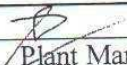
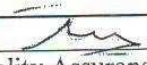
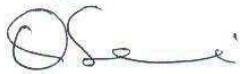



Annex J: SOP- Handling of Raw Materials

STANDARD OPERATING PROCEDURE

Procedure	SOP-QA-015	Compilation Date	25/03/2007
Edition n°	5	In force since	01/04/2007
Replace edition n°	4	Expiry date	30/03/2009
Reason	Update	Copy n°	
Written by:		Checked by:	
Approved by:			

Title: Handling of chemical raw materials

Distribution List

Original: Quality Assurance
Copies: Quality Control - Managing Director - Plant Manager - Production

1. PURPOSE

This procedure regulates and defines the operations the handling of Chemical Raw Materials.

2. APPLICATION FIELD

This procedure refers to the purchased Raw Materials.

3. RESPONSIBILITY

The procedure is periodically checked by the Quality Assurance or by the Quality Control. They must ensure that the operators follow the procedure.

4. DESCRIPTION

UNLOADING


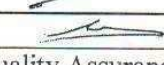


When new raw materials arrive they are unloaded and placed in the appropriate quarantine areas. When this designated area is full the raw materials can be placed in an alternative storage area, but chains must surround them and a sign indicating that product is in "quarantine".

NB Different products or materials are to be stored on separate pallets, i.e. different materials cannot be stored on same pallet, however SAME materials with different batch numbers can be stored on SAME pallet.

CONTROL

The following controls are to be carried out on arrival of raw materials to the store:

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Reason	Update	Copy n°	
Written by:		Checked by:	
Approved by:	Plant Manager 	Quality Assurance 	

Title: Handling of chemical raw materials

- The Supplier name is cross-checked from the Approved Supplier list. If the name of Supplier is not in the list, the store keeper informs immediately the Quality Unit.
- Check of packaging integrity (cleaning and integrity) of the raw materials received. Any nonconformance is listed on the Goods Received Form
- Label reconciliation is done by the responsible store keeper and recorded on the Goods Received Form
- Counting the number of drums or pellets which must correspond to the information reported on the supplier's documentation
- A number of drums are statistically chosen ($\sqrt{n} + 1$), weighed and data compared to the supplier's documentation.
- The allowed tolerance is of $\pm 1\%$
- If one of the selected drums does not conform to the tolerance all the whole batch must be weighed
- The number of drums to be weighed must conform to the table shown below:

Number of drums received	Number of drums to be weighed
1-3	All
4	3
5-9	4
10-16	5
17-25	6
26-36	7
37-49	8
50-64	9
65-81	10
82-100	11
100	At least 11

STANDARD OPERATING PROCEDURE

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Written by:	<i>[Signature]</i>	Checked by:	<i>[Signature]</i>
Approved by:	Plant Manager <i>[Signature]</i>	Quality Assurance <i>[Signature]</i>	

Title: Handling of chemical raw materials

RECORDING

- The storekeeper records the incoming raw material in the appropriate book, assigning a consecutive number that will be the batch number for that lot. Incoming raw materials will be assigned a consecutive alphanumeric code that is the letter P followed by four digits e.g. P3111. In the case of recycled solvents the letter R will be assigned together to a four- digit number, e.g. R0001.
- The storekeeper labels the raw material with the yellow quarantine label (refer to the Labeling SOP-QA-008)
- The store keeper fills in the REQUEST FOR ANALYSIS form and gives it to the Quality Control personnel, who in turn after carrying out the necessary test determines if the product is approved or rejected and label the product accordingly.
- Depending on the label that the Quality Control has attached the product will be moved to the designated area, that is if the product is approved (green label) it is moved to the approved area and if product is rejected (red label) it is transferred to the rejected area. In the latter case the product is returned to the supplier.

MOVEMENT

- The store keeper must record the movement of the raw materials that are issued to the production on the stock movement card. The stock movement card will contain the following information:
- - Product
 - Product Code
 - Int Batch no.
 - Weight received
 - Data received
 - Packaging
 - Date
 - Qty Taken
 - Used in

STANDARD OPERATING PROCEDURE

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Written by:		Checked by:	
Approved by:	 Plant Manager	 Quality Assurance	

Title: Handling of chemical raw materials

- Batch
- Balance
- Comments
- Signature

Marsa Plant

STANDARD OPERATING PROCEDURE

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Approved by:	Plant Manager	Quality Assurance	

Title: Handling of chemical raw materials

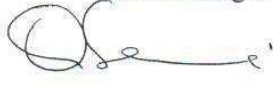

ATTACHMENT

- Attachment 1 Stock Movement Card
- Attachment 2 Request for Analysis
- Attachment 3 Goods Received Form
- Attachment 4 Process Flow chart

Change History

Date of change	Replaces edition	By:	Details of change
25.1.07	4	Jonathan Farrugia	New Logo in Header; Attachments update, (√n + 1) added in Section 4. Process Flow chart as Attachment 4. Label Reconciliation and Approved Suppliers List. Goods Received Form

STANDARD OPERATING PROCEDURE

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Approved by:	Plant Manager 	Quality Assurance 	

Title: Handling of chemical raw materials

Attachment 1: Stock Movement card

Sheet no: _____

Product: _____
 Int. batch no. _____
 Weight received _____

Product Code: _____
 Date received: _____
 Packaging _____

Date	Qty taken	Used for	Batch	Balance	Comments	Signature

CONTROLLED COPY

Marsa Plant

STANDARD OPERATING PROCEDURE

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Approved by:	Plant Manager	Quality Assurance	

Title: Handling of chemical raw materials

Attachment 2: Request for analysis

RAW MATERIALS

Request for Analysis

Date _____

Product name _____ Product code _____

Supplier _____ Internal Batch number _____

Weight _____ Number of Drums or bags _____

Requested by _____ Received by _____

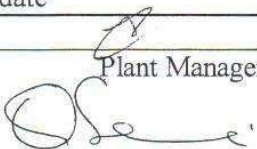
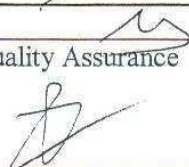
P CONFIDENTIAL

 **Amino**
Chemicals

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Chemicals
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L Marsa Plant

STANDARD OPERATING PROCEDURE

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Approved by:	 Plant Manager	 Quality Assurance	

Title: Handling of chemical raw materials

Attachment 3:

Goods Received Form

[Handwritten signature]

Goods Received Form

Page 1 of 1

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36	37	38	39	40	41	42	43	44	45	46	47	48	49	50	51	52	53	54	55	56	57	58	59	60	61	62	63	64	65	66	67	68	69	70	71	72	73	74	75	76	77	78	79	80	81	82	83	84	85	86	87	88	89	90	91	92	93	94	95	96	97	98	99	100	101	102	103	104	105	106	107	108	109	110	111	112	113	114	115	116	117	118	119	120	121	122	123	124	125	126	127	128	129	130	131	132	133	134	135	136	137	138	139	140	141	142	143	144	145	146	147	148	149	150	151	152	153	154	155	156	157	158	159	160	161	162	163	164	165	166	167	168	169	170	171	172	173	174	175	176	177	178	179	180	181	182	183	184	185	186	187	188	189	190	191	192	193	194	195	196	197	198	199	200	201	202	203	204	205	206	207	208	209	210	211	212	213	214	215	216	217	218	219	220	221	222	223	224	225	226	227	228	229	230	231	232	233	234	235	236	237	238	239	240	241	242	243	244	245	246	247	248	249	250	251	252	253	254	255	256	257	258	259	260	261	262	263	264	265	266	267	268	269	270	271	272	273	274	275	276	277	278	279	280	281	282	283	284	285	286	287	288	289	290	291	292	293	294	295	296	297	298	299	300	301	302	303	304	305	306	307	308	309	310	311	312	313	314	315	316	317	318	319	320	321	322	323	324	325	326	327	328	329	330	331	332	333	334	335	336	337	338	339	340	341	342	343	344	345	346	347	348	349	350	351	352	353	354	355	356	357	358	359	360	361	362	363	364	365	366	367	368	369	370	371	372	373	374	375	376	377	378	379	380	381	382	383	384	385	386	387	388	389	390	391	392	393	394	395	396	397	398	399	400	401	402	403	404	405	406	407	408	409	410	411	412	413	414	415	416	417	418	419	420	421	422	423	424	425	426	427	428	429	430	431	432	433	434	435	436	437	438	439	440	441	442	443	444	445	446	447	448	449	450	451	452	453	454	455	456	457	458	459	460	461	462	463	464	465	466
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Issue Number: 1

GRF No: _____

Date: _____

ORD No: _____

Sig:

Accounts Office use only

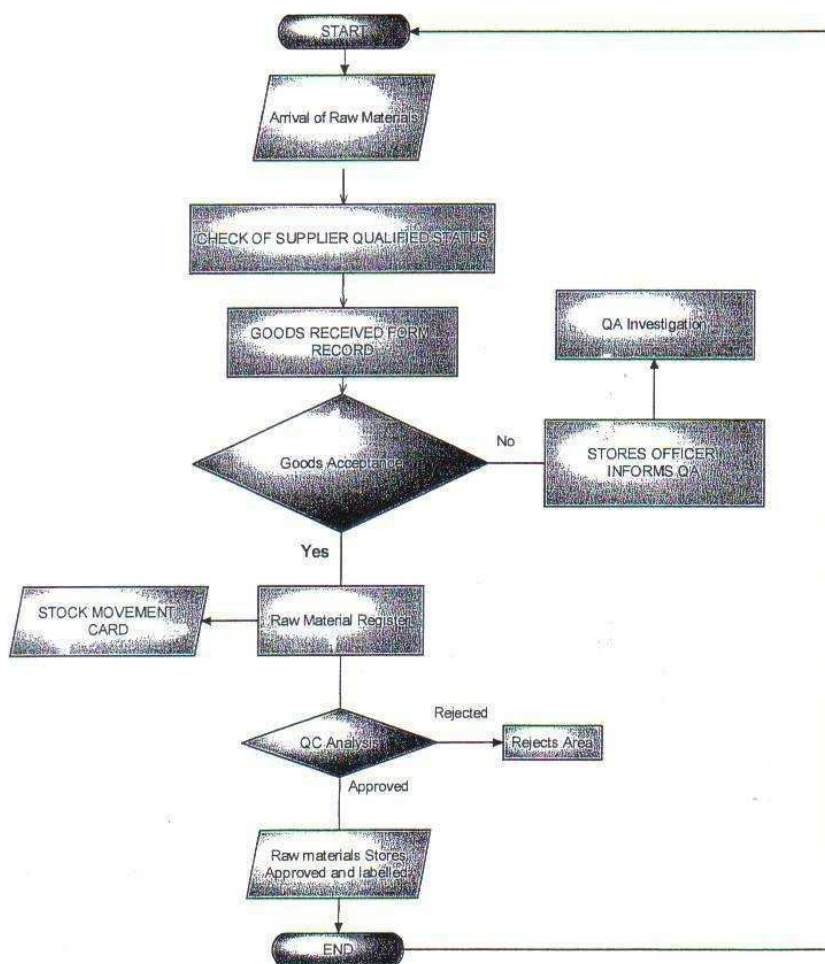
* Accepted means No cleaning and integrity issues have been reported on the packaging materials of the raw materials received.

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Approved by:	Plant Manager <i>[Signature]</i>	Quality Assurance <i>[Signature]</i>	

Title: Handling of chemical raw materials

PROCESS FLOW CHART



Amino Chemicals Ltd
A 61, Industrial Estate,
Marsa

Integrated Pollution Prevention and Control Regulations 2002

Responses to queries dated 25.08.2006

B1.3

See Document 110/AMINO, which is the relevant documentation from MIP prior to occupation of the industrial premises. Document 111/AMINO is the relevant Site Map.

Currently neither the oil drums store area nor the solvent store area are bunded. We shall be transferring the storage facility to the A50 Factory Extension and these storage areas are all bunded and have the relative safety requirements and spillage containment requirements as per EU legislation.

B2.1

- 1a- Yes we produce Fosinopril Sodium on an industrial basis
- 1b- 3.5 tons/yr
- 1c- Fexofenadine Hydrochloride is being produced on an industrial scale at about 2 tons/yr. Losartan has been discontinued.
- 1d- We have started producing Terbinafine on an industrial basis, at 2 tons/yr.
- 1e- We expect an FDA inspection in the first quarter of 2007. A copy of their report and findings will be made available upon completion.

3 Mr. Philip Micallef Mob: 9949 0676

4

- 5a- i Yes
- ii Yes

b

- c We have provided for the following training of our personnel:
 - i. boiler operator (steam driver)
 - ii. forklifter drivers
 - iii. firefighting basics (for all employees), and in-house training for production personnel and maintenance personnel.
 - iv. first aid training
 - v. Good Manufacturing Practice training by the mother company

A list of personnel and their relative training is shown in Document 112/AMINO

- 5d The waste is collected in tanks and sent abroad for incineration according to EU regulations.
- 5e As per 5d above
- 5f As per 5d above.
- 5g Only wash water drains are connected to the public sewers. Spent chemicals and contaminated water from the lab are collected and sent abroad for incineration as per 5d above.
- 5h Rejected materials are collected and sent for incineration abroad as per 5d above.

B2.2

1

FEXO 7/P
HS Code: 2933-3999
CAS No.: 832088-63-3

FOSINOPRIL ZPA6
HS Code: 2933-9990.999
CAS No.: 103201-78-1

FOSINOPRIL ZPA7
HS Code: 2933.9990.902501
CAS No: 467430-13-3

Benzimidazole
HS Code: 2933.9990
CAS No.: 409098-86-8

2

3	N,N DIMETILFORMAMIDE	R61
	N,N DIMETHYACETAMIDE	R61
	DICHLOROMETHANE	R40
	FORMALDEHYDE	R40

B2.3

- 1 We use a sulphuric acid solution for basic vapor control.
- 2
- 3 These are stored indoors, in our warehouse.
- 4 At present no, but since the company has acquired an extension to the same factory, we shall be shifting our storage and warehousing facilities there, and adequate bunding has been prepared.
- 5 Yes, 5 of our underground tanks are dedicated for pure fresh solvent
- 6 Yes we have two steam generating boilers, which run on diesel fuel (gasoil).
- 7 Yes
- 8 Details of scrubbers can be found in Document 113/AMINO.

Emissions

- 9 The air release points are the following:
 - Tank vents
 - Laboratory
 - Scrubbing towers
 - Drying Department air conditioning system
- 10 At present, particulate matter is only controlled in the drying dept. This is done through the use of fine filters and differential pressure devices on the same filters. Apart from this, the company is embarking on a program of installing additional scrubbers in strategic positions.

Water Discharges.

- 11 The amount of waste water generated is as indicated in the final documentation. At present this is not treated, but contained and exported abroad for authorized incineration in mainland Europe.
- 12 Yes, rainwater is segregated from the process water.
- 13 Yes there is a fire fighting basin within our premises, and this has a capacity of about 300 cu.mtrs.

- 14 Process drains are collected and put in the underground storage tanks, awaiting incineration abroad. Plant drains do not form part of this system at present. Explained in further detail in final documentation
- 15 Rain water is collected and used for the fire fighting system. When full, the water is then let off to the public roads system.
- 16 There is a typing error as you have pointed out. This should read as follows:

‘ If allowed by the quality of the recovered solvent, these solvents may be recovered and re-used in the same synthesis’

We would add that if the recovered solvent is contaminated by water or other impurities, these would be collected and stored in the underground tank and eventually sent abroad for incineration.

B2.4, B2.6, B3.1

1

- a The wastes being produced on site have the following European Codes

EWC 070703
EWC 140602

At present, the liquid wastes from the processes are being collected and sent to Munich, Germany for incineration. Any liquid wastes from the scrubbers are also collected and sent for incineration.

Regarding solid contaminated wastes, we are in the process of obtaining Notification in order to dispose of these solids overseas. At the moment, we are storing these materials on our site, under close supervision.

- b We estimate about 1250 tons of liquid waste per year, but this is dependant upon production runs.
- c Liquid waste is shipped in tank-tainers ready for dispatch on ocean going vessels.
- d There is no specific packaging to be used since the tank-tainers are already certified for ocean vessels.
- e We have on site 2 in number underground tanks, purposely built.
- f Yes we bulk the waste prior to shipment.

- g Activities commenced in 2002.
- h When in production, our facility works continuously. Having said that, we are a batch type producing facility.
- 2 As advised in final documentation
- 3 For the recovery to be beneficial, the water conductivity must be less than 2 microSiemens and without trace element contamination. At present we do not have the facility to recover spent solvents, but we are in the process of installing equipment which will help us recover a substantial amount of these solvents.
- 4 The units are (kgs).
- 5 As advised in final documentation
- 6 At present we have two log books on site. These are the Visitors Log Book and the Incident Report Book. These log books are available for inspection at any time during production hours.

B2.4.1

Document 114/AMINO includes the amended document.

B2.5

Document 115/AMINO includes the amended document.

B2.6

- 1 All our wastes are exported to Munich Germany for incineration. Exportation proof as shown in 116/AMINO
- 2 The term 'external disposal' is referred to the exportation from Malta to Germany for authorized incineration under EU Laws.
- 3 The other solvents are used in other processes which are not our routine production. We currently have 15 processes, of which only 3 are major production runs.

B2.8

- 1 No we have not yet finalized such a policy, but we hope to do so very soon.
- 2 As shown in final documentation

- 3 Yes we have the appropriate chemical suits and gear to handle spillages if and where they occur.
- 4 Containment procedures included
- 5 As included in final documentation

B2.9

- 1 The environmental noise assessment will be carried out by an independent source according to BS 4142 and submitted by the end of January, 2007.
- 2 Factory grid is being supplied in Document 118/AMINO

B2.10

- 1
- 2
- 3 We sample for Acetone

B4.1

- 1 We do not currently measure particulate matter being produced. We appreciate its potential significant environmental effect.

B4.2

- 1 No it has not been installed due to economies of scale. As part of a collective effort from local industry, we have been trying to get planning permission for the installation of a common local incinerator to dispose of wastes, but this has not been forthcoming from the authorities.

B5.1

- 1 No.
- 2 The Pharmaceutical Authority of Malta
- 3 The waste water reprocessing plant mentioned in B4.2 has not been installed, and there are no plans to revive this idea. We are not embarking on the idea to install a fractionating column to recover some solvents being spent in the waste water. The other proposed document contained in this file should be consulted.