INTERNATIONAL PROGRAMME ON CHEMICAL SAFETY

Health and Safety Guide No. 91

# ISOPHORONE HEALTH AND SAFETY GUIDE

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WORLD HEALTH ORGANIZATION, GENEVA 1995

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Health and Safety Guide No. 91

# ISOPHORONE
# HEALTH AND SAFETY GUIDE

This is a companion volume to
Environmental Health Criteria 174: Isophorone

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# INTRODUCTION

The Environmental Health Criteria (EHC) monographs produced by the International Programme on Chemical Safety include an assessment of the effects on the environment and on human health of exposure to a chemical or combination of chemicals, or physical or biological agents. They also provide guidelines for setting exposure limits.

The purpose of a Health and Safety Guide is to facilitate the application of these guidelines in national chemical safety programmes. The first three sections of a Health and Safety Guide highlight the relevant technical information in the corresponding EHC. Section 4 includes advice on preventive and protective measures and emergency action; health workers should be thoroughly familiar with the medical information to ensure that they can act efficiently in an emergency. Within the Guide is a Summary of Chemical Safety Information which should be readily available, and should be clearly explained, to all who could come into contact with the chemical. The section on regulatory information has been extracted from the legal file of the International Register of Potentially Toxic Chemicals (IRPTC) and from other United Nations sources.

The target readership includes occupational health services, those in ministries, governmental agencies, industry, and trade unions who are involved in the safe use of chemicals and the avoidance of environmental health hazards, and those wanting more information on this topic. An attempt has been made to use only terms that will be familiar to the intended user. However, sections 1 and 2 inevitably contain some technical terms. A bibliography has been included for readers who require further background information.

Revision of the information in this Guide will take place in due course, and the eventual aim is to use standardized terminology. Comments on any difficulties encountered in using the Guide would be very helpful and should be addressed to:

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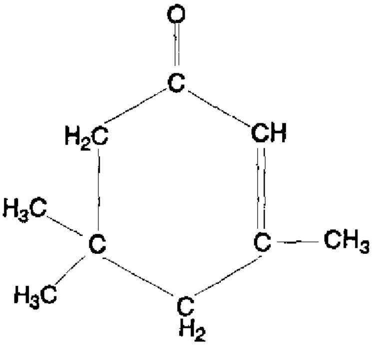
International Programme on Chemical Safety
World Health Organization
1211 Geneva 27
Switzerland

THE INFORMATION IN THIS GUIDE
SHOULD BE CONSIDERED AS A
STARTING POINT TO A COMPREHENSIVE
HEALTH AND SAFETY PROGRAMME

# 1. IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES, ANALYTICAL METHODS

## 1.1 Identity

| | |
|---|---|
| Common name: | Isophorone |
| Synonyms: | 2-cyclohexen-1-one, 3,5,5,-trimethyl;<br>3,5,5-trimethyl-2-cyclohexene-1-one;<br>1,1,3-trimethyl-3-cyclohexene-5-one;<br>alpha-isophorone; isoacetophorone; isoforone;<br>izoforon; 1,5,5-trimethyl-3-oxo-cyclohexene |
| Empirical formula: | $C_9H_{14}O$ |
| Chemical structure: |  |
| Relative molecular mass: | 138.2 |
| CAS registry number: | 78-59-1 |
| RTECs registry number: | GW7700000 |
| EEC number: | 606-012-00-8 |
| EINECS number: | 1011260 |

## 1.2 Physical and Chemical Properties

Isophorone is a colourless liquid. Its odour has been described as similar to those of peppermint and camphor. It is soluble in water and is miscible in all proportions with aliphatic and aromatic hydrocarbons, alcohols, ethers, esters, ketones, and chlorinated hydrocarbons. Physical and chemical data are summarized in Table 1.

Table 1. Physical and chemical data of isophorone

| | Value |
|---|---|
| Specific gravity (20 °C/4 °C) | 0.922 |
| Boiling point at 1013 hPa | 215 °C |
| Freezing point | -8.1 °C |
| Refractive index | 1.4775 n$^{20}$D |
| Viscosity at 20 °C | 2.6m Pas |
| Coefficient of cubic expansion at 20 °C | 0.00085 °C$^{-1}$<br>0.00078 °C$^{-1}$ |
| Surface tension at 20 °C | 30 mN/m |
| Vapour pressure | 0.4 mbar (20 °C)<br>0.26 mmHg (25 °C) |
| Vapour density (air = 1) | 4.7 |
| Concentration in saturated air at 20 °C and 1013 hPa | approx. 1941 mg/m$^3$ (340 ppm) |
| Solubility at 20 °C | |
| Isophorone in water | 12.0-17.5 g/litre |
| Water in isophorone | 53 g/litre |
| Log $K_{ow}$ (20 °C) | 1.67 (measured)<br>1.7 (estimated) |
| Solubility parameters (Hansen) | |
| delta | 19.2 (J/cm$^3$)1/2 |
| deltaD | 16.6 (J/cm$^3$)1/2 |
| deltaP | 8.2 (J/cm$^3$)1/2 |
| deltaH | 7.4 (J/cm$^3$)1/2 |
| Hydrogen bonding parameter, gamma | 14.9 |
| Flashpoint, closed cup | 85 °C |
| Explosion limits in air | 0.8-3.8 vol-% |
| Ignition temperature | 455-470 °C |
| Heat of evaporation at 215 °C | 349.2 kJ/kg |
| Heat of combustion (p = const. at 20 °C) | 38 100 kJ/kg |
| Relative permittivity at 20 °C | 19.9 |
| Specific resistivity | 1 × 10$^7$ ohm × cm |

# IDENTITY, PHYSICAL AND CHEMICAL PROPERTIES, ANALYTICAL METHODS

A typical, commercial sample of isophorone may contain 1-3 % of the isomer beta-isophorone (3,5,5-trimethyl-3-cyclohexene-1-one) with the sum of alpha- and beta-isomers exceeding 99 %.

Isophorone is stable and may be stored in steel or aluminium containers. Prolonged periods of storage may lead to slight yellowing.

## 1.3 Conversion Factors

The following conversion factors have been calculated for 22 °C and 1013 hPa:

1 ppm=5.71 $mg/m^3$
1 $mg/m^3$=0.175 ppm.

## 1.4 Analytical Methods

The purity of technical isophorone may be determined by capillary gas chromatography (GC) with a flame ionization detector (FID). Recommended conditions are shown in Table 2.

Earlier methods for the determination of isophorone in air were based on adsorption on charcoal; however, it has been found that isophorone adsorbed on charcoal decomposes during storage. More recent methods involve adsorption on polymers, such as XAD resins or Tenax-GC, followed by desorption and analysis by capillary GC with FID.

The determination of isophorone in wastewater samples and fish tissues may be achieved using solvent extraction, clean-up with gel permeation chromatography, and analysis by GC/MS, in both the electron impact and chemical ionization modes.

Table 2. Gas chromatographic conditions for the analysis of technical isophorone

| Column | Fused silica capillary | Macrobore |
|---|---|---|
| Coating | OV - 1701 | CP Wax 52CB |
| Dimensions | 60 m/0.25 mm | 25 m/0.53 mm |
| Injector temperature | 240 °C | 250 °C |
| Temperature-Programme | 6 min 70°-220° @ 4°/min | 10 min 105°-120° @ 6°/min<br>2 min 120°-150° @ 10°/min |

## 1.5 Production and Use

Isophorone is produced commercially by the catalytic condensation of acetone at elevated temperature and pressure and is purified by distillation. Worldwide annual production capacity was estimated to be 92 000 tonnes in 1988.

Isophorone is used as a chemical intermediate for the synthesis of a variety of organic chemicals.

Isophorone is a solvent for a number of natural and synthetic resins and polymers, such as polyvinyl chlorides and acetates, cellulose derivatives, epoxy and alkyd resins, and polyacrylates. It is therefore used as a high boiling solvent in industrial air drying and stoving paints, nitro emulsion leather finishes, and the manufacture of vinyl resin-based printing inks for plastic surfaces. Isophorone is also used as a solvent for some pesticide formulations, especially for emulsifiable concentrates of anilides and carbamates.

# 2. SUMMARY AND EVALUATION

## 2.1 Environmental Transport, Distribution, and Transformation

Isophorone may enter the environment from numerous industries, waste and waste-water disposal, and its use as a solvent and a pesticide carrier. Following release into water or soil, environmental concentrations decrease as a result of volatilization and biodegradation. Isophorone in the atmosphere is removed by photochemical processes with an estimated half-life of about 30 min (based on a mathematical model). In a Die-away test, isophorone was biodegraded by approximately 70% in 14 days and 95% after 28 days. The results of biodegradation studies are variable and limited. Water solubility, soil adsorption coefficients, and polarity indicate that significant adsorption by suspended solids and sediments is unlikely to occur.

Although isophorone has been found in fish tissues, the data and the physical and chemical properties suggest that significant bioconcentration is unlikely. A half-life of one day has been measured in a single fish species.

## 2.2 Environmental Levels and Human Exposure

Isophorone has not been measured in ambient air. An isophorone concentration in coal fly ash of 490 μg/kg (490 ppb) has been reported. Isophorone has been identified in surface waters (0.6-3 μg/litre), groundwater (10 μg/litre), urban run-off (10 μg/litre), and landfill leachate (29 μg/litre).

Isophorone has been identified in industrial wastewater at 100 μg/litre. After classical secondary treatment, the concentration of isophorone in the effluent was 10 μg/litre.

Isophorone has been identified in lake sediments (0.6-12 μg/kg dry weight).

It has also been identified in tissues from several species of fish at concentrations of up to 3.61 mg/kg wet weight.

Isophorone was not detected in the edible parts of bean plants, rice, or sugar beet, following application as a pesticide carrier.

## 2.3 Kinetics and Metabolism in Laboratory Animals and Humans

Distribution studies on rats using $^{14}$C-isophorone showed that 93% of orally administered radioactivity appeared mainly in the urine and expired air within 24 h. The tissues retaining the highest concentration after this period were the liver, kidney, and preputial glands.

The metabolites identified in the urine of rabbits after oral administration of isophorone resulted from the oxidation of the 3-methyl group, reduction of the keto group, and hydrogenation of the double link of the cyclohexene ring, and were eliminated as such, or, in the case of the alcohols, as the glucuronide derivatives.

Percutaneous $LD_{50}$ values indicate that isophorone is rapidly absorbed through the skin.

## 2.4 Effects on laboratory mammals and *in vitro* test systems

The acute toxicity of isophorone is low, oral $LD_{50}$ values being > 1500 mg/kg in the rat, >2200 mg/kg in the mouse, and >2000 mg/kg in the rabbit. Dermal $LD_{50}$ values were 1700 mg/kg in the rat and > 1200 mg/kg in the rabbit. Acute effects from dermal exposure in rats and rabbits ranged from mild erythema to scabs. Conjunctivitis and corneal damage have been reported on direct application to the eye or exposure to high concentrations of isophorone. No skin sensitization was reported in guinea-pigs using the Magnusson-Kligman test.

In acute and short-term oral studies on rodents given high doses (≥ 1000 mg/kg), degenerative effects in the liver as well as CNS depression were seen and there were some deaths. In 90-day studies, the no-observed-effect levels (NOELs) in rats and mice were evaluated to be 500 mg/kg body weight per day. In a 90-day oral study on Beagle dogs (with limited numbers), no effects were seen at doses of up to 150 mg/kg body weight per day.

In acute and short-term inhalation studies reviewed, irritation, haematological effects, and decreased body weights were noted. Since the study designs were inadequate, no NOEL could be determined and no inference for human health could be made.

Isophorone does not induce gene mutations in bacteria, chromosomal aberrations *in vitro*, DNA repair in primary rat hepatocytes, or bone-marrow micronuclei in mice. Positive effects were observed only in the absence of an exogenous metabolic system in L5178Y TK +/- mouse lymphoma mutagenesis assays as well as in a sister chromatid exchange assay. Isophorone induced morphological transformation *in vitro* in the absence of an exogenous metabolism system. Isophorone did not induce sex-linked recessive lethal mutations in *Drosophila*. The weight of the evidence of all mutagenicity data supports the contention that isophorone is not a potent DNA reactive compound. In an *in vivo* assay, no DNA binding was observed in the liver and kidneys (organs affected in the carcinogenicity bioassays).

In long-term oral toxicity studies on mice and rats, male rats showed several proliferative lesions of the kidney. The role of $\alpha_{2u}$-globulin accumulation in the etiology of these lesions has been recognized. Since significant amounts of $\alpha_{2u}$-globulin have not been detected in humans, this mechanism of carcinogenesis appears not to be relevant in humans. Preputial gland carcinomas were observed in five high-dose male rats and two clitoral gland adenomas were seen in low-dose female rats with exposure to isophorone. These may also be related to $\alpha_{2u}$-globulin accumulation. Isophorone exposure was associated with some neoplastic lesions of the liver, and the integumentary and the lymphoreticular systems of male mice, as well as nonneoplastic liver and adrenal cortex lesions, but this was not observed in treated female mice.

In the only available long-term inhalation study on rats and rabbits, irritation of the eye and nasal mucosa as well as lung and liver changes were observed at approx. 1347 mg/m$^3$ (250 ppm). However, this may have been because of limitations in the study.

Very limited studies on rats and mice indicate that isophorone does not affect the fertility or cause developmental toxicity in experimental animals.

The fact that central nervous system depression occurs in experimental animals could indicate a possible neurotoxic effect. Isophorone also elicited a positive effect in the behavioural despair swimming test.

## 2.5 Effects on Humans

The odour of isophorone can be detected at a concentration as low as 1.14 mg/m$^3$ (0.2 ppm). Eye, nose, and throat irritation have been reported at concentrations below 28.5 mg/m$^3$ (5 ppm); above 1142 mg/m$^3$ (200 ppm) nausea, headache, dizziness, faintness, and inebriation have been reported.

### 2.6 Effects on Other Organisms in the Laboratory and Field

No data on terrestrial animals were available.

Acute $LC_{50}$ values are available for several freshwater and marine species. $EC_{50}$s (96-h) (based on cell count and chlorophyll) ranged from 105 to 126 mg/litre; 48-h $LC_{50}$s for *Daphnia magna* ranged from 117 to 120 mg/litre, and 96-h $LC_{50}$s for freshwater fish ranged from 145 to 255 mg/litre.

$LC_{50}$s (96-h) for marine invertebrates ranged from 12.9 to 430 mg/litre. The 96-h $LC_{50}$ for a single marine fish species was between 170 and 300 mg/litre. Data from studies with measured exposure concentrations did not differ from those of studies with nominal concentrations. NOELs for *Pimephales promelas*, tested in different laboratories, ranged from 14 to 45.4 mg/litre.

The available data suggest that the toxicity of isophorone for aquatic organisms is low.

# 3. CONCLUSIONS AND RECOMMENDATIONS

## 3.1 Conclusions

### 3.1.1 *General population exposure*

Isophorone is used as a solvent for resins, polymers, and pesticide formulations. Dermal and inhalation exposure may occur, but will most likely be minimal. Data are available that show that isophorone can occur in μg/litre concentrations in drinking-water and fish. In view of the low toxicity of isophorone in experimental studies and the low levels of exposure from environmental sources, the risks for the general population appear to be minimal.

### 3.1.2 *Occupational exposure*

In the absence of adequate engineering controls and industrial hygiene measures, occupational exposure to isophorone may exceed acceptable levels and cause eye, skin, and respiratory irritation; other health effects may occur at higher concentrations. No studies on long-term health effects in workers were available for review by the Task Group.

### 3.1.3 *The environment*

Isophorone may be released into the environment following its use as a pesticide carrier and its ubiquitous use as a solvent. Low concentrations have been identified in several environmental compartments, though it has a low environmental persistence due to biodegradation, volatilization, and photochemical oxidation processes. The available data suggest that the toxicity of isophorone for aquatic organisms is low.

## 3.2 Recommendations

### 3.2.1 *General population and occupational exposure*

Care should be taken to prevent contamination of groundwater and air.

Workers involved in the manufacture or use of isophorone should be protected from exposure by means of adequate engineering controls and appropriate industrial hygiene measures. Levels of occupational exposure should be kept within acceptable limits and should be monitored regularly.

### 3.2.2 *Further studies*

Health surveillance of exposed workers should be conducted and reported on.

Actual levels of isophorone in the waters surrounding industrial areas should be determined.

Adequate short term/long-term inhalation studies on experimental animals should be conducted, in order to determine safe levels of occupational exposure.

Information is required on the anaerobic biodegradation of isophorone, especially as it has been identified in landfill leachate.

# 4. HUMAN HEALTH HAZARDS, PREVENTION AND PROTECTION, EMERGENCY ACTION

## 4.1 Main Human Health Hazards, Prevention and Protection, First Aid

Isophorone vapours are irritating to the eyes and the respiratory tract. Prolonged exposure may cause fatigue and malaise. Prolonged contact with liquid isophorone may irritate the skin.

### 4.1.1 *First aid and medical treatment*

#### *4.1.1.1 Eye contact*

Immediately flush eyes with plenty of water. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Medical attention should be obtained.

#### *4.1.1.2 Skin contact*

Contaminated clothing should be removed and the affected area of the skin thoroughly flushed with water. If skin irritation occurs, medical attention should be obtained.

#### *4.1.1.3 Inhalation*

Provide fresh air. Monitor breathing, and give oxygen if breathing is difficult.

#### *4.1.1.4 Ingestion*

Seek medical advice immediately. Wash out mouth with water. Emesis may be indicated soon after ingestion, unless the patient is unconscious. Let the victim ingest charcoal (30-100 g in adults) as a slurry, to limit absorption of isophorone from the intestine.

### 4.1.2 *Safe handling*

#### *4.1.2.1 Personal protection*

Atmospheric levels should be kept below the recommended occupational exposure limits by local exhaust ventilation. Respirators should be worn in areas where these limits are likely to be exceeded. Skin and eye protection should be worn where exposure is likely to occur. Nitrile rubber gloves are recommended.

## 4.2 Fire and Explosion Hazards

Isophorone is flammable. Suitable extinguishing media are water spray, carbon dioxide, foam, or dry powder.

The explosion limits in air are 0.8-3.8 vol.%.

## 4.3 Storage

Containers should be kept tightly closed and stored in a well-ventilated area.

## 4.4 Transport

Local requirements regarding the movement of hazardous goods or wastes must be complied with. Containers should be checked to ensure that they are sound and labels undamaged before despatch. For regulations see section 6.4.

## 4.5 Spillage and Disposal

### 4.5.1 *Spillage*

The area should be evacuated and sources of ignition removed. Self-contained breathing apparatus, gloves, goggles, face shield, and boots should be worn. Liquid should be prevented from entering sewers, basements, and workpits.

Small-scale spillages should be absorbed on paper towels and the paper burnt, away from other combustible material.

For medium-scale spillages, the liquid should be absorbed with sand or earth and all material should be removed to a safe place for subsequent incineration. The contaminated area should be washed out with plenty of water.

For large-scale spillages, the spilt liquid should be prevented from spreading by the use of sand or earth. The liquid should be transferred to a salvage tank if possible; otherwise it should be treated as for medium-scale spillages. The local authorities should be informed at once, if the spilt liquid enters the surface-water drains.

### 4.5.2 *Disposal*

This combustible material may be burned in a chemical incinerator. The product should not be buried or dumped in a landfill.

# 5. HAZARDS FOR THE ENVIRONMENT AND THEIR PREVENTION

The toxicity of isophorone for aquatic and terrestrial species is low.

Industrial discharges and any spillage or unused product should be prevented from polluting the environment and spreading to vegetation or waterways and should be treated and disposed of properly (section 4.5.2).

# 6. CURRENT REGULATIONS, GUIDELINES, AND STANDARDS

The information given in this section has been extracted from the International Register of Potentially Toxic Chemicals (IRPTC) legal file and other United Nations sources. The intention is to give the reader a representative but non-exhaustive overview of current regulations, guidelines, and standards.

The reader should be aware that regulatory decisions about chemicals, taken in a certain country, can only be fully understood in the framework of the legislation of that country. Furthermore, the regulations and guidelines of all countries are subject to change and should always be verified with the appropriate regulatory authorities before application.

## 6.1 Previous Evaluations by International Bodies

None available.

## 6.2 Exposure Limit Values

Some exposure limit values are given in the table on the next page.

## 6.3 Specific Restrictions

In Germany, isophorone may not be handled by adolescents or pregnant, or nursing, women.

## 6.4 Labelling, Packaging, and Transport

The European Community legislation requires labelling as an irritant substance using the symbol:

# CURRENT REGULATIONS, GUIDELINES, AND STANDARDS

**Exposure limit values in some countries**

| Medium | Specification | Country/ organization | Exposure Limit Description | Value | Effective date |
|---|---|---|---|---|---|
| AIR | | Finland | Threshold limit value (TLV) | 28 mg/m$^3$ (5 ppm) | 1987 |
| | | Germany | Maximum worksite concentration (MAK)<br>- time-weighted average (TWA) | 28.0 mg/m$^3$ | 1980 |
| | | Russian Federation | Ceiling value | 1.0 mg/m$^3$ | 1978 |
| | | Sweden | Hygienic limit value | 30.0 mg/m$^3$ | 1985 |
| | | United Kingdom | Recommended limit (RECL) | | |
| | | | - time-weighted average (TWA) | 25 mg/m$^3$ | 1985 |
| | | | - short-term exposure level (STEL) (10-min-TWA) | 25 mg/m$^3$ | |
| | | USA | Permissible Exposure Limit (OSHA) | | |
| | | - DOL/OSHA | 8-h time-weighted average (TWA) | 23.0 mg/m$^3$ (4 ppm) | 1989 |
| | | - NIOSH | Recommended Exposure Limit (REL)<br>up to a 10-h TWA | 23 mg/m$^3$ (4 ppm) | 1988 |
| | | - ACGIH | Threshold limit value (TLV)<br>Ceiling value (15-min) | 28 mg/m$^3$ (5 ppm) | 1992 |

The label must read:

> *Irritating to eyes, respiratory system and skin; in case of contact with eyes, rinse immediately with plenty of water and seek medical advice.*

Regulations on the Transport of Dangerous Goods:

| | |
|---|---|
| RID/ADR: | Class 3, No. 32C |
| ADNR: | Class 3, No. 4, category K3 |
| GGVSee/IMDG-Code: | Not classified |
| IATA-RAR: | Article No. 1939 |

### 6.5 Waste Disposal

In the USA, isophorone is rated as a persistent compound, and any non-domestic waste must be treated as a toxic pollutant. Specific instructions are given for notification and incineration. Permits are required for its discharge and discharge limits have been set.

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