2-Propanone: Human health tier II assessment

17 May 2013

CAS Number: 67-64-1

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.

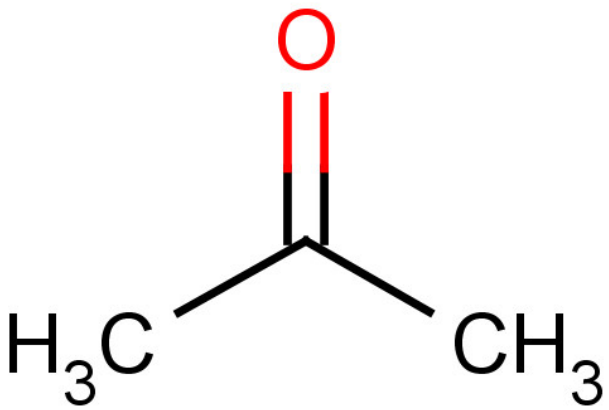
This chemical or group of chemicals are being assessed at Tier II because the Tier I assessment indicated that it needed further investigation.

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

Disclaimer

Acronyms & Abbreviations

Chemical Identity

Synonyms	Acetone Dimethylformaldehyde Dimethyl Ketone Methyl Ketone Pyroacetic acid
Structural Formula	
Molecular Formula	C3H6O
Molecular Weight (g/mol)	58.08
Appearance and Odour (where available)	A colourless liquid with a characteristic sweet and fruity odour at low concentrations. It is highly flammable and soluble with water.
SMILES	C(C)(C)=O

Import, Manufacture and Use

Australian

The following Australian industrial uses were reported under previous mandatory and/or voluntary calls for information.

The chemical has reported commercial use including:

- as a solvent; and
- manufacturing other chemicals.

The chemical is listed on the 2006 High Volume Industrial Chemicals List (HVICL) with a total reported volume between 1000 and 9999 tonnes.

International

The following international uses have been identified through European Union Registration, Evaluation and Authorisation of Chemicals (EU REACH) dossiers; the Organisation for Economic Cooperation and Development Screening information data set International Assessment Report (OECD SIAR); Galleria Chemica; Substances and Preparations in the Nordic countries (SPIN) database; the European Commission Cosmetic Ingredients and Substances (CosIng) database; United States (US) Personal Care Product Council International Nomenclature of Cosmetic Ingredients (INCI) Dictionary; and eChemPortal: OECD High Production Volume chemical program—OECD HPV, the US Environmental Protection Agency's Aggregated Computer Toxicology Resource—ACToR, and the US National Library of Medicine's Hazardous Substances Data Bank—HSDB.

The chemical has reported cosmetic use in:

- nail polish and nail polish removers;
- bath oils and salts;
- cleansing products;
- hair sprays;
- skin care preparations;
- a fragrance compound; and
- finger paints.

The chemical has reported domestic use including:

- as a component of adhesives;
- as a solvent;
- in washing and cleaning products;
- in aerosols and air care products;
- in metal surface treatment products, including galvanic and electroplating products; and
- in polishes and wax blends.

The chemical has reported commercial use including:

- in adhesives and sealants;
- in anti-freeze and de-icing products;

- in coatings and paints;
- in leather tanning;
- in lubricants and greases;
- in dyes;
- as a component of explosives; and
- in welding and soldering products.

The chemical has reported site-limited use including:

- as an intermediate in production of other substances;
- in laboratory chemicals;
- in rubber production and processing;
- in polymer manufacturing and processing; and
- in mining chemicals and oil field drilling and production operations.

Restrictions

Australian

The chemical is currently listed in the Poisons Standard (Standard for the Uniform Scheduling of Medicines and Poisons (SUSMP)) in Schedule 5—"**except** in preparations containing 25 per cent or less of designated solvents".

International

Food Packing:

Japan's specifications and standards for food additives—standards for use—applying generally to food additives. Restriction: only for extracting components from such nuts in the process of the manufacture of guarana beverages or for fractionating components of fats or oils. Shall be removed before the preparation of the finished food.

US FDA indirect food additives: adhesives and components of coatings—substances for use only as components of adhesives—adhesives.

Existing Work Health and Safety Controls

Hazard Classification

The chemical is classified as hazardous with the following risk phrases for human health in the Hazardous Substances Information System (HSIS) (Safe Work Australia):

Xi: R36 (Irritating to eyes)

R66 (Repeated exposure may cause skin dryness or cracking)

R67 (Vapours may cause drowsiness and dizziness).

Exposure Standards

Australian

The chemical has an exposure standard of 1185 mg/m³ (500 ppm) time weighted average (TWA) and 2375 mg/m³ (1000 ppm) short-term exposure limit (STEL).

International

The following are identified (Galleria Chemica):

An exposure limit (STEL) of 450 – 3620 mg/m³ in countries such as China, Greece, Hungary, India, United Kingdom and Canada.

An exposure limit (TWA) of 295 – 2400 mg/m³ in countries such as Norway, Denmark, Japan, India, France, Ireland, Latvia, Malta, Spain, United Kingdom and Canada.

Health Hazard Information

Toxicokinetics

The chemical is highly volatile and soluble in water. The chemical is readily absorbed through the skin of humans and measurable in blood and alveolar air (REACH). After 20 hours, the amount in the blood, alveolar air and urine in human subjects returned to background levels. The chemical is efficiently and effectively metabolised to a variety of products that are used as building blocks for synthesising glucose, amino acids, and other more complex biochemicals. Excretion occurs predominately via urine and also by exhalation. It is found within almost all organs and tissues within the body and is produced in the liver as one of the three ketone bodies formed when stored fats and lipids are broken down as a source of energy.

Acute Toxicity

Oral

The chemical was reported to exhibit low acute toxicity via the oral route.

In two non guideline studies, an LD50 of 5800 mg/kg bw in female and 7190 mg/kg bw in young adult male, Sprague Dawley rats was reported by oral gavage. Clinical signs included decreased activity, ataxia, tremors, and convulsions (REACH; OECD 1999).

Dermal

The chemical was reported to exhibit low acute toxicity via the dermal route.

An LD50 > 7426 mg/kg bw was reported for male and female white rabbits and male Hartley guinea pigs on intact and abraded skin (OECD 1999, REACH). Animals were exposed for 24 hours using an occlusive patch.

Inhalation

The chemical was reported to exhibit low acute toxicity via the inhalation route. However, animal studies demonstrated acute narcotic effects of the chemical dependent upon both the length and magnitude of the exposure (OECD 1999). The chemical is classified as hazardous with the risk phrase 'Vapours may cause drowsiness and dizziness' (R67) in HSIS (Safe Work Australia).

In a non guideline study (REACH), an LC50 of 55700 ppm was determined in male Sprague Dawley rats. In this study 5 animals/sex/dose were exposed by whole body inhalation vapour for a three hour duration period. Central nervous system depression and narcosis were observed.

In another non guideline study (OECD 1999), a four hour LC50 value of 32000 ppm was determined. In this study six female Carworth Farms Nelson rats were exposed via the whole body to chemical vapour.

Corrosion / Irritation

Respiratory Irritation

The respiratory irritation potential was investigated in two studies by measuring the concentration-related decline in the respiration rate of mice. The RD50 (concentration causing a 50 % respiratory rate decrease) values derived in the studies were 183970 mg/m³ and 55725 mg/m³ (OECD 1999).

Skin Irritation

The chemical is not a skin irritant but is a defatting agent to the skin (OECD 1999). The chemical is classified as hazardous with the risk phrase 'Repeated exposure may cause skin dryness or cracking' (R66) in HSIS (Safe Work Australia).

In a non guideline study (REACH), the chemical showed no irritation to the skin of guinea pigs after repeated dermal application based on macroscopic scores for erythema and oedema and on the assessment of epidermal thickness and cellular inflammatory responses. The chemical was applied onto shaved skin of 10 Dunkin Hartley guinea pigs with 10 µL/cm² /three times daily for three days, using open conditions.

Eye Irritation

The chemical is currently classified with the risk phrase 'Irritating to eyes' (Xi; R36) in Australia (Safe Work Australia—HSIS). The data available support this classification.

In a reliable study similar to OECD TG 405 (REACH), two New Zealand white rabbits were exposed to 0.1 mL of the chemical applied to the conjunctival sac of both eyes (washed out after 24 hours) and observed up to seven days following exposure. Average scores for corneal opacity (1.25), iris lesion (0), conjunctivae (2) and chemosis (1) were reported. Iris remained unchanged and the chemosis was reversible within seven days. Corneal opacity and redness of the conjunctivae decreased to a maximum score of 1 on day seven. Based on the reversibility of severity within four days, full reversibility of the slight effects is expected within 14 days.

In an OECD TG 405 (REACH), six New Zealand White rabbits were exposed to 0.01 mL of the chemical applied to the centre of the cornea of one eye (washed out after 24 hours) and observed up to seven days following exposure. Mean scores from light microscopy groups for the three hour observation time point were: corneal opacity (12.1), conjunctivae (9.2) and iris (3.8). The irritant effects of the chemical, based on Draize scores, were fully reversible within seven days.

Observation in humans

Humans exposure to the chemical vapour in the air, in either occupational situations or in experimental studies, resulted in frequent complaints of eye irritation (ATSDR 1994). Concentrations of ≥ 100 ppm in the air have been reported as irritating to the eyes.

Sensitisation

Skin Sensitisation

The chemical was reported to be not sensitising in the guinea pig maximisation test or the mouse ear swelling test (REACH; OECD 1999).

In a guinea pig maximisation test (REACH), 10 female Dunkin Hartley guinea pigs were exposed to intradermal and epicutaneous application of 100 % of the chemical and then rechallenged 21 days later with either epicutaneous or open patch testing. No positive skin responses were found.

In a mouse ear swelling test (REACH), 15 Balb mice were exposed to topical application of 100 % of the chemical on day 0 and day 2 to the right ear. A subcutaneous injection of 0.05 ml of Freund's complete adjuvant was administered on day 2. On day 9, ear thickness was measured immediately before topical application of the chemical onto both sides of the ear. Ear thickness was again measured on day 10. No increase in ear thickness occurred, indicating no sensitising potential.

Repeated Dose Toxicity

Oral

Systemic effects were observed at high doses with a NOAEL of 900 mg/kg bw/day for male rats and 1700 mg/kg bw/day for female rats. Nephropathy and haemosiderosis in the spleen of male rats were the main concern. These effects do not meet hazard classification criteria.

In a 13 week study similar to OECD TG 408 study (REACH), 200, 400, 900, 1700 or 3400 mg/kg bw/day of the chemical was administered to 10 male Fischer 344 rats and 300, 600, 1200, 1600 or 3100 mg/kg bw/day of the chemical to females. At the highest dose tested the mean body weight gains of males and females were 27.5 % and 13.5 % lower than controls. No other relevant toxicological findings were observed in female rats up to the highest dose tested. In male rats, an increased incidence and severity of nephropathy in the kidneys, haemosiderosis in the spleen, and mild leukocytosis and depression of erythrocytes were found at the two highest doses tested. At 3400 mg/kg bw/day, significant depressions of sperm motility, cauda epididymal weight, epididymal weight, and significantly increased incidence of abnormal sperm were observed. The absolute testis weight was also decreased by 5 % at the highest dose. A NOAEL of 1700 mg/kg bw/day for females based on reduced mean body weight gains, and a NOAEL of 900 mg/kg bw/day for males based on nephropathy and haemosiderosis in the spleen were derived.

In a 13 week OECD TG 408 study in B6C3F1 mice the chemical was administered via daily drinking water to 10 animals at concentrations of 380, 611, 1353, 2258 or 4858 mg/kg bw/day for males and 892, 2007, 4156, 5945, and 11298 mg/kg bw/day for females. A significant decrease in spleen weight and increase in liver weight were reported in females at the highest dose tested. Centrilobular hepatocellular hypertrophy was seen in 2 out of 10 females at the highest dose. Males displayed no toxicologically relevant effects up to the highest dose tested. There were no changes in reproductive parameters, including sperm morphology. NOAELs of 4858 mg/kg bw/day for males and 5945 mg/kg bw for females were reported (REACH).

Dermal

There is no specific repeat dose toxicity study. However, the chemical has been used as a solvent in several dermal carcinogenicity studies in mice, using different test volumes from 0.025 to 0.2 mL, corresponding to doses from 20 to 160 mg of the chemical per mouse, with two or three treatments a week for up to 573 days (REACH). In these studies, no noticeable effects on survival or incidence of skin neoplasms were described.

Inhalation

In an eight week non guideline study in male Sprague Dawley rats, a lowest observed effect concentration (LOEC) of 19000 ppm for systemic toxicity was reported.

The chemical was administered via whole body vapour inhalation in a single concentration of 19,000 ppm for 2, 4 or 8 weeks exposure for 3 hours/day, 5 days/week to 9 animals/sex/dose (REACH). While brain and kidney weights were significantly decreased compared to controls there were no corresponding histopathological changes. Furthermore, the changes were reversible within the 2 weeks of post-treatment observation.

Genotoxicity

The chemical was negative in a range of *in vitro* and in vivo genotoxicity studies (OECD 1999).

In vitro studies in *Salmonella typhimurium* strains TA 1535, TA 1537, TA 97, TA 98 and TA 100, with and without S9 metabolic activation mix, following OECD TG 471 (bacterial reverse mutation assay) were negative up to 10 mg/plate (REACH). In another in vitro study following OECD TG 473 (in vitro mammalian chromosome aberration test) in mammalian Chinese hamster ovary (CHO) cells, with and without metabolic activation, there was no increased incidence of structural aberrations up to concentrations of 5 mg/mL. In an in vitro study similar to the OECD TG 476 (In vitro mammalian cell gene mutation test) using mouse lymphoma L5178Y cells, without metabolic activation, there were no increases in mutant frequency.

A 13 week in vivo non guideline micronucleus assay (REACH) using 10 B6C3F1 mice/sex/dose, administered daily via drinking water with either 5000, 10000 or 20000 ppm of the chemical, showed no significant induction of micronuclei in normochromatic erythrocytes in peripheral blood.

In another in vivo non guideline micronucleus assay (REACH) 10 Chinese hamsters/sex/dose, administered via intraperitoneal injection with a single dose of 865 mg/kg bw, there was no increase of the rate of micronuclei in bone marrow cells.

Carcinogenicity

The chemical was reported to be not carcinogenic in mice when dermally applied (OECD 1999).

In a non guideline study female ICR mice were administered 100 µL of 100 % of the chemical 3 times/week for 424 days to 29 animals/sex/dose, onto shaved skin (REACH). There was no macroscopic or histopathologic development of local or systemic tumours.

An overview of existing data on the chemical used as a vehicle control in several dermal carcinogenicity studies performed using several strains of mice shows that the chemical is not carcinogenic via the dermal route (REACH).

Reproductive and Developmental Toxicity

The chemical showed minimal reproductive and developmental effects in animals exposed through inhalation or drinking water (OECD 1999). Reproductive and developmental effects were observed at high doses and secondary to maternal toxicity, so the chemical does not show specific reproductive or developmental toxicity.

An OECD TG 414: Prenatal Developmental Toxicity Study (REACH, OECD 1999) was done in Sprague Dawley rats and CD-1 mice. In rats, the chemical was administered daily at 1045, 5220, or 26110 mg/m³ via whole body inhalation to Group A (30 mated rats) and B (seven mated rats) from gestation day 6 – 19, 6 hours/day; or Group C – (virgin rats) for 14 days, 6 hours/day. In mice, the chemical was administered at concentrations of 1045, 5220, or 15665 mg/m³ under the same conditions. Maternal toxicity was seen with the highest dose in rats in the form of significantly reduced body weight gains and in mice in the form of increased absolute and relative liver weights. Mice and rats exposed to the highest dose had a statistically significant reduction in foetal weight and a statistically significant increase in the incidence of late resorptions. The no observed effect level (NOEL) for developmental toxicity was found to be 5220 mg/m³ for both rats and mice. No teratogenic effects were observed at any of

the exposure concentrations tested and the NOEL for teratogenicity was greater than or equal to 15665 mg/m³ for mice and 26110 mg/m³ for rats.

In a 13 week non guideline repeated dose toxicity oral gavage study (REACH), the chemical was administered daily via drinking water to 10 B6C3F1 mice/sex/dose at 380, 1353 or 4858 mg/kg bw/day for males and 892, 4156 or 11298 mg/kg bw/day for females. The NOEL for reproductive parameters and systemic toxicity in male mice was 4858 mg/kg bw/day based on histopathology of epididymis, seminal vesicles, prostate, testes, and sperm morphology. In female mice, the NOEL for reproductive effects was 11298 mg/kg bw/day and the LOAEL for systemic toxicity was 11298 mg/kg bw/day based on histopathology of ovaries, uterus and vaginal cytology.

In a 13 week study described above using Fischer 344 rats, 10 males were administered with 200, 400, 900, 1700 or 3400 mg/kg bw/day of the chemical or administered to 10 females with 300, 600, 1200, 1600 or 3100 mg/kg bw/day. At 3400 mg/kg bw/day, significant depressions of sperm motility, cauda epidydimal weight, epididymal weight, and significantly increased incidence of abnormal sperm were observed. The absolute testis weight was also decreased by 5 % at the highest dose. The NOAEL for the reproductive effects was 1700 mg/kg bw/day.

In another non guideline reproductive study (REACH) using male Wister rats, the chemical was administered daily from 5000 mg/L in drinking water for 8 weeks or 10000 mg/L in drinking water for 4 weeks. Clinical signs, body weight, food and water consumption, organ weights, and clinical biochemical parameters were examined. In the last week of the 4 week study, each male was mated with an untreated female rat to investigate reproductive performance. A NOEL of 10000 mg/L was determined for male fertility.

Other Health Effects

Neurotoxicity

The chemical is classified as hazardous with the risk phrase ‘Vapours may cause drowsiness and dizziness’ (R67) in HSIS (Safe Work Australia). The available data support this classification (refer above).

Mild neurobehavioural changes were observed in female rats exposed to 4 hours/day for two weeks at concentrations of 7120, 14240, 28480, and 37975 mg/m³ (OECD 1999). At concentrations of 14240 mg/m³, inhibition of avoidance behaviours was observed, and at higher concentrations, ataxia after a single exposure occurred in several animals, although rapid tolerance developed and ataxia was not seen on subsequent days.

Risk Characterisation

Critical Health Effects

The critical health effects for risk characterisation include eye irritation, and drowsiness and dizziness caused by vapour. The chemical may also cause skin dryness or cracking following repeated exposure.

Public Risk Characterisation

The chemical is currently listed on Schedule 5 of the Poisons Standard for preparations containing more than 25 % of the chemical. At concentrations greater than 25 %, a number of warning statements, first aid instructions, and safety directions relating to Schedule 5 apply. The current controls are considered adequate to minimise the risk to public health posed by domestic and cosmetic products containing the chemical. Therefore, the risk to public health is not considered to be unreasonable.

Occupational Risk Characterisation

During product formulation, dermal, ocular and inhalation exposure of workers to the chemical may occur, particularly where manual or open processes are used. These may include transfer and blending activities, quality control analysis, and cleaning and maintenance of equipment. Worker exposure to the chemical at lower concentrations may also occur during use of formulated products containing the chemical. The level and route of exposure will vary depending on the method of application and work practices employed.

Given the critical systemic acute and local health effects of the chemical, the chemical may pose an unreasonable risk to workers if adequate control measures to minimise dermal, ocular and inhalation exposure to the chemical are not implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business or undertaking (PCBU), e.g. an employer at a workplace, has adequate information to determine appropriate controls. Based on the available data, the hazard classification in HSIS is considered appropriate.

NICNAS Recommendation

Current risk management measures are considered adequate for the protection of public and workers' health and safety, provided that all requirements are met under workplace health and safety and poisons legislation as adopted by the relevant state or territory. No further assessment is required.

Regulatory Control

Public Health

Products containing the chemical should be labelled in accordance with state and territory legislation (SUSMP).

Work Health and Safety

The chemical is recommended for classification and labelling under the current approved criteria and adopted GHS as below. This does not consider classification of physical hazards and environmental hazards.

Hazard	Approved Criteria (HSIS)[a]	GHS Classification (HCIS)[b]
Acute Toxicity	Vapours may cause drowsiness and dizziness (R67)*	May cause drowsiness or dizziness - Specific target organ tox, single exp Cat. 3 (H336)
Irritation / Corrosivity	Irritating to eyes (Xi; R36)*	Causes serious eye irritation - Cat. 2A (H319)
Repeat Dose Toxicity	Repeated exposure may cause skin dryness or cracking (R66)*	Repeated exposure may cause skin dryness and cracking (AUH066)

[a] Approved Criteria for Classifying Hazardous Substances [NOHSC:1008(2004)].

[b] Globally Harmonized System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third Edition.

[*] Existing Hazard Classification. No change recommended to this classification

Advice for consumers

Products containing the chemical should be used according to the instruction on the label.

Advice for industry

Control measures

Control measures to minimise the risk from dermal, ocular and inhalation exposure to the chemical should be implemented in accordance with the hierarchy of controls. Approaches to minimise risk include substitution, isolation and engineering controls. Measures required to eliminate or minimise risk arising from storing, handling and using a hazardous chemical are dependent on the physical form and the manner in which the chemical is used. Examples of control measures which may minimise the risk include, but are not limited to:

- air monitoring to ensure control measures in place are working effectively and continue to do so;
- minimising manual processes and work tasks through automating processes;
- work procedures that minimise splashes and spills;
- regularly cleaning equipment and work areas; and
- using protective equipment that is designed, constructed, and operated to ensure that the worker does not come into contact with the chemical.

Guidance on managing risks from hazardous chemicals are provided in the *Managing Risks of Hazardous Chemicals in the Workplace—Code of Practice* available on the Safe Work Australia website.

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. Guidance in selecting personal protective equipment can be obtained from Australian, Australian/New Zealand or other approved standards.

Obligations under workplace health and safety legislation

Information in this report should be taken into account to assist with meeting obligations under workplace health and safety legislation as adopted by the relevant state or territory. This includes, but is not limited to:

- ensuring that hazardous chemicals are correctly classified and labelled;
- ensuring that (material) safety data sheets ((m)SDS) containing accurate information about the hazards (relating to both health hazards and physicochemical (physical) hazards) of hazardous chemical are prepared; and
- managing risks arising from storing, handling and using a hazardous chemical.

Your work health and safety regulator should be contacted for information on the work health and safety laws in your jurisdiction.

Information on how to prepare an (m)SDS and how to label containers of hazardous chemicals are provided in relevant codes of practice such as the *Preparation of Safety Data Sheets for Hazardous Chemicals— Code of Practice* and *Labelling of Workplace Hazardous Chemicals—Code of Practice*, respectively. These codes of practice are available from the Safe Work Australia website.

A review of the chemical's physical hazards has not been undertaken as part of this assessment.

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