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Regulatory Compliance Report of Product under Regulation (EU) No 528/2012

This report has been composed with the purpose of establishing the regulatory status and obligations under Regulation (EU) No 528/2012 regarding the client's product, which is and/or will be exported into European by Chinese exporters. All descriptions and judgments are based on and refer to Regulation (EU) No 528/2012.

Disclaimer: This report has been composed on the basis of understanding the Regulation (EU) No 528/2012, which entered into force on the 1st of September, 2013, and the product information supported by client. CIRS shall not be responsible for any error of the content raised by the renewal of EU Regulation, the promulgation of new guidance, or the variation of product information.



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Objective

The target market of the desiccant of the consignor is EU. Since (EU) No 528/2012 (Hereinafter referred to as BPR) has come into force, consignor commissions consignee of CIRS to analysis the regulatory obligations of the product under BPR to avoid the loss and unnecessary barriers during the process of compliance with BPR.

Regulatory background

EU biocidal products regulation, BPR, was promulgated by European Parliament and Council on 27th June 2012 and entered into force on 1st September 2013.

BPR has repealed and replaced the current EU biocidal product directive, Directive 98/8/EC (hereinafter referred to as BPD).

BPR takes active substances which are used in the biocidal products, biocidal products and treated articles into supervision.

Product information

The product of consignor is Plantpack Desiccant of which active substance of the product is carbon.

The mechanism of action is to absorb water molecules in the air physically.

The function of the product is drying while there is no destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on any harmful organisms.

The original label has been attached in Annex I.

Regulatory analysis

In accordance with regulatory background above, the scope of BPR is **active substances (AI)** with the intention of use in biocidal products (BP), **biocidal products (BP)** and **treated articles (TA)**.

In accordance with the definition of **active substances** with the intention of use in biocidal products to article 3(1)(C), active substance means a substance or a micro-organism that has an action on or against harmful organisms.

In accordance with the definition of **biocidal product** to article 3(1)(A), biocidal product means — any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action, — any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.

In accordance with the definition of treated article to Article 3(1)(L) to BPR, treated article means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products.

The product is a desiccant consisting of carbon as active substance. The main function of the product is drying. The mechanism of action is to absorb water molecules in the air physically not chemically. Thus, it doesn't fall into scope of definition of biocidal product. Meanwhile, the material of package contacting with carbon is paper, which is neither treated with nor incorporated with biocidal products. Therefore, the package doesn't fall into scope of definition of treated article.

According to the supervision scope of BPR, Plantpack desiccant is neither a biocidal product nor a treated article and is not required to comply with BPR.

Regulation reference

The articles referred to in the report are listed as follows:

- Article 3(1)(A) to Regulation (EU) No 528/2012
- Article 3(1)(C) to Regulation (EU) No 528/2012
- Article 3(1)(L) to Regulation (EU) No 528/2012

The original articles referred to in the report are listed in the Annex II.



Conclusion

The product of desiccant doesn't meet the definition of biocidal product or treated article. Hence Plantpack desiccant is not required to comply with BPR.

Meanwhile, the product may be supervised by other EU regulations.

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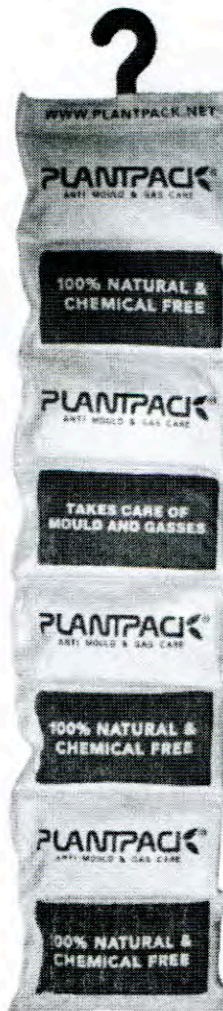


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Annex I - Original label of Plantpack Dessicant





Annex II – Original Articles Reference

Article 3.1(A) to Regulation (EU) No 528/2012

‘Biocidal product’ means

— any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action,

— any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action.

A treated article that has a primary biocidal function shall be considered a biocidal product.

Article 3.1(C) to Regulation (EU) No 528/2012

‘Active substance’ means a substance or a micro-organism that has an action on or against harmful organisms;

Article 3.1(L) to Regulation (EU) No 528/2012

‘Treated article’ means any substance, mixture or article which has been treated with, or intentionally incorporates, one or more biocidal products;