

16-July-2001

AR201-13124A

2001 JUL 20 PM 1:46

RECEIVED  
OPPT/MSID

## ROBUST SUMMARY FOR 1,1-DIFLUOROETHANE

### Summary.

1,1-Difluoroethane (HFC- 152a) is expected to exist solely in the vapor-phase in the ambient atmosphere. Vapor-phase HFC- 152a is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals with an atmospheric half-life of about 472 days. The long atmospheric lifetime of this chemical suggests that some HFC-152a is expected to gradually diffuse into the stratosphere above the ozone layer where it will slowly degrade due to direct photolysis from UV-C radiation. In water, HFC-152a is not expected to adsorb to sediment or particulate matter and it is expected to volatilize rapidly from water surfaces. Estimated half-lives for a model river and model lake are 2 and 77 hours, respectively. Bioconcentration is expected to be low based upon an estimated BCF value of 2. Highly chlorinated/fluorinated compounds are not expected to biodegrade rapidly (Boethling et al., 1994), thus, biodegradation is not expected to be an important environmental fate process (HSDB, 2000). Since no test data are available, further evaluation is needed for confirmation.

HFC- 152a is a gas at room temperature and has low acute toxicity in the mammalian systems evaluated via inhalation. The inhalation studies were conducted using Good Laboratory Practices (GLP) and demonstrate that HFC-152a behaves similarly to other structurally similar fluorocarbons. In addition to the acute inhalation toxicity studies, a 2-year inhalation study with a 3-month interim sacrifice was conducted with HFC-152a. No significant toxicological effects were observed at the 3-month sacrifice and no histopathological or weight effects on reproductive organs of either male or female rats were observed in the 2-year bioassay. HFC-152a was not a developmental toxicant in a rat developmental toxicity study. HFC-152a was not mutagenic in the *in vitro* bacterial reverse mutation test (Ames test) in *Salmonella typhimurium* and *Escherichia coli* strains. However, HFC- 152a showed evidence of weak clastogenicity in an *in vitro* human lymphocyte chromosome aberration test. Further evaluation of the chromosome aberration potential using an *in vivo* micronucleus test produced negative results.

No ecotoxicological studies have been conducted with HFC- 152a and there is very little or no ecotoxicology data for similar non-chlorinated, fluorocarbon compounds. Modeling of several physical-chemical parameters, fate processes, and aquatic toxicity was conducted to help provide insight into the behavior in the environment and the aquatic toxicity of a homologous series of 4 fluorocarbon compounds (HFC-152a, HFC- 134a, HFC- 125, and hexafluoroethane).

Syracuse Research Corporation models for estimating physical-chemical properties and fate processes were used to estimate  $\log_{10}$  Kow (Meylan and Howard, 1995), water solubility at 25°C (Meylan and Howard, 1996), Henry's Law Constant (Meylan and Howard, 1991), and ultimate biodegradation (Boethling et al., 1994). The dominant fate

16-July-2001

process controlling distribution of these compounds in the environment is volatilization (Mackay et al., 1996).

Compound	log <sub>10</sub> Kow (Estimated)	Water Solubility	Henry's Law Constant	Ultimate Degradation
HFC- 152a (C <sub>2</sub> H <sub>4</sub> F <sub>2</sub> )	<b>1.13</b>	<b>2671</b> mg/L	3.5E-01 atm-m <sup>3</sup> /mole	Weeks
HFC-134a (C <sub>2</sub> H <sub>2</sub> F <sub>4</sub> )	<b>1.68</b>	<b>768</b> mg/L	1.5E00 atm-m <sup>3</sup> /mole	Weeks- months
HFC-125 (C <sub>2</sub> HF <sub>5</sub> )	1.55	<b>867</b> mg/L	3.1 E00 atm-m <sup>3</sup> /mole	Weeks- months
Hexafluoroethane (C <sub>2</sub> F <sub>6</sub> )	2.15	<b>223</b> mg/L	2.4E+01 atm-m <sup>3</sup> /mole	Months

ECOSAR (Meylan and Howard, 1999) was used to predict the aquatic toxicity of the 4 fluorocarbon compounds to green algae, daphnids (planktonic freshwater crustaceans), and fish. ECOSAR predictions are based on actual toxicity test data for classes of compounds with similar modes of action, i.e., narcosis in the case of fluorocarbons. Predicted log<sub>10</sub> Kow values were used as input for the ECOSAR model. To help gauge the sensitivity of the prediction to this parameter, ECOSAR predictions were made using 2 Kow values. The initial Kow value was based on the estimated value from the Syracuse Research Corporation model except for the measured value of 0.75 for HFC-152a (Jow and Hansch, 1995). The second Kow value was empirically selected to be approximately log<sub>10</sub> 0.5 greater than the initial measured or estimated value.

Compound	log <sub>10</sub> Kow	Algae, 96-hr EC <sub>50</sub> (mg/L)	Daphnid, 48-hr EC <sub>50</sub> (mg/L)	Fish, 96-hr LC <sub>50</sub> (mg/L)
<b>HFC-152a</b> <b>(C<sub>2</sub>H<sub>4</sub>F<sub>2</sub>)</b>	<b>0.75*</b>	<b>419</b>	<b>720</b>	<b>733</b>
HFC-134a (C <sub>2</sub> H <sub>2</sub> F <sub>4</sub> )	1.5	140	231	223
HFC-125 (C <sub>2</sub> HF <sub>5</sub> )	2.0	51	81	76
HFC-125 (C <sub>2</sub> HF <sub>5</sub> )	1.5	165	272	263
HFC-125 (C <sub>2</sub> HF <sub>5</sub> )	2.0	60	95	89
Hexafluoroethane (C <sub>2</sub> F <sub>6</sub> )	2.0	69	110	102
Hexafluoroethane (C <sub>2</sub> F <sub>6</sub> )	2.5	25	38	35

\* measured value

The only actual test data available are for HFC-134a. Results of aquatic testing of this compound with daphnids and fish indicated that the daphnid 48-hour EC<sub>50</sub> was 980 mg/L and the 96-hour fish LC<sub>50</sub> was 450 mg/L (Stewart and Thompson, 1991; Thompson,

**16-July-2001**

1991). Based on the ECOSAR predictions, the actual toxicity test data, and the high Henry's Law Constant for these compounds, HFC-152a is unlikely to represent an unacceptable risk to aquatic organisms or wildlife.

Emissions from HFC- 152a manufacturing facilities are small and industrial hygiene monitoring data during manufacture and industrial use show exposure to be well under acceptable exposure limits. Though consumer exposure has not been measured directly, modeling based on measurement of similar uses shows consumer exposure to be minimal during intended uses. Due to its low toxicity and low exposure potential, HFC-152a does not represent an unacceptable risk to human health or the environment. Although many of the studies available for HFC- 152a were conducted prior to implementation of the OECD Guidelines, much of the data available are scientifically valid. While a specific guideline reproductive toxicity test was not conducted, histopathological evaluation and organ weight measurements were made on reproductive organs during the 2-year inhalation study.

**References for the Summary:**

Boethling, R. S. et al. (1994). Environ. Sci. Technol., 28:459-465 (BIOWIN Software available from Syracuse Research Corp., Environmental Science Center, Syracuse, NY 13210).

HSDB (2000). Hazardous Substance Data Bank (HSDB/5205).

Jow, P. and Hansch, C. (n.d.). Pomona College, unpublished analysis (cited in Hansch, C. and A. Leo (1995). Exploring QSAR Fundamentals and Applications in Chemistry and Biology, Amer. Chem. Soc., Washington, DC).

Mackay, D. et al. (1996). Environ. Toxicol. Chem., 15(9):1627-1637.

Meylan, W. M. and P. H. Howard (1991). Environ. Toxicol. Chem., 10:1283-1293 (HENRYWIN Software available from Syracuse Research Corp., Environmental Science Center, Syracuse, NY 13210).

Meylan, W. M. and P. H. Howard (1995). J. Pharm. Sci., 84:83-92.

Meylan, W. M. and P. H. Howard (1996). Environ. Toxicol. Chem., 15:100-106.

Meylan, W. M. and P. H. Howard (1999). User's Guide for the ECOSAR Class Program, Version 0.993 (Mar 99), prepared for J. Vincent Nabholz and Gordon Cas, U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics, Washington, DC, prepared by Syracuse Research Corp., Environmental Science Center, Syracuse, NY 132 10 (submitted for publication).

**16-July-2001**

Stewart, K. M. and R. S. Thompson (1991). ICI Group Environmental Laboratory Report No. BL3908/B, ICI, UK (cited in Berends, A. G. et al. (1999). Arch. Environ. Contam. Toxicol., 36(2): 146-15 1).

Thompson, R. S. (199 1). ICI Group Environmental Laboratory Report No. BL4035/B, ICI, UK (cited in Berends, A. G. et al. (1999). Arch. Environ. Contam. Toxicol., 36(2):146-151).

16-July-2001

TEST PLAN FOR 1,1-DIFLUOROETHANE

1,1-Difluoroethane (HFC-152a) CAS No. 75-37-6	Data Available	Data Acceptable	Testing Required
	Y/N	Y/N	Y/N
<b>PHYSICAL/CHEMICAL CHARACTERISTICS</b>			
Melting Point	Y	Y	N
Boiling Point	Y	Y	N
Vapor Pressure	Y	Y	N
Partition Coefficient	Y	Y	N
Water Solubility	Y	Y	N
<b>ENVIRONMENTAL FATE</b>			
Photodegradation	Y	Y	N
Stability in Water	Y	Y	N
Transport (Fugacity)	Y	Y	N
Biodegradation	N	N	Y
<b>ECOTOXICITY</b>			
Acute Toxicity to Fish	Y	Y	N
Acute Toxicity to Invertebrates	Y	Y	N
Acute Toxicity to Aquatic Plants	Y	Y	N
<b>MAMMALIAN TOXICITY</b>			
Acute Toxicity	Y	Y	N
Repeated Dose Toxicity	Y	Y	N
Developmental Toxicity	Y	Y	N
Reproductive Toxicity	Y	Y	N
Genetic Toxicity Gene Mutations	Y	Y	N
Genetic Toxicity Chromosomal Aberrations	Y	Y	N