

Brenntag South Africa Quality & Regulatory
Frequently asked questions / Self-Assessment Questionnaire

Dear Valued Customer,

Brenntag is the global market leader in full-line distribution of chemicals & ingredients and offers a range of value-added services. Our portfolio comprises specialty and industrial chemicals and ingredients from a world-class supplier base. Building on its long-standing experience, unmatched global reach, and local excellence, Brenntag works closely alongside its partners to make their business more successful.

At Brenntag South Africa (BSA), we ensure that the materials we supply are manufactured in accordance with global industry standards & local regulatory requirements. Brenntag South Africa is currently ISO 9001, ISO 45001, ISO 14001 and FSSC 22000 certified.

Due to increasing regulatory requirements, Brenntag South Africa receives a significant number of questionnaires and queries from our customers regarding our quality certification(s) / management system.

Unfortunately, we are unable to complete each customer's unique questionnaire individually. To respond to these requests in a timely and efficient manner, and to ensure that we provide consistent information in all cases, we have established a standardised frequently asked questions / Self-assessment Questionnaire package to facilitate the exchange of quality and safety-related information with our customers.

We are committed to our relationship with you, our customer, and we are convinced that this is an improvement in information management which will allow us to respond more quickly to your enquiries as we strive to always provide excellent service and support to you. Thank you for your continued interest in our products.

Sincerely



Sally Green
Quality & Regulatory Manager
Brenntag South Africa

A. GENERAL INFORMATION

Company Name	Brenntag South Africa (Pty) Ltd
Registered office location	247 15th Road, Randjespark, Midrand , 1685
Registration Number	1952/001517/07
Vat number	4520105356

BSA Sites

Johannesburg	Cape Town	Eastern Cape	Durban
<u>Midrand</u> 247 15 th Road, Randjespark, Midrand, 1685 +27 (0)10 020 91 00 (Registered Head Office, warehouse, tank farm)	<u>Killarney Gardens</u> 11 Mansell Road, Killarney Gardens, 7441 +27(0) 21 020 1800 (Office, warehouse)	<u>Port Elizabeth</u> Unit 1 Baysuites, 1 Humewood Road, Humewood, Port Elizabeth, 6001 +27 (0)10 020 91 00 (Office)	<u>Prospecton</u> 6 Stroude place, Prospecton Isipingo, Durban, 4126 +27(0) 21 020 1800 (Office, warehouse, tank farm)
<u>Pomona 1</u> Unit 2, Ext 149. Elgin Street, Pomona, Kempton Park, 1619 +27(0) 10 020 9100 (Office, food and pharmaceutical warehouse, flavour blending and repacking facility)	<u>Paarden Eiland</u> 7 Dorsetshire Street, Paarden Island, 7405 +27(0) 21 020 1800 (Office, warehouse)		
<u>Pomona 2</u> 298 Elgin Road, Pomona Kempton Park, 1619 +27(0) 10 020 9100 (office, warehouse, blending and repacking facility)			

B. NAMES OF CONTACT PERSON(S)

Senior Director BSP Sub-Saharan Africa	Morgan Govender Phone: +27(0) 10 020 9100 E-Mail: morgan.govender@brenntag.com
Head of Q&R and Responsible Pharmacist (Production)	Lindi Diedericks Mobile: +27(0) 84 492 6212 Email: lindi.diedericks@brenntag.com
Quality & Regulatory Manager	Sally Green Mobile: +27 (0) 82 563 1536 Email: sally.green@brenntag.com
Responsible Pharmacist (Warehousing)	Ezekiel Nkere Mobile: +27 (0) 83 296 1002 Email: ezekiel.nkere@brenntag.com
Head of HSE	Marlene Cilliers Mobile: +27(0) 63 345 1846 Email: marlene.cilliers@brenntag.com

C. CERTIFICATIONS & MEMBERSHIPS:
C.1. Certifications:

Certificate	Certifying Entity	Site(s)
SAHPRA Licence to distribute scheduled substances	SAHPRA	Pomona 1
ISO 9001:2015 (Quality Management Systems)	NQA	Midrand Killarney Gardens Pomona 1 & 2 Prospecton Paarden Eiland Port Elizabeth (1 Humewood Road)
FSSC 22000 (Food Safety System Certification)	ProCert	Pomona 1
ISO 45001 (Occupational Health and Safety Management)	NQA	Midrand Killarney Gardens Pomona 1 & 2 Prospecton Paarden Eiland Port Elizabeth (1 Humewood Road)
ISO 14001 (Environmental Management)	NQA	Midrand Killarney Gardens Pomona 1 & 2 Prospecton Paarden Eiland Port Elizabeth (1 Humewood Road)
Letter of Good Standing (COID)	Department of Labour	All sites
Certificates of Acceptability for Food Premises R638	-	Killarney Gardens Prospecton Pomona 1 & 2
Ecovadis Sustainability Rating – Gold medal	-	Brenntag SE (Group)
SANS 1827 (The Safety of Water treatment chemicals for use in the food industry)	SABS	Pomona 2
SANS 1853 (Disinfectants, detergent-disinfectants and antiseptics for use in the food industry)	SABS	Pomona 2
SANS 1828 (Cleaning Chemicals for use in the food industry)	SABS	Pomona 2
B-BBEE	EmpowerLogic (Pty) Ltd	Brenntag South Africa (Pty) Ltd
Rainforest Alliance	Rainforest Alliance	Pomona 1 Killarney Gardens Prospecton
Sedex	Sedex	Pomona 1 Killarney Gardens Prospecton

C.2. Industry Memberships:

CTFA	Cosmetic Toiletry & Fragrance Association of South Africa
Coschem	Society of Cosmetic Chemists South Africa
HPA	The Health Products Association of Southern Africa
SAAFFI	South African Association of the Flavour & Fragrance Industry
Plastics SA	Plastics South Africa
IOM3	Institute on Materials – Rubber (South Africa)

C.3. Licenses:

Curt Georgi Flavours (Site: Pomona 1)	Pomona 1
Roundtable on Sustainable Palm Oil (RSPO) Distributor License	Killarney Gardens

D. INTEGRATED MANAGEMENT SYSTEM (IMS) INFORMATION (ALL SITES)

The scope of BSA's IMS includes purchasing, storage, sales, repacking and distribution of raw materials to the food, beverage, pharmaceutical, animal feed, personal care, plastic, rubber, coatings and construction, water treatment, chemical and general industry. It also includes the blending, storage and distribution of solvents and chemicals.

This section gives an overall view of the IMS for all BSA sites.

D.1 Integrated Management System	
Integrated Management System (IMS) manual in place	Yes
IMS Policy in place	Yes
IMS certification in place	All sites: ISO 9001:2015 (Quality), 14001:2015 (Environment), 45001:2018 (Occupational Health and Safety) Pomona 1: FSSC 22000 (Food Safety); SAHPRA Licence to distribute scheduled substances Pomona 2: SABS Permits for SANS 1827, 1828, 1853
Is the Quality & Regulatory (Q&R) department separate from Operations Department and separate from Health, Safety & Environment Department?	Yes
Is there a Change Control / Management of Change Procedure in place?	Yes
Are the effectiveness of changes being reviewed?	Yes
Do you notify customers in writing of any Changes relating to suppliers / products you become aware of?	Yes
Is there a Corrective and Preventative Action (CAPA) procedure in place, with effectiveness review?	Yes
Is there a Non-Conformance procedure in place and are all non-conformances investigated?	Yes
Are Change Controls and Non-Conformances reviewed and approved by appropriate personnel, including Q&R?	Yes

D.2 Standard Operating Procedures (SOP) / Process Flows	
All business units have Process flows?	Yes
Receiving SOP in place?	Yes
Dispatch SOP in place	Yes
Loading /offloading Work Instructions (Midrand & Prospecton)	Yes
Spillage SOP in place	Yes
Forklift driving SOP in place	Yes
Non-conformance SOP in place	Yes
Incident and Near-miss Reporting SOP in place?	Yes
CAPA SOP in place	Yes

D.3 Document control and storage	
Is there a system in place to ensure appropriate control and retention of documented information?	Yes
Updated SOP's available?	Yes
Are all available documents (such as SOP's, organograms, floor plans, process flows and work instructions) approved and controlled with document numbers, and version numbers?	Yes
Are superseded / obsolete documents archived?	Yes
Are Good Documentation Practices (GDocP) adhered to?	Yes

D.4 Human Resources	
Is there an organization chart?	Yes
Is Job Profiles available for all relevant personnel?	Yes
Is an effective employee-training program in place for company?	Yes
Staff trained on the applicable procedures?	Yes
Has relevant PPE been identified, supplied free of charge and staff trained on use? Worn-out and old PPE replaced?	Yes
The PPE (Personal Protective Equipment) issued by the company includes but not limited to: <ul style="list-style-type: none"> • Safety boots • Hard Hats (Operations) • Acid/flam overalls for Operations staff • HACCP for repacking staff • Full face respirators (Blending & repack team) • Gloves (PVC/Latex/other as per work area) • Other additional PPE as per scope of work 	Yes
Are there adequate toilet facilities available?	Yes
Are these kept clean and in good repair?	Yes
Are employees required to report health issues?	Yes

D.5 Pest control	
Is there a pest control programme?	Yes
Is an external service provider used?	Yes
Are bait stations installed and maps available?	Yes
Is the service provider a registered pest control company?	Yes, Service provider details: Killarney Gardens (Servest) Pomona 1 (Ecolab) Midrand (Rentokil) Durban (Pest A side) Pomona 2 (Meridian Hygiene)
Do they service the facility on a monthly basis?	Yes
Do you have fly traps installed?	Yes (Pomona 1)
Are pest control records maintained and available for inspection?	Yes
Are SDS's (Safety Data Sheets) available for any pesticides, etc. used by the pest control company?	Yes

D.6 Warehouse	
Is the storage facility cleaned on a regular basis?	Yes
Is this cleaning documented?	Yes
Is access to the facility controlled?	Yes
Are materials stored and handled in a manner to prevent deterioration, damage, or contamination?	Yes
Are any 3 rd party warehousing & distribution services used?	Yes
Do you have a written procedure in place for approving 3 rd party warehouses?	Yes
Is 3 rd party warehousing part of your external audit program?	Yes

D.7 Maintenance	
Implement maintenance and preventive maintenance programs to keep equipment etc. in a good state of repair?	Yes
Is there an equipment list available?	Yes

D.8 Receiving and dispatching of stock	
Is stock rotation controlled?	Yes, according to FEFO
Are incoming goods inspected?	Yes, visually
Are these inspections documented?	Yes
Are outgoing goods inspected?	Yes, visually
Are these inspections documented?	Yes
Are allergens stored separately?	Yes
Are non-conforming products stored separately?	Yes
Is this documented?	Yes
Are returned products stored separately?	Yes
Is this documented?	Yes
Is stock controlled by computer system (SAP)?	Yes
Is stock handled and stored in a manner to prevent contamination, deterioration and intermixing?	Yes
Is stock stored off the floor?	Yes

Is there a unique internal batch number assigned to received stock?	Yes
Is any sampling of stock performed when receiving the material?	No

D.9 Transport	
Are own vehicles inspected for cleanliness before loading?	Yes
Is this inspection of vehicles documented?	Yes
Do drivers check materials in their care?	Yes, during loading and unloading
Are own vehicles kept in good working condition?	Yes
Are third party vehicles used for shipments?	Yes
Are these vehicles inspected for cleanliness?	Yes
Is there a 3 rd party transporter vetting process in place?	Yes
Driver competency verified pre-each load?	Yes

D.10 Ethical Trade	
Do you have a Code of Business Conduct and Ethics in place?	Yes
Do you have a Supplier Code of Conduct in place?	Yes
Does the company have a written commitment that demonstrates its respect for internationally recognized human rights and labor standards, including fundamental rights at work?	Yes
Do you have a Grievance Procedure Policy in place?	Yes
Do you have an elimination of Harassment in the Workplace Policy in place?	Yes

D.11 Occupational Health, Safety, Environmental & Security (HSE & S)	
Do you have a person responsible for Occupational Health, Safety, Environmental & Security Topics?	Yes
Do you have a Health, Safety and Environmental policy?	Yes (IMS Policy)
Do you have HSE Committee meetings quarterly?	Yes
Is there an HSE induction programme in place for staff, visitors, contractors and transporters? a. Annual refresher b. On-boarding	Yes
Legal Appointment, with relevant training? i.e. a. 16.2 b. 8.2.i c. SHE Reps d. Fire Team e. First Aiders f. Permit Issuer g. Incident investigator	Yes
Have you performed a Health & Safety risk assessment?	Yes
Are employees trained on relevant Health & Safety risks?	Yes
Is an Emergency Preparedness Plan in place?	Yes

Drills conducted?	Yes
Is there contractor management process in place?	Yes
Does the company track on safety performance? i.e. a. Fatality rating b. Reportable injury rating c. Disabling injury rating d. Lost time injury rating	Yes
Are occupational Hygiene Surveys conducted?	Yes
Is there a medical plan in place for relevant personnel? Pre-employment medical Annual medical for relevant staff Exit medical Monthly Chronic monitoring	Yes
Are HSE Committee meetings conducted?	Yes
Are any of your sites listed as MHI?	Yes – Midrand Pomona2 & Prospecton
Are all your firefighting equipment serviced timeously and records retained?	Yes
Is there Aspects and Impacts Process in place?	
Is there Environmental Management Plan?	Yes
Are SDS's readily available?	Yes
Is there site security Procedure? i.e. a. Entry controlled (all entering)? b. Screening at point of entry in place? c. Movement of visitors controlled?	Yes

D.12 Supplier approval	
Do you have a supplier approval programme in place?	Yes
Do you keep an up-to-date list of your approved suppliers?	Yes
Do you purchase only from approved suppliers and distributors/agents?	Yes
Do all products have raw material specifications?	Yes
Are all products issued with a Certificate of Analysis (CoA)?	Yes

D.13 Internal Audits	
Is there an internal auditing programme in place?	Yes
Are Internal audits for the IMS system conducted?	
Are all internal auditors trained on ISO 9001:2015, 14001:2015, 45001-2018?	Yes
Are reports retained for the Internal audits conducted?	Yes

D.14 Customer Audits	
Would you permit customers to perform an on-site audit?	Yes,
Do you allow 'for cause' audits (in addition to any scheduled compliance audits) to investigate specific deviations or GMP (Good Manufacturing Practices) concerns?	Yes

D.15 Customer Complaints	
Are all customer complaints investigated?	Yes
Are root causes, corrective actions & preventative actions documented?	Yes
Is there a system to capture, record and manage customer complaints?	Yes

D.16 Recalls	
Do you have a recall procedure in place?	Yes
Recall procedure is in place and mock recalls conducted annually at a minimum.	Yes

E. PHARMACEUTICAL QUALITY SYSTEM (PQS) / FOOD SAFETY MANAGEMENT SYSTEM (FSMS) - POMONA 1

The scope of the BSA FSMS includes blending and packing of flavours, repacking of bulk food ingredients into smaller packs, storage and distribution of food ingredients.

The scope of the BSA PQS includes importing, warehousing and distribution of pharmaceutical materials, repacking of bulk ingredients into smaller packs.

These systems are only applicable to **the Pomona 1 site of BSA** and below assessment is only applicable to this site, **in addition** to the information provided above in Section D.

E.1 GMP (Good Manufacturing Practices) and GWP (Good Warehousing Practices)	
Are GMP and GWP being followed at the site?	Yes

E.2 Raw materials & laboratory testing	
Are raw materials manufactured locally or imported?	Locally & imported
Do you make use of an in-house or outsourced laboratory testing to confirm supplier specifications? (Post importation testing)	No

E. 3 Documents / SOP's / Process flows	
Is there a Site Master File (SMF) in place?	Yes
Is there a Quality Risk Assessment and management procedure in place for food and pharmaceutical products?	Yes
Blending SOP in place (Pomona1)?	Yes
Repacking SOP in place (Pomona1)?	Yes
Is a version-controlled floor plan available for Pomona 1?	Yes

E.4 Warehouse (Building)	
Type of location	Industrial Park
Type of building	Brick & Mortar
Is there a floor plan available indicating the flow of personnel and material?	Yes
Are separate areas for receiving and dispatch available?	Yes
Do the receiving and dispatch bays have adequate covering in place?	Yes

Are wooden pallets heat treated or made of plastic?	Yes
Does the facility maintain separate areas for eating, smoking, rest rooms and lockers for changing?	Yes
Total area of the site	Building: 7 400 m ² Site: 8 000 m ²

E.5 Data Integrity	
Are there adequate procedures to ensure Data Integrity?	Yes

E.6 Human Resources	
Are all staff trained on good hygiene and housekeeping practices as per GMP and food safety requirements?	Yes
Is the company organogram available showing key personnel linked to the Pharmaceutical Quality System and Food Safety?	Yes

E.7 Hygiene / Good manufacturing (GMP) practices	
Are water wash basins or hand sanitizers available at or near the work stations?	Yes
Do you have policies on no wearing of jewelry in the repacking and blending area?	Yes
Is there a system in place which ensures that personnel with infectious diseases or other apparent illnesses are not involved in operations where health conditions could adversely affect products?	Yes

E.8 Traceability	
Can a batch be traced back to the producer within 4 working hours?	Yes
Is this documented?	Yes
Do you have a system that ensures upstream and downstream traceability of products?	Yes

E.9 Management meetings	
Are Pharmaceutical Quality System (PQS) /Food safety Management review meetings scheduled at least twice yearly?	Yes
Are monthly PQS /Food safety review meetings held by the Q&R team?	Yes

E. 10 Quarantine / Rejected material	
Are there SOP's in place for handling of returned, rejected and quarantined goods?	Yes
Are there procedures in place to prevent the inadvertent usage of rejected raw materials?	Yes
Is rejected / quarantined material held in a dedicated location / area?	Yes

E. 11 Temperature Control	
Is there a temperature and humidity control system in place for the repacking and blending area?	Yes, HVAC
What is the classification of the repacking clean room area?	Grade D / ISO Class 8
Is daily temperature recording maintained and up to date?	Yes, we have iMonnit temperature monitoring system in place.
Has temperature mapping of the flammable store and warehouse been performed?	Yes
Are loggers placed in positions in warehouse as per mapping exercise and calibrated?	Yes

E. 12 Environmental monitoring of re-packing and blending areas (PQS & Food safety)	
Do you have a documented environmental monitoring schedule?	Yes
Is your environmental schedule risk-based	Yes
Are test performed internal or external?	Externally by an accredited service provider

E. 13 Cleaning	
Is there a procedure in place describing the cleaning process? (area & relevant equipment)	Yes
Are cleaning materials correctly stored and labelled?	Yes

E. 14 Training	
Are there adequate personnel who are qualified by appropriate education, training and/or experience available?	Yes
Has GMP / GWP /FS training been conducted?	Yes
Is there a system in place to document training provided / training needs?	Yes

E. 15 Repacking	
Is line clearance, opening and closure performed for each re-packing being performed?	Yes
Is there a SOP in place for labelling of material after being repacked?	Yes
Does Q&R review repacking documents to release?	Yes

E. 16 Flavour Blending	
What type of water is used during production of flavours?	Potable water
Is water being tested at regular intervals?	Yes
Is the in-process control supervised by Q&R?	Yes
Are there sieves in the production lines?	Yes
Are products halaal certified where applicable?	Yes
Are products kosher certified where applicable?	Yes
Does Q&R review blending documents to release?	Yes

E.17 Validation	
Is there a Validation Master Plan in place?	Yes

E. 18 Calibrations	
Is there a procedure that describes calibration intervals for instruments, equipment and gauges?	Yes
Are instruments, equipment and gauges calibrated regularly, and calibration records maintained?	Yes
Are daily verifications performed on the scales?	Yes
Are all equipment / instruments / gauges clearly labeled with the last date of calibration and when next due for recalibration?	Yes
Who performs the calibrations?	Approved external service providers

E.19 Food Defense and Food Fraud	
Do you have a Food Defense Plan developed in accordance with FSSC 22000?	Yes
Have you addressed Food Fraud Prevention Plan in accordance with FSSC 22000?	Yes

E.20 Allergen Management	
Do you have an allergen policy and procedure implemented?	Yes
Are there any allergens on your site? If yes please list	Yes – Egg, Wheat, Soy, Sulphur dioxide (\geq 10ppm), Cow's milk, Fish
Are employees aware of allergen-containing products held in the facility?	Yes
Are controls in place to prevent cross-contamination of products by allergens?	Yes