Chemicals that are unlikely to require further regulation to manage risks to human health

Evaluation statement

25 September 2023

Draft



Table of contents

Contents

AICIS evaluation statement	3
Subject of the evaluation	3
Chemicals in this evaluation	3
Reason for the evaluation	3
Parameters of evaluation	3
Summary of evaluation	4
Summary of introduction, use and end use	4
Human health	4
Conclusions	5
Supporting information	6
References	12

AICIS evaluation statement

Subject of the evaluation

Chemicals that are unlikely to require further regulation to manage risks to human health

Chemicals in this evaluation

See **Supporting information** for the list of chemicals included in the evaluation.

Reason for the evaluation

Evaluation is needed to provide information on human health risks.

Parameters of evaluation

This evaluation provides information on chemicals, listed on the Australian Inventory of Industrial Chemicals (the Inventory), identified during the Evaluation Selection Analysis (ESA) process as unlikely to require further regulation to manage risks to health. The ESA takes into account the intrinsic hazard of the chemical, the potential human exposure and existing risk management measures.

Based on the use category, the ESA process first sought to validate the absence of the following hazards:

- Site limited: neurotoxic, carcinogenic, mutagenic or a reproductive toxin.
- Commercial: as above, plus very high acute toxicity, high repeat dose toxicity, high corrosivity and respiratory sensitisation.
- Domestic: as above, plus moderate acute toxicity, moderate repeat dose toxicity, skin sensitisation and moderate corrosivity.
- Cosmetic: any classifiable hazard, including harmful by acute exposure and irritating to skin and eyes.

Where these hazards were identified, we considered whether the hazards would be present under the likely conditions of use, which were determined based on available information. For example, where a chemical is irritating because of its extreme pH, and the formulated product will be at a more neutral pH, the irritant property is not relevant to the product. This evaluation statement provides key information used during the ESA process, including the highest use category and additional information on any factors that have contributed to risk conclusions.

During the ESA, we may also identify chemicals that are only used in laboratories in very small quantities. No evaluation of hazards was undertaken for these chemicals.

Summary of evaluation

Summary of introduction, use and end use

See **Supporting Information** for the highest use category identified for each chemical. The categories used by AICIS, in order of increasing exposure, are:

- Non-industrial, excluded uses (only): food, therapeutic, agricultural, and veterinary.
- Site limited: only used in large chemical operations.
- Commercial: used by small factories, scattered through the community, industrial cleaning, operations, and rare use by specialised hobbyist members of the public.
- Domestic: used in products generally available to the public, excluding cosmetics.
- Cosmetic: personal care products.

Human health

Summary of health risk

Public

Based on the available information, there are no identified risks to the public that require further regulation to manage the risk to human health. Although some of the chemicals with cosmetic and domestic uses may have potential health hazards, risks to the public are minimised by:

- the concentrations to which the public are exposed
- normal precautions being taken when using domestic products to avoid skin and eye contact
- the systemic bioavailability of chemicals.

See supporting information for additional information on any factors that have contributed to the risk conclusions. Any requirements under poisons legislation as adopted by the relevant state or territory should be met to minimise risk.

Workers

Based on the available information, there are no identified risks to workers that require further regulation to manage the risk to health.

Although chemicals in this evaluation may meet the criteria for classification according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) based on the highest category of use identified (see **Supporting information**), controls to manage the risk to workers are expected to be in place.

All requirements under workplace health and safety as adopted by the relevant state or territory should be met to minimise risk.

Conclusions

The conclusions of this evaluation are based on the information described in this statement.

The Executive Director proposes to be satisfied that the identified human health risks can be managed within existing risk management frameworks. This is provided that all requirements are met under environmental, workplace health and safety and poisons legislation as adopted by the relevant state or territory.

Note: Obligations to report additional information about hazards under *Section 100* of the *Industrial Chemicals Act 2019* apply.



Supporting information

CAS No	Chemical Name	Highest Use Category (Human Health)	Additional information
54-86-4	3-Pyridinecarboxylic acid, sodium salt	Commercial	-
55-22-1	4-Pyridinecarboxylic acid	Site-Limited	-
59-67-6	3-Pyridinecarboxylic acid	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
76-49-3	Bicyclo[2.2.1]heptan-2-ol, 1,7,7-trimethyl-, acetate, endo-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
76-50-6	Butanoic acid, 3-methyl-, 1,7,7- trimethylbicyclo[2.2.1]hept-2-yl ester, endo-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
90-42-6	[1,1'-Bicyclohexyl]-2-one	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
93-60-7	3-Pyridinecarboxylic acid, methyl ester	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
98-52-2	Cyclohexanol, 4-(1,1-dimethylethyl)-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
98-92-0	3-Pyridinecarboxamide	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
98-98-6	2-Pyridinecarboxylic acid	Commercial	-
108-93-0	Cyclohexanol	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
116-02-9	Cyclohexanol, 3,3,5-trimethyl-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.

CAS No	Chemical Name	Highest Use Category (Human Health)	Additional information
124-76-5	Bicyclo[2.2.1]heptan-2-ol, 1,7,7-trimethyl-, exo-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
126-81-8	1,3-Cyclohexanedione, 5,5-dimethyl-	Site-Limited	-
132-16-1	Iron, [29H,31H-phthalocyaninato(2-)- N29,N30,N31,N32]-, (SP-4-1)-	Domestic	-
137-03-1	Cyclopentanone, 2-heptyl-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
464-45-9	Bicyclo[2.2.1]heptan-2-ol, 1,7,7-trimethyl-, (1S-endo)-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
499-69-4	Cyclohexanol, 2-methyl-5-(1-methylethyl)-, (1.alpha.,2.beta.,5.alpha.)-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
502-42-1	Cycloheptanone	Site-Limited	-
504-02-9	1,3-Cyclohexanedione	Site-Limited	-
507-70-0	Bicyclo[2.2.1]heptan-2-ol, 1,7,7-trimethyl-, endo-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
516-03-0	Ethanedioic acid, iron(2+) salt (1:1)	Commercial	-
555-34-0	Ethanedioic acid, iron(3+) sodium salt (3:1:3)	Commercial	-
563-67-7	Acetic acid, rubidium salt	Site-Limited	-
583-59-5	Cyclohexanol, 2-methyl-	Domestic	-
583-60-8	Cyclohexanone, 2-methyl-	Domestic	-
584-09-8	Carbonic acid, dirubidium salt	Site-Limited	-
589-91-3	Cyclohexanol, 4-methyl-	Commercial	-
590-67-0	Cyclohexanol, 1-methyl-	Commercial	-
591-23-1	Cyclohexanol, 3-methyl-	Commercial	-
591-24-2	Cyclohexanone, 3-methyl-	Site-Limited	-
765-69-5	1,3-Cyclopentanedione, 2-methyl-	Site-Limited	-

CAS No	Chemical Name	Highest Use Category (Human Health)	Additional information
767-54-4	Cyclohexanol, 3,3,5-trimethyl-, trans-	Commercial	-
825-25-2	Cyclopentanone, 2-cyclopentylidene-	Site-Limited	-
830-13-7	Cyclododecanone	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
873-94-9	Cyclohexanone, 3,3,5-trimethyl-	Commercial	-
930-68-7	2-Cyclohexen-1-one	Site-Limited	-
933-48-2	Cyclohexanol, 3,3,5-trimethyl-, cis-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
1310-82-3	Rubidium hydroxide (Rb(OH))	Site-Limited	-
2408-37-9	Cyclohexanone, 2,2,6-trimethyl-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
2459-09-8	4-Pyridinecarboxylic acid, methyl ester	Site-Limited	-
2695-37-6	Benzenesulfonic acid, 4-ethenyl-, sodium salt	Commercial	-
2756-56-1	Bicyclo[2.2.1]heptan-2-ol, 4,7,7-trimethyl-, propanoate, exo-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
4621-04-9	Cyclohexanol, 4-(1-methylethyl)-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
4819-67-4	Cyclopentanone, 2-pentyl-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
5655-61-8	Bicyclo[2.2.1]heptan-2-ol, 1,7,7-trimethyl-, acetate, (1S-endo)-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
7488-54-2	Sulfuric acid, dirubidium salt	Commercial	-
7492-41-3	Bicyclo[2.2.1]heptan-2-ol, 1,7,7-trimethyl-, formate, endo-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.

CAS No	Chemical Name	Highest Use Category (Human Health)	Additional information
7549-41-9	Pentanoic acid, 1,7,7-trimethylbicyclo[2.2.1]hept-2-yl ester, endo-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
7779-73-9	Butanoic acid, 3-methyl-, 1,7,7-trimethylbicyclo[2.2.1]hept-2-yl ester, exo-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
7790-29-6	Rubidium iodide (RbI)	Commercial	
7791-11-9	Rubidium chloride (RbCl)	Site-Limited	-
9049-71-2	Poly[oxy(methyl-1,2-ethanediyl)], .alphahydroomegahydroxy-, ether with .betaD-fructofuranosyl .alphaD-glucopyranoside	Domestic	-
11115-91-6	Iron manganese oxide	Domestic	-
12062-81-6	Iron manganese oxide (FeMnO3)	Domestic	-
12111-24-9	Calciate(3-), [N,N-bis[2- [bis(carboxymethyl)amino]ethyl]glycinato(5-)]-, trisodium	Commercial	-
13074-65-2	Cyclopentanone, 2-hexyl-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
13126-12-0	Nitric acid, rubidium salt	Site-Limited	-
13268-42-3	Ethanedioic acid, ammonium iron(3+) salt (3:3:1), trihydrate	Commercial	-
14024-18-1	Iron, tris(2,4-pentanedionato-O,O')-, (OC-6-11)-	Commercial	-
14221-47-7	Ferrate(3-), tris[ethanedioato(2-)-O,O']-, triammonium, (OC-6-11)-	Commercial	-
18765-38-3	Silicic acid (H4SiO4), tetrakis(2-butoxyethyl) ester	Commercial	-
19088-74-5	Carbonic acid, monorubidium salt	Site-Limited	-
19529-40-9	Ferrate(2-), [N,N-bis[2- [bis(carboxymethyl)amino]ethyl]glycinato(3-)]-, ammonium hydrogen	Cosmetic	-

CAS No	Chemical Name	Highest Use Category (Human Health)	Additional information
19922-72-6	Benzenesulfonic acid, 4-ethenyl-, ammonium salt	Commercial	-
21129-27-1	Cyclohexanol, 1-methyl-4-(1-methylethyl)-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
21922-58-7	Bicyclo[3.2.1]octan-8-one, 1,5-dimethyl-	Site-Limited	-
25639-42-3	Cyclohexanol, methyl-	Commercial	-
26301-10-0	.alphaD-Glucopyranoside, .betaD- fructofuranosyl, polymer with methyloxirane and oxirane	Commercial	-
26914-43-2	Benzenesulfonic acid, ethenyl-	Commercial	-
27457-28-9	Benzenesulfonic acid, ethenyl-, sodium salt	Commercial	-
39393-07-2	Poly(oxy-1,2-ethanediyl), .alphahydroomegahydroxy-, ether with .betaD-fructofuranosyl .alphaD-glucopyranoside	Commercial	-
56731-02-3	Poly[oxy(methyl-1,2-ethanediyl)], .alphahydroomegahydroxy-, ether with .betaD-fructofuranosyl .alphaD-glucopyranoside and 1,2,3-propanetriol	Commercial	-
58479-55-3	Butanoic acid, 1,7,7-trimethylbicyclo[2.2.1]hept-2-yl ester, exo-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
63182-06-9	Benzenesulfonic acid, ethenyl-, lithium salt	Commercial	-
65443-14-3	Cyclopentanone, 2,2,5-trimethyl-5-pentyl-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
67634-11-1	Cyclohexanol, 2-(1,1-dimethylethyl)-4-methyl-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
74219-20-8	Bicyclo[2.2.1]heptan-2-ol, 1,7,7-trimethyl-, formate, (1R-endo)-	Commercial	-

CAS No	Chemical Name	Highest Use Category (Human Health)	Additional information
82640-18-4	Iron, complexes with diazotized 3-amino-2-hydroxy-5-nitrobenzenesulfonic acid monosodium salt coupled with diazotized 2-amino-4-nitrophenol and resorcinol, sodium salts	Domestic	-
95962-14-4	Cyclopentanone, 2-[2-(4-methyl-3-cyclohexen-1-yl)propyl]-	Cosmetic	Data available on the function of the chemical indicate that it may be used in cosmetics, but only at low concentrations.
103513-07-1	.alphaD-Glucopyranoside, .betaD- fructofuranosyl, polymer with methyloxirane, 2,2'-oxybis[ethanol] and 1,2-propanediol	Commercial	-
103513-09-3	.alphaD-Glucopyranoside, .betaD-fructofuranosyl, polymer with 1,2-ethanediol and methyloxirane	Site-Limited	-
103513-10-6	.alphaD-Glucopyranoside, .betaD-fructofuranosyl, polymer with methyloxirane and 2,2'-oxybis[ethanol]	Commercial	-
105118-94-3	Ferrate(1-), [[N,N'-(2-hydroxy-1,3-propanediyl)bis[N-(carboxymethyl)glycinato]](4-)]-, ammonium, (OC-6-21)-	Commercial	-
122489-39-8	Ferrate(2-), [[N,N'-1,3-propanediylbis[N- (carboxymethyl)glycinato]](4-)- N,N',O,O',ON,ON']-, (OC-6-21)-	Commercial	-

References

AICIS (Australian Industrial Chemicals Introduction Scheme) (2019), <u>The Industrial Chemicals Act 2019</u>, AICIS, accessed 18 September 2023.

AICIS (Australian Industrial Chemicals Introduction Scheme) (n.d.), <u>The Australian Inventory</u> of <u>Industrial Chemicals (Inventory)</u>, AICIS, accessed 18 September 2023.



