



Independent Human Health and Environmental Hazard Assessments of Dispersant Chemicals in Australia, produced by NICNAS and CSIRO

AMSA/National Plan preamble to the three independent reports by:

NICNAS (April 2014)	<i>Chemicals used as oil dispersants in Australia: Stage 1. Identification of chemicals of low concern for human health</i>
NICNAS (October 2014)	<i>Chemicals used as oil dispersants in Australia: Stage 2. Summary report of the human health hazards of oil spill dispersant chemicals</i>
CSIRO (August 2015)	<i>A review of the ecotoxicological implications of oil dispersant use in Australian waters.</i>

The Australian National Plan Dispersant Strategy

The Australian National Plan for Maritime Environmental Emergencies has had a longstanding dispersant response strategy that is transparent, fit for purpose and effective, and safe to use for people and the environment. At all stages of dispersant management: acceptance and purchase; storage and transport; and application in spill, the National Plan requires transparency. These requirements, results and processes are all published on the AMSA website. To ensure that Australia has suitable information to undertake all these steps, AMSA has always sought the best independent advice it could find. Most recently AMSA addressed questions of human health hazards and environmental hazards.

Health hazard assessment by National Industrial Chemicals Notification and Assessment Scheme (NICNAS)

NICNAS comprehensively addressed the question of dispersant health hazard in two stages. The first stage assessment identified 2 of 11 chemicals to be of low concern for human health. The second stage was a more full assessment that concluded that 7 of the 11 chemicals were of no concern. The remaining four were considered hazardous based on Safe Work Australia's Approved Criteria for Classifying Hazardous Substances. Of these three were already in the Safe Work Australia Hazardous Substances Information System (HSIS) and the fourth will be added to HSIS by NICNAS for completeness, now the assessment has been completed.

Environmental hazard assessment by CSIRO

CSIRO reported on the state of knowledge of the environmental hazards from dispersant use worldwide and within Australian waters. CSIRO noted that modern dispersants are much less toxic than spilled oil. However, their use can increase localised oil toxicity, but this is very short-lived due to the dilution effects and will result in much lower exposure and dosage than without dispersant use. They noted that some areas, some species groups and some organism life-stages are more susceptible to oil and oil/dispersant exposure than others. AMSA has addressed this in National Plan and AMSA policies.

AMSA response to the independent reports

AMSA has for many years been aware of the chemical constituent of dispersants, and has in place rigorous procedures and safeguards for purchase, storage, handling and use of dispersants, that minimize human exposure at all phases of the dispersant cycle. These were reviewed and revised in light of the new information.

AMSA accepts low environmental toxicity dispersant formulations that are also readily biodegradable. The rigorous requirements for secure storage and transport ensure no inadvertent release. Pre-use assessment through a rigorous and robust expert NEBA also ensures the right dispersant is used on the right oil at the right time in the right location and for the right duration. When specific knowledge gaps cannot be addressed during a response, a precautionary approach is taken to the NEBA and use approval. Any time a dispersant is used, real-time and post-application monitoring occurs to assess its effectiveness and effects.

Any questions or comments, please use the AMSA contact us page on the AMSA website.

Paul Irving, Scientific Coordinator, AMSA. May 2016

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Australian Government

Department of Health

National Industrial Chemicals

Notification and Assessment Scheme

Chemicals used as oil dispersants in Australia: identification of chemicals of low concern for human health

APRIL 2014

Executive Summary

Oil dispersants are chemical mixtures of surface active agents used to manage oil spills. They act by combining with large floating masses of oil and facilitating the dispersion of oil into small microscopic droplets that then disperse throughout the water column.

The Australian Maritime Services Authority (AMSA) has identified eleven oil dispersant chemicals as being used in the treatment of oil spills in Australia. This report describes the methodology used for screening the 11 oil dispersant chemicals to determine listing on the Australian Inventory of Chemical Substances (AICS), and to identify the chemicals of low concern for human health.

All of the 11 oil dispersant chemicals were confirmed to be listed on AICS, and a detailed risk assessment of one of the eleven chemicals has previously been undertaken by NICNAS for uses of the chemical other than as an oil dispersant.

The Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework has been developed by NICNAS to identify and rapidly assess chemicals on the AICS that have not been subject to previous assessment. The IMAP Framework includes a method of identifying chemicals of low concern for human health, which has been adapted and validated to identify oil dispersant chemicals of low human health concern. A single method was utilised for both discrete chemicals and polymers; however, different validation rules were applied to the two classes of chemicals to identify chemicals of low concern for human health.

The approach to identify chemicals of low concern utilised six steps:

1. Using existing national or international lists of substances considered to be of low concern identified in the IMAP Framework;
2. Analysing these lists for their applicability to identify oil dispersant chemicals of low concern to human health;
3. Comparing oil dispersant chemicals with the lists;
4. Applying validation rules developed by NICNAS;
5. Applying further validation rules, developed by NICNAS, based on expert judgement to identify additional oil dispersant chemicals of low human health concern; and
6. Using validation rules to identify polymers of low concern.

Using this approach, two of the eleven oil dispersants were identified as chemicals of low concern for human health and 9 chemicals were determined to require further assessment. This approach is a screening process and is an efficient method to identify chemicals of low human health concern. Exclusion of chemicals from the low concern category does not imply that these chemicals represent a risk to human health. The approach identifies chemicals that need further analysis of the hazards to determine if they are of low concern. Further in-depth analysis of the hazards of the chemicals may result in a conclusion of low risk to human health. Appendix A of the report provides a list of the chemicals screened and the different steps at which chemicals were identified as of low concern.

Introduction

Oil dispersants are chemical mixtures of surface active agents used to manage oil spills. They act by combining with large floating masses of oil and facilitating the dispersion of oil into small microscopic droplets that then disperse throughout the water column. Oil dispersants are surfactant – solvent formulations that are sprayed (often from crop-spraying aircraft) onto oil slicks to promote more rapid dispersal into the water column, and dilution throughout prior to biodegradation by microorganisms. A majority of the less viscous oils dissolve and disperse in seawater to some extent under local wave and wind energy. Human exposures to oil dispersants may represent exposures to complex mixtures of the specific ingredients, as well as to mixtures of these ingredients with chemicals in the oil spills to which they have been applied. However, identification of specific ingredients in oil dispersants allows some estimation of their potential toxicity.

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) was contracted by the Australian Maritime Safety Authority (AMSA) to screen the chemicals used in oil dispersant products. Data provided by AMSA indicated that currently seven oil dispersant products are used in Australia. The data further indicated that eleven chemicals, mostly surfactants and solvents, are commonly present in these products.

The overall objective of the project is to screen the chemicals used as oil dispersants to

- determine the listing of the chemicals in the Australian Inventory of Chemical Substances (AICS) and
- identify those chemicals that are of low human health concern.

This report describes the approaches utilised for screening the eleven chemicals to confirm their regulatory status in Australia and to identify chemicals of low human health concern.

Methodology

Status of the oil dispersant chemicals on the Australian Inventory of Chemical Substances (AICS)

The Australian Inventory of Chemical Substances (AICS) is the legal device that distinguishes new from existing chemicals.

AICS is a listing, corrected as required, of all industrial chemicals in use in Australia between 1 January 1977 and 28 February 1990. In addition, it includes new assessed chemicals as well as chemicals that were regulated by other Australian regulators and have since become industrial chemicals.

AICS is maintained by NICNAS and contains around 40,000 chemicals. Any chemical not included in AICS is regarded as a new industrial chemical unless it is outside the scope of the *Industrial Chemicals (Notification and Assessment) Act 1989* or is otherwise exempt

from notification. New industrial chemicals must be notified and assessed before being manufactured in, or imported into, Australia. Chemicals on AICS can be imported or manufactured in Australia without first being notified to NICNAS as new chemicals, regardless of whether they have been assessed or not yet assessed by NICNAS.

AMSA provided NICNAS with a list of eleven chemicals (Table 2) that are ingredients of oil dispersant products. A search of the AICS was conducted using the Chemical Abstract Services (CAS) Numbers to determine whether the eleven oil dispersant chemicals were listed on AICS and whether these chemicals have been assessed by NICNAS.

Identification of chemicals of low concern for human health

The methodology for identifying oil dispersant chemicals of low human health concern is based on that developed by the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for the Inventory Multi-tiered Assessment and Prioritisation (IMAP) Framework¹. The IMAP Framework enables the identification and rapid assessment of chemicals on the AICS that have not been subject to previous assessment. The IMAP methodology was independently validated by scientific experts in Australia and is based primarily on that used by Health Canada as part of the categorisation of the Canadian chemicals inventory, the Domestic Substances List (DSL). The IMAP Framework includes a method of identifying chemicals of low concern to human health. This methodology is considered applicable to identifying oil dispersant chemicals of low human health concern and was adapted for this activity. A single approach was utilised for both discrete chemicals and polymers; however, different validation rules are applied to discrete chemicals and polymers to identify those chemicals and polymers of low human health concern.

The approach to identify chemicals of low concern for human health utilises six steps:

- 1) Use of existing national or international lists of substances considered to be of low concern identified in the IMAP Framework;
- 2) Analysis of these lists for their applicability for identifying oil dispersant chemicals of low concern for human health;
- 3) Comparison of oil dispersant chemicals with the lists;
- 4) Validation rules developed by NICNAS;
- 5) Further validation rules, developed by NICNAS, based on expert judgement to identify additional oil dispersant chemicals of low human health concern;
- 6) Validation rules to identify polymers of low concern.

Step 1: Use of existing national or international lists of substances considered to be of low concern

The following schemes were identified in which substances were determined to be of low human health concern based on review, critical evaluation of data and expert peer review:

- Canada SimHaz tool;

¹ Identification of chemicals of low concern for human health. <http://www.nicnas.gov.au/chemical-information/imap-assessments/the-imap-framework>

- Annex IV of the European Union (EU) Regulation that deals with Registration, Evaluation, Authorisation and Restriction of Chemical substances (REACH);
- Annex V of the EU REACH Regulation;
- United States Environmental Protection Agency (US EPA) High Production Volume (HPV) Challenge Program;
- Inert Ingredients Eligible for US Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) 25(b) pesticide products;
- US Food and Drug Administration's (FDA) Generally Recognized as Safe (GRAS) list;

Canada SimHaz tool

As part of the categorisation of the DSL by Health Canada, chemicals were assessed using a 'simple hazard tool' (SimHaz tool) where information for identification of high or low hazard chemicals was sourced from various agencies based on weight of evidence for multiple hazard endpoints. The SimHaz tool was restricted to hazard based systems which had a well-delineated basis and involved some level of expert consensus/international agreement. This tool considered the following lists to determine low hazard chemicals:

- **Health Canada Pest Management Regulatory Authority (PMRA) Pesticide Formulant List 4A.** List 4A is a list of pest control formulations of minimal toxicological concern. The list was based on the US EPA Minimal Risk Inerts List 4A. The 4A list has since been updated with the FIFRA list (discussed below).
- **Draft list of chemicals that do not need assessment in the OECD High Production Volume (HPV) Chemicals Program.** The Organisation for Economic Cooperation and Development (OECD) has recognised certain chemicals as low hazard based on their intrinsic properties. These chemicals have been provisionally set aside. This list is not a stand-alone list but rather a compilation of existing lists from the US EPA and EU; these are considered separately below.
- **Annex II to Council Regulation (EEC) 793/93** of 23 March 1993 on the evaluation and control of the risks of existing substances: List of substances exempt from the provisions of Articles 3 and 4. This regulation has since been repealed and replaced with Regulation (EC) No 1907/2006. The new regulation replaced Annex II with an updated Annex IV (exemptions from the obligation to register in accordance with article 2(7)(a)). Annex IV is considered separately (see below).
- **US EPA HPV Challenge Program.** Chemicals not considered to be candidates for testing under the HPV Challenge Program, based on preliminary US EPA review indicating that 'testing using the Screening Information Data Set (SIDS) base set would not lead to further understanding of the chemicals' properties. This included chemicals listed under HPV 'indicator 1'. This list is considered separately (see below).

Annex IV of the EU REACH Regulation²

Annex IV of REACH contains a list of substances which are exempt from registration on the basis of sufficient information on intrinsic properties for them to be regarded as

² http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review-annexes/index_en.htm#h2-4

representing low risk. Substances included in Annex IV are exempt from registration (as well as downstream user requirements and evaluation) for all possible uses irrespective of the tonnage at which they are manufactured or imported (currently or in the future). The European Commission established a set of criteria³ to determine what was considered sufficient information. Originally, Annex IV reproduced the list of substances exempt from the obligation to report information under the repealed Existing Substances Regulation (Regulation (EEC) No. 793/93). In 2008, this list was revised by the EU based on agreed hazard criteria covering data availability, physicochemical and toxicity criteria. As a result of the review⁴, three chemicals (vitamin A, carbon and graphite) were removed due to potential toxicity.

Annex V of the EU REACH Regulation⁵

Annex V of Regulation (EC) No. 1907/2006 (REACH) sets out substances that are exempt from the registration, evaluation and downstream use provisions of REACH because registration is deemed inappropriate or unnecessary and their exemption does not prejudice the objectives of REACH.

Some chemicals covered by the Annex are not exempt from other obligations of REACH. Several entries on this Annex relate to chemicals occurring in nature that are not chemically modified. Some entries make reference to hazardous properties which are included or excluded. Importers and manufacturers must hold data to demonstrate that the hazardous properties criteria are met. Whilst some entries list specific chemicals, others are more generic.

Entries listed in Annex V considered relevant for inclusion in the IMAP but not relevant for the oil dispersant chemicals are:

- substances which occur in nature, if they are not chemically modified: vegetable fats, vegetable oils, vegetable waxes; animal fats, animal oils, animal waxes; fatty acids from C6 to C24 and their potassium, sodium, calcium and magnesium salts; and glycerol⁶;
- cement clinker, magnesia;
- glass, ceramic frits;
- compost and biogas; and
- hydrogen and oxygen.

US EPA HPV Challenge Program

The US EPA High Production Volume (HPV) chemicals are those which are manufactured in or imported into the USA in amounts greater than one million pounds per year. The US EPA HPV Challenge program for data availability used indicators to signify whether the chemical falls outside the scope of the HPV Challenge program. The chemicals under 'indicator 1' are

³ http://ec.europa.eu/enterprise/sectors/chemicals/files/reach/com_rev_anx_iv_criteria_en.pdf

⁴ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:268:0014:0019:EN:PDF>

⁵ http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review-annexes/index_en.htm#h2-4

⁶ unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC with the exception of those only classified as flammable [R10], as a skin irritant [R38] or as an eye irritant [R36], or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII, or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).

generally considered safe – these chemicals (based on preliminary EPA review) were not considered a candidate for testing under the HPV Challenge program as testing would not further the understanding of the chemicals' properties. Chemical lists under the US HPV program have been annotated periodically since they were first posted on October 9, 1998.

Inert Ingredients Eligible for FIFRA [Federal Insecticide, Fungicide, and Rodenticide Act] 25(b) pesticide products⁷

The US Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) requires all pesticides, with very limited exceptions, to be registered with the US EPA before they can legally be sold or used in the USA. In 1996, the US EPA exempted certain pesticides, considered to pose minimum risk to humans and the environment, from this requirement provided the products satisfy certain conditions.

These products were exempted based in part on their minimal risk status, and in part as an effort on the part of the US EPA to reduce the cost and regulatory burden on businesses so that the Agency could focus its limited resources on pesticides that pose a greater risk. This exemption list updates a previous list called 'US EPA list 4A' under Pesticide Registration Notice 2000-6.

US FDA Generally Recognized as Safe (GRAS) list (Type 1)⁸

This list contains food substances that are not subject to premarket review and approval by the US FDA because they are generally recognised, by qualified experts, to be safe under the intended conditions of use. Their safety was established by a long history of use in food or by virtue of their nature. Each substance was evaluated and categorised into types according to conclusions on safety provided by scientific experts external to the FDA. The Type 1 category contains substances where there is no information available on the substance that demonstrates, or suggests reasonable grounds to suspect, a hazard to the public when they are used at levels that are now current or might reasonably be expected in the future.

Step 2: Analysis of low concern lists for applicability for identifying oil dispersant chemicals of low concern for human health

The lists described above were analysed to determine their applicability for identifying oil dispersant chemicals of low human health concern.

The lists were grouped into four categories based on availability of updated lists, whether conditions of use were required for the low concern status or reduced regulatory requirements based on origin as indicated in Table 1.

⁷ http://www.epa.gov/opprd001/inerts/section25b_inerts.pdf

⁸ <http://www.accessdata.fda.gov/scripts/fcn/fcnNavigation.cfm?rpt=scogsListing>

Table 1: Identified lists/groups for determining chemicals of low concern

Category	Identified Schemes/Lists	Used to identify oil dispersant chemicals of low concern for human health
Updated list available	Pesticide Formulant 4A - Health Canada, PMRA	No
	OECD HPV list	No
Lists of chemicals identified as safe with no condition of use	US EPA HPV Indicator 1	Yes
	REACH Annex IV	Yes
Lists of chemicals identified as low risk under conditions used	Inert Ingredients Eligible for FIFRA (list 4a)	Yes with validation (see below)
	US FDA GRAS	Yes
	Canada SimHaz Tool	Yes
Lists of chemicals with reduced regulatory requirements based on their origin	REACH Annex V	Yes with validation (see below)

As the uses and large volumes of oil dispersant chemicals are likely to be very different from those under which they have been considered low risk in other jurisdictions, it was considered important to apply additional validation rules (step 4) on chemicals identified by the FIFRA and US FDA GRAS lists to ensure that oil dispersant chemicals that warrant assessment are not included as chemicals of low concern for human health.

Step 3: Comparison of oil dispersant chemicals with the low concern chemical lists

The 11 chemicals, 8 discrete chemicals and 3 polymers, used in oil dispersants for oil spill remediation were compared with the lists above. Three chemicals were identified as potentially of low concern based on their entries in these lists.

Step 4: Validation rules developed by NICNAS

A set of validation rules developed by NICNAS for the IMAP framework, characterises chemicals meeting the following criteria as requiring further assessment:

- 1) Chemicals identified as a concern or for which regulatory action has been taken overseas;
- 2) Chemicals meeting hazard criteria developed by NICNAS for use in the IMAP Framework based on any of the following sources:

- Safework Australia's Hazardous Substances Information System (HSIS);
 - European Union (EU) Regulation on Classification, Labelling and Packaging (EU CLP; conversion of old EU classifications to adopted GHS);
 - International Agency for Research on Cancer (IARC);
 - National Toxicology Program - Report on Carcinogens (NTP ROC);
 - EU list of endocrine disrupters; and
 - List of neurotoxic chemicals from ATSDR;
- 3) Chemicals included in the Schedule for Uniform Scheduling of Medicines and Poisons (except where the listing is in Appendix B⁹);
 - 4) Chemicals removed from Annex IV of REACH as part of the review process; and
 - 5) Strong or moderate acids and bases, quaternary ammonium salts, and anhydrous deliquescent materials.

Step 5: Further validation rules developed by NICNAS, based on expert judgement, to identify additional chemicals of low concern for human health

An analysis of the chemicals internationally recognised as safe and/or of low risk allowed NICNAS to develop further validation rules for identifying additional chemicals that may be considered of low concern for human health.

Binary inorganics and organic acid salts

The hazard profiles of binary inorganics and organic acid salts were characterised taking into consideration the toxicity of the anion and cation respectively. The following anions, cations and organic acids were identified for potential inclusion in the list of chemicals generally considered safe: Na⁺, K⁺, Mg²⁺, Ca²⁺, Cl⁻, CO₃⁻², PO₄⁻³, NO₃⁻¹, OH⁻, O⁻², and SO₄⁻² and simple salts of acetate, citrates, lactates, tartrates, malates and di- and tri- phosphates. This was based on the occurrence of a number of such simple salts on the lists discussed above, and the absence of classifications under HSIS for simple salts except where these are classified for local irritant properties relating to acidity, basicity or desiccation.

Hydrates

As hydrates of a substance or hydrated ions are formed by association of a substance with water, the hydrates of chemicals considered as low concern for human health are to be also considered as low concern for human health, as will hydrates where the anhydrous form is ruled out due to desiccation effects.

Step 6: Validation rules to identify polymers of low concern

Validation rules developed for discrete chemicals were considered inappropriate for polymers. Therefore an additional set of validation rules was developed to identify polymers of low concern. Validation for polymers involves a comparison of the polymers to the NICNAS New Chemicals Programme Polymer of Low Concern (PLC) criteria.

⁹ SUSMP Appendix B: Substances considered not to require control by scheduling.
<http://www.comlaw.gov.au/Details/F2012L01200>

The PLC criteria used in the NICNAS New Chemicals Programme are based on certain characteristics such as Number Average Molecular Weight (NAMW), proportion of low molecular weight species, Functional Group Equivalent Weight (FGEW) for reactive functional groups and the stability of the polymers (NICNAS Handbook).

In this validation rule, reactive functional groups (RFGs) are identified in the polymers under consideration. These RFGs are then screened against RFGs considered low concern as described in the NICNAS PLC criteria. Polymers with RFGs other than those considered low concern in the PLC criteria were not considered to be of low concern for human health.

Identification of Oil dispersant chemicals used in Australia and their regulatory status

AMSA provided NICNAS with the names of oil dispersant products currently being used in Australia for oil spill clean-up. These products are:

1. Corexit EC9527A
2. Corexit EC9500A
3. Slickgone LTSW
4. Slickgone NS
5. Slickgone EW
6. Ardrex 6120
7. Finasol 51

Table 2 lists the eleven chemicals identified by AMSA as oil dispersant chemicals that are present as active constituents in the seven oil dispersant products listed above. It should be noted, however, that not all the eleven chemicals are present in each of the products. Each product contains one or more of these eleven chemicals.

Table 2: Oil dispersant chemicals used in Australia

CAS Number	Chemical substance	Type
577-11-7	Dioctyl sodium sulfosuccinate	Surfactant
1338-43-8	Sorbitan, mono-(9Z)-9-octadecenoate	Surfactant
9005-65-6	Polyoxy-1,2-ethanediyl derivatives of sorbitan, mono-(9Z)-9-octadecenoate	Surfactant
9005-70-3	Polyoxy-1,2-ethanediyl derivatives of sorbitan, tri-(9Z)-9-octadecenoate	Surfactant
103991-30-6	Ethoxylated fish oil	Surfactant
8002-26-4	Tall oil	Surfactant

112-34-5	Butyldiglycol; Diethylene glycol monobutyl ether	Solvent
64742-47-8	Petroleum distillates, hydrotreated light fraction	Solvent
29911-28-2	Dipropylene glycol monobutyl ether	Solvent
111-76-2	2-Butoxyethanol	Solvent
57-55-6	Propylene glycol	Solvent

A search of AICS indicated that all eleven chemicals are listed on AICS, and are therefore considered existing chemicals and can be imported or manufactured in Australia without being first notified to NICNAS. The search also revealed that one chemical (2-Butoxyethanol, CAS No. 111-76-2) has been assessed by NICNAS.

NICNAS is currently assessing the human health and environmental impacts of previously unassessed industrial chemicals listed on AICS under the Inventory Multi-tiered Assessment and Prioritisation (IMAP) framework. The main objectives of the IMAP framework are the identification and rapid assessment of existing chemicals of concern, leading to enhancements in chemical safety information flow and chemicals management. It is a transparent approach to the assessment of the large number of chemicals on the national inventory and is responsive to the needs of industry, community and government.

Application of the approach to identify oil dispersant chemicals of low human health concern

The 11 chemicals, three of which are polymers, were compared with the lists of chemicals of low concern identified above (Step 3). Three chemicals were identified as potentially of low concern based on their entries on these lists (Step 3) and eight chemicals were identified as requiring further assessment.

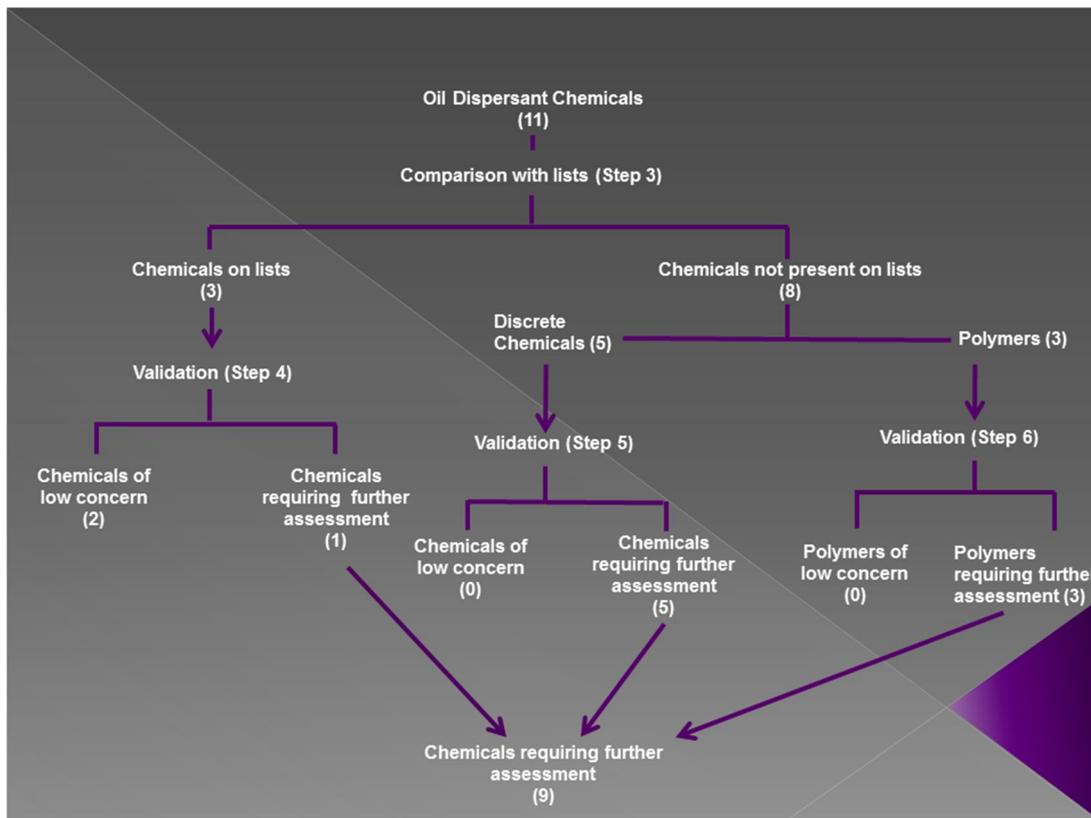
The set of validation rules developed by NICNAS to identify chemicals requiring further assessment was applied to the three chemicals (Step 4) for confirmation of their potential low concern. One chemical was identified through application of these rules as requiring assessment and was removed from the list of low concern.

Further validation rules, developed by NICNAS, based on expert judgement, were applied to the 8 chemicals identified as requiring further assessment (Step 3) to determine chemicals of low concern among these chemicals (Step 5). Based on the application of the validation rules, no chemicals were identified as of low concern for human health. Two chemicals were identified to be of low concern for human health based on this approach.

The set of validation rules to identify polymers of low concern was applied to the three polymers among these chemicals (Step 6). The reactive functional groups (RFGs) in the three polymers were identified and screened against RFGs considered low concern as described in the NICNAS Polymer of Low Concern (PLC) criteria. No polymers were identified as PLCs by application of this validation rule. The three polymers are therefore considered as needing further assessment.

Figure 1 provides a schematic representation of the application of the approach and the validation rules, and the results.

Figure 1: Application of the approach and the validation rules, and the results



The results of application of the approach and validation rules to the 11 oil dispersant chemicals are contained in Appendix A. Two chemicals, listed in Table 3, were identified to be of low concern based on this approach. The common names of the chemicals, where available and different from the chemical names, are also indicated in the table.

Table 3: Chemicals identified as low concern for human health

CAS No.	Chemical Name	Common Name
8002-26-4	Tall oil	Tall oil
1338-43-8	Sorbitan, mono-(9Z)-9-octadecenoate	Sorbitan Monooleate

Conclusion

The 11 chemicals provided by AMSA as being used in oil spills remediation were screened for their listing on AICS and identification of chemicals of low concern for the human health. The screening indicated that:

- All eleven chemicals identified as being used in oil spills remediation are listed on AICS indicating that they are existing chemicals and are not required to be notified to NICNAS prior to being imported or manufactured.
- NICNAS has conducted an in depth risk assessment of one chemical (2-butoxyethanol) for uses other than as oil dispersants.
- Of the 11 chemicals, 2 (Tall oil and sorbitan monooleate) were determined to be of low concern for human health.
- None of the three polymers used as oil dispersants met the NICNAS criteria for polymers of low concern and were thus determined to be chemicals requiring further assessment.

Exclusion of the remaining 9 chemicals from the low human health concern list in Table 2 does not imply that these chemicals represent a risk to human health. A further in-depth analysis of these chemicals may result in a conclusion of low hazard to human health.

Appendix A

Application of approach and validation rules to identify chemicals of low concern through Steps 3 to 6.

CAS No.	Chemical Name	Step 3	Step 4	Step 5	Step 6 (PLC Criteria)
577-11-7	Diocetyl sodium sulfosuccinate (Docusate sodium)				
1338-43-8	Sorbitan, mono-(9Z)-9-octadecenoate (Sorbitan Monooleate)	Included in Annex IV	Low Concern		
9005-65-6	Polyoxy-1,2-ethanediyl derivatives of sorbitan, mono-(9Z)-9-octadecenoate				
9005-70-3	Polyoxy-1,2-ethanediyl derivatives of sorbitan, tri-(9Z)-9-octadecenoate				
103991-30-6	Ethoxylated fish oil				
8002-26-4	Tall oil	Listed in GRAS	Low concern		
112-34-5	Butyldiglycol; Diethylene glycol monobutyl ether; 2-(2-butoxyethoxy)ethanol				
64742-47-8	Petroleum distillates, hydrotreated light fraction				
29911-28-2	Dipropylene glycol monobutyl ether				
57-55-6	Propylene glycol	Listed in GRAS	Listed in HSIS (No longer Low concern)		
111-76-2	2-Butoxyethanol; ethylene glycol mono-n-butyl ether				