

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 additive within 45 days of receiving the notification, or within 45 days of publication of the disqualification notice in the FEDERAL REGISTER, whichever occurs sooner.

[61 FR 35364, July 5, 1996, as amended at 61 FR 58747, Nov. 18, 1996]

§ 80.162 Additive compositional data.

For a detergent additive product to be eligible for use by detergent blenders in complying with the gasoline detergency 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.

(A) Unless the additive manufacturer (or other certifying party) provides EPA with data to substantiate that a carrier oil does not act to enhance the detergent additive package's ability to control deposits, any carrier oil contained in the detergent additive package, whether petroleum-based or synthetic, must be treated as a detergent-active component in accordance with the additive compositional reporting requirements in § 80.162(a)(2). Such data should be sent by certified mail to the address specified in § 80.174(b).

(B) [Reserved]

(iii) Except as provided in paragraph (a)(3)(iv) of this section, detergent additive packages which do not satisfy the restrictions in this paragraph (a)(3) must be separately registered. EPA may disqualify an additive for use in satisfying the requirements of this subpart if EPA determines that the variability included within a given detergent additive registration may reduce the deposit control effectiveness of the detergent package such that it may invalidate the minimum recommended concentration reported in accordance with the applicable requirements of § 80.161(b)(1)(ii).

(iv) A change in minimum concentration requirements resulting from a modification of detergent additive composition shall not require a new detergent additive registration or a change in existing registration if:

(A) The modification is effected by a detergent blender only for its own use

or for the use of parties which are subsidiaries of, or share common ownership with, the blender, and the modified detergent is not sold or transferred to other parties; and

(B) The modification is a dilution of the additive for the purpose of ensuring proper detergent flow in cold weather; and

(C) Gasoline is the only diluting agent used; and

(D) The diluted detergent is subsequently added to gasoline at a rate that attains the detergent's registered minimum recommended concentration, taking into account the dilution; and

(E) EPA is notified, either before or within seven days after the dilution action, of the identity of the detergent, the identity of the diluting material, the amount or percentage of the dilution, the change in treat rate necessitated by the dilution, and the locations and time period of diluted detergent usage. The notification shall be sent or faxed to the address in § 80.174(c).

(b) For detergent-active polymers and detergent-active carrier oils which are reported as the product of other chemical reactants:

(1) Identification of the reactant materials and the manufacturer's acceptance criteria for determining that these materials are suitable for use in synthesizing detergent components. The manufacturer must maintain documentation, and submit it to EPA upon request, demonstrating that the acceptance criteria reported to EPA are the same criteria which the manufacturer specifies to the suppliers of the reactant materials.

(2) A Gel Permeation Chromatograph (GPC), providing the molecular weight distribution of the polymer or detergent-active carrier oil components and the concentration of each chromatographic peak representing more than one percent of the total mass. For these results to be acceptable, the GPC test procedure must include equipment calibration with a polystyrene standard or other readily attainable and generally accepted calibration standard. The identity of the calibration standard must be provided, together with the GPC characterization of the standard.

(c) For non-detergent-active carrier oils, the following parameters:

(1) T10, T50, and T90 distillation points, and end boiling point, measured according to applicable test procedures cited in § 80.46.

(2) API gravity and viscosity

(3) Concentration of oxygen, sulfur, and nitrogen, if greater than or equal to 0.5 percent (by weight) of the carrier oil

(d) Description of an FTIR-based method appropriate for identifying the detergent additive package and its detergent-active components (polymers, carrier oils, and others) both qualitatively and quantitatively, together with the actual infrared spectra of the detergent additive package and each detergent-active component obtained by this test method. The FTIR infrared spectra submitted in connection with the registration of a detergent additive package must reflect the results of a test conducted on a sample of the additive containing the detergent-active component(s) at a concentration no lower than the concentration(s) (or the lower bound of a range of concentration) reported in the registration pursuant to paragraph (a)(3)(i)(B) of this section.

(e) To provide a basis for establishing an affirmative defense to presumptive liability pursuant to § 80.169(c)(4)(i)(D)(2)(i), specific physical parameters must be identified which the manufacturer considers adequate and appropriate, in combination with other information and sampling requirements under this subpart, for identifying the detergent additive package and monitoring its production quality control.

(1) Such parameters shall include (but need not be limited to) viscosity, density, and basic nitrogen content, unless the additive manufacturer specifically requests, and EPA approves, the substitution of other parameter(s) which the manufacturer considers to be more appropriate for a particular additive package. The request must be made in writing and must include an explanation of how the requested physical parameter(s) are helpful as indicator(s) of detergent production quality control. EPA will respond to such requests in writing; the additional pa-

rameters are not approved until the certifier receives EPA's written approval.

(2) The manufacturer shall identify a standardized measurement method, consistent with the chemical and physical nature of the detergent product, which will be used to measure each parameter. The documented ASTM repeatability for the method shall also be cited. The manufacturer's target value for each parameter in the detergent package, and the expected range of production values for each parameter, shall be specified.

(3) EPA will consider the parameter measurements to be an acceptable basis for establishing an affirmative defense to presumptive liability, if the expected range of variability differs from the target value by an amount no greater than five times the standard repeatability of the test procedure, or by no more than 10 percent of the target value, whichever is less. However, in the case of nitrogen analysis or other procedures for measuring concentrations of specific chemical compounds or elements, when the target value is less than 10 parts per million, a range of variability up to 50 percent of the target value will be considered acceptable.

(4) If a manufacturer wishes to rely on measurement methods or production variability ranges which do not conform to the above limitations, then the manufacturer must receive prior written approval from EPA in order to be assured that any related parameter measurements will be considered an acceptable basis for establishing an affirmative defense. A request for such allowance must be made in writing. It must fully justify the adequacy of the test procedure, explain why a broader range of variability is required, and provide evidence that the production detergent will perform adequately throughout the requested range of variability.

[61 FR 35366, July 5, 1996, as amended at 66 FR 55889, Nov. 5, 2001; 70 FR 69245, Nov. 14, 2005]