

RESPIRTEK AQUEOUS READY BIODEGRADABILITY TESTING SCHEME

1. Scope

- 1.1 The RespirTek Aqueous Ready Biodegradability Certification can be granted to the following Products:
 - 1.1.1 All raw materials
 - 1.1.2 All intermediate products
 - 1.1.3 All finished products
- 1.2 Certification of Product and the use of the associated Mark do not constitute or imply that applicable regulatory requirements, standards, or laws have been satisfied. Responsibility for compliance with such requirements rests solely with Applicant.

2. Definitions

- 2.1 **Applicant:** The Applicant shall mean the company that submitted the Product for evaluation and certification.
- 2.2 **Biodegradable Additive:** Any ingredient whose functional role in the Product is to promote or catalyze biodegradation.
- 2.3 **Certification Mark.** The term Certification Mark (“Mark”) shall refer to any common law or registered trademark owned by RespirTek, Inc. (“RespirTek”), or its affiliates, used in the certification of Products.
- 2.4 **Certification period:** The duration of time, commencing upon official certification and ending upon expiration, during which continued use of the Certification Mark and associated claims by the Applicant is authorized, contingent with ongoing compliance with the RespirTek certification requirements.
- 2.5 **Component:** An individual, distinct layer or part of a Product, such as a film, coating, laminate, or other discrete material within the overall composite structure.
- 2.6 **FTIR:** Fourier transform infrared spectroscopy.
- 2.7 **Organic constituent:** Any chemical, intentionally added to the Product as a result of the manufacturing process—including a constituent of an added ingredient or mixture—containing one or more atoms of carbon covalently bonded to atoms of another element (excluding inorganic carbon compounds such as carbonates and oxides).
- 2.8 **Original component sample:** Sample of a component of the Product submitted at initial certification.
- 2.9 **Original Product sample:** Sample of the Product submitted at initial certification.
- 2.10 **Product:** The term Product (“Product”) shall mean an Applicant’s raw material, intermediate product, or finished product that has been submitted for testing or evaluation, for purposes of obtaining, extending, or renewing certification.

3. General Requirements

3.1 Product Characterization

3.1.1 The following information shall be provided for the Product (if applicable) and for each ingredient and organic constituent intentionally added to the Product:

- (a) Chemical name
- (b) Chemical Formula
- (c) Trade name
- (d) Manufacturer
- (e) Percent by mass in the Product
- (f) CAS number
- (g) Functional role

3.1.2 FTIR and photographs of the Product shall be documented by RespirTek.

- (a) If the Product is multilayered (e.g., laminated) or contains other discrete materials within the overall structure of the Product, then a sample of each component shall be analyzed via FTIR.

3.2 Biodegradability

3.2.1 The Product shall be tested for biodegradability by RespirTek after initiation of the application, according to the Testing Requirements (Section 4).

4. Testing Requirements

4.1 The Product as a whole or each of the organic constituents that make up the Product shall meet all OECD requirements for a ready biodegradability classification as defined in OECD (2006), *Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3* [6.1] when tested via an appropriate aerobic aqueous test (see

4.2 Appendix 1).

4.2.1 In well-founded exceptional cases, additional or alternate testing may be required.

4.3 Organic constituents present at levels between 1-40% as a percentage of total organic carbon (TOC) shall be tested individually for compliance.

4.4 As an alternative to testing a single organic constituent individually, the level of biodegradation of an organic constituent may be determined by using an artificial blend of the Product consisting of at least 40% by TOC of the organic constituent being tested that is otherwise the same.

4.5 The following Products and organic constituents are exempt from testing:

4.5.1 Products and organic constituents classified as readily biodegradable in water according to a REACH registration.

4.5.2 Products and organic constituents demonstrating at least 60% biodegradation within 14 days according to the NITE CSCL database.

4.5.3 Products and organic constituents that meet the requirements for exemption from the 10-day window criteria [6.1] and that demonstrate at least 60% biodegradation within 28 days according to the NITE CSCL database.

4.5.4 Products and organic constituents classified as readily biodegradable according to the EPA CompTox database.

4.5.5 Surfactants on the EPA Safer Chemical Ingredient list with a Green Circle code.

4.5.6 Products and organic constituents that hold a current RespirTek Aqueous Ready Biodegradability certification.

4.5.7 Products and organic constituents that have been tested for biodegradability by RespirTek within 3 years of the application date, with test initiation having begun no later than March 31, 2026, the testing and results of that otherwise meet all testing requirements described in Section 4.

(a) Products and organic constituents using this exemption shall have an existing FTIR analysis documented by RespirTek, or a sample of the Product or organic constituent shall be submitted for FTIR analysis according to Section 3.1.2 upon application.

(b) If certification is approved, and notwithstanding the Certification Period defined in the Product Certification Agreement and any associated exhibits, the certification period for Products using this exemption shall be the greater of:

(i) 3 years from the issuance date of the final report, or

(ii) 2 years from the approval date for certification.

4.6 The sum of constituents present in the Product at less than 1% as a percentage of TOC, not tested individually for compliance, and not otherwise exempt based on the criteria described in Section 4.5 shall not exceed 5% by TOC.

4.7 Equivalent Forms

4.7.1 Testing in support of certification of a Product holding a current and active RespirTek Aqueous Ready Biodegradability certification may be applied to certification of additional Products that are compositionally identical except for one or more of the following attributes:

- (a) Physical dimensions (thickness, diameter, etc.)
- (b) Density
- (c) Dilution in water
- (d) Grade of constituents that make up the Product
- (e) Proportion of organic constituents, provided the following:
 - (i) All other testing requirements as described in Section 4 are met.
 - (ii) For Products that contain a Biodegradable Additive, biodegradability must have been demonstrated using a proportion of the Biodegradable Additive no higher than its lowest proportion in all Products.

5. Certification Period Extension and Renewal Requirements

5.1 Certification Period Extension Requirements

5.1.1 Applicant must submit to RespirTek a completed application form (Control #821) stating that the Product, as marketed, and any representative samples submitted for certification extension are unchanged and unmodified from their form at the time of their certification - or that any changes have received prior approval from RespirTek.

5.1.2 A representative sample of the Product shall be submitted for FTIR analysis.

- (a) If the Product is multilayered, then each layer of the Product shall be submitted and analyzed separately via FTIR.
- (b) The Product sample submitted for extension shall be identifiably the same composition as the original Product sample.
- (c) All component samples submitted for extension shall be identifiably the same composition as the corresponding original component sample.

5.2 Certification Renewal Requirements

5.2.1 Applicant must submit to RespirTek a completed certification renewal form (Control #810) stating that the Product, as marketed, and any representative samples submitted for certification extension are unchanged and unmodified from their form at the time of their certification - or that any changes have received prior approval from RespirTek.

5.2.2 A representative sample of the Product shall be submitted for FTIR analysis.

- (a) If the Product is multilayered, then each layer of the Product shall be submitted and analyzed separately via FTIR.
- (b) The Product sample submitted for extension shall be identifiably the same composition as the original Product sample.

- (c) All component sample submitted for extension shall be identifiably the same composition as the corresponding original component sample.

5.2.3 The Product shall be tested for biodegradability according to Section 4.

- (a) Notwithstanding Section 4.1, at least 55% biodegradation as theoretical CO₂ evolution or oxygen demand, or at least 65% removal of dissolved organic carbon must be achieved by the end of the 10-day window for any Product or organic constituent tested (or within 28 days for Products and organic constituents that meet the requirements for exemption from the 10-day window criteria [6.1]).
- (b) The exemptions listed in Section 4.5 may be applied.
- (c) Testing of Equivalent Forms of the Product may be used in support of certification renewal of the Product as described in Section 4.7.
 - (i) Section 5.2.3(c) does not apply if testing of the Product is used in support of certification of any other Equivalent Forms.

6. References

- 6.1 OECD (2006), *Revised Introduction to the OECD Guidelines for Testing of Chemicals, Section 3*, OECD Guidelines for the Testing of Chemicals, Section 3, OECD Publishing, Paris, <https://doi.org/10.1787/9789264030213-en>.
- 6.2 OECD (1992), *Test No. 301: Ready Biodegradability*, OECD Guidelines for the Testing of Chemicals, Section 3, OECD Publishing, Paris, <https://doi.org/10.1787/9789264070349-en>.
- 6.3 OECD (2014), *Test No. 310: Ready Biodegradability - CO₂ in sealed vessels (Headspace Test)*, OECD Guidelines for the Testing of Chemicals, Section 3, OECD Publishing, Paris, <https://doi.org/10.1787/9789264224506-en>.
- 6.4 ISO 7827: “*Water quality – Evaluation of the “ready”, “ultimate” aerobic biodegradability of organic compounds in an aqueous medium – Method by analysis of dissolved organic carbon (DOC)*”
- 6.5 ISO 9408: “*Water quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium by determination of oxygen demand in a closed respirometer*”
- 6.6 ISO 9439: “*Water quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium – Carbon dioxide evolution test*”
- 6.7 ISO 10707: “*Water quality – Evaluation in an aqueous medium of the “ultimate” aerobic biodegradability of organic compounds – Method by analysis of biochemical oxygen demand (closed bottle test)*”
- 6.8 ISO 14593: “*Water quality – Evaluation of ultimate aerobic biodegradability of organic compounds in aqueous medium – Method by analysis of inorganic carbon in sealed vessels (CO₂ headspace test)*”
- 6.9 ASTM D5864, *Standard Test Method for Determining the Aerobic Aquatic Biodegradation of Lubricants or Their Components*, ASTM International, West Conshohocken, PA

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- 6.10 ASTM D6139, *Standard Test Method for Determining the Aerobic Aquatic Biodegradation of Lubricants or Their Components Using the Gledhill Shake Flask*, ASTM International, West Conshohocken, PA
- 6.11 ASTM D6731, *Standard Test Method for Determining the Aerobic, Aquatic Biodegradability of Lubricants or Lubricant Components in a Closed Respirometer*, ASTM International, West Conshohocken, PA

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Appendix 1

Suitable Test Methods and Specifications

1. OECD 301A

1.1 The Product or organic constituent shall be soluble in water.

1.2 Biodegradability may not be able to be determined if the Product or organic constituent:

1.2.1 Is volatile.

(a) Volatility can be detected by:

(i) Observing mass loss of a sample of the Product or organic constituent over a short period of time.

(ii) Observing baseline noise while a sample of the Product or organic constituent is loaded (but not inserted into the combustion chamber) of a TOC analyzer.

1.2.2 Adsorbs

1.3 DOC depletion from abiotic processes shall be accounted for.

2. OECD 301B

2.1 Biodegradability may not be able to be determined if the Product or organic constituent is volatile.

2.1.1 Volatility can be detected as described in Section 1.2.1(a) of this appendix.

2.2 The inorganic carbon (IC) content of the Product or organic constituent shall be no more than 5% of its total carbon (TC) content.

3. OECD 301C

3.1 If the Product or organic constituent contains nitrogen or if its exact chemical formula is unknown, then oxygen uptake due to nitrification shall be accounted for.

4. OECD 301D

4.1 If the Product or organic constituent contains nitrogen or if its exact chemical formula is unknown, then oxygen uptake due to nitrification shall be accounted for.

5. OECD 301E

5.1 The Product or organic constituent shall be soluble in water.

5.2 Biodegradability may not be able to be determined if the Product or organic constituent:

5.2.1 Is volatile.

(a) Volatility can be detected as described in Section 1.2.1(a) of this appendix

5.2.2 Adsorbs

5.3 DOC depletion from abiotic processes shall be accounted for.

6. OECD 301F

6.1 If the Product or organic constituent contains nitrogen or if its exact chemical formula is unknown, then oxygen uptake due to nitrification shall be accounted for.

7. OECD 310

8. ISO 7827

8.1 The Product or organic constituent shall be soluble in water.

8.2 Biodegradability may not be able to be determined if the Product or organic constituent:

8.2.1 Is volatile.

(a) Volatility can be detected as described in Section 1.2.1(a) of this appendix

8.2.2 Adsorbs

8.3 DOC depletion from abiotic processes shall be accounted for.

8.4 One of the following conditions shall be met by the end of the test period:

8.4.1 The difference of extremes of replicate values of the removal of the Product or organic constituent is less than 20%.

8.4.2 All replicate values of the removal of the Product are at least equal to the degree required for a biodegradability classification.

9. ISO 9408

9.1 If the Product or organic constituent contains nitrogen or if its exact chemical formula is unknown, then oxygen uptake due to nitrification shall be accounted for.

9.2 One of the following conditions shall be met by the end of the test period:

9.2.1 The difference of extremes of replicate values of the removal of the Product or organic constituent is less than 20%.

9.2.2 All replicate values of the removal of the Product are at least equal to the degree required for a biodegradability classification.

10. ISO 9439

10.1 Biodegradability may not be able to be determined if the Product or organic constituent is volatile.

10.1.1 Volatility can be detected as described in Section 1.2.1(a) of this appendix.

10.2 The inorganic carbon (IC) content of the Product or organic constituent shall be no more than 5% of its total carbon (TC) content.

10.3 One of the following conditions shall be met by the end of the test period:

10.3.1 The difference of extremes of replicate values of the removal of the Product or organic constituent is less than 20%.

10.3.2 All replicate values of the removal of the Product are at least equal to the degree required for a biodegradability classification.

11. ISO 10707

11.1 If the Product or organic constituent contains nitrogen or if its exact chemical formula is unknown, then oxygen uptake due to nitrification shall be accounted for.

11.2 One of the following conditions shall be met by the end of the test period:

11.2.1 The difference of extremes of replicate values of the removal of the Product or organic constituent is less than 20%.

11.2.2 All replicate values of the removal of the Product are at least equal to the degree required for a biodegradability classification.

12. ISO 14593

12.1 One of the following conditions shall be met by the end of the test period:

12.1.1 The difference of extremes of replicate values of the removal of the Product or organic constituent is less than 20%.

12.1.2 All replicate values of the removal of the Product are at least equal to the degree required for a biodegradability classification.

13. ASTM D5864

13.1 Inoculum shall not be pre-adapted.

13.2 Biodegradability may not be able to be determined if the Product or organic constituent is volatile.

13.2.1 Volatility can be detected as described in Section 1.2.1(a) of this appendix.

13.3 The inorganic carbon (IC) content of the Product or organic constituent shall be no more than 5% of its total carbon (TC) content.

13.4 One of the following conditions shall be met by the end of the test period:

13.4.1 The difference of extremes of replicate values of the removal of the Product or organic constituent is less than 20%.

13.4.2 All replicate values of the removal of the Product are at least equal to the degree required for a biodegradability classification.

14. ASTM D6139

14.1 Inoculum shall not be pre-adapted.

14.2 Biodegradability may not be able to be determined if the Product or organic constituent is volatile.

14.2.1 Volatility can be detected as described in Section 1.2.1(a) of this appendix.

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- 14.3 The inorganic carbon (IC) content of the Product or organic constituent shall be no more than 5% of its total carbon (TC) content.
- 14.4 One of the following conditions shall be met by the end of the test period:
 - 14.4.1 The difference of extremes of replicate values of the removal of the Product or organic constituent is less than 20%.
 - 14.4.2 All replicate values of the removal of the Product are at least equal to the degree required for a biodegradability classification.
- 15. ASTM D6731
 - 15.1 Inoculum shall not be pre-adapted.
 - 15.2 If the Product or organic constituent contains nitrogen or if its exact chemical formula is unknown, then oxygen uptake due to nitrification shall be accounted for.
 - 15.3 One of the following conditions shall be met by the end of the test period:
 - 15.3.1 The difference of extremes of replicate values of the removal of the Product or organic constituent is less than 20%.
 - 15.3.2 All replicate values of the removal of the Product are at least equal to the degree required for a biodegradability classification.