, 2006 and categorized under "A" or "B" category depending upon the location of the plant outside or inside the notified industrial area. In the instant case, the plant is located outside the industrial area and is category "A" project. The Expert Appraisal Committee(I) in the 81<sup>st</sup> meeting held on 12-14<sup>th</sup> May, 2008 exempted the project from the preparation of EIA/EMP report and public hearing as per section 7(ii) of EIA Notification, 2006.

6.0 Based on the information submitted by the Project Authorities, the Ministry of Environment and Forests hereby accords the environmental clearance to the above project under the provisions of EIA Notification dated 14<sup>th</sup> September, 2006 subject to compliance of the following specific and general conditions:

**A SPECIFIC CONDITIONS:**

- i. The effluent generated shall be segregated into low TDS and high TDS streams. The high TDS stream (100m<sup>3</sup>/d) will be forced evaporated in the Multiple Effect Evaporator (MEE). The low TDS stream from process, floor washings and reactor washings (150 m<sup>3</sup>/d) will be treated in the ETP followed by RO treatment. The effluent from the boiler (148 m<sup>3</sup>/d), Cooling Tower (400 m<sup>3</sup>/d) and DM / Softener (100 m<sup>3</sup>/d) will be sent to RO. The permeates from the RO will be recycled and rejects will be sent to Multiple Effect Evaporator. The scrubbed effluent (20 m<sup>3</sup>/d) from incinerator will be evaporated in the MEE. The domestic effluent (162 m<sup>3</sup>/d) will be treated in the ETP followed by RO treatment. The treated effluent will be used for green belt development.
- ii. The process emissions in the form of HCl, NH<sub>3</sub> and SO<sub>2</sub> shall be scrubbed with scrubber and emissions shall meet the prescribed standards. A hood with a dedicated scrubber shall be provided to scrub the bromine emissions.
- iii. The project authorities shall provide the chilled brine solution in secondary condenser for condensation of the VOCs and ensure that the solvent recovery shall not be less than 95%. The solvents shall be recovered from the reactors, boilers, Wiped Film Evaporator and fractional distillation columns.
- iv. The company shall provide the monitoring arrangement with vents and regular monitoring shall be carried out and reports submitted to the SPCB, CPCB and Ministry's Regional Office at Bangalore

- v. To prevent solvent loss, following measures shall be taken :
- a. Reactor shall be connected to chilled brine condenser system
  - b. Reactor and solvent handling pump shall have mechanical seals to prevent leakages.
  - c. The condensers shall be provided with sufficient HTA and residence time so as to achieve more than 95% recovery
  - d. Solvents shall be stored in a separate space specified with all safety measures.
  - e. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.
  - f. Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses.
- vi. The process emissions VOCs and particulate matter from various units shall conform to the standards prescribed by the concerned authorities from time to time. At no time, the emission levels shall go beyond the stipulated standards. In the event of failure of pollution control system(s) adopted by the unit, the unit shall be immediately put out of operation and shall not be restarted until the desired efficiency has been achieved.
- vii. Fugitive emissions in the work zone environment, product, raw materials storage area etc. shall be regularly monitored. The emissions shall conform to the limits imposed by APCCB.
- viii. For control of fugitive emission and VOCs following steps shall be followed :
- a. Closed handling system shall be provided for chemicals
  - b. Reflux condenser shall be provided over reducer
  - c. Solvent handling pump shall be provided with mechanical seals to prevent leakages
  - d. System of leak detection and repair of pump/pipeline based on preventive maintenance.
  - e. Solvent shall be taken from underground storage tanks to reactors through closed pipeline. Storage tanks shall be vented through trap receiver and condenser operated on chilled water.
- ix. During transfer of materials, spillages shall be avoided and garland drains be constructed to avoid mixing of accidental spillages with domestic waste and storm drains.
- x. The project authorities shall develop greenbelt in 202.3 Acre project area as per the guidelines of CPCB to mitigate the effect of fugitive emission.
- xi. Adequate financial provision shall be made in the budget of the project for implementation of the above suggested environmental safeguards. Fund so earmarked shall not be diverted for any other purposes.
- xii. Occupational health surveillance of the workers shall be done on a regular basis and records maintained as per the Factories Act.
- xiii. The company shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling.

**B. GENERAL CONDITIONS**

- i. The project authorities shall strictly adhere to the stipulations of the SPCB/state government or any statutory body.
- ii. No further expansion or modifications in the plant shall be carried out without prior approval of the Ministry of Environment and Forests. In case of deviations or alterations in the project proposal from those submitted to this Ministry for clearance, a fresh reference shall be made to the Ministry to assess the adequacy of conditions imposed and to add additional environmental protection measures required, if any.
- iii. The project authorities shall strictly comply with the rules and regulations under Manufacture, Storage and Import of Hazardous Chemicals Rules, 1989 as amended. Authorization from the SPCB shall be obtained for collection, treatment, storage, and disposal of hazardous wastes.
- iv. Ambient air quality monitoring stations shall be set up in the downwind direction as well as where maximum ground level concentration are anticipated in consultation with the State Pollution Control Board.
- v. For control of process emissions, stacks of appropriate height as per the Central Pollution Control Board guidelines shall be provided. The scrubbed water shall be sent to ETP for further treatment.
- vi. The company shall undertake following Waste Minimization measures :-
  - i. Metering of quantities of active ingredients to minimize waste.
  - ii. Reuse of by-products from the process as raw materials or as raw material substitutes in other processes.
  - iii. Maximizing recoveries
  - iv. Use of automated material transfer system to minimize spillage.
  - v. Use of "Closed Feed" system into batch reactors.
- vii. The project authorities must strictly comply with the rules and regulations with regard to handling and disposal of hazardous wastes in accordance with the Hazardous Wastes (Management and Handling) Rules, 2003. Authorization from the SPCB shall be obtained for collections/treatment/ storage/disposal of hazardous wastes.
- viii. The overall noise levels in and around the plant area shall be kept well within the standards (85 dBA) by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all sources of noise generation. The ambient noise levels shall conform to the standards prescribed under Environment (Protection) Act, 1986 Rules, 1989 viz. 75 dBA (day time) and 70 dBA (night time).
- ix. A separate Environmental Management Cell equipped with full fledged laboratory facilities shall be set up to carry out the environmental management and monitoring functions.
- x. The project authorities shall provide rainwater harvesting system and ground water recharge.

- xi. The implementation of the project vis-à-vis environmental action plans shall be monitored by Ministry's Regional Office /SPCB / CPCB. A six monthly compliance status report shall be submitted to monitoring agencies.
- xii. The project proponent shall inform the public that the project has been accorded environmental clearance by the Ministry and copies of the clearance letter are available with the SPCB and may also be seen at Website of the Ministry at <http://envfor.nic.in>. This shall be advertised within seven days from the date of issue of the clearance letter, at least in two local newspapers that are widely circulated in the region of which one shall be in the vernacular language of the locality concerned and a copy of the same shall be forwarded to the Ministry's Regional Office.
- xiii. The project authorities shall inform the Regional Office as well as the Ministry, the date of financial closure and final approval of the project by the concerned authorities and the date of start of the project.

7.0 The Ministry may revoke or suspend the clearance, if implementation of any of the above conditions is not satisfactory.

8.0 The Ministry reserves the right to stipulate additional conditions, if found necessary. The company in a time bound manner shall implement these conditions.

8.0 Any appeal against this environmental clearance shall lie with the National Environment Appellate Authority, if preferred within a period of 30 days as prescribed under Section 11 of the National Environment Appellate Authority Act, 1997.

9.0 The above conditions shall 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 and Handling) Rules, 2003 and the Public Liability Insurance Act, 1991 alongwith their amendments and rules.

  
(Dr. P L Ahujarai)  
Director

**Copy to :-**

1. The Secretary, State Deptt. of Environment, Government of Andhra Pradesh, Mantralaya, Hyderabad.
2. The Chairman, Central Pollution Control Board, Parivesh Bhavan, CBD-cum-Office Complex, East Arjun Nagar, Delhi-110032.
3. The Chairman, Andhra Pradesh State Pollution Control Board, Paryarana Bhawan, A-3, Industrial Area, Sanathnagar Hyderabad- 500 018 Andhra Pradesh.
4. The Chief Conservator of Forests (Central), Regional Office (SZ), Kendriya Sadan, IVth Floor, E&F Wing, 17<sup>th</sup> Main Road, Koramangala, Bangalore-560034.
5. Principal Chief Conservator of Forests (Wild Life), Government of Andhra Pradesh, Tulja Bhavan, M J Market, Hyderabad, Andhra Pradesh.
6. Monitoring Cell, Ministry of Environment and Forests, Paryavaran Bhavan, CGO Complex, New Delhi- 110003.
7. Guard file/Record file/Monitoring file.

  
(Dr. P L Ahujarai)  
Director

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## A LIST OF PROPOSED PRODUCTS

S. No	Name of the product	Production TPA
01	NAPROXEN	840
02	DEXTROMETHORPHON HBr	250
03	IOPAMIDOL	180
04	NABUMETONE	200
05	VALACYCLOVIR	150
06	LEVETIRACETAM	80
	<b>Sub total</b>	<b>1700</b>
07	5PHENYL HYDANTION	01
08	AWING	60
09	BWING	100
10	DIBOC	40
11	PQ CARBONATE	01
12	KETROLAC	01
13	PROGUNIL HCL	10
14	SULPHAZINE	20
15	CHLOROPRUGUNIL HCL	02
16	CYCLOPENTADECANOLIDE	10
17	O <sub>2</sub> CYCLOCYTIDINE HCL	02
18	LAMIVUDINE	01
19	SODIUM STIBO GLUCONATE	01
20	TAMSULOSIN HCL	0.1
21	ZOLPIDEM TARTRATE	02
22	QUETIAPINE	01
23	HOBT	01
24	ATAVAQUONE	10
25	CARVEDILOL	15
26	CME	40
27	PWS	12
28	TDZ	10
29	LAMOTRIGINE	40

*P. Ahujara*

S. No	Name of the product	Production TPA
30	GABAPENTIN	10
31	N-METHYL-3-ACETAMIDOACETOPHENONE	0.5
32	SITAMAQUINE TOSYLATE	0.07
33	MUSTARD ALCOHOL	01
34	MARCOUMAR	02
35	N-HYDROXY SUCCINIMIDE	05
36	TRYPEPTIDE	0.2
37	TOPIRAMATE	01
38	NIACIN	10
39	KETO ACID	01
40	RIZATRIPTAN	0.1
41	SIBUTRAMINE HYDROCHLORIDE MONOHYDRATE	0.5
42	ME ALCOHOL	01
43	FREE AMINE	40
44	RESIDRONATE SODIUM	0.5
45	DESLORDTADINE	03
46	Z-VALA	50
47	METHOXY MORPHINAN HCl	10
48	TELMISARTAN	4.5
49	FOSPHENYTIN SODIUM	01
50	SERTRALINE HCl	02
51	S-BINAP	01
52	LORATIDINE	02
53	LATANOPROST	0.1
54	NATEGLINIDE	0.1
55	VALSARTAN	02
56	OLMESARTAN MEDOXOMI	01
57	CANDESARTAN CILEXETIL	01
58	IRBESARTAN	01
59	LANSOPROZOLE	02
60	SB 223412	02
	<b>Sub Total</b>	<b>535.67</b>
	<b>Total</b>	<b>2235.67</b>

Note: At any given time 16 products will be manufactured, 6 products (S. No. 1 to 6) continuously every day and 10 products out of ( S. No. 7 to 60) on Campaign basis.

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*P. Ahyjeen*