

UNDERSTANDING DIFFERENT PRODUCT TYPES AVAILABLE FROM CLAYTON PLANT PROTECTION.

Clayton's growing product portfolio is a hybrid mix of 'Generic products', 'Parallel imported products' and 'Third party products'. The current Regulatory system can be complex and confusing, so we have provided a quick reference summary of the different types of products we market.



Generic Products

A generic product, also referred to as an 'off-patent product', is a product that is manufactured after the expiration of a patent or other exclusive rights, by a company that does not hold the original patent, and without (the need for) a license from the original patent holder. Generic products are developed, authorised, manufactured and marketed under the same strict rules and requirements as the "original" products.

New product authorisations can be submitted and assessed by the authorities under a number of different technical assessment streams, these are listed below and contain active links to the respective page/section on hse.gov.uk:

New products (Technical assessment type)

- [New product similar to existing authorised product](#)
- [New product supported by full data package](#)
- **[New product based on unprotected data](#)**
- [New product based on Authorisation via Article 40 \(Northern Ireland only\)](#)
- [New Northern Ireland only parallel trade permit and Northern Ireland only own-use parallel trade permit](#)

Most Clayton Generic registrations are **currently authorised 'based on unprotected data'**

Products approved via this method must be 'identical' or 'similar' to a named reference product. This means the ingredients or 'recipe' for the product submitted by Clayton Plant Protection must be very close or identical to a named reference product.

For example, the product Clayton El Nino (500g Diflufenican) has the reference product Hurricane (also 500g Diflufenican). As well as the main active ingredients being the same, all co-formulants must also be.

New sources of the active substance submitted as part of the application must meet the EU or UK defined minimum concentration of the active substance and the maximum concentration of all impurities present at $\geq 0.1\%$ w/w.



Because products submitted for approval by this assessment stream are deemed 'identical' or 'similar' to a named reference product, no efficacy data needs to be submitted since the authorities are satisfied the products performance will be equal to the named reference.

Submissions via this assessment stream require all supporting data e.g. toxicity studies to be out of data protection. This data protection is granted when new products are first registered or re-registered following the renewal of the authorisation of the contained active ingredients.

To establish the constituent parts or 'recipe' of any given product, Clayton Plant Protection work with a network of experienced, specialist consultants who are able to reverse engineer or deconstruct existing products to establish the constituent parts and their concentrations.

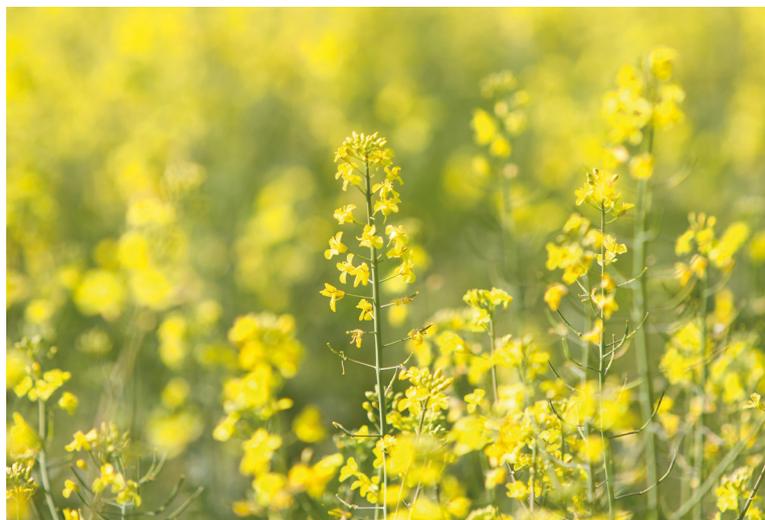
Clayton then work in partnership with a global network of supply chain consultants and manufacturers to source the active ingredients and co-formulants for their products. In order to gain authorization, these must meet the exacting standards of both the EU and UK regulators with minimum concentrations for active substance and maximum impurity levels. Clayton Generic products are then formulated in the UK or EU at toll manufacturers that meet Clayton's exacting standards.

Since the 'recipe' for products approved by Clayton via the unprotected data stream is identical to the reference products Clayton are happy to warrant the performance and compatibility of their products at the same standard as the reference products, providing reassurance and peace of mind to our customers.

Parallel Import Products

A parallel import license describes a product that is imported from an EU Member State which is identical to the reference UK product. It differs from a generic license in that a parallel import PPP is still manufactured by the authorisation holder of the reference product, but it is re-labelled and sometimes repacked by the parallel import licence holder.

Under current legislation all EAMUs automatically carry across from the UK reference product to a parallel product using that product as a reference. <https://www.hse.gov.uk/pesticides/pesticides-registration/>



Clayton Plant Protection **warrant tank mixes** for our complete range of parallel import PPP's as per the original authorisation holders recommended tank mixes for the reference product in the UK.

Clayton Plant Protection adopt the current and ongoing Product Stewardship guidelines of the Manufacturers on which their Parallel Import Licenses are based

Now the UK has left the European Union, the UK Regulator, the Chemical Regulation Division of HSE, are no longer accepting applications for parallel import products/licenses.

The reason given is that *"the parallel trade provisions of the EU pesticide regime were entirely reliant on the sharing of confidential information and data between member states to demonstrate that products are identical. This information is no longer available."*

All existing parallel approvals will also expire under the following timelines unless their existing expiry date is sooner:

- 31 December 2022 – Last sales by authorisation holder (e.g. Clayton)
- 30 June 2023 – Last sales by third parties (e.g. Distributors)
- 30 June 2024 – Last use and storage by anyone (e.g. Farmers)

Clayton believe that parallel import products make a significant contribution to UK Agriculture and are actively campaigning for a longer term position for parallels since they believe there must be alternative ways to demonstrate the identity of products.

Third Party Products

As well as developing and marketing their own generic and parallel products, Clayton Plant Protection also market a number of products on behalf of other manufacturers who share Clayton's values but do not have an active presence in the UK.

These products are a mix of generic products and new innovative active ingredients which enable Clayton to offer a broader portfolio of high quality products to meet farmer needs.

Find Out More

Further information on Clayton's product range including labels can be found at www.claytonpp.com

Head Office

Clayton Plant Protection,
Bracetown Business Park,
Clonee, Dublin
tel. **00353-1-8210127**
email. info@claytonpp.com

Information in this Technical Bulletin is for guidance only. Brand names used in this Bulletin are trademarks of Clayton Plant Protection and of other manufacturers, in which proprietary rights may exist. Always use Plant Protection Products safely.