



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

# **New Off-Patent/Generic Agrochemicals - post 2011**

**A new report, the 8th 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**

**Contract Manufacturers**

**Marketing Companies**

**Intermediate Suppliers**

**R&D-based Multinationals**

**Investment Companies**

## New Off-Patent/Generic Agrochemicals – post 2011

Features **24 active substances** whose patents will expire between 2011-2015 (in some countries patent term extension beyond 2015 may exist).

Benthiavalicarb (Kumiai and Ihara)	Boscalid (BASF)
Chromafenozide (Nippon Nohyaku and Sankyo)	Cloransulam-methyl (Dow AgroSciences)
Cyflufenamid (Nippon Soda)	Dimoxystrobin (BASF)
Dinotefuran (Mitsui Toatsu)	Ethaboxam (Lucky Ltd)
Flonicamid (ISK Biosciences)	Florasulam (Dow AgroSciences)
Iodosulfuron-methyl-sodium (Bayer CropScience)	Isoxadifen-ethyl (Bayer CropScience)
Mesosulfuron-methyl (Bayer CropScience)	Nitenpyram (Takeda)
Oxasulfuron (Syngenta)	Oxaziclomefone (Kumiai and Ihara)
Prothioconazole (Bayer CropScience)	Pyrifthalid (Syngenta)
Simeconazole (Sankyo)	Spirodiclofen (Bayer CropScience)
Spiromesifen (Bayer CropScience)	Thiamethoxam (Syngenta)
Tolfenpyrad (Mitsubishi)	Trifloxysulfuron (Syngenta)

() denotes Inventor company

## Report Outline

### Section 1: Defending a market post patent expiry

With over 70% of all products off-patent the top six R&D based companies control over 75% of the market – how do they achieve this?

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, crystalline form, process and formulation patents, technical know-how and data protection.

### Section 2: Developing new off-patent/generic agrochemical

Since 2002, Enigma has identified 114 active substances with patent expiries between 2002 and 2015. 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 187 existing active substances are given providing the generic manufacturer opportunities to enter the hitherto restricted market.

## Section 3: Profiles of 24 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.

## TABLE OF CONTENTS

<b>Section 1 Defending a market post patent expiry</b>		
Section No.	Section Title	Page No.
1	Introduction	2
1.1	Companies	2
1.1.1	R&D-based Companies	2
1.1.2	Off-Patent/Generic companies	5
1.2	Products	7
1.2.1	Proprietary Products	7
1.2.2	Proprietary Off-patent Products	8
1.2.3	Generic Products	9
1.3	Post-Patent Defence Strategies	9
1.3.1	Data Protection	10
1.3.2	Data Protection And Market Exclusivity	11
1.3.2.1	Existing Active Substances (EAS)	11
1.3.2.2	New Active Substances (NAS)	18
1.3.3	Intellectual Property Rights (IPR)	23
1.3.3.1	Supplementary Protection Certificates (SPCs)	23
1.3.3.2	Patent Portfolios	24
	Example 1: Mixture Patents - Azoxystrobin	25
	Example 2: Mixture Patents - Diflufenican	26
	Example 3: Crystalline Form Patents - Nicosulfuron	26
	Example 4: Crystalline Form Patents - Metazachlor	27
	Example 5: Process Patents - Fipronil	27
	Example 6: Formulation Patents - Clomazone	28
1.4	Other Post-patent Strategies	28
1.4.1	Technical Defence Via Process Know-how	28
1.4.2	Key Intermediates	29
1.5	Mesotrione Case Study	30

<b>Section 1 Defending a market post patent expiry</b>		
1.5.1	Introduction	30
1.5.2	Post-patent Defence Strategies	31
1.5.2.1	Active Ingredient Patent	31
1.5.2.2	Mixture Patents	31
1.5.2.3	Process Patents	31
1.5.2.4	Formulation Patents	32
1.5.2.5	Data Protection	32
1.6	Flonicamid Case Study	33
1.6.1	Patents	33
1.6.2	Data Protection – EU Directive 91/414	34
1.6.3	Patents and Data Protection Time Line	35

<b>Section 2 Developing a new generic agrochemical</b>		
Section No.	Section Title	Page No.
2.1	Generic Companies	37
2.1.1	Mixed Portfolio Of Generic and Proprietary Off-patent Products	37
2.1.2	Marketing Companies	38
2.1.3	AS Manufacturing Companies	38
2.2	Increasing Percentage Of Off-patent Products	39
2.3	Potential New Generic Agrochemicals	40
2.3.1	Candidate Active Substances	40
	Example 1: Fluazinam	43
	Example 2: Iodosulfuron-methyl-sodium	43
	Example 3: Spiroxamine	44
	Example 4: Amicarbazone	44
2.4	Choosing The Right Generic	45
2.4.1	The Marketing Environment	45
2.4.2	The Manufacturing Process For Active Substances	46
2.4.3	Intellectual Property Rights (IPR)	46

<b>Section 2 Developing a new generic agrochemical</b>		
2.4.4	Registration And Data Protection Issues	48
2.5	Generic Market Entry Strategies	51
2.5.1	Mergers And Acquisitions	51
2.5.2	Product Acquisitions	51
2.5.3	Marketing Alliances – “Authorised Generics”	51
2.5.4	Contract Manufacture	52
2.5.5	Task Forces	52
2.5.6	Expiry Of Data Protection For Existing Active Substances (2004 – 2015)	53
2.6	Active Substance From Previous Report With Data Protection expiring 2011 – 2015	61
2.7	Active Substance From Previous Report With SPCs expiring 2011 - 2015	62

<b>Section 3 Profiles of Active Substances</b>		
Active Substance No.	Active Substance	Page No.
	Introduction	65
1	Benthiavali carb	66
2	Boscalid	73
3	Chromafenozide	81

<b>Section 3 Profiles of Active Substances</b>		
Active Substance No.	Active Substance	Page No.
4	Cloransulam-methyl	87
5	Cyflufenamid	94
6	Dimoxystrobin	101
7	Dinotefuran	107
8	Ethaboxam	114
9	Flonicamid	121
10	Florasulam	129
11	Iodosulfuron-methyl-sodium	137
12	Isoxadifen-ethyl	145
13	Mesosulfuron-methyl	150
14	Nitenpyram	158
15	Oxasulfuron	165
16	Oxaziclomefone	172
17	Prothioconazole	179
18	Pyrifthalid	187
19	Simeconazole	192
20	Spirodiclofen	197
21	Spiromesifen	203
22	Thiamethoxam	210
23	Tolfenpyrad	218
24	Trifloxysulfuron	225

# Purchase Contract

**New Off-Patent/Generic Agrochemicals  
- post 2011**

The purchase price for a Restricted Licence is	£3,250	*
The purchase price for a Corporate Licence is	£5,250	*
Company Name:		
Address for delivery:		
Fax:	Phone:	E-mail:
Authorising Agent (print):		(signature):
Position in Company:		
Date:		

\* Please tick (✓) the licence you require.

Please print out and E-mail to:

[nigel.uttley@enigmamarketingresearch.com](mailto:nigel.uttley@enigmamarketingresearch.com)

## **Corporate Licence**

A Corporate Licence is issued under the following terms to The Company.

The Report is intended only for the sole and confidential use within The Company. The Company refers to all employees of The Company and employees of affiliate companies in which The Company owns, directly or indirectly, a fifty percent or greater financial interest. In addition, The Company may under adequate confidentiality agreements allow access to The Report for temporary and specific use to third parties.

The Company may produce hard copies and/or distribute electronically The Report to its employees as defined above.

## **Restricted Licence**

A Restricted Licence is issued under the following terms to The Company.

A Restricted Licence is intended for the use of 1-3 employees of The Company. The Company refers to 1-3 employees of The Company and/or of affiliate companies in which The Company owns, directly or indirectly, a fifty percent or greater financial interest. In addition, The Company may under adequate confidentiality agreements allow access to The Report for temporary and specific use to third parties.

The Company may produce hard copies and/or distribute electronically The Report to its employees as defined above.

## **Definitions**

The Report – New Off-Patent/Generic Agrochemicals – Post 2011.

The Company – The company as defined on the Purchase Order Contract.

## DISCLAIMER

Whilst every effort has been made to ensure that the patent information given herein is accurate, this report cannot be considered to be an exhaustive review of the patents status of the compound and no guarantee can be given as to its accuracy or completeness.

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.

Unless otherwise stated, the patent expiry dates given are projected expiry dates based on the filing dates (or where appropriate grant dates) of the patents, assuming that all of the annual renewal fees have been paid and assuming also that the patents have not been revoked or otherwise allowed to lapse. Moreover, in certain countries it is possible for the term of a patent relating to an agrochemical to be extended and, where we are aware of such extensions, they have been noted in this report. However, the absence of any mention of patent term extensions in this report should not be taken as an authoritative statement that no such extensions have been granted. We would strongly recommend that the official UK (or other country) patent office register be inspected to obtain final confirmation as to the current status or expiry dates of the patents.

The fact that any product is identified as being manufactured or offered for sale is not an indication to import, sell, keep or use such products in any particular country as there may be patents in force which may make such acts unlawful. Any person considering doing so should make all necessary enquiries to ensure that to import, sell, keep or use such products should not infringe any persons patent rights in those countries which he/she intends to do so.