

## SCREENING-LEVEL HAZARD CHARACTERIZATION SPONSORED CHEMICAL

### 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CASRN 68411-81-4)

### SUPPORTING CHEMICALS

#### 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8)

The High Production Volume (HPV) Challenge Program<sup>1</sup> was conceived as a voluntary initiative aimed at developing and making publicly available screening-level health and environmental effects information on chemicals manufactured in or imported into the United States in quantities greater than one million pounds per year. In the Challenge Program, producers and importers of HPV chemicals voluntarily sponsored chemicals; sponsorship entailed the identification and initial assessment of the adequacy of existing toxicity data/information, conducting new testing if adequate data did not exist, and making both new and existing data and information available to the public. Each complete data submission contains data on 18 internationally agreed to “SIDS” (Screening Information Data Set<sup>1,2</sup>) endpoints that are screening-level indicators of potential hazards (toxicity) for humans or the environment.

The Environmental Protection Agency’s Office of Pollution Prevention and Toxics (OPPT) is evaluating the data submitted in the HPV Challenge Program on approximately 1400 sponsored chemicals by developing hazard characterizations (HCs). These HCs consist of an evaluation of the quality and completeness of the data set provided in the Challenge Program submissions. They are not intended to be definitive statements regarding the possibility of unreasonable risk of injury to health or the environment.

The evaluation is performed according to established EPA guidance<sup>2,3</sup> and is based primarily on hazard data provided by sponsors; however, in preparing the hazard characterization, EPA considered its own comments and public comments on the original submission as well as the sponsor’s responses to comments and revisions made to the submission. In order to determine whether any new hazard information was developed since the time of the HPV submission, a search of the following databases was made from one year prior to the date of the HPV Challenge submission to the present: (ChemID to locate available data sources including Medline/PubMed, Toxline, HSDB, IRIS, NTP, ATSDR, IARC, EXTOXNET, EPA SRS, etc.), STN/CAS online databases (Registry file for locators, ChemAbs for toxicology data, RTECS, Merck, etc.) and Science Direct. OPPT’s focus on these specific sources is based on their being of high quality, highly relevant to hazard characterization, and publicly available.

OPPT does not develop HCs for those HPV chemicals which have already been assessed internationally through the HPV program of the Organization for Economic Cooperation and

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<sup>1</sup> U.S. EPA. High Production Volume (HPV) Challenge Program; <http://www.epa.gov/chemrtk/index.htm>.

<sup>2</sup> U.S. EPA. HPV Challenge Program – Information Sources; <http://www.epa.gov/chemrtk/pubs/general/guidocs.htm>.

<sup>3</sup> U.S. EPA. Risk Assessment Guidelines; <http://cfpub.epa.gov/ncea/raf/rafguid.cfm>.

Development (OECD) and for which Screening Initial Data Set (SIDS) Initial Assessment Reports (SIAR) and SIDS Initial Assessment Profiles (SIAP) are available. These documents are presented in an international forum that involves review and endorsement by governmental authorities around the world. OPPT is an active participant in these meetings and accepts these documents as reliable screening-level hazard assessments.

These hazard characterizations are technical documents intended to inform subsequent decisions and actions by OPPT. Accordingly, the documents are not written with the goal of informing the general public. However, they do provide a vehicle for public access to a concise assessment of the raw technical data on HPV chemicals and provide information previously not readily available to the public.

<p><b>Chemical Abstract Service Registry Number (CASRN)</b></p>	<p><b>68411-81-4</b></p>
<p><b>Chemical Abstract Index Name</b></p>	<p><b>2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated</b></p>
<p><b>Structural Formula</b></p>	<div style="text-align: center;"> <p>R1 = H or CH3; R2 = H or CH3</p> </div>
<p style="text-align: center;"><b>Summary</b></p> <p>The commercial product is a clear colorless liquid with high water solubility and a vapor pressure comparable to water since it is formulated as an aqueous solution containing approximately 20% water. The pure material cannot be isolated but it would be expected to have high water solubility and negligible to low vapor pressure. The chemical is expected to have high mobility in soil. Volatilization of the chemical is considered low based on the estimated Henry's Law constants of the supporting chemical. The rate of hydrolysis is considered negligible. The rate of atmospheric photooxidation is considered rapid. The chemical is expected to have moderate persistence (P2) and low bioaccumulation potential (B1).</p> <p>Acute oral and inhalation toxicity of the supporting chemical CASRN 1854-26-8, in rats and mice, is low. In oral repeated-dose studies in rats with the supporting chemical CASRN 1854-26-8, mortality in males, and mineralization in the testes and heart were observed at 6000 mg/kg-bw/day; the NOAEL for systemic toxicity was 3000 mg/kg-bw/day. In mice, no adverse effects were observed after repeated oral exposures; the NOAEL for systemic toxicity was 6000 mg/kg-bw/day. No specific reproductive toxicity studies were available. There were no effects on the male and female reproductive organs in the oral repeated-dose studies with mice; mineralization of the testes was observed in a rat. In an oral prenatal developmental toxicity study in rats, the supporting chemical, CASRN 1854-26-8 showed no maternal or developmental toxicity and the NOAEL was 640 mg/kg-bw/day. The supporting chemical CASRN 1854-26-8, was mutagenic in bacteria <i>in vitro</i> and did not induce micronuclei in mice <i>in vivo</i>.</p> <p>The acute hazard to fish and aquatic invertebrates is based on the toxicity values for the supporting chemical CASRN 1854-26-8, of 880 mg/L and &gt;200 mg/L, respectively. The acute hazard to aquatic plants is based on the toxicity value for CASRN 68411-81-4 of 146.3 mg/L (biomass). The chronic hazard to aquatic invertebrates is based on the toxicity value for the supporting chemical, CASRN 1854-26-8, of ≥ 100 mg/L.</p> <p>No data gaps were identified under the HPV Challenge Program.</p>	

The sponsor, SOCMA Urea Resins Group, a consortium of Hickson DanChem Corporation, Noveon, Inc. and OMNOVA Solutions Inc., submitted a Test Plan and Robust Summaries to EPA for 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CASRN 68411-81-4; CA Index Name: 2-imidazolidinone, 4,5-dihydroxy-1,3-bis (hydroxymethyl)-, methylated] on December 3, 2001. EPA posted the submission on the ChemRTK HPV Challenge website on February 26, 2002 (<http://www.epa.gov/chemrtk/pubs/summaries/2imidazo/c13551tc.htm>). EPA comments on the original submission were posted to the website on December 11, 2002. Public comments were also received and posted to the website. The sponsor submitted updated/revised documents on July 21, 2003 and February 11, 2005, which were posted to the ChemRTK website on August 28, 2003 and March 29, 2005, respectively.

### **Justification for Supporting Chemical**

The sponsor provided data for supporting chemical 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8) and some estimated values for 2-imidazolidinone, 4,5-dihydroxy-1,3-bis(methoxymethyl)- (CASRN 3001-61-4). These compounds share the same basic structure with the sponsored chemical, differing only by the degree of methylation. In addition, the methylated sponsored chemical is expected to undergo rapid demethylation to the non-methylated chemicals in mammalian and aquatic species. Therefore, the toxicity of the methylated sponsored chemical would be similar to those of the non-methylated analog. Because only estimated data were provided for CASRN 3001-61-4, this supporting chemical was not included in this hazard characterization. CASRN 1854-26-8 has been assessed in the OECD HPV program and the published data can be viewed at the following link: <http://www.chem.unep.ch/irptc/sids/OECD/SIDS/sidspub.html>. The Agency concluded that the submitter adequately supported information provided for the purposes of the HPV Challenge Program.

## **1 Chemical Identity**

### **1.1 Identification and Purity**

The following description is taken from the final Test Plan (2005):

CASRN 68411-81-4 is methylated to an undetermined extent. Methylation occurs primarily such that one or both R1 groups are methyl groups instead of hydrogen atoms. It is possible that some R2 groups are also methyl instead of hydrogen.

CASRN 68411-81-4 is manufactured by the reaction of glyoxal, urea and formaldehyde followed by methylation using methanol. The chemical is not isolated and is produced and sold as an aqueous solution containing low levels (<1.0%) formaldehyde.

### **1.2 Physical-Chemical Properties**

The physical-chemical properties of CASRN 68411-81-4 and its supporting chemical, CASRN 1854-26-8 are summarized in Table 1. The commercial product containing CASRN

68411-81-4 is a clear colorless liquid with high water solubility and a vapor pressure comparable to water. The pure material is expected to have high water solubility and negligible to low vapor pressure.

<b>Table 1. Physical-Chemical Properties of 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated<sup>1,2</sup></b>		
<b>Property</b>	<b>SPONSORED CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated</b>	<b>SUPPORTING CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-</b>
CASRN	68411-81-4	1854-26-8
Molecular Weight	178–234	178
Physical State	Clear colorless solution in water (technical product)	Clear colorless solution in water (technical product)
Melting Point	<b>-39°C (measured for technical product)</b>	<b>-35°C (measured for technical product)</b>
Boiling Point	<b>118.5°C (measured for technical product; mild decomposition)</b>	<b>118.5°C (measured for technical product); 396°C (estimated)<sup>3</sup></b>
Vapor Pressure	Similar to water (technical product); Negligible, pure material	Similar to water (technical product); $2.3 \times 10^{-9}$ (estimated) <sup>3</sup>
Water Solubility	<b>&gt;5,000,000 mg/L at 20°C (measured) (Miscible)</b>	Miscible; $1 \times 10^6$ mg/L (estimated) <sup>3</sup>
Dissociation Constant (pK <sub>a</sub> )	Not applicable	Not applicable
Henry's Law Constant	Negligible, pure material	$1.06 \times 10^{-12}$ atm-m <sup>3</sup> /mole (estimated)
Log K <sub>ow</sub>	<b>-3.2 (measured)</b>	<b>-2.2 (measured)</b>

<sup>1</sup>SOCMA Urea Resins Group (SURG). February 23, 2005. Revised Robust Summaries and Test Plans for 2-Imidazolidinone, 4,5-Dihydroxy-1,3- Bis(hydroxymethyl)-, Methylated. <http://www.epa.gov/chemrtk/pubs/summaries/2imidazo/c13551tc.htm>.

<sup>2</sup>Technical products are produced as aqueous solutions containing approximately 20% water; therefore, measured properties likely reflect values for water.

<sup>3</sup>U.S. EPA. 2008. Estimation Programs Interface Suite™ for Microsoft® Windows, v3.20. United States Environmental Protection Agency, Washington, DC, USA. <http://www.epa.gov/opptintr/exposure/pubs/episuite.htm>.

## **2 General Information on Exposure**

### **2.1 Production Volume and Use Pattern**

The chemical had an aggregated production and/or import volume in the United States of 1 million to 10 million pounds during calendar year 2005.

Non-confidential information in the IUR indicated that the industrial processing and uses of the chemical include “other”. Non-confidential information in the IUR indicated that data about the commercial/consumer and children’s products containing the chemical are “not readily obtainable”. The HPV submission for this chemical states that the chemical is primarily used in textile manufacture as industrial intermediates to cross-link molecules in the cloth, so that the finished textile cloth will have “memory” to retain crease or other desired shape.<sup>4</sup>

## 2.2 Environmental Exposure and Fate

No quantitative information is available on releases of this chemical to the environment.

The environmental fate properties are provided in Table 2. CASRN 68411-81-4 is expected to have high mobility in soil. A commercial mixture consisting of 76.34% dihydroxydimethylolethyleneurea, methylated (CASRN 68411-81-4), 1.0% potassium sulfate (CASRN 7778-80-5), 0.18% formaldehyde (CASRN 50-00-0), <0.1% methanol (CASRN 7732-18-5), and 22.48% water (CASRN 7734-18-5) was not readily biodegradable using a modified Sturm (OECD 301B) test. However, CASRN 1854-26-8 (73.9% CASRN 1854-26-8 and 26.1% water) was significantly degraded using a modified AFNOR (OECD 301A) test and was classified as inherently biodegradable. Volatilization of CASRN 68411-81-4 is considered low based on the estimated Henry's Law constants of the supporting chemicals. The rate of hydrolysis is considered negligible. CASRN 68411-81-4 is expected to have moderate persistence (P2) and low bioaccumulation potential (B1).

<b>Property</b>	<b>SPONSORED CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy- 1,3-bis(hydroxymethyl)-, methylated</b>	<b>SUPPORTING CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxy- methyl)-</b>
CASRN	68411-81-4	1854-26-8
Photodegradation Half-life	1.4–1.8 hours (estimated)	1.4 hours (estimated)
Hydrolysis Half-life	Stable	Stable
Biodegradation	<b>4.5% after 28 days (not readily biodegradable)</b>	<b>60–70% after 28 days (inherently biodegradable); 28% after 58 days; 38% after 28 days; 70% after 2 months</b>
Bioconcentration	BCF = 3 (estimated) <sup>2</sup>	BCF = 3 (estimated) <sup>2</sup>
Log K <sub>oc</sub>	1 (estimated) <sup>2</sup>	1 (estimated) <sup>2</sup>
Fugacity (Level III Model)		
Air	0.00133%	0.00133%

<sup>4</sup> PCA Services, Inc., January 21, 2005. Test Plan for Methylated 2-Imidazolidinone. Accessed, 12/10/08. <http://www.epa.gov/chemrtk/pubs/summaries/2imidazo/c13551rt2.pdf>

Table 2. Environmental Fate Characteristics of 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated <sup>1</sup>		
Property	SPONSORED CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy- 1,3-bis(hydroxymethyl)-, methylated	SUPPORTING CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxy- methyl)-
Water	42.8%	42.8%
Soil	57.1%	57.1%
Sediment	0.0638%	0.0638%
Persistence <sup>3</sup>	P2	P2
Bioaccumulation <sup>3</sup>	B1	B1

<sup>1</sup>SOCMA Urea Resins Group (SURG). February 23, 2005. Revised Robust Summaries and Test Plans for 2-Imidazolidinone, 4,5-Dihydroxy-1,3-Bis(hydroxymethyl)-, Methylated.  
<http://www.epa.gov/chemrtk/pubs/summaries/2imidazo/c13551tc.htm>.

<sup>2</sup>U.S. EPA. 2008. Estimation Programs Interface Suite™ for Microsoft® Windows, v3.20. United States Environmental Protection Agency, Washington, DC, USA.  
<http://www.epa.gov/opptintr/exposure/pubs/episuite.htm>.

<sup>3</sup>Federal Register. 1999. Category for Persistent, Bioaccumulative, and Toxic New Chemical Substances. *Federal Register* 64, Number 213 (November 4, 1999) pp. 60194–60204.

### **3 Human Health Hazard**

#### ***Acute Oral Toxicity***

##### ***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

(1) Fischer 344 rats (5/sex/dose) were administered the test substance via gavage at 256, 640, 1600, 4000 or 10,000 mg/kg-bw and observed for 14 days. There was no mortality.

**LD<sub>50</sub> > 10,000 mg/kg-bw**

(2) Gassner rats (5/sex/dose) were administered the test substance via gavage at doses ranging from 90 to 2880 mg/kg-bw and observed for 7 days. There was no mortality.

**LD<sub>50</sub> > 2880 mg/kg-bw**

(3) B6C3F1 mice (5/sex/dose) were administered the test substance (in corn oil) via gavage at 256, 640, 1600, 4000 or 10,000 mg/kg-bw and observed for 14 days. Mortality (1 male) occurred at 1600 mg/kg-bw, but not at higher doses.

**LD<sub>50</sub> > 10,000 mg/kg-bw**

#### ***Acute Inhalation Toxicity***

##### ***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

(1) Fischer 344 rats (5/sex) were exposed to the test substance aerosol (whole body) at a nominal concentration of 11.0 mg/L (measured concentration was 3.1 mg/L) for 4 hours and were observed for 14 days. There was no mortality.

**LC<sub>50</sub> > 3.1 mg/L**

(2) B6C3F1 mice (5/sex) were exposed (whole body) to the test substance aerosol at a nominal concentration of 2.5 mg/L (measured concentration was 3.0 mg/L) for 4 hours and observed for 14 days. There was no mortality.

**LC<sub>50</sub> > 3.0 mg/L**

### *Repeated-Dose Toxicity*

#### ***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

(1) In a 13-week study, Fischer 344 rats (10/sex/dose) were administered the test substance via oral gavage at 0, 1000, 3000 or 6000 mg/kg-bw/day for 5 days/week. Three males died at 6000 mg/kg-bw/day. The males at the mid- and high-doses had lower body weight gain and lower body weights at termination than controls; the statistical significance was not stated. Clinical signs of toxicity at these doses were soft stool and yellow ano-genital staining. One high-dose male exhibited hypoactivity, decreased grasping reflex, hypothermic extremities and ataxia. No toxicologically significant organ weight changes occurred. One high-dose male showed moderate bilateral mineralization of the testes. Treatment-related mild mineralization in the heart was seen in two high-dose males. Some animals were likely to have been affected by the Sendai virus.

**LOAEL = 6000 mg/kg-bw/day** (based on mortality in males and effects on testes and heart)

**NOAEL = 3000 mg/kg-bw/day**

(2) In a 13-week study, B6C3F1 mice (10/sex/dose) were administered the test substance via oral gavage at 0, 1000, 3000 or 6000 mg/kg-bw/day for 5 days/week. All dosed females showed an increased body weight compared to the controls; the statistical significance was not stated. No treatment-related effects were noted in microscopic examination of tissues from the control and high-dose groups. Some animals were likely to have been affected by the Sendai virus.

**NOAEL = 6000 mg/kg-bw/day** (based on no adverse effects at the highest dose tested)

### *Reproductive Toxicity*

There were no studies specifically designed to assess the reproductive toxicity of either the sponsored or supporting chemical. Evaluation of reproductive organs in repeated-dose studies were used to address the reproductive toxicity endpoint for the purposes of the HPV Challenge Program.

#### ***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

(1) In the 13-week repeated-dose study in Fischer 344 rats described above, no effects were noted upon microscopic examination of the sex organs (including testes, epididymis, prostate, preputial gland, uterus, ovaries and clitoral gland) in males treated up to 3000 mg/kg-bw/day and females treated up to 6000 mg/kg-bw/day. One high-dose male showed moderate bilateral mineralization of the testes at 6000 mg/kg-bw/day.

(2) In the 13-week repeated-dose study in B6C3F1 mice described above, no effects were noted upon microscopic examination of the sex organs (including testes, epididymis, prostate, preputial gland, uterus, ovaries and clitoral gland) in males or females treated up to 6000 mg/kg-bw/day.

### *Developmental Toxicity*

#### ***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

Pregnant Wistar rats (23/dose) were administered 250, 500 or 1000 mg/kg-bw/day (64.1% in water equivalent to 0, 160, 320 or 640 mg/kg-bw/day, respectively) of the test substance via gavage during gestational days 7 – 16. No mortality was seen. There were no effects on body weights and food consumption. Gravid uterus weight, crown-rump lengths, litter size, sex ratios, fetal and transplacental weights were unaffected by exposure to the test substance. There was no increase in the number of early or late resorptions. Morphological examination of the fetuses did not reveal any compound-related effect.

**NOAEL (maternal and developmental toxicity) = 640 mg/kg-bw/day** (based on no effects at the highest dose tested)

### *Genetic Toxicity – Gene Mutation*

#### *In vitro*

#### ***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

(1) In a reverse-mutation assay, *Salmonella typhimurium* strains TA98, TA100, TA1535 and TA1537 were exposed to the test substance at concentrations of 33 – 10,000 µg/plate using DMSO as a solvent or 333 – 10,000 µg/plate using water as a solvent and in the presence or absence of metabolic activation. The cytotoxic concentration was 10,000 µg/plate for most strains. Positive controls were tested concurrently and responses were appropriate. Test material was not mutagenic in strains TA1535 or TA1537. In the presence of metabolic activation and using DMSO as a solvent, results were questionable in 50% of tests (2 out of 4) in strain TA100, while using water as a solvent, all tests were positive. Weakly positive or questionable results were found in strain TA98 in the presence or absence of metabolic activation using water as a solvent. One of five tests using TA98 with DMSO as a solvent and in the presence of metabolic activation showed a weak positive response.

**CASRN 1854-26-8 was mutagenic in these assays.**

(2) In a reverse-mutation assay, *Salmonella typhimurium* strain TA102 was exposed to the test substance at concentrations of 1 – 5000 µg/plate in a plate incorporation and preincubation test and concentrations of 2 – 10,000 µg/plate in a preincubation test in the presence and absence of metabolic activation. No further details were provided in the robust summary.

**CASRN 1854-26-8 was not mutagenic in this assay.**

### *Genetic Toxicity – Chromosomal Aberrations*

#### *In vivo*

***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

In a mouse micronucleus assay, NMRI mice of both sexes (number and sex distribution not stated) were administered the test substance via gavage at 500, 1000 or 2000 mg/kg-bw (as a 75% solution containing 1% formaldehyde) and examined for micronuclei in bone marrow. Positive controls were tested concurrently, but control responses were not provided. Samples of bone marrow were taken at 24 hours for all doses as well as 48 hours for the high dose. No cytotoxicity was observed.

**CASRN 1854-26-8 did not induce micronuclei in this assay.**

**Conclusion:** Acute oral and inhalation toxicity of the supporting chemical CASRN 1854-26-8, in rats and mice, is low. In oral repeated-dose studies in rats with the supporting chemical CASRN 1854-26-8, mortality in males, and mineralization in the testes and heart were observed at 6000 mg/kg-bw/day; the NOAEL for systemic toxicity was 3000 mg/kg-bw/day. In mice, no adverse effects were observed after repeated oral exposures; the NOAEL for systemic toxicity was 6000 mg/kg-bw/day. No specific reproductive toxicity studies were available. There were no effects on the male and female reproductive organs in the oral repeated-dose studies with mice; mineralization of the testes was observed in a rat. In an oral prenatal developmental toxicity study in rats, the supporting chemical, CASRN 1854-26-8 showed no maternal or developmental toxicity and the NOAEL was 640 mg/kg-bw/day. The supporting chemical CASRN 1854-26-8, was mutagenic in bacteria *in vitro* and did not induce micronuclei in mice *in vivo*.

#### **4 Hazards to the Environment**

##### ***Acute Toxicity to Fish***

***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

Golden orfe (*Leuciscus idus*. 10/concentration) were exposed to nominal concentrations of 0, 1000, 2150, 4640 or 10,000 mg/L (approximately 0, 400, 860, 1856 or 4000 mg/L based on 40% active ingredient) under static conditions for 96 hours. The mortality rates at 96 hours were 0/10, 5/10, 10/10 and 10/10 at the 1000, 2150, 4640 and 10,000 mg/L, respectively.

**96-h LC<sub>50</sub> = 880 mg/L**

##### ***Acute Toxicity to Aquatic Invertebrates***

***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

Water fleas (*Daphnia magna*, five replicates of four daphnia per concentration) were exposed to nominal concentrations of 0, 62.5, 125, 250 or 500 mg/L (approximately 0, 25, 50, 100 or 200 mg/L based on 40% active ingredient) under static conditions for 48 hours. None of the organisms died or exhibited signs of toxicity.

**48-h EC<sub>50</sub> > 200 mg/L**

### *Toxicity to Aquatic Plants*

#### ***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)-, methylated (CASRN 68411-81-4)***

Green algae (*Scenedesmus subspicatus*) were exposed to the test substance (76.3%) at nominal concentrations of 7.2, 15.4, 33.2, 71.5 or 154.0 mg/L for 72 hours. The mean measured concentrations were 22.0, 53.4 and 167.0 mg/L for the 33.2, 71.5 and 154.0 mg/L, respectively. The values below are based on 100% active material.

**72-h EC<sub>50</sub> (biomass) = 146.3 mg/L**

**72-h EC<sub>50</sub> (growth) > 167 mg/L**

#### ***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

(1) Green algae (*Scenedesmus subspicatus*) were exposed to the test substance at nominal concentrations of 7.81, 15.63, 31.25, 62.5, 125, 250 or 500 mg/L (40% active ingredient) under static conditions for 72 hours. The percent cell density with respect to control was 98.5, 102, 55.2, 26.4, 12.5, 3.26 and 0 for the 7.81, 15.63, 31.25, 62.5, 125, 250 and 500 mg/L concentrations, respectively. Based on 100% active ingredient, the EC<sub>50</sub> was 14.76 mg/L

**72-h EC<sub>50</sub> (biomass) = 14.8 mg/L**

(2) Green algae (*Scenedesmus subspicatus*) were exposed to the test substance at nominal concentrations of 7.81, 15.63, 31.25, 62.5, 125, 250 or 500 mg/L of a test substance (40% active ingredient) under static conditions for 96 hours. The percent cell density with respect to control was 86, 91.8, 40.8, 10.7, 3.79, 0.38 and -0.05 for the 7.81, 15.63, 31.25, 62.5, 125, 250 and 500 mg/L concentrations, respectively. Based on 100% active ingredient, the EC<sub>50</sub> was 11.36 mg/L.

**96-h EC<sub>50</sub> (biomass) = 11.4 mg/L**

### *Chronic Toxicity to Aquatic Invertebrates*

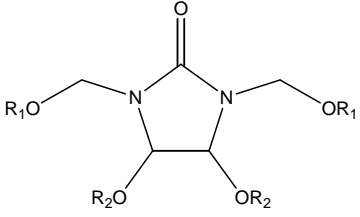
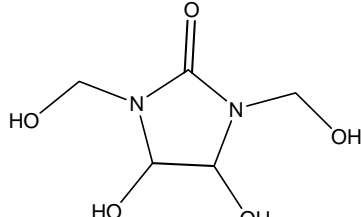
#### ***2-Imidazolidinone, 4,5-dihydroxy-1,3-bis(hydroxymethyl)- (CASRN 1854-26-8, Supporting Chemical)***

Water fleas (*D. magna*) were exposed to the test substance (70% active ingredient) at nominal concentrations ranging from 0.2 to 100 mg/L under static renewal conditions for 21 days. No other information was provided.

**21-d NOEC ≥ 100 mg/L**

**Conclusion:** The acute hazard to fish and aquatic invertebrates is based on the toxicity values for the supporting chemical CASRN 1854-26-8, of 880 mg/L and >200 mg/L, respectively. The acute hazard to aquatic plants is based on the toxicity value for CASRN 68411-81-4 of 146.3 mg/L (biomass). The chronic hazard to aquatic invertebrates is based on the toxicity value for the supporting chemical, CASRN 1854-26-8, of ≥ 100 mg/L.

**Table 3. Summary Table of the Screening Information Data Set  
as Submitted under the U.S. HPV Challenge Program**

Endpoints	SPONSORED CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy- 1,3-bis(hydroxymethyl)-, methylated (CASRN 68411-81-4)	SUPPORTING CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy- 1,3-bis(hydroxymethyl)- (CASRN 1854-26-8)
Structure	 <p style="text-align: center;">R1 = H or CH3; R2 = H or CH3</p>	
<b>Summary of Human Health Data</b>		
Acute Oral Toxicity LD <sub>50</sub> (mg/kg-bw)	No data > 10,000 (RA)	> 10,000
Acute Inhalation Toxicity LC <sub>50</sub> (mg/L)	No data > 3.0 (RA)	> 3.0
Repeated-Dose Toxicity NOAEL/LOAEL Oral (mg/kg-bw/day)	No data (rat) NOAEL = 3000 LOAEL = 6000 (RA)  (mouse) NOAEL = 6000 (hdt) (RA)	(rat) NOAEL = 3000 LOAEL = 6000  (mouse) NOAEL = 6000 (hdt)
Reproductive Toxicity NOAEL/LOAEL Oral (mg/kg-bw/day)	No data No effects were seen following evaluation of reproductive organs in a 13-wk oral repeated-dose toxicity study in mice; mineralization of testes in a rat (RA)	No effects were seen following evaluation of reproductive organs in a 13-wk oral repeated-dose toxicity study in mice; mineralization in testes of a rat
Developmental Toxicity NOAEL/LOAL Oral (mg/kg-bw/day) Maternal/Developmental Toxicity	No data NOAEL = 640 (hdt) (RA)	NOAEL = 640 (hdt)
Genetic Toxicity – Gene Mutation <i>In vitro</i>	No data Positive (RA)	Positive
Genetic Toxicity – Chromosomal Aberrations <i>In vivo</i>	No data Negative (RA)	Negative

**Table 3. Summary Table of the Screening Information Data Set  
as Submitted under the U.S. HPV Challenge Program**

Endpoints	SPONSORED CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy- 1,3-bis(hydroxymethyl)-, methylated (CASRN 68411-81-4)	SUPPORTING CHEMICAL 2-Imidazolidinone, 4,5-dihydroxy- 1,3-bis(hydroxymethyl)- (CASRN 1854-26-8)
<b>Summary of Environmental Effects – Aquatic Toxicity Data</b>		
<b>Fish</b> 96-h LC <sub>50</sub> (mg/L)	No data 880 (RA)	<b>880</b>
<b>Aquatic Invertebrates</b> 48-h EC <sub>50</sub> (mg/L)	No data > 200 (RA)	<b>&gt; 200</b>
<b>Aquatic Plants</b> 72-h EC <sub>50</sub> (mg/L) (growth) (biomass)	>167 <b>146.3</b>	<b>14.8</b>
<b>Chronic Toxicity to Invertebrates</b> 21-day EC <sub>50</sub> (mg/L)	No data NOEC ≥ 100 (RA)	<b>NOEC ≥ 100</b>

Measured data in bold text; (RA) = read across; (hdt) = highest dose tested