

Annex I

Comments

Part A – Duly made

Part B – Duly made

Section	Comments	Duly made	MEPA's replies to feedback by Amino Chemicals July 2007
			GENERAL COMMENT: 1. Kindly reply using this template, and submit your reply in a word document. 2. Kindly note that all your replies have to be part of the consolidated version of the IPPC application which will then be available to the public.
B1.1	OK.	✓	
B1.2	OK.	✓	
B1.3		✓	Site report: Following the letter sent to MIP, did MIP reply?  <i>No. We therefore have included our own site report of the state of the factory prior to our occupation based on well known facts and the MIP statement made. This is included in Ref. 000/AMINO</i>

			<p>Kindly submit an electronic version of the MIP report and the photograph.</p> <p><i>We are supplying eight copies of the required document in electronic format.</i></p> <p>Site map: OK. Provide the site plan in electronic version.</p> <p><i>We are supplying eight copies of the required document in electronic format.</i></p> <p>The site plan found in the right hand corner of the map needs to be extracted into A4 size.</p> <p><i>We are supplying eight copies of the required document in electronic format.</i></p>
B2.1	<p>1. Kindly provide more updated information, i.e.</p> <p>a. Are you still producing Fosinopril Sodium on an industrial basis?</p> <p>b. What is the production rate?</p> <p>c. Did you start producing Fexofenadine Hydrochloride and Losartan on an industrial scale? What is their production rate?</p> <p>d. Did you start producing something else?</p> <p>e. Do you have a more recent correspondence from the FDA, following a more recent inspection?</p>	✓	<p>1. a. OK b. OK c. OK. Since when have you been producing Fexofenadine Hydrochloride?</p> <p><i>Trial batches and development started 2001. Commercial operations started 2003.</i></p> <p>d. OK. Since when have you been producing Terbinafine?</p>

<p>2. The Site Master File is not relevant to question B1.3. But is relevant to question B2.1.</p> <p>3. Kindly provide a 24 hour contact telephone number.</p> <p>4. Total number of employees does not agree with the sub groupings given</p> <p>5. Questions on the Site Master File dated September 2003:</p> <p>a. Section 1.8 – i. Do you still have just one outside contractor? ii. Is it still Capital Pest Control?</p> <p>b. Kindly provide a summary of findings following an internal audit as mentioned in pg 13, and a list of actions taken.</p> <p>c. What type of training has been given to the employees?</p> <p>d. What happens to the brine produced by the RO plant (pg 24)?</p> <p>e. What happens to the discharge i.e condensed volatiles, from the scrubber tower?</p> <p>f. Where do the cleaning waters of the reactors go?</p> <p>g. Are the drains in the laboratory connected directly with the public sewers?</p> <p>h. How are the rejected materials managed? i.e. where do they go (pg 33)?</p>	<p><b><i>Trial batches and development started 2002. Commercial operations started 2004.</i></b></p> <p>e. Kindly submit the report from FDA that took place in the first quarter of 2007.</p> <p><b><i>We are submitting the FDA Report No. 483 which is strictly confidential (see Annex A). Not to be shown in public. We also include an alternative statement to this report, which may be used for public viewing.</i></b></p> <p>2. No reference to this question is found in your replies. Kindly amend IPPC application form part B and include reference to Site Master File in question B2.1.</p> <p><b><i>IPPC Application amended accordingly.</i></b></p> <p>3. OK</p> <p>4. OK</p> <p>5. a. i. OK ii. OK</p> <p>b. OK</p> <p>c. Kindly clarify the type of training given by</p>
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			<p>providing a brief description of the course content. May be you wish not to make public the list of names due to the Data Protection Act. Kindly indicate if you wish this data to be kept confidential, and not shown to the public during public consultation.</p> <p><i>Annex B includes the course details for the fire fighting courses provided on site Annex C is the boiler training course content and Annex D is the Amino Chemical's response regarding the GMP training.</i></p> <p>d. OK e. OK f. OK g. OK h. OK</p>
B2.2	<p>1. Kindly provide the HS code and the CAS no of the following raw materials which are found in 004/Amino.</p> <p>FEXO 7/P FOSINOPRIL ZPA6 FOSINOPRIL ZPA7 Benzimidazole</p> <p>2. What is the quantity used per year of solvents and other VOC containing compounds?</p> <p>3. Do any of your raw materials carry one or more of the</p>	✓	<p>1. OK</p> <p>2. OK. This qualifies you under LN 225 of 2001. Monitoring requirements are specified in this legislation. Also, the legislation (regulation 5(6)) requires that VOCs carrying certain risk phrases (such as R61) are substituted "as far as possible...by less harmful substances or preparations within the shortest possible time". Until / if not substituted, an emission limit value</p>



	<p>following risk phrases as a result of their VOC-content: R40, R45, R46, R49, R60, R61?</p>		<p>of 2mg/Nm<sup>3</sup> must be applied for discharges of these particular compounds if the mass flow rate is greater than or equal to 10g/h (regulation 5(7)).</p> <p>An emission limit value is also defined for discharges of halogenated VOCs carrying the risk phrase R40 (or R68) if the mass flow of these compounds is greater or equal to 100g/h (regulation 5(8)); these VOCs do not need to be substituted however.</p> <p>Kindly submit the mass flow rate of dichloromethane. (N.B. Mass flow refers to the sum of the compounds causing the said 'risk' labelling, and the ELV also refers to the mass sum of the individual compounds.)</p> <p><i>We use dichloromethane for the production of Perindopril Erbumine. The production method of this product is not the property of Amino Chemicals and we include a statement to this effect in Appendices D1a. We also include calculation statements for various chemicals as required.</i></p> <p>3. Ok. Does any of your raw materials carry the risk phrase of R 68?</p> <p><i>No</i></p>
B2.3	1. Do you make use of any other chilled solution in the	✓	1. Ok

<p>scrubbers, apart from water and NaOH? E.g do you make use of thermal oils?</p> <p>2. Provide a general mass balance of the process to indicate the consumption and emissions of VOCs, water to WWTP, waste process solid, waste solvents and waste water, in kg/day. Detailed calculations of the production of VOCs should be submitted. This should be based on the requirements of the Solvent directive – 1999/13/EC which is transposed in LN225/2001. These should include emissions from tank farm, from the condensers, (which are to have enough capacity to remove the vapours from the vent stream, and taking into consideration as well any forms of leakages), and scrubbers.</p> <p>3. Where are the unused/ recovered solvents stored?</p> <p>4. Is there any bunding?</p> <p>5. Apart from the spent solvents, do you store anything else, in the underground tanks?</p>	<p>2. Since deadline submitted in your reply to the requested submission was 3-4 months, can you thus, kindly provide the General Mass Balance of VOC?</p> <p><i>We advise that this is still in the process of being prepared, but will be completed by end 2007.</i></p> <p>3. Noted. Will these be also transferred to A 50 Factory Extension? <b>Yes</b></p> <p>4. Noted</p> <p>5. Noted.</p> <p>i. Kindly confirm that overall there are 7 underground tanks at the installation– 2 for spent solvents and 5 for pure, fresh solvents.</p> <p><b>Confirmed</b></p> <p>ii. Are these 7 underground tanks going to be removed from A61, and shifted to A50?</p> <p><b>No, these are additional to the existing ones.</b></p>
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<p>6. Do you have a boiler on site to generate the steam needed? What type of fuel is used for the boiler?</p> <p>7. Do you have cooling towers?</p> <p>8. Kindly provide technical details of the scrubbers, e.g technical data sheets.</p> <p><b>Emissions</b></p> <p><b>Air emissions</b></p> <p>9. Which are the air release points?</p> <p>10. How is particulate matter controlled? Do you monitor it?</p>	<p>6. Noted. Kindly provide the rated thermal input of each of the two steam boilers.</p> <p><i>Boiler 1 Seveso:</i>                      <i>O/P = 1.0MW</i>  <i>I/P = 1.1MW</i></p> <p><i>Boiler 2 Mingazzini:</i>              <i>O/P = 1.6MW</i>  <i>I/P = 1.78MW</i></p> <p><i>( Boiler 1 value is approximate since no nameplate rating available)</i></p> <p>7. Noted.</p> <p>8. Noted.</p> <p>9. Noted.</p> <p>10. Noted. Kindly provide the following:</p> <p>a. The pore size of the filters?</p> <p><i>The pore size of the filters is 0.3 microns</i></p> <p>b. A calculation of the concentration of particulate matter from each release point</p> <p><i>We advise the following. The air release point</i></p>
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<p><b>Water Discharges</b></p> <p>11. How much waste water is generated? Is it treated? Where?</p> <p>12. Is rainwater segregated from process water, and from non contaminated water such as boiler and reverse</p>	<p><i>from the laboratory does not produce particulates of any significant nature, whilst the tank vents only produce vapors. The scrubbers are not monitored, whilst the drying department does have filters.</i></p> <p><i>We attach in Annex F some technical details of the filters in use.</i></p> <p>c. Stack height</p> <p><i>The stack height is approximately 5 mtrs</i></p> <p>d. Does the term filters refer to "fabric filters"?</p> <p><i>We currently employ 'glass fibre filters'</i></p> <p>11. Noted.</p> <p>a. Kindly confirm that when the proposed fractional distillation system is in place, all the effluent from the process drains (which are currently being exported) and washing water from plant drains will be channelled to the fractional distillation system.</p> <p><i>Yes, this is confirmed. For clarification's sake, we define plant drains as being wash water from plant equipment only. The wash water from industrial floors will not be part of the</i></p>
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<p>osmosis rejects, as required by BAT?</p> <p>13. Is there a fire fighting basin with enough capacity to contain fire fighting water?</p> <p>14. Are the process drains and the plant drains segregated?</p> <p>15. Is rain water collected and used?</p> <p>16. Kindly clarify and explain document no.4 in Document 007, with special emphasis to the sentence before the last.</p>	<p><i>plant drains, and hence will not be recycled. This will go directly to the factory sewer connection.</i></p> <p>12. Kindly clarify if rain water is segregated from non contaminated water.</p> <p><i>Yes, we confirm segregation does take place.</i></p> <p>13. Noted. If as suggested the water reservoir is to be used for firefighting:</p> <ul style="list-style-type: none"> <li>i. a pump must be added in order to pump the water up.</li> <li>ii. <i>We confirm this is already in place.</i> the outlet must be approved by a fire fighting company</li> <li>iii. <i>We confirm this is already in place.</i> you should have a 'ring main' The points above will be part of the IPPC permit.</li> </ul> <p><i>We confirm this is already in place.</i></p> <p>14. Noted.</p> <p>15. Noted.</p>
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			<p>16. a. Document No. 4 is implying that solvent is recovered on site. What is the percentage recovered solvents that is re-used in the same synthesis per year?</p> <p><i>The solvent recovery rate is currently quite low since we don't have a fractional distillation column in place. We estimate less than 20%.</i></p> <p>b. The sentence in document No.4 is still not clear, since it is not clear by what is meant, that the recovered solvent may be recovered in the same synthesis. Kindly clarify.</p> <p><i>Currently, the recycled solvents can only be used in the processes of origination, this being due to their low quality. When we install the fractional distillation column, the quality of the solvents will be much purer, and hence may be used in a wider range of applications.</i></p>
B2.4	<p>1. Kindly provide a list of waste that is produced on site, with the European Waste Catalogue (ECW) Code, the quantity, and the proposed treatment (waste management technique). Kindly include as well, gaseous emissions and liquid discharges from the scrubber, waste water discharges, and filters and absorbents, amongst others. A simple flowchart could make it easier to clearly show the sources, and quantities. Kindly</p>	✓	

<p>provide as well the following information regarding waste:</p> <p>a. <i>A description of the type of waste category/s to be handled/produced at the facility.</i></p> <p>b. <i>Projected quantities of waste to be handled at the facility.</i></p>	<p>1a. Kindly provide ECW code of packaging waste?  <i>The packaging wastes generated at our facility fall into the following codes:</i></p> <p><i>15.01.01 – paper and cardboard packaging</i>  <i>15.01.02 – plastic packaging</i>  <i>15.01.04 – metallic packaging</i>  <i>15.01.07 – glass packaging</i></p> <p>1b. i. Kindly provide quantities of packaging waste produced on site.</p> <p><i>15.01.01 – 1200kg</i>  <i>15.01.02 – 8700kg</i>  <i>15.01.04 – 16000kg</i>  <i>15.01.07 – 300kg</i></p> <p>i. Does the 700 tons of liquid waste per year include both liquid waste from the processes as well as from the scrubbers? Kindly provide the individual quantities of liquid wastes from the processes and the liquid wastes from the scrubbers.</p> <p><i>Yes.</i>  <i>Process waste = 600MT</i>  <i>Scrubber waste = 100MT</i></p>
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<p>c. Information on how waste will be transported to/off the site.</p> <p>d. Information on packaging to be used for such transport.</p> <p>e. Storage and reception facilities on site.</p>	<p>1c. In your reply no reference was made to how waste is transported to/off the site. Please describe in detail, e.g. how the waste from the site is transferred to the tank-tainers, how often waste is exported, etc.</p> <p><i>Wastes are collected via pipelines from the process drain points and sent to the underground tanks. When enough waste has been collected for a full tank-tainer consignment, such a vessel is brought to site and parked adjacent to the tank farm. A standard procedure is followed whereby flexible hoses are connected to the tank-tainer, and the waste is pumped into the vessel under manned supervision. When full, the liquid within the flexible hoses is sent back into the underground storage.</i></p> <p><i>Based on last years production, we export around 28 shipments a year, all of which are clearly documented and approved by the local authorities. We attach Annex E for your perusal, which is the SOP's pertaining to this activity.</i></p> <p>1d. Noted</p> <p>1e. Noted. Your answer details the storage facilities. Kindly provide details on the reception facilities on site. This could be cross-referred to the answer give in 1c.</p> <p><b><i>The tank-tainer operation at factory MRA 050 and MRA 061 will be identical, using hoses and pump</i></b></p>
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<p>f. Bulk storage of waste prior to its handling.</p> <p>g. <i>Projected date of commencement for the activity.</i></p> <p>h. The daily hours of operation of the facility.</p> <p>2. Concentration in waste gases is not given. Some data is given in document 016 but only THF sampling results are given. Kindly provide VOC concentration as mg TOC/m<sup>3</sup> at STP, using a recognized international standard – ideally European.</p> <p>3. Wherever disposal is mentioned in 011/AMINO, kindly specify why it is being disposed and not recovered.</p> <p>4. Kindly specify the units of the numbers given in 011/AMINO.</p> <p>5. kindly provide a reporting template on the amount of waste you disposes of as well as to where this is being disposed to.</p> <p>6. A log book should be made available whereby any particular incidents, name of visitors etc should be reported to.</p>	<p><i>sets to transfer liquids from/ into tank- tainers. Wastes from MRA 061 will be pumped upto MRA 050 for collection there.</i></p> <p><i>The existing underground storage in MRA 061 will then be used for recycled solvents and fresh solvents for production.</i></p> <p><i>We would though like to point out that in case of severe circumstances, such as industrial strikes or late arrivals of waste bound tank- tainers, we could convert the use of one of the MRA 061 underground tanks back to waste collection until such a time as the situation returns to normal.</i></p> <p>1f. Noted</p> <p>1g. Noted</p> <p>1h. Kindly clarify if your installation works on a 24 hour basis, 7 days a week , all days of the year, or just during production.</p> <p><i>We current produce 5 days a week, on a two shift basis ( 16 hrs per day).</i></p> <p>4. Please refer to comment found in B2.3 (2). The units are kgs.</p>
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			<p>5. Ok</p> <p>6. Ok. Kindly include units in the final version of the text, which will be part of the consolidated version of the IPPC application.</p> <p>7. Your reply does not answer the question. The reporting template asked for, was related to all the type of waste generated on site, not related to VOCs. Since this was not given, this will be part of the IPPC permit.</p> <p>8. Noted.</p>
B2.4.1	Kindly submit some of your recent laboratory results as a proof that no discharge of such chemicals is actually taking place.	✓	<p>Noted. Since your effluent is exported, no copies of laboratory results are needed.</p> <p>The Legal notice quoted in your amended reply is not the correct legal notice. The correct legal notice, as quoted in the IPPC application Part B is LN 203 of 2002. Thus kindly correct your reply to B2.4.1.</p> <p><i>Amended accordingly</i></p>
B2.5	Kindly submit some of your recent laboratory results as a proof that no discharge of such chemicals is actually taking place.	✓	<p>Noted. Since your effluent is exported, no copies of laboratory results are needed.</p> <p>The Legal notice quoted in your amended reply is not the correct legal notice. The correct legal notice, as quoted in the IPPC application Part B is LN 139 of</p>

			2002. Thus kindly correct your reply to B2.5. <i>Amended accordingly</i>
B2.5.1	OK.	✓	
B2.6	<ol style="list-style-type: none"> <li>1. Kindly specify where toluene and other hazardous waste is usually exported to, providing proof of recent past export.</li> <li>2. Kindly clarify the meaning of 'external disposal' so as not to be misleading to the public who will be reading the IPPC application.</li> <li>3. What is the use of the other solvents which are not used in the core process (e.g. n-hexane, isopropyl-alcohol, etc?)</li> </ol>	<ol style="list-style-type: none"> <li>1. ✓</li> </ol>	<ol style="list-style-type: none"> <li>1. Ok</li> <li>2. Ok</li> <li>3. i. Noted. ii. With regards to your reply, it is understood that 12 processes out of 15 are non-routine production. Are these always the same processes or they change, thus changing the raw materials?  <i>The majority of these are pilot-scale development processes, and are not full production line runs. The raw materials for these processes change.</i>  ii. Or is the list of raw materials given in the original application document 004, exhaustive, i.e. it includes all the chemicals that are needed to produce the non-routine production as well?</li> </ol>

			<i>The list of raw materials is exhaustive for all processes</i>
B2.7.1		✓	
B2.7.2		✓	
B2.8	1. Did you finalise the Fire and Evacuation Policy? If yes, kindly submit.	✓	1. Noted The emergency plan has to include the following amongst others: a. An emergency plan on how to inform or evacuate the general public or the civil Protection. <i>Noted.</i> b. If as suggested the water reservoir is to be used for firefighting a pump must be added in order to pump the water up. <i>Already in place</i> c. Outlets must be placed at intervals away from the plant to cover all the directions of the plant. <i>Already in place.</i> 2. SOP is noted. Kindly note the following: a. Inform CPD for a Hazmat team. <i>Noted</i>
	2. Kindly forward the SOP procedures that deal with spills and contamination.		



	<p>3. Kindly confirm that you have available appropriate chemical suits and gear to handle spillages.</p> <p>4. Are containment procedures available? Please explain.</p> <p>5. Since this contingency plan is dated 2003, does it actually cater for the improvements that actually took place at your installation after 2003?</p>		<p>b. Add telephone numbers of CPD to the SOP. <i>Noted</i></p> <p>c. The site SOP must be at the main gate so that any Emergence worker can refer to. <i>Noted</i></p> <p>3. Noted.</p> <p>4. Noted.</p> <p>5. The SOP attached with your replies is dated 30/11/2006. Kindly confirm that this will be improved in the light of the advise given to you by the American Consultant.</p> <p><i>We confirm this will be amended accordingly.</i></p>
B2.9	<p>1. Kindly submit the Environmental noise assessment report. This has to be based on BS4142, as a standard methodology.</p> <p>2. Kindly submit the Factory Grid mentioned in the inspection report</p>	✓	<p>1. Kindly submit the environmental noise assessment report based on BS4142. <i>This has still not yet been completed, but should be finalised by the end of the year.</i></p> <p>2. Noted.</p>
B2.10	<p>Is the methodology submitted following a standard methodology? E.g EN 13526: 2001 (Specifies a set of minimum performance requirements for an</p>	✓	<p>1. Noted</p>

	instrument using flame ionisation detection, together with procedures for its calibration and operation, for the measurement of the mass concentration of total gaseous organic carbon (TOC) in flue gases. Is suitable for the measurement of gaseous or vapour phase TOC emissions from Solvent Using Processes.)		
	2. Kindly indicate where SOx measurements are found in the data submitted.		2. Noted. What is the Sulphur content of the heavy fuel oil used in the boilers?
	3. What pollutants do you sample for in waste gas emissions from scrubber? – only THF results are given.		3. Noted.
B2.11	Ok	✓	
B2.12	Ok	✓	
B3	OK.	✓	
B4.1	1. What about particulate matter produced? Do you know how much is produced, and its potential significant environmental effect?	✓	Noted
B4.2	Has the waste water reprocessing plant mentioned in 019/AMINO been installed? Is it operational? What volumes of waste water are being treated / year?	✓	Noted
B5.1	1. So no EIA was requested from your end before the	✓	1. Noted.

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	<p>beginning of operations?</p> <p>2. Kindly write the name of the local competent authority mentioned in 019/AMINO.</p> <p>3. Kindly submit further information on the wastewater reprocessing plant. Is it in place? How does it operate? How does this tie in with adverse effects on neighbouring factories and with assessment of alternative sites?</p>		<p>2. Noted</p> <p>3. Noted.</p>
B6.1		✓	
B6.2		✓	
B6.3		✓	
B7.1		✓	
B7.2-8		✓	

**Other comments:**

Kindly read and sign the attached Data Protection Clause (Annex II).