



**E N I G M A**  
MARKETING RESEARCH

# **New Off-Patent/Generic Agrochemicals - Post 2013**

**A new report, the 9th in the series, on the market for off-patent/generic agrochemicals which will assist companies to:**

- Identify their next off-patent/generic active substance for development.
- Develop new opportunities in the buoyant and expanding off-patent/generic agrochemical sector.
- Understand the issues of developing new off-patent/generic agrochemicals.
- Analyse strategies for post-patent expiry market defence strategies.
- Monitor competitor intelligence.

This report is essential for companies wishing to progress in the dynamic agrochemical market:-

**Generic Manufacturers**

**Marketing Companies**

**Inventor Companies**

**Contract Manufacturers**

**Intermediate Suppliers**

**Investment Companies**

# New Off-Patent/Generic Agrochemicals – Post 2013

Features *29 active substances* the patents of which will expire between 2013-2017\*

Active Ingredient	Activity	Inventor Company	Major Marketing Companies
Benthiavalicarb	Fungicide	Kumiai	Kumiai, Certis
Benzobicyclon	Herbicide	SDS Biotech	SDS, Gowan, ISK, Nissan, Hokko
Bistrifluron	Insecticide	Dongbu Hannong	Dongbu Hannong
Boscalid	Fungicide	BASF	BASF, Bayer CropScience
Cyflufenamid	Fungicide	Nippon Soda	Nippon Soda, Certis
Dinotefuran	Insecticide	Sankyo Agro	Mitsui Toatsu, Valent (Sumitomo Chemical), Hokko, Gowan
Ethaboxam	Fungicide	LG Life Sciences	Sumitomo Chemical
Fenamidone	Fungicide	Bayer CropScience	Bayer CropScience
Fentrazamide	Herbicide	Nihon Bayer Agrochem	Bayer CropScience, Kumiai
Fluoxastrobin	Fungicide	Bayer CropScience	Bayer CropScience
Foramsulfuron	Herbicide	Bayer CropScience	Bayer CropScience
Isoxadifen-ethyl	Safener	Bayer CropScience	Bayer CropScience, Du Pont
Mesosulfuron	Herbicide	Bayer CropScience	Bayer CropScience
Metaflumizone	Insecticide	Nihon Nohyaku	Nihon Nohyaku, BASF
Metalaxyl-M	Fungicide	Syngenta	Syngenta
Metrafenone	Fungicide	BASF	BASF
Orthosulfamuron	Herbicide	ISAGRO	ISAGRO, Chemtura
Orysastrobin	Fungicide	BASF	BASF
Penoxsulam	Herbicide	Dow AgroSciences	Dow AgroSciences
Penthiopyrad	Fungicide	Sankyo Agro	Mitsui Chemicals, Du Pont

Active Ingredient	Activity	Inventor Company	Major Marketing Companies
Proquinazid	Fungicide	Du Pont	Du Pont
Prothioconazole	Fungicide	Bayer CropScience	Bayer CropScience
Pyraclostrobin	Fungicide	BASF	BASF
Pyridalyl	Insecticide	Sumitomo Chemical	Sumitomo Chemical
S-metolachlor	Herbicide	Syngenta	Syngenta, Du Pont
Spirotetramat	Insecticide	Bayer CropScience	Bayer CropScience
Thiamethoxam	Insecticide	Syngenta	Syngenta
Topramezone	Herbicide	BASF	BASF, Amvac, Nippon Soda
Zoxamide	Fungicide	Dow AgroSciences	Gowan

\* in some countries patent term extension beyond 2017 may exist.

## Report Outline

### Section 1: Defending A Market Post Patent Expiry

How do inventor companies defend markets once basic patents have expired?

In preparation for patent expiry a variety of strategic options are utilised by the inventor company to defend market share:

- **Intellectual Property Rights**
- **Protected Registration Data**
- **Technical Defence via Process Know How**
- **Marketing Alliances - “Authorised Generic”**

In this section practical examples of post-patent defence strategies are given including, mixture, process and formulation patents, technical know-how, data protection, key intermediates and economies of scale. Time-lines featuring patents, Supplementary Protection Certificates (SPCs) and data protection issues demonstrate how difficult it is for generic companies to enter the more protected markets of the EU and US. Examples of recent patent litigation cases are also given.

Patent expiry dates and data protection periods are also identified for the active ingredients featured in this report.

## Section 2: Developing A New Off-Patent/Generic Agrochemical

Since 2002, Enigma has identified 137 active substances with patents expiring between 2002 and 2017. With so many active substances coming off patent choosing the right off-patent/generic to develop requires analysis of the following key areas:

- **The Marketing Environment**
- **Intellectual Property Rights**
- **Chemistry/Technology of Manufacture**
- **Registration Issues**

Each area is reviewed and the key strategies employed by generic companies to enter markets are discussed.

Practical examples are given where gaps in the original patent portfolio exist providing generic companies an opportunity to enter the market prior to expiry of the active substance patent.

In this section, dates for the expiry of data protection in the EU for 242 existing active substances are given providing the generic manufacturer opportunities to enter the hitherto restricted market.

Supply Chain Management is crucial to secure the supply chain for generic companies having invested relatively large resources into obtaining registrations. In addition, the position of China as a major source of active ingredients is discussed and how this might develop over the next five years.

## Section 3: Profiles Of 29 Active Substances

The Active Substance profiles contained in this report will help you determine which strategy, or combination of strategies is likely to be employed by the patent holder in order to protect market share.

### Key data in active substance profile:

#### Patents

- European patent number and expiry date
- UK Supplementary Protection Certificates (SPCs)
- US patent number and expiry date
- INPADOC patent family

#### Product Profile

- Activity
- Major mixture products
- Trade names
- Biochemistry
- Mode of action
- Uses
- Types of formulated products
- Major crops
- Major markets

#### Registration Issues

- US Environmental Protection Agency (EPA)
- EU Directive 91/414
- Web links to registration documents

#### Chemistry

- Synthetic pathway
- Alternative synthetic pathway (where appropriate)
- Key intermediates

#### Summary

- Analysis of the opportunity for generic competition.

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# Purchase Order Contract

**New Off-Patent/Generic Agrochemicals  
- post 2013**

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The Report – New Off-Patent/Generic Agrochemicals – Post 2013.

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This report identifies those patents believed to be the basic product patents for the compound in question. However, it is possible that there may be other patents and patent applications, not identified in this report, relating to *inter alia* particular derivatives, salts, isomers, crystalline forms, uses, compositions and processes for the manufacture of the product, and which may be relevant to the commercialisation of the product.

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