



Site Quality Self-Assessment

based on

Rx-360 Supplier Assessment Questionnaire Module 2, Site Specific Information

Relevant for

MilliporeSigma Sheboygan Falls Facility
5485 County Road V Sheboygan Falls,
WI 53085, USA

An affiliate of Merck KGaA, Darmstadt, Germany

The site self-assessment covers our quality management system for the following activities:
manufacturing of Flavours & Fragrances

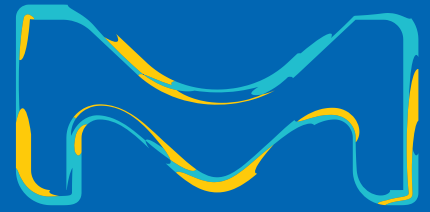
The site also processes products which do not fall under any of the above mentioned regulated areas. For these products, other quality standards apply. For details, please refer to our non-GMP Quality Site Self-Assessment.



As a trusted partner of our customers, we deliver quality
- always.

Merck KGaA
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany

The life science business of Merck KGaA,
Darmstadt, Germany operates as
MilliporeSigma in the U.S. and Canada.



Information

This document is based on the Rx-360 Consortium's Supplier Assessment Questionnaire template, Module 2. The contents of this questionnaire are built on the Rx-360 questionnaire version 3.0 intact with no question added or deleted. Rx-360's CEO/COO gave permission to Life Science to use the Rx-360 logo.



Merck KGaA
Corporation with General Partners
Frankfurter Str. 250
64293 Darmstadt, Germany

The life science business of Merck KGaA,
Darmstadt, Germany operates as
MilliporeSigma in the U.S. and Canada.

Please check here if additional documents are attached.

SECTION 1. General Site Information

1.1	Site or Facility-Specific Name: Aldrich Chemical Company, LLC
1.2	Address: 5485 County Road V, Sheboygan Falls, WI 53085-2814, USA GPS Coordinates: Latitude:43.673968 Longitude: -87.781175
1.3	Phone: Please contact your local Sales representative
1.4	Email: Please contact your local Sales representative
1.5	Fax: Please contact your local Sales representative
1.6	Website: www.sigma.aldrich.com/flavors-fragrances

SECTION 2. General Site Operating Information

2.1	What year did the site start operating? Aldrich began business in 1951, purchased the Sheboygan Falls site in 1977, adding buildings over the 41 year period.
2.2	What is the primary activity of the site? (e.g. manufacturing, distribution, etc.) manufacturing, quality control and packaging
2.3	To which, if any, subdivision of the parent company does the site belong? Merck KGaA, Darmstadt, Germany, Life Science division
2.4	Size of site (in sq. ft. or m.): 500,000 sq. ft on 77 acres developed and 592 acres owned.
2.5	Please list or attach the normal hours/schedule of the facilities, including shutdown dates (if applicable): 24 hours a day, 5 days a week Site shutdown 2 days during Thanksgiving (end of November) Site shutdown 2 days during Christmas (end of December)
2.6	Total number of employees on site: Approximately 630 employees
2.7	Total number of employees in Quality: 80 total in Quality Control and Quality Assurance
2.8	Total number of employees in Manufacturing: 280 in Manufacturing (appr. 30 employees in flavors & fragrances operation), 65 packaging

2.9	<p>What quality management system is utilized on site?</p> <input checked="" type="checkbox"/> ISO 9001 <input type="checkbox"/> ISO 13485 <input type="checkbox"/> 21 CFR Part 210/211 <input type="checkbox"/> 21 CFR Part 820 <input type="checkbox"/> European GMP, Eudralex Volume 4 Part I <input type="checkbox"/> European GMP, Eudralex Volume 4 Part II <input type="checkbox"/> ICH Q7 <input checked="" type="checkbox"/> HACCP <input checked="" type="checkbox"/> ISO 22000 <input checked="" type="checkbox"/> Other Please describe: ISO 14001, Food defence, HARPC, 21 CFR 117 and (EC) No 852/2004 Which Regulatory initiatives does the site follow/comply with? <input checked="" type="checkbox"/> REACH <input checked="" type="checkbox"/> RoHs <input checked="" type="checkbox"/> Ca Prop. 65 <input checked="" type="checkbox"/> WEEE
2.10	Does the company/site have an export license? <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A
2.11	<p>Is the site registered with any government regulatory agency (FDA registration, GMP certification, etc.)?</p> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A If yes, please specify. FDA food facility registration #15537241694 Wisconsin Dept. of Agriculture, Trade and Consumer Protection (#482568) US Environmental Protection Agency (RCRA hazardous waste generator) US Department of Homeland Security
2.12	By whom is the site inspected (regulatory or third party) and list inspections within the last three years: AIB (FSSC 22000), DQS (ISO 9001:2015), Rabbi Gershon Segal (Kosher), IFANCA (Halal), Wisconsin Department of Agriculture Homeland Security 2016
2.13	How often, as an annual average, is the site audited by customers or third parties? 10-15
2.14	<p>Has an Rx-360 audit been performed at this site?</p> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No Please also state the date of the audit if applicable. 12/4/2024 Learn more about the Rx-360 Joint Audit Program@ here.
2.15	<p>Are you willing to have Rx-360 conduct an audit on behalf of your customers according to the Rx-360 audit programs on your site?</p> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2.16	<p>Are you willing to have your customers conduct audits on your site?</p> <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
2.17	Please list regulatory sanctions impacting the site within the last five years (i.e. warning letters, CEP suspension, import alerts, etc.): none

2.18	Does the site outsource any quality-related activity? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A			
	If answering yes, please specify the activities: Pest control, selected analytical testing and clibration services			
2.19	Please check the supplier controls in place for this facility:			
2.19a	Quality Agreements with Suppliers	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19b	Subcontractor Qualification/Audit Program	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19c	Periodic Review of Supplier Performance	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19d	Supplier Feedback Program	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19e	Approved Material Supplier List	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
2.19f	Approved Service Supplier List	<input checked="" type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

Additional comments:

Please note that the checks in 2.9, 2.11 and 2.12 refer to GMP processing,
The site also processes non-GMP related product. Please refer to non-GMP Site Self-Assessment

SECTION 3. Objectionable Materials On Site

3.1	Does the site or production plant produce, process or store any of the following?	Yes	No	Not Applicable
3.1a	Beta-Lactam Antibiotics	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1b	Steroids and/or hormones	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1c	High potency compounds	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1d	Materials of animal origin/Biologics	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3.1e	Live virus or micro-organism	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1f	Allergens	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1g	Genetically Modified Organisms (GMO)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
3.1h	Agrochemicals (Pesticides, Herbicides, Fungicides, etc.)	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

3.1i	<p>Other (Please specify): 3.1d: yes for GMP production, no for non-GMP production</p> <p>For GMP production we declare: No use of Cytotoxins, No use of APIs, No use of Food allergens (US FDA, EU EFSA, Japan Ministry of Health) ,but toxic, hazardous chemicals</p>
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SECTION 4. Cross-Contamination Control

4.1	Are any of the following cross-contamination controls in place?	Yes	No	Not Applicable
4.1a	Dedicated Facilities	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1b	Access Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1c	Dedicated Personnel	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1d	Dedicated Gowning	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1e	Procedural Controls	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.1f	Other (Please specify): All materials are stored in sealed containers. Containers are opened only in isolated rooms with line clearance after each product is handled.			

Additional Comments:

Some materials derived from highly refined oils or distillates or extracts from allergen sources. Third party analysis verified end products are allergen-free. Some materials derived from highly refined oils or extracts from animal sources. Some materials derived from highly refined oils or distillates from GMO plant-sources.

SECTION 5. Site Operating Policies

5.1	Does the site utilize the following written policies, programs or procedures?			
Site Specific:		Yes	No	Not Applicable
5.1a	Environmental, Health and Safety	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1b	Facility Environmental Control Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1c	General Facility Cleaning Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1d	Hygiene and Sterilization Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1e	Validated Equipment Cleaning Procedures	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
5.1f	Preventative Maintenance Program/Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1g	Pest Control Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1h	Master Production Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality:				
5.1i	Quality Control/Quality Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1j	Quality Manual	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1k	Periodic Product Quality Review	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1l	Master Validation Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1m	Risk Assessment Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1n	Supplier Approval Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1o	Monitoring and Review of Approved Suppliers	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1p	Mechanism to Reduce Testing	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1q	Receiving Incoming Inspection	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1r	Change Control Procedures	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1s	Document Management Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1t	Document Retention Policy	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1u	Change Notification Procedures for Clients	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1v	Control of Nonconforming Material	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1w	Deviation/Investigation Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1x	Out of Specification Policy and Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1y	Sampling Procedure/Sampling Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1z	Raw Material Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1aa	CAPA Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1bb	Label Control and Accountability	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1cc	Product Release Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1dd	Employee Training Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ee	Stability, Expiration, and Shelf-Life Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

5.1ff	Product Retention Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1gg	Recall Procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1hh	Customer Complaint Handling	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ii	Equipment validation/qualification procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1jj	Internal audit/self-inspection program procedure	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1kk	Site Security/Site Access Control Policies	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1ll	New Hire Program/Induction Program	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Business Continuity/Contingency Plan:				
5.1mm	Disaster Recovery Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1nn	Pandemic Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1oo	Supply Chain Emergency Preparedness Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1pp	Business Continuity/Contingency Plan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
5.1qq	Can the company provide a plan upon request? OR provide a short description below: Can be disclosed in an audit.			

SECTION 6. Quality Assurance and Production

		Yes	No	Not Applicable
6.1	Does the site have an independent and defined Quality Assurance/Quality Management Division?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2	Does QA/QM have authority over the following:			
6.2a	Policies and procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2b	Review of documentation for release?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.2c	Release or rejection of incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.3	Does QA/QM investigate and resolve quality complaints?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.4	Does QA/QM investigate and resolve internal deviations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.5	Does QA/QM have the authority to assign a disposition to materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.6	Does QA/QM review manufacturing and testing records prior to release?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.7	Does the facility utilize computerized systems for managing GxP activities and data?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

6.8	Are relevant computerized systems 21 CFR part 11 and EU GMP annex 11 compliant?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.9	Does the site use statistical methods for consistency and uniformity?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.10	Does the site use controlled documents for following and recording manufacturing instructions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.11	Does the company qualify and/or validate manufacturing procedures?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.12	Is any environmental monitoring conducted in production/finishing areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.13	Does the site supply BSE/TSE declarations?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.14	Does the site supply a declaration of Elemental Impurities?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.15	Are ICH Q3C solvents used in the manufacturing process of supplied materials?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
6.15a	If Yes, what class of solvent is used?			
6.16	Are stability studies carried out according to ICH guidance?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.17	Are solvents and mother liquor reused/recycled?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.18	Does the site have a process water treatment system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.18a	Please check all that apply to the system: <input checked="" type="checkbox"/> City/potable water <input type="checkbox"/> Distilled water <input checked="" type="checkbox"/> Dionized water <input type="checkbox"/> Water for injection (WFI) <input checked="" type="checkbox"/> Reverse Osmosis <input type="checkbox"/> Clean steam <input checked="" type="checkbox"/> Ultra-filtrated water (purified water) <input type="checkbox"/> Other:			
6.19	Does the plant have a batch/lot system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19a	Is the system traceable?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19b	Is it unique?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.19c	Is batch/lot manufacturing continuous?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
6.19d	Is manufacturing batch by batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.20	Does the site perform on-plant audits prior to approving critical GxP suppliers?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.21	Does the site audit critical GxP suppliers after initial approval?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.22	Does the site inspect incoming materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.23	Does the site test incoming materials to defined specifications?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.24	Does the site establish purchase specifications for raw materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.25	Is the equipment multi-use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.26	Does the site qualify equipment installation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.27	Does the site qualify equipment operation?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

6.28	Does the site qualify equipment performance?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.29	Are production critical use instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.30	Is rework allowed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.31	Is reprocessing allowed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.32	Are manufacturing and packaging activities traceable to the equipment, areas, and materials used?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.33	Are production materials handled and stored in a manner to prevent degradation, contamination and cross-contamination?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
6.34	If answering 'not applicable' for any of the above, please elaborate: 6.6 The site does not release the F&F products, release is done at other site 6.19a: Site potable water is used for cleaning and the water quality is checked 6.26 - 6.28: in the means of ISO 2200, not in the means of pharma IQ,OQ,PQ 6.30,6.31: for rework and reprocessing: documented cleaning between uses is performed			

Additional Comments:

SECTION 7. Laboratory Procedures		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
7.1	Does the site have standard procedures for sample handling/tracking?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1a	Does the site have standard procedures for retaining samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.1b	Does the site have standard procedures for retesting samples?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.2	Does the site have written and approved specifications and test methods?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.3	Are laboratory instruments calibrated regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.4	Is there a standard procedure in place for analytical method development?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>

7.5	Does the site qualify and/or validate analytical test procedures?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.6	Does the site perform stability testing on materials and/or products?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.7	Are retention samples of key raw materials maintained?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7.8	Are standards traceable to their preparation and reagents used?	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
7.9	Are retention samples of finished products maintained?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.10	Are shelf life/retest/expiration dates available and standardized?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.11	Does the company provide a certificate of analysis (CoA) and/or a Certificate of Conformation/Compliance (CoC) for each lot or batch?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.12	Does the CoA/CoC contain the manufacture name and location?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7.13	Is the CoA/CoC signed/e-signed by a Quality representative?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7.14	If a repacker performs analyses, will the CoA reflect both the original manufacturing site data as well as the repacking site data?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
7.15	If answering 'not applicable' for any of the above, please elaborate: 7.4: analytical method developed at other sites. 7.8: Prepared standards not used at the site.			

Additional Comments:

N/A is checked for the section 7 as the site does not release F&F products, release testing is done at another site, the checks in section 7 describe laboratory procedure for F&F products.

Name/Address on CoA contains 24 hr contact information and owning site address

SECTION 8. Packaging, Storage and Transport		<input type="checkbox"/> N/A for this Site		
		Yes	No	Not Applicable
8.1	Does the site have a validated or qualified labeling system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.2	Are batch production records retained and available?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.3	Are packaging and labeling areas separate from production?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

8.4	Are barcode readers in use and challenged regularly?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.5	Are vision systems in use?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.6	Is product ever packaged without a label being initially applied (i.e. bright stocking)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.7	Do labels include shelf life/expiration dates?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.8	Do labels include lot/batch number?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.9	Do labels include requirements for storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.10	Is tamper evident seal used for each container of supplied materials?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.11	Does the company use a First-In-First-Out or First-Expiration-First-Out system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12	Does the company maintain appropriate storage conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.12a	Are those storage conditions monitored and documented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.13	Does the site make available a description of storage and/or warehouse conditions?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.14	Does the site distribute products via a third party?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.15	Are good distribution policies implemented?	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
8.16	Are transport mechanisms dedicated?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.17	Does the company validate shipping method?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>
8.18	Does the company validate packaging methods?	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Additional Comments:

Third party distributors used in select regions.

I (Supplier) confirm that the information provided in this questionnaire is correct and can be verified.

Title: Quality Assurance Supervisor

Date: 11/25/2025

Additional Site-Specific Information

(not based on Rx 360 Supplier Assessment Questionnaire)

9. Food Safety Management System		Yes	No
9.1	Does the facility have a documented food safety management system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.2	Is a food safety plan maintained at the site?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.3	Is there a designated food safety and/or HACCP team?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.4	Does the food safety/HACCP team meet regularly to review the food Safety management system?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.4.a	How often?	1/month	
9.5	Is any non-food production performed at the site?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.5.a	Is the non-food production segregated from the food facility?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.6	Is organoleptic testing performed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.7	Are any of the following added to the product:		
9.7.a	Artificial colors?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.7.b	Silicon dioxide (SiO ₂)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.7.c	Monosodium glutamate (MSG)	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.7.d	Guanylates and/or Inosinates?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.9	Are any materials treated with the following:		
9.9.a	Chemical treatment:		
9.9.a.i	Fumigation?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.9.a.ii	Ethylene oxide (EtO)?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.9.a.iii	Methyl bromide?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.9.b	Irradiation?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.9.c	Steam treatment?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.9.d	Heat treatment?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.9	Indicate which internal audits are performed and their frequency: GMP audit (monthly), ISO 9001 (annually), ISO 22000/22002 (annually)		
9.10	Is there a written recall procedure?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.11	Is there a lot traceability system that allows for traceability backwards to materials received and forwards to lots shipped?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.11.a	Does the traceability system include packaging supplies?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.12	Are traceability exercises performed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.12.a	How often?	2/year	
9.12.b	Indicate acceptable recover:	100%	
9.12.c	Indicate acceptable recovery time:	4 hours	
9.12.d	Do traceability exercises include direct-contact packing supplies?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.13	Is there a packaging supply supplier selection and approval process?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.13.a	Are there established specifications and/or conformity requirements for packaging supplies?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.13.b	Are packaging supplies inspected for cleanliness and integrity prior to being approved for use?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.13.c	Is there a process for managing non-conforming packaging supplies?	<input checked="" type="checkbox"/>	<input type="checkbox"/>

		Yes	No
9.14	Is there a pest control program for all areas including raw material and packaging supply storage areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.14.a	Are toxic pest baits or pesticides used in any areas?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.14.b	Is there a pesticide usage log?	N/A	
9.14.c	Is there a pest sighting log available to employees?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.14.d	Are the grounds maintained so there are no excessive weeds or plant growth?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.15	Is there a documented master cleaning schedule?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.16	Are cleaning chemicals stored in non-production areas?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.17	Does the facility have a glass/brittle plastic program?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.17.a	Is the facility regularly inspected for glass/brittle plastic and how often?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.17.b	How often?	1/month	
9.19	Are diesel power vehicles used anywhere in the facility?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.19	Are only food grade lubricants used with the food processing equipment?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.20	Is latex used anywhere in the facility?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.21	Are incoming and outgoing vehicles inspected for cleanliness prior loading or offloading?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.22	Are metal detectors used?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.23	Is there a documented food defense program?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.23.a	Are security cameras used?	<input type="checkbox"/>	<input checked="" type="checkbox"/>
9.23.b	Are all site entrances monitored and/or locked and alarmed?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
9.23.c	How often is the food defense program reviewed?	annually	

10.	Fair Trade / Sustainability	Yes	No
10.1	Is the site registered to any fair trade and/or sustainability organization?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	SEDEX registered – Sedex number S000000045396		
10.2	Has the site undergone any fair trade and/or sustainability audits?	<input checked="" type="checkbox"/>	<input type="checkbox"/>
	SMETA 4-Pillar audit		

For more information on fair trade and sustainability minerals visit us at: emdgroup.com/en/sustainability-report Here you will find information including:

Environmental Policy	Supplier Code of Conduct
Social Policy	Bioethics Policy
Fiscal Policy	Labor Policy
Statement on Conflict Minerals	Annual Global Citizenship Reports
UN Global Compact Communication on Progress	