Cetonal: Environment tier III assessment

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Preface

This assessment was carried out by staff of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) using the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework.

The IMAP framework addresses the human health and environmental impacts of previously unassessed industrial chemicals listed on the Australian Inventory of Chemical Substances (the Inventory).

The framework was developed with significant input from stakeholders and provides a more rapid, flexible and transparent approach for the assessment of chemicals listed on the Inventory.

Stage One of the implementation of this framework, which lasted four years from 1 July 2012, examined 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This included chemicals for which NICNAS already held exposure information, chemicals identified as a concern or for which regulatory action had been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

Stage Two of IMAP began in July 2016. We are continuing to assess chemicals on the Inventory, including chemicals identified as a concern for which action has been taken overseas and chemicals that can be rapidly identified and assessed by using Stage One information. We are also continuing to publish information for chemicals on the Inventory that pose a low risk to human health or the environment or both. This work provides efficiencies and enables us to identify higher risk chemicals requiring assessment.

The IMAP framework is a science and risk-based model designed to align the assessment effort with the human health and environmental impacts of chemicals. It has three tiers of assessment, with the assessment effort increasing with each tier. The Tier I assessment is a high throughput approach using tabulated electronic data. The Tier II assessment is an evaluation of risk on a substance-by-substance or chemical category-by-category basis. Tier III assessments are conducted to address specific concerns that could not be resolved during the Tier II assessment.

These assessments are carried out by staff employed by the Australian Government Department of Health and the Australian Government Department of the Environment and Energy. The human health and environment risk assessments are conducted and published separately, using information available at the time, and may be undertaken at different tiers.

This chemical or group of chemicals are being assessed at Tier III because the Tier II assessment indicated that it needed further investigation. The report should be read in conjunction with the Tier II assessment.

For more detail on this program please visit: www.nicnas.gov.au.

Acronyms & Abbreviations

Synopsis

The chemical that is the subject of this assessment is more commonly known as cetonal. It has industrial uses as a fragrance ingredient. Cetonal was assessed in the Tier II environment assessment of fragrance chemicals with limited available data and was recommended for a Tier III assessment under the IMAP framework (NICNAS, 2015).

The Tier II environmental risk characterisation for cetonal indicated potentially unreasonable risks to the aquatic environment based on an estimated environmental exposure concentration that exceeded the no unacceptable adverse effect concentration for aquatic life. In the absence of other information, the assessment relied on default assumptions regarding the annual introduction volume for industrial chemicals. The default introduction volume was used to estimate the environmental exposure that would result from use of this chemical as a fragrance ingredient in personal care and household cleaning products. It was noted that relying on default introduction volumes could result in an overestimation of risks to aquatic life. A key finding of the Tier II assessment was that further refinement of the risk characterisation would be dependent on the availability of new information which includes the volume of the chemical that is used as a fragrance ingredient.

Rationale for Tier III Assessment

Following consultation with industry, NICNAS received new information on the volume of cetonal that is used globally as a fragrance ingredient. This new information indicates that the environmental emissions of the chemical that result from its use as a fragrance ingredient in Australia were overestimated in the Tier II environment assessment. New hazard information has also become available for cetonal which can now be used to reassess the risks posed to the environment by industrial uses of this chemical.

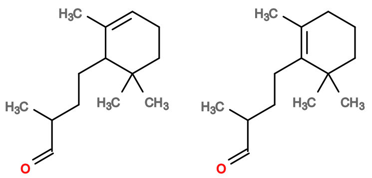
This Tier III assessment will also provide updated information on the chemical structure and composition of technical cetonal produced for industrial uses.

Chemical Identity

Technical cetonal is composed of a mixture of two structural isomers (CAS RNs 73398-85-3 and 84518-22-9), which differ only in the location of the *endo*-cyclic alkene group. It is prepared by an organic transformation reaction which uses a mixture of dihydroionone isomers as the starting material (CAS RNs 31499-72-6 and 17283-81-7) (Ford, et al., 1992).

Several reference sources depict an incorrect structure for cetonal (LMC, 2011, 2013; US EPA, 2008). In these, the side chain methyl group is placed on the carbon atom adjacent to the cyclohexene ring. Correctly, the methyl group is attached to the carbon atom adjacent to the aldehyde group (CAS, 2019; PubChem, 2008). The confusion arises as the "alpha" in the chemical name, Cyclohexenebutanal, α,2,2,6-tetramethyl-, can alternately be interpreted as alpha- relative to the ring, or alpha- relative to the aldehyde. The Chemical Abstracts Service (CAS) has confirmed this name uses "conjunctive" nomenclature, where in this case, the numbers for the ring methyl substituents are relative to the position of attachment of the side chain to the ring, while "alpha" is relative to the aldehyde. This is confirmed by the synthetic method for preparation of technical cetonal (Ford, et al., 1992).

The chemical structure information provided for this substance in the Tier II environment assessment has been updated here to indicate the mixture of structural isomers in technical cetonal, and the correct position of the methyl group on the butanal side chain:

Synonyms	cetonal orris butanal 2-methyl-4-(2,6,6-trimethyl-1(2)-cyclohexen-1-yl)butanal
Structural Formula	
Molecular Formula	$C_{14}H_{24}O$
Molecular Weight (g/mol)	208.34
SMILES	C1(C)(C)C(CCC(C)C=O)C(C)=CCC1 C1(C)(C)C(CCC(C)C=O)=C(C)CCC1

Physical and Chemical Properties

The measured physical and chemical property data for cetonal were retrieved from the registration dossier for this chemical submitted under the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) legislation in the European Union (REACH, 2019a):

Physical Form	liquid

Melting Point	-88.5 – -87.4°C
Boiling Point	267.3°C
Vapour Pressure	16 Pa (20°C)
Water Solubility	4.63 mg/L
Ionisable in the Environment?	no
log K_{ow}	5.5

Cetonal is a volatile neutral organic chemical which is slightly soluble in water. The measured octanol-water partition coefficient (K_{ow}) indicates that it is highly lipophilic.

Import, Manufacture and Use

Cetonal is used as a fragrance chemical in perfuming and fragrance products (IFRA, 2016). According to information provided by the International Fragrance Association (IFRA), 100–1000 kilograms per annum of cetonal was used globally as a fragrance ingredient (IFRA, 2016). No other industrial uses of cetonal have been identified.

The chemical has reported non-industrial use as a food flavouring agent (EFSA, 2008).

Environmental Regulatory Status

The following new or updated international regulatory status information for cetonal has been identified and is presented here as a supplement to the information already presented in the Tier II assessment:

Canada

Cetonal is listed on the Canadian Domestic Substances List (DSL) as an existing substance in commerce in Canada (Environment and Climate Change Canada, 2018). During the Categorization of the DSL, it was categorised as not Persistent (not P), Bioaccumulative (B) and inherently Toxic to the Environment (iT_E) (Environment and Climate Change Canada, 2019).

Cetonal is listed for assessment as part of the third phase of the Chemicals Management Plan (Government of Canada, 2019). The preparation of a draft ecological risk assessment is underway.

European Union

Cetonal is a registered chemical under the REACH legislation (ECHA, 2019).

Cetonal is listed on the European Commission’s Cosmetic Ingredient database (CosIng) as a perfuming ingredient in cosmetics (European Commission, 2019).

South Korea

Cetonal is listed as a new chemical substance on the Korean Existing Chemical Inventory (KECI) (NCIS, 2019). It is not listed on the Korean Registration, Evaluation, Authorisation and Restriction of Chemicals (K-REACH) Inventory (K-REACH, 2019).

Cetonal, and mixtures containing at least 25% cetonal, are classified as toxic substances under the Toxic Chemical Control Act (NCIS, 2019). Chemicals designated as toxic substances have additional reporting and labelling requirements for use in South Korea.

United States of America

Cetonal is listed on the United States Environmental Protection Agency (US EPA) Chemical Substance Inventory, established under the Toxic Substances Control Act 1976 (US EPA, 2018). It is registered as ‘active’ on the Chemical Substance Inventory, which indicates that it has recently been manufactured, imported or processed by industry in the USA.

Environmental Exposure

Cetonal is a synthetic organic chemical and its occurrence in the environment results exclusively from human activity. The chemical is used as a fragrance ingredient in consumer products which can result in emissions to the environment from point sources such as sewage treatment plants (STP), and from diffuse sources. Diffuse sources include emissions to the atmosphere by volatilisation of the chemical from the use of consumer products in domestic situations.

Chemicals used in cosmetics, personal hygiene and cleaning products are typically released to sewers in wastewater as a normal part of their use pattern. Depending on degradation and partitioning processes of chemicals in sewage treatment plants, some fraction of the quantity of chemicals in wastewater entering STPs can be emitted to the air compartment, to rivers or oceans in treated effluent, or to soil through application of biosolids to agricultural land. Based on standard removal efficiencies for volatile and lipophilic organic chemicals in STPs, 94% of cetonal will be removed from wastewater, with the majority partitioning to sludge (71%), a smaller fraction lost to biodegradation (19%), and a minor fraction partitioning to air (4%) (Struijs, 1996). Based on the predicted partitioning and degradation of cetonal in STPs, emissions to both environmental surface waters and soils are considered as part of this assessment.

Environmental Fate

Cetonal is a mixture of two structural isomers and they have slightly different properties. The calculations performed to model the environmental fate of cetonal have been conducted on both isomers and the results are presented as a range with the estimated values for each isomer determining the limits of the reported ranges.

Partitioning

Cetonal is expected to partition to soil or water when released into the environment.

Cetonal is a volatile neutral organic chemical with low solubility in water. The calculated Henry’s Law constant is in the range of 94–111 Pa-m^3/mol (US EPA, 2008), which indicates the chemical is highly volatile from water and moist soil. Cetonal is lipophilic and will adsorb to the organic component of soil. The calculated soil adsorption coefficient (K_{oc}) is 416–478 L/kg, which indicates it has medium mobility in soil.

Calculations with a standard multimedia partitioning (fugacity) model assuming equal and continuous distributions to air, water and soil compartments (Level III approach) predict that cetonal will partition to the soil compartment (81–82%) and the water compartment (17.5–18%). However, assuming sole release to water the chemical will predominately remain in the water compartment (97.6%).

Degradation

Cetonal is rapidly degraded in the environment by natural processes.

Based on the results of calculations with a standard quantitative structure-property relationship (QSPR), cetonal will undergo rapid photo-oxidation by hydroxyl radicals in the atmosphere with a calculated half-life of 0.8–1 hours. The calculations were performed assuming a typical hydroxyl radical concentration of 1.5×10^6 molecules/cm^3 and 12 hours of sunlight per day (US EPA, 2008).

The biodegradability of cetonal was evaluated in two screening studies conducted according to OECD Test Guideline (TG) 301F (Manometric Respirometry test). In one study, 54% degradation of cetonal occurred in 28 days. In a second study, 70% degradation of cetonal occurred in 28 days with 60% biodegradation achieved within the 10 day window (REACH, 2019a). This indicates that cetonal can be assumed to undergo rapid and ultimate biodegradation in the environment. The scientific literature indicates that biodegradation of the chemical is likely to involve oxidation of the aldehyde to form the corresponding carboxylic acid as a primary degradation product (Vasiliou, et al., 2000).

Bioaccumulation

Cetonal has a moderate to high potential to bioaccumulate in aquatic life.

No studies of the bioaccumulation of cetonal in aquatic life were identified. The measured octanol-water partition coefficient for cetonal exceeds the threshold for categorisation as a bioaccumulation hazard in aquatic life (log K_{ow} ≥ 4.2).

The estimated bioconcentration factor (BCF) for cetonal in fish from upper trophic levels without correction for biotransformation is 15 560 L/kg wet weight (US EPA, 2008). However, when the effects of biotransformation are included, the calculated BCF is between 1756–1811 L/kg wet weight, which indicates that the bioaccumulation potential of cetonal is moderate to high, but is below the categorisation threshold (BCF ≥ 2000 L/kg). The transformation rate constant used in this calculation was 0.135–0.14 per day, which gives an estimated biological half-life for the chemical of 4.9–5.1 days.

Aldehydes taken up by microbes, plants and animals are metabolised by cellular enzymes such as aldehyde dehydrogenase (Vasiliou, et al., 1999). This enzyme catalyses the conversion of exogenous and endogenous aldehydes to the corresponding carboxylic acids. Carboxylic acids are more water soluble than the parent aldehydes, which provides a pathway for excretion of the chemical.

Transport

The chemical is not expected to undergo long range transport based on its short half-life in the atmosphere.

Predicted Environmental Concentration (PEC)

The predicted concentration of cetonal in surface waters resulting from industrial uses is 51 nanograms per litre (ng/L).

The Tier II assessment of this chemical relied on an assumed annual introduction volume in Australia of 100 tonnes which resulted in a PEC of 9350 ng/L. The global volume of use for this chemical for its identified industrial use as a fragrance ingredient is only a fraction of this assumed introduction volume (between 100–1000 kg, or < 1%). Taking into account the revised upper limit of the annual introduction volume (1000 kg) and including the effect of partitioning and biodegradation of the chemical in STPs, the revised predicted environmental concentration for cetonal is 51 ng/L.

It is noted that the concentration of cetonal in the environment may be higher than estimated here as a result of emissions resulting from non-industrial uses of cetonal as a flavouring agent.

Environmental Effects

Effects on Aquatic Life

Cetonal is toxic to aquatic organisms. The chemical has a non-specific reactive mode of toxic action.

A read-across approach was used to fill an identified data gap for acute toxicity to fish. The alpha-methyl aldehyde, lilial (3-(4-tert-butylphenyl)-2-methylpropanal; CAS RN 80-54-6), was identified as a suitable analogue based on structural similarity, similar lipophilicity (log K_{ow} = 4.2), and a similar reactive mode of toxic action. A comparison of the measured toxicity of cetonal and lilial to the same species of aquatic invertebrate (*Daphnia magna*) under similar test conditions shows that the acute toxicity of these two chemicals is comparable, although it is possible that the acute toxicity of cetonal may be marginally underestimated using lilial as an analogue.

Both cetonal and lilial are categorised as having non-specific reactive toxicity to aquatic organisms (LMC, 2013).

Acute toxicity

The following measured median effective concentration (EC50) values for the effects of cetonal on aquatic invertebrates and algae were retrieved from the REACH registration dossier for the chemical (REACH, 2019a). The median lethal concentration (LC50) value for fish and the EC50 value for aquatic invertebrates presented below for the analogue chemical, lilial (CAS RN 80-54-6), was obtained from the REACH dossier for this chemical obtained from the REACH dossier for this chemical (REACH, 2019b):

Taxon	Endpoint	Method
Fish	96 h LC50 = 2.04 mg/L	Analogue chemical *Danio rerio* OECD TG 203 Mortality
Invertebrates	48 h EC50 = 0.739 mg/L	Experimental *Daphnia magna* OECD TG 202 Immobilisation observed
	48 h EC50 = 2.51 mg/L	Analogue chemical *Daphnia magna* 79/831/EWG Immobilisation observed
Algae	72 h EC50 ≥ 3.29 mg/L	Experimental *Pseudokirchneriella subcapitata* OECD TG 201 Growth inhibition observed

Aldehydes such as cetonal and lilial can cause toxic effects through irreversible reactions with the nucleophilic residues of biomolecules and enzymes in cells (LoPachin and Gavin, 2014). This reactivity can impair many important cellular processes including enzyme function, as well as denaturing proteins and affecting DNA. These effects can ultimately lead to disruption of cells (cytolysis).

Chronic toxicity

The following no observed effect concentration (NOEC) value for algae was retrieved from the REACH registration dossier for cetonal (REACH, 2019a):

Taxon	Endpoint	Method
Algae	72 h NOEC = 0.935 mg/L	Experimental *Pseudokirchneriella subcapitata* OECD TG 201 Growth inhibition observed

Effects on Terrestrial Life

Cetonal has low toxicity to mammals. An acute oral toxicity study in rats showed an oral median lethal dose (LD50) value greater than 5000 mg/kg bw (REACH, 2019a).

No suitable data were available to characterise the hazards of cetonal to other terrestrial life.

Predicted No-Effect Concentration (PNEC)

The PNEC for cetonal is 7.39 micrograms per litre (µg/L).

Aquatic invertebrates are the most sensitive taxonomic group to the acute toxic effects of this chemical based on the available data (including read-across data). Therefore, the measured 48 h EC50 of 0.739 mg/L for invertebrates was used to calculate the aquatic PNEC for cetonal. An assessment factor of 100 was used in this calculation as it was performed using the lowest measured value which is an acute toxicity endpoint.

Categorisation of Environmental Hazard

The categorisation of the environmental hazards of cetonal according to domestic environmental hazard thresholds is presented below (EPHC, 2009; NICNAS, 2017):

Persistence

Not Persistent (Not P). Based on the rapid degradation of the chemical in the environment, it is categorised as Not Persistent.

Bioaccumulation

Not Bioaccumulative (Not B). Based on the estimated BCF value for the chemical and taking into account biotransformation and elimination of the chemical in fish, it is characterised as Not Bioaccumulative.

Toxicity

Toxic (T). Based on a measured aquatic toxicity endpoint for invertebrates below 1 mg/L, the chemical is categorised as Toxic.

Summary

Cyclohexenebutanal, α,2,2,6-tetramethyl- is categorised as:

- Not P
- Not B
- T

Risk Characterisation

Cetonal is toxic to aquatic organisms and the chemical has a moderate to high bioaccumulation potential in fish. However, cetonal is rapidly and ultimately biodegradable in water and will not persist in the aquatic environment. The chemical is also rapidly degraded in the atmosphere and will not persist in the air compartment.

Based on the PEC and PNEC values determined above, the following Risk Quotient (RQ = PEC ÷ PNEC) has been calculated for release of cetonal into surface waters:

PEC (μg/L)	PNEC (μg/L)	RQ
0.051	7.39	0.0069

An RQ of lower than one indicates that industrial uses of cetonal do not pose an unreasonable risk to the environment, as the estimated environmental concentration does not exceed levels that cause adverse effects.

Cetonal will be released to soils through the application of biosolids to agricultural land, but poses a low risk to the soil compartment. The concentration of the chemical in biosolids is expected to be very low based on its low volume of use in Australia. There is a negligible risk of accumulation of the chemical in soils as cetonal is rapidly and ultimately biodegradable.

Key Findings

Cetonal is used as a fragrance ingredient in consumer products. It is toxic to aquatic organisms and has a moderate to high bioaccumulation potential. However, the chemical is rapidly degraded by natural processes and it will not persist in the environment.

Based on revised estimates of the scale of industrial uses of this chemical in Australia, it is currently considered to pose a low risk to surface waters when discharged in the treated effluents of sewage treatment plants. The chemical does not currently pose a risk to the soil environment.

The chemical is not a PBT substance according to domestic environmental hazard criteria.

Recommendations

No further assessment of the chemical is required unless data indicating higher volume industrial use resulting in substantial emissions to the environment are identified.

Environmental Hazard Classification

In addition to the categorisation of environmental hazards according to domestic environmental thresholds presented above, the classification of the environmental hazards of cyclohexenebutanal, α,2,2,6-tetramethyl- according to the third edition of the United Nations' Globally Harmonised System of Classification and Labelling of Chemicals (GHS) is presented below (UNECE, 2009):

Hazard	GHS Classification (Code)	Hazard Statement
Acute Aquatic	Category 1 (H400)	Very toxic to aquatic life
Chronic Aquatic	Category 1 (H410)	Very toxic to aquatic life with long-lasting effects

The classification of the acute aquatic hazards of cetonal was performed based on the toxicity data presented in this assessment. The long-term aquatic hazard classification was determined using the most stringent outcome method as is outlined by the GHS guidance for classification of chemicals with insufficient chronic toxicity data.

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