Australian Government
Department of Health
Australian Industrial Chemicals Introduction Scheme

# 1-Propene, 2,3,3,3-tetrafluoro-

## Evaluation statement

**30 June 2022**

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# AICIS evaluation statement

## Subject of the evaluation

1-Propene, 2,3,3,3-tetrafluoro-

## Chemical in this evaluation

| Name | CAS registry number |
|---|---|
| 1-Propene, 2,3,3,3-tetrafluoro- | 754-12-1 |

## Reason for the evaluation

Information has been provided as a result of specific information obligations on the terms of the Inventory listing.

## Parameters of evaluation

The chemical, 1-propene, 2,3,3,3-tetrafluoro- (CAS No. 754-12-1) is listed in the Australian Inventory of Industrial Chemicals (the Inventory) with a specific requirement to provide information as a term of the Inventory listing (see **Supporting information**).

The chemical was assessed in 2015 as a new industrial chemical in the standard notification category under *Section 23* of the *Industrial Chemicals Notification and Assessment (ICNA) Act 1989* (NICNAS 2015a; NICNAS 2015b).

An introducer has provided information under *Section 101 of the Industrial Chemicals Act 2019.*

The information indicated that the chemical is to be introduced:

- as a commercial product for use as a do-it-yourself (DIY) top-up refrigerant to refill all types of motor vehicle air conditioning (MVAC) systems
- to the public in 396 g size pre-charged cylinders.

The use of the chemical as a component of refrigerant for MVACs is the same as that already assessed. However, the use in Australia was previously assessed solely for use by qualified technicians. Therefore, the use as DIY top-up refrigerant was considered a significant change in the circumstances of the originally assessed introduction.

Furthermore, new hazard information has become available since the assessment in 2015.

This evaluation considers all new information and provides advice on the risk to workers, public and the environment identified from the significant change of introduction for the chemical. The evaluation also assessed whether the human health and environmental risks resulting from any change in introduction by import of the chemical can be managed within existing risk management frameworks.

This evaluation report should be read in conjunction with assessment reports: STD 1535 and STD 1556 (NICNAS 2015a; NICNAS 2015b).

# Summary of evaluation

## Summary of introduction, use and end use

The chemical has the following reported Australian uses:

- refrigerant for MVAC systems of passenger cars and light trucks
- refrigerant for residential and commercial stationary air conditioning and refrigeration systems
- as a DIY top-up refrigerant to refill all types of MVAC systems.

The availability of the product for domestic use is expected to be widespread.

The chemical has previously been assessed as being imported in Australia:

- in a neat form or as a component of refrigerants (at ≤60% concentration) in tanks in a shipping container
- at ≤100% concentration in imported units (motor vehicle air conditioning systems, stationary air conditioning systems and stationary refrigeration systems).

The new information indicates that the chemical may be imported in 396 g size pre-charged cylinders containing the chemical at approximately 85%.

## Human health

### Summary of health hazards

The critical health effects for risk characterisation include potential systemic long term effects (developmental toxicity and carcinogenicity) following inhalation exposure. The toxicological investigations conducted on the chemical are discussed in detail in assessment reports: STD 1535 and STD 1556 (NICNAS 2015a; NICNAS 2015b), and additional toxicological data is presented in the **Supporting Information** section.

Based on the data available, the chemical has low acute toxicity via inhalation in various animal species. The following median lethal concentration (LC50) values were reported:

- LC50 >405,800 ppm/4 hours in rats, study conducted in accordance with the Organisation for Economic Co-operation and Development (OECD) Test Guideline (TG) 403
- LC50 >20,345 ppm/4 hours in rats, study conducted in accordance with the OECD TG 403
- LC50 >99,830 ppm/4 hours in mice (non-guideline study)
- LC50 >102,000 ppm/1 hour in rabbits (non-guideline study).

No data are available on acute oral and acute dermal toxicity for this chemical.

The chemical is not expected to be a skin or eye irritant, or cause skin sensitisation due to its gaseous state as the chemical is expected to rapidly diffuse away from the contact surface. No signs of skin, eye or respiratory irritation/corrosivity effects and sensitisation were reported following acute and chronic exposure to the chemical. However, in its liquefied state, the chemical can cause frostbite upon contact with the skin or damage to eyes.

Several repeat dose inhalation studies were conducted in accordance with OECD TG 412 in various animal species including:

- in rats treated with the chemical at concentrations of up to 50,000 ppm (6 h/day, 5 days/ week), no adverse effects were reported following 14 day, 28 day and 90 day exposures. No chemical related effects were reported in rats exposed to the chemical by inhalation (6 h/day, 5 days/ week) at concentrations up to 800 ppm for 28 days.
- in rabbits exposed to the chemical at concentrations up to 5500 ppm for 28 days, no adverse effect concentrations (NOAECs) of 500 ppm and 1000 ppm were reported in male and female rabbits, respectively, due to increased incidence and/or severity of acute skeletal muscle necrosis in both sexes.
- in minipigs, NOAECs for cardiotoxicity and skeletal muscle toxicity of 10,300 ppm (maximum dose tested) and 10,200 (maximum dose tested) were reported for 14 days and 28 days, respectively. It was reported that pigs are a better model to assess the cardiovascular toxicity in humans compared to rabbits (Feldman 2014).

Based on the above animal data, the chemical is expected to be of low toxicity to humans following repeated inhalation exposure.

The chemical did not cause toxicity or myocardial effects in beagle dogs (6 males) when exposed by inhalation (vapour) at concentrations of up to 120,189 ppm (highest dose tested). The NOAEC for cardiac sensitisation was reported to be >120,189 ppm.

Positive results have been reported in in vitro mutagenicity tests, however genotoxic effects were not observed in vivo. In an in vitro bacterial reverse mutation assay, the chemical was mutagenic when administered as a gas, but not mutagenic when administered at up to 12% in air. There was no evidence of clastogenicity when tested in human lymphocytes however an increase in mutant frequency was observed in the presence of metabolic activation in mouse lymphoma cells in vitro. The chemical was reported to be non-genotoxic in in vivo unscheduled DNA synthesis and in vivo micronucleus tests in rats and mice. The chemical did not induce DNA damage in the liver and lung cells of rats in an in vivo alkaline comet assay.

The chemical is not expected to cause reproductive toxicity based on a 2-generation reproductive inhalation study in rats. In a 2-generation reproductive inhalation study conducted in accordance with OECD TG 416, a NOAEC for reproductive toxicity of 49,958 ppm (the highest dose tested) was determined in rats.

The developmental toxicity of the chemical was determined to be inconclusive based on effects observed in a prenatal developmental study in rabbits. In the absence of further longer term multigenerational study, these effects cannot be ruled out. There were significant differences in the toxicity effects reported between rats and rabbits in the prenatal developmental studies conducted as follows:

- in an inhalation study conducted in accordance with OECD TG 414, no significant treatment related effects indicative of maternal and developmental toxicity were observed in rats. The maternal and developmental NOAEC of 50,315 ppm (highest dose tested) was determined.
- in an inhalation study conducted in accordance with OECD TG 414 a maternal NOAEC of <2500 ppm was established due to mortality and signs of toxicity at all doses tested (2500 ppm, 4000 ppm, 5000 ppm and 7500 ppm) in rabbits. An embryo/foetal developmental NOAEC of 4000 ppm was determined in rabbits based on malformations in the cardiovascular system of foetuses at the higher doses.

In toxicogenomic studies on the chemical, gene expression changes were used to assess the carcinogenic potential of the chemical in the female mouse liver, male rat kidney and

female mouse lung from animals exposed by inhalation to 10,054 ppm and 49,728 ppm for 90 days. No treatment related histopathological lesions were observed in the liver or kidneys following exposure at 10,054 ppm and 49,728 ppm. Based on these results, the chemical was predicted to be non-carcinogenic in these organs. However, gene expression changes in the male rat kidney suggested potential endocrine related effects. Histopathological effects in the lungs were limited to minimal inflammation observed in 1 out of 10 mice in each of the dose groups. Given that lung tumours were reported at very high doses, a significant risk for lung tumour induction in humans is not supported under realistic inhalation exposure conditions to the chemical. In the absence of more reliable carcinogenicity studies, it is not possible to determine the carcinogenicity potential of the chemical.

The physicochemical characteristics of the chemical may also contribute to the hazard of the chemical. The chemical vapours are heavier than air and can reduce the amount of oxygen available for respiration. In addition, contact with rapidly evaporating liquid can cause frostbite to the skin or damage to eyes.

The hazardous decomposition product, hydrogen fluoride (HF) (CAS No. 7664-39-3), may be formed after heating or combustion of the chemical.

## Hazard classifications relevant for worker health and safety

The chemical does not satisfy the criteria for classification according to the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) (UNECE 2017) for hazard classes relevant for work health and safety. This does not consider classification of physical hazards and environmental hazards.

## Summary of health risk

### Public

The previously assessed use of the chemical as a refrigerant was limited for use in industrial settings and/or handled by professional technicians. The public was not expected to have direct exposure to the chemical; hence, public exposure was considered low when used in this manner.

A new use for the chemical as a DIY air conditioning top up or recharge kit for all types of vehicles has been provided. The chemical will be contained in a 396 g size canister, which will be available for consumers to refill their vehicle air conditioning systems. The refill operation was described as attaching a quick connect fitting on one end of a recharge hose from the canister to a dedicated service port. The canister is equipped with a trigger, which is manually squeezed to dispense the chemical into the air conditioning system. The charging operation is fast and could be completed within 10 minutes.

Public exposure is expected to be widespread during DIY refilling operations. However, dermal, ocular and inhalation exposure is expected to be low unless there is accidental leakage. The canisters are equipped with a safety mechanism where charging is not possible if the recharge hose is incorrectly fitted to the service port.

In a worst case scenario where the hazardous decomposition product, HF, is generated from accidental release, exposure is expected to be low because of the low volume of the chemical contained in the container and as refilling operations are generally conducted in well ventilated (outdoor) areas.

Although the chemical may have potential health hazards, the risks to the public are minimised by:

- the small volume of chemical to which the public are exposed and/or the short duration of exposure
- the infrequent use of the chemical
- normal precautions being taken when using domestic products to avoid skin and eye contact
- safe design of MVAC systems (in accordance with ISO 13043 (ISO 2011) and SAE Standard J639 (SAE 2011).

When used in the proposed manner, there are no identified risks to the public that require management. However, if new information on the chemical becomes available indicating reproductive toxicity, developmental toxicity and/or carcinogenicity effects, further risk management may be required.

**Workers**

Potential routes of occupational exposure are dermal, ocular and inhalation. The chemical is a gas at room temperature; therefore, inhalation is the main expected route of exposure. Dermal and ocular exposure to the chemical as a liquefied gas or as a gas may occur during transfer operations or accidental leakages.

The risks of being exposed to HF above the relevant health based limit was very low, in the order of $5 \times 10^{-12}$ events per hour of vehicle operation and a comparative analysis showed that these risks were well below those commonly considered acceptable by the public and regulatory agencies (SAE 2013).

In Australia, it is mandatory that a person who carries out work in relation to refrigeration and air conditioning equipment must hold a national Refrigerant Handling Licence. There are also a variety of safety requirements and use guidelines for employing refrigerants such as:

- The Australian Automotive Code of Practice 2008 (DEWHA 2008)
- Australia and New Zealand Refrigerant Code of Practice 2007 (AIRAH and IRHACE 2007)
- Flammable Refrigerants – Safety Guide (AIRAH 2018).

Therefore, professional workers are expected to have the proper equipment and training to minimise their risks from exposure to the chemical. For use in MVAC systems, worker exposure is further mitigated by the safety requirements for design of the units (SAE 2020) and requirements for cylinder size and connectors with containers (SAE2013) for use in professional servicing.

Overall, if control measures (see proposed means of managing risk) are in place and good practices are followed to limit exposure to the chemical and its decomposition product, HF, the proposed use of the chemical is unlikely to pose a risk to workers.

# Environment

## Summary of environmental hazard characteristics

The ecotoxicity studies (including environmental exposure and fate assessment) conducted on the chemical are discussed in detail in the assessment reports: STD 1535 and STD 1556 (NICNAS 2015a and NICNAS 2015b).

According to domestic environmental hazard thresholds and based on the available data the chemical is:

- Not persistent
- Not bioaccumulative
- Not toxic.

## Environmental hazard classification

The chemical is not classified hazardous according to the GHS (UNECE 2017) for environmental hazard. This does not consider classification of physical hazards and health hazards.

## Summary of environmental risk

The chemical is a gas at environmentally relevant temperature and pressure, and is expected to be released into the atmospheric compartment following its use or disposal. The chemical may be released to the atmospheric compartment as a result of accidental leakages when used as a refrigerant for air conditioning and refrigeration systems. New vehicle emits <5 g/year. In the event of a collision in which the air conditioning system is compromised, the entire refrigerant charge of 400−1200 g may be released. Stationary air conditioning units release about 10 to 25% of their charge annually. As a refrigerant, the chemical is expected to be recovered during maintenance or at end of service life for disposal via an approved product stewardship scheme for either recycling or destruction.

Consumers are expected to dispose of any units containing the notified chemical through specialist service centres. The chemical is not expected to be present in any emission or effluent.

In the atmosphere, the chemical may also undergo long range transport, but it is not expected to be a significant contributor to global warming or ozone depletion. The chemical is not expected to contribute to stratospheric ozone depletion because it does not contain chlorine or bromine (Papadimitriou 2007).

The chemical is of low hazard to aquatic organisms and is not expected to be released to the aquatic compartment. The chemical degrades to trifluoroacetic acid (TFA) under environmental conditions. Based on available information, TFA exhibits ecotoxicity, is persistent, and has the potential for Long Range Transport (LRTP) (BAuA 2021). However, the contribution to TFA levels from use of the chemical is expected to be negligible.

Overall, on the basis of the global warming potential and the use pattern, the chemical is not expected to pose a risk to the environment.

# Proposed means for managing risk

## Inventory listings

The specific requirement to provide information as a term of the Inventory listing should be varied under *Section 86 of the Industrial Chemicals Act 2019* to align the specific information requirement with the risk identified and considered in this evaluation statement as follows:

| Terms of listing | 1-Propene, 2,3,3,3-tetrafluoro- |
|---|---|
| Specific requirements to provide information to the Executive Director under Section 101 of the IC Act | Obligations to provide information apply. You must tell the Executive Director within 20 working days if:<br>– the function or use of the chemical has changed or is likely to change significantly from a component of refrigerant for MVACs and stationary air conditioning and refrigeration systems<br>– the container of the notified chemical for use in professional servicing of MVAC systems is greater than 23 L in size<br>– the container of the notified chemical for consumer use as do-it-yourself servicing of motor vehicle MVAC systems is greater than 396 g in size<br>– the amount of chemical being introduced has increased, or is likely to increase, significantly (≥150 tonnes annually)<br>– the chemical has begun to be manufactured in Australia. |

## Public health

### Information relating to safe introduction and use

The following measures should be taken by manufacturers, distributors or unit owners, where applicable, to minimise public exposure to the chemical (see **Summary of health risk** section):

- equipment should be maintained and monitored for leaks, with immediate corrective action taken where leaks are detected
- safe use instructions for MVAC products containing the chemical should be available for do-it-yourself users.

## Workers

### Information relating to safe introduction and use

The information in this statement including recommended hazard classifications, should be used by a person conducting a business or undertaking at a workplace (such as an

employer) to determine the appropriate controls under the relevant jurisdiction Work Health and Safety laws.

Recommended control measures that could be implemented to manage the risk arising from dermal, ocular and inhalation exposure to the chemical include, but are not limited to:

- using closed systems or isolating operations
- using local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker
- minimising manual processes and work tasks through automating processes
- adopting work procedures that minimize splashes and spills
- cleaning equipment and work areas regularly
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

These control measures should be supplemented with:

- conducting health monitoring for any worker who is at significant risk of exposure to the chemical, if valid techniques are available to monitor the effect on the worker's health
- conducting air monitoring to ensure control measures in place are working effectively and continue to do so.

Recommended engineering controls to minimise the risk from exposure and use of the chemical include:

- use in MVAC systems, the chemical should only be used for passenger cars and light trucks that adhere to all the safety requirements of SAE J639 (SAE 2020) or ISO 13043:2011 (ISO 2011), including requirements for a flammable warning label, high-pressure compressor cut-off switch and pressure relief devices, and unique fittings
- design, installation, operation, and maintenance of the chemical in stationary air conditioning and refrigeration systems should be in accordance with Flammable Refrigerants - Safety Guide (AIRAH 2018)
- fittings consistent with SAE J2844 (SAE 2013) should be used for connections with refrigerant containers in professional servicing of MVAC systems.

Recommended safe work practices to minimise the risk from exposure and use of the chemical should:

- follow all applicable safety precautions stated in The Australian Automotive Code of Practice 2008 for *Control of Refrigerant Gases during Manufacture, Installation, Servicing or De-commissioning of Motor Vehicle Air Conditioners*, Australia and New Zealand Refrigerant Handling Code of Practice 2007 and Flammable Refrigerants Safety Guide (AIRAH 2018)
- ensure all workers carrying out work in relation to refrigeration and air conditioning equipment hold a national Refrigerant Handling Licence.

Measures required to eliminate, or manage risk arising from storing, handling and using a hazardous chemical depend on the physical form and the manner in which the chemical is used.

Personal protective equipment should not solely be relied upon to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk.

The Model Codes of Practice by Safe Work Australia (SWA) provide information on how to manage the risks of hazardous chemicals in the workplace, prepare an SDS and label containers of hazardous chemicals. Your Work Health and Safety regulator should be

contacted for information on Work Health and Safety laws and relevant Codes of Practice in your jurisdiction.

# Conclusions

The conclusions of this evaluation are based on the information described in this Evaluation Statement and the public report of the assessment on 1-propene, 2,3,3,3-tetrafluoro- (NICNAS 2015a and 2015b), which includes more detailed information on human health and environmental hazard and risk.

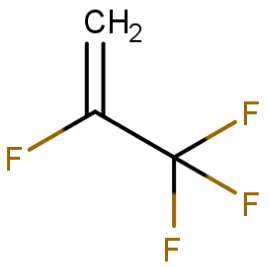
The Executive Director is satisfied that the identified human health and environmental risks from the advised change of introduction can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety, and poisons legislation as adopted by the relevant state or territory and the proposed means of managing risks are implemented.

The specific requirement to provide information as a term of the Inventory listing under *Section 101 of the IC Act* assists with managing the risks from introduction of the chemical. The information currently required to be provided is no longer aligned with the risks identified in this evaluation statement. Therefore, a variation to the specific requirement to provide information as a term of the Inventory listing is necessary to manage the risks from introduction of the chemical (see **Proposed means of managing risk)**.

Note: Obligations apply to report additional information about hazards under *Section 100* and to provide any information specifically required by the terms of the Inventory listing under *Section 101, of the Industrial Chemicals Act 2019.*

# Supporting information

## Chemical identity

| | |
|---|---|
| Chemical name | 1-Propene, 2,3,3,3-tetrafluoro- |
| CAS | 754-12-1 |
| Synonyms | 1,1,1,2-tetrafluoro-2-propene;<br>1234yf;<br>HFO-1234yf;<br>2,3,3,3-tetrafluoro-1-propene;<br>2,3,3,3-tetrafluoropropene;<br>2,3,3,3-tetrafluoropropylene;<br>HFC 1234yf; and<br>R 1234yf |
| Structural formula |  |
| Molecular formula | C3H2F4 |
| Molecular weight (g/mol) | 114.04 |
| SMILES | FC(=C)C(F)(F)F |
| Chemical description | Organic compound, colourless liquefied gas at 20 ºC and 101.3 kPa |

## Existing Australian regulatory controls

### AICIS

The chemical is listed on the Inventory with a specific requirement to provide information as a term of the Inventory listing. This term is published as:

- Specific information requirement: Obligations to provide information apply. You must tell us within 28 days if the circumstances of your importation or manufacture (introduction) are different to those in our assessment

Under *Section 75(2)(c) of the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019* the notification obligations under *Subsections 64(1) and*

*(2) of the old law (ICNA Act)* are taken to be specific information requirements to be provided to the Executive Director.

The assessment reports recommended the following circumstances under which the Director must be notified in writing within 28 days by an introducer (*Section 64(1) of* the *Industrial Chemicals Notification and Assessment (ICNA) Act 1989*):

- the container of the notified chemical for use in professional servicing of motor vehicle air conditioning (MVAC) systems is smaller than 2.3 L or greater than 23 L in size
- further information on the carcinogenicity, mutagenicity, reproductive toxicity and developmental toxicity of the notified chemical becomes available.

Additionally under Section 64(2) of the ICNA Act, a person who introduces an industrial chemical that has been assessed under this Act must within 28 days of becoming aware of any of the following circumstances since the assessment, notify the Director in writing:

(a) the function or use of the chemical has changed, or is likely to change, significantly;
(b) the amount of the chemical being introduced has increased, or is likely to increase, significantly;
(c) in the case of a chemical not manufactured, or proposed to be manufactured, in Australia at the time of the assessment - it has begun to be manufactured in Australia;
(d) the method of manufacture of the chemical in Australia has changed, or is likely to change, in a way that may result in an increased risk of an adverse effect of the chemical on occupational health and safety, public health or the environment;
(e) additional information has become available to the person as to an adverse effect of the chemical on occupational health and safety, public health or the environment.

### Public

No specific controls are currently available for the chemical.

### Workers

The chemical is not listed on the Hazardous Chemical Information System (HCIS) and no specific exposure standards are available in Australia (SWA).

### Environment

The industrial use of the chemical is not subject to any specific national environmental regulations.

## International regulatory status

### United States of America

The United States Environment Protection Agency (US EPA) has issued a significant new use rule (SNUR) under *Section 5(a)(2) of the Toxic Substances Control Act (TSCA) for* the chemical substance, 1-propene, 2,3,3,3-tetrafluoro-, effective 2 December 2013 (US EPA 2013), as follows:

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance identified as 1-propene, 2,3,3,3-tetrafluoro- (PMN P–07–601; CAS No. 754–12–1) is subject to reporting under this Section for the significant new uses described in paragraph (a)(2) of this Section.

(2) The significant new uses are:

(i) *Industrial, commercial, and consumer activities.*

A significant new use is use other than as a refrigerant in motor vehicle air conditioning systems in new passenger cars and vehicles (i.e.,as defined in 40 CFR 82.32(c) and (d));

§ 721.80(m) (commercial use other than in passenger cars and vehicles in which the original charging of motor vehicle air conditioning systems with the PMN substance was done by the motor vehicle original equipment manufacturer (OEM));

§ 721.80(o) (use in consumer products other than products used to recharge the motor vehicle air conditioning systems in passenger cars and vehicles in which the original charging of motor vehicle air conditioning systems with the PMN substance was done by the motor vehicle OEM).

The above activity requires persons who intend to manufacture, import, or process the chemical substance for a use that is designated as a significant new use by this final rule to notify EPA at least 90 days before commencing that activity.

# Health hazard information

For supporting information, refer to the assessment reports: STD 1535 and STD 1556. Since the assessment in 2015, additional hazard information became available and included in this Evaluation statement.

## Acute toxicity

### Inhalation

In an acute inhalation toxicity study conducted in accordance with OECD TG 403, Crl:CD(SD) rats (5/sex/dose) were exposed to the chemical (single exposure; nose only) for 4 h at 19,700 ppm nominal concentration (20,345 ppm analytical concentration), and observed for 14 days. No mortality was reported. No sub-lethal clinical effects were reported and no effect on body weights was observed (REACH).

## Repeat dose toxicity

### Inhalation

In a 28-day study conducted in accordance with OECD TG 412, Crl:CD(SD) rats (5/sex/dose) were administered the chemical by inhalation (nose-only) at 200, 400 ppm and 800 ppm, 6 h/day, 5 days/week. No mortality was reported. No adverse effects on gross morphology, histopathology and clinical observations were reported. A No Observed Adverse Effect Concentration (NOAEC) of ≥800ppm was determined for the study (REACH).

## Genotoxicity

**In Vitro**

Negative results were reported in a bacterial reverse mutation assay (OECD TG 471) in *Salmonella typhimurium* TA 98, TA 100, TA 1535 and TA 1537, and in *Escherichia coli* WP2 uvrA, with and without metabolic elevation, at concentrations up to 12% in air (corresponding to the upper explosive limit of the chemical) (REACH).

Negative results were also reported in an in vitro mammalian chromosome aberration assay (OECD TG 473) in human lymphocytes, with and without metabolic activation, at concentrations up to 12% in air (REACH).

The chemical was tested for its potential to induce mutations at the thymidine kinase (TK) locus of mouse lymphoma L5178Y cells (OECD TG 476). Mouse lymphoma L5178Y cells were exposed to the chemical (as gas) at concentrations of 76, 60, 40, 20 and 10% (v/v), with S9 metabolic activation (4 hour exposure) and without S9 metabolic activation (4 and 24 hours). The chemical was cytotoxic at concentrations ≥40% in the presence of S9. There was a significant increase in mutant frequency at 20% concentration in the presence of S9 only. There was no cytotoxicity or increased in mutant frequency reported up to the highest concentration tested in the absence of S9 (REACH).

**In Vivo**

In an in vivo mammalian erythrocyte micronucleus test (OECD TG 474), Crl:CD(SD) rats (6/sex/dose) were exposed to the chemical by inhalation (nose-only) at 418 and 847 ppm air, m (analytical concentrations) in air for 3 days (6 hours/day). The incidence of micronucleated polychromatic erythrocytes (MPE) did not increase in any of the treated groups, indicating a lack of clastogenicity (REACH).

In a combined in vivo mammalian erythrocyte micronucleus test (OECD TG 474) and alkaline comet assay (OECD 489), male Wistar rats (5/dose) were exposed to the chemical by inhalation (nose-only) at 5000, 15000 or 50000 ppm in air, for 3 days (6 hours on day 1 and 2; 2 hours on day 3). Liver and lung cells were examined for comet assay and bone marrow cells for micronucleus test. There was no increased of MPE in the bone marrow up to the highest concentration tested; hence, chemical exposure did not result in chromosomal damage. No statistically significant increase in mean tail intensity up to the highest concentration tested, indicating that the chemical did not induce DNA damage in the liver and lung cells of rats (REACH).

# Environmental effects

For supporting information, refer to the assessment reports: STD 1535 and STD 1556.

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