General information	
Company Details	
Company	Mitsui Chemicals Europe GmbH
Contacts	
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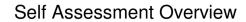| |
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| Company Details: Refer to :https://eu.mitsuichemicals.com/index.htm |
| Products: https://eu.mitsuichemicals.com/service/search_results.htm |
| Policies: https://jp.mitsuichemicals.com/en/corporate/policylist.htm |

Section 1 - Quality System		Answer	Comment
1	Certification:	Yes	German production site: IATF16949, ISO14001, ISO50001, ISO45001 Dutch production site: IATF16949, ISO90001, ISO14001.
2	Is there a formal written and communicated quality policy ?	Yes	Written and communicated to the staff.
3	Is there a formal written quality system ?	Yes	According to a.m. certifications.
4	Are there primary quality measures and targets including KPI`s?	Yes	Summarized within Management review.
5	Are SOP's (Standard Operating Procedures) and quality documents reviewed and approved	Yes	
6	Are there clearly seperated areas for raw materials, finished goods and reject material?	Yes	Seperated warehouses for raw and finished materials. Every pallet is marked with a bar code, the state of the goods is documented in the ERP-system
7	Is there a written product recall procedure ?	Yes	Tested once a year
8	Is there a procedure for managing all kind of complaints?	Yes	

9	Are regular corrective and preventive action meetings held ?	Yes	Regular meetings with both production sites. CIP list available
10	Within what timeframe do you respond to your customers in case of claims and complaints?	Yes	3D provided within 24h.
11	Have you set up a system to follow up the complaints?	Yes	Claimtool within SAP.
12	Are all operatives made aware of quality issues and reject figures ?	Yes	Regular product and quality trainings for all involved staff members.
13	Are regular internal audits of the systems carried out and documented ?	Yes	According to internal audit plan
14	Is there a formal induction scheme for all employees?	Yes	Onboarding programm for all employees.
15	Have you established job descriptions / work profiles?	Yes	
18	Is there a business continuity plan ?	Yes	
19	Do you maintain reasonable product liability insurance?	Yes	
20	Do you have a system in place for continuous improvement?	Yes	Continuous improvement plan linked to management review.

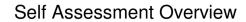| Section 2 - Process Control Procedures		Self assessment	Comments
21	Are clear process instructions issued to production ?	Yes	SOP for all processes.
22	Do actual process parameters follow process instructions ?	Yes	
23	Are actual process conditions recorded (digitally or manually) and stored ?	Yes	Minimum 10 years, not terminated now
24	Is SPC (Statistic Process Control) used to control the process ?	Yes	FMEA and other SPC tools done at toll compounder.
25	How do you ensured that correct raw materials are used at all times during the process ? Are samples checked online by operators and are inspection sheets signed by supervisor/manager	Yes	Incoming goods control. Wrong materials do not enter production site. Laboratory analysis of raw materials.
26	Are samples of finished products retained for future reference?	Yes	10 years at warehouse.
27	Is there a preventive maintenance plan?	Yes	
28	Are the maintenance records kept?	Yes	Before 10/2018 for 10 years, since then in electronical form without termination date.
29	Is there a formal emergency plan?	Yes	
30	Is equipment, which gets into contact with the product, constructed of materials that will not be	Yes	
31	Is production start-up procedure approved by Quality Control?	Yes	
32	Is line clearance SOP also conducted between operations?	Yes	

33	Is there a written procedure that documents deviations from process and specification requirements?	Yes	
34	Are in-line inspection systems used to monitor the process?	N/A	Complete closed system, process parameters continously monitored.
35	Are in-line inspection systems regularly checked to be sure that functionality is given?	N/A	Complete closed system, process parameters continously monitored.
36	Do you make a validation of shelf life the finished products?	No	1 year shelf life after delivery date is guaranteed.
37	If your company has several production-sites; is it traceable, at which of the sites the product	Yes	
38	Is your production seasonal?	No	Whole year production.

Section 3 - Quality Assurance Procedures		Self assessment	Comments
39	Is there a separate QC Laboratory ?	Yes	German site: Laboratory belonging to complete Polymer Holding Dutch site: Internal laboratory of the plant. Both laboratories are covered by IATF 16949 certification of the actual company.
40	Is the laboratory manned during all production hours ?	Yes	
41	Are there written test procedures ?	Yes	All finished products are tested according to MCE´s instructions.
42	Are there written calibration procedures ?	Yes	Calibration by external company.
43	Are there written procedures to assure that gauges, tools, and test equipments are maintained and calibrated?	Yes	Done by external company according to calibration plan.
44	Are there specified test frequencies ?	Yes	Instructed by MCE.
45	Do the technicians have a specification for the finished product. If so how often is this updated ?	Yes	Updates only on demand.
46	Is there a formalized hold / rejection procedure ?	Yes	Instructed to all staff members.
47	Are documented test results kept ?	Yes	Eletronically in the ERP system.
48	Are their dedicated people defined to release the finised products?	Yes	Only QC/QA department can release the finished products.

49	Are there actions defined if those process parameters are outside the limits?	Yes	If there are any measurements during production process showing exceeded limits of production parameters, our production QM Team will inform the MCE Quality depertment for instruction. Relevant sublots are blocked in the ERP System and `not for sales´ until further decission of MCE QM.
50	Is there a system to ensure that the product meets the quality agreed with customers?	Yes	After production is finished the QM-department receives all quality data. If acceptable the QM department then releases the production in SAP. If product is OOS QM and TS follows internal guidelines how to handle the material.
51	Is a traceability system in place to all measured values in finished product?	Yes	Eletronically in the ERP system based on barcodes.
52	Is a traceability system in place covering all raw materials, auxiliary materials and the involved production lines used?	Yes	Tested at least once a year and on demand.
53	Can all records be fully traced in case of customer complaint, for all aspects of raw materials, process record / machines used / QA results ?	Yes	All finished products receive Barcodes by which traceability can be secured during whole supply chain.
54	Do you send quality documentation with the delivery ?	Yes	Certificate of Analysis will be sent together with the delivery papers.
55	Has the manufacturing process been qualified / validated?	Yes	Internal audit of the whole production process.
56	Are the in-line inspection systems been qualified / validated?	N/A	Internal audit of the whole production process.
57	Are test methods and test equipments verified / validated?	Yes	Internal audit of the whole production process.
58	Are quality history records maintained for in process data and final product?	Yes	Eletronically in the ERP system.

Section 4 - Change Control		Self assessment	Comments
59	Is a change control system in place?	Yes	According to internal MCE guideline.
60	Does this change control system covering all relevant changes in starting materials, production process, test methods and packing?	Yes	According to internal MCE guideline.
61	Are changes documented and is Quality Management involved into evaluation, tracing and approval?	Yes	
62	Do you manage any customer development projects / changes of requests?	Yes	Technical Service and Sales team take care of specific customer requests.
63	In case of changes does your company send information to its customers, even if not applied for?	Partial	MCE is informing about changes of the specifications and/or quality of finished products. Not about any changes within production process.

Section 5 - Raw Materials		Self assessment	Comments
64	Is there an approved supplier list?	Yes	
65	Does a formal system exist for the evaluation of your suppliers?	Yes	Originally done by Japanese mother company Mitsui Inc. Additional supplier evaluation within MCE existent.
66	Are all material suppliers audited ?	Partial	Self audit assessment sent to all raw material suppliers. No on site audits done for all suppliers.
67	Are written specifications available for all raw materials?	Yes	
68	Are raw materials tested on delivery against an agreed specification ?	Partial	Most, but not all raw materials are tested against specification at incoming goods control.
69	Are records for testing / inspections of incoming goods maintained?	Yes	Electronically within ERP system.
70	Are raw material clearly labelled and identified ?	Yes	Only correct labeled materials are accepted.
71	Is traceability working to raw materials and raw materials test results?	Yes	
72	Are retained samples of raw materials kept?	No	Supplier to provide retain samples if necessary
73	Do you have a corrective action procedure for non-conforming material, including written	Yes	

74	Are materials rotated on a first-in-first-out (FIFO) basis?	Yes	

Section 6 - Storage and Transit		Self assessment	Comments
75	Are raw materials stored on site ?	Yes	Only for short term productions. Remaining raw materials stored at external warehouses.
76	Is there a segregation of stored Work in Process material from raw material and finished goods?	Yes	Secured by barcode system. Furthermore physical segregation.
77	Are finished goods stored on site ?	No	Immediately shuttled to external warehouse partners.
78	Is the warehouse climate controlled (temperature, humidity) and is it recorded?	No	Always stable condition inside the warehouse.
79	Is there a protection of raw material, WIP and finished goods against dirt (contamination in general) ?	Yes	All pallets closed and wrapped with shrink foil.
80	Are all finished goods clearly labelled ?	Yes	
81	Is the rotation of finished products based on FIFO principle?	Yes	
82	Are finished products transported by your own logistics department?	No	External logistical partners.
83	Do you have transport specifications signed by your service providers, containing hygiene	Yes	
84	For transporting products in bulk, are tanks or containers sealed?	Yes	
85	Do you require a cleaning certificate?	Yes	EFTCO Cleaning certificate.
86	Is there a system to identify the location of raw material, WIP and finished stock ?	Yes	Barcode system.
87	Do vehicles comply with hygiene requirements and are they inspected before 'unloading' and	Yes	Internal checklist in place for all trucks.

Section 7 - Hygiene		Self assessment	Comments
88	Is the site accredited in any hygiene standards ? (BRC/IOP, IFS, 22000)	No	No food certification. Also not yet planned for the future.
89	Is there a formal hygiene policy and hygiene procedures ? If so review the working practice and documentation :	Yes	Internal hygiene policies. Known by all staff members.
90	Is there a formal glass policy ?	Yes	Glass forbidden on production site
91	Are there written or illustrated clothing and personal hygiene requirements visualized on all	Yes	
92	Is protective clothing worn ?	Yes	Overall, helmets, safety shoes.
93	Are private clothes segregated from works clothes?	Yes	

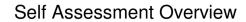| 94	is there a cleaning process for protective clothing?	Yes	
95	Is there a formal jewellery policy ?	Yes	Not allowed in production area.
96	Is eating, drinking and smoking prohibited on the production floor ?	Yes	
97	Are all windows/doors into the production area closed/proofed/screened ?	Yes	
98	Are all lights, UV tubes etc properly shielded in case of breakage ?	Yes	
99	Are pallets or raw materials stored outside the manufacturing area and inside buildings ?	Yes	Temporary short outside storage of some raw materials is possible. Finished products are only stored inside.
100	Is there a written/documented cleaning procedure for plant/equipment ?	Yes	
101	Are there procedures for housekeeping and cleaning of equipment including method and frequency? Which areas and equipment are covered by the cleaning and house-keeping procedures?	Yes	Doors/gates to the production facilities are equipped with automatic locking systems. o Regular cleaning of the sanitary rooms o Regular cleaning of break rooms o Regular cleaning of offices maintenance plan
102	Is the standard of cleaning regularly audited ?	Yes	Checked by internal-, certification-, customer audits.
103	Is there a formal HACCP procedure for all processes ?	No	No food certification. Therefore no official HACCP concept. However Critical Control points are defined for the production process.
104	Have you done a food safety management hazard risk assessment according to the requirements in FSSC 22000, BRC v5 packaging or similar standard?	Partial	MCE and SAE are not certificated according any food norm. However several risks are monitored and checked at production site.
105	Is there an established pest control program ?	Yes	Done by external company.
106	Are all records of pest control kept?	Yes	
107	Are electronic or other insect/fly killers in operation ?	Yes	
108	Are locker rooms, sanitary facilities and social rooms segregated form production areas?	Yes	
109	Are entrances into production areas equipped by hand wash basins and disinfectants?	Yes	
110	Are hand washings signs displayed in all toilets and are disinfectants installed?	Yes	
111	Have you defined methods/routes for management of waste?	Yes	"GraNull" programm installed and followed.
112	Are you setting up measures for reducing packaging?	Yes	

113	Are you able to offer your customers solutions for managing the waste generated by your	No	
114	Are infectious diseases reported and are the employees trained on the issue?	Yes	Regular hygiene and medical trainings for all staff members.
115	Have you taken into account the following hazards: metal glass wood microbiologics chemical	Yes	Metal seperator and magnets installed -No glass allowed in production area -Deduster and filters installed to avoid any contamination with foreign (wood) objects. -No microbiological hazards within production process -Chemical hazards are supervised

Section 8 - Product Safety		Self assessment	Comments
116	Is there a nominated person / team for product safety, legal affairs?	Yes	Internal EHS department.
117	Do you comply with applicable legislation (REACH, Food contact, GMP...)?	Yes	For more details please contact us.
118	Is there information available on substances with Specific Migration Limits (SML)?	Yes	Provided on request for materials suitable for food contact.
119	Do you assess food contact suitability during process and product development? If so, please give details	Yes	Our EHS-dept. is involved to assess the relevant grades regarding Food-Contact suitability
120	Is food contact awareness form part of you supplier audits or assessments?	Partial	Food business section within the Supplier Self Assessment of MCE.
121	Do you carry out odour or taint testing of your products?	N/A	
122	Is there a responsible person for REACH?	Yes	Internal EHS department.
123	Can the production site entered by every person?	No	Production site can only be entered by staff members.
124	Have you checked the presence of allergenic substances within your products?	Yes	Corresponding statement available on demand.
125	Do you communicate information on substances in articles as required by Article 33 (REACH)?	N/A	Art. 33 (REACH) is applicable to articles only, not to raw materials like our products. A corresponding statement on SVHC in our materials can be provided on request.

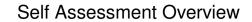| 126	Are there systems in place to protect products, premises and brands from malicious actions , e.g. by restricted access to the production area and protection from manipulation of electronic systems?	Yes	
127	Specify access rules for visitors and drivers in place?	Yes	Registration required at the reception, only certain areas open to visitors. registration required at the reception, only certain areas accessible for drivers
128	Are there systems in place to protect products from malicious actions and contamination, including taint and odour, through the entire logistics chain? This includes all steps from the production site to the customer site, including all oursourced logistics operations.	Partial	Access control and monitoring: We implement strict access controls for our production areas and monitor access to sensitive areas and equipment. Only authorized employees with appropriate permissions have access to certain areas. Security awareness and training:We conduct regular training and awareness sessions for our employees to inform them of potential threats and train them to recognize and report suspicious activity. Vetting of suppliers and contractors:** We carefully vet all suppliers and contractors who have access to our production facility to ensure that they adhere to the same security standards as we do and do not pose any security risks. Cyber security and IT protection:** We employ robust cyber security measures to protect our production facilities and systems from cyber threats. These include firewalls, antivirus software, regular security updates and patches, and training for employees on how to deal with phishing attacks and other cyber threats. Production facility is also fenced off

129	Are there systems in place to minimise the risk of purchasing fraudulent raw materials and to ensure that all product descriptions and claims are legal, accurate and verified.	Yes	Laboratory checks against agreed specification. Incoming goods control including check of delivery papers, labels, condition of the delivered material.

Section 9 - H&S and Environmental	Self assessment	Comments
130 Is there a nominated person / team for H&S?	Yes	
131 Is there an established H&S policy ?	Yes	
132 Are H&S KPI's recorded and communicated ?	Yes	
133 Did the supplier had fatal accidents in the last year?	No	
134 Is there an established Environmental policy ?	Yes	
135 Does the supplier have environmental targets and reporting system in place?	Yes	
136 Did the supplier had environmental incidents in the last year?	No	
137 Is there any recycled material used in the production?	No	No post consumer recycling process.
138 Are your H&S, Environmental and Social Responsibility policies communicated to all employees?	Yes	Can be found at: https://eu.mitsuichemicals.com/index.htm

Section 10- Human Resource-Training-Ethics	Self assessment	Comments
139 Is there a system for managing training of staff (including training plan/skill matrix, introductoryand recurring trainings, documentation, detection of missed trainings)?	Yes	Training matrix, divided by staff level grade.
140 Does the system include hygiene and contamination prevention (GMP-training)? If yes, what is the frequency of recurring GMP-trainings?	Yes	Once per year or when there are changes or adjustments
141 Does the supplier have a code of conduct & ethics policy, including bribery, corruption and fraud?	Yes	Can be found at: https://eu.mitsuichemicals.com/index.htm
142 Does the supplier have a Social Responsibility Directive or Policy, including: Human Rights, Consumer Protection and Community?	Yes	Can be found at: https://eu.mitsuichemicals.com/index.htm
143 Do you use temporary staffing agencies?	Yes	Only if necessary.
144 Did the supplier have incidents of harassment or discrimination in the last year?	No	