FEB - 2 2009

DuPont Fluoroproducts
Fluorochemicals Lab
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January 26, 2009

National Organic Standards Board
Program Manager
USDA/AMS/TM/NOP
Room 4008 South
Ag Stop 0268
1400 Independence Avenue, SW
Washington, DC 20250

Dear Sir/Madam:

DuPont Fluoroproducts respectfully submits the attached petition to the National Organic Standards Board for the inclusion of aerosol propellant 1,1, difluoroethane (DFE) on the National List for the National Organic Program.

Addition of DFE will allow aerosol products approved for NOP use to be formulated with an environmentally beneficial propellant.

This petition was prepared according to the guidelines provided in the Federal Register notice of January 18, 2007, Vol. 72, No. 11, Page 2167.

Please contact me if there are any questions.

Sincerely,

Joseph Creazzo
Senior Technical Service Consultant
302-999-4167
joseph.a.creazzo@usa.dupont.com

JC/paf
Attachment

FEB - 2 2009

Petition to the National Organic Standards Board (NOSB) for 1,1 Difluoroethane (DFE or HFC-152a)

Item A—Please indicate which section or sections the petitioned substance will be included on and/or removed from the National List.

Ξ Synthetic substances allowed for use in organic crop production, § 205.601.
□ Non-synthetic substances prohibited for use in organic crop production, § 205.602.
□ Synthetic substances allowed for use in organic livestock production,§ 205.603.
□ Non-synthetic substances prohibited for use in organic livestock production, § 205.604.
□ Non-agricultural (non-organic) substances allowed in or on processed products labeled as ''organic'' or ''made with organic (specified ingredients),''§ 205.605.
□ Non-organic agricultural substances allowed in or on processed products labeled as ''organic,'' § 205.606.

Item B—Please provide concise and comprehensive responses in providing all of the following information items on the substance being petitioned:

1. The substance's chemical or material common name.

1,1 Difluoroethane (DFE)

2. The manufacturer's or producer's name, address and telephone number and other contact information of the manufacturer/producer of the substance listed in the petition.

Manufacturer

DuPont Fluoroproducts
Chestnut Run Plaza
P.O. Box 80702
Wilmington, DE 19880-0702

Contact
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3. The intended or current use of the substance such as use as a pesticide, animal feed additive, processing aid, nonagricultural ingredient, sanitizer or disinfectant. If the substance is an agricultural ingredient, the petition must provide a list of the types of product(s) (*e.g.*, cereals, salad dressings) for which the substance will be used and a description of the substance's function in the product(s) (*e.g.*, ingredient, flavoring agent, emulsifier, processing aid).

1,1 Difluoroethane is a propellant intended for use as an inert ingredient in many different aerosol product formulations. The current petition is being made in order to clear this material as an inert ingredient for use in U.S. EPA registered pesticide formulations that contain active ingredients approved for use under the National Organic Program (NOP). As a propellant, 1,1 difluoroethane will function to dispense active ingredients from the container to the application site in order to control crop pests.

4. A list of the crop, livestock or handling activities for which the substance will be used. If used for crops or livestock, the substance's rate and method of application must be described. If used for handling (including processing), the substance's mode of action must be described.

As a propellant, 1,1 difluoroethane generates the pressure in a container that dispenses active ingredients for pest control. 1,1 difluoroethane would be a component of crop protection products that would be used on crops for which the products' organically approved active ingredients are intended. This petition requests listing 1,1 difluoroethane as a synthetic substance allowed for use in organic crop production, including application to field and row crops, perennial fruit and nut crops, greenhouse and nursery crops and any other organic agricultural or horticultural crop.

Aerosol products would typically use about 10-55% propellant in their formulations. The application method dispenses product from aerosol canisters that are loaded with NOP approved organic active ingredients and any other necessary NOP approved inert ingredients, and then charged with propellant. The canisters are employed to project the product onto crops to be protected from insect, disease or weed pests. As the lowest-boiling formulation component, any propellant that dispenses with the product immediately volatilizes, minimizing any amount that may contact or remain with the treated crops.

5. The source of the substance and a detailed description of its manufacturing or processing procedures from the basic component(s) to the final product. Petitioners with concerns for confidential business information may follow the guidelines in the Instructions for Submitting CBI listed in #13.

1,1 difluoroethane is synthetically manufactured via catalytic reaction of a chlorocarbon feedstock with hydrofluoric acid. The final product is neutralized with a caustic solution, dried to remove moisture, and distilled to remove impurities to a purity level of 99.9% +.

6. A summary of any available previous reviews by State or private certification programs or other organizations of the petitioned substance. If this information is not available, the petitioner should state so in the petition.

None

7. Information regarding EPA, FDA, and State regulatory authority registrations, including registration numbers. If this information does not exist, the petitioner should state so in the petition.

1,l-Difluoroethane, CAS # 75-37-6, was granted two exemptions from the requirement of a tolerance for an inert ingredient. The exemptions are established in 40 CFR part 180.910 [formerly 40 CFR180.1001 (c)] and in 40 CFR part 180.930 [formerly 40 CFR180.1001 (e)].

1,l-Difluoroethane, CAS # 75-37-6, is also approved by the U.S. FDA for use as a blowing agent in the manufacture of polystyrene foamed plastics intended for use in contact with food, as listed in 21 CFR 178-3010.

8. The Chemical Abstract Service (CAS) number or other product numbers of the substance and labels of products that contains the petitioned substance. If the substance does not have an assigned product number, the petitioner should state so in the petition.

CAS # 75-37-6

9. The substance's physical properties and chemical mode of action including (a) Chemical interactions with other substances, especially substances used in organic production; (b) toxicity and environmental persistence; (c) environmental impacts from its use and/ or manufacture; (d) effects on human health; and, (e) effects on soil organisms, crops, or livestock.

DFE is used as a propellant in aerosol products and is considered an inert ingredient in these applications. See attached Technical Information Bulletin ATB-29 "Dymel® 152a".

10. Safety information about the substance including a Material Safety Data Sheet (MSDS) and a substance report from the National Institute of Environmental Health Studies. If this information does not exist, the petitioner should state so in the petition.

MSDS attached. There is no report from the National Institute of Environmental Health Studies.

11. Research information about the substance which includes comprehensive substance research reviews and research bibliographies, including reviews and bibliographies which present contrasting positions to those presented by the petitioner in supporting the substance's inclusion on or removal from the National List. For petitions to include non-organic agricultural substances onto the National List, this information item should include research concerning why the substance should be permitted in the production or handling of an organic product, including the availability of organic alternatives. Commercial availability does not depend upon geographic location or local market conditions. If research information does not exist for the petitioned substance, the petitioner should state so in the petition.

No research of this type exists for 1,1-Difluoroethane

12. A ''Petition Justification Statement'' which provides justification for any of the following actions requested in the petition:

A. Inclusion of a Synthetic on the National List, §§ 205.601, 205.603, 205.605(b)

□ Explain why the synthetic substance is necessary for the production or handling of an organic product.

Crop protection is an important aspect of growing food and fiber. Aerosol application of organically approved active ingredients is an advantageous method of delivering active ingredients to applicable use sites for crop protection. Aerosol products are currently used in many different cropping systems. This petition calls for approval of 1,1 difluoroethane as a synthetic substance allowed for use in organic crop production. This substance is efficacious as a propellant, cost effective, and provides an environmentally positive option as a propellant for crop protection products that are applied as aerosols. With increasing global warning concerns, 1,1 difluoroethane offers the advantage of low global warming potential without contributing to ground-level smog and ozone formation.

□ Describe any non-synthetic substances, synthetic substances on the National List or alternative cultural methods that could be used in place of the petitioned synthetic substance.

There are no non-synthetic liquefied gas propellants.

With respect to other listed substances, 1,1,1,2-tetrafluoroethane (CAS No. 811-97-2), n-butane (CAS No. 106-97-8) and dimethylether (CAS No. 115-10-6) are on the U.S. EPA's most current (August 2004) List 4B Inert Ingredient List. The disadvantage for 1,1,1,2-tetrafluoroethane is it's global warming potential, which is over 11 times higher than 1,1-difluoroethane's (1430 versus 124, respectively). The disadvantage for n-butane and dimethylether is that they contribute to ground-level smog and ozone formation, and are regulated as "volatile organic compounds" (VOCs).

□ Describe the beneficial effects to the environment, human health, or farm ecosystem from use of the synthetic substance that support its use instead of the use of a non-synthetic substance or alternative cultural methods.

See attached EPA report addressing "Reassessment of the Two Exemptions from the Requirement of a Tolerance for 1,1–Difluoroethane"

In addition to low toxicity, 1,1 Difluoroethane has very well balanced environmental properties. As a fluorochemical, it has zero ozone depletion potential, very low global warming potential, and an atmospheric lifetime that precludes it from contributing to ground level ozone formation or local air quality issues.

DUPONT

Dymel®

aerosol propellents

Dymel 152a Hydrofluorocarbon 152a

Fluorochemicals Laboratory
E. I. duPont de Nemours and Company

Introduction

Hydrofluorocarbon 152a (HFC-152a) is an aerosol propellant containing no chlorine atoms, and as such, falls completely outside concerns about stratospheric ozone destruction by chlorofluorocarbons or other chlorinated hydrocarbons. It has an Ozone Depletion Potential of 0.00 and the U.S. Environmental Protection Agency has found it is *not* a Volatile Organic Compound (VOC), i.e., it has negligible photochemical reactivity (55 FR 11418). DuPont's registered trademark for HFC-152a is Dymel 152a.

Dymel 152a can be used alone or mixed with other common aerosol propellants in a wide range of personal or industrial product categories where the product is dispensed as a spray, e.g., hair spray, cologne, deodorant, etc. Dymel 152a also produces excellent foams or mousses and is used in a number of commercial aerosol foam products, e.g., hair styling and skin conditioning mousses.

There has been recent renewed interest in Dymel 152a as a result of state regulations to limit VOC emissions from a wide range of consumer products including aerosol products. Dymel 152a propellant may offer options to meet these regulations in paints, adhesives and other aerosol products including personal products, e.g., hair spray.

The vapor pressure of Dymel 152a is 63 psig at 70°F (4.16 bar at 20°C) which is close to that of CFC-12 or dimethyl ether; furthermore, its low molecular weight (66.1) means that a low weight percent of propellant is generally required to produce an acceptable degree of atomization. A similar argument has been used to describe the advantages of hydrocarbon propellants, however Dymel 152a has several physical properties which make it superior to the hydrocarbon propellants for certain applications.

Dymel 152a has an LEL (lower explosive limit) of 3.9 volume percent in air and it does not give a flame extension or flashback in the standard test used to measure the flammability of aerosol products. Isobutane, on the other hand, has an LEL of 1.8 volume percent in air, and gives a flame extension of greater than 22 inches where sprayed through a typical antiperspirant valve. As a result, Dymel 152a and Dymel 152a/hydrocarbon blends can be used to produce aerosol formulations possessing a lower degree of flammability than their hydrocarbon-propelled counterparts. This may be an advantage in products with high propellant levels, e.g., antiperspirants.

Dymel 152a forms azeotropes with each of the three most common hydrocarbon propellants and with Dymel A (dimethyl ether). The use of a Dymel 152a/hydrocarbon or Dymel 152a/Dymel A propellant blend whose composition will not change during use of the aerosol product represents still another attractive alternative.

The liquid density of Dymel 152a is 0.91 g/cc at 70°F (21.1°C) compared to 0.56 g/cc for isobutane. This difference makes it possible to obtain reduced settling rates in products containing suspended solids, improvements in emulsion stability with aqueous-based products, and greater product net

weights for equivalent container sizes compared with hydrocarbon-based formulations. It is completely miscible with most organic liquids and other active ingredients used in aerosol formulations and has a very low taste and odor level. Furthermore, the solubility of Dymel 152a in water and its strong resistance to hydrolysis allow its use in a variety of water-based products as well. Several unique formulation possibilities (e.g., quick-breaking foams, hair styling mousses) have already been demonstrated.

Toxicological evaluations have demonstrated that Dymel 152a has a very low order of acute and chronic inhalation toxicity. The compound is not a mutagen, teratogen or carcinogen. DuPont's workplace exposure limit (AEL) for it is 1000 ppm.

Contents

Table 1
Physical Properties of Dymel 152a

Formula	CH_3CHF_2
Molecular Weight	66.1
Boiling Point, °F	–13
Vapor Pressure, psig	
70°F	63
130°F	177
Vapor Pressure, bar	
20°C	4.16
50°C	10.86
Liquid Density, g/cc	
70°F	0.908
130°F	0.816
20°C	0.911
50°C	0.830
Solubility in Water at 1 atm and 77°F (25°C), wt %	0.28
Kauri-Butanol Value	11
Solubility Parameter	7
Liquid Viscosity at 70°F (21.1°C), cp	0.243
Flammability Limits in Air, vol %	3.9–16.9
Tag. Open Cup Flash Point	<–58°F (<–50°C)
Ozone Depletion Potential	0
Global Warming Potential (100 yr. Integrated Time Horizon)	140
Volatile Organic Compound	No

Toxicity Summary of Hydrofluorocarbon 152a

Hydrofluorocarbon 152a has a low order of toxicity on both an acute and chronic basis. Although a TLV® has not been established for HFC-152a, a value of 1,000 ppm (v/v; 8-hour TWA) seems appropriate based on its low toxicity and analogy to other fluorocarbons.

The main physiological action of HFC-152a is that of "weak anesthesia" at high inhaled levels. Its 4-hour Approximate Lethal Concentration (ALC) in rats is 383,000 ppm[1]. Like other halocarbons and hydrocarbons, under gross misuse or abuse conditions, HFC-152a is capable of sensitizing the heart to the body's own adrenalin. However, even in experimental screening studies using dogs and simulating stress with a large intravenous dose of adrenalin, cardiac sensitization was not observed at exposure levels below 150,000 ppm[2].

In a subchronic inhalation study[3], rats were exposed to HFC-152a at 100,000 ppm for 16-hours daily for 2 months with no adverse effects except for microscopic evidence of slight respiratory irritation. In a more recent study[1], when rats were exposed at 100,000 ppm for 6 hours/day, 5 days/week for 2 weeks, there were no significant effects relative to clinical, hematological, blood chemistry, urine analytical, or histopathological indices.

A lifetime inhalation toxicity study[4] has also been conducted on HFC-152a. Rats (120 #/sex/exposure level) were exposed for 6 hours/day, 5 days/week for 24 months to 0, 2,000 10,000 or 25,000 ppm. Under the conditions of this experimental study, HFC-152a was not carcinogenic and produced no lifeshortening toxic effects in rats exposed by inhalation for 24 months at concentrations ≤25,000 ppm (v/v).

In a study[5] designed to determine reproductive toxicity potential, groups of 27 pregnant rats were exposed by inhalation to 5,000 or 20,000 ppm HFC-152a for 6 hours/day on days 6–15 of gestation. There was no evidence of maternal toxicity, embryotoxicity, or teratogenicity under these experimental conditions. In another study[6] (Ames Test) designed to screen for mutagenic potential, HFC-152a was not mutagenic in *Salmonella typhimurium* bacteria, with or without metabolic activation.

In conclusion, based on acute and chronic animal toxicity studies and many years of human experience, HFC-152a at or below an occupational limit (8-hour TWA) of 1,000 ppm should pose no hazard relative to general toxicity, carcinogenicity, mutagenicity or teratogenicity. This fluorocarbon exhibits a very low degree of reactivity in biological system.

Glossary

TLV: Threshold Limit Value

TWA: Time Weighted Average

v/v: volume/volume

ppm: parts per million

References

1. Unpublished DuPont Haskell Laboratory Data, 1975.
2. Reinhardt, C. F., et al. *Arch. Environ. Hlth. 22:* 265–269, 1971.
3. Lester, D., and L. A. Greenberg. *Arch. Ind. Hyg. Occup. Med. 2:* 335-344, 1950.
4. Unpublished DuPont Haskell Laboratory Data, 1982.
5. Unpublished DuPont Haskell Laboratory Data, 1979.
6. Logstaff, E., et al. *Toxicol. Appl. Pharmacol. 72:* 15–31, 1984.

Figure 1. Saturated Vapor Pressure of Dymel 152a

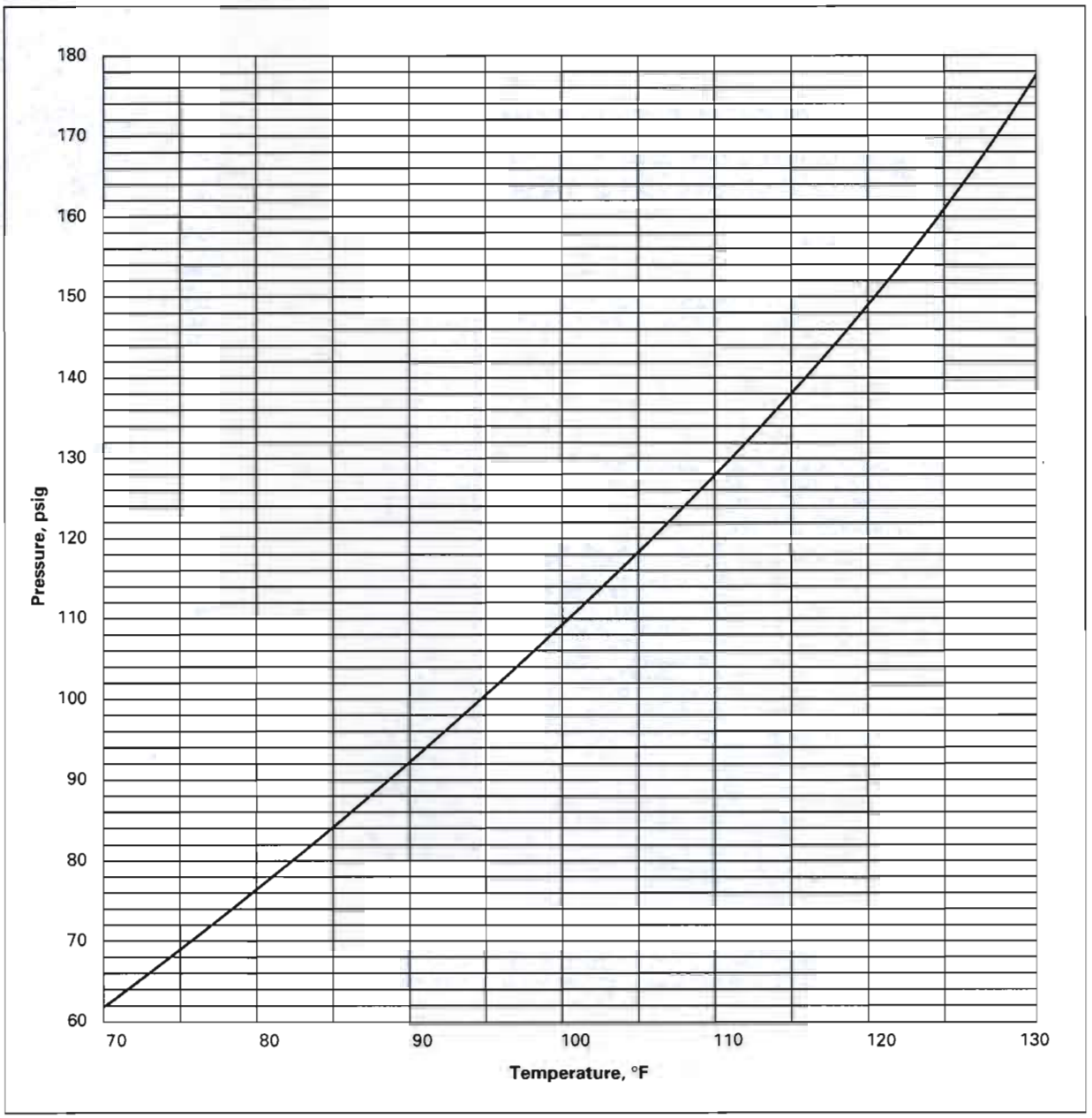
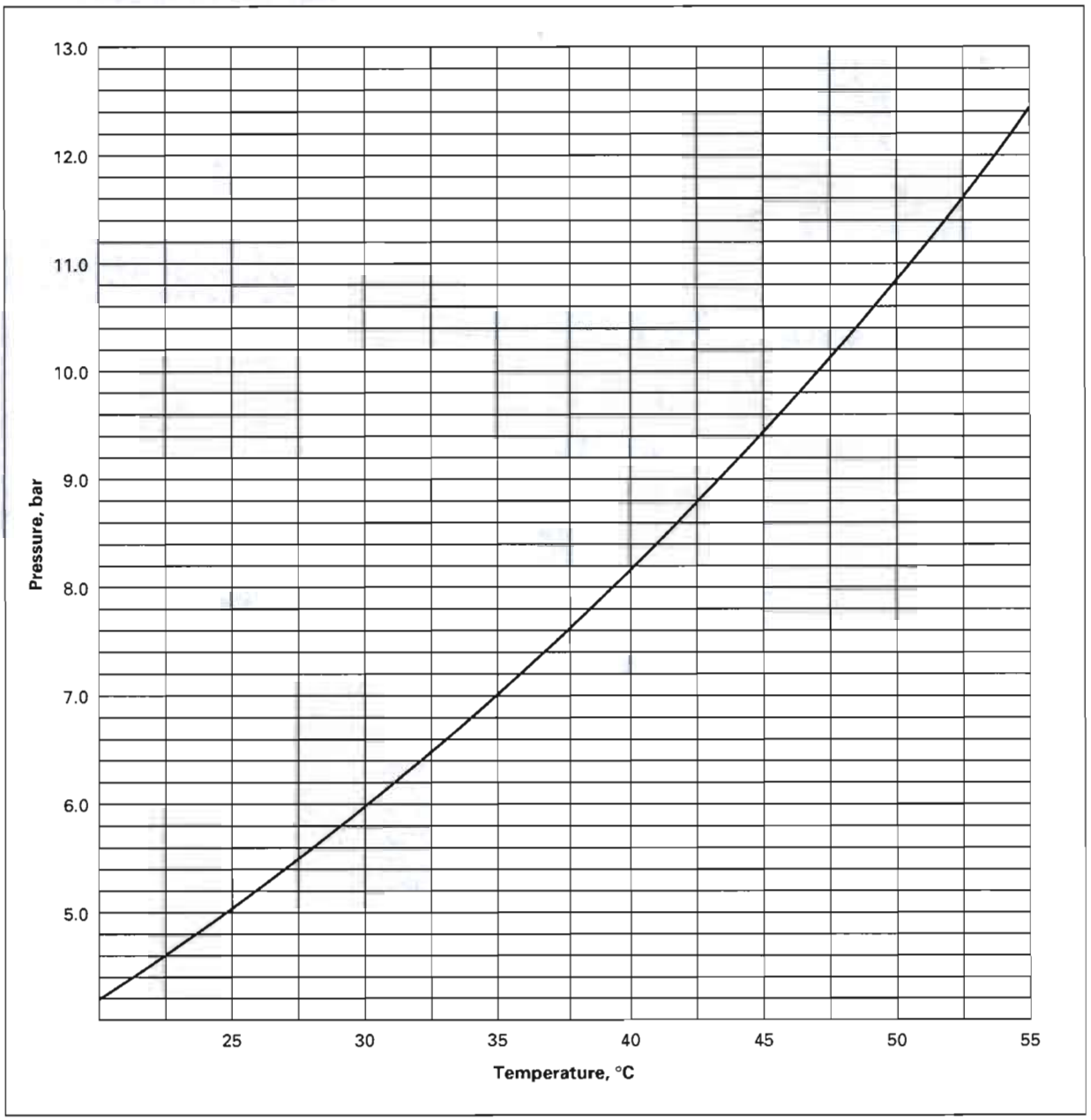


Figure 2. Saturated Vapor Pressure of Dymel 152a



Triangular-Coordinate Charts

The following triangular-coordinate charts are available from the Fluorochemicals Laboratory. They provide vapor pressure data at 70°F (21.1°C) for each of the ternary mixtures listed below:

Components
Dymel 152a/Propane/Isobutane
Dymel 152a/n-Butane/Ethanol
Dymel 152a/Isobutane/Ethanol
Dymel 152a/Ethanol/Water
Dymel 152a/Ethanol/Dymel A
Dymel 152a/Ethanol/Dymel 134a

Stability/Compatibility of Dymel 152a

Dymel 152a is a relatively inert chemical. It does not undergo reaction with the solvents commonly used in aerosol formulations, e.g., ethanol, chlorocarbons, hydrocarbon solvents, etc. It is also very stable to hydrolysis, especially under alkaline conditions. It is a propellant in several water-based commercial hair styling mousse formulations packaged in aluminum containers. Although no stability problems resulting from the use of Dymel 152a as a propellant are anticipated, formulations should be thoroughly tested prior to marketing them to ensure this is the case.

Dymel 152a is compatible with a wide range of elastomers and plastics. As an example, Buna N, butyl or Neoprene gasketing materials can be used with it. However, like many other fluorochemicals, Dymel 152a is not compatible with Viton®. It does not craze or attack the plastics commonly used in the aerosol industry. Compatibility tests have been run with several plastics that are prone to attack by solvents and propellants. The results are presented below:

Table 2
Compatibility of Selected Plastics with Dymel 152a

Plastic	Four hours at 75°F (23.9°C)
ABS Polymer	0
Polycarbonate	0
Polymethyl methracrylate	0
Polystyrene	0

Codes:

0 = Suitable for use in contact with Dymel 152a
1 = Probably suitable for use
2 = Probably not suitable for use
3 = Not suitable for use
4 = Plastic disintegrated or dissolved in liquid

Binary Azeotropes of Dymel 152a

Table 3
Binary Azeotropes of Dymel 152a with Hydrocarbon and Dimethyl Ether Propellants

		Vapor Pressure			
		psig		bar	
Azeotrope	Composition	70°F*	130°F	21.1°C	54.4°C
Dymel 152a/Propane	45/55	130	295	8.96	20.34
Dymel 152a/Isobutane	75/25	72	190	4.96	13.10
Dymel 152a/n-Butane	85/15	68	180	4.69	12.41
Dymel 152a/Dymel A	55/45	61	169	4.21	11.65

* *Handbook of Aerosol Technology*, 2nd Ed., P. A. Sanders.

Note 1: The composition of an azeotrope varies with temperature. The values given are average values over the temperature range 70°F–130°F (21.1°C–54.4°C)

Note 2: *"The Aerosol Handbook,"* 2nd Ed., M. A. Johnsen gives the composition of the HFC-152aa/propane azeotrope as 79/21, respectively.

Table 4
Spray Characteristics of Blends of Dymel 152a with Ethanol and Water

Composition, wt %			Vapor Pressure		
Dymel 152a	Water	EtOH	psig @ 70°F	bar @ 21.1°C	Spray Characteristic*
72	—	28	50	3.45	Fine
45	—	55	40	2.76	Fine
45	9	46	50	3.45	Fine
30	—	70	30	2.07	Medium
30	10	60	40	2.76	Medium
30	20	50	50	3.45	Medium
21.5	—	78.5	20	1.38	Coarse
21.5	11.5	67	30	2.07	Coarse
21.5	19.5	59	40	2.76	Coarse
21.5	29	48.5	50	3.45	Coarse/Streamy
10	25	65	20	1.38	Streamy
10	34	56	30	2.07	Streamy
10	40	50	40	2.76	Streamy
5	38.5	56.5	20	1.38	Stream
5	47	48	30	2.07	Stream
5	52	43	40	2.76	Stream

*Precision #0.80″ × 0.018″ valve and 0.018″ standard actuator.

Classification of Spray Characteristics

Very Fine	The spray disappears at a distance of about 2–3 feet after it leaves the actuator. The spray causes no wetting of paper when sprayed from a distance of about one foot.
Fine	The spray travels for a distance of at least 5–6 feet before disappearing. Slight wetting of paper occurs at a distance of about one foot.
Medium	The spray tends to travel in a horizontal path and the particle size is noticeably larger than that in a fine spray. Definite wetting of paper occurs at a distance of about one foot.
Coarse	Fall-out of large droplets from the spray is evident. Heavy wetting of paper occurs at a distance of two feet.
Streamy	A broken stream consisting of mixture of spray and stream.
Stream	A stream with little or no spray.

Sprays with properties intermediate between any of the groups shown above are classified as medium-fine, medium-coarse, etc.

Flame Projection Test Results

Table 5
Prototype Products Using Dymel 152a Propellant

Product	Valve	Prop. Conc	Solvent	Flame Proj, in	Flash Back, in	VP (70°F), psig
Hair Spray	(1)	25/75	EtOH	17	6	37
Personal Deodorant	(2)	30/70	EtOH	15	0	49
Cologne	(3)	18/82	EtOH	7	3	27
Topical Antiseptic	(4)	75/25	EtOH	0	0	60
Pan Sprays	(5)	25/75	Corn oil	19	0	62
Space Insecticide	(6)	32/68	Kerosene & Trichloroethane	17	0	34
Hornet/Wasp Spray	(7)	17/83	IPA & Trichloroethane	16	0	30
Residual Insecticide	(8)	15/85	Kerosene	22+	4	47
Spray Lubricant	(6)	95/05*	Trichloroethane	2	0	34
Mold Release Spray	(9)	90/05**	Trichloroethane	2	0	28
Electronic Cleaner	(10)	10/90	Freon® TF	0	0	22
Penetrating Oil	(6)	25/75	—	22	0	37

(1) Precision .013/.018 valve, .016 MBRT actuator.
(2) Precision .018/.025, .013 vapor tap valve, .016 MBRT actuator.
(3) Risdon .016/.040 valve, .016 MB actuator.
(4) Precision .025/.018, .013 vapor tap valve, .016 MBRT actuator.
(5) Precision .013/.010 valve, .013 MB actuator.
(6) Precision .080/.018 valve, .018 standard actuator.
(7) Precision .080/3x.040, .020 total release actuator.
(8) Precision .080/.018 valve, .025 total release actuator.
(9) Newman-Green B-14-10 valve, model 150-16-16 actuator.
(10) Newman-Green B-14-10 valve, model 110-20-32 actuator or Model 102-20-18 actuator with #805 extension tube.

* "Propellant" was Dymel 152a/1,1,1-trichloroethane (30/70)
** "Propellant" was Dymel 152a/1,1,1-trichloroethane (20/80)

Flame Projection Test Results (Metric Units)

Table 6
Prototype Products Using Dymel 152a Propellant

Product	Valve	Prop. Conc	Solvent	Flame Proj, cm	Flash Back, cm	VP (21.1°C), bar
Hair Spray	(1)	25/75	EtOH	43.2	15.2	2.55
Personal Deodorant	(2)	30/70	EtOH	38.1	0	3.38
Cologne	(3)	18/82	EtOH	17.8	7.6	1.86
Topical Antiseptic	(4)	75/25	EtOH	0	0	4.14
Pan Sprays	(5)	25/75	Corn oil	48.3	0	4.27
Space Insecticide	(6)	32/68	Kerosene & Trichloroethane	43.2	0	2.34
Hornet/Wasp Spray	(7)	17/83	IPA & Trichloroethane	40.6	0	2.07
Residual Insecticide	(8)	15/85	Kerosene	55.9+	10.2	3.24
Spray Lubricant	(6)	95/05	Trichloroethane	5.1	0	2.34
Mold Release Spray	(9)	95/05	Trichloroethane	5.1	0	1.93
Electronic Cleaner	(10)	10/90	Freon TF	0	0	1.52
Penetrating Oil	(6)	25/75	—	55.9	0	2.55

(1) Precision .330/.457 valve, .406 MBRT actuator.
(2) Precision .457/.635, .330 vapor tap valve, .406 MBRT actuator.
(3) Risdon .406/1.016 valve, .406 MB actuator.
(4) Precision .635/.457, .330 vapor tap valve, .406 MBRT actuator.
(5) Precision .330/.254 valve, .330 MB actuator.
(6) Precision 2.032/.457 valve, .457 standard actuator.
(7) Precision 2.032/3x1.016, .508 total release actuator.
(8) Precision 2.032/.457 valve, .635 total release actuator.
(9) Newman-Green B-14-10 valve, model 150-16-16 actuator.
(10) Newman-Green B-14-10 valve, model 110-20-32 actuator or Model 102-20-18 actuator with #805 extension tube.

* "Propellant" was Dymel 152a/1,1,1-trichloroethane (30/70).
** "Propellant" was Dymel 152a/1,1,1-trichloroethane (20/80).

The information contained herein is based on technical data and tests that we believe to be reliable and is intended for use by persons having technical skill, at their own discretion and risk. Because conditions of use are outside of DuPont's control, we can assume no liability for results obtained or damages incurred through the application of the data presented.

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246023A Printed in U.S.A.
Reorder No.: H-64411

The MSDS format adheres to the standards and regulatory requirements of the United States and may not meet regulatory requirements in other countries.

"DYMEL" 152a AEROSOL PROPELLANT
3027FR Revised 15-SEP-2004

CHEMICAL PRODUCT/COMPANY IDENTIFICATION

Material Identification

"DYMEL" is a registered trademark of DuPont.

Corporate MSDS Number : DU001260
CAS Number : 75-37-6
Formula : CH3CHF2
CAS Name : ETHANE, 1,1-DIFLUORO-

Company Identification

MANUFACTURER/DISTRIBUTOR
DuPont Fluoroproducts
1007 Market Street
Wilmington, DE 19898

PHONE NUMBERS
Product Information : 1-800-441-7515 (outside the U.S. 302-774-1000)
Transport Emergency : CHEMTREC 1-800-424-9300(outside U.S. 703-527-3887)
Medical Emergency : 1-800-441-3637 (outside the U.S. 302-774-1000)

COMPOSITION/INFORMATION ON INGREDIENTS

Components

Material	CAS Number	%
ETHANE, 1,1-DIFLUORO- (HFC 152a)	75-37-6	100

HAZARDS IDENTIFICATION

Potential Health Effects

Inhalation of HFC-152a may cause nonspecific discomfort such as nausea, headache or weakness, or temporary nervous system depression with dizziness, confusion, incoordination, drowsiness or unconsciousness.

Higher exposures may lead to irritation of nose, throat, and lungs with cough, difficulty breathing or shortness of breath, temporary alteration of the heart's electrical activity with irregular pulse, palpitations, or inadequate circulation, or abnormal kidney function as detected by laboratory tests. Gross overexposure may be fatal.

(HAZARDS IDENTIFICATION - Continued)

Individuals with preexisting diseases of the central nervous system, cardiovascular system, lungs or kidney may have increased susceptibility to the toxicity of excessive exposures.

Carcinogenicity Information

None of the components present in this material at concentrations equal to or greater than 0.1% are listed by IARC, NTP, OSHA or ACGIH as a carcinogen.

FIRST AID MEASURES

First Aid

INHALATION
If high concentrations are inhaled, immediately remove to fresh air. Keep person calm. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician.

SKIN CONTACT
In case of contact, immediately flush skin with plenty of water for at least 15 minutes. Treat for frostbite if necessary, by gently warming affected area.

EYE CONTACT
In case of contact, immediately flush eyes with plenty of water for at least 15 minutes. Call a physician.

INGESTION
Ingestion is not considered a potential route of exposure

Notes to Physicians

Because of possible disturbances of cardiac rhythm, catecholamine drugs, such as epinephrine, should be used with special caution only in situations of emergency life support.

FIRE FIGHTING MEASURES

Flammable Properties

Flash Point	: <-50 C (<-58 F)
Flammable limits in Air, % by Volume	
LEL	: 3.9
UEL	: 16.9
Autoignition	: 454 C (849 F)

(FIRE FIGHTING MEASURES - Continued)

Fire and Explosion Hazards:

Flammable. Cylinders are equipped with temperature and pressure relief devices but may still rupture under fire conditions. Use water spray to cool cylinders and tanks.

HFC-152a fire decomposition by-products will include hydrofluoric acid, and possibly carbonyl fluoride. Avoid contact with these materials, which are toxic and irritating. Evacuate personnel immediately in the event of a fire involving HFC-152a.

Extinguishing Media

Water Spray, Water Fog, Dry Chemical.

Carbon dioxide. "Alcohol" foam.

Fire Fighting Instructions

Keep container cool with water spray. If gas exiting container ignites, stop flow of gas. Do not put out the fire unless leak can be stopped immediately. Self-contained breathing apparatus (SCBA) is required if containers rupture and contents are released under fire conditions.

ACCIDENTAL RELEASE MEASURES

Safeguards (Personnel)

NOTE: Review FIRE FIGHTING MEASURES and HANDLING (PERSONNEL) sections before proceeding with clean-up. Use appropriate PERSONAL PROTECTIVE EQUIPMENT during clean-up.

Accidental Release Measures

If a spill can cause a concentration in excess of 1,000 ppm, turn off valves and ignition sources. Evacuate area. Ventilate area, especially low places where heavy vapors might collect. Wear self-contained breathing apparatus (SCBA).

If this product is spilled and not recovered, or is recovered as a waste for treatment or disposal, the CERCLA Reportable Quantity is 100 lbs. (Release of an unlisted Hazardous Waste characteristic of ignitability).

HANDLING AND STORAGE

Handling (Personnel)

Avoid breathing high concentrations of vapors and avoid liquid contact with skin or eyes. Use with sufficient ventilation to keep employee exposure below recommended limits. Lines and equipment which will contain "DYMEL" 152a Aerosol Propellant should be pretested with nitrogen using soapy water to detect leaks.

Storage

Clean, dry area. Do not heat above 52 deg C 125 deg F.

EXPOSURE CONTROLS/PERSONAL PROTECTION

Engineering Controls

Normal ventilation for standard manufacturing procedures is generally adequate. Local exhaust should be used when large amounts are released. Mechanical exhaust should be used in low or enclosed places. Ground all equipment and cylinders before use. Use explosion-proof electrical equipment rated Class I, Group D in Division 1 locations. In Division 2 locations, all spark-producing electrical equipment must be explosion-proof and rated Class I, Group D. Non-sparking motors need not be explosion-proof.

Personal Protective Equipment

Impervious gloves and chemical splash goggles should be worn when handling the liquid. Fire protective clothing (NOMEX) with antistatic control should be worn when handling this product. Under normal manufacturing conditions, no respiratory protection is required when using this product. Self-contained breathing apparatus (SCBA) is required if a large release occurs.

Exposure Guidelines

Exposure Limits

"DYMEL" 152a AEROSOL PROPELLANT

PEL	(OSHA)	: None Established
TLV	(ACGIH)	: None Established
AEL *	(DuPont)	: 1000 ppm, 8 Hr. TWA
WEEL	(AIHA)	: 1000 ppm, 8 Hr. TWA

* AEL is DuPont's Acceptable Exposure Limit. Where governmentally imposed occupational exposure limits which are lower than the AEL are in effect, such limits shall take precedence.

PHYSICAL AND CHEMICAL PROPERTIES

Physical Data

Boiling Point	: -25 C (-13 F)
Vapor Pressure	: 87 psia at 25 deg C (77 deg F)
Vapor Density	: 2.4 (Air = 1.0) at 25 deg C (77 deg F)
% Volatiles	: 100 WT%
Solubility in Water	: 0.28 WT% @ 25 C (77 F) (87 psia)
Odor	: Slight ethereal
Form	: Gas
Color	: Clear, colorless
Density	: 0.90 g/cc at 25 deg C (77 deg F) - Liquid

STABILITY AND REACTIVITY

Chemical Stability

Material is stable. However, avoid open flames and high temperatures.

Incompatibility with Other Materials

Incompatible with alkali or alkaline earth metals- powdered Al, Zn, Be, etc.

Polymerization

Polymerization will not occur.

Other Hazards

Decomposition : Decomposition products are hazardous. This material can be decomposed by high temperatures (open flames, glowing metal surfaces, etc.) forming hydrofluoric acid and possibly carbonyl fluoride.

TOXICOLOGICAL INFORMATION

Animal Data

Oral ALD:	>1500 mg/kg in rats
Inhalation ALC, 4 hr:	383,000 ppm in rats

HFC-152a has not been tested for skin and eye irritancy, nor for animal sensitization.

Ingestion of single high doses of HFC-152a caused weight loss and lethargy.

(TOXICOLOGICAL INFORMATION - Continued)

Inhalation of high levels of HFC-152a caused labored breathing, lung irritation, lethargy, incoordination and loss of consciousness. Cardiac sensitization occurred in dogs exposed to a concentration of 150,000 ppm in air and given an intravenous epinephrine challenge.

Repeated inhalation exposures caused increased urinary fluoride, reduced kidney weight, and reversible kidney changes. Based on an independent peer review the reversible kidney changes are considered artifacts of the tissue and slide processing and not a compound related effect.

Animal testing demonstrate no carcinogenic activity nor developmental effects. No animal data are available to define reproductive effects of HFC-152a.

HFC-152a has not produced genetic damage in bacterial cultures. There are reports indicating that HFC-152a produced genetic damage in some mammalian cell culture tests. A weak genotoxic effect in germ cells of Drosophila melanogaster has been reported. It has not been tested in animals.

DISPOSAL CONSIDERATIONS

Waste Disposal

Reclaim by distillation, incinerate, or remove to a permitted waste facility. Comply with Federal, State, and local regulations.

This material may be a RCRA Hazardous waste upon disposal due to the ignitability characteristic.

TRANSPORTATION INFORMATION

Shipping Information

DOT/IMO

Proper Shipping Name	: 1,1-DIFLUOROETHANE
Hazard Class	: 2.1
UN No.	: 1030
DOT/IMO Label	: FLAMMABLE GAS
Special Information	: CARGO AIRCRAFT ONLY

Shipping Containers

Cylinders
Ton Tanks

REGULATORY INFORMATION

U.S. Federal Regulations

TSCA Inventory Status : Reported/Included.

TITLE III HAZARD CLASSIFICATIONS SECTIONS 311, 312

Acute : Yes
Chronic : No
Fire : Yes
Reactivity : No
Pressure : Yes

LISTS:

SARA Extremely Hazardous Substance	-No
CERCLA Hazardous Substance	-(*)
SARA Toxic Chemicals	-No

*See Disposal Information

"DYMEL" 152a is a flammable gas as defined by OSHA in 29CFR 1910.1200(c). Use of this product may require compliance with 29CFR 1910.119, Process Safety Management of Highly Hazardous Chemicals.

OTHER INFORMATION

NFPA, NPCA-HMIS

NPCA-HMIS Rating

Health	: 1
Flammability	: 4
Reactivity	: 1

Personal Protection rating to be supplied by user depending on use conditions.

The data in this Material Safety Data Sheet relates only to the specific material designated herein and does not relate to use in combination with any other material or in any process.

Responsibility for MSDS	: MSDS Coordinator
>	: DuPont Fluoroproducts
Address	: Wilmington, DE 19898
Telephone	: (800) 441-7515

# Indicates updated section.

This information is based upon technical information believed to be reliable. It is subject to revision as additional knowledge and experience is gained.

End of MSDS

FEB - 2 2009

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

July 27, 2005

MEMORANDUM

SUBJECT: Reassessment of the Two Exemptions from the Requirement of a Tolerance for 1,1-Difluoroethane

FROM: Bipin Gandhi
Minor Use, Inerts and Emergency Response Branch
Registration Division (7505C)

THRU: Pauline Wagner, Inerts Coordinator
Registration Division (7505C)

TO: Dan Rosenblatt, Chief
Minor Use, Inerts and Emergency Response Branch
Registration Division (7505C)

Background

Attached is the science assessment for 1,1-difluoroethane. The purpose of this document is to reassess two existing exemptions from the requirement of a tolerance for residues of this inert ingredient as required under the Food Quality Protection Act (FQPA section 408). This assessment summarizes available information on the use, physical/chemical properties, toxicological effects, environmental fate, ecotoxicity, and exposure profiles of 1,1-difluoroethane. In performing this assessment, the Agency has relied extensively upon reviews of 1,1-difluoroethane previously performed for the Integrated Risk Assessment System (IRIS) and by the High Production Volume Chemical Challenge Program (HPV).

Executive Summary

This report evaluates 1,1-difluoroethane (CAS Reg. No. 75-37-6), a pesticide inert ingredient for which an exemption from the requirement of a tolerance exists for its residues when used as propellant in pesticide formulations applied to raw agricultural commodities under 40 CFR §180.910 and as propellant in pesticide formulations applied to animals under 40 CFR §180.930.

This hazard assessment relies upon assessments of 1,1-difluoroethane performed by IRIS and HPV programs.

Taking into consideration all available information on 1,1-difluoroethane, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to 1,1-difluoroethane when considering inhalation exposure through food commodities and all other nonoccupational sources of inhalation exposure for which there is reliable information. Therefore, it is recommended that the exemptions from the requirement of a tolerance established for residues of 1,1-difluoroethane when used as propellant in pesticide formulations applied to raw agricultural commodities and used as propellant in pesticide formulations applied on animals can be considered reassessed as safe under section 408(q) of the FFDCA.

I. Introduction

This report evaluates 1,1-difluoroethane (CAS Reg. No. 75-37-6), a pesticide inert ingredient for which an exemption from the requirement of a tolerance exists for its residues when used as propellant in pesticide formulations applied to raw agricultural commodities under 40 CFR §180.910 and as propellant in pesticide formulations applied to animals under 40 CFR §180.930. The exemption from tolerances were established on July 29, 1996 (61 FR 39351, FRL 5386-8)

1, 1-Difluoroethane is widely used worldwide as an aerosol propellant in food and non-food commodities, as refrigerant and as an intermediate in the synthesis of 1-chloro-1,1-difluoroethane (refrigerant 142b).

The concentration of 1,1-difluoroethane as a propellant in pesticide formulations ranges from 14% to 78% by weight in the pesticide formulation.

Other names for 1,1-Difluoroethane include: Difluoroethane; ethane, 1,1-difluoro-; ethylene fluoride; ethylidene difluoride; ethylidene fluoride; Freon 152a; Algofrene type 67; HFC 152a; R 152a; Genetron 100; Genetron 152a; Refrigerant 152a (Toxnet SIS, 2005).

II Use Information

Pesticides

The two tolerance exemptions for 1,1-difluoroethane being reassessed in this document are given in Table 1 below.

Table 1. Tolerance Exemptions Being Reassessed in this Document				
Tolerance Exemption Expression	**40 CFR §**	**Use Pattern (Pesticidal)**	**CAS Reg No.**	**List Classification**
1, 1-Difluoroethane (CAS Reg No. 75-37-6)	180.910[1/]	For aerosol pesticide formulations used for insect control in food and feed-handing establishments and animals.	75-37-6	2
1, 1-Difluoroethane (CAS Reg No. 75-37-6)	180.930[2/]	For aerosol pesticide formulations used for insect control in food and feed-handing establishments and animals.		

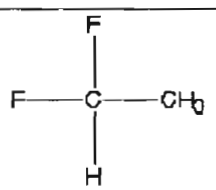
1. Residues listed in 40 CFR §180.910 [formerly 40 CFR§ 180.1001(c)] are exempted from the requirement of a tolerance when used as inert ingredients in pesticide formulations when applied to raw agricultural commodities.
2. Residues listed in 40 CFR §180.930 [formerly 40 CFR§ 180.1001(e)] are exempted from the requirement of a tolerance when used as inert ingredients in pesticide formulations when applied to animals.

Other Uses

1,1-Difluoroethane is also used as an aerosol in non-food commodities, refrigerant and in the synthesis of 1-chloro-1,1-difluoroethane.

III. Physical and Chemical Properties

Some of the physical and chemical characteristics of 1, 1-difluoroethane are given in Table 2 below.

Table 2. Physical and Chemical Properties for 1, 1-Difluoroethane		
Parameters	**Value**	**Source**
Structure	 1, 1-difluoroethane	Toxnet SIS, 2005

Molecular Formula	$C_2H_4F_2$	Toxnet SIS, 2005
Molecular Weight	66.1	Toxnet SIS, 2005
Color/form	Colorless, odorless gas	Toxnet SIS, 2005
Melting point	-117°C	Toxnet SIS, 2005
Boiling Point	-24.7°C	Toxnet SIS, 2005
Critical Temperature and pressure	113.3°C @ $4.52x10^6$ Pa	Toxnet SIS, 2005
Solubility	17.8 g/L water @ 25°C	Toxnet SIS, 2005
Density/Specific gravity	0.91 @ 21°C	Toxnet SIS, 2005
Heat of combustion	-4.42 kcal/g	Toxnet SIS, 2005
Heat of vaporization	0.078 kcal/g	Toxnet SIS, 2005
Octanol/Water partition. Coefficient.	Log K_{ow} = 0.75	Toxnet SIS, 2005
Vapor Density	203 (air = 1)	Toxnet SIS, 2005
Vapor Pressure	4,550 mm Hg @ 25°C	Toxnet SIS, 2005

IV. Hazard Assessment

A. Hazard Profile

This hazard assessment relies upon reviewed assessments of 1,1-difluoroethane performed by IRIS and HPV submission to the Agency. The HPV program determined that the submitted data were adequate for the purposes of the HPV challenge program, although some of the robust summaries needed to be enhanced. For the purposes of the tolerance reassessment, the enhanced robust summaries were used.

The IRIS evaluation of 1,1-difluoroehthane states that "1,1-difluoroetathane is a gas mainly used as propellant, refrigerant and as an intermediate in the synthesis of 1-chloro-1,1-difluoriethane. It is non-toxic to rats and mice via inhalation exposure, the main route of exposure. It is non-teratogenic and no adverse effects on reproductive cycles of laboratory animals.

B. Toxicological Data

Acute toxicity:

One acute oral toxicity study for 1,1-difluoroethane was cited in the HPV data. The data were deemed to be of low reliability because of the uncertainties associated with using a gas in

an oral dosing suspension. However, the study reported the approximated lethal dose to be > 1500mg/kg.

No data on dermal toxicity, dermal or eye irritation or dermal sensitization were identified.

1,1-Difluoroethane is practically non-toxic following acute inhalation exposure. Groups of 6 male ChR-CD rats were exposed whole body to concentrations of 0, 66,400, 175,200, 319,000, 383,000 and 437,000 ppm 1,1-difluoroethane for 4 hours. There was one death at the 383,000 ppm concentration and two deaths at 437,000 ppm concentration. During the exposure period, labored breathing, lethargy, and unresponsiveness to sound were observed. Following exposure no clinical signs were observed, and there was no pathology seen at necropsy after the 14-day observation period. . (Haskell Report No 699-75 cited in HPV Robust summaries for 1,1-difluoroethane).

In another study no adverse effect was reported at 200,000 ppm for 2 hours of exposure to male albino rats. (IRIS)

Cardiac/Pulmonary Sensitization:

The effects of 1,1-difluoroethane were studied on the ventricular function of dogs and mice. Concentration of 10 and 20% of 1,1-difluoroethane caused depression of myocardial contractility in dogs.(Aviado and Belje, 1974) In an additional study, male Beagle dogs (12/group) were exposed to 50,000 or 150,000ppm for 5 minutes. The dogs were given a control injection of epinephrine (0.008mg/kg) iv prior to exposure and a challenge injection of the same dose was given to the animals after a 5 minute exposure to 1,1-difluoroethane. Cardiac arrhythmia was observed in 3 dogs at the 150,000 ppm exposed group, but no response was seen at 50,000 ppm .(HPV Robust Summaries) In another study, the bronchopulmonary system of mice was influenced by 1 to 2% concentration of 1,1-difluoroethane and respiration by 2.5 to 5% of 1,1-difluoroethane. The chemical did not cause spontaneous cardiac arrhythmia in the mouse, but it did cause sensitization of the heart of epinephrine in mice that had experimental bronchopulmonary lesions (Brody, Watanabe and Aviado, 1974).

Subchronic toxicity:

Subchronic studies did not report any adverse effects from inhalation exposure to 1,1-difluoroethane.

When CD male rats were exposed to 100,000 ppm for 6/hours/day for 5/days per week for 2 weeks no adverse effects were observed. Reversible depression of central nervous system was seen during exposure, but resolved when exposure ceased. (IRIS). Similar results were

observed when the above sub-chronic study was repeated (Haskell study No. 699-75 cited in IRIS).

Chronic Toxicity/Carcinogenicity

In a two year chronic study male and female Crl:CDBR rats were exposed whole body to 0, 2000, 10,000 and 25,000 ppm 1,1-difluoroethane for 6/hrs day 5/days/wk. At the end of the study there was a dose-related increase in urinary fluoride concentration and excretion in males and females at the two higher doses and serum creatinine was significantly elevated at these two higher doses. There was no increase in mortality in the treated groups or any treatment related pathology. There was no carcinogenicity at any dose level (Haskell study No. 8-82 cited in HPV Robust Summary for 1,1-difluoroethane).

In another study no chronic adverse effects were observed except mild chronic irritation when make rats were exposed to 100,000 ppm for 16 hours/day for 2 months (IRIS).

Genetic Toxicity:

Reliable genotoxicity studies generally showed negative results. The *in vitro* chromosome aberration test in human lymphocytes was weakly positive.

Du Pont studied the 1,1-difluoroethane for bacterial reverse mutation with and without activation and the results were negative (Haskell Report No. 4032 cited in HPV Robust Summary for 1,1-difluoroethane).

In vitro chromosome aberration test in human lymphocytes showed statistically significant increases in the proportion of the aberrant cells both with and without activation. The study authors concluded that 1,1-difluoroethane gave a weakly positive response. (Haskell Report No. 4032 cited in HPV Robust Summary for 1,1-difluoroethane).

An *in vivo* rat Micronucleus Test in Sprague Dawley rats dosed with 1,1-difluoroethane did not show any evidence of chromosome damage or bone marrow cell toxicity when administered by whole body inhalation. (DuPont Study No. 5426 cited in HPV Robust Summary for 1,1-difluoroethane).

Development Toxicity:

Pregnant female rats were exposed to 0, 5000 and 50,000 ppm of 1,1-difluoroethane 6 hours per day from gestation day 6 to 15. No clinical signs of maternal toxicity or body weight changes were reported. No gross pathological abnormalities were observed in ovaries, uterine horns, vital organs or tissues of the treated animals. The number of corpora lutea, implantation sites, and live fetuses per litter were similar in all groups. Fetal body measurements in treated groups did not differ from controls. There were no statistical significant soft tissue abnormalities. The NOAEL for maternal toxicity and for development toxicity was 50,000 ppm and LOAEL was not determined in ether case (Haskell Report No. 437-79 cited in HPV Robust Summaries for 1,1-difluoroethane).

Reproductive Toxicity:

The two-year rat whole body inhalation study for 1,1-difluoroethane in conducted by Haskell Laboratory (Report No. 8-82 in HPV Robust Summary for 1,1-difluoroethane, EPA, 2001), included data on the histopathology and weights of the reproductive organs of the treated animals. No histopathological or weight effects were reported for any dose group of either sex in the study. The Du Pont SHE Excellence Center Robust Summary (HPV Report) considered the reliability of this aspect of the original Haskell Report to be medium, because a suboptimal study design was used.

No standard reproductive toxicity studies for 1,1-difluoroethane were identified.

C. Metabolism And Pharmacokinetics:

No data were identified for the metabolism and pharmacokinetics of 1,1-difluoroethane.

D. Special Considerations for Infants and Children:

Based on the inhalation exposure to the animals and therefore, lack of concern for human health effects, a safety factor analysis has not been used to assess the risks resulting from the use of 1,1-difluoroethane as a pesticide inert ingredients (as propellant) and an additional tenfold safety factor for the protection of infants and children is also not necessary.

V. Exposure Assessment:

Exposure of 1,1-difluoroethane to the general population is solely via inhalation route because of its gaseous characteristics. Humans may get inhalation exposure through the use of food and non-food aerosol containers. Exposure of 1,1-difluoroethane is practically negligible through its use as refrigerant because it is used in sealed systems and a small amount may escape through leaks will be dissipated and diluted in the air. Since 1,1-difluoroethane is non-toxic to rats and mice and it is non-carcinogen, non-teratogen and has no adverse effects on reproductive cycles of laboratory animals, it is not expected to have adverse effects on humans through the exposure of 1,1-difluoroethane.

VI. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

For 1,1-difluoroethane, a qualitative assessment for all pathways of human exposure (food, drinking water, and residential) is appropriate given the lack of human health concerns associated with exposure to 1,1-difluoroethane.

VII. Cumulative Exposure

Section 408(b)(2)(D)(v) of the FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider "available information" concerning the cumulative effects of a particular pesticide's residues and "other substances that have a common mechanism of toxicity."

Unlike other pesticides for which EPA has followed a cumulative risk approach based on a common mechanism of toxicity, EPA has not made a common mechanism of toxicity finding as to 1,1-difluoroethane and any other substances and this material does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has not assumed that 1,1-difluoroethane has a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see the policy statements released by EPA concerning common mechanism determinations and procedures for cumulating effects from substances found to have a common mechanism on EPA's website at http://www.epa.gov/pesticides/cumulative/

VIII. Environmental Fate Characterization/Drinking Water Considerations

According to model of gas/particle partitioning of semi-volatile organic compounds in the atmosphere , 1,1-difluoroethane is expected to exist solely as a vapor in the ambient atmosphere. The atmospheric half-life of about 472 days at an atmospheric concentration. This long atmosphere lifetime of this chemical suggests some 1,1-difluoroethane is expected to diffuse into the stratosphere above the ozone layer where it will slowly degrade due to direct photolysis from UV-radiation (HPV Robust Summaries for 1,1-fluoroethane).

The estimated half-life for a model river and model lake are 2 and 77 hours respectively. 1,1-Difluoroethane is not expected to adsorb to suspended solids and sediment in water based on

the measured log value of 0.75. 1,1–Difluoroethane is expected to volatilize rapidly from the surfaces (HPV Robust Summaries for 1,1-difluoroethane).

As per EPIWIN Version 3.05, 1,1-difluoroethane is distributed 99.9%, 0.111%, 0.01% and <0.01% in air, water, soil and sediment respectively. Bioconcentration factor of 2 was determined using a measured log K_{ow} of 0.75 which suggest that bioconcentration in aqueous organisms is low (HPV Robust Summaries for 1,1-fluoroethane).

Ecotoxicity:

The 96 hours LC_{50} for fish is calculated at 733/mg/L. The 46 hours EC_{50} for Daphnia is calculated at 720mg/L. The 96 hours EC_{50} for Algae is calculated at 419 mg/L concentration. All three values are theoretical values based on ECOSAR model. Based on the ECOSAR model and high Henry Law Constant 1,1-difluoroethane is unlikely to represent an unacceptable risk to aquatic organisms or wildlife (HPV Robust Summaries for 1,1-difluoroethane).

IX. Human Health Risk Characterization

1,1-Difluoroethane is practically non-toxic following acute or chronic inhalation exposures. It is not a developmental or reproductive toxicant in rat studies and is negative for cancer in a two year rat inhalation study. It is not mutagenic in a *in vitro* bacterial reverse mutation assay and shows some weak clastogenicity in an *in vitro* human lymphocyte chromosome aberration test, but further evaluation of its ability to cause chromosome damage in and *in vivo* micronucleus test was negative. There is evidence that 1,1-difluoroethane can cause cardiac effects is some species, most notably heart arrhythmia in the dog.

Evaluations of IRIS and HPV data have concluded that there are no safety concerns associated with the use of 1,1-fluoroethane as propellant used in pesticide formulations for insect controls in food and feed establishments and as propellant used in pesticide formulations used on animals. Taking into consideration all available information on 1,1-difluoroethane, it has been determined that there is a reasonable certainty that no harm to any population subgroup will result from aggregate exposure to 1,1-difluoroethane when considering dietary exposure and all other non-occupational sources of pesticide exposure for which there is reliable information. Therefore, it is concluded that the exemptions from the requirement of a tolerance established for residues of 1,1-difluoroethane in/on raw agricultural commodities and animals can be considered reassessed as safe under section 408(q) of the FFDCA.

X. Ecotoxicity and Ecological Risk Characterization

Based on the information submitted above, 1, 1-difluoroethane binding to sediments or the concentration in water in less than 0.1% which is based on theoretical calculations.

Therefore, no hazard to environment. The concentration of 1,1-difluoroethane will be very low in water and thus no hazard to eco system.

XI References

Aviado, D.M. and M.A. Belej. 1975. Toxicity of aerosol propellants in the respiratory and circulatory systems. V. Ventricular function in the dog. Toxicology 3, 79-86.

Brody, R.S., T. Watanabe and D.M. Aviado. 1975. Toxicity of aerosol propellants in the respiratory and circulatory systems. III. Influence of bronchopulmonary lesion on cardiopulmonary toxicity in the mouse. Toxicology 2, 173-184.

EPA. 2001. Du Pont SHE Excellence Center Robust Summary for 1,1-difluoroethane 2001. Posted on the EPA' s HPV Challenge Program ChemRTK Web Site on August 22, 2001 at <http://www.epa.gov/chemrtk/1difluoro/c13124.pdf >.

IRIS. 2005. 1,1-difluoroethane; CASRN 75-37-6. <http://www.epa.gov/iris/subst/0665.htm>.

Toxnet SIS. 2005. Specialized Information Service. On-line Scientific Search Engine, National Library of Medicine, National Institute of Health.< http://toxnet.nlm.nih.gov>. Search term: CAS No: 75-37-6; Hazardous Substance Databank (last revised: *02/14/2003*); accessed *2005*.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

DATE: July 27, 2005

ACTION MEMORANDUM

SUBJECT: Inert Reassessment – 1,1-Difluoroethane (CAS Reg. No. 75-37-6)

FROM: Dan Rosenblatt, Chief
Minor Use, Inerts, and Emergency Response Branch

TO: Lois A. Rossi, Director
Registration Division

I. FQPA REASSESSMENT ACTION

Action: Reassessment of two inert exemptions from the requirement of a tolerance. The two current exemptions are to be maintained.

Chemical: 1,1-Difluoroethane
CFR: 40 CFR part 180.910 [formerly 40 CFR 180.1001(c)] and 40 CFR part 180.930 [formerly 40 CFR 180.1001 (e)]
CAS #: 75-37-6

Use Summary: 1,1-Difluoroethane is employed for aerosol pesticide formulations used for insect control in food and feed-handing establishments and animals. The predominant use of this chemical is in consumer products, including used as an aerosol propellant in food and non-food commodities, as refrigerant, and in the synthesis of 1-chloro-1,1-difluoroethane.

II. MANAGEMENT CONCURRENCE

I concur with the reassessment of the two exemptions from the requirement of a tolerance for the inert ingredient, 1,1-Difluoroethane, CAS # 75-37-6. I consider the two exemptions established in 40 CFR part 180.910 [formerly 40 CFR180.1001(c)] and in 40

CFR part 180.930 [formerly 40 CFR 40 CFR180.1001(e)] to be reassessed for purposes of FFDCA's section 408(q) as of the date of my signature, below. A Federal Register Notice regarding these tolerance exemptions reassessment decision will be published in the near future.

Donald R Stubbs

Lois A. Rossi, Director
Registration Division

Date: 7/27/05

CC: Debbie Edwards, SRRD
Joe Nevola, SRRD