Environmental Protection Agency

§ 80.161 Detergent additive certification program.

(a) Effective dates and applicability of requirements. (1) As of July 1, 1997:

(i) Detergent additives for the control of port fuel injector deposits (PFID) and/or intake valve deposits (IVD) in gasoline engines may not be transferred or sold for use in compliance with this subpart unless such additives have been certified according to the requirements of this section.

(ii) Except as provided in §80.169(c)(8), PFID and IVD control additives may not be added to gasoline or post-refinery component (PRC) for compliance with this subpart unless such additives have been certified according to the requirements of this subpart.

(b) Detergent additive certification requirements. For a detergent additive package to be certified as eligible for use by detergent blenders in complying with the gasoline detergency requirements of this subpart, the requirements listed in this paragraph (b) must be satisfied for such detergent. Subject to the provisions of paragraph (e) of this section, if the certifier fails to conduct the specified tests or to submit the specified materials, or if EPA judges the testing or materials to be inadequate, or if the detergent fails EPA confirmatory deposit control performance testing pursuant to §80.167, the Administrator may deny or withdraw the detergent’s eligibility to be used to satisfy the detergency requirements of this subpart.

[61 FR 35363, July 5, 1996]
(1) The detergent additive manufacturer must properly register the detergent additive under 40 CFR part 79. For this purpose:

(i) The compositional data required under §79.21(a) of this chapter shall include the information specified in §80.162.

(ii) The minimum recommended additive concentration required under §79.21(d) of this chapter shall be reported to EPA in units of gallons of detergent additive package per 1000 gallons of gasoline or PRC, provided to four digits. This concentration is the lowest additive concentration (LAC) referred to in §80.170, and shall be reported as follows:

(A) For a detergent additive registered for use in unleaded gasoline, the minimum concentration must be determined and reported for each certification option under which the manufacturer wishes to certify the additive pursuant to §80.163.

(1) In the case of a detergent certified for use in California gasoline based on an existing certification granted by the California Air Resources Board (CARB), pursuant to §80.163(d), the minimum recommended concentration must equal or exceed the amount specified in the CARB certification.

(B) For a detergent registered for use in California gasoline based on an existing certification granted by the California Air Resources Board (CARB), pursuant to §80.163(d), the minimum recommended concentration must equal or exceed the amount specified in the CARB certification.

(2) In the case of any other detergent certification option, the minimum recommended concentration must equal or exceed the amount mixed into the associated test fuel specified in §80.164, which was shown to satisfy the PFID and IVD deposit control performance tests and standards specified in §80.165.

(B) For a detergent registered for use in leaded gasoline, the minimum recommended concentration must be no less than the amount shown to be needed for control of carburetor deposits, pursuant to the test procedure and test fuel guidelines in §80.166.

(C) Once it has been registered by EPA, the minimum recommended concentration specified by a detergent manufacturer to detergent blenders and other users of the additive, pursuant to paragraph (c) of this section, may not be changed without first notifying EPA. Such notification should be sent by certified mail to the address specified in §80.174(b). The change in minimum concentration must be supported by existing certification data or else the notification to EPA must be accompanied by new certification information which demonstrates that the modification is consistent with the requirements of paragraphs (b)(1)(ii)(A) and (B) of this section.

(D) A manufacturer may use a single set of certification test data to demonstrate the deposit control effectiveness of more than one registered detergent additive product, provided that:

(1) The additive products contain all of the same detergent-active components and no detergent-active components other than those contained in common; and

(2) The minimum concentration recommended for the use of each such additive product is specified such that, when each additive product is mixed in gasoline at the recommended concentration, each of its detergent-active components will be present at a final concentration no less than the lowest concentration of that component which was present when the tested additive product met the PFID and IVD performance standards specified in §80.165.

(2) The detergent additive manufacturer (or other certifying party) must submit to EPA a sample of the actual detergent additive package which was used in the certification testing specified in §80.164 or, if such sample is not available, then a sample which has the same composition as the package used in certification testing.

(i) The sample volume shall be between 250 ml and 500 ml.

(ii) The sample shall be packaged in a container which has a resealable closure and which will maintain sample integrity for at least one year. The container shall be labeled with the name and address of the manufacturer and the name of the detergent additive package.

(iii) Any known shelf life limitations, and any available information on optimal temperature, light exposure, or other conditions to prolong sample shelf life, shall be provided.

(iv) If the certifying party wishes to claim that the sample or any accompanying documents are entitled to special handling for reasons of business confidentiality, the party must clearly identify the sample or documents as
such. EPA will handle any samples or documents with such claims according to the regulations at 40 CFR part 2.

(v) The sample shall be submitted to EPA, at the address provided in §80.174(a), within seven days of the date on which the certification letter for the detergent package is sent to EPA as required by paragraph (b)(3) of this section.

(3) The detergent additive manufacturer (or other certifying party) shall submit a certification letter for the detergent additive package to the address in §80.174(b). The party must use certified or express mail with return receipt service. The letter shall be signed by a person legally authorized to represent the certifying party and shall contain the following information:

(i) Identifying information.
   (A) The name and address of the detergent additive manufacturer.
   (B) In any case where the certifier is not the detergent additive manufacturer, such as in the case of a fuel-specific certification pursuant to §80.163(c), the name and address of the certifier.
   (C) The commercial identifying name of the detergent additive product as registered under the requirements of §79.21 of this chapter.

(ii) A statement attesting that:
   (A) The detergent package which is the subject of this certification has been tested according to applicable procedural and test fuel requirements in this subpart and has met the applicable performance standards; and
   (B) The testing was conducted in a manner consistent with good engineering practices; and
   (C) Complete documentation of the test fuel formulation and IVD demonstration procedures, detergent performance test procedures, and test results are available for EPA’s inspection upon request.

(iii) The name and location of the laboratory(ies) at which the certification testing was conducted and the dates during which the testing was conducted.

(iv) For each option under which certification is sought pursuant to §80.163, specifications of the test fuel(s) in which the detergent underwent performance testing. These fuel specifications must include:
   (A) The sulfur content in weight percent.
   (B) The T-90 distillation point in degrees Fahrenheit.
   (C) The olefin content in volume percent.
   (D) The aromatic content in volume percent.
   (E) The identity and volume percent of any oxygenate compound.
   (F) The source of the test fuel(s) and/or fuel blend stocks used to formulate the test fuel(s).

(v) In the case of a national or PADD certification (pursuant to §80.163(a) or (b)) for which the test fuel was specially formulated from refinery blend stocks, the results of the IVD demonstration test, pursuant to §80.164(b)(3).

(vi) In the case of a fuel-specific detergent certification, pursuant to §80.163(c), the definition of the segregated gasoline pool, including any permitted PRC, for which the certification is sought, and the fuel parameter percentile distributions determined for the subject gasoline pool, as specified in §80.164(c). The percentile distributions must include all of the fuel parameters listed in paragraph (b)(3)(iv) (A) through (D) of this section, along with any other fuel parameter(s) which the certifier wishes to use to define the certification fuel. As specified in §80.164(c)(1)(iv), the procedures used to measure the additional parameters must be identified, as well as the levels of these additional parameters present in the test fuel(s).

(vii) In the case of a certification for California gasoline based on an existing certification granted by CARB, pursuant to §80.163(d), a copy of the CARB certificate.

(viii) The test concentration(s) of the subject detergent additive in each test fuel, and the corresponding test results (percent flow restriction demonstrated in the PFID test and milligrams of deposit per valve demonstrated in the IVD test).

(ix) For each option under which certification of the detergent is sought, the minimum recommended concentration which the certifying party seeks to establish for the detergent additive
package, pursuant to paragraph (b)(1)(ii) of this section.

(4) EPA will acknowledge receipt of the detergent certification letter. The effective date of certification will be the sooner of 60 days from the date on which EPA receives the certification letter, or the certifier’s receipt of EPA's acknowledgement of the certification letter. However, neither the passage of 60 days nor EPA's acknowledgement will signify acceptance by EPA of the validity of the information in the certification letter or the adequacy or potency of the detergent sample submitted pursuant to paragraph (b)(2) of this section. EPA may elect at any time to review the detergent certification data, analyze the submitted detergent additive sample, or subject the detergent additive package to confirmatory testing as described in §80.167 and, where appropriate, may disqualify a detergent certification according to the provisions in paragraph (e) of this section.

(c) The minimum concentration reported in the detergent registration according to the provisions of paragraph (b)(1)(ii) of this section, plus any restrictions in use associated with that concentration, must be accurately communicated in writing by the additive manufacturer to each fuel manufacturer or detergent blender who purchases the subject detergent for purpose of compliance with the gasoline detergency requirements of this subpart, and to any additive manufacturer who purchases the subject additive with the intent of reselling it to a fuel manufacturer for this purpose.

(d) The rate at which a detergent blender treats gasoline with a detergent additive package must be no less than the minimum recommended concentration reported for the subject detergent additive pursuant to paragraph (b)(1)(ii) of this section, except under the following conditions:

(1) If a detergent blender possesses deposit control performance test results as specified in §80.165 or §80.166 which show that the minimum treat rate recommended by the manufacturer of a detergent additive product exceeds the amount of that detergent actually required for effective deposit control, then, upon informing EPA in writing of these circumstances, the detergent blender may use the detergent at the lower concentration substantiated by these test results.

(2) The notification to EPA must clearly specify the name of the detergent product and its manufacturer, the concentration recommended by the detergent manufacturer, and the lower concentration which the detergent blender intends to use. The notification must also attest that the required data are available to substantiate the deposit control effectiveness of the detergent at the intended lower concentration. The notification must be sent by certified mail to the address specified in §80.174(b).

(3) At its discretion, EPA may require that the detergent blender submit the test data purported to substantiate the claimed effectiveness of the lower concentration of the detergent additive. In addition, EPA may require the manufacturer of the subject detergent additive to submit test data substantiating the minimum recommended concentration specified in the detergent additive registration. In either case, EPA will send a letter to the appropriate party; the supporting data will be due to EPA within 30 days of receipt of EPA’s letter.

(i) If the detergent blender fails to submit the required supporting data to EPA in the allotted time period, or if EPA judges the submitted data to be inadequate to support the detergent blender’s claim that the lower concentration provides a level of deposit control consistent with the requirements of this section, then EPA will disapprove the use of the detergent at the lower concentration. Further, the detergent blender may be subject to applicable liabilities and penalties pursuant to §§80.169 and 80.172 for any gasoline or PRC it has additized at the lower concentration.

(ii) If the detergent manufacturer fails to submit the required test data to EPA within the allotted time period, EPA will proceed on the assumption that data are not available to substantiate the minimum recommended concentration specified in the detergent registration, and the subject additive may be disqualified for use in complying with the requirements of this section.
subpart, pursuant to the procedures in paragraph (e) of this section. The detergent manufacturer may also be subject to applicable liabilities and penalties in §§80.169 and 80.172.

(iii) If both parties submit the required information, EPA will evaluate the quality and results of both sets of test data, and will either approve or disapprove the use of the lower treat rate submitted by the detergent blender. EPA will inform both parties of the results of its analysis.

(e) Disqualification of a detergent additive package. (1) When EPA makes a preliminary determination that a detergent additive certifier has failed to comply with the detergent certification requirements of this section, including a failure to submit required materials for a detergent additive or submission of materials which EPA deems inadequate, or if a detergent additive fails confirmatory testing conducted pursuant to §80.167, EPA shall notify the additive certifier by certified mail, return receipt requested, setting forth the basis for that determination and informing the certifier that the detergent may lose its eligibility to be used to comply with the degrency requirements of this section.

(2) If EPA determines that the detergent certification was created by fraud or other misconduct, such as a negligent disregard for the truthfulness or accuracy of the required information, the detergent certification will be considered void ab initio and the disqualification will be retroactive to July 1, 1997 or the date on which the additive product was first certified, whichever is later.

(3) The certifier will be afforded 60 days from the date of receipt of the notice of intent to disqualify the detergent additive to submit written comments concerning the notice, and to demonstrate or achieve compliance with the specific requirements which provide the basis for the proposed disqualification. If the certifier does not respond in writing within 60 days from the date of receipt of the notice of intent to disqualification, the detergent disqualification shall become final and the Administrator shall notify the certifier of such final disqualification order. If the certifier responds in writing within 60 days from the date of receipt of the notice of intent to disqualify, the Administrator shall review and consider all comments submitted by the certifier before taking final action concerning the proposed disqualification. All correspondence regarding a disqualification must be sent to the address provided in §80.174(b).

(4) As part of a written response to a notice of intent to disqualify, a certifier may request an informal hearing concerning the notice. Any such request shall state with specificity the information the certifier wishes to present at such a hearing. If an informal hearing is requested, EPA shall schedule such a hearing within 90 days from the date of receipt of the request. If an informal hearing is held, the subject matter of the hearing shall be confined solely to whether or not the certifier has complied with the specific requirements which provide the basis for the proposed disqualification. If an informal hearing is held, the designated presiding officer may be any EPA employee, the hearing procedures shall be informal, and the hearing shall not be subject to or governed by 40 CFR part 22 or by 5 U.S.C. 554, 556, or 557. A verbatim transcript of each informal hearing shall be kept and the Administrator (or designee) shall consider all relevant evidence and arguments presented at the hearing in making a final decision concerning a proposed disqualification.

(5) If a certifier who has received a notice of intent to disqualify submits a timely written response, and the Administrator (or designee) decides after reviewing the response and the transcript of any informal hearing to disqualify the detergent for use in complying with the requirements of this subpart, the Administrator (or designee) shall issue a final disqualification order and forward a copy of the disqualification order to the certifier by certified mail. Notice of the disqualification order will also be published in the Federal Register. The disqualification will become effective as of the date on which the copy of the order is received by the certifier. If the certifier is also a blender of the disqualified additive, then the certifier...
must stop using the ineligible detergent upon receipt of the disqualification order.

(6) Within 10 days of receipt of EPA’s notification of the final decision to disqualify a detergent additive package pursuant to this paragraph (e), the detergent certifier must submit to EPA, at the address specified in §80.174(b), a list of its customers who use the disqualified detergent. Failure to do so may subject the certifier to liabilities for violations of §80.168 that result from the use of the uncertified detergent. EPA shall inform the certifier’s customers by certified mail that the detergent is no longer eligible for compliance with the requirements of this subpart. These parties must stop using the ineligible detergent additive package and substitute an eligible detergent within 45 days of receiving the notification, or within 45 days of publication of the disqualification notice in the Federal Register, whichever occurs sooner.

§80.162 Additive compositional data.

For a detergent additive product to be eligible for use by detergent blenders in complying with the gasoline de
tergency requirements of this subpart, the compositional data to be supplied to EPA by the additive manufacturer for the purpose of registering a detergent additive package under §79.21(a) of this chapter must include the items listed in this section. In the case of items requiring measurement or other technical analysis, and for which a specific test procedure is not stipulated herein, the procedure must conform to reasonable and customary standards of repeatability and reproducibility, and reasonable and customary limits of detection and accuracy for the type of test procedure or analytic procedure in question. At EPA’s request, detailed documentation of any such test procedure must be submitted within 10 days of the registrant’s receipt of EPA’s request.

(a) A complete listing of the components of the detergent additive package and the weight and/or volume percent (as applicable) of each component of the package.

(1) When possible, standard chemical nomenclature shall be used or the chemical structure of the component shall be given. Polymeric components may be reported as the product of other chemical reactants, provided that the supporting data specified in paragraph (b) of this section is also reported.

(2) Each detergent-active component of the package shall be classified into one of the following designations:

(i) Polyalkyl amine;
(ii) Polyether amine;
(iii) Polyalkylsuccinimide;
(iv) Polyalkylaminophenol;
(v) Detergent-active petroleum-based carrier oil;
(vi) Detergent-active synthetic carrier oil; and
(vii) Other detergent-active component (identify category, if feasible.)

(3) Composition variability.

(i) The composition of a detergent additive reported in a single additive registration (and the detergent additive product sold under a single additive registration) may not:

(A) Include detergent-active components which differ in identity from those contained in the detergent additive package at the time of certification testing; or

(B) Include a range of concentration for any detergent-active component such that, if the component were present in the detergent additive package at the lower bound of the reported range, the deposit control effectiveness of the additive package would be reduced as compared with the level of effectiveness demonstrated during certification testing. Subject to the foregoing constraint, a detergent additive product sold under a particular additive registration may contain a higher concentration of the detergent-active component(s) than the concentration(s) of such component(s) reported in the registration for the additive.

(ii) The identity or concentration of non-detergent-active components of the detergent additive package may vary under a single registration provided that such variability does not reduce the deposit control effectiveness of the additive package as compared with the level of effectiveness demonstrated during certification testing.

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