United States Department of Agriculture
Agricultural Marketing Service | National Organic Program
Document Cover Sheet
https://www.ams.usda.gov/rules-regulations/organic/petitioned-substances

Document Type:

☒ **National List Petition or Petition Update**

A petition is a request to amend the USDA National Organic Program's National List of Allowed and Prohibited Substances (National List).

Any person may submit a petition to have a substance evaluated by the National Organic Standards Board (7 CFR 205.607(a)).

Guidelines for submitting a petition are available in the NOP Handbook as NOP 3011, National List Petition Guidelines.

Petitions are posted for the public on the NOP website for Petitioned Substances.

☐ **Technical Report**

A technical report is developed in response to a petition to amend the National List. Reports are also developed to assist in the review of substances that are already on the National List.

Technical reports are completed by third-party contractors and are available to the public on the NOP website for Petitioned Substances.

Contractor names and dates completed are available in the report.

June 29, 2023

National Organic Standards Board
Crop Subcommittee
USDA-AMS-NOP 1400 Independence Ave. SW.,
Room 2648-S, Mail Stop 0268
Washington, DC 20250-0268

**Subject: Letter to NOSB Post Discussion on Potassium Sorbate During April 2023 Meeting**

Dear Ms. Amy Bruch and NOSB committee,

Thank you for your motion and consideration of potassium sorbate (KS) as an allowed input ingredient for crop disease and insect control. We also thank the public for their comments and the members of OMRI for their time and effort in providing a complete technical report (TR) on KS.

By means of this letter, we hope to provide additional information for concerns raised during the April 2023 meeting regarding the history, end-use, and health/environmental effects of KS. We also welcome dialogue with the board to further support the KS petition.

KS Pesticide Registration History

During the meeting, board member, Lewis, discussed the registration history of KS and speculated on a reason why KS is not a popular pesticide for crop protection. We conducted a review on products containing KS that were previously registered by US EPA. The US EPA pesticide product and label system rendered products registered for mold inhibiting/control on non-crop materials and food processing/packaging. All products have been cancelled since the 1980s. The information indicates that KS, as an active ingredient, does not have a history of registered use for crop protection (see Table 1: List of Sorbic acid, potassium salt products at US EPA).

KS is a FIFRA 25(b) minimal risk active ingredient. Products under this category are not monitored by US EPA. However, registration is required at the state level. Currently, there is no database available to pull information on products registered with KS as an active ingredient for the petitioned use.

To our knowledge, KS is already being used as an organic input ingredient because it is in the channel of trade as an inert ingredient in pesticide formulations for organic farming.

Table 1: List of Sorbic acid, potassium salt products at US EPA.

| Product Name | EPA Reg. No. | Registration Status |
| --- | --- | --- |
| GUARD POTASSIUM SORBATE MOLD & ROPE INHIBITOR | 5564-4 | Cancelled (OCT 10, 1989) |
| KOPPERS MOLD CONTROL CONCENTRATE 50 | NC780033 | Cancelled (SEP 13, 1983) |
| MOLD CONTROL CONCENTRATE 50 | AL800004 | Cancelled (MAR 12, 1985) |
| MOLD CONTROL CONCENTRATE 50 | MS780033 | Cancelled (APR 02, 1984) |
| POTASSIUM SORBATE | 10442-3 | Cancelled (JUL 01, 1987) |
| POTASSIUM SORBATE FCC | 7085-35 | Cancelled (SEP 02, 1986) |
| POTASSIUM SORBATE FOOD GRADE | 10571-4 | Cancelled (NOV 23, 1985) |
| SENTRY POTASSIUM SORBATE (FOOD CHEMICALS CODEX GRADE) | 10352-3 | Cancelled (JUL 19, 1980) |
| SOILSERV PARATHION-SORBIC GRANULAR | 6973-4608 | Cancelled (JUL 20, 1987) |
| SORBISTAT-K | 1007-73 | Cancelled (DEC 31, 1987) |
| SUPREME SPOREX-K POTASSIUM SORBATE | 9942-4 | Cancelled (OCT 31, 1986) |
| TANOWER POTASSIUM SORBATE | 10829-2 | Cancelled (JUL 01, 1987) |
| TANOWER POTASSIUM SORBATE GRANULES | 10829-1 | Cancelled (JUL 01, 1987) |

<u>End-Use of KS</u>

Interest in control of insects such as spider mite was discussed during the April meeting. KS is a known inhibitor of mold and fungus. The success of our KS end-use product, OR-159-B, as a fungicide is dependent on the pH of the spray solution being between 4.5 to 5. Foliar application with a contact mode of action (MOA) on disease is the primary use. The limited exploratory insect trials conducted by Oro Agri show that the use of KS will suppress whiteflies (study provided in petition). Insect suppression may be selective and variable due to a possible indirect MOA. Literature reveals sufficient evidence that the nutritional value of potassium may affect the plant's ability to resist pest attacks. The observed suppression may be indirect via induced plant health as a result of the bio-available potassium supplied by KS.[1,2,3,4] Further such evidence was observed by Oro Agri through improved color development, from supplied potassium, in table grapes where a powdery mildew trial was conducted (Enclosure A). We do not recommend the use of KS on other insects pending further research, which has not been a focus area in the development of our product but definitely planned.

Members of NOSB were interested in additional efficacy data for various other crop diseases. Along with this letter we enclose additional studies conducted on botrytis/powdery mildew on grapes and late blight/early blight on potatoes (Enclosure B, C). In summary, KS is comparable to conventional and organic certified active ingredients. No phytotoxicity was observed for the KS treated crops. KS is effective and can be used in resistance management programs in rotation with residual fungicides. It would be an additional tool for organic farmers and enable them to reduce dependency on other organically approved substances like copper and sulfur. Copper is known to be highly persistent in the environment, while sulfur is used at very high levels in certain crops with associated impact on the environment, applicators, and phytotoxic effects in certain crops and conditions. Compared with sulfur, KS has a broader spectrum of activity and control that is not only effective on powdery mildew, but also such diseases as downy mildew, Phomopsis, botrytis, early blight, and late blight.

Health and Environmental Concerns

Due to the regulatory status and extensive regulatory review of KS to date, we have reason to believe that little to no research will be conducted by the industry to add to the health and environmental data already available for KS. As provided in the TR, KS is an ingredient reviewed by US regulatory bodies and considered safe for commercial use. It is GRAS by FDA and present on US EPA's categorized lists as low toxicity. Although the EPA categorized lists are no longer being updated, EPA continues to monitor KS as a preservative/antioxidant on the Safer Chemical Ingredients List (SCIL) under the Safer Choice program meeting EPA's safer product standards. Ingredients in this program undergo a strict expert review including carcinogenicity, mutagenicity, and environmental toxicity and fate (Enclosure D). In the Safer Choice program, KS is a "green circle" ingredient, verified as low concern based on the data reviewed.

The TR and discussion heavily revolved around the health and environmental concerns of KS and/or sorbic acid. Unfortunately, as you are aware, little information is available in this area to confirm the effects of each item listed in the TR. Regarding persistence in the environment, TR Q4 provides that KS is readily metabolized by microorganisms in the soil, and microorganisms can degrade sorbic acid. Additionally, the petitioned use of KS is labeled for foliar application, with no requirement of tolerance. Little interaction with the soil is expected. Sorbic acid and its salts are very low in ecotoxicity and not persistent in the environment. Our product applied typically at 0.5 to 1 gallon per acre with the KS content of 45% mainly directed at foliar coverage would not likely have a significant effect on soil pH. Furthermore, the directions for application are very specific to maintain a pH of 4.5-5 in the spray solution, hence should any part of the spray solution reach the soil surface, it is unlikely to cause an increase in general soil pH profile.

For the above reasons and data presented in the TR, we conclude that there will be little to no concern when using KS as a foliar crop protection product. KS will provide an excellent alternative for organic growers to reduce their reliance on some existing substances like copper and sulfur. It will help manage resistance to diseases when used in rotation or in tank-mixture with more selective and/or systemic fungicides.

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We kindly ask the above information is considered to further the decision of the KS petition. Oro Agri is open to discussion with NOSB about KS potential and efficacy for crop disease control and insect suppression.

Feel free to contact me directly if you have any questions.

Sincerely,

Mai Yarbrough
Oro Agri, Inc
Regulatory Affairs Manager
mai.yarbrough@oroagri.rovensa.com
(559)442-4996

*Enclosures:*

A) *Grape PM color improvement OR-159-B.pdf*
B) *Grapes Botrytis_PM OR-159-B.pdf*
C) *Late-Early Blight OR-159-B.pdf*
D) *EPA Safer Choice Criteria.pdf*

*References:*

1) *Kiran Bala, AK Sood, Vinay Singh Pathania and Sudeshna Thakur. Effect of plant nutrition in insect pest management: A review. J Pharmacogn Phytochem 2018;7(4):2737-2742.*

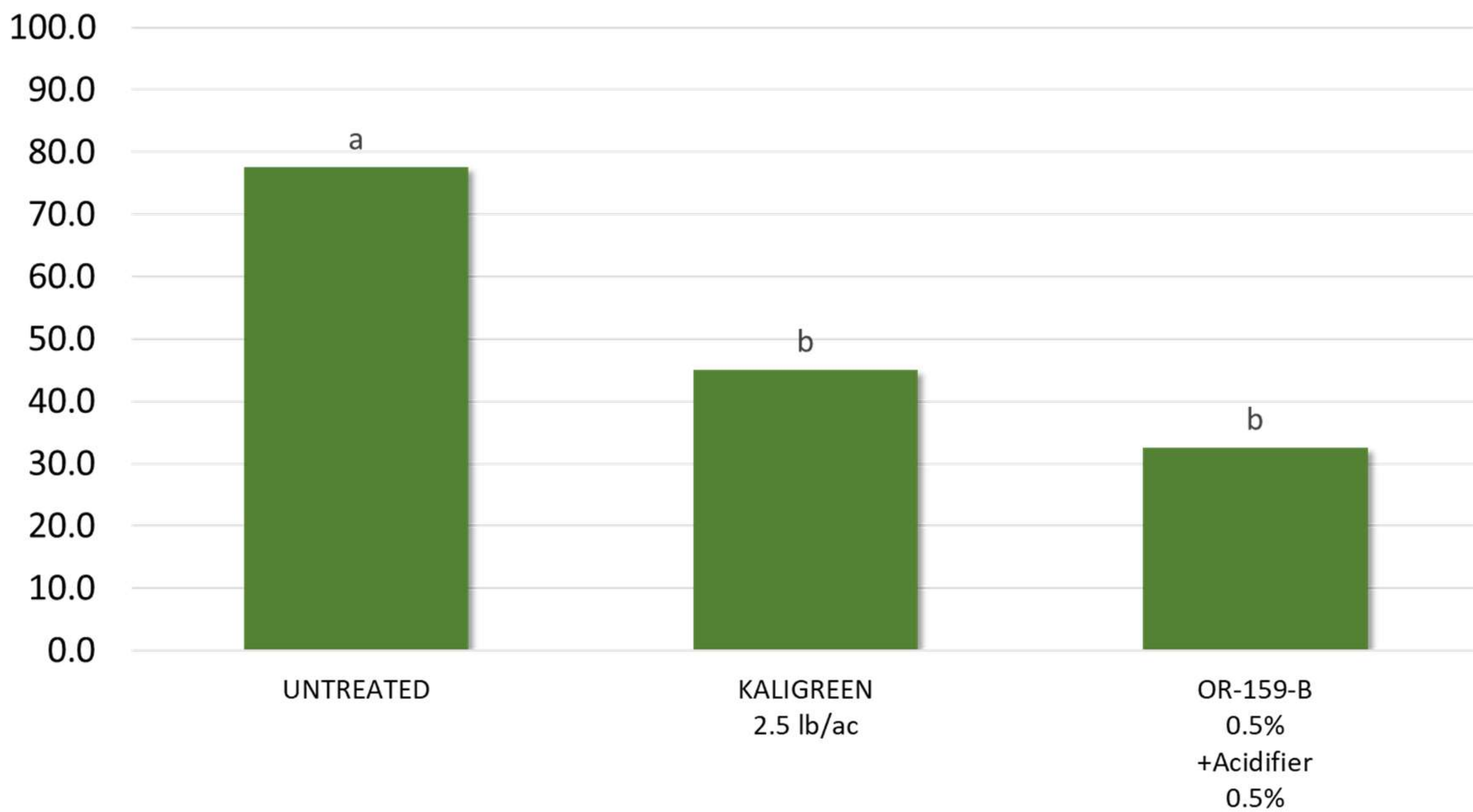
2) *Lemons, J. (2022). Potassium nitrate: Boosts tolerance to pests and diseases. Retrieved from* *https://sqmnutrition.com/en/essays/potassium-nitrate-improves-plant-resistance-to-pests-and-diseases/*

3) *PDA Potash News. (2020). Potassium and Pest Pressure.* *https://www.pda.org.uk/wp/wp-content/uploads/2020/10/potassium-and-pest-pressure-pda-newsletter-oct-2020.pdf*

4) *Amtmann, A., Troufflard, S., & Armengaud, P. (2008). The effect of potassium nutrition on pest and disease resistance in plants. Physiologia Plantarum (København. 1948), 133(4), 682–691.* *https://doi.org/10.1111/j.1399-3054.2008.01075.x*

# Control of powdery mildew on table grapes

## Infection incidence on leaves (% leaves with infection) after 4 sprays




- OR-159-B + Acidifier significantly reduced disease incidence on leaves
- OR-159B + Acidifier slightly better than the standard product KALIGREEN
- NO phyto on leaves or bunches

Bars with same letter not significantly different (n=4, LSD, *p*<0.1)

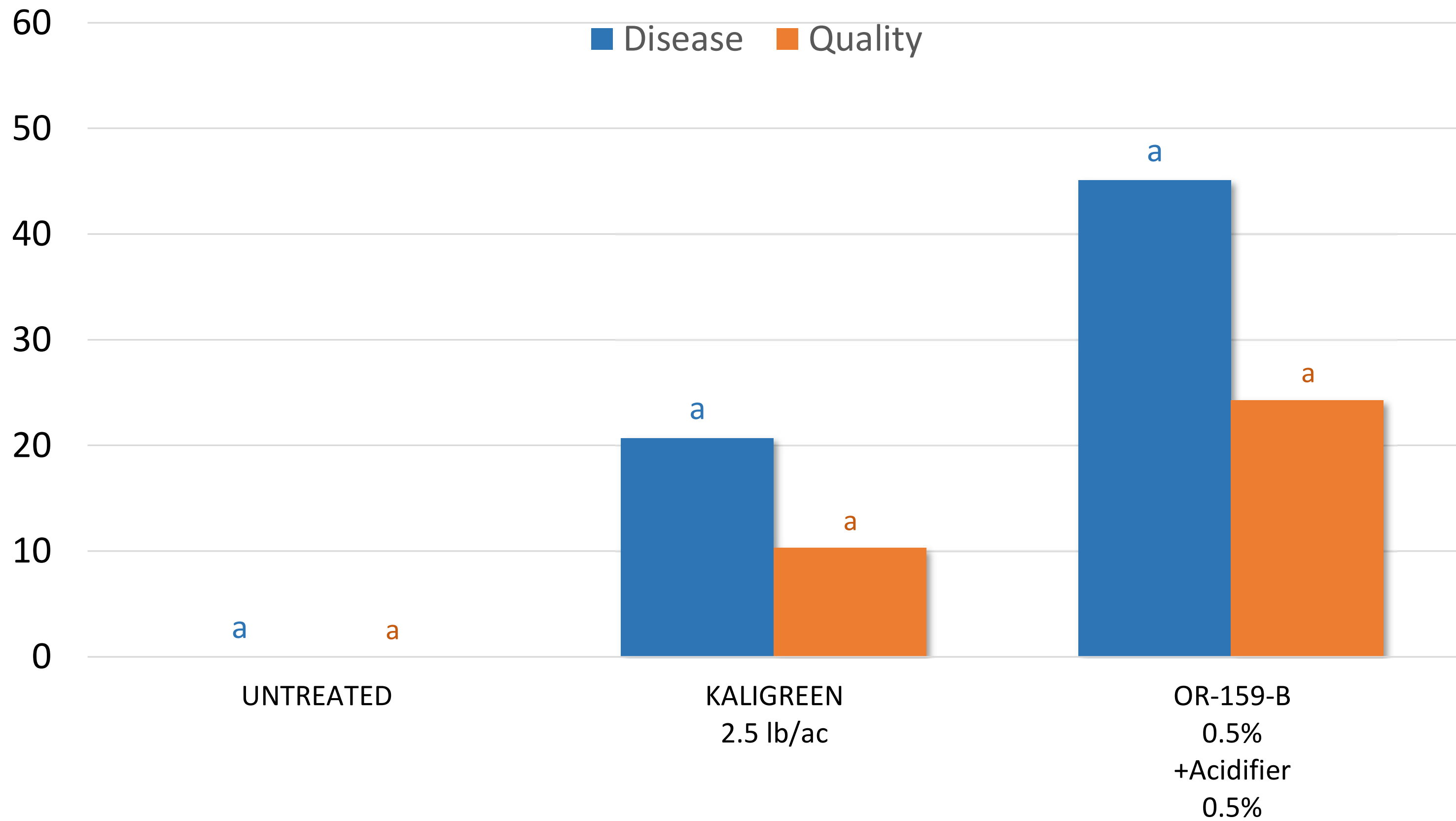
Foliar Application:
5 sprays at 14-18 day intervals (Apr 23 – June 23)
Volume: 100 gal/ac 940 Lt/ha)

Variety: Crimson

US VITVI F 210323

# Control of powdery mildew on table grapes

**% improvement in disease severity (36 DA-E) and bunch quality over untreated* at harvest**




- * Fruit quality as affected by berry rot and color
- Best treatment = OR-159-B + Acidifier 1:1
- NO phyto on bunches

Bars with same letter not significantly different (n=4, LSD, *p*<0.1)

Foliar Application:
5 sprays at 14-18 day intervals (Apr 23 – June 23)
Volume: 100 gal/ac 940 Lt/ha)

Variety: Crimson

US VITVI F 210323

## Control of powdery mildew on grapes

### Pictures taken at harvest

Improved color development

Untreated

Kaligreen 2.5 lbs

OR-159-B 0.5% + Acidifier 0.5%

All rates per 100 gal.

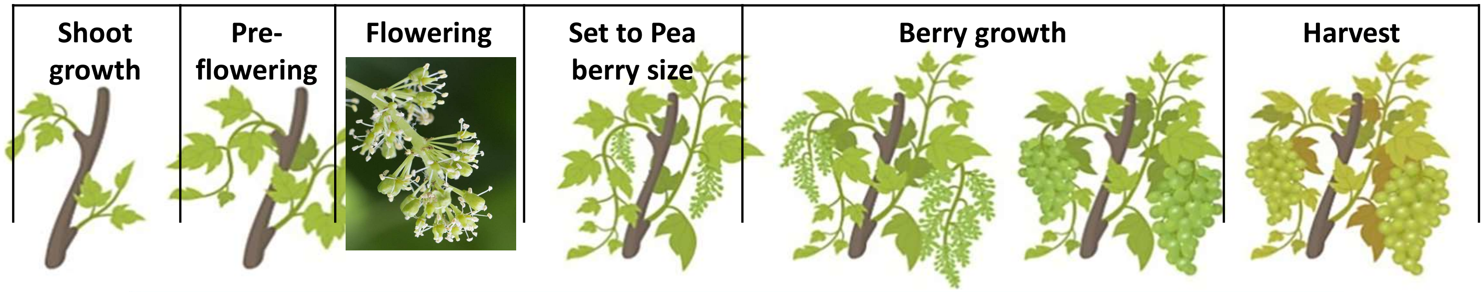
5 foliar sprays: April 23, May 7 and 24, June 7 and 23.
Water Volume: 100 gal/ac (~935 Lt/ha)

Grape variety: Crimson
Vine age: 15 years

US VITVI F 230323

# Grapes – Disease control

## 2021 Treatment program




11 Sprays started at 6 in shoot length then 7-9 day spray intervals

| Spray dates: | Jun 6 | Jun 15 | Jun 22 | Jun 29 | Jul 7 | Jul 14 | Jul 20 | Jul 27 | Aug 3 | Aug 10 | Aug 17 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Standard program: | Manzate Max (mancozeb) 0.56 gal | | Abound (azoxystrobin) 15.5 fl oz | | Pristine (Boscalid +Pyraclostrobin) 23 oz | | Vanguard (cyprodinil) 10 oz | Pristine (Bosclaid +Pyraclostrobin) 23 oz | | | Vanguard 10 oz (cyprodinil) Switch 14 oz (cyprodinil+Fludioxinil) Nufilm |

**Evaluations**

Sep 6 Botrytis

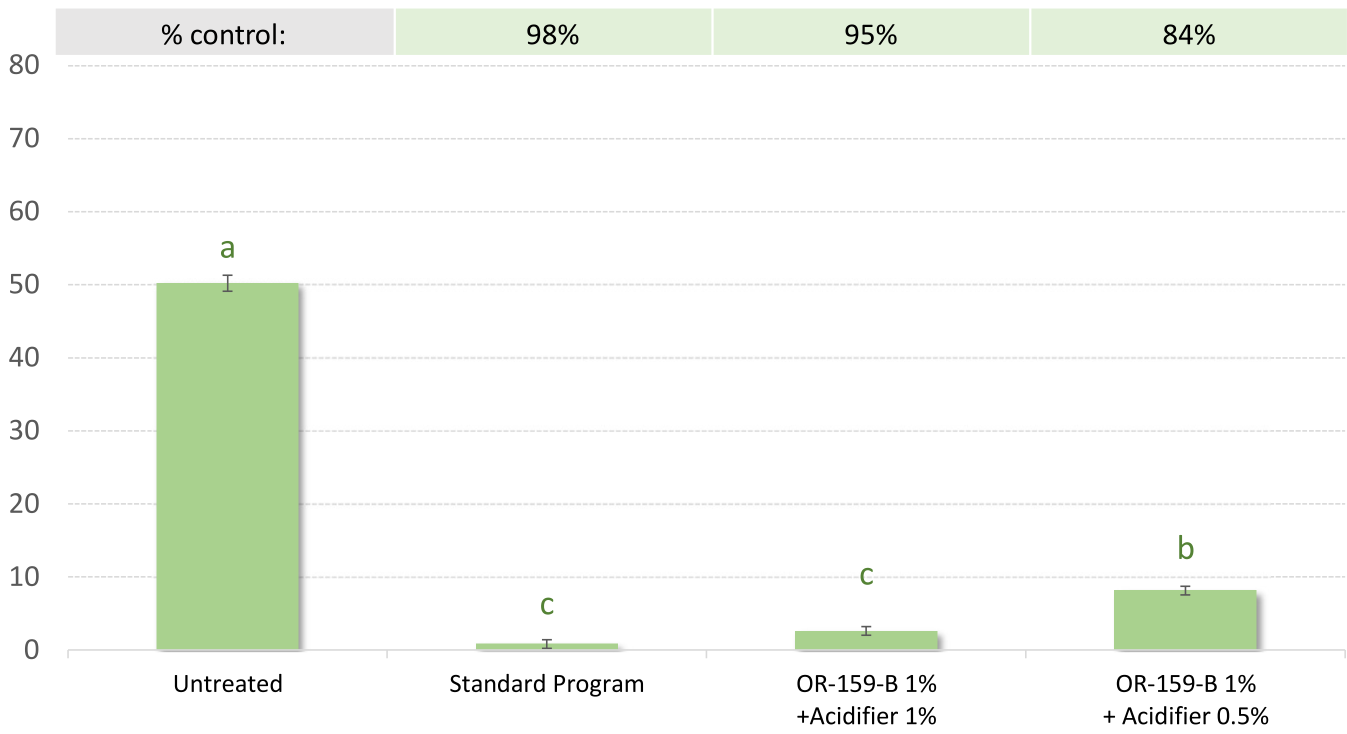
Sep 13 Powdery Mildew

Incidence: % leaves or clusters infected
Severity: % area infected on diseased samples only
Disease index = Incidence x Severity/100

US VITVI F 210320

# Control of Botrytis on Foch grapes

## Disease index clusters (0-100) after 11 sprays




- All treatments significantly reduced infection
- OR-159-B 1% + Acidifier = STANDARD PROGRAM
- NO phyto on leaves or clusters

Disease Index = Incidence x Severity/100
Bars with same letter not significantly different (n=4, $p$<0.05)

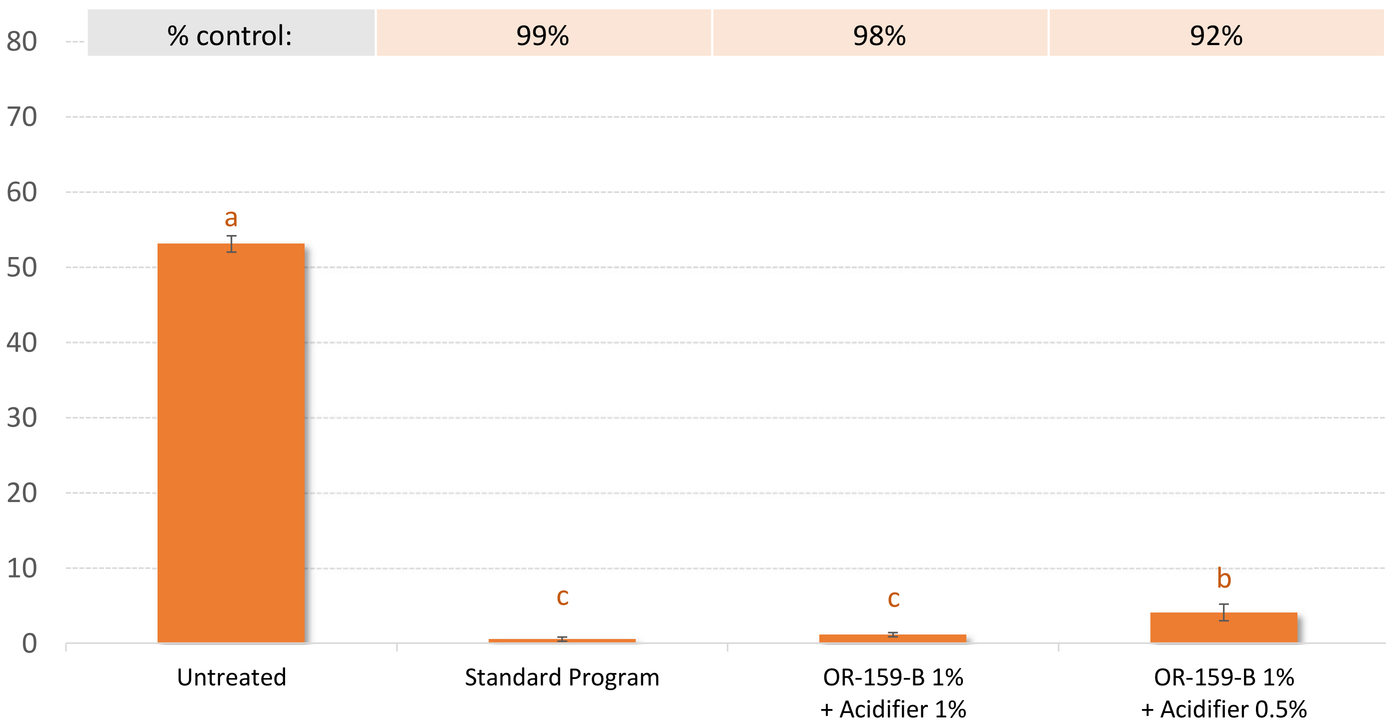
Foliar Application: 11 sprays at 7-10 day intervals (June 6– August 17)
Volume: 50 gal/AC

Variety: Marechal Foch

US VITVI F 210320

# Control of Powdery mildew on Foch grapes

## Disease index on leaves (0-100) after 11 sprays




- All treatments significantly reduced infection
- OR-159-B 1% + Acidifier = STANDARD PROGRAM
- NO phyto on leaves or clusters

Disease Index = Incidence x Severity/100
Bars with same letter not significantly different (n=4, $p$<0.05)

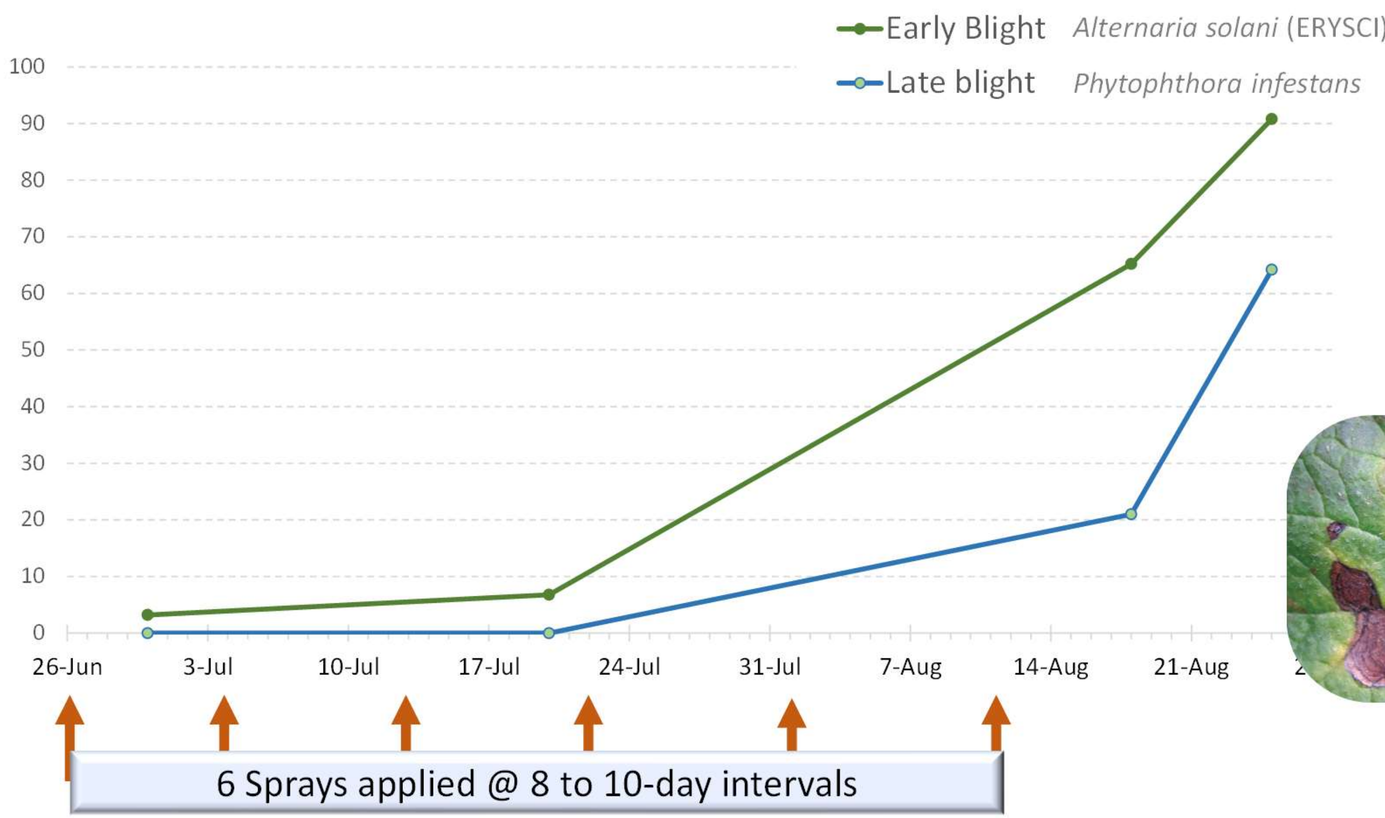
Foliar Application: 11 sprays at 7-10 day intervals (June 6– August 17)
Volume: 50 gal/AC

Variety: Marechal Foch

US VITVI F 210320

# Development of foliar diseases on Potatoes

## % plants infected (Incidence) on UNTREATED plots




- Preventative program
- Early blight symptoms appearing after 1 spray
- Late blight symptoms appearing after spray 4
- Infection by both diseases increased sharply after the last spray

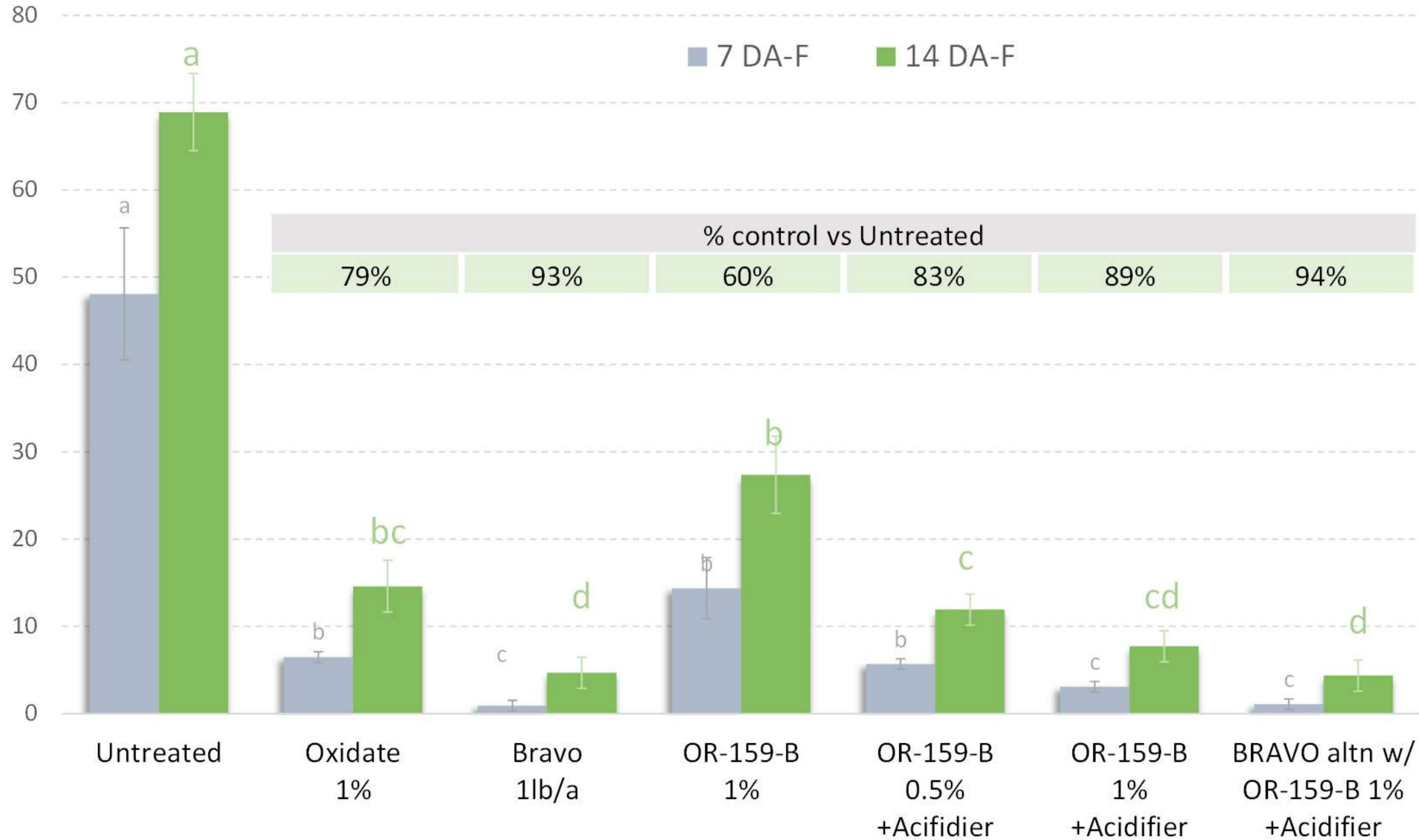
Application vol: 40 gal/a (370 L/ha)
6 Applications starting about 4 weeks after emergence with 8 to 10-day intervals

Variety: Russet Burbank
Plant: April 26, Emerge: June 1,
Tuber initiation: June 20
Defoliation Sept 05, Harvest Oct 14

US SOLTU F 200320

# Control of Early Blight in Potatoes

## % overall infection* at 7 and 14 days after application 6




- OR-159-B 1% + Acidifier = Bravo
- OR-159-B 0.5% + Acidifier = Oxidate
- OR-159-B can be used in a resistance management program with residual fungicides such as Bravo

*Overall infection = Incidence x severity/100
Oxidate: Hydrogen peroxide 27% + peroxy-acetic acid 2% (OIM)
Bravo Weatherstick: chlorothalonil 54% SC (Conventional)
Error bars: Std error (n=5, p<0.10)

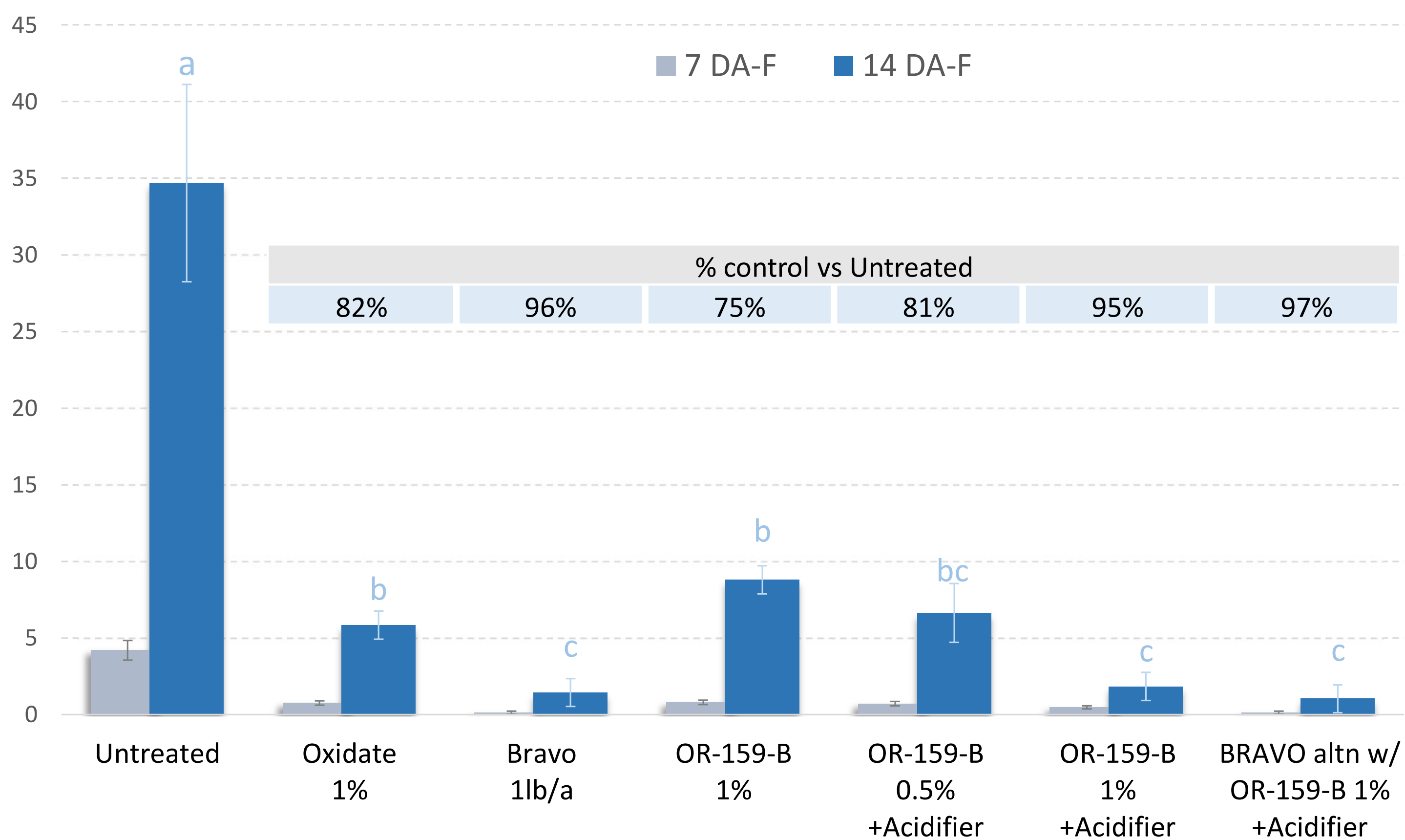
Application vol: 40 gal/a (370 L/ha)
6 Applications starting about 4 weeks after emergence with 8 to 10-day intervals
Acidifier applied at same rate as OR-159-B

Variety: Russet Burbank
Plant: April 26, Emerge: June 1,
Tuber initiation: June 20
Defoliation Sept 05, Harvest Oct 14

US SOLTU F 200320

# Control of Late Blight in Potatoes

## % overall infection* at 7 and 14 days after application 6




- OR-159-B 1% + Acidifier = Bravo
- OR-159-B 0.5% + Acidifier = Oxidate
- OR-159-B can be used in a resistance management program with residual fungicides such as Bravo

*Overall infection = Incidence x severity/100
Oxidate: Hydrogen peroxide 27% + peroxy-acetic acid 2% (OIM)
Bravo Weatherstick: chlorothalonil 54% SC (Conventional)
Error bars: Std error (n=5, p<0.10)

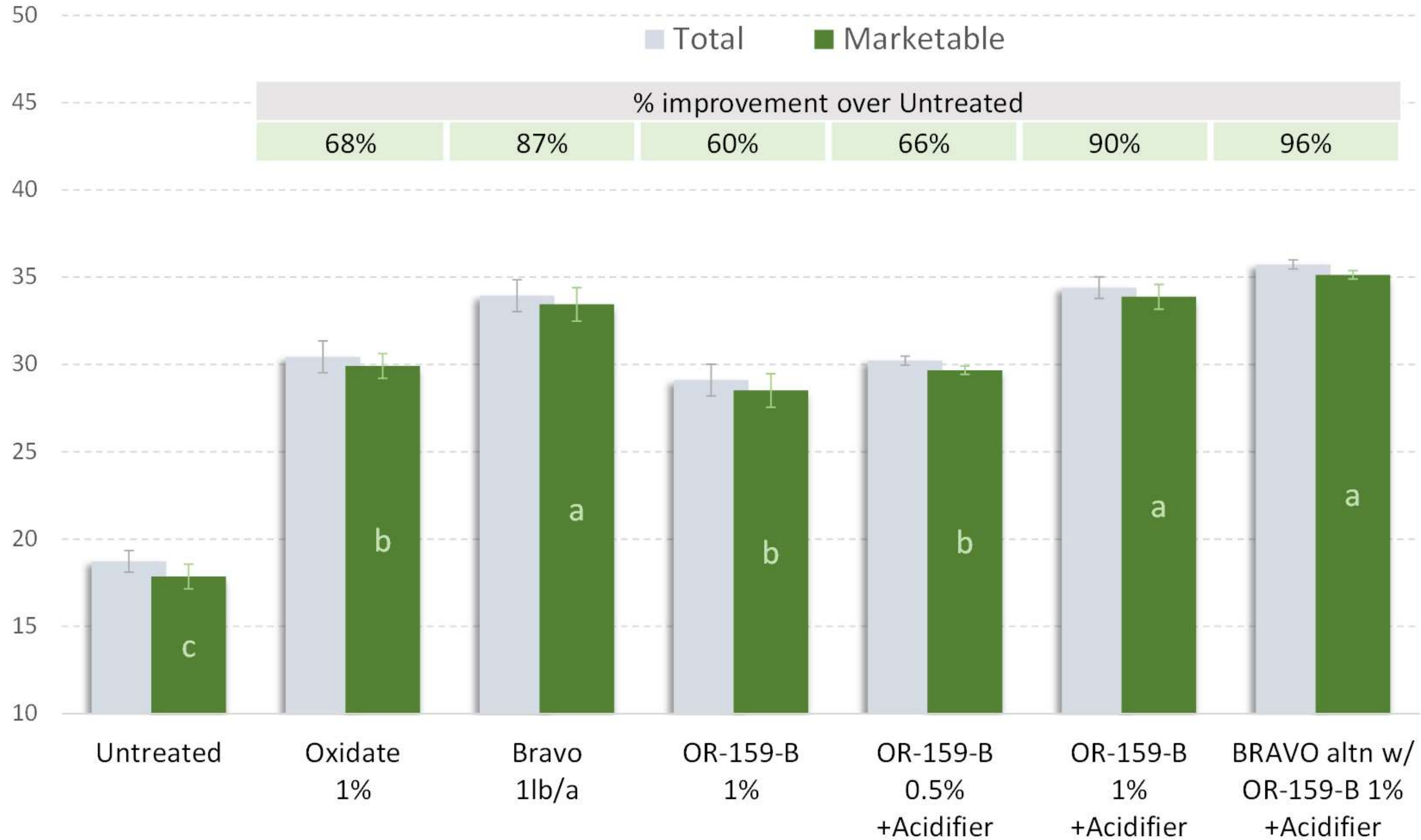
Application vol: 40 gal/a (370 L/ha)
6 Applications starting about 4 weeks after emergence with 8 to 10-day intervals
Acidifier applied at same rate as OR-159-B

Variety: Russet Burbank
Plant: April 26, Emerge: June 1,
Tuber initiation: June 20
Defoliation Sept 05, Harvest Oct 14

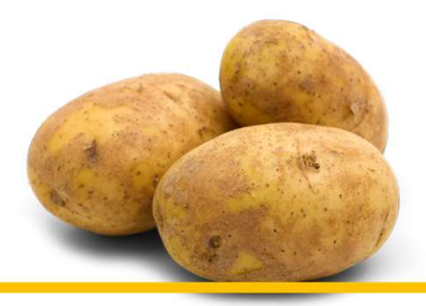
US SOLTU F 200320

# Yield of potatoes following control of foliar diseases

## Total yield and Marketable yield (t/acre)




- All treatments significantly improved marketable yield
- Marketability improved from 95% in Untreated to ~98% in all treatments
- OR-159-B 1% + Acidifier = Bravo
- OR-159-B can be used in a resistance management program with residual fungicides such as Bravo



*Overall infection = Incidence x severity/100
Oxidate: Hydrogen peroxide 27% + peroxy-acetic acid 2% (OIM)
Bravo Weatherstick: chlorothalonil 54% SC (Conventional)
Error bars: Std error (n=5, p<0.10)

Application vol: 40 gal/a (370 L/ha)
6 Applications starting about 4 weeks after emergence with 8 to 10-day intervals
Acidifier applied at same rate as OR-159-B

Variety: Russet Burbank
Plant: April 26, Emerge: June 1,
Tuber initiation: June 20
Defoliation Sept 05, Harvest Oct 14

US SOLTU F 200320

## EPA's Safer Choice Criteria for Colorants, Polymers, Preservatives, and Related Chemicals

The Safer Choice approach to product review and labeling focuses on identifying the safest possible chemical ingredients, within a functional class context, that are necessary for a product to perform well. The general requirements in the *Safer Choice Master Criteria for Safer Chemical Ingredients* serve as the reference set of benchmarks on which Safer Choice bases its chemical ingredient-specific criteria. The criteria also constitute a baseline set of toxicity parameters, with functionality-driven tailoring, that all ingredients without component- specific criteria must address to be considered for use in Safer Choice products.

While EPA has used the stringent and comprehensive elements of the Master Criteria to evaluate ingredient classes, its experience in implementing the Safer Choice Program has demonstrated that most functional classes require a tailored approach. For example, colorants, polymers, and certain preservatives have as part of their functionality the ability to resist degradation. They also typically lack a complete set of measured toxicity data, for which Safer Choice substitutes data based on predictive models, estimation techniques, and expert judgment. EPA has therefore adapted its criteria for colorants, polymers, preservatives, and related chemicals (e.g., defoamers) to accommodate specific functional-class characteristics, like persistence, permitting the listing of the safest chemicals in those classes.

Although modifying the Master Criteria to some extent, the provisions serve largely to clarify, elaborate on, and make more transparent the technical considerations involved in evaluating chemicals in the functional classes without tailored criteria. The approach Safer Choice has adopted retains the human health safety thresholds from the Master Criteria, but allows flexibility in environmental toxicity and fate endpoints, as appropriate to chemicals that persist as part of their functionality. To address the lack of data common to many of these chemicals, Safer Choice relies on a mix of estimated, measured and authoritative list-based data elements. (Please note that any modifications to the component-class criteria will not alter the prohibition on the use of listed carcinogens, mutagens or reproductive or developmental toxicants, or persistent, bioaccumulative and toxic chemicals in Safer Choice products.)

**Colorants, Polymers, Preservatives, and Related Chemicals** (extract from the Safer Choice Standard, section 5.8)

Colorants (including pigments and optical brighteners), polymers, and certain preservatives (including antioxidants) (and other chemicals referenced in section 5.14) include as part of their functionality the ability to resist degradation and be effective over long periods. They also can be complex molecules and mixtures and often lack measured toxicity data. To identify the safest available chemicals in each class given their functional characteristics, the toxicity thresholds in the Master Criteria will be used to evaluate human health endpoints, and the thresholds in section 5.8.3 will be used for environmental endpoints. Data on these chemicals will be required as per 5.8.3, unless noted otherwise.

### 5.1 Polymers

To be acceptable for labeled products, polymers must have low-concern characteristics.[1] Also, the requirements of this section apply to the low molecular weight components of polymers (typically less than 1,000 daltons). Safer Choice encourages the use of degradable polymers whenever possible; only those that do not degrade into CMRs or PBTs will be allowed.

Special conditions for certain categories of polymer: In addition to the requirements in 5.8.3, polymers that are respirable or water-absorbing must be in solution. Anionic polymers used as chelating agents must meet the requirements in the Safer Choice Criteria for Chelating Agents, except section 5.9, Environmental Toxicity and Fate, which must be addressed as per 5.8.3. Perfluoroalkyl polymers, allowed only in floor finishes, must, at a minimum, be limited to fluorinated carbon-chain lengths of less than eight atoms.

### 5.2 Preservatives

Preservatives have biocidal properties and time-sensitive functionality. Safer Choice will allow use only at the lowest effective level. In addition to the CMR and PBT prohibitions in 5.2, preservatives that release CMRs or PBTs or whose reaction byproducts are CMRs or PBTs will not be allowed.

### 5.8.3 Special requirements

For colorants, polymers, and preservatives, the toxicological endpoints in the Master Criteria will be addressed as follows:

1) *For Acute Mammalian Toxicity (section 5.1 of the Master Criteria), Neurotoxicity (5.4), Repeated Dose Toxicity (5.5), and Skin Sensitization (5.8), the following apply*:

   Data requirements: Screen Authoritative Lists. Chemicals with new measured data not yet reviewed by authoritative bodies may be subject to review.
2) *For Carcinogenicity (section 5.2 of the Master Criteria), Genetic Toxicity (5.3),*

[1] Described in the Sustainable Futures' Interpretive Assistance Document for Assessment of Polymers (http://www.epa.gov/oppt/sf/pubs/iad_polymers_june2013.pdf).

*and Reproductive and Developmental Toxicity (5.6), and Respiratory Sensitization (5.7), the following apply:*

Data requirements: Screen specified R-Phrases and Authoritative Lists. Available data, measured and/or estimated, for the chemical and/or a suitable analog may be reviewed against the criteria using a weight-of-evidence approach.

3) *Environmental Toxicity and Fate*

Limitation on Persistent, Bioaccumulative and Toxic chemicals: Acceptable chemicals must not be persistent (half-life ≥ 60 days), bioaccumulative (BCF/BAF ≥ 1,000), and aquatically toxic* (LC/EC50 ≤ 10 mg/L or NOEC/LOEC ≤ 1 mg/L).

Limitation on very Persistent and very Bioaccumulative chemicals: Acceptable chemicals must not be very persistent (half-life > 180 days or recalcitrant) and very bioaccumulative (> 5,000).

Limitation on very Persistent and very Toxic chemicals: Acceptable chemicals must not be very persistent (half-life > 180 days or recalcitrant) and very aquatically toxic* (LC/EC50 < 1.0 mg/L or NOEC/LOEC < 0.1 mg/L).

Data requirements: Screen Authoritative Lists. Available data, measured and/or estimated, for the chemical and/or a suitable analog may be reviewed against the criteria using a weight-of-evidence approach.

*Excludes the algal shading effects of colorants.