C. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA. The RFA applies only to rules subject to notice-and-comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. This rule is not subject to notice-and-comment requirements because the agency has invoked the APA ''good cause'' exemption under 5 U.S.C. 553(b).

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications. It will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175. This good cause final action simply extends the date for the EPA to take action on a petition. Thus, Executive Order 13175 does not apply to this rule.

G. Executive Order 13045: Protection of Children From Environmental Health and Safety Risks

The EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of ''covered regulatory action'' in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution or Use

This action is not subject to Executive Order 13211, because it is not a significant regulatory action under Executive Order 12866.

I. National Technology Transfer and Advancement Act (NTTAA)

This rulemaking does not involve technical standards.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

The EPA believes that this action is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This good cause final action simply extends the date for the EPA to take action on a petition and does not have any impact on human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, and the EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. The CRA allows the issuing agency to make a rule effective sooner than otherwise provided by the CRA if the agency makes a good cause finding that notice-and-comment rulemaking procedures are impracticable, unnecessary or contrary to the public interest (5 U.S.C. 808(2)). The EPA has made a good cause finding for this rule as discussed in Section II.B of this document, including the basis for that finding.

IV. Statutory Authority

The statutory authority for this action is provided by sections 110, 126 and 307 of the CAA as amended (42 U.S.C. 7410, 7426 and 7607).

V. Judicial Review

Under section 307(b)(1) of the CAA, judicial review of this final rule is available only by the filing of a petition for review in the U.S. Court of Appeals for the appropriate circuit by February 27, 2017. Under section 307(b)(2) of the CAA, the requirements that are the subject of this final rule may not be challenged later in civil or criminal proceedings brought by us to enforce these requirements.

List of Subjects in 40 CFR Part 52

Environmental protection, Administrative practices and procedures, Air pollution control, Electric utilities, Incorporation by reference, Intergovernmental relations, Nitrogen oxides, Ozone.

Dated: December 15, 2016.

Gina McCarthy,

Administrator.

[FR Doc. 2016–31256 Filed 12–28–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2016–0007 and EPA–HQ–OPP–2016–0008; FRL–9950–40]

Isobutyl Acetate and Isobutyric Acid; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes exemptions from the requirement of a tolerance for residues of isobutyl acetate (CAS Reg. No. 110–19–0) and isobutyric acid (CAS Reg. No. 79–31–2) when used as inert ingredients (solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest. Technology Sciences Group Inc. on behalf of Jeneil Biosurfactant Company submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting establishment of these exemptions from the requirement of a tolerance. This regulation eliminates the need to establish maximum permissible levels for residues of isobutyl acetate and isobutyric acid.

DATES: This regulation is effective December 29, 2016. Objections and requests for hearings must be received on or before February 27, 2017, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The dockets for this action, identified by docket identification (ID) numbers EPA–HQ–OPP–2016–0007 and EPA–HQ–OPP–2016–0008, are available at *http://www.regulations.gov* or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460–0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OPP Docket is (703) 305–5805. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: Michael Goodis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington,

DC 20460–0001; main telephone number: (703) 305–7090; email address: *RDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at *http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.*

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA–HQ–OPP–2016–0007 or EPA–HQ–OPP–2016–0008 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before February 27, 2017. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA–HQ–OPP–2016–0007 or EPA–HQ–OPP–2016–0008, by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *http://www.epa.gov/dockets/contacts.html.*

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *http://www.epa.gov/dockets.*

II. Petition for Exemption

In the **Federal Register** of April 25, 2016 (81 FR 24044) (FRL–9944–86), EPA issued a document pursuant to FFDCA section 408, 21 U.S.C. 346a, announcing the filing of a pesticide petition (IN–10846 for isobutyl acetate; IN–10852 for isobutyric acetate) by Technology Sciences Group Inc., (1150 18th Street NW., Suite 1000, Washington, DC 20036) on behalf of Jeneil Biosurfactant Company (400 N. Dekora Woods Blvd. Saukville, WI 53080). The petition requested that 40 CFR 180.910 be amended by establishing exemptions from the requirement of a tolerance for residues of isobutyl acetate (CAS Reg. No. 110–19–0) and isobutyric acid (CAS Reg. No. 79–31–2) when used as inert ingredients (solvent) in pesticide formulations applied to growing crops and to raw agricultural commodities after harvest. That document referenced the summaries of the petitions prepared by Technology Sciences Group Inc. on behalf of Jeneil Biosurfactant Company, the petitioner, which is available in the docket, *http://www.regulations.gov.* A comment was received on the notice of filing concerning petition #IN–10846. EPA's response to this comment is discussed in Unit V.B.

III. Inert Ingredient Definition

Inert ingredients are all ingredients that are not active ingredients as defined in 40 CFR 153.125 and include, but are not limited to, the following types of ingredients (except when they have a pesticidal efficacy of their own): Solvents such as alcohols and hydrocarbons; surfactants such as polyoxyethylene polymers and fatty acids; carriers such as clay and diatomaceous earth; thickeners such as carrageenan and modified cellulose; wetting, spreading, and dispersing agents; propellants in aerosol dispensers; microencapsulating agents; and emulsifiers. The term ''inert'' is not intended to imply nontoxicity; the ingredient may or may not be chemically active. Generally, EPA has exempted inert ingredients from the requirement of a tolerance based on the low toxicity of the individual inert ingredients.

IV. Aggregate Risk Assessment and Determination of Safety

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is ''safe.'' Section 408(b)(2)(A)(ii) of FFDCA defines ''safe'' to mean that ''there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.'' This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to ''ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . .''

EPA establishes exemptions from the requirement of a tolerance only in those cases where it can be clearly demonstrated that the risks from aggregate exposure to pesticide chemical residues under reasonably foreseeable circumstances will pose no appreciable risks to human health. In order to determine the risks from aggregate exposure to pesticide inert ingredients, the Agency considers the toxicity of the inert in conjunction with possible exposure to residues of the inert ingredient through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings. If EPA is able to determine that a finite tolerance is not necessary to ensure that there is a reasonable certainty that no harm will result from aggregate exposure to the inert ingredient, an exemption from the requirement of a tolerance may be established.

Consistent with FFDCA section 408(c)(2)(A), and the factors specified in FFDCA section 408(c)(2)(B), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for isobutyl acetate and isobutyric acid including exposure resulting from the exemption established by this action. EPA's assessment of exposures and risks associated with isobutyl acetate and isobutyric acid follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered their validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. Specific information on the studies received and the nature of the adverse effects caused by isobutyl acetate and isobutyric acid as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies are discussed in this unit.

Only acute toxicity data are available on isobutyric acid and no data are available on isobutyl acetate. However, upon ingestion, isobutyl acetate is rapidly and completely hydrolyzed to isobutanol and acetic acid. Isobutyric acid is a metabolic product of isobutanol.

Isobutanol is metabolized by alcohol dehydrogenase to form isobutyric acid via conversion to isobutyraldehyde. Therefore, toxicity data on isobutanol are considered suitable to assess repeated exposure to isobutyl acetate and isobutyric acid. Since acetic acid is currently exempted from tolerance under 40 CFR 180.910 without limitation, this risk assessment focuses on toxicity data available on isobutanol.

The acute oral and dermal toxicities are low for isobutyric acid. Isobutyric acid has an acute oral lethal dose (LD_{50}) ≥ 2,230 milligram/kilogram (mg/kg) in rats and rabbits. The acute dermal LD_{50} = 475 mg/kg in rabbits. The acute inhalation LC_{50} > 9.59 milligram/liter (mg/L) in rats. It is corrosive to the eye and skin in rabbits. Isobutyric acid is not a dermal sensitizer in rabbits. Isobutanol has an acute oral LD_{50} ≥ 2,830 mg/kg in rats. The acute dermal acute LD_{50} ≥ 2,000 mg/kg in rabbits. The acute inhalation LC_{50} > 6,000 parts per million (ppm) (approximately equivalent to 6,000 mg/L) in rats. Isobutanol is severely irritating to the eye and minimally to moderately irritating to the skin in rabbits.

Based on the subchronic data available, isobutanol is not toxic up to the limit dose of 1,000 milligram/kilogram/day (mg/kg/day). In a 90-day oral toxicity study via gavage in rats, hypo-activity, ataxia and salivation were observed at 1,000 mg/kg/day of isobutanol. In another 90-day oral toxicity study with isobutanol via drinking water in rats, no adverse effects were observed at doses up to 16,000 ppm (approximately 1,450 mg/kg/day), the highest dose tested (HDT). The study conducted via drinking water in rats is considered more relevant to human exposure and therefore more reflective of potential human toxicity.

In developmental toxicity studies with isobutanol via inhalation in rats and rabbits, neither maternal nor developmental toxicity is seen at doses up to 10,000 mg/m^3 (approximately 3,060 mg/kg/day), the HDT in both studies and above the limit dose of 1,000 mg/kg/day.

Similarly, no adverse effects are observed in a two-generation reproductive study with isobutanol via inhalation in rats at doses up to 2,500 ppm (approximately 2,326 mg/kg/day).

Carcinogenicity studies with isobutyl acetate, isobutyric acid or isobutanol are not available. However, a chronic toxicity study in rats treated with isobutantol in drinking water for 53–56 weeks did not show any evidence of toxicity or tumors at doses as high as 200 mg/kg/day. In addition, no toxicity is observed in other studies at doses below 1,450 mg/kg/day with isobutanol. Moreover, mutagenicity studies are negative with isobutanol and isobutyric acid. An Ames test, unscheduled DNA synthesis and mouse lymphoma assay are negative when tested with isobutyric acid. The Ames test, mouse lymphoma, Comet and micronucleus assays are negative when tested with isobutanol. Therefore, isobutyl acetate and isobutyric acid are not expected to be carcinogenic.

A neurotoxicity screening battery with isobutanol via the inhalation route of exposure in rats was available for review. Also, neurotoxicity endpoints were evaluated in an acute toxicity study in rats with isobutanol via the inhalation route of exposure. No adverse effects were observed in the functional observational battery, motor activity, schedule control operant behavior or neuropathology at doses up to 1,500 ppm (approximately 1,408 mg/kg/day) and 2,500 ppm (approximately 2,326 mg/kg/day) in rats in the neurotoxicity screening battery and acute toxicity studies, respectively. EPA concluded that isobutyl acetate and isobutyric acid are not expected to be neurotoxic.

Immunotoxicity studies with isobutyric acid and isobutanol are available for review. Mouse cell-mediated immune response is not modulated by isobutyric acid in a host-resistant assay using *Listeria* monocytogenes. Humoral immunity is unaffected in mice as measured by the antibody plaque-forming cell response to sheep erythrocytes. Also, a lymphocyte mitogenesis test with isobutanol showed mitogenic activity is not inhibited in stimulated B and T cells from mouse spleen. Therefore, isobutyl acetate and isobutyric acid are not expected to be immunotoxic.

Metabolism studies are not available for isobutyl acetate. Limited data are available on isobutyric acid and isobutanol. A metabolism study with a single dose of isobutyric acid via gavage in rats showed that it is rapidly metabolized and the majority eliminated as expired CO_2. Less than 1.0% of the dose is found in feces and 3.21–4.61% in urine. A metabolism study with isobutanol via gavage in rabbits showed that it is rapidly metabolized. 0.5% is excreted in the urine or exhaled air. Identified metabolites are isobutyraldehyde, isobutyric acid, and isovaleric acid. There is no concern for the metabolites isobutyraldehyde and isovaleric acid as they will be conjungated and excreted.

B. Toxicological Points of Departure/Levels of Concern

The available toxicity studies indicate that isobutanol has very low toxicity. The lowest NOAEL (316 mg/kg/day) in the database occurred in a 90-day oral toxicity study with isobutanol via gavage in rats. Hypo-activity, ataxia and salivation were seen at 1,000 mg/kg/day. In a second study conducted for 90 days with isobutanol via drinking water in rats, the aforementioned effects weren't seen at doses as high 1,450 mg/kg/day. The drinking water study in rats represents a more realistic route for human exposure to isobutyric acid and isobutyl acetate, and is considered more reflective of potential toxicity. Therefore, since no signs of toxicity were observed at doses up to the limit dose in oral and inhalation toxicity studies, an endpoint of concern for risk assessment purposes was not identified. Since no endpoint of concern was identified for the acute and chronic dietary exposure assessment and short and intermediate dermal and inhalation exposure, a quantitative risk assessment

for isobutyric acid and isobutyl acetate is not necessary.

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to isobutyl acetate and isobutyric acid, EPA considered exposure under the proposed exemption from the requirement of a tolerance. EPA assessed dietary exposures from isobutyl acetate and isobutyric acid in food as follows:

Under this exemption from the requirement of a tolerance, residues of isobutyl acetate and isobutyric acid may be found on foods from crops that were treated with pesticide formulations containing isobutyl acetate and isobutyric acid. However, a quantitative dietary exposure assessment was not conducted since a toxicological endpoint for risk assessment was not identified.

2. *Dietary exposure from drinking water.* Since a hazard endpoint of concern was not identified for the acute and chronic dietary assessment, a quantitative dietary exposure risk assessment for drinking water was not conducted, although exposures may be expected from use on food crops.

3. *From non-dietary exposure.* The term ''residential exposure'' is used in this document to refer to non-occupational, non-dietary exposure (*e.g.,* textiles (clothing and diapers), carpets, swimming pools, and hard surface disinfection on walls, floors, and tables).

Isobutyl acetate and isobutyric acid may be used in pesticide products and non-pesticide products that may be used in and around the home. Based on the discussion in Unit IV.B., a quantitative residential exposure assessment for isobutyl acetate and isobutyric acid was not conducted.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider ''available information'' concerning the cumulative effects of a particular pesticide's residues and ''other substances that have a common mechanism of toxicity.''

Based on the available data, isobutyl acetate and isobutyric acid do not have a toxic mechanism; therefore, section 408(b)(2)(D)(v) does not apply.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

As part of its qualitative assessment, the Agency did not use safety factors for assessing risk, and no additional safety factor is needed for assessing risk to infants and children. Based on an assessment of isobutyl acetate and isobutyric acid, EPA has concluded that there are no toxicological endpoints of concern for the U.S. population, including infants and children.

E. Aggregate Risks and Determination of Safety

Because no toxicological endpoints of concern were identified, EPA concludes that aggregate exposure to residues of isobutyl acetate and isobutyric acid will not pose a risk to the U.S. population, including infants and children, and that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to isobutyl acetate and isobutyric acid residues.

V. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. Response to Comments

A comment was received from a private citizen who was concerned about the safety and impact pesticides on food on human health. The Agency understands the commenter's concerns and recognizes that some individuals believe that no residue of pesticides should be allowed. However, under the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA), EPA is authorized to establish pesticide tolerances or exemptions where persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by the statute, which EPA has determined here.

VI. Conclusions

Therefore, exemptions from the requirement of a tolerance are established under 40 CFR 180.910 for residues of isobutyl acetate (CAS Reg. No. 110–19–0) and isobutyric acid (CAS Reg. No. 79–31–2) when used as inert ingredients (solvent) in pesticide formulations applied to growing crops and raw agricultural commodities after harvest.

VII. Statutory and Executive Order Reviews

This action establishes tolerance exemptions under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled ''Regulatory Planning and Review'' (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the

various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VIII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 16, 2016.

Daniel J. Rosenblatt,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.910, add alphabetically the inert ingredients to the table to read as follows:

§ 180.910 Inert ingredients used pre- and post-harvest; exemptions from the requirement of a tolerance.

Inert ingredients	Limits	Uses
* * * * * * *		
Isobutyl Acetate (CAS Reg. No. 110–19–0)		Solvent.
Isobutyric Acid (CAS Reg. No. 79–31–2)		Solvent.
* * * * * * *		

[FR Doc. 2016–31211 Filed 12–28–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 405, 410, 411, 414, 417, 422, 423, 424, 425, and 460

[CMS–1654–CN3]

RIN 0938–AS81

Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements; Corrections

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical and typographical errors that appeared in the final rule published in the November 15, 2016 **Federal Register** (81 FR 80170). That rule is entitled, ''Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements.''

DATES: This correcting document is effective January 1, 2017.

FOR FURTHER INFORMATION CONTACT: Jessica Bruton (410) 786–5991.

SUPPLEMENTARY INFORMATION:

I. Background

In FR Doc 2016–26668 (81 FR 80170 through 80562), the final rule entitled, ''Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule and Other Revisions to Part B for CY 2017; Medicare Advantage Bid Pricing Data Release; Medicare Advantage and Part D Medical Loss Ratio Data Release; Medicare Advantage Provider Network Requirements; Expansion of Medicare Diabetes Prevention Program Model; Medicare Shared Savings Program Requirements'' there were a number of technical and typographical errors that are identified and corrected in this correcting document. These corrections are effective as if they had been included in the document published November 15, 2016. Accordingly, the corrections are effective January 1, 2017.

II. Summary of Errors

A. Summary of Errors in the Preamble

On page 80252, in our discussion of certain primary care services, we made typographical errors and referenced the final HCPCS G-codes incorrectly.

On page 80268, we made a typographical error in the new locality number for Stockton-Lodi-CA.

On page 80330, due to a drafting error, we inadvertently stated that we did not receive any comments on our proposals for the Electroencephalogram (EEG) family of codes, CPT Codes 95812, 95813, and 95957.

On page 80540, we inadvertently included language in our discussion of ICRs regarding payment to organizations that provide Medicare Diabetes Prevention Program Services.

On page 80543, due to a drafting error, in our discussion of RVUs relative to 2016, we inadvertently used the result descriptors incorrectly.

On page 80543, due to typographical errors the title of Table 51 and the CY 2017 RVU Budget Neutrality Adjustment are incorrect.

B. Summary and Correction of Errors in the Addenda on the CMS Web Site

Due to a data error, the incorrect CY 2017 PE RVUs are included in Addendum B for HCPCS codes G0422