ProcellaCOR® Herbicide Product Summary and Use Restrictions

This document is a review of the aquatic herbicide ProcellaCOR® (EPA Reg. No. 67690-80); (SEPRO, 2019). It contains product-specific information related to use characterization, as well as toxicity, of the product to human health and non-target organisms. This document complements the review of the active ingredient florpyrauxifen-benzyl and the ProcellaCOR aquatic modeling and benthic organisms risk assessment conducted by MDAR/MassDEP (MDAR/MassDEP 2019).

1. Product Formulation

The product label indicates that ProcellaCOR herbicide is a liquid formulation containing florpyrauxifen-benzyl at a concentration of 2.7% by mass, which corresponds to 0.21 lb of active ingredient per gallon of product (SEPRO, 2019).

The identity of the other ingredients (also referred to as inert ingredients) in ProcellaCOR herbicide is proprietary; therefore, the manufacturer does not identify the other ingredients on the product label or safety data sheet (SDS). EPA requires submission of the other ingredients and reviews them to ensure compliance with regulations (40 CFR 158.630). EPA requires labels of pesticide products to identify any inert ingredient that it has determined is of "toxicological concern." The ProcellaCOR label does not identify inert ingredients of toxicological concern. Foliar applications require the use of a spray adjuvant that is appropriate for aquatic sites.

2. Use Characterization

2.1 Use Sites

The product label for ProcellaCOR EC herbicide specifies that this product may be applied for management of freshwater aquatic vegetation in slow-moving or quiescent waters with little or no outflow. These include ponds, lakes, reservoirs, freshwater marches, wetlands, drainage ditches, non-irrigation canals, and shoreline and riparian areas in or adjacent to these sites. ProcellaCOR is herbicidally active on many submerged, emergent, and floating aquatic plants. The product may be applied directly to the water for control of submerged aquatic vegetation or as a foliar spray for control of emergent and floating vegetation.

2.2 Application Methods

Aquatic applications of ProcellaCOR are made as a liquid. In-water applications can be made by using undiluted product or diluted with water. ProcellaCOR may be broadcast applied to the water surface or injected below the water surface as undiluted product or diluted with water. Foliar application to floating or emergent vegetation in water bodies or shoreline and riparian areas may be made by directed application techniques or may be broadcast applied by using ground equipment or water craft. The label also includes instruction for application by aircraft.

2.3 Use Rates

The label use rate instructions are based on Prescription Dose Units (PDU). The use of PDU is intended to facilitate the calculation of the amount of product required in 1 acre-foot of water. A PDU corresponds to 0.0052 lb active ingredient or 3.17 fl oz of product.

- Subsurface rates range from 1-25 PDUs per 1 acre-foot of water, depending on the target species and percent area of waterbody treated. The product label provides information on the amount of product required per surface acre and water depth to achieve the desired water concentration. The maximum use rate of 25 PDUs per acre-foot of water volume corresponds to an active ingredient concentration of 50 ppb[1]. Up to three applications may be made per year, with at least 14 days between applications

- Foliar broadcast application use rates are 5.0 to 10.0 PDU per acre per application. Foliar applications may be made more than once per season. The maximum total from all combined applications is limited to 20 PDU per acre per year. Foliar spray also requires the addition of an adjuvant.

- Foliar spot application: 5.0 to 10.0 PDU per 100 gallons (0.12 to 0.24% product) plus adjuvant.

- Effective label rates for certain specific weeds are much lower than the maximum application rate. For example, the label rate for watermilfoils is up to 5 PDU. Aquatic weed control specialists have indicated that watermilfoil is a major target species for weed control in Massachusetts. In addition, it was indicated that repeat applications are not expected to be used in Massachusetts (Solitude, personal communication, 2019).

2.4 Target Species

ProcellaCOR will control various submerged, floating and emerged weed species. It is effective against aquatic problem species such as Eurasian and Variable watermilfoil, hydrilla, alligator weed, parrot feather, water hyacinth, water primrose and pond weed. A complete list of weeds controlled can be found on the product label (SEPRO, 2019).

3. Human Health Effects of the Product Formulation

As part of the pesticide product registration, EPA requires information on the toxicity of the product formulation to assess hazards to humans and domestic animals. Acute toxicity data inform the label statements to provide the pesticide user with information regarding the toxicity, irritation, and dermal sensitization hazards associated with the use of the pesticide product. The label also includes information on medical treatment and measures to reduce the potential for exposure. A series of statements and warnings, including the signal word[2], a child hazard warning, a statement on the hazard to humans and domestic animals, and a first aid statement, as well as information on personal protective equipment (PPE) is also included.

The signal word 'Caution" and precautionary statement on the ProcellaCOR EC product label [3] are based on the moderate eye irritation hazard. The precautionary statement informs the user to avoid contact with eyes or clothing, and wash with soap and water after handling the product. Personal protection equipment requirements include long-sleeved shirt and pants, shoes plus

[1] The unit ppb is used throughout this document and is equivalent to µg/L or µg/kg.
[2] The signal word describes the acute toxicity of the formulated pesticide product and is determined by the most severe toxicity category assigned to the five acute toxicity studies and can be either: Danger, Warning or Caution.
[3] ProcellaCOR product labels and SDS available at SEPRO website: https://www.sepro.com/aquatics/procellacor

socks, protective eyewear, and waterproof gloves. The first aid statement provides information to mitigate effects in the event of eye exposure to the product.

MDAR has reviewed the summary document of toxicological studies, exposure data and information for the product formulation (Breaux, 2015). That document indicates that the ProcellaCOR EC formulation exhibited very low acute mammalian toxicity via oral and dermal routes. No mortality was observed following oral and dermal treatment of rats with 5000 mg product/kg body weight. The acute oral and dermal LD_{50} was >5000 mg/kg and classified in the lowest toxicity category (Category IV)[4].

A 4-hour inhalation study with rats indicated very low toxicity (Category IV) with an LC_{50} of >5.4 mg/L. Mild or slight eye irritation was observed in a study with rabbits and cleared by 72 hours (Category III). There was no evidence of any potential for skin irritation or skin sensitization in studies with rabbits and guinea pigs, respectively. Subchronic and chronic testing with the formulated product was not required based on criteria specified in federal regulations (40 CFR 158.500)[5].

Comparison of the acute toxicity information for the active ingredient (see Review of Florpyrauxifen-benzyl for Application to Massachusetts Lakes and Ponds, MDAR/MassDEP, 2019) to the acute toxicity information for the ProcellaCOR EC formulation indicates that there are no substantial differences in acute toxicity effects.

The Safety Data Sheet[6] provides information, primarily intended for handlers and users as well as first-responders, and includes information on the composition, properties, and toxicity and hazards of the product. The product is not hazardous under the criteria of the Federal OSHA hazard communication standard.

4. Ecological Effect Studies with Product Formulations

Data for the product formulation provide information about the overall toxicity from exposure to the mixture of active ingredient and other or 'inert' formulation ingredients. Exposure to the product formulation mixture is relevant for an acute exposure scenario. The formulated mixture does not persist beyond the acute exposure time window as dispersion, dilution and degradation processes take place. Consequently, federal regulations require acute toxicity studies for both the technical grade active ingredient (TGAI) and the formulated end product (40 CFR § 158.630)[7]. Chronic studies with the formulated product are not required.

Toxicity data for two product formulations considered for aquatic use were included in EPA's ecological risk assessment document (USEPA, 2017). ProcellaCOR EC (2.7% a.i.) is currently registered by EPA, while ProcellaCOR SC (26.8% a.i.) was evaluated but not registered. The

[4] Federal regulations (40 CFR 156.62)[4] specify the criteria for the acute toxicity categories for pesticide products, ranging from Category I (most toxic) to Category IV (least toxic).
[5] 40 CFR § 156.62 - Toxicology data requirements table. Accessed at: https://www.govinfo.gov/app/details/CFR-2012-title40-vol25/CFR-2012-title40-vol25-sec158-500
[6] ProcellaCOR product labels and SDS available at SEPRO website: https://www.sepro.com/aquatics/procellacor
[7] 40 CFR § 158.630 - Terrestrial and aquatic non-target organisms data requirements table. Accessed at: https://www.law.cornell.edu/cfr/text/40/158.630

toxicity data for both formulations will be considered here, even though the EC formulation is the product that is registered in MA at this time. The inclusion of the SC formulation data complements the EC formulation data set.

EPA notes that the active ingredient application of formulated products to water is not solubility limited as is the case with TGAI (see also active ingredient review, MDAR/MassDEP, 2019). The solubility of the active ingredient increases when it is part of the formulated product. The toxicity studies with the formulated products thereby provided data for higher active ingredient concentrations that complement the toxicity data for the TGAI.

Fish studies: In the study with the EC formulation on common carp no mortalities were observed and non-definitive LC_{50} of >3.2 mg a.i. equivalent/L and NOAEC of 3.2 mg a.i./L. Sub-lethal effects (surfacing and/or lethargy) were observed in all fish in the 3.2 mg a.i./L group throughout the study.

Testing of the SC formulation on common carp showed no mortalities and established a LC_{50} > 0.59 mg a.i. equivalent/L and NOAEC of >0.526 mg a.i./L. Sub-lethal effects (lethargy, difficulty maintaining equilibrium) were observed in the 0.222 mg a.i./L & 0.526 mg a.i./L groups.

Aquatic invertebrates: The EC formulation is moderately toxic to water flea with an EC_{50} of 1.32 mg a.i. equivalent/L. No treatment-related effects were observed at or below the 0.700 mg a.i./L level. Testing with the SC formulation on water flea indicated lower toxicity with a non-definitive EC_{50} of >22.2 mg a.i./L. No treatment- related effects were observed at or below the 22.2 mg a.i./L level.

The SC formulation was tested on two species of marine invertebrates. An acute shell-deposition study with Eastern oyster indicated a non-definitive IC_{50} of >0.270 mg a.i. equivalent/L. No additional sub-lethal effects were observed. Testing with mysid shrimp established a non-definite LC_{50} of >0.370 mg a.i. equivalent/L. No sublethal effects were observed.

Comparison of the maximum label application rate of 0.050 mg a.i equivalent/L (50 ppb) with the endpoints for fish and invertebrate species reviewed above indicates that there is low potential for acute effects to these species.

5. Adjuvants

The application of ProcellaCOR to emergent and floating vegetation requires the addition of an adjuvant to the tank mix. Adjuvants are generally broadly defined as any substance separately added to a spray tank mixture that will improve the performance of the pesticide product. Since adjuvant products don't make pesticidal claims, they are not required to be registered. Where a product label directs the user to add a particular adjuvant before use, EPA will treat that adjuvant as an "other ingredient" in making the registration decision, and will assure that any necessary tolerances or exemptions from the requirement of a tolerance are established. It should be noted that residues of pesticide adjuvants in or on food commodities are subject to the requirements of the Federal Food, Drug and Cosmetic Act, which means that a food additive regulation or exemption from the requirement of a tolerance is needed for any substance used as a pesticide adjuvant that is applied to food crops.

Adjuvants that applicators in Massachusetts have reported using, including Agri-Dex, Cide-Kick and Cygnet Plus, are labeled for aquatic use.

A risk characterization of adjuvants that may be used with the application of aquatic herbicides is available on the MDAR's website for aquatic vegetation management[8]. The assessment indicates that even at the high-end estimated spray volumes, the adjuvants commonly used with aquatic herbicides would not pose risk to aquatic organisms in general, but one could pose risk to endangered species. The adjuvants used by aquatic applicators operating in Massachusetts do not exceed LOCs and pose the lowest risk among the adjuvants that were evaluated.

6. Risk Mitigation

The product label for ProcellaCOR EC Herbicide includes a number of statements and instructions that mitigate risks to non-target organisms. In addition to these label instructions, MDAR and MassDEP have additional recommendations and restrictions, some of which supercede some of the label restrictions.

Label statements for ProcellaCOR EC Herbicide include the following advice:

Environmental Hazards
Under certain conditions, treatment of aquatic weeds can result in oxygen depletion or loss due to decomposition of dead plants, which may cause fish suffocation. Water bodies containing very high plant density should be treated in sections to prevent the potential suffocation of fish.

Resistance Management
ProcellaCOR EC is classified as a WSSA Group 4 Herbicide (HRAC Group). Weed populations may contain or develop biotypes that are resistant to ProcellaCOR EC and other Group 4 herbicides. If herbicides with the same mode of action are used repeatedly at the same site, resistant biotypes may eventually dominate the weed population and may not be controlled by these products. Unless ProcellaCOR EC is used as part of an eradication program or in a plant management system where weed escapes are aggressively controlled, do not use ProcellaCOR EC alone in the same treatment area for submersed and emergent plant control for more than 2 consecutive years, unless used in combination or rotated with an herbicide with an alternate mode of action.

Application to Water Used for Irrigation on Turf and Landscape Vegetation
To reduce the potential for injury to sensitive vegetation, follow the waiting periods between application and irrigation) and restrictions given in the product label, and inform those who irrigate with water from the treated area. Follow local and state requirements for informing those who irrigate.

[8] Herbicides for Aquatic Vegetation Management: https://www.mass.gov/herbicides-for-aquatic-vegetation-management

For applications to invasive freshwater aquatic vegetation in slow-moving/quiescent areas of rivers (coves, oxbows or similar sites), *users must be aware of relevant downstream use of water for irrigation that may be affected by the treatment and must ensure all label restrictions are followed. All potential downstream water intakes with irrigation practices that may be affected by the treatment must be documented and affected irrigation users notified of the restrictions associated with such treatment.*

Additional restrictions may be imposed on the use of these products in Massachusetts lakes and ponds within the permitting process, which can address project-specific situations.

6. Recommendations and Massachusetts Use Restrictions

- The maximum permissible application concentration should be 10 ppb, applied no greater than three times per year.
- Florpyrauxifen-benzyl should not be applied to estuarine and marine waters or to freshwater systems with direct outflow to estuarine/marine waters.
- Methods for application of this product in Massachusetts are restricted to in-water applications and foliar applications from a boat or ground equipment.
- Florpyrauxifen-benzyl should be excluded from use in State-listed aquatic species habitats, unless otherwise authorized in writing on a case-by-case basis by the MA Division of Fisheries and Wildlife pursuant to MA Endangered Species Act (321 CMR 10.14 or 10.18).

References

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