

# Implications of European regulations restricting the use of Carbendazim in coatings manufacture

## ABSTRACT

A widely used fungicide for dry-film preservation of coatings, Carbendazim, has recently gone through a classification and labeling change in the EU. This new hazard classification will deeply affect its use, since it has practical implications for product labeling, worker protection, waste management and commercialization to non-professional users. There are, however, a variety of alternatives for those manufacturers who decide not to include Carbendazim in their paint formulations.

## 1. INTRODUCTION

Carbendazim is a very effective fungicide used, among many other applications, for the protection of finished coatings from the attack of a wide spectrum of fungi. It has been used successfully for a number of years and it has many advantages among which are its cost-performance, efficacy over a wide range of pH and its compatibility with paint ingredients.

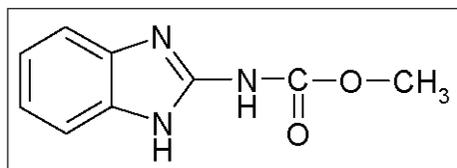
As is described in detail below, Carbendazim has undergone a major change in its hazard classification as a dangerous substance: it changes from being "Harmful" and "Mutagen category 3" to being Toxic, Mutagen category 2 and Toxic for Reproduction category 2. The downstream consequences of this change in classification are to be seen in several aspects of European legislation referring to the classification system of Directive 67/548/EEC<sup>1</sup>, principally,

- classification and labelling of preparations
- worker protection
- waste management
- marketing and use
- biocidal product authorization

## 2. CHEMICAL DESCRIPTION OF CARBENDAZIM

Carbendazim, CAS RN. 10605-21-7

Synonyms:  
2-(Methoxycarbonylamino)-benzimidazole,  
Methyl-N-benzimidazol-2-ylcarbamate,  
N-Benzimidazol-2-ylcarbamic acid methylester, BCM



## 3. DETAILS ON THE CLASSIFICATION AND LABELING CHANGE OF CARBENDAZIM

EU Commission Directive 2004/73/EC<sup>2</sup> of 29 April 2004 adapting to technical progress for the twenty-ninth time (29<sup>th</sup> ATP) Council Directive 67/548/EEC (also called the "Dangerous Substances Directive") on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances was published in the Official Journal of the European Union on 30<sup>th</sup> April 2004, and has entered into force on May 20<sup>th</sup> 2004.

The 29<sup>th</sup> ATP modifies the classification of about 1000 products (listed in Annex 1A), among which is Carbendazim.

### 3.1. Timeline

May 20<sup>th</sup> 2004: 29<sup>th</sup> ATP came into force at the European Level.

October 31<sup>st</sup> 2005: EU Member States must bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 31<sup>st</sup> October 2005. This means that the exact date from which this Directive is transposed into National Law will vary among EU member states. In any case, this should happen before the end of October 2005.

### 3.2. Carbendazim (as pure substance) undergoes the following classification changes (as classified by the Dangerous Substances Directive):

Before the 29 <sup>th</sup> ATP:	After the 29 <sup>th</sup> ATP:
Mutagen category 3 Not classified for reproduction toxicity Possible risk of irreversible effects (R68) Xn - harmful	Mutagen Category 2 May cause heritable genetic damage (R46) Toxic for Reproduction category 2, May impair fertility (R60), May cause harm to the unborn child (R61) N: dangerous for the environment Very toxic for aquatic organisms. May cause long term adverse effects in the aquatic environment (R50-53)

### 3.3. Changes in labelling of Carbendazim containing Biocidal Product formulations (as classified by the Dangerous Preparations Directive)

Labelling of biocidal formulations containing Carbendazim, if used alone without any other classified substances (active substance concentrations between 2,5-25% w/w) is as follows:

Before the 29 <sup>th</sup> ATP:	After the 29 <sup>th</sup> ATP:
Xn - harmful R68 - Possible risks of irreversible effects	T - Toxic N - Dangerous for the environment R46 - May cause heritable genetic damage R60 - May impair fertility R61 - May cause harm to the unborn child R51/53 - Toxic for aquatic organisms. May cause long term adverse effect in the aquatic environment
	  

### 3.4. Changes in labeling of finished products (eg. paints and coatings) containing Carbendazim

Labeling of end products (i.e. paints and coatings) containing between 0,1% w/w (1000 ppm) and 0,25% w/w Carbendazim (2500 ppm):

Before the 29 <sup>th</sup> ATP:	After the 29 <sup>th</sup> ATP:
No labeling due to Carbendazim	T - toxic R46 - May cause heritable genetic damage
	

However, end products (paints, coatings and related products) containing less than 0,1% w/w Carbendazim (less than 1000 ppm a.i.) will not have any specific labelling due to their Carbendazim content.



## 4. RELEVANCE OF THE CHANGE FOR THE PAINT MANUFACTURER

As an incoming raw material into the manufacturing site, European Regulations require special measures for the protection of workers as well as for the management of waste and waste packaging.

### 4.1. Protection of Workers

Directive 2004/37/EC<sup>3</sup> of 20 April 2004 is probably the most important piece of legislation that affects Carbendazim containing products. The aim of this directive is the protection of workers against risks arising from carcinogens or mutagens at work. Within the definitions of this Directive, "mutagens" are defined by all Category 1 and 2 mutagens listed in Annex 1 of the Dangerous Substances Directive or Part B of Annex II to Directive 1999/45/EC<sup>4</sup>. This means that Carbendazim is defined as a mutagen for the purpose of this Directive at = or > 0.1 %.

This Directive repeals several existing Directives and therefore has already entered into force.

In consequence, the obligations for employers where Carbendazim containing biocides are used are as follows:

- Need for carrying out an exposure and risk assessment for the workers manipulating the biocide.
- Have a program in place for replacing the use of the mutagen by less dangerous substances or preparations. Employers must submit their findings to the relevant authorities.
- Need to manipulate the product in closed systems if the assessment reveals a risk to the worker.
- If the products need to be manipulated by workers, this regulation specifies a large number of risk reduction measures, that range from limitation of stocks, limitation of number of workers exposed, design of work methods, limitation of the risk areas, design of special cleaning and waste collection methods among others.
- Information and training: specific information and training programs need to be in place for workers.
- Information to the authorities: in case the risk assessment reveals a risk to workers, employers shall present to the authorities a detailed report on risk reduction measures taken.

At the practical level this legislation will apply to workers exposed to the concentrated biocidal product, intermediate production material, finished paint and wastes containing = or > 0.1% Carbendazim.

### 4.2. Management of waste

All waste (whether hazardous or not) is subject to Directive 75/442/EEC<sup>5</sup> while hazardous waste is also subject to Directive 91/689/EEC<sup>6</sup>. The Annexes of this latter Directive list the generic categories of hazardous waste, their constituents and the properties that render the wastes hazardous. Article 2 of Commission Decision 2000/532/EC<sup>7</sup> allocates concentration ranges to certain properties listed in Annex III of Directive 91/689/EEC and for property "H11" (mutagenic) a waste will be classified as hazardous if it contains one or more mutagenic substances of category 1 or 2 classified as R46 at a total concentration of = or > 0.1%. Commission Decision 2000/532/EC also establishes a single Community list of wastes. These lists include wastes arising from the manufacture, formulation, supply and use of coatings, adhesives, sealants and printing inks area (listed category 08) as are also waste packaging (listed category 15).

Waste packaging that has contained biocidal product formulations or waste in general containing = or > than 0.1% Carbendazim would therefore be classified as hazardous with obvious implications of increased cost/complexity for the associated waste management.

## 5. RESTRICTIONS FOR COMMERCIALIZATION OF FINISHED PAINTS

The new classification of Carbendazim will have two important consequences, namely in connection to the Marketing and Use Directive (76/769/EEC)<sup>8</sup> that regulates and protects consumers from contact with certain dangerous substances and preparations as well as in the criteria used for awarding certain European Eco-labels.

### 5.1. Marketing and Use Directive

As a consequence of its mutagen category 2 classification, all those end products (paints and coatings) using over 0,1% (over 1000 ppm Carbendazim), will not be allowed to be placed on the market for sale to the general public. This means that all of these paints and coatings will be banned from the Do-It-Yourself (DIY) channel. Such products will be labelled with the name of the substance and the phrase "Restricted to professional users".

However, those end products (paints and coatings) containing less than 0,1% Carbendazim (less than 1000 ppm Carbendazim) will have no restrictions for sale through the DIY channel.

### 5.2. European Eco-labelling Programs

As a consequence of its mutagen category 2 and reproductive toxicity category 2 classifications, we foresee that products containing Carbendazim will be excluded from many European eco-labelling criteria. We have analyzed in detail the compliance with the European Eco-label for paints and Varnishes (Commission Decision 2002/739/EC<sup>9</sup> of 3 September 2002) as well as the German Blue Angel (RAL- UZ-102 for Low Emission Wall Paints).

The European Eco-label has in its criteria a specific limitation on Dangerous Substances, both by establishing requirements for the classification and labelling of the paint itself as well as for the ingredients used in its manufacture. These criteria clearly limit the use of category 2 mutagens and reproductive toxins in Eco-labelled paints.

Similarly, the German Blue Angel (RAL-UZ 102) criteria clearly states that they do not accept paints that contain ingredients classified as toxic, mutagenic or reproductive toxins (amongst other exclusion criteria based on hazard classification), which is the case of Carbendazim under the new classification; therefore paints containing

Carbendazim will not be eligible for the German Blue Angel eco-label.

## 6. IMPLICATIONS FOR THE BIOCIDAL PRODUCTS DIRECTIVE (THE BPD)

Carbendazim is not yet classified in Annex 1 of the BPD, however the Directive establishes clear criteria which will be followed when the Annex is prepared. The Technical Notes for Guidance (TNsG) in support of Directive 98/8/EC<sup>10</sup> (the BPD) covering the *Principles and Practical Procedures for the Inclusion of Active Substances in Annexes 1, 1A and 1B*, (April 2002) cite article 5(2) of the BPD with the following text "The BPD (Art 5 (2)) states that "A biocidal product classified according to Council Directive 1999/45/EC as a category 1 or 2 mutagen.....shall not be authorized for marketing to, or use by the general public". Moreover it states that "The risk to the general public from secondary exposure to these substances would also usually be unacceptable." It continues by stating "if genotoxic substances are listed on Annex 1, they should be considered as strong candidates for comparative assessment....it is essential that such active substances be subject to strict risk management". The TNsG also contains similar guidance for category 1 and 2 reproductive toxins. It is therefore foreseeable that the BPD will go further than the Marketing and Use Directive as to the limitations for marketing to the general public.

## 7. AVAILABLE SUBSTITUTES

There are a few but very effective fungicidal active ingredients that are available in the European market today and which have been notified for the Biocidal Products Directive: Dichloro-2-n-octyl-4-isothiazolin-3-one (DCOIT), 2-octyl-2H-isothiazol-3-one (OIT), Iodo-2-propynyl butyl carbamate (IPBC) and Zinc pyrithione (ZPT) are some of the best performing and best known to paint manufacturers. All of them have advantages and disadvantages both from the efficacy and from the toxicological/ecotoxicological point of view, which will surely be coming up to a greater public knowledge as the above mentioned regulations and consequent pressure on Carbendazim come into force.

## 8. CONCLUSIONS AND OUTLOOK FOR THE FUTURE

Given the facts stated above, it is foreseeable that paint manufacturers will gradually start evaluating (if they have not done so already) the available substitutes, and we expect to see a move away from Carbendazim over the coming years. However, the future of these substitutes will depend greatly on their toxicological/ecotoxicological profiles, since some of these substances have not yet been classified, and therefore cannot undergo a detailed regulatory analysis as we are able to carry out in this article.

What is indeed very clear is that the toxicological/ecotoxicological profiles of future active ingredients will be just as important or even more important than the cost efficacy performance, which has been the primary criteria in the past. In the coming years, with the coming of age of the Biocidal Products Directive, the horizon will be greatly clarified, since efficacious biocides with an adverse toxicological/ecotoxicological profile will no doubt be severely limited or removed from the market.

## REFERENCES

1. Council Directive 67/548/EEC of July 1967 on the approximation of the laws, regulations and administrative provisions relating to classification, packaging and labelling of dangerous substances
2. Commission Directive 2004/73/EC of 29 April 2004 adapting to technical progress for the 29th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
3. Directive 2004/37/EC of the European Parliament and of the Council of 29th April 2004 on the protection of workers from risks related to exposure to carcinogens or mutagens at work (Sixth individual Directive within the meaning of Article 16 (1) of Council Directive 89/391/EEC)
4. Directive 1999/45/EC of the European Parliament and of the Council of May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member states relating to the classification, packaging and labeling of dangerous preparations
5. Council Directive 75/442/EEC of 15 July 1975 on waste
6. Council Directive 91/689/EEC of 12 December 1991 on hazardous waste
7. Commission Decision (2000/532/EC) of May 2000 replacing Decision 94/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 75/442/EEC on waste and Council Decision 94/904/EC establishing a list of hazardous waste pursuant to Article 1 (4) of Council Directive 91/689/EEC on hazardous waste
8. Council Directive 76/769/EEC on the approximation of laws, regulations and administrative provisions of the Member states relating to the restrictions on the marketing and use of certain dangerous substances and preparations
9. Commission Decision (2002/739/EC) of 3 September 2002 establishing revised ecological criteria for the award of the Community eco-label to indoor paints and varnishes and amending Decision 1999/10/EC
10. Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market

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