Symphony environmental

Regulatory Statement

15th June 2015

GENERAL REGULATORY STATEMENT SYMPHONY ENVIRONMENTAL $d_2w^®$ POLYOLEFIN DEGRADABLE ADDITIVE MASTERBATCHES

This statement covers $d_2w^®$ Additive Grades: 93114, 93190, 93224, 93264, 93275, 93283, 93389, 93462, 93390, 94114, 94283, 94389 and 94395.

Intended end use: For addition to polyolefin plastics to achieve controlled degradation after a finite food or food packaging shelf life.

1 COMPLIANCE WITH REGULATION NO.1935/2004 (EC)

The key requirements of this Regulation for materials in contact with food are:

Article 3 which requires that "Materials and articles shall be manufactured in compliance with good manufacturing practice so that, under normal or foreseeable conditions of use, they do not transfer their constituents to food which could:

a) Endanger human health.

b) Bring about an unacceptable change in the composition of the food.

c) Bring about deterioration in the organoleptic characteristics thereof.

The Regulation refers to the final packaging. The above $d_2w^®$ Additive Grades for use in the packaging comply with Article 3 on the basis that:

a) Only monomers and other starting materials listed in EU Regulation No.10/2011 (as amended by EU Regulation No.321/2011, EU Regulation No.1282/2011, EU Regulation No.1183/2012, EU Regulation No. 202/2014 and EU Regulation 2015/174) on plastic materials and articles intended to come into contact with food are used in the polymer carrier resins for $d_2w^®$ degradable additive masterbatches. None of these substances have associated specific migration or quantity limits.

b) The carrier-resins used within these $d_2w^®$ degradable masterbatches are therefore authorised for use in Plastic Materials through their listing in EU Regulation No.10/2011 (as amended by EU Regulation No.321/2011, EU Regulation No.1282/2011, EU Regulation No. 1183/2012, EU Regulation No. 202/2014 and EU Regulation 2015/174).

c) The transition metal catalysts incorporated in the $d_2w^®$ masterbatches have specific migration-limit restrictions.

d) Grades 93190 and 94395 contain a proprietary additive with a specific migration limit of 5mg/kg.

e) Experience with specific migration testing of products containing the d2w additives listed in this statement, at the recommended addition rate of 1%, under test conditions of 10 days at 60°C, with the food stimulants 10% ethanol (Simulant A), 3% acetic acid (Simulant B) and vegetable oil (Simulant D2) are that the finished products comply with the specific migration requirements of EU Regulation 10/2011.

Similarly, experience with overall migration testing of products containing the d2w masterbatch listed in this statement at the recommended addition rate of 1% under the test condition 10 days of 40°C (Test Number OM3) are that the finished products comply with the overall migration requirements of EU Regulation 10/2011.

However, it is the customer's responsibility to ensure that their finished products comply with the requirements of EU Regulation 10/2011 as amended under the intended conditions of use.

f) Compliance with Article 3 assumes that contact with food occurs within the shelf life of the product, prior to the onset of packaging degradation. If products containing these additive grades are to be used in contact with food for extended periods or at elevated temperatures, there is the risk that volatile plastic degradation products could taint food. Therefore, prior testing with respect to taint for such applications is advised.

g) Please contact Symphony's Technical dept. for further grade-specific information.

Article 17 of 1935/2004 requires that:

a) The traceability of materials and articles shall be ensured at all stages in order to facilitate control, the recall of defective products, consumer information and the attribution of responsibility.

b) With due regard to technological feasibility, business operators shall have in place systems and procedures to allow identification of the businesses from which and to which materials or articles and, where appropriate, substances or products covered by this Regulation and its implementing measures used in their manufacture are supplied. That information shall be made available to the competent authorities on demand.

c) The materials and articles which are placed on the market in the Community shall be identifiable by an appropriate system which allows their traceability by means of labeling or relevant documentation or information.

$d_2w^{®}$ Additive Grades comply with Article 17 of 1935/2004 on the basis that:

a) Symphony has a system of batch traceability for incoming raw materials

b) Symphony's products are manufactured under unique product and batch codes

2 COMMISSION REGULATION (EC) NO. 2023/2006 - GOOD MANUFACTURING PRACTICE FOR MATERIALS AND ARTICLES INTENDED TO COME INTO CONTACT WITH FOOD

This Regulation applies to all sectors and to all stages of manufacture, processing and distribution of materials and articles, up to but excluding the production of starting substances.

$d_2w^®$ Additive Grades comply with Regulation (EC) No 2023/2006 on the basis that

a) Symphony's quality control and documentation systems for the manufacture of $d_2w^®$ additives are in compliance with Regulation (EC) No. 2023/2006.

3 SUBSTANCES SUBJECT TO A RESTRICTION IN FOOD (Dual use Food Additives)

No dual use food additives subject to a quantitative or compositional restriction in food (Directives 2008/60/EC, 95/45/EC and 2008/84/EC) and capable of migrating into food are present in $d_2w^®$.

4 ADDITIONAL INFORMATION

US FDA Regulations

$d_2w^®$ products are compliant with FDA regulations for food contact. The products are formulated using a polyethylene-base resin that meets the requirements of FDA Code of Federal Regulations Chapter, 21, Section177.1520 (olefin polymers).

Additives used in the $d_2w^®$ formulation are approved for use in food contact materials, through their listing with applicable limitations in:
Regulation 21 CFR 178.2010 Antioxidant and /or stabilisers for polymers
Regulation 21 CFR 175.300 Resinous and polymeric coatings

EU Packaging and Packaging Waste Directive 94/62/EC

This regulation refers to finished products. None of the listed additive grades are designed to contain the restricted heavy metals (cadmium, chromium (VI), lead or mercury) specified in the Directive.

Restriction of use of certain epoxy derivatives (Regulation 1895/2005/EC)

BADGE, NODGE and BFDGE are not used in any $d_2w^®$ additive grades.

Phthalate plasticisers

Phthalate plasticisers are not designed to be component parts of these additive grades.

REACH-Regulation (EC) 2007/1906

The $d_2w^{®}$ range of oxo-degradable additives do not contain any of the substances listed in REACH Annex XIV, Substances of Very High Concern (SVHC) Candidate list, in a concentration above 0.1% (w/w).

The current list of all SVHC can be accessed via the link:
http://echa.europa.eu/web/guest/candidate-list-table

The $d_2w^{®}$ range of oxo-degradable additives do not contain any of the substances listed in Annex XVII of Regulation (EC) 1907/2006.

Endocrine Disruptors

Symphony's $d_2w^{®}$ additive grades do not contain Bisphenol A or other substances suspected of being endocrine disruptors.

Allergic Substances – Directive 2003/89/EC

d_2w additives do not contain any allergic substances as outlined in Annex IIIA of Directive 2003/89/EC.

Genetically Modified Materials

d_2w additives are not designed to contain genetically modified material.

This declaration is for the Symphony products specified above and is valid for 2 years from date of issue. An updated statement will be provided on request if the information on which the declaration is based has changed or new regulatory requirements impact on its validity.

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Disclaimer: The information contained herein is based upon data believed to be up-to-date and correct at the time of writing. It is provided to our customers to aid relevant risk assessments /risk management for compliance with regulatory requirements for food contact materials. Persons receiving this information must exercise their independent judgement in determining its appropriateness for a particular purpose.