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**NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME
(NICNAS)**

FULL PUBLIC REPORT

Polymer in Mater-Bi CF & CS

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:

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**Director
NICNAS**

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FULL PUBLIC REPORT**Polymer in Mater-Bi CF & CS****1. APPLICANT AND NOTIFICATION DETAILS**

APPLICANT(S)

Plastral Pty Ltd. (ABN 68 000 144 132)
130 Denison St
HILLSDALE NSW 2036

NOTIFICATION CATEGORY

Limited: Synthetic polymer with $M_n \geq 1000$ Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)

Data items and details claimed exempt from publication:

Chemical Name, Other Names, CAS Number, Molecular and Structural Formulae, Spectral Data, Methods of Detection and Determination, Molecular Weight, Purity, Import Volume and Polymer Constituents.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)

Variation to the schedule of data requirements is claimed as follows:

Vapour Pressure, Hydrolysis as a Function of pH, Partition Co-efficient, Adsorption/Desorption, Dissociation Constant, Flash Point, Flammability Limits and Autoignition Temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)

None

NOTIFICATION IN OTHER COUNTRIES

None

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)

Mater-Bi CF03A, Mater-Bi CF51A (Product containing the notified polymer)
Mater-Bi CS01B, Mater-Bi CS01M, Mater-Bi CF01U and Mater-Bi CF01M (Notified polymer)

MOLECULAR WEIGHT

> 10000 Da

ANALYTICAL DATA

Reference IR, GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 99%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (> 1% by weight) None

ADDITIVES/ADJUVANTS None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES

Loss of monomers is expected to be minimal due to the low level of residual monomers in the notified polymer.

DEGRADATION PRODUCTS

Under extreme conditions degradation occurs. Degradation will start at temperatures over 230°C. Degradation products include oligomers and monomers, or their derivatives such as tetrahydrofuran. Degradation will lead to a lower viscosity of the polymer and to a higher melting index. However, the notified polymer is biodegradable and biodegradation will include breakdown of ester bonds.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: Solid granules of a white/pale yellow opaque colour

| Property | Value | Data Source/Justification |
|---|--|--|
| Melting Point | 133°C | Measured |
| Density | 1180 kg/m ³ at room temperature | Measured |
| Vapour Pressure | Not determined | Expected to be extremely low due to the high molecular weight of the notified polymer. |
| Water Solubility | Not soluble in water | Measured |
| Hydrolysis as a Function of pH | Not Determined | The notified polymer contains groups that might hydrolyse under severe conditions, but is expected to be stable under environmental pH of 4-9 due to low water solubility. |
| Partition Coefficient (n-octanol/water) | Not Determined | The notified polymer is not soluble in water and may not distribute between water and octanol. |
| Adsorption/Desorption | Not Determined | The notified polymer is not soluble in water and is expected to associate with sediment. |
| Dissociation Constant | Not determined | The notified polymer is not expected to be ionised in the environmental pH range 4 – 9. |
| Particle Size | Average is 3 mm. | Measured |
| Flash Point | Not determined | High molecular weight polymer. |
| Autoignition Temperature | > 300°C | Estimated |
| Explosive Properties | Not determined | High molecular weight polymer without any chemical moieties that would contribute to the polymer being explosive. |

DISCUSSION OF PROPERTIES

For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity

The notified polymer is stable under normal conditions. There are no chemical groups that would imply oxidising properties. Degrades at > 230°C.

Dangerous Goods classification

Based on the available data the notified polymer is not classified according to the Australian Dangerous Goods Code (FORS, 1998). However it is combustible if the surrounding temperature is sufficiently high enough (Autoignition temperature > 300°C).

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

The polymer will be imported as 100% polymer as well as in mixtures at 5-95% in poly-lined 750kg net cardboard boxes.

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

| <i>Year</i> | <i>1</i> | <i>2</i> | <i>3</i> | <i>4</i> | <i>5</i> |
|---------------|----------|----------|----------|----------|----------|
| <i>Tonnes</i> | 100-300 | 100-300 | 100-300 | 300-1000 | 300-1000 |

PORT OF ENTRY
Melbourne and Sydney

IDENTITY OF RECIPIENTS
The notified polymer will be supplied to large processors of plastics.

TRANSPORTATION AND PACKAGING
The notified polymer in poly-lined 750kg cardboard boxes will be transported by road.

USE
The notified polymer and compounds containing the notified polymer will be used to produce a range of finished articles including shopping bags, nappies and hygiene products.

OPERATION DESCRIPTION
There will no reformulation. The imported notified polymer and mixtures containing it will be ready to be converted into articles, using conventional plastics processing machinery, into a variety of products. Processes include film blowing, injection moulding, extrusion and blow moulding.

Transfer of polymer from initial packaging to process machinery hoppers is often done by vacuum hose. Articles produced from the polymer will be manually handled during packaging.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

| <i>Category of Worker</i> | <i>Number</i> | <i>Exposure Duration (hours/day)</i> | <i>Exposure Frequency (days/year)</i> |
|---|---------------|--|---|
| Waterside and Transport | 10 | 1-2 | 10 |
| Warehouse | 3 | 2 | 24 |
| Process workers/operators at plastic processors | 150 | 8 | 230 |

EXPOSURE DETAILS

Waterside, transport and warehouse workers will not open imported containers of the polymer compound containing the notified polymer. The possibility of exposure to the notified polymer on breaching the containers is minimal as the notified polymer is expected to have a very low vapour pressure. Workers will routinely wear protective overalls and safety footwear.

Worker exposure during the plastics processing is expected to be low as the polymer compound containing the notified polymer will be automatically fed into an enclosed machine for film blowing, injection moulding, extrusion or blow moulding. All the plastics processing operations will be performed in an enclosed and automatic system and this should minimise worker exposure to any fumes emitted during moulding. In addition, personal protective equipment will be routinely used and will include safety glasses, gloves, protective coveralls and safety footwear. Workers may be exposed to residual dust if some material has a substantially smaller particle size than average.

6.1.2. Public exposure

The public will only be exposed to articles comprised of or containing the notified polymer.

Exposure will be predominately dermal however the notified polymer is not expected to be bioavailable based on the high molecular weight.

6.2. Human health effects assessment

No toxicity data were submitted

Toxicokinetics, metabolism and distribution.

The notified polymer is not expected to be absorbed across biological membranes, based on the high molecular weight ($> 10,000 \text{ g}\cdot\text{mol}^{-1}$).

The notified polymer is a high molecular weight, water insoluble polymer and therefore has the potential of causing lung overloading where significant inhalation of respirable particles could occur.

Health hazard classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety

The main route of exposure to the notified polymer (up to 100% concentration) for workers is expected to be dermal exposure, during plastic processing. The engineering controls and personal protective equipment in place during such processes should limit potential for exposure.

Significant inhalation exposure is not expected due to the granular nature of the notified polymer, its low vapour pressure and the engineering controls used. Therefore, the risk of lung overloading is expected to be low.

Overall, the OHS risk presented by the notified polymer is expected to be low, based on the low exposure to workers and the assumed low hazard of the notified polymer.

6.3.2. Public health

The risk to public health is considered to be low based on the low exposure and assumed low hazard of the notified polymer.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE

During normal processing, the notified polymer is not expected to be released to the environment. However, there may be release of fumes by forced ventilation from processing equipment.

RELEASE OF CHEMICAL FROM USE

The notified polymer and compounds containing the notified polymer will be used to produce shopping bags, nappies, hygiene products and other products. Ultimately the notified polymer is expected to have the same fate as these products at the end of their useful life.

RELEASE OF CHEMICAL FROM DISPOSAL

The majority of products made from the notified polymer are expected to be disposed of to landfill under current arrangements, but increasing quantities may be diverted to commercial composting streams as facilities become available. Products made from the notified polymer may be disposed of in suitable commercial scale composting facilities, where such facilities are available and willing to accept them, and subject to compliance with local requirements for acceptability of compostable waste. However, soiled nappies or soiled hygiene products made from the notified polymer should only be disposed of to landfill for sanitary/public health reasons. Products made from the notified polymer may also be disposed of by home composting at the discretion of the home composter, but extended periods may be required for complete breakdown of larger articles.

7.1.2 Environmental fate

The products containing the notified polymer are likely to be used throughout Australia. The major environmental exposure is expected to be due to the disposal of shopping bags, nappies, and hygiene products to landfill. In landfill, the notified polymer is expected to associate with, and become immobilised in the soil matrix. Due to its low water solubility, the notified polymer will remain bound within the soils and sediments of the landfill and will be slowly biodegraded by the biotic processes.

The notified polymer has been awarded the use of the 'OK COMPOST' conformity mark by the AIB-Vinçotte International company. According to this certificate the notified polymer has been found biodegradable as per AVI test program with reference OK 1 edition D. The certificate claims that the notified polymer has also been found compostable as per EN 14995 (12-2006): Plastics – Evaluation of compostability – Test scheme and specification. The test data that support this certification are evaluated in Appendix B. Pilot scale trials with film and pellets show that the polymer film (75 or 115 µm thickness) disintegrates during composting under conditions representative of commercial composting, but that pellets appear to retain their integrity under these conditions. Disintegration has similarly been demonstrated for thicker films made from Mater-Bi CF51A (225 µm) and Mater-Bi CF03A (217 µm), which contain the notified polymer as part of a blend.

A blend containing the notified polymer (Mater-Bi CF03A) has also been awarded the use of the 'OK COMPOST HOME' conformity mark by AIB-Vinçotte International (certificate dated 18 December 2008). According to this certificate, the material (film with a maximum thickness of 60 µm) has been found biodegradable as per AVI test program with reference OK 2 edition C "Home compostability of products". The test data that support this certification are evaluated in Appendix B. The polymer film (44 or 67 µm thickness) was incubated at a lower temperature (28°C) in order to have confidence that disintegration would occur under home composting conditions, which generally do not reach the high temperatures (> 50°C) obtained during industrial composting processes. In addition, a powder containing the notified polymer was incubated at 28°C in aerobic soil, with complete mineralisation to carbon dioxide demonstrated.

7.1.3 Predicted Environmental Concentration (PEC)

No PEC has been calculated as no significant releases of the notified polymer to the aquatic compartment are expected to occur. Due to the widespread use and the expected slow biodegradation, estimation of the Predicted Environmental Concentration (PEC) of the notified polymer is not possible.

7.2. Environmental effects assessment

Phytotoxicity tests conducted on the compost derived from the notified polymer indicate that under the conditions of the studies, the plants cress or summer barley (dicotyledonous and monocotyledonous plants respectively) did not show any effects on the germination and growth with the use of the notified polymer-amended compost at up to 10-50% concentration.

Summary of phytotoxic effects is presented in Appendix B.

7.3. Environmental risk assessment

Disposal of the notified polymer to landfill is unlikely to present a hazard to the environment as it will be as finished products. Bioconcentration and leaching are both considered as unlikely to occur, due to the high molecular weight of the notified polymer and its low water solubility (Connell, 1990).

Disposal by commercial composting of plastic film made from the notified polymer is not expected to compromise the composting process or final compost quality. However, similar disposal of the notified polymer in pellet form, or as larger articles, is likely to produce compost containing the notified polymer in its original form, with consequent reduction in the aesthetic quality of the compost. Plastics are unsightly in the final compost and can cause the product to exceed the permitted levels of physical contaminants as prescribed by the Australian Standard, and hence the marketability. While such contaminants can be expected to degrade over the longer term in compost-amended soil, plastic articles may only be acceptable for commercial composting at the discretion of the operator.

Plastic film made from a blend (Mater-Bi CF03A) containing the notified polymer has similarly been shown to disintegrate under home composting conditions. While pellets and larger articles have not been tested for compostability under these conditions, and may be expected to retain their original form based on the results from simulated industrial composting, home composters are likely to use their own judgements and

observations in deciding whether such items can be added to the compost heap. The demonstrated mineralisation in soil of Mater-Bi CF03A powder (containing the notified polymer) indicates that pellets and larger articles would eventually degrade in home composting/gardening situations, but no data are available to determine how long this might take.

The Plastics and Chemicals Industry Association has developed a product stewardship guide and commitment entitled "Using Degradable Plastics in Australia" as a voluntary industry initiative in partnership with the Department of the Environment, Water, Heritage and the Arts (PACIA, 2007). The 2007 document discusses biodegradability and compostability, noting that all compostable plastics are biodegradable, but that not all biodegradable plastics are compostable. Furthermore, the document notes that home composting conditions are different to commercial composting conditions, with separate testing procedures for each. Based on the data submitted, articles made from the notified polymer may be acceptable for home composting at the discretion of the home composter, although degradation is likely to be slow unless the items are in the form of thin film. Although probably impractical for domestic situations, the suitability of larger items for home composting would be improved if they are ground to a powder before addition to the compost heap.

The phytotoxicity studies on germination and growth indicate that there is minimal risk posed by the components of biodegradation of the notified polymer.

The notified polymer is not expected to reach the aquatic compartment from the proposed use, and taking into account the information provided by the notifier, the overall risk to the environment is expected to be low.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification

Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment

Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment

On the basis of the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- Employers should ensure engineering controls are present to minimise occupational exposure to any fumes emitted during moulding and to any nuisance dust.
- A copy of the MSDS should be easily accessible to employees.
- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer may be disposed of to commercial composting, subject to availability of commercial composting facilities and compliance with local requirements for acceptability of compostable waste. Some facilities may only accept the notified polymer for commercial composting as thin film, because of the stability of larger items over the typical 6 week timeframe of commercial operations. Soiled nappies or soiled hygiene products should only be disposed of to landfill for sanitary/public health reasons. Items made from the notified polymer may be added to home compost heaps, but home composters can expect degradation in compost heaps and garden soils to be slow unless the items are in the form of thin film.

Storage

- Store in a cool dry well ventilated area away from heat source.

Emergency procedures

- Spills/release of the notified polymer should be handled by sweeping up and recovery, with a view to recycling. Any material not suitable for recycling may be disposed of to landfill.

Regulatory Obligations

Secondary Notification

This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical is listed on the Australian Inventory of Chemical Substances (AICS).

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifier, other importer or manufacturer:

- (1) Under Section 64(1) of the Act; if
 - the polymer has a number-average molecular weight of less than 1000; or

or

- (2) Under Section 64(2) of the Act; if
 - the function or use of the polymer has changed from producing a range of finished articles including, shopping bags, nappies and hygiene products, or is likely to change significantly;
 - the amount of polymer being introduced has increased from 1,000 tonnes, or is likely to increase, significantly;
 - the polymer has begun to be manufactured in Australia;
 - additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

Material Safety Data Sheet

The MSDS of the notified polymer and products containing the notified polymer provided by the notifier were reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Melting Point 133°C

Method Differential Scanning Calorimetry (DSC)
 Remarks Using a Perkin Elmer Diamond Differential Scanning Calorimeter
 Test Facility Novamont s.p.a (2007)

Density 1180 kg/m³ at room temperature

Method Mohr Westphal method
 Remarks Using an analytical balance Sartorius AC 120S equipped with a Sartorius Kit YDK 01.
 Test Facility Novamont s.p.a (2007)

Water Solubility Not soluble in water

Method A certain amount of notified polymer granules was dried for 24 hours at 50°C in vacuum and weighed. The dried granules were dipped in water (at ambient temperature) for 24 hours. Finally they were dried again for 24 hours at 50°C in vacuum and weighed.
 Remarks No relevant mass change was noted after the immersion in water. The data showed that some water uptake took place, consisting in +0.033% of the initial mass of the granules. No swelling was observed. The polymer can be considered as “not soluble in water”.
 Test Facility Novamont S.pA (2008)

Dissociation Constant

Remarks The polymer is substantially –OH (Hydroxy) terminated. Few acidic groups are present due to starting acid monomers; the dissociation constants of such monomers are between 3.54 and 4.5.

Particle Size Average is 3 mm.

Method Unspecified
 Remarks CS01B granules have cubic shape. The average granules number needed to achieve a 1 g mass is between 27 and 31. The granulation system might be changed in the future and that the shape of the granules might become spheroidal; the average diameter should be around 3 mm.
 Test Facility Novamont s.p.a (2008)

Autoignition Temperature Estimated to be far above 300°C

Remarks The Limit Oxygen Index (L.O.I.) of the material in the physical form of a film, has been determined (according to ASTM D 2863-2000) to be about 37%. Such figure indicates that the material is not ignitable. The L.O.I. is the minimum percentage of oxygen (in a mixture of oxygen and nitrogen) needed for the sample to burn. Therefore, as a general indication materials having L.O.I. values lower than 21% are considered flammable, while materials having L.O.I higher than 21% are considered not ignitable.

APPENDIX B: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

B.1. Environmental Fate

B.1.1. Aerobic biodegradation under controlled composting conditions

| | |
|------------------|---|
| TEST SUBSTANCE | Mater-Bi CF01U powder. Cellulose powder was used as reference item. |
| METHOD | ISO 14855 (1999): Determination of the ultimate aerobic biodegradability and disintegration of plastics under controlled composting conditions (part of CEN norm EN 13432 (2000): Requirements for packaging recoverable through composting and biodegradation – test scheme and evaluation criteria for the final acceptance of packaging; identical with ASTM D 5338.98). |
| Exposure Period | 45 days |
| Remarks – Method | <p>Test and reference items were mixed with inoculum in approximate ratios of 1-1.5 parts total solids to 6 parts total solids. The mixtures were incubated at 58°C in airtight reactors, with shaking at weekly intervals. The inoculum was derived from the organic fraction of municipal solid waste, by stabilisation and maturation in a compost bin under controlled aeration, followed by sieving (5 mm screen).</p> <p>The incubated mixtures were aerated by pressurised dry air, with precise control of flow rates. Continuous analysis of exhaust gases for CO₂ and O₂ at regular intervals, together with regular measurement of flow rate, allowed the percentage conversion of C to CO₂ to be determined, after subtraction of background production from the blank inoculum.</p> |
| RESULTS | <p>Biodegradation of cellulose was rapid, reaching 74.6% after 12 days, and 98.8% after 45 days. Mater-Bi CF01U powder also biodegraded rapidly, reaching 25.0% after 10 days, 90.3% after 32 days, and 98.4% (99.6% relative to cellulose) after 45 days.</p> <p>One of the three test replicates was not included in the above results because a technical failure led to loss of aeration between days 21 and 28. Production of CO₂ ceased during this interval but resumed when aeration was restored and reached comparable levels to the other two replicates after 45 days. Inclusion of this replicate increased the average biodegradation percentage to 98.8% (100% relative to cellulose).</p> |
| CONCLUSION | Results confirm that Mater-Bi CF01U powder is completely biodegradable under controlled composting conditions. |
| TEST FACILITY | Organic Waste Systems (2005a) |

B.1.2. Aerobic biodegradation in soil

| | |
|------------------|--|
| TEST SUBSTANCE | Mater-Bi CF03A powder (product containing the notified polymer). Cellulose powder was used as reference item. |
| METHOD | ISO 17556 (2003): Plastics - Determination of the ultimate aerobic biodegradability in soil by measuring the oxygen demand in a respirometer or the amount of carbon dioxide released. |
| Exposure Period | 300 days |
| Remarks – Method | Test and reference items were mixed with inoculum and incubated at 28°C |

in airtight reactors. Readers of the test report are referred to the study plan for further details on the procedure used, but no study plan was submitted. The inoculum was an Italian soil, with a pH of 7.7 and a C/N ratio of 10.5 after addition of the test substance.

The incubated mixtures were aerated by pressurised dry air, with precise control of flow rates. Continuous analysis at regular intervals of CO₂ collected in KOH traps, together with regular measurement of flow rate, allowed the percentage conversion of C to CO₂ to be determined, after subtraction of background production from the blank inoculum.

| | |
|---------------|---|
| RESULTS | Biodegradation of cellulose reached 82.2% after 180 days, and 84.8% after 300 days. Mater-Bi CF03A powder also biodegraded, reaching 53.1% after 180 days and 77.0% (90.8% relative to cellulose) after 300 days, but was initially slow with only 7.8% biodegradation after 25 days. |
| CONCLUSION | Results confirm that Mater-Bi CF03A (product containing the notified polymer) powder is completely biodegradable in aerobic soil at 28°C. |
| TEST FACILITY | Organic Waste Systems (2008a) |

B.1.3. Disintegration in pilot-scale composting

| | |
|------------------|--|
| TEST SUBSTANCE | Mater-Bi CF01U film (75 µm) and pellets. |
| METHOD | ISO 16929 (2002): Plastics – determination of the degree of disintegration of plastic materials under defined composting conditions in a pilot-scale test (part of ASTM D 6400-04: Standard specification for compostable plastics). prEN 14045 (2001): Evaluation of the disintegration of packaging materials in practical oriented tests under defined composting conditions (part of CEN norm EN 13432 (2000): Requirements for packaging recoverable through composting and biodegradation – test scheme and evaluation criteria for the final acceptance of packaging). |
| Exposure Period | 12 weeks |
| Remarks – Method | This test in 200 L composting bins simulated a real and complete composting process. The test substance (1% film and 9% pellets) was mixed with fresh biowaste (vegetable, garden and fruit waste fortified with 11% extra structural material) derived from the organic fraction of source-separated municipal solid waste and composted in an insulated bin, with monitoring of temperature and exhaust gas composition, until fully stabilised compost was obtained. The final compost was to be sieved (2, 5 and 10 mm screens). Disintegration was evaluated by manual selection. Pellets were included for subsequent phytotoxicity testing. |
| RESULTS | The biowaste met criteria for moisture content, pH and volatile solids. The C/N ratio was low, but increased to optimum levels after addition of the notified polymer. The temperature profile satisfied the criteria that the daily temperature remain above 60°C (but below 75°C) for a week and above 40°C for 4 weeks, the latter achieved by moving the compost bins into an incubation room at 45°C after 2.7 weeks. Duplicate test bins were combined, but kept separate by a net, after 1.5 weeks, so as to compensate for volume reduction and maintain optimum temperature. After this time, the polymer amended compost remained warmer than the unamended compost. This was ascribed to the degradation of the test |

substance. Similarly, carbon dioxide production was slightly higher in the test bins from weeks 3 to 8.

The pH increased from 7.1 to a plateau at about 9 within a few weeks, satisfying the criterion that the pH increase above 7 and not fall below 5 during composting.

Slide frames containing the notified polymer film showed small cracks after 1 week and clear holes after 2 weeks. A broad border of test film remained after 4 weeks, but only small pieces were present in the slides after 5 weeks. The framed polymer film had completely disappeared after 8 weeks. Similar observations were made for the unframed pieces of film (10 cm x 10 cm). Tears were apparent after 1 week, and fungal growth after 2 weeks. A few pieces could still be seen after 4 and 6 weeks, but none after 8 weeks.

Final control and test composts were stable and mature as indicated by a Rottegrad score of V. There was no obvious difference between the final compost under control and test conditions after the 10 mm screen, except for the presence of residual pellets in the latter on close inspection. The extent to which these may have degraded or fragmented does not appear to have been investigated. No finer screening was conducted.

| | |
|---------------|--|
| CONCLUSION | Results confirm that Mater-Bi CF01U film disintegrates in pilot scale composting and can not be seen in the final compost. The Mater-Bi CF01U pellets do not appear to degrade or fully disintegrate under these conditions. |
| TEST FACILITY | Organic Waste Systems (2005b) |

B.1.4. Disintegration in pilot-scale composting

| | |
|------------------|--|
| TEST SUBSTANCE | Mater-Bi CS01B film (115 µm) and Mater-Bi CF51A film (225 µm) – notified polymer and product containing the notified polymer, respectively. |
| METHOD | ISO 16929 (2002): Plastics – determination of the degree of disintegration of plastic materials under defined composting conditions in a pilot-scale test (part of ASTM D 6400-04: Standard specification for compostable plastics). EN 14045 (2003): Evaluation of the disintegration of packaging materials in practical oriented tests under defined composting conditions (part of CEN norm EN 13432 (2000): Requirements for packaging recoverable through composting and biodegradation – test scheme and evaluation criteria for the final acceptance of packaging). |
| Exposure Period | 12 weeks |
| Remarks – Method | This test in 200 L composting bins simulated a real and complete composting process. The test substances were mixed at 1% with fresh biowaste (vegetable, garden and fruit waste fortified with 11% extra structural material) derived from the organic fraction of source-separated municipal solid waste and composted in an insulated bin, with monitoring of temperature and exhaust gas composition, until fully stabilised compost was obtained. The final compost was sieved (2, 5 and 10 mm screens). Disintegration was evaluated by manual selection. |
| RESULTS | The biowaste met criteria for moisture content, pH (initially 6.7, increasing to 8.2-8.5 in the final test composts) and volatile solids. The C/N ratio was a little low in the biowaste but reached the optimal range in |

the test bins (19 for the biowaste, and 20 after addition of the test item).

The operational parameters showed that the test was valid. The temperature remained above 60°C for a week in control bins and about 2 weeks in the test bins, reaching a maximum of 75°C and remaining above 40°C for more than 4 consecutive weeks. One of the bins overheated to 76°C but was immediately cooled to establish lower temperatures.

After 2 weeks of composting, the pieces of Mater-Bi CS01B film started to show tears. Large pieces remained after 4 weeks, but these were strongly reduced in size after 8 weeks. Two weeks later, the pieces started to fall apart and showed tears. Only a few small fragments were retrieved after the final sieving. The average disintegration (to pieces larger than 2 mm) was 97.1%.

The Mater-Bi CF51A film was largely intact after 2 weeks, not showing tears until 4 weeks had elapsed. Large fragments remained after 8 and 10 weeks, but there was no visible contamination in the final compost. A few small fragments were retrieved after the final sieving. The disintegration (to pieces larger than 2 mm) was 98.1% in the one bin that was examined. The other bin was not evaluated because of a critical loss of moisture that was only rectified after excessive delay.

Final control and test composts were stable and mature as indicated by a Rottegrad score of V. The average pH was 9. The C/N ratio was 9-12. An absence of volatile fatty acids and highly decreased volatile solids in the final compost indicated that the composting process had proceeded well.

| | |
|---------------|---|
| CONCLUSION | Results confirm that Mater-Bi CS01B film (115 µm) and Mater-Bi CF51A film (225 µm) disintegrate in pilot scale composting, leaving only small fragments in the final compost at 12 weeks. |
| TEST FACILITY | Organic Waste Systems (2008b) |

B.1.5. Disintegration in pilot-scale composting

| | |
|------------------|---|
| TEST SUBSTANCE | Mater-Bi CF03A (product containing the notified polymer) film (217 µm) |
| METHOD | ISO 16929 (2002): Plastics – determination of the degree of disintegration of plastic materials under defined composting conditions in a pilot-scale test (part of ASTM D 6400-04: Standard specification for compostable plastics). EN 14045 (2003): Evaluation of the disintegration of packaging materials in practical oriented tests under defined composting conditions (part of CEN norm EN 13432 (2000): Requirements for packaging recoverable through composting and biodegradation – test scheme and evaluation criteria for the final acceptance of packaging). |
| Exposure Period | 12 weeks |
| Remarks – Method | This test in 200 L composting bins simulated a real and complete composting process. The test substance (1% concentration as 10 x 10 cm pieces) was mixed with biowaste consisting of vegetable, garden and fruit waste to which 11% extra structural material was added in order to obtain optimal composting conditions, and composted in an insulated bin, with monitoring of temperature and exhaust gas composition, until fully stabilised compost was obtained. The final compost was sieved (2, 5 and 10 mm screens). Disintegration was evaluated by manual selection. |

| | |
|---------------|---|
| RESULTS | <p>The biowaste met criteria for moisture content, pH (initially 5.1, increasing to 7.4 after 1.6 weeks) and volatile solids. The C/N ratio was optimal (27 for the biowaste, and 28 after addition of the test item).</p> <p>The operational parameters showed that the test was valid. The temperature remained above 60°C for a week in control bins and about 2 weeks in the test bins, reaching a maximum of 75°C and remaining above 40°C for more than 4 consecutive weeks.</p> <p>After 1 week of composting, the pieces of film were intact and clearly visible. Two weeks later, the pieces started to fall apart and showed tears. After 6 weeks, a few pieces were still visible, but most had disintegrated. Small fragments could still be seen after 8 weeks, but not after 10 weeks. No pieces were retrieved after the final sieving.</p> <p>Final control and test composts were stable and mature as indicated by a Rottegrad score of V. The average pH was 9. The C/N ratio was 9-13, and highly decreased volatile solids indicated that the composting process had proceeded well.</p> |
| CONCLUSION | Results confirm that Mater-Bi CF03A (product containing the notified polymer) film with a thickness of 217 µm disintegrates in pilot scale composting and cannot be seen in the final compost. |
| TEST FACILITY | Organic Waste Systems (2008c) |

B.1.6. Disintegration during composting at ambient temperature

| | |
|------------------|--|
| TEST SUBSTANCE | Mater-Bi CF03A (product containing the notified polymer) film (44 and 67 µm) |
| METHOD | ISO 20200 (2004): Plastics – determination of the degree of disintegration of plastic materials under simulated composting conditions in a laboratory-scale test. |
| Exposure Period | 26 weeks |
| Remarks – Method | This laboratory-scale test was conducted at 28°C to simulate home composting, in which conditions generally don't reach the high temperatures (> 50°C) of industrial composting. The test films were mounted in slide frames which were mixed with compost (mature compost < 10 mm mixed with 20% freshly milled vegetable, fruit and garden waste) and incubated in the dark, with regular stirring and moistening if needed. |
| RESULTS | <p>The mixed compost and biowaste was not characterised in the test report.</p> <p>After 2 weeks of composting, the pieces of film showed tears. After 12 weeks, the test films were only visible at the edges of the slides. Small fragments could still be seen after 16 weeks. The slides that contained the thicker film were empty at 26 weeks, but tiny pieces of the thinner film, representing less than 10% of the original area, could still be seen at the borders.</p> |
| CONCLUSION | Results confirm that Mater-Bi CF03A (product containing the notified polymer) film with a thickness of 44 or 67 µm disintegrates at 28°C in laboratory-scale composting. |

summer barley plants in 25% and 50% Mater-Bi EN CF01U compost/reference substrate mixture compared to blank compost mixtures. According to CEN norm EN 13432 (2000) and ASTM D 6400-04 the germination rate and the plant biomass of the test compost should be more than 90% of those from the corresponding blank compost. The Mater-Bi CF01U compost fulfils these criteria.

For statistical analysis of the results, the 'Anova single factor test' at $P \leq 0.05$ was used. The results are compared with the lowest significant difference procedure of Fisher. Again no difference was found.

| | |
|---------------|--|
| CONCLUSION | Under the conditions of study the composted notified polymer appears to have no negative effect on the emergence and growth of summer barley plants. |
| TEST FACILITY | Organic Waste Systems (2005c) |

B.1.8. Phytotoxicity (Dicotyledonous plant)

| | |
|------------------|---|
| TEST SUBSTANCE | Composted notified polymer |
| METHOD | CEN norm EN 13432 (2000) and ASTM D 6400-04 Requirements for packaging recoverable through composting and biodegradation and Standard specification for compostible plastic – Test |
| Exposure Period | 11 days |
| Tested plant | Cress |
| Remarks - Method | The test is conducted in flower pots of 500 ml, containing a mixture of compost (prepared as above) and reference substrate. Each compost is tested in two mixing ratios of compost and reference substrate: 1/3 and 1/1 on a volumetric basis. |

After germination at 20°C under glass plates, the pots are exposed to a light intensity of 3000 lux for 12 hours per day as above. In order to avoid side effects, the position of each pot is changed during the testing period.

RESULTS

Table 1 Test set-up summer cress plant growth

| Treatment | Volume of | | Weight | |
|--|---------------------|------------------------------------|---------------------|------------------------------------|
| | Ref Sub (ml/pot) | Compost ^(a) (ml/pot) | Ref Sub (ml/pot) | Compost ^(a) (ml/pot) |
| 4 × Reference substrate | 500 | 0 | 168 | 0 |
| 4 × Blank compost (1:3) | 375 | 125 | 126 | 61 |
| 4 × Blank compost (1:1) | 250 | 250 | 84 | 122 |
| 4 × Mater-Bi CF01U + NO ₃ ⁻ –N compost (1:3) | 375 | 125 | 126 | 69 |
| 4 × Mater-Bi CF01U + NO ₃ ⁻ –N compost (1:1) | 250 | 250 | 84 | 137 |

(a) Volumetric density of Reference substrate = 0.336 kg/L
Blank compost = 0.487 kg/L
Mater – Bi CF01U compost = 0.549 kg/L

Table 2 Germination rate of cress (%)

| Test series | Germination rate (%) | |
|--|----------------------|-----|
| | AVG | STD |
| Reference substrate | 96.5 | 06 |
| Blank compost 1/3 | 94.3 | 2.6 |
| Blank compost 1/1 | 93.3 | 1 |
| Mater-Bi CF01U + NO ₃ ⁻ –N compost 1/3 | 95.8 | 0.5 |
| Mater-Bi CF01U + NO ₃ ⁻ –N compost 1/1 | 96 | 1.2 |

AVG = average, STD = standard deviation

Table 3 Fresh and dry weight yield of cress: absolute and relative to reference substrate

| Test series | (g) | | Fresh Weight yield (% relative to reference substrate) | |
|----------------------------|------|------|---|-----|
| | AVG | STD | AVG | STD |
| Reference substrate | 2.8 | 0.36 | 100 | 13 |
| Blank compost 1/3 | 5.85 | 0.27 | 209 | 10 |
| Blank compost 1/1 | 5.45 | 0.27 | 195 | 10 |
| Mater-Bi CF01U compost 1/3 | 5.05 | 0.12 | 180 | 4 |
| Mater-Bi CF01U compost 1/1 | 5.04 | 0.21 | 180 | 7 |
| Test series | (g) | | Dry Weight yield (% relative to reference substrate) | |
| | AVG | STD | AVG | STD |
| Reference substrate | 0.23 | 0.05 | 100 | 23 |
| Blank compost 1/3 | 0.28 | 0.04 | 118 | 16 |
| Blank compost 1/1 | 0.28 | 0.01 | 119 | 5 |
| Mater-Bi CF01U compost 1/3 | 0.26 | 0.01 | 113 | 4 |
| Mater-Bi CF01U compost 1/1 | 0.25 | 0.02 | 109 | 9 |

AVG = average, STD = standard deviation

Table 4 Germination and dry weight plant yield of both mixtures of notified polymer compost as a percentage of the corresponding mixture of blank compost

| Test series | Germination rate (as % of blank compost) | Dry weight plant yield (as % of blank compost) |
|----------------------------|--|--|
| Mater-Bi CF01U compost 1/3 | 102 | 96 |
| Mater-Bi CF01U compost 1/1 | 103 | 91 |

Remarks - Results

The nitrification process in the test compost was lower as compared to the blank compost resulting in a different C/N ratio at start between the control and test samples. The higher NO₃⁻ -N content could have a fertilizing effect and favour plant growth, especially in the case of summer barley. Therefore the test compost was enriched with NO₃⁻ -N up to similar nitrate level as in the blank compost.

Dry weight plant yield differences are more directly related to compost and reference substrate conditions. Therefore, dry weight yield was used for further comparison.

No negative effect was seen on the germination and plant growth of summer barley plants in 25% and 50% Mater-Bi EN CF01U compost/reference substrate mixture compared to blank compost mixtures. According to CEN norm EN 13432 (2000) and ASTM D 6400-04 the germination rate and the plant biomass of the test compost should be more than 90% of those from the corresponding blank compost. The Mater-Bi CF01U compost fulfils these criteria.

For statistical analysis of the results, the 'Anova single factor test' at P ≤ 0.05 was used. The results are compared with the lowest significant difference procedure of Fisher. Again no difference was found.

CONCLUSION

Under the conditions of study the composted notified polymer appears to have no negative effect on the emergence and growth of cress plants.

TEST FACILITY

Organic Waste Systems (2005d)

B.1.9. Bioaccumulation

No bioaccumulation study was undertaken. However, the notified polymer is not expected to bioaccumulate due to its high molecular weight.

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