

agriculture, forestry & fisheries

Department: Agriculture, forestry & fisheries **REPUBLIC OF SOUTH AFRICA**

FREE SALES AND TOL FORMULATION APPLICATION PROCEDURES

Issued by the Registrar: Act No. 36 of 1947, Private Bag X343, Pretoria 0001, Republic of South Africa

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JULY 2018

1. FREE SALES CERTIFICATES APPLICATION REQUIREMENTS

- Application fee
- Application letter with clear motivation(s)
- If the certificate is required for the approval of the product in another country. The country where approval is sought should be indicated on the application letter.
- After approval is gained in another country, the applicant needs to submit certified copies of registration certificate(s) for the Registrar to update the admin records. This should be submitted within a period of six months after registration or approval is granted and before sales/use of the product begins in another country.
- If the certificate is required for renewal purposes. The applicant should include certified copies of the registration certificates six months to date of expiry and before any new certificate is issued.
- The Free Sales Certificate will remain valid for 12 months
- If the certificate is required to add an additional manufacturing site or formulator, the requirements for additional manufacturing site/formulator must be met.
- If the certificate is required for a product not registered in the destination country, an import permit application with letter of request by the designated authorities in the destination country must be submitted. The designated authorities in the destination country should give specific reasons including details of intended use of the product, as to why SA should allow export of a particular product to the destination country.
- For active ingredients listed on the UN Conventions such as Rotterdam, Stockholm, Montreal Protocol, SAICM, Minamata, etc. The requirements as prescribed by the Department of Environmental Affairs must be met.
- The certificate cannot be used for any other purpose as per the conditions listed by the Registrar
- The certificate will be issued with the following information appearing i.e. the registration holder name, registration number, brand name, active ingredient(s), validity period, and any other conditions determined by the Registrar.

2. TOLL FORMULATION PROCEDURE APPLICATION (FOR SA COMPANIES FORMULATING PRODUCTS REGISTERED IN OTHER COUNTRIES BUT NOT IN SSOUTH AFRICA).

A written affidavit with emphasis on section 3 and 7 of the Act and should be addressed to the Registrar. The affidavit should be accompanied by the following documents:

- Application fee
- Toll formulation agreement
- Application letter with clear motivation(s) and also indicating the export port
- Quantities of active ingredient/s that have to be imported, and quantities that will be formulated and exported.

- Letter of supply of the technical material indicating the physical address of the manufacturing site
- Manufacturing method
- Certified copies of registration certificates in the destination country or certified copies of Free Sales Certificates
- Certificate of analysis
- Formulation letter of agreement.
- Full formulation composition adding up to 100%.
- For active ingredients listed on the UN Conventions such as Rotterdam, Stockholm, Montreal Protocol, SAICM, Minamata, etc. The requirements as prescribed by the Department of Environmental Affairs must be met.
- Certified copies of valid registration certificates of countries where the product(s) will be exported.