Australian Government
Department of Health and Ageing
NICNAS

INVENTORY MULTI-TIERED ASSESSMENT AND PRIORITISATION (IMAP)

HUMAN HEALTH TIER II ASSESSMENT FOR

Hexanedioic acid

CAS Registry Number: 124-04-9

PREFACE

As part of the reform regarding assessment of Existing Chemicals, the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is implementing a new framework to address the human health and environmental impacts of industrial chemicals, not yet assessed, on the Australian Inventory of Chemical Substances (AICS).

The framework provides a more rapid, flexible and transparent approach for the assessment of existing chemicals.

The Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework was developed, with significant input from stakeholders, and will be applied in stages.

Stage One of this program, which will take three years, started 1 July 2012 and is examining 3000 chemicals meeting characteristics identified by stakeholders as needing priority assessment. This includes chemicals for which NICNAS already holds exposure information, chemicals identified as a concern or for which regulatory action has been taken overseas, and chemicals detected in international studies analysing chemicals present in babies' umbilical cord blood.

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.

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

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

ACRONYMS & ABBREVIATIONS

ACToR	Aggregated Computational Toxicology Resource (US)
AICS	Australian Inventory of Chemical Substances
ASTDR	Agency for Toxic Substances and Disease Registry (US)
bw	bodyweight
CAS	Chemical Abstracts Service
CFR	Code of Federal Regulations (US)
CHO	Chinese hamster ovary
CosIng	Cosmetic Ingredients and Substances database (EU)
d	day
DNA	Deoxyribonucleic acid
EC	European Commission
EC3	Estimated concentration three
ECHA	European Chemicals Agency
ESIS	European Chemical Substances Information System
EU	European Union
EU RAR	European Union Risk Assessment Report
FDA	Food and Drug Administration (US)
FSANZ	Food Standards Australia and New Zealand
g	gram
g/mol	grams per mole
GHS	Globally Harmonized System of Classification and Labelling of Chemicals*
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GPMT	Guinea Pig Maximisation Test
h	hour
HGPRT	hypoxanthine guanine phosphoribosyltransferase
HPV	high production volume
HSDB	Hazardous Substances Data Bank
HSIS	Hazardous Substances Information System
HVICL	High Volume Industrial Chemicals List
IARC	International Agency for Research on Cancer
INCHEM	International Programme on Chemical Safety (also known as IPCS)
INCI	International Nomenclature of Cosmetic Ingredients
ip	intraperitoneal
IRIS	Integrated Risk Information System (US)
IUCLID	International Uniform Chemical Information Database
iv	intravenous
kg	kilogram
L	litre
LC50	median lethal concentration
LD50	median lethal dose
LCLo	lowest published lethal concentration
LLNA	local lymph node assay
LOAEL	lowest observed adverse effect level
LOEL	lowest observed effect level
m^3	cubic metre
mg	milligram
mg/cm^3	milligrams per cubic centimetre
mg/kg bw/d	milligrams per kilogram bodyweight per day
min	minute
mL	millilitre
µg	microgram
µL	microlitre
(m)SDS	(material) Safety Data Sheet

NIOSH	National Institute for Occupational Safety and Health (US)
NOAEC	no observed adverse effect concentration
NOAEL	no observed adverse effect level
NOEC	no observed effect concentration
NOEL	no observed effect level
NOHSC	National Occupational Health and Safety Commission
NTP	National Toxicology Program (US)
OECD	Organisation for Economic Cooperation and Development
OEL	occupational exposure limit
PCBU	person conducting a business or undertaking
PEL	permissible exposure limit
PND	postnatal day
ppb	parts per billion
PPE	personal protective equipment
ppm	parts per million
REACH	Registration Evaluation Authorisation of Chemicals (ECHA)
SD	Sprague Dawley
SIAP	SIDS Initial Assessment Profile (OECD)
SIAR	SIDS Initial Assessment Report (OECD)
SIDS	Screening Information Data Set (OECD)
SMILES	simplified molecular-input line-entry system
SPIN	Substances in Preparations In the Nordic countries
STEL	short-term exposure limits
STV	short-term value
SUSMP	Standard for the Uniform Scheduling of Medicines and Poisons (The Poisons Standard**)
TCLo	lowest published toxic concentration
TEEL	temporary emergency exposure limits
TSCA	Toxic Substances Control Act (US EPA)
TG	test guideline
TGA	Therapeutic Goods Administration
TLV	threshold limit values
TWA	time weighted average
UN	United Nations
US	United States of America
US EPA	United States Environmental Protection Agency
WHS	Work, Health and Safety
wt	weight
w/w	weight per weight

Glossary

NICNAS uses the IPCS Risk Assessment Terminology (IPCS, 2004) glossary, which includes:
Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment; and
Part 2: IPCS Glossary of Key Exposure Assessment Terminology.
The IPCS Risk Assessment Terminology can be accessed at:
http://www.who.int/ipcs/methods/harmonization/areas/ipcsterminologyparts1and2.pdf

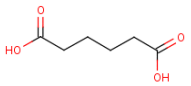
*****Globally Harmonised System of Classification and Labelling of Chemicals (GHS) United Nations, 2009. Third edition. Can be accessed at: http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html

******The Poisons Standard (the SUSMP) can be accessed at: http://www.tga.gov.au/industry/scheduling-poisons-standard.htm

Hexanedioic acid

CAS No: 124-04-9

Chemical Identity

Synonyms	Adipic acid 1,4-Butanedicarboxylic acid 1,6-Hexanedioic acid Adipinic acid
Structural Formula	
Molecular Formula	C6H10O4
Molecular Weight (g/mol)	146.141
Appearance and Odour (where available)	White, odourless, crystalline solid. In crystalline form, the substance appears colourless, while as a powder, it appears white.
SMILES	C(=O)(O)CCCCC(=O)O

Import, Manufacture and Use

Australian

The chemical has reported commercial use in Australia as an oxidising agent. The reported introduced volume in 2006 was between 100 and 1000 tonnes (NICNAS, 2006).

International

The following international uses have been identified via the European Union Registration Evaluation Authorisation of Chemicals (EU REACH) Dossiers, Galleria Chemica, the Substances in Preparations in the Nordic countries (SPIN) database, the Cosmetic Ingredients and Substances (CosIng) database, Personal Care Council Website (INCI Dictionary) and through eChemPortal (the Organisation for Economic Cooperation and Development (OECD) HPV, the Aggregated Computer Toxicology Resource (ACToR) and the Hazardous Substances Data Bank (HSDB)).

The chemical has reported cosmetic use as:

- a buffering and masking agent; and
- a fragrance ingredient and pH adjuster, e.g. in permanent wave products.

The chemical has reported domestic use including:

- adhesives, binding agents;
- cleaning and washing agents, e.g. in the production of dish washing machine tablets; and
- paints, lacquers and varnishes.

The chemical has reported commercial use including:

- solvents and softeners;
- pH and process regulation agents;
- construction materials and flux agents for casting or joining materials; and
- leather tanning, dye, finishing, impregnation and care products.

The chemical has reported site-limited use including:

- oil and gas extraction: flue gas desulphurisation, in products such as flocculants, precipitants and

neutralisation agents; and
- intermediate use in the production of lubricating oil additives and polymer preparations.

Restrictions

Australian

No known restrictions are available.

International

No known restrictions are available.

Existing Worker Health And Safety Controls

Hazard classification

The chemical is classified as hazardous with the following risk phrases in the Hazardous Substances Information System (HSIS) (Safe Work Australia):
Xi; R36 (Irritating to eyes)

Exposure standards

Australian

No specific exposure standards are available.

International

The following are identified (Galleria Chemica):
TWA: 5 mg/m³ (Canada, Denmark, Indonesia, Iceland, Ireland, Poland, Malaysia, Singapore, Spain, USA)
STEL: 10 mg/m³ (Canada, Poland)

Health Hazard Information

Toxicokinetics

Oral administration by gavage of radiolabelled adipic acid to fasted rats resulted in 70% of the dose being exhaled as CO_2. It was also detected in the urine along with identified metabolites such as urea, glutamic acid, lactic acid, beta-ketoadipic acid, and citric acid. It was found that adipic acid is metabolised by beta-oxidation, similarly to fatty acids, with acetate being identified as a metabolite (OECD, 2006).

Human studies (seven volunteers received 7 g of adipic acid over 10 days) have shown that 15-75% of the orally administered dose was found unchanged in the urine (OECD, 2006).

Acute Toxicity

Oral

The chemical is reported to have low acute toxicity via the oral route (LD50 = 5560 mg/kg bw in rats and 1900 mg/kg bw in mice) (OECD, 2006; REACH, 2012).

In a study (similar to OECD TG 401) conducted on Sprague Dawley rats with a gavage dose up to 10,000 mg/kg bw of adipic acid (99.8% as a 50% suspension in carboxymethyl cellulose), mortalities were seen during the first 48 hours. Lethal doses were reported to cause acute dilation of the heart and acute congestive hyperanaemia, glandular stomach ulceration, paleness of the liver and reddening of intestinal mucosa. No gross pathological changes were observed in animals that survived to termination at 14 days. An LD50 of 5560 mg/kg bw was established (OECD, 2006; REACH, 2012).

In another experiment, a single dose of 5000 mg/kg bw of adipic acid (33.3% suspension in 0.85% saline) to ten male rats caused no signs of toxicity (OECD, 2006; REACH, 2012).

In mice (13 animals per sex per dose), oral administration of 1500, 2000, and 2500 mg/kg bw of adipic acid (6% suspension in 0.5% methyl cellulose) resulted in an LD50 value of 1900 mg/kg bw. Mortalities were observed in all test doses (3/13 in 1500 mg/kg bw group; 8/13 in 2000 mg/kg bw group; 9/13 in 2500 mg/kg bw group). Autopsy of animals that died showed distention of the stomach and small

intestine with spastic contraction of the caecum. Intestinal haemorrhage and irritation were also observed (OECD, 2006; REACH, 2012).

Dermal

The chemical is reported to be of low acute toxicity via the dermal route (LD50 >2000 mg/kg bw) (OECD, 2006; REACH, 2012).

Adipic acid was tested in a 24-hour dermal exposure under occlusive conditions as a 40% solution in corn oil. New Zealand White rabbits were exposed to 5010 mg/kg bw (n=1) or 7940 mg/kg bw (n=2) of adipic acid. No mortalities were observed in either dose group. Animals showed reduced appetite and activity. Necropsy after 14 days' observation showed normal viscera (OECD, 2006; REACH, 2012).

Inhalation

The chemical is reported to be of low acute toxicity via the inhalation route (LC50 >7.7 mg/L in rats) (OECD, 2006; REACH, 2012).

In a study comparable to the OECD TG 403, Sprague Dawley rats (10 animals per sex per dose) were exposed for 4 hours (nose only) to 7.7 mg/L of adipic acid (99.8 %) dust. No mortalities were observed in any of the test group. No change in body weight nor changes in gross pathology were observed during the 14 days observation period. It was determined that the LC50 of adipic acid is >7.7 mg/L in air (OECD, 2006; REACH, 2012).

Corrosion / Irritation

Skin irritation

The chemical is reported to be a slight skin irritant in rabbits. It was a moderate irritant in scarified skin (OECD, 2006; REACH, 2012). The irritation scores reported do not warrant a hazard classification.

Vienna White rabbits (n=6) received occlusive application of adipic acid (0.5 g of a 50% aqueous suspension) for 24 hours. The test area was observed after 24 hours, 3 days, and 8 days post application. Reversible reddening was observed at the intact skin but disappeared after three days. Mild to severe reddening and oedema were observed at the scarified skin, but were reversible after one week. The mean erythema score was 1.1 and the mean oedema score was 0 between the 24 and 72 hour time point (OECD 2006; REACH, 2012).

On another study conducted on rabbits (n=2), adipic acid (99.8% or 80% aqueous paste) was applied occlusively on intact skin (back and ear) for 20 hours. The test area was observed after 24 hours, 3 days, and 8 days post-application. Reversible reddening of the ear was observed after 20 hours but disappeared after 72 hours. The Draize scores for mean erythema and oedema were 0 at 24, 48, and 72 hour time points (OECD 2006; REACH, 2012).

Eye irritation

The chemical is currently classified as hazardous with the risk phrase 'Irritating to eyes' (Xi; R36) in HSIS (Safe Work Australia). Based on the data available (mean iris lesion score of 1.8 in Himalayan rabbits), the existing hazard classification requires amendment to indicate serious eye damage.

The chemical is reported to be a severe eye irritant in rabbits (OECD, 2006; REACH, 2012).

In an experiment conducted on Himalayan rabbits (n=3) according to the OECD Guideline 405 in compliance with GLP, the chemical (100 mg, >99.8% purity) was applied for 24 h with an observation period up to 21 days post application. Severe irritation of the iris and corneal opacity was observed in all animals that were tested. The results were summarised as follows: mean cornea score = 2.3 (fully reversible within 16 days); mean iris score = 1.8 (fully reversible within 9 days); mean conjunctival score = 1 (fully reversible within 13 days); mean chemosis score = 1 (fully reversible within 12 days) (OECD 2006, REACH, 2012).

In another study, the chemical (0.1 mL, 99.8% purity) was applied to rabbit eyes (n=6), which were

examined 24 h, 48 h, 72 h and 8 days post application. Symptoms included: irritation of the conjunctiva, scar formation, and inflammation of the iris. The results were summarised as follows: mean cornea score = 1.3 (not reversible within 8 days); mean iris score = 0.83 (not reversible within 8 days); mean conjunctival redness score = 2 (not reversible within 8 days); mean chemosis score = 2 (not reversible within 8 days) (OECD 2006, REACH, 2012).

Respiratory irritation

No data are available.

Observation in humans

The exposure to the chemical may have caused mucosal irritation in 7 out of 12 workers. However, workers did not wear respiratory protection and they were also exposed to other chemicals such as various glycols and glycerine (OECD, 2006).

Workers exposed over an extensive period (average 9.2 years) complained of respiratory irritation at concentrations of 0.47-0.79 mg/m³ of the chemical. Due to the acidic character of the substance, a local irritation potential is plausible (OECD, 2006).

Based on the information available, classification as a respiratory irritant is warranted.

Sensitisation

Skin sensitisation

The chemical is not a skin sensitiser.

In an experiment that was conducted on male albino guinea pigs (n=10 per dose), four intradermal injections (one per week over a three-week period) of adipic acid [0.1 mL of a 1.0% (w/v) solution] were administered as the initial induction exposure to the chemical. After a two week rest period, approximately 0.05 mL of 50% and 25% suspensions of adipic acid in propylene glycol was applied on the shaved intact shoulder skin of the test and control animals. The chemical produced very mild to no skin irritation, but it did not cause sensitisation (OECD, 2006; REACH, 2012).

Repeat Dose Toxicity

Oral

The chemical is of low chronic toxicity via the oral route.

In a two year study that was conducted on Carworth Farm strain rats (19-20 males or females per group), adipic acid was administered with the basal laboratory diet at doses of approximately 0, 75, 750, 2250, 3750 mg/kg bw/day. The percent survival for each group was higher than the control group. No treatment related effects were observed during necropsy. The NOAEL was determined to be approximately 750 mg/kg bw/day (OECD, 2006; REACH, 2012).

In a 33 weeks study in rats (13-15 animals per group), adipic acid was administered with a standard diet at doses of 0, 1600, or 3200 mg/kg bw/day. Mortalities were observed from the first week until the fourth week (n=10). Surviving animals showed retarded weight gain and suffered from heavy diarrhoea during the first three weeks, but recovered during the fifth week. Histopathology has revealed slight effects on liver and inflammation of intestines at 1600 mg/kg bw/day. No NOAEL was obtained in this study but the LOAEL was estimated to be approximately 1600 mg/kg bw/day. This study examined only the liver and intestine histopathology (OECD, 2006; REACH, 2012).

Dermal

No data are available.

Inhalation

The chemical is of low chronic toxicity via the inhalation route.

Alderley Park rats were exposed to 15 applications of adipic acid dust (126 mg/m³) for 6 hours. No signs

of toxicity or pathological changes during necropsy were observed. The NOAEC was determined to be >126 mg/m³. However, the histopathological observations conducted in the study were limited (OECD, 2006; REACH, 2012).

Genotoxicity

The chemical is reported to be non-mutagenic in various in vitro and in vivo studies.

In a study conducted according to the OECD Test Guideline 476 (in vitro Mammalian Cell Gene Mutation test) on Chinese hamster lung fibroblasts (V79), adipic acid (99.92%) was administered, with and without metabolic activation, at concentrations of up to 10 mM using HPRT as the target gene. The chemical was found to be non-mutagenic in this study. Negative results were also observed in two other in vitro studies: a chromosome aberration test using human fibroblast (WI-38) without metabolic activation with adipic acid concentrations of up to 200 mg/L; and a bacterial reverse mutation assay (OECD TG 471) using *Salmonella typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 or *Escherichia coli* WP2 strain with or without metabolic activation and adipic acid concentration of up to 10 mg/plate (OECD, 2006; REACH, 2012).

In a host mediated assay using *S. typhimurium* TA-1530 and G-46 or *Saccharomyces cerevisiae* D3 as indicator strains,10 male mice were gavaged with 3.75, 37.5 and 375 mg/kg bw/day of adipic acid for one or 5 days. There was no significant increase in mutant frequencies except for the *S. cerevisiae* D3 single dose study, where an increased mutation frequency was observed with a dose response. However, further experiments using the same study animals that were gavaged with 5000 mg/kg bw once and 2500 mg/kg bw/d for 5 days with adipic acid showed negative results for all 3 indicator strains. Positive controls in all these experiments were functional (OECD, 2006; REACH, 2012).

Negative results were also reported in the following in vivo studies:

- Cytogenetic studies involving 5 male rats that were gavaged with up to 5000 mg/kg bw (acute studies) and up to 2500 mg/kg bw (5-day subacute study), in which the metaphase chromosomes of the bone marrow cells were scored for different genotoxic markers such as chromatid/chromosome gaps and breaks, aberrations, and polyploidy (OECD, 2006; REACH, 2012); and
- A dominant lethal assay, in which each of the 10 male rats that were gavaged with adipic acid were mated to two virgin female rats. Females were sacrificed two weeks after mating to determine the fertility index, pre-implantation loss, and any lethal effects on the embryos. It was concluded that adipic acid does not induce dominant lethal mutations in doses up to 5000 mg/kg bw (OECD, 2006; REACH, 2012).

Carcinogenicity

Based on the results of a two year carcinogenicity study in rats, the chemical is not carcinogenic.

In a two year rat (Carworth Farm strain) study (19-20 males or females per group), adipic acid was administered with the basal laboratory diet at doses of approximately 0, 75, 750, 2250, 3750 mg/kg bw/day. The survival rate for each group was higher than the control group. Autopsy data from all animals, including those that died during the course of the two year feeding program and those who were sacrificed at the end of the study period, were analysed for any incidence of tumours and/or lung pathology. The incidence of tumours in the treated groups was similar to that of the control groups. The NOAEL was determined to be approximately 750 mg/kg bw/day (OECD, 2006; REACH, 2012).

Reproductive and developmental toxicity

The chemical is not a reproductive or developmental toxicant based on the available information.

Pregnant albino CD-1 mice (25 animals per group, 31 in the highest dose group) were dosed daily with 0, 2.6, 12, 56, or 263 mg/kg bw/day of adipic acid during 6-15 days of gestation for a duration of 10 days. On day 17 of gestation, animals were subjected to a caesarean section. Administration of adipic acid did not cause any effects on implantation and survival of foetuses. The number of abnormalities that were observed in the tissues of the treated groups did not differ from those that occurred for the control group. The NOAEL for maternal and developmental toxicity was estimated to be >263 mg/kg bw/day (OECD, 2006; REACH, 2012).

In the two year carcinogenicity study (described previously), no adverse effects were reported in histopathological examination of the ovaries and uterus of the surviving female rats sacrificed at the end of the study period. Incidences of ovarian cysts were noted in both control and experimental rats (OECD, 2006; REACH, 2012).

Risk Characterisation

Critical Health Effects

The critical effects for risk characterisation are severe eye irritation and possible respiratory irritation.

Public Risk Characterisation

Although use in cosmetic or domestic products in Australia is not known, the chemical is reported to be used in cosmetics and domestic products overseas. Use concentrations in these products are not known, however the concentration of free adipic acid used in cosmetics is not expected to be high when used it as a buffering agent. Eye and respiratory irritation are not expected from exposure to low concentrations of free adipic acid in cosmetic or domestic products.

Occupational Risk Characterisation

Given the critical health effects, the risk to workers from this chemical is considered low, particularly at concentrations below 10% or if adequate control measures to minimise occupational exposure to the chemical are implemented. The chemical should be appropriately classified and labelled to ensure that a person conducting a business, or an employee at a workplace, has adequate information to determine appropriate controls to protect workers handling the chemical.

NICNAS Recommendation

The chemical is considered to be fully assessed at the Tier II level with risk management measures considered adequate to protect public and workers, subject to amendment of the existing hazard classification.

Regulatory Control

Public Health

Considering the available information, to indicate low public exposure from this chemical, no regulatory controls are recommended.

Occupational 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.

	Approved Criteria (HSIS)[a]	***GHS Classification***
Irritation / Corrosivity	Risk of serious eye damage (Xi; R41) Irritating to respiratory system (Xi; R37)	Causes serious eye damage - Cat. 1 (H318) May cause respiratory irritation - Specific target organ tox, single exp Cat. 3 (H335)

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

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

Advice for consumers

Products containing the chemical should be used according to label instructions.

Advice for industry

Control measures

Control measures to minimise the risk from dermal/ocular/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 storage, handling and use of 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:

- use of local exhaust ventilation to prevent the chemical from entering the breathing zone of any worker;
- minimisation of manual processes and work tasks through automation of processes;
- work procedures that minimise splashes and spills;
- regular cleaning of equipment and work areas; and
- use of 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 be relied upon on its own to control risk and should only be used when all other reasonably practicable control measures do not eliminate or sufficiently minimise risk. Guidance in selection of 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
- management of risks arising from storage, handling and use of 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 physical hazards of the chemical has not been undertaken as part of this assessment.

References

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