



E N I G M A
MARKETING RESEARCH

New Off-Patent/Generic Agrochemicals - Post 2017

A new report, the 9th in the series, on the market for off-patent/generic agrochemicals with patents expiring between 2017 and 2022.

The report includes:

- **blockbuster products such as chlorantraniliprole, a broad-spectrum, systemic, insecticide, active against all major lepidopteran pests**
- **thiencarbazone-methyl, mixed with many other active ingredients, for the control of grass and broad-leaf weeds on corn/maize and wheat.**
- **niche products such as the rice fungicide isotianil**

This report will assist companies to:

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

In addition to patents to the active ingredient, data is provided covering SPCs to the active ingredient AND mixture products (see end of brochure for further details)

Our previous reports have been purchased by multinational agrochemical companies and small national agrochemical companies and endorsements can be seen on our web site including:-

“great value in helping us map the future of our development in the growing off-patent sector” Christina Cheng, Senior Business Analyst, Nufarm Limited, Australia

“great value in identifying our future new products in the growing off-patent sector” André Schreuder, Managing Director, Villa Crop Protection (Pty) Ltd.

Report Outline

Section 1 (Pages 1 – 53): Identifying the next generation of off-patent active ingredients

Since 2000, Enigma has identified over 180 active ingredients with patents expiring between 2000 and 2019. This is our ninth report profiling 26 a.i.s. which will lose patent protection between 2017 and 2022 and addressing the issues which face the generic manufacturer when assessing which a.i.(s) is most suited for development. With so many active ingredients coming off patent, choosing the right off-patent/generic to develop requires in-depth analysis of many key areas including:

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

Intellectual Property Rights (IPR), in the form of patents and data protection for registrations, is fundamentally important to the dynamics of the agrochemical industry and dictates the market share balance between the R&D sector (innovator companies) and the generic sector. Mixture products and new formulations can also be granted patent protection and have resulted in significant segmentation of the market protecting it from generic competition.

In the IPR section, patent term extensions (SPCs), data protection, the segmentation of the market through mixture products, marketing/licence deals and manufacturing know-how are discussed as strategies used by inventor companies to extend market protection from generic competition.

Assessing the “Knowledge Gap” is of paramount importance and failure to diligently examine each area is likely to lead to delays in market entry, lower than predicted returns and/or even abandonment of the project resulting in considerable loss of development costs.

Section 2 (pages 54 – 210): Profiles of 26 active ingredients

The active ingredient 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 for each active ingredient profile:

- European patent number and expiry date
- SPCs for the active ingredient
- SPCs for mixture products
- US patent number
- Major commercial and registration development milestones
- Major crops
- Major markets
- Major mixture products
- Synthetic pathway

Profiles of 26 *active ingredients* the patents of which will expire between 2017-2022*

| Active Ingredient | Inventor Company | Activity |
|---------------------|----------------------------|-------------|
| Aminopyralid | Dow AgroSciences | herbicide |
| Amisulbrom | Nissan Chemical Industries | fungicide |
| Chlorantraniliprole | DuPont | insecticide |
| Cyprosulfamide | Bayer CropScience | safener |
| Fenpyrazamine | Sumitomo Chemical | fungicide |
| Flubendiamide | Nihon Nohyaku | insecticide |
| Flucetosulfuron | LG Chem Investment | herbicide |
| Fluopicolide | Bayer CropScience | fungicide |
| Isotianil | Bayer CropScience | fungicide |
| Mandipropamid | Syngenta | fungicide |
| Metamifop | Dongbu Hannong Chemicals | herbicide |
| Metofluthrin | Sumitomo Chemical | insecticide |
| Metrafenone | BASF | fungicide |
| Orthosulfamuron | Isagro | herbicide |
| Penflufen | Bayer CropScience | fungicide |
| Pinoxaden | Syngenta | herbicide |
| Pyrasulfotole | Bayer CropScience | herbicide |
| Pyrifluquinazon | Nihon Nohyaku | insecticide |
| Pyrimisulfan | Ihara Chemical Industry | herbicide |
| Pyroxasulfone | Kumiai Chemical Industry | herbicide |
| Pyroxulam | Dow AgroSciences | herbicide |
| Saflufenacil | BASF | herbicide |
| Tembotrione | Bayer CropScience | herbicide |
| Thiencarbazone | Bayer CropScience | herbicide |
| Topramezone | BASF | herbicide |
| Valifenalate | Isagro | fungicide |

* in some countries patent term extensions may exist beyond 2022.

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Definitions

The Report – New Off-Patent/Generic Agrochemicals – Post 2017.

The Company – The Company as defined in the Purchase Order Contract.

Purchase Order Contract

**New Off-Patent/Generic Agrochemicals
- post 2017**

| | | |
|--|---------|--------------|
| The purchase price for a Restricted Licence is | £3,650 | * |
| The purchase price for a Corporate Licence is | £6,250 | * |
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| Authorising Agent (print): | | (signature): |
| Phone: | E-mail: | |
| Position in Company: | | |
| Date: | | |

* Please tick (✓) the type of licence you require.

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Supplementary Protection Certificates (SPCs)

SPCs form part of the European Patent Act. SPCs can extend the life of a patent for a maximum of 5 years over and above the standard 20 year term. The actual patent term extension depends on a number of issues and revolves around the first marketing date of the product.

It is essential that any company planning to enter the EU market must establish whether patents for the active ingredient, mixture products or other secondary patents have expired including whether SPCs were granted and their current status. It is important to understand that patent information is only a snap shot in time and that the patent information given in this report will change through the life time of the report. In our 2015 report only 2 SPC entries (one a granted SPC and the other an application for a SPC) for amisulbrom (Table 1 see below) existed yet the data for this, the 2017 report (Table 2 see below), now has 5 entries all for granted SPCs.

Clients wishing a more detailed explanation should contact Enigma or a qualified patent agent.

(Table 1): SPC data for amisulbrom (May 2014)

| Product | Company | N°SPC | S | N°PAT | DATPAT | AMM1 | AMMC | EXSPC |
|------------|----------------------------|-----------|---|------------|------------|-----------|-----------|------------|
| AMISULBROM | NISSAN CHEMICAL INDUSTRIES | DE111042P | G | DE69842143 | 23/10/1998 | UK 070928 | DE 090408 | 28/09/2022 |
| AMISULBROM | NISSAN CHEMICAL INDUSTRIES | GB110041P | A | EP1031571 | 23/10/1998 | UK 070928 | UK 070928 | 27/09/2022 |

(Table 2): SPC data for amisulbrom (April 2017)

| Product | Company | N°SPC | S | N°PAT | DATPAT | AMM1 | AMMC | EXSPC |
|------------|----------------------------|-----------|---|------------|------------|-----------|-----------|------------|
| AMISULBROM | NISSAN CHEMICAL INDUSTRIES | CH140001P | G | EP1031571 | 23/10/1998 | | CH 131210 | 22/10/2023 |
| AMISULBROM | NISSAN CHEMICAL INDUSTRIES | DE111042P | G | DE69842143 | 23/10/1998 | UK 070928 | DE 090408 | 28/09/2022 |
| AMISULBROM | NISSAN CHEMICAL INDUSTRIES | ES143004P | G | ES2362500 | 23/10/1998 | UK 070928 | ES 131202 | 28/09/2022 |
| AMISULBROM | NISSAN CHEMICAL INDUSTRIES | FR150020P | G | EP1031571 | 23/10/1998 | UK 070928 | FR 141107 | 28/09/2022 |
| AMISULBROM | NISSAN CHEMICAL INDUSTRIES | GB110041P | G | EP1031571 | 23/10/1998 | UK 070928 | UK 070928 | 27/09/2022 |

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.