

**COMPLIANCE REPORT OF CONDITIONS
MENTIONED IN ENVIRONMENTAL CLEARANCE
FOR THE PROJECT**

**Expansion of Manufacturing of Bulk Drug and Intermediates
from 12.85 TPM to 34.8658 TPM
(Period October 2020 to March 2021)**

By



**M/s. Vadivarhe Speciality Chemicals Ltd;
Gut No. 204, Nashik Mumbai Highway,
Taluka - Igatpuri, District - Nashik,
Pin Code - 422 403 State - Maharashtra**

Submitted by



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Brief About the Proposed Project

1. Proposed Project : Expansion of Bulk Drugs and Intermediates
2. Proposed Capacity : 12.85 TPM to 34.8658 TPM
(Expansion Project)
3. Type of Project : As per EIA Notification 2006
Category "A" 5 (f) Section
"Synthetic Organic Chemicals
Industry (Bulk Drugs and
Intermediates)
4. Location Details : Gut No. 204, Nashik-Mumbai
Highway, At Post – Wadivarhe,
Taluka - Igatpuri, District – Nashik,
State – Maharashtra Pin - 422 403
5. Land Area : The proposed expansion project will
be in the existing land area of
12,500 sq. mtr.
6. Project Proponent : M/s. Vadivarhe Speciality
Chemicals Ltd;
7. Name of the Project Proponent : Shri. Pramod Waman Gajare,
Director of the Company
8. Cost of the Proposed Project : 15 Crore (Existing 21 crore)
9. Environmental Clearance Granted : MoEF & CC New Delhi, EC Letter
dated 8th February 2021
file No. J- 11011/2016-IA (I)
Impact Assessment Division

Point-wise EC Compliance Status to various stipulations, terms and conditions laid down by Ministry of Environment Forest & Climate Change (MoFE & CC) New Delhi

Compliance Period October 2020 to March 2021 (EC Received on 8 th February 2021)		
Compliance Conditions		
Specific Conditions		
Sl. No.	Terms and Conditions	Compliance
i	The Bank guarantee shall be released after successful implantation of the Remediation Plan and Natural and Community Resources Augmentation Plan, and after recommendation by Regional Office of the Ministry, EAC and approval of the Regulatory Authority. In case of failure to complete the remediation plan within stipulated time line, the fresh bank guarantee shall be submitted.	The point is noted , we are abide of complying and implementing the remediation plan, natural and community resource augmentation plan submitted during the EAC Meeting of the proposed expansion project within the time frame for the release of BG submitted to the State Pollution Control Board. (Copy Attached)
ii	As proposed, Rs. 216.82 Lakhs towards Remediation plan and Natural and Community Resource Augmentation plan to be spend within a span of three years as per Annexure, whereas bank guarantee shall be for 5 years.	Agreed , as proposed Rs. 216.82 lakhs will spend towards remediation plan, natural and resource augmentation plan within a span of three years as per plan submitted (Attachment 1) and release of BG after 5 years. (final break up of 216.82 to be attached)
iii	Approval / permission of the CGWA / SGWA shall be obtained before drawing ground water for the project activities, if applicable. State Pollution Control Board (SPCB) concerned shall not issue Consent to Operate (CTO) till the project proponent obtains such permission.	<ul style="list-style-type: none"> Noted, however it is to be mentioned here that, the industry is drawing surface water for the existing project and will also be for proposed expansion project from Mukane Dam, for which permission for drawl of surface water is already taken from Irrigation Department for existing plant. (Attachment 2) and for proposed project permission is being processed for drawl of additional water. No ground water will be drawn for the proposed expansion project.
iv	Preventive measures to be taken to control ignition sources in bulk storage	<ul style="list-style-type: none"> All preventive measures are being taken to control ignition

	<p>area and fire protection system to be established above ground storage tanks. Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done.</p>	<p>sources in bulk storage area for the existing plant and fire protection system is in place storage tanks. Solvents are stored in a specified place with all safety measures.</p> <ul style="list-style-type: none"> • Adequate control measures are provided to detect fire and fight fires. • The major firefighting arrangement provided includes: 40 numbers of optical smoke detectors along with 8 numbers manual call points and 8 numbers hooters. • Fire Fighting Arrangements : Fire hydrant system consisting of 17 numbers of fire hydrants have been installed and 69 numbers of fire extinguishers consisting ABC, CO2 and Foam type are installed at various location of the premises. • Nitrogen Plant is provided for blanketing while transfer of flammable solvents. Training is provided to concern personnel for the operations. • Earthing is provided in all the electrical equipment wherever solvent handling is done. Same will done in proposed expansion project also if required. • Flame proof electrical fittings are used wherever solvent handling is done. We have also provided earth point identification for all over the plant location. We have also earth monitoring system for our solvent storage facility, and earth continuity meter at solvent loading and pumping system.
v	<p>Proper measures to be taken to prevent internal tank explosion. Chemicals that are water reactive needs to be separated</p>	<ul style="list-style-type: none"> • The company is taking proper measures and made arrangement to prevent internal tank / drums explosion. The following safety

	from chemicals that do not react with water.	<p>measures have been implemented in the solvent storage area in the existing plant :</p> <ol style="list-style-type: none"> 1. Gas detectors are available 2. Alarm system are in place 3. Fire hydrant system is available 4. Fire extinguishers are in place 5. Jumpers are in place at flange points 6. Earthing and bonding are in place <ul style="list-style-type: none"> • Following control measures are also implemented in the existing plant and will be continued in the proposed expansion project: <ol style="list-style-type: none"> 1. Fencing and No Smoking for prohibited area, warning signage are displayed in Hindi English and local language at prominent places. 2. Trainings are conducted to all personnel's involved / engaged in handling solvent activity. 3. PPE's are also provided. • Chemicals that are water reactive required in the proposed expansion project will be separated from other chemicals and stored in a safe and protected containers to avoid to react with water.
vi	Proper precautions to be taken to prevent inadvertent mixing of chemicals. Standard operating procedures to be strictly followed during handling of chemicals. Solvents shall be stored in a separate space specified with all safety measures.	Proper precautions are being taken in the existing plant and will be continued in the proposed expansion to prevent inadvertent mixing of chemicals and spillages. SoP's are adopting to prevent any mixing of chemicals and spillages during handling of chemicals and solvents. Separate storages are in place for chemicals and solvents with all safety measures and guideline. (Attachment 3)
vii	Risk assessment studies conducting 3 D modelling studies for identification of hazards, consequence analysis due to the accidental release of hazardous chemicals, quantification of risk based	Risk assessment studies conducting 3 D modeling studies for identification of hazard consequence analysis due to the accidental release of chemicals and quantification of risk based on failure

	on failure probability of equipment, mitigation measures to reduce risk and delineation of disaster management plan shall be undertaken and submitted to the Ministry within 3 months.	probabilities of equipments, mitigation measures to reduce risk and delineation of disaster management plan are carried out and report is already submitted to MoEF & CC. (Copy attached at Attachment 4)
viii	The company shall comply with all the environmental protection measures and safeguards proposed in the documents submitted to the Ministry. All the recommendations made in the EIA / EMP in respect of environmental management, and risk mitigation measures relating to the project shall be implemented.	Noted , and will comply as per the documents submitted and recommendation in EIA / EMP Report in respect of Environment Management and Risk Mitigation Measures related to the project.
ix	As already committed by the project proponent, Zero Liquid Discharge shall be ensured and no waste / treated water shall be discharged outside the premises. Treated effluent shall be reused in the process / utilities. Treated Industrial effluent shall not be used for gardening / greenbelt development / horticulture.	Agreed , it is ensured that zero liquid discharge will be achieved and no waste / treated effluent shall be discharged out-side the premises. The treated industrial effluent shall not be used for green belt development / gardening / horticulture. (The water balance diagram is attached at Attachment 5)
x	Continuous online (24x7) monitoring system for stack emissions shall be installed for measurement of flue gas discharge and the pollutants concentration, and the data to be transmitted to the CPCB and SPCB server. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel / drain carrying effluent within the premises.	Noted , continues online 24x7 monitoring system for stack emissions shall be installed for measurements of flue gas discharge and pollutant concentration and data will be transmitted to Central Pollution Control Board and State Pollution Control Board Server. For online continuous monitoring of effluent, the unit shall install web camera with night vision capability and flow meters in the channel / drain carrying effluent within the premises. The activity regarding installation of continues monitoring system will be carried out in consultation with the State Pollution Control Board.
xi	The storage of toxic / hazardous raw material shall be bare minimum with respect to quantity and inventory. Quantity and days of storage shall be submitted to the Regional Office of	Noted and will comply.

	Ministry and SPCB along with the compliance report.	
xii	Occupational Health Center for surveillance of the worker's health shall be set up. The health data shall be used in deploying the duties of the workers. All workers & employees shall be provided with required safety kits / mask for personal protection.	Occupational Health Center already existing in the company , the company is regularly making the health check-ups of the workers and employees (Attachment 6) and accordingly deployment of the duties of the workers / employees is made in the company. The company is providing PPE's to the workers and the employees.
xiii	Training shall be imparted to all employees on safety and health aspects of chemicals handling. Safety and visual reality training shall be provided to employees.	Agreed and will comply , however the company is regularly and periodically arranging induction training to their workers and employees those who are engaged in chemicals / solvents handling for safety and health aspects along with the visual trainings. Pre-employment and periodic employment health checkup and health record is being maintained by the company. (Attachment 7)
xiv	The unit shall make the arrangement for protection of possible fire hazards during manufacturing process in material handling. Fire-fighting system shall be as per the norms.	As mentioned in compliance of point no. IV, adequate fire control measures are in place for protecting the possible fire hazardous during the manufacturing process in the material handling. Firefighting system is already available in the company as mentioned earlier at various locations in the premises.
xv	Solvent management shall be carried out as follows: (a) Reactor shall be connected to chilled brine condenser system (b) Reactor and solvent handling pump shall have mechanical seals to prevent leakages (c) Solvents shall be stored in a separate space specified with all safety measures (d) Proper earthing shall be provided in all the electrical equipment wherever solvent handling is done (e) Entire plant shall be flame proof. The solvent storage tanks shall be provided with breather valve to prevent losses	Noted , and all these from (a) to (f) are in practice in the existing plant and will also be continued in the proposed expansion plant. (Attachment 8)

	(f) All the solvent storage tanks shall be connected with vent condensers with chilled brine circulation.	
xvi	Total fresh water requirement shall not exceed 37.92 cum/day, proposed to be met from Mukane Dam water supply through tankers. Necessary permission in this regards shall be obtained from the concerned regulatory authority, and renewed from time to time.	Noted and agreed , the permission for water requirement for the existing plant is already taken from the irrigation department copy attached (Attachment 9) and the permission for additional water requirement for the proposed expansion is in process. The total fresh water requirement will not exceed 37.92 cum/day.
xvii	Storm water from the roof top shall be channelized through pipes to the storage tank constructed for harvesting of rain water in the premises and harvested water shall be used for various industrial processes in the unit. No recharge shall be permitted within the premises. Process effluent / any waste water shall not be allowed to mix with storm water.	Noted , however it is to be mentioned here that storm water drains and collection tank are already constructed. The rain water harvested is being used for flushing and washing to save raw / treated water.
xviii	The company shall undertake waste minimization measures as below (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 material substitutes in other processes (c) Use of automated filling to minimize spillage (d) Use of Close Feed system into batch reactors (e) Venting equipment through vapor recovery system (f) Use of high pressure hoses for equipment clearing to reduce waste water generation	Noted and agreed , a. Waste minimization is our top most priority. It may be noted that there is no active ingredients, but all the raw materials are added through pipelines, so that spillages and contamination of area / soil or other means of waste generation are minimum. b. There will be by-products generation from the proposed manufacturing of drugs and intermediates however these by-products will not be reused in the other manufacturing processes as it is not required and will be sold to the authorized vendors. c. All the raw materials that are charged in the reactor will be through pipeline so there are negligible chances for spillages. d. Point noted, however closed feed system in batch reactors is already in practice in the existing

		<p>manufacturing and same practice will be adopted for manufacturing of the proposed products.</p> <p>e. Although vapor condensing system for recovery of solvent is already installed in the existing plant, new scrubber will be installed in the proposed expansion manufacturing to control vapors, if any.</p> <p>f. The company is already using high pressure hoses for equipment cleaning to reduce waste water generation in the existing project and same will be practiced in the proposed expansion project.</p> <p>These practices (a) to (f) are already being adopted by the company in the existing plant and will be continued in proposed expansion unit also. (Attachment 10)</p>
xix	<p>The green belt of at least 5-10 m width shall be developed in nearly 33% of the total project area, mainly along the plant periphery. Selection of plant species shall be as per the CPCB guidelines in consultation with the State Forest Department. Records of tree canopy shall be monitored through remote sensing map.</p>	<ul style="list-style-type: none"> • Plantation within the plant premises is already developed in 4,600 sq mtr (36.8%) area of the total plant area (12,500 sq mtr). • Additional plantation around periphery of the plot boundary is also being carried out (Number of plants 190) as per Central Pollution Control Board guidelines. Proper maintenance of the plantation is being conducted by the company with the help of forest officer. (Attachment 11)
xx	<p>As per the Ministry's OM dated 30/09/2020 superseding the OM dated 01/05/2021 regarding the Corporate Environmental Responsibility, and as per the action plan proposed by the project proponent to address the public hearing and socio-economic issues in the study area, the project proponent</p>	<ul style="list-style-type: none"> • Noted and will comply as per CER action plan proposed and also as per the ministry's OM dated 30/09/2020 to address the public hearing and socioeconomic issues in the study area. • The company will provide support for educational assistant,

	shall provide support for educational assistance, cleanliness and hygiene program to the schools, medical assistance, Plantation, Sanitation and waste management, drinking water facility in the nearby villages. The action plan shall be completed within three years as proposed. All the commitments made during public hearing shall be satisfactorily implemented.	cleanliness, and hygiene programs to the schools, medical assistance, plantation, sanitation, waste management, drinking water facility in nearby villages. <ul style="list-style-type: none"> The action plan given will be completed within 3 years. We ensure the satisfactory implementation of the commitments made during the public hearing.
xxi	A separate Environmental Management Cell (having qualified person with Environmental Science / Environmental Engineering / specialization in the project area) equipped with full-fledged laboratory facilities shall be set up to carry out the Environmental Management and Monitoring functions.	The company is having its Environment Management Cell and safety unit equipped with all the facilities related to the monitoring, analysis and manpower. (Attachment 12) . The management of the industry believes in conforming and maintaining the standard set up by the State Pollution Control Board, in totality. The organogram of EMC which is functional at M/s. Vadivarhe Speciality Chemicals Ltd; along with responsibilities are shown in (Attachment 13)
Compliance of other General Conditions		
i	No further expansion or modification in the plant, other than mentioned in the EIA Notification, 2006 and its amendments, shall be carried out without prior approval of the Ministry of Environment, Forest and Climate Change / SEIAA, as applicable. 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 / SEIAA, as applicable, to assess the adequacy of conditions imposed and to add addition environmental protection measures required, if any	Agreed and point is noted. The EC granted by MoEF & CC New Delhi on 08/02/2021 for the expansion of the product manufacturing from 12.85 TPM to 34.8658 TPM. The proposed expansion is to be carried out in the existing land area. Please see the attached EC Letter from MoEF & CC New Delhi at (Attachment 14) . We have already obtained CTE for the proposed expansion from MPCB (Attachment 15) and after issuing EC letter for the proposed expansion CTO of the proposed manufacturing products is in process from MPCB.
ii	The energy source for lighting purpose shall be preferably LED based, or advanced having preference in energy conservation and environment betterment.	<ul style="list-style-type: none"> Noted, the total power requirement will be 450 KVA. The main source of power is MSEDCL. Solar Electricity Generation Plant is installed at the factory premises for the

		<p>energy generation between 886 units to 1063 units per day and utilized for the production activity. Same will be practiced for the proposed expansion project.</p> <ul style="list-style-type: none"> • For lighting purpose as mentioned in the condition LED based or advanced having preference in energy conservation and environment betterment is in practice presently and will be continued further.
iii	<p>The overall noise levels in and around the plant area shall be kept well within the standards by providing noise control measures including acoustic hoods, silencers, enclosures etc. on all source of noise generation. The ambient noise levels shall conform to the standards prescribed under the Environment (Protection) Act, 1986 Rules, 1989 viz 75 dBA (day time) and 70 dBA (night time).</p>	<ul style="list-style-type: none"> • Noted and will Comply, we are regularly monitoring noise levels, in and around the plant area and found to be within the prescribed limit of Central Pollution Control Board for day and night time. However for noise control measure acoustic hoods, silencers and enclosures etc. will be provided at all the sources of noise generation. • We have made mandatory use of PPE's for all the workers working in the noise generating area and equipments. We have made the peripheral plantation to reduce / attenuate the noise effect to the surrounding area. (Attachment 16)
iv	<p>The company shall undertake all relevant measures for improving the socio-economic conditions of the surrounding area. CER activities shall be undertaken by involving local villages and administration and shall be implemented. The company shall undertake eco-developmental measures including community welfare measures in the project area for the overall improvement of the environment.</p>	<p>The point is noted and will comply, all the relevant measures will be taken-up for improving the socio-economic conditions of the surrounding. CER activities shall be undertaken and implemented by involving local villages and administration. The company shall undertake eco-developmental measures including community welfare measures in the project area for improving the environment.</p>

v	The company shall earmark sufficient funds towards capital cost and recurring cost per annum to implement the conditions stipulated by the Ministry of Environment, Forest and Climate Change as well as the State Government along with the implementation schedule for all the conditions stipulated herein. The funds so earmarked for environment management / pollution control measures shall not be diverted any other purpose.	Agreed and will comply.
vi	A copy of the clearance letter shall be sent by the project proponent to concerned Panchayat, Zilla Parishad / Municipal Corporation, Urban local Body and the local NGO, if any from whom suggestions / representations, if any were received while processing the proposal.	Complied (Attachment 17)
vii	The project proponent shall also submit six monthly reports on the status of compliance of the stipulated Environment Clearance conditions including results of monitored data (both in hard copies as well as by e-mail) to the respective Regional Office of MoEF&CC, the respective Zonal Office of CPCB and SPCB. A copy of Environmental Clearance and six monthly compliance status report shall be posted on the website of the company.	Noted and will comply
viii	The environmental statement for each financial year ending 31 st March in Form-V as is mandated shall be submitted to the concerned State	<ul style="list-style-type: none"> • Noted and will comply, we are regularly submitting Environment Statement for each financial year ending 31st March

	<p>Pollution Control Board as prescribed under the Environment (Protection) Rules, 1986, as amended subsequently, shall also be put on the website of the company along with the status of compliance of environment clearance condition and shall also be sent to the respective Regional Offices of MoEF & CC by e-mail.</p>	<p>in Form V to State Pollution Control Board.</p> <ul style="list-style-type: none"> The status of compliance of Environment Clearance condition shall also be submitted to Regional Office of the MoEF & CC through e-mail.
ix	<p>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 / Committee and may also be seen at Website of the Ministry and at https://parivesh.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 concerned Regional Office of the Ministry.</p>	<p>Complied (Attachment 18)</p>
x	<p>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 date of start of the project.</p>	<p>Noted, and will comply. However it is to be mentioned here that the existing facilities and infrastructure will be utilized for the proposed expansion project as per the requirement of the demand of the market.</p>
xi	<p>This Environmental clearance is granted subject to final outcome of Hon'ble Supreme Court of India, Hon'ble High Court, Hon'ble NGT and any other Court of Law, If any, as may be applicable to this project.</p>	<p>The point is noted.</p>