Clearcast Ġ Herbicide Product Evaluation and Recommendation

This document is a review of the aquatic herbicide Clearcast® (EPA. Reg. No. 241-437-67690); (SEPRO, 2013). It contains product-specific aspects related to use characterization, inert formulation ingredients and adjuvants, and toxicity and effects of these ingredients to human health and non-target organisms. This document complements the MDAR/MassDEP review of the active ingredient imazamox (MDAR/MassDEP 2013).

1. Product Formulation

The product label indicates that Clearcast herbicide is a liquid formulation containing the ammonium salt of imazamox at a concentration of 12.1% by mass, which corresponds to 1 lb of acid equivalent per gallon of product (SEPRO, 2013).

The identity of the other ingredients (also referred to as inerts) in Clearcast herbicide is considered proprietary; therefore, the manufacturer does not identify the other ingredients on the general or supplemental product labels or material safety data sheets (MSDS). EPA requires labels of pesticide products to identify any inert ingredient that it has determined is of "toxicological concern." The Clearcast label does not identify inert ingredients of toxicological concern.

Proprietary information on the other formulation ingredients was obtained. The proprietary ingredients were evaluated as part of this review, but their identity cannot be disclosed here for reasons of confidentiality.

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 the imazamox-formulated Clearcast herbicide specifies that this product may be applied for the control of vegetation in and around aquatic sites and terrestrial non-crop sites. Clearcast is herbicidally active on many submerged, emergent, and floating broadleaf and monocot aquatic plants. The product may be applied directly to the water for control of submerged aquatic vegetation or a foliar spray for control of emergent and floating vegetation.

Aquatic uses of imazamox are for control of undesirable submerged, emergent and floating aquatic vegetation in and around standing and slow-moving water bodies. These include control of undesirable wetland, riparian and terrestrial vegetation growing in and around standing and flowing water.

Imazamox may also be applied terrestrially to non-crop sites for control of a number of weed species specified on the label.

2.2 Application Methods

Aquatic applications of imazamox herbicide products such as Clearcast are made as a liquid. Clearcast may be broadcast applied to the water surface or injected below the water surface as undiluted product or diluted with water. Application may be by directed application techniques or may be broadcast applied by using ground equipment or water craft. In addition, the products may also be used for cut stump, cut stem and frill and girdle treatments within aquatic sites to treat emergent vegetation. Clearcast may also be applied in a drawdown situation.

2.3 Use Rates

The label use rates per application of Clearcast Herbicide are:

- Subsurface rates that produce 50 to 500 ppb imazamox in the water column. The product label provides information on the amount of product required per surface acre and water depth to achieve the desired water concentration.
- Foliar broadcast application: 16 – 64 fl. oz. of product per acre (0.125 – 0.5 lb imazamox per acre)
- Foliar spot application: up to 5% Clearcast by volume.

2.4 Target Species

Clearcast Herbicide will control various submerged, floating, emerged and terrestrial/marginal weed species. It is effective against aquatic problem species such as Eurasian water milfoil, hydrilla, alligator weed, cattail, parrot feather, phragmites, purple loosestrife, water hyacinth, water primrose and pond weed. A complete list of weeds controlled can be found on the product label (SEPRO, 2013).

3. Human Health Effects of Other Ingredients

Both active and inert ingredients undergo scientific evaluation before approval by the USEPA. The agency must have sufficient data to make a safety determination regarding human health and the environment. For those inert ingredients applied to food, a tolerance or tolerance exemption is required. All food-use inert ingredients are also permitted for nonfood uses such as for ornamental plants, rights-of-way, aquatic use, structural use, etc.

Based on the information available on the USEPA website for pesticide inert ingredients[1], the inert ingredients in Clearcast Herbicide are approved for both nonfood and food uses.

The chemical-by-chemical approach in risk assessment does not address mixture toxicity and thereby adds uncertainty. EPA's approach with toxicity assessment of mixtures is based on grouping of chemicals that exhibit their effects through a common mechanism. However, this is only applied to the cumulative risk assessments of active ingredients.

[1] Pesticide Inert Ingredients: http://www.epa.gov/opprd001/inerts/

4. Ecological Effects of Other Formulation Ingredients

The “inert” or “other” ingredients in the product formulation were not considered in the ecological risk assessment conducted by EPA. As mentioned above, all inert ingredients in pesticide products undergo scientific evaluation before approval for use by the EPA. The Agency must have sufficient data to determine that the use of the product will not cause unreasonable adverse effects to the environment. The inert ingredients in Clearcast Herbicide have all been approved for application on nonfood and food sites.

For the purpose of the review presented here, the risks of the other formulation ingredients to aquatic non-target organisms were evaluated based on the consideration of toxicity information and concentrations in the formulation.

The combined effect of multiple substances was assessed by using the concentration additions approach. The combined effect of multiple compounds or substances is calculated by summation of the concentration of each compound divided by an effect concentration for that compound. This approach is considered to provide a conservative estimate of the mixture effect with relatively small likelihood of underestimating effects due to interactions (Lydy et al., 2004; Junghaus et al., 2006; Belden et al., 2007; Backhaus and Faust, 2012). The concentration addition approach is commonly applied by the use of toxic units (TU). The TU is defined as the quotient c_i/ECx_i which rescales the absolute concentrations of substances to individual potencies. The combined effect is estimated by the summation of TUs. This approach was used in the assessment of the combined effect of imazamox and other formulation ingredients. The assessment was based on the estimated environmental concentrations of imazamox and other formulation ingredients. Only acute effects were evaluated here.

The toxicity information for the other (inert) ingredients was obtained from the open literature and government review documents. Based on the limited availability of toxicity endpoint values, the quantitative analysis described above was only possible for one of the inert ingredients. Toxicity endpoints were not available for the other inert ingredients and therefore calculation of their contribution to the total of toxic units was not possible. The risk of these inert ingredients was qualitatively assessed based on their toxicity information. Such information included toxicity observations such as low toxicity at expected levels associated with the concentrations in the formulations and comparison to naturally occurring levels. It was concluded that these compounds are of a nature and/or present at levels in the product such that use of it as directed would not cause adverse aquatic ecological effects.

The results of the concentrations additions approach are shown in **Appendix 1**. These results indicate that imazamox dominates the combined chemical effects from the exposure to the mixture to fish and algae. If one applies the level-of-concern (LOC) thresholds as used in ecological risk assessment by EPA, the LOC for acute high risk of 0.5 is not exceeded for fish, invertebrates or algae. The LOC for endangered species of 0.05 is exceeded for algae.

The concentration addition approach is not recommended for assessment of chronic effects from exposure from mixtures (Backhaus and Faust, 2012). The differences in environmental fate, such as dissipation rates and partitioning behavior, also complicate the exposure assessment for longer exposure times. The conclusions of a chronic risk evaluation are described in the imazamox review document (Section 3.3). Chronic risk to aquatic organisms is expected to be low.

5. Adjuvants

The application of Clearcast Herbicide 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 include Agri-Dex, Cide-Kick and Cygnet Plus are labeled for aquat`ic use.

A risk characterization of adjuvants that may be used with the application of this aquatic herbicide is found in **Appendix 2.** 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 did not exceed LOCs and poses the lowest risk among the adjuvants that were evaluated.

6. Risk Mitigation

The potential movement from the application area and subsequent risk to non-target organisms is addressed by product label statements. Label statements for Clearcast Herbicide include the following advice:

Environmental Hazards
The herbicide may be hazardous to plants outside the treatment area. Do not apply to water except as specified on the label. Do not contaminate water when disposing of equipment washwaters or rinsate. Ensure that spray drift to non-target species does not occur.

Precautions for Potable Water Intakes
The product may be applied directly to water within one-quarter mile of an active potable water intake but concentrations of imazamox should not exceed 50 μg/L. *If concentrations of greater than 50 «g/L are required, the water intake must be turned off until the water concentration can be shown to be less than 50* μg/L. *The label also*

specifies that Clearcast may be applied to potable water sources at concentrations up to 500 «g/L to within a distance of ¼ mile from an active potable water intake.

Application to Waters used for Irrigation
To prevent adverse effects on crops, water treated with Clearcast Herbicide may not be used for irrigation purposes unless the concentration is below 50 «g/L. Water from still or quiescent water bodies that received foliar applications at rates of á 2 quarts per acre may be used for irrigation 24 hours after application. This requirement is related to treatment of emerged and floating vegetation in which >25% of the area has been treated and which is < 100 feet from an irrigation intake; and to treatment of submerged vegetation in an area that is < 100 feet from an irrigation intake. There are no irrigation restrictions for treated water from flowing waters with a depth of 4 feet or more that received foliar applications at rates á 2 quarts per acre.

Endangered Plant Species
To prevent impacts to endangered plant species, the product is not to be applied in a way that adversely affects federally or state listed endangered and threatened species.

Avoiding Injury to Non-Target Plants
When making applications along shorelines where desirable plants may be present, caution should be exercised to avoid spray contact with their foliage or spray application to the soil in which they are rooted. Shoreline plants that have roots that extend into the water in an area where the herbicide has been applied generally will not be adversely affected by uptake of the herbicide from the water.

Managing Off-Target Movement
To minimize spray drift, the label contains drift reduction advisory information addressing various equipment- and weather-related factors that determine the potential for spray drift. These factors include control of droplet size, application height, swath adjustment, wind, temperature and humidity, and temperature inversions.

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.

7. Recommendations and Massachusetts Use Restrictions

No additional restrictions on the application of this product beyond those specified on the label are necessary.

References

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Appendix 1

Aquatic Toxicity Assessment of Clearcast Herbicide Formulation

In order to assess the toxicity of combined exposure of active and other formulation ingredients, the toxic unit approach was used to estimate combined toxicity. The toxic unit approach is based on concentration addition. The combined effect of multiple compounds or substances is calculated by summation of the concentration divided by an effect concentration. Only acute effects were evaluated. The concentration addition approach is not recommended for assessment of chronic effects from exposure from mixtures (Backhaus and Faust, 2012). The differences in environmental fate, such as dissipation rates and partitioning behavior, also complicate the exposure assessment for longer exposure times. The conclusions of a chronic risk evaluation are described in the imazamox review document (Section 3.3).

The concentration addition is commonly applied by the use of toxic units (TU). The TU is defined as the quotient c_i/ECx_i which rescales the absolute concentrations of substances to individual potencies. The combined effect is estimated by the summation of TUs.

Only one of the other ingredients included in TU calculations (indicated as 'Other ingredient 1'). Based on the limited availability of toxicity endpoint values, the quantitative analysis described above was only possible for one of the inert ingredients. Toxicity endpoints were not available for the other inert ingredients and therefore calculation of toxic units was not possible.

The TU values were calculated for fish, aquatic invertebrates and algae. The results are shown in Fig. A1-1, below. These results indicate that for fish and algae the combined effect is dominated by the effect of imazamox, with very small contributions from effects of the other ingredient included in the analysis. The toxicity endpoint of Other Ingredient 1 for invertebrates was not available. The Sum of TU could not be calculated and therefore is not shown in Fig. A1-1.

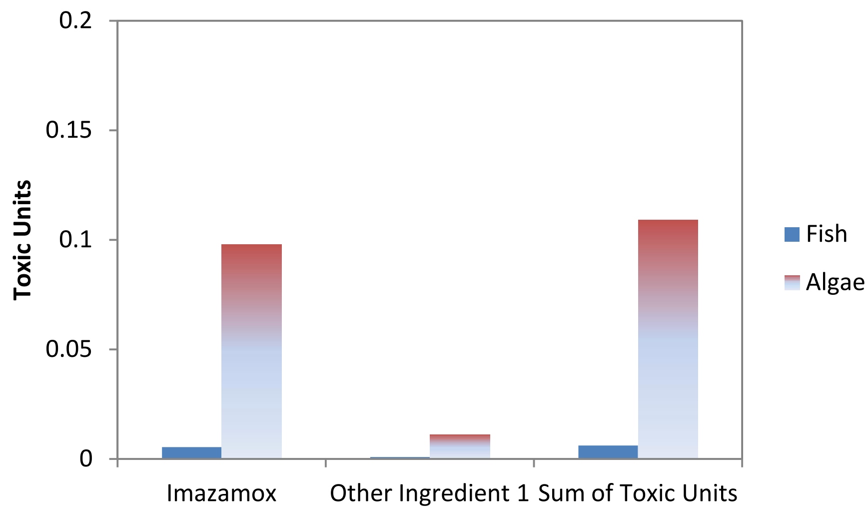

Figure A2-1 Toxic Units of formulation ingredients for acute effects to fish and algae. The TU value for invertebrates is not shown because the toxicity endpoint for inert ingredient was not available.

Toxic Unit (TU) calculations

Toxic Unit calculations for acute effects from exposure to Clearcast Herbicide formulation ingredients illustrated in Fig. A1-1 are shown below. Information on the EECs and EC_{50}/LC_{50} for imazamox can be found in the review document for flumioxazin (MDAR/MassDEP, 2013, Section 3.1 and 3.2). Toxicological endpoints were only available for one other ingredient.

Ingredient	EEC mg/L	EC50/LC50 Fish mg/L	TU	EC50 Aq. Invert. mg/L	TU	EC50 Algae mg/L	TU
Imazamox	0.500	94.2	0.00531	115	0.004348	5.1	0.0980
Other Ingredient 1	0.0041	5.0	0.00082	--	--	0.37	0.0111
Sum of TU:			0.006128		0.004348		0.1091

Appendix 2

Risk Assessment of Adjuvants Used with Aquatic Herbicides

The Clearcast Herbicide label indicates that treatment of emergent or floating vegetation requires the addition of an adjuvant in the tank mix. The label suggests the use of methylated seed oils or nonionic surfactants at recommended manufacturer's rates.

The risk assessment of several adjuvant products that are commonly used with the application of aquatic herbicides is presented below.

Toxicity Characterization

The toxicity of adjuvants was considered in risk assessments of herbicide applications in estuaries in Washington State (Entrix, 2003) and San Francisco (Pless, 2005). Commonly used adjuvants included non-ionic alkylphenol ethoxylates and/or fatty acids (e.g., R-11®, X-77®), and crop-oil based concentrates (e.g., Agri-Dex®, Hasten®). On the basis of EPA toxicity criteria, the non-ionic alkylphenol ethoxylates (e.g., R-11®, X-77®) are moderately acutely toxic to aquatic species. The crop-oil based surfactants would be considered practically non-toxic. Smith et al. (2004) characterized the toxicity of four surfactants to juvenile rainbow trout and implications for their use over water. The 96-h LC_{50} values were 6.0 mg/L for R-11®, 17 mg/L for LI 700®, 74 mg/L for Hasten, and 271 mg/L for Agri-Dex®. The 96-h EC_{50}s (on-bottom gilling behavior) were 4.4 mg/L for R-11® and 17 mg/L for LI 700®.

Curran (2003) determined the toxicity of formulated herbicide product Arsenal Herbicide (a.i., imazapyr) with and without the adjuvants Agri-Dex® and Hasten® using juvenile rainbow trout. The 96-h LC_{50} value for Arsenal Herbicide without adjuvant was 77,716 mg/L. In systems containing Arsenal plus adjuvant, the 96-h LC_{50} was expressed as mg/L surfactant and were reported to be 113 mg/L for Hasten® and 479 mg/L for Agri-Dex®. These values were compared with the LC_{50} values for the surfactants alone which were 74 mg/L for Hasten® and 271 mg/L for Agri-Dex®. Since this source of information was a meeting abstract, no further evaluation of data was possible for the review presented here. The authors concluded that the data suggest that the Arsenal Herbicide formulation has low toxicity to juvenile rainbow trout, the toxicity of the tank mixes is driven by the surfactants, and depending on the type of surfactant and its percentage in the tank mix, surfactants may pose greater hazard to non-target species than Arsenal Herbicide.

Adjuvants and surfactants were also considered in human health and ecological effects risk assessments of imazapyr use for controlling vegetation in riparian corridors (AMEC, 2009). The most frequently used adjuvants were identified to be Agri-Dex®, Dyne-Amic®, Class-Act® and R-11®. It should be noted that the assessment did not consider direct applications to water. Reference was made to a study by Smith et al. (2004), which was cited above. While toxicity data were reviewed, the document did not include a formal exposure and risk assessment for the adjuvants.

Additional adjuvants that applicators in Massachusetts have reported using include Cide-Kick and Cygnet Plus. These adjuvants contain *d*-limonene as the major surfactant. Limonene is slightly toxic to fish and aquatic invertebrates with LC_{50} values of 80 mg/L and 39 mg/L, respectively (USEPA, 1994).

Exposure Assessment

Pless (2005) considered several adjuvants as used in tank mixes in the ecological risk assessment. The environmental properties and toxicity of adjuvants were also considered with the assessment of imazapyr herbicide use in estuaries in Washington State (Entrix, 2003). Both reviews estimated adjuvant concentration in water in an estuary scenario. For the purpose of this special review presented here, the environmental concentrations of two adjuvants Agri-Dex® and Hasten® were estimated in a pond application scenario as described below.

It was assumed that the adjuvant was used in a 1% v/v concentration in the tank mix (the label requires >0.25%). It was further assumed that the application volume was 50 gallons per acre (label requirement is >5 gal for ground applications). A 1% v/v adjuvant concentration in the 50 gal spray volume would correspond to a 1.89 L adjuvant volume per acre. Based on the density of Agri-Dex (0.879 kg/L, Agri-Dex MSDS), this volume corresponds to 1.66 kg Agri-Dex adjuvant per acre. The peak concentration of Agri-Dex® in a 1-acre water body with a 1-foot depth can be calculated as follows: 1.66×10^6 mg / (4047 m^2 × 0.3048 m × 1000 L/m^3) = 1.35 mg/L. For the 6.56-feet (2-meter) and 3-feet depths the concentrations are 0.21 mg/L(mg/L) and 0.45 mg/L(mg/L), respectively. The values for the adjuvants Hasten®, Cide-Kick and Cygnet Plus are very similar for the same adjuvant concentration given that the densities of these adjuvants are very similar to Agri-Dex (0.87-0.9 kg/L). It should be noted that these calculations assumed no interception by target vegetation and no sorption to sediment. The adjuvant concentrations calculated above are slightly lower than the values for adjuvant concentrations that were reported in Entrix (2003). Those calculations assumed a density of 1 kg/L, whereas the actual density of the adjuvant products Agri-Dex® and Hasten® is less than 1 kg/L.

The Clearcast Herbicide label does not specify spray volumes for foliar treatments other than 10 gallons or more. A reasonable high-end estimate for spray volume could be 100 gallons per acre. Consequently, to calculate the highest level, the concentration of 1.35 mg/L in a 1-ft deep pond would have to be multiplied by 2 in this case: 2.70 mg/L in a 1-ft deep pond.

Risk Assessment

As pointed out in the review by Pless (2005), the toxicity of the herbicide/adjuvant mixture is driven by the surfactant. The risk quotients presented by Pless (2005), based on environmental concentrations in an estuary scenario, were in the range of 0.13-0.051. The higher value was determined in association with the adjuvant Hasten®. That value marginally exceeded the level of concern (LOC) of 0.05 for endangered fish. It was pointed out that the highest measured exposure was extremely conservative in that the pesticide was applied directly to the estuary sediment (mud flat) without interception by vegetation and measured in the 3 hours later in the first overflow.

For the consideration of the application in a pond, the estimated environmental concentrations (EECs) of the Agri-Dex® and Hasten® adjuvants were calculated above. These two adjuvants were selected based on the availability of toxicity data for product with adjuvant (Curran et al., 2003). The highest estimated concentration in a water body with 1-foot depth was 1.35 mg/L. Based on the 96-hr LC_{50} of 479 mg/L expressed as adjuvant (Curran et al., 2003) for the product plus adjuvant mixture, the risk quotient is 0.0028. For the Hasten® adjuvant, the risk quotient would be 0.012. For the limonene-based adjuvants Cide-Kick and Cygnet Plus, the risk quotient would be 0.016. These values are below levels of concern for aquatic species as established by USEPA (2011), the most sensitive for endangered species acute risk being 0.05.

Entrix (2003) conducted a risk assessment of four adjuvants that have uses with glyphosate- and imazapyr-based aquatic herbicides. In addition to Hasten® and Agri-Dex®, the LI 700® and R-11® were included in the exposure and risk assessment. Since the spray-volume requirements for glyphosate-based herbicide are higher compared to imazapyr-based herbicides, the risk quotients were evaluated as a function of spray volume. The risk quotients were based on the LC_{50} values for juvenile rainbow trout as reported by Smith et al. (2004). The same procedure was used here for the concentrations developed for a pond scenario as described in Section 3.2 of the imazapyr review document. Figure A2-1 shows that the R-11 adjuvant exceeds the most sensitive Level of Concern (LOC) over the entire application volume range considered, while the Hasten® and Agri-Dex® adjuvants do not exceed the most sensitive LOC even at the highest application volume. In the review by Entrix (2003), it is pointed out that glyphosate-based herbicides require large application volumes (up to 100 gal/acre for efficacy), while 5 to 20 gal/acre can be used for imazapyr-based herbicides to yield equivalent results. Consequently, imazapyr-based herbicide applications are associated with lower adjuvant exposures compared to glyphosate-based herbicides.

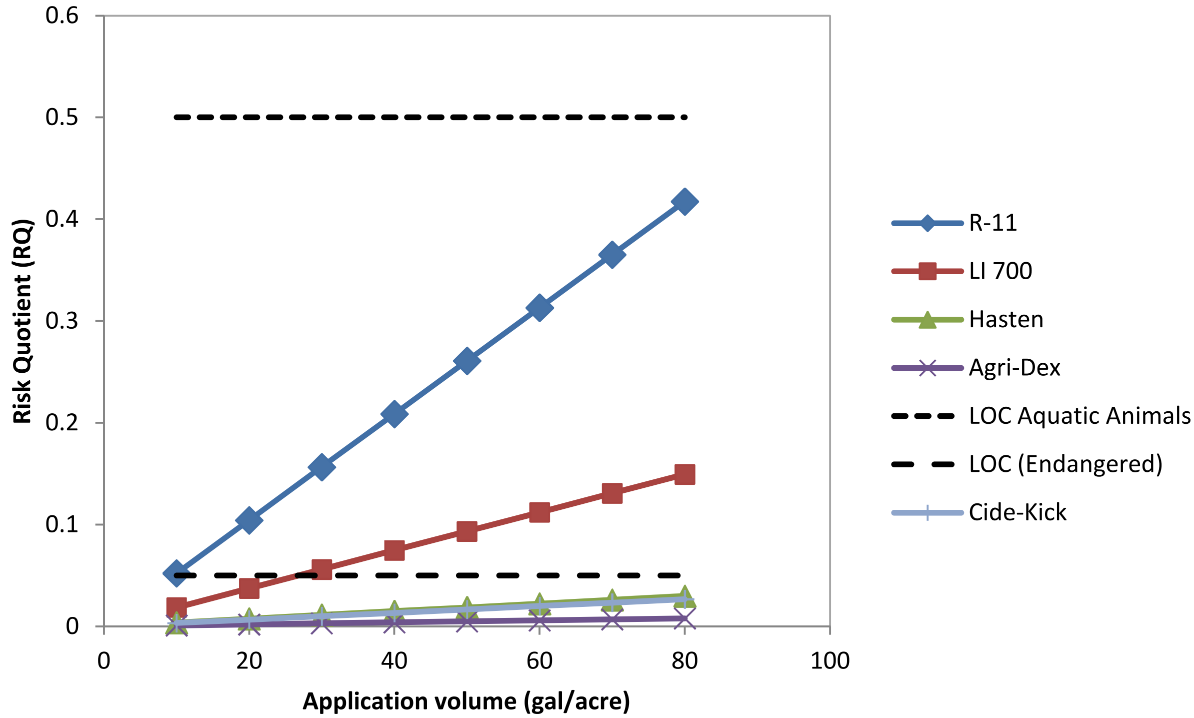

Figure A2-1. Risk quotient (RQ) of four spray adjuvants based on adjuvant concentrations associated with applications to a 1-foot deep water body. The adjuvant concentration was 1% v/v. The risk quotient was calculated based on the 96-h LC50 values for rainbow trout as reported by Smith et al. (2004) and USEPA (1994). The RQ values are compared with the Levels of Concern (LOC) for acute risk as developed by US EPA (2011). Adjuvants used by applicators operating in Massachusetts include Agri-Dex and Cide-Kick.

Smith et al. (2004) estimated the water depth at which the 96-h LC_{50} value for juvenile trout would be reached with an application volume of 20 gal/acre and labeled tank mix concentration (0.5 – 5%). When used at the minimum recommended percentage of adjuvant in the tank mix the LC_{50} depth was <16 mm for R-11 and < 5 mm for the Agri-Dex®, Hasten® and LI 700®. At the maximum label recommended percentages of adjuvant in the tank mix, the LC_{50} depth for Agri-Dex would remain <5 mm, for Hasten it would be 10 mm and for LI 700 it would be 43 mm. It was concluded that Agri-Dex posed the lowest hazards to fish among the surfactants evaluated.

In the case of Clearcast Herbicide, a high-end estimate of spray volume is 100 gal per acre. From the graph depicted in Fig. 1 above, it can be concluded that at that spray volume, the R-11 adjuvant would approach the LOC for aquatic animals. The LI700 adjuvant would not exceed the LOC for aquatic animals, but would exceed the LOC for endangered species. The Hasten, Agri-Dex and Cide-Kick adjuvants would not exceed the LOC for aquatic animals or endangered species.

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