**Existing Chemical**
**Secondary Notification**
**Assessment Report**
**NA/103S**

**October 2017**

**Australian Government**
**Department of Health**
National Industrial Chemicals
Notification and Assessment Scheme

# Polysiloxanes, di-Me, 3-[3-[(3-coco amidopropyl)dimethylammonio]-2-hydroxypropoxy]propyl group-terminated, acetates (salts)

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME

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# Preface

This assessment was carried out under the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). This scheme was established by the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), to aid in the protection of the Australian people and the environment by assessing the risks of industrial chemicals, providing information and making recommendations to promote their safe use. NICNAS assessments are carried out by staff employed by the Australian Government Department of Health in conjunction with the Australian Government Department of the Environment and Energy.

This assessment report is available for viewing and downloading from the NICNAS website or available on request, free of charge, by contacting NICNAS. For requests and enquiries please contact the NICNAS Administration Coordinator at:


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Director
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# Overview

## Background

Polysiloxanes, di-Me, 3-[3-[(3-coco amidopropyl)dimethylammonio]-2-hydroxypropoxy] propyl group-terminated, acetates (salts) is a siloxane polymer with a quaternary ammonium alkyl chain at each end of the polymer. Its Chemical Abstracts Service Registry Number (CAS RN) is 134737-05-6.

NICNAS assessed it under the limited notification category in 1993 and it is now listed on the Australian Inventory of Chemical Substances (AICS).

No human health or environmental hazard classifications were made at the time of the new chemical assessment. In 2014, additional data on the notified polymer indicated that its short-chain form (ABIL Quat 3270; number average molecular weight (NAMW) ~1670) is a skin sensitiser and has environmental toxicity. It therefore warranted a secondary notification. This assessment focuses on the new data provided.

## Exempt Information (Section 75 of the Act)

No details are claimed as exempt information.

## Importation volume and uses

The polymer functions as a cationic surfactant. It was originally reported as being imported in two grades, ABIL Quat 3270 (NAMW ~1670) and ABIL Quat 3272 (NAMW ~3200). Applicants for this secondary notification assessment specified importing two grades, ABIL Quat 3272 and ABIL Quat 3474 (NAMW ~7000), while no applicants specified importing ABIL Quat 3270. In addition, information submitted indicates that ABIL Quat 3676 (NAMW ~7000), another polymer grade, is expected to replace ABIL Quat 3474 in the near future but is currently not imported into Australia.

The maximum import volume of the polymer is up to 4.7 tonnes per annum, compared to an initial annual introduction of 2 tonnes in the original assessment. The majority of the import volume (up to 4 tonnes) is of ABIL Quat 3272 at a concentration of 50% polymer in propylene glycol for reformulation. The remaining volume is of ABIL Quat 3272 or ABIL Quat 3474 as part of finished products.

Applicants use grades ABIL Quat 3272 and ABIL Quat 3474 as a conditioning agent in leave-on and rinse-off hair care products at a concentration of up to 2.5%. They also use ABIL Quat 3272 as a component of fabric softeners for domestic washing machines at a concentration of up to 5%.

## Human health effects

Acute oral toxicity studies on ABIL Quat 3270, ABIL Quat 3272 and ABIL Quat 3474 were submitted for the secondary notification assessment. These studies confirm that the polymer is of low acute oral toxicity and support the findings of the new chemical assessment.

Based on toxicological studies for skin and eye irritation submitted at the time of the new chemical assessment, ABIL Quat 3270 is considered as not irritating to skin and eyes. However, new studies on ABIL Quat 3270, ABIL Quat 3272 and ABIL Quat 3474 submitted for the secondary notification assessment showed the polymer is slightly irritating to skin and eyes.

Skin sensitisation studies on ABIL Quat 3270 and ABIL Quat 3272, which were not available for the original assessment, were submitted for the secondary notification assessment. No sensitisation data were available for ABIL Quat 3474.

Available data show that ABIL Quat 3270 is a strong skin sensitiser. However, testing of ABIL Quat 3272 at a non-optimal lower dermal induction concentration (5%) than that used for ABIL Quat 3270 (10% concentration dermally) did not report sensitisation. Given the incomplete dataset, we cannot rule out a sensitisation potential for all grades of polymer, particularly ABIL Quat 3272 at concentrations higher than 5%, from a weight of evidence approach. All reported grades of the polymer have quaternary ammonium groups and likely have different levels of low molecular weight species (for which data are also incomplete) that can add to its skin sensitising potential.

With the quaternary ammonium groups situated at each end of the polymer, a longer neutral polymer backbone will result in a lower charge density and, thus, impart lower toxicity. To establish a cut-off, the total combined functional group equivalent weight (FGEW) of any cationic group of the polymer is used (where a low charge density polymer will have a total combined FGEW at least 5,000). Therefore, with the polymer containing 2 cationic quaternary ammonium groups, it may be regarded as a low charge density polymer and would be unlikely to be a skin sensitiser if the NAMW $\geq$ 10,000. All reported polymer grades in this secondary notification assessment have NAMW less than 10,000 and, therefore, are likely to be skin sensitisers. The grades of the notified polymer with NAMW < 10,000 are therefore recommended for classification as 'Skin sensitiser (Category 1A): May cause an allergic skin reaction' under the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) (United Nations, 2009).

Genotoxicity studies on ABIL Quat 3270 and ABIL 3272, which were unavailable for the original assessment, were also submitted for the secondary notification assessment. These studies show that ABIL Quat 3270 and ABIL Quat 3272 are not mutagenic.

## Occupational exposure and health risks

No changes in operational procedures for handling and formulating the notified polymer were notified for this secondary notification assessment. Therefore, the occupational exposure scenario from the new chemical assessment is still applicable. ABIL Quat 3272 is blended locally into reformulated products (with up to 2.5% notified polymer) prior to distribution to the public and hair salon workers. There is potential for dermal, and possibly ocular, exposure to the polymer (up to 50% concentration) during reformulation at blending sites, and to a lesser extent (up to 2.5% concentration) with hair salon workers.

Following the assessment of the new data for the secondary notification, the notified polymer is assessed to be a potential skin sensitiser. This may be an unreasonable health risk for workers involved in reformulation. However, the control measures already in place to minimise exposures (i.e. the use of enclosed systems when splashing or spillages are anticipated and the use of personal protective equipment (PPE)), will also effectively control the newly identified sensitisation hazard.

Professional end-users in hair salons may be exposed to the polymer through use of hair care products containing the polymer at up to 2.5%. The principal route of exposure will be dermal, with possible accidental ocular exposure. While the polymer has the potential to cause sensitisation and irritation, such effects are expected to be concentration-dependent and unlikely at the proposed use concentration. Therefore, the risk of skin or eye irritation or skin sensitisation in hair salon workers with use of products containing ABIL Quat 3272 and

ABIL Quat 3474 at proposed use concentrations is expected to be low.

## Public exposure and health risks

The public will be exposed to the notified polymer by use of consumer hair care products and domestic-use fabric softeners containing the polymer at up to 5% concentration. The principal route of exposure will be dermal, with some potential for possible accidental ocular exposure. While the polymer has the potential to cause sensitisation and irritation, such effects are expected to be concentration-dependent and unlikely at the proposed use concentrations (up to 5%).

There are no specific restrictions on the use of the polymer in cosmetic products internationally. In Australia, however, restrictions are in place for consumer products containing the notified polymer where it is covered by the entry for 'Quaternary ammonium compounds' listed in the Poisons Standard (SUSMP, 2017). These compounds are listed in Schedules 5 and 6, where the substances are to be respectively labelled with "Caution" for ≤ 20% concentration or "Poison" for concentration greater than 20%. Preparations containing ≤ 5% concentration of quaternary ammonium compounds do not require labelling. Therefore, the risk of skin or eye irritation or skin sensitisation in consumers with use of products containing ABIL Quat 3272 and ABIL Quat 3474 at proposed use concentrations (up to 5%) is expected to be low.

## Environmental effects

Ecotoxicological data on ABIL Quat 3270 and ABIL Quat 3474 for fish, daphnia and algae, and ABIL Quat 3272 for algae were submitted for the secondary notification assessment. Based on the submitted data, the notified polymer is considered to be very toxic to fish and daphnia, and toxic to algae.

The established cut-off of the polymer grade having a NAMW ≥ 10,000 for it to be regarded as a low charge density polymer and, thus, unlikely to be hazardous to human health can also be applied to environmental effects and environmental hazard classifications. The grades of the notified polymer with NAMW < 10,000 are, therefore, recommended for classification as 'Acute Category 1: Very toxic to aquatic life' under the GHS (United Nations, 2009). Further, based on the acute toxicity and the unknown biodegradability of the polymer, it is recommended for classification as 'Chronic Category 1: Very toxic to aquatic life with long lasting effects' under the GHS.

## Environmental exposure and risks

Most of the notified polymer is expected to be released to sewers. At sewage treatment plants, the polymer is expected to mostly partition to sludge due to its cationic properties and surface activity. Based on the maximum import volume and assessed use pattern, the release of the notified polymer to surface waters is not expected to reach ecotoxicologically significant quantities in the aquatic environment. Based on the predicted environmental concentration (PEC)/predicted no effect concentration (PNEC) ratio and the assessed use pattern, the notified polymer is not considered to pose an unreasonable risk to the environment.

# Recommendations

This section provides the recommendations arising from the secondary notification assessment of the notified polymer, and incorporates the applicable recommendations from the new chemical assessment report (NICNAS, 1993). The hazard classifications presented below are according to the GHS (United Nations, 2009). No human health or environmental hazard classifications were made at the time of the new chemical assessment.

Recommendations are directed principally at:

- regulatory bodies
- importers
- reformulators of the notified polymer.

Implicit in these recommendations is that best practice is implemented to minimise occupational exposure.

## Recommendations to national bodies

Based on the assessment findings, the notified polymer is recommended to Safe Work Australia for classification and labelling according to the GHS (United Nations, 2009) as below:

- Skin sensitiser (Category 1A): H317 – May cause an allergic skin reaction
- Acute Aquatic Toxicity (Category 1): H400 – Very toxic to aquatic life
- Chronic Aquatic Toxicity (Category 1): H410 – Very toxic to aquatic life with long lasting effects

It is recommended that the classification be accompanied by a note that the classification only applies to polymer grades with NAMW < 10,000.

## Recommendations to importers

### Hazard communication

*Labels*

Importers of the notified polymer should update their labels to reflect the new hazards identified by this assessment. In addition, importers should review their labels for compliance with the *Labelling of workplace hazardous chemicals – Code of practice* (Safe Work Australia, 2011).

*Safety Data Sheets (SDS)*

Under the *Model Work Health and Safety Regulations* (Safe Work Australia, 2016a) and the Commonwealth, state and territory regulations introduced in accordance with these model regulations, employees must have easy access to SDSs for hazardous substances at their workplace. SDSs, previously called Material Safety Data Sheets, provide information to those who use the hazardous substance.

Importers of the notified polymer should:

- update their SDS to reflect the new hazards identified by this assessment

- review their SDS for compliance with the *Preparation of safety data sheets for hazardous chemicals - Code of practice* (Safe Work Australia, 2016b)
- ensure that employees exposed to the polymer have easy access to a copy of the SDS.

**Control measures**

*Occupational controls*

A person conducting a business or undertaking (PCBU) at a workplace should implement the following engineering controls to minimise occupational exposure to the notified polymer during reformulation processes:

- enclosed, automated processes, where possible
- adequate general and local exhaust ventilation.

A PCBU at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer during reformulation processes:

- avoid skin and eye contact.

A PCBU at a workplace should ensure that the following personal protective equipment (PPE) is used by workers to minimise occupational exposure to the notified polymer during reformulation processes:

- safety glasses
- impervious gloves
- protective coveralls.

Guidance in selection of PPE can be obtained from Australian, Australian/New Zealand or other approved standards.

If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the GHS (United Nations, 2009) as adopted for industrial chemicals in Australia, workplace practices and control procedures consistent with provisions of state and territory hazardous substances legislation should be in operation.

*Environment*

On the basis of the risk quotient (RQ) ratio, maximum annual import volume and assessed use patterns, the notified polymer is not expected to pose an unreasonable risk to the environment.

*Disposal*

Where reuse or recycling are not appropriate, disposal of the notified polymer should occur in accordance to relevant Commonwealth, state, territory and local government legislation.

*Storage*

Containers should be securely closed and stored according to container label instructions.

*Emergency procedures*

Spills or accidental release of the notified polymer should be handled by physical containment, collection and subsequent safe disposal.

*Health surveillance*

As the notified polymer is a potential skin sensitiser, employers should monitor the health of any worker identified in the workplace risk assessment as having a significant risk of sensitisation. Employers should review the publication *Health Monitoring for Exposure to Hazardous Chemicals – Guide for Medical Practitioners* (Safe Work Australia, 2013).

# Secondary notification

This risk assessment is based on the information available at the time of the secondary notification. The Director may call for the reassessment of the chemical under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act), an introducer (importer/manufacturer) of the notified polymer has post-assessment regulatory obligations to notify NICNAS when any of these circumstances change.

Therefore, the Director of NICNAS must be notified in writing within 28 days by the notifiers, other importer or manufacturer:

(1) Under Section 64(1) of the Act, if:

- the importation volume exceeds 5 tonnes per annum of the notified polymer
- the concentration of the notified polymer in end-use products exceeds 5%
- new toxicity data become available for the notified polymer
- new ecotoxicity data or any environmental fate data (i.e. bioaccumulation, adsorption coefficient on soil and sediment sludge, etc.) become available for the notified polymer
- new findings indicate that the removal of the notified polymer at sewage treatment plants is or is expected to be less than 90% used in this secondary notification.

or

(2) Under Section 64(2) of the Act, if:

- the function or use of the polymer has changed from being a component of hair care products and fabric softeners, or is likely to change significantly
- the polymer has begun to be manufactured in Australia
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health or the environment.

The Director will then decide whether a reassessment (i.e. a secondary notification and assessment) is required.

# Abbreviations and acronyms

| | |
|---|---|
| Act, the | Commonwealth Industrial Chemicals (Notification and Assessment) Act 1989 |
| AICS | Australian Inventory of Chemical Substances |
| bw | body weight |
| CAS RN | Chemical Abstracts Service Registry Number |
| Da | Daltons (units of molecular weight) |
| DOC | dissolved organic carbon |
| EC50 | median effective concentration or half maximal effective concentration |
| EL50 | effective loading rate resulting in 50% effect |
| FGEW | functional group equivalent weight |
| FHSA | *Federal Hazardous Substances Act* (United States Consumer Product Safety Commission) |
| g | gram |
| g/cm³ | grams per cubic centimetre |
| GHS | Globally Harmonized System of Classification and Labelling of Chemicals (United Nations) |
| ha | hectare |
| hazard | inherent property of an agent or situation having the potential to cause adverse effects when an organism, system or (sub)population is exposed to that agent; intrinsic property of a substance to cause harm |
| HCIS | Hazardous Chemical Information System |
| IR | infrared |
| kg | kilogram |
| L | litre |
| LC50 | median lethal concentration |
| LD50 | median lethal dose |
| $m^2$ | square metre |
| $m^3$ | cubic metre |
| µg | microgram |
| mg | milligram |
| mg/kg bw | milligram per kilogram bodyweight |
| mL | millilitre |
| ML | megalitre |
| MSDS | (Material) Safety Data Sheet, also see SDS |
| MW | molecular weight |
| NAMW | number-average molecular weight |

| | |
|---|---|
| NICNAS | National Industrial Chemicals Notification and Assessment Scheme |
| NMR | nuclear magnetic resonance |
| NOEC | no observed effect concentration |
| NOEL | no observed effect level |
| OECD | Organisation for Economic Co-operation and Development |
| Pa | pascal |
| PCBU | person conducting a business or undertaking |
| PEC | predicted environmental concentration |
| PNEC | predicted no effect concentration |
| PPE | personal protective equipment |
| ppm | parts per million |
| risk | probability or likelihood of harm and the likely extent of the harm; the probability of an adverse effect in an organism, system or (sub)population caused under specified circumstances by exposure to an agent |
| RQ | risk quotient |
| SDS | Safety Data Sheet (also see MSDS) |
| STP | sewage treatment plant |
| SUSMP | Standard for the Uniform Scheduling of Medicines and Poisons |
| TG | test guideline |
| WAF | water accommodated fraction |
| WAMW | weight average molecular weight |
| w/w | weight to weight |

# 1. Introduction

## 1.1 Background

Polysiloxanes, di-Me, 3-[3-[(3-coco amidopropyl)dimethylammonio]-2-hydroxypropoxy] propyl group-terminated, acetates (salts), CAS RN 134737-05-6, is a siloxane polymer with a quaternary ammonium alkyl chain at each end of the polymer. It was notified by International Sales and Marketing Pty Ltd/Salkat Australia Pty Ltd and assessed by NICNAS as a new chemical under Section 32 of the *Industrial Chemicals (Notification and Assessment) Act 1989* (the Act) under the limited notification category. The new chemical assessment report NA/103 (NICNAS, 1993) was published in May 1993, and the notified polymer was listed on the AICS in May 1998.

No human health or environmental hazard classifications were made at the time of the new chemical assessment. In 2014, additional data on the polymer indicated that the short-chain form of the polymer (ABIL Quat 3270; NAMW ~1670) is a skin sensitiser and has environmental toxicity. It therefore warranted a secondary notification to review the hazard profile of the notified polymer and the related effect on the risks to human health and environment. This assessment focuses on the new data provided.

Data submitted for the original assessment on use, exposure and toxicity are summarised in this report in the relevant sections. Details of the studies provided for assessment as a new chemical are reproduced in Appendix A.2. New data submitted for this assessment are discussed in detail and identified by the abbreviation **ND**.

## 1.2 Declaration

A notice was published in the Chemical Gazette of July 2016, requiring a secondary notification of Polysiloxanes, di-Me, 3-[3-[(3-coco amidopropyl)dimethylammonio]-2-hydroxypropoxy]propyl group-terminated, acetates (salts), in accordance with Section 65(2) of the Act. The declaration required the provision of any information relevant to the assessment of the notified polymer not covered in the new chemical assessment. This included the following:

1) Identity, properties and uses:
    a. Trade name(s) under which the polymer is marketed by the introducer and the chain length associated with each trade name.
    b. Annual import volumes of the polymer, specifying the volumes under each trade name.
    c. Molecular weight information on the polymer for each trade name including:
        i. Number Average Molecular Weight (NAMW)
        ii. Weight Average Molecular Weight (WAMW)
        iii. % of Low MW Species < 1000 Da
        iv. % of Low MW Species < 500 Da.
    d. The concentration of the polymer in imported and end-use products.
    e. Proposed end-uses, and types of end-users (e.g. public, commercial, industry etc.), of products containing the polymer.

f. If used in industries other than cosmetics, please indicate the percentage of the product used:
    i. in industrial settings
    ii. in commercial settings (e.g. tradespeople, etc)
    iii. by Do-It-Yourself (DIY) users.
g. Any additional physico-chemical data that are available for the polymer.
h. Description of the reformulation/repacking process and disposal of wastes resulting from the process.
i. Description of end-uses and disposal of any wastes.
j. The percentage of total imported polymer that is expected to be released as:
    i. residues in empty containers
    ii. leaks and spills
    iii. washings from equipment used to reformulate and apply the products.
k. The expected fate for each of the above releases of the polymer (e.g. landfill, sewer etc.).

2) Human health and environmental data:
    a. Toxicity data for the sensitisation end point for the polymer, or a suitable analogue.
    b. Any additional toxicology data that are available for the polymer, or a suitable analogue.
    c. Full ecotoxicology study reports for fish, daphnia and algae toxicity for the polymer, or a suitable analogue.

## 1.3 Objectives

The objectives of this assessment are to review the new data made available since the publication of the new chemical assessment report and, where appropriate, to revise the original assessment to:

- characterise the human health hazards associated with the polymer
- characterise the environmental hazards associated with the polymer
- characterise the risks of adverse effects resulting from exposure to workers and the general public from the use of the polymer
- based on the above, make appropriate recommendations to control exposures and/or reduce potential health risks for workers and the general public, as required.

## 1.4 Peer review

During all stages of preparation, this report has been subject to internal peer review by NICNAS.

## 1.5 Applicants

Following the secondary notification declaration of the notified polymer, nine companies applied for assessment of this polymer. The original notifier, International Sales and Marketing Pty Ltd/Salkat Australia Pty Ltd, has stopped importing the polymer. Distribution of the notified polymer was transferred to Redox Pty Ltd.

In accordance with the Act, NICNAS provided the applicants with a draft copy of the report for comment during the corrections/variations phases of the assessment. The applicant details are as follows:

Avon Products Ltd
120 Old Pittwater Road
Brookvale, NSW 2100

Cosmetic Suppliers Pty Ltd
Level 3, 64-67 Foveaux Street
Surry Hills, NSW 2010

Dateline Imports Pty Ltd
Unit 8, Discovery Cove, 1801 Botany Road
Banksmeadow, NSW 2019

Estee Lauder Pty Ltd
165-175 Mitchell Road
Erskineville, NSW 2043

L'Oreal Australia Pty Ltd
564 St Kilda Road
Melbourne, VIC 3004

La Biosthetique Australia Pty Ltd
Unit 4, 5-15 Epson Road
Rosebery, NSW 2018

Miele Australia Pty Ltd
1 Gilbert Park Drive
Knoxfield, VIC 3180

Procter & Gamble Australia Pty Ltd
Level 4, 1 Innovation Road
Macquarie Park, NSW 2113

Redox Pty Ltd
2 Swettenham Road
Minto, NSW 2566

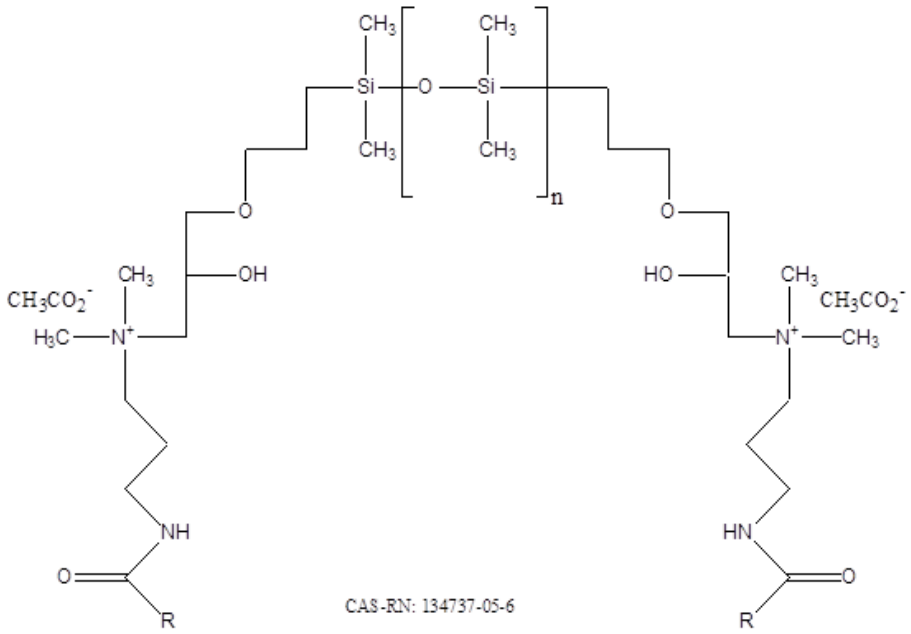
## 1.6 Exempt information

No details are claimed exempt information.

# 2. Chemical identity, physical and chemical properties

The chemical identity, physical and chemical data assessed by NICNAS in the new chemical assessment report (NICNAS, 1993) are reproduced in this report. New data submitted for this secondary notification assessment are indicated as **ND**.

## 2.1 Chemical identity

| | |
|---|---|
| **Chemical name:** | Polysiloxanes, di-Me, 3-[3-[(3-coco amidopropyl)dimethylammonio]-2-hydroxypropoxy]propyl group-terminated, acetates (salts) |
| **CAS number:** | 134737-05-6 |
| **Marketing names:** | ABIL Quat 3270, ABIL Quat 3272, ABIL Quat 3474, ABIL Quat 3676 |
| **Other names:** | Siloxanes and silicones, di Me, 3- [3-[(3-cocoaminopropyl) dimethyl- ammonio] 2-hydroxypropoxy] propyl group terminated, acetates (salts)<br>Quaternium 80 (**ND**) |
| **Molecular formula:** | Unspecified |
| **Structural formulae:** |  |

R = coco-alkyl ($CH_3(CH_2)_{5\text{-}15}CH_2$)

n = ~8-9 (ABIL Quat 3270)
~30 (ABIL Quat 3272)
80-90 (ABIL Quat 3474, ABIL Quat 3676) (**ND**)

The 4 reported grades, ABIL Quat 3270, ABIL Quat 3272, ABIL Quat 3474 and ABIL Quat 3676 are defined by a single CAS name and number. Each grade differs by the chain length of the notified polymer it contains and is identified by its NAMW (below) in this assessment report. The two highest NAMW grades (ABIL Quat 3437 and 3676) differ only by additive composition (Section 2.2).

**Molecular weight (MW):**

| | |
|---|---|
| Number-average molecular weight (NAMW) | ~1670 (ABIL Quat 3270)<br>~3200 (ABIL Quat 3272)<br>~7000 (ABIL Quat 3474, ABIL Quat 3676) (**ND**) |
| Weight-average molecular weight (WAMW) | ~11,900 (ABIL Quat 3272) (**ND**) |
| % of Low MW Species < 1000 | ~30-50% (estimated) (ABIL Quat 3270) (**ND**)<br>6.64% (ABIL Quat 3272) (**ND**) |
| % of Low MW Species < 500 | 3.33% (ABIL Quat 3272) (**ND**) |

**Polymer constituents:**

| *Chemical Name* | *CAS No.* | *Weight % starting** | *Weight % residual* |
|---|---|---|---|
| Siloxanes and Silicones, di-Me, 3-(2-oxiranylmethoxy) propyl group-terminated | 102782-97-8 | 57.9 | < 0.3 |
| Amides, coco, N-[3-(dimethylamino)propyl] | 68140-01-2 | 36.2 | < 0.3 |
| Acetic acid | 64-19-7 | 5.9 | < 0.3 |

*Starting weight % values of each constituent are for the grade ABIL Quat 3270. The starting weight % values were not submitted for ABIL Quat 3272, ABIL Quat 3474 and ABIL Quat 3676.

| | |
|---|---|
| **Method of detection of determination:** | Infra-red spectroscopy<br>$^{13}$C NMR spectroscopy<br>$^{1}$H NMR spectroscopy<br>Gas chromatography<br>Thermal gravimetric analysis |

| **Spectral data for ABIL Quat 3270:** | |
|---|---|
| IR | 3267, 2961, 2926, 2855, 1653, 1576, 1400, 1260, 1092, 1032, 802 $cm^{-1}$ |
| $^{13}$C NMR | -0.6, 0.3, 0.5, 13.4, 22.0, 22.2, 22.7, 24.0, 25.3, 28.6, 28.8, 28.9, 31.2, 35.4, 35.5, 44.6, 51.7, 62.8, 63.4, 72.2, 73.7, 76.7, 77.1, 77.5, 173.7, and 176.6 (TMS) ppm |
| $^{1}$H NMR | The peak positions were not easily estimated from the scale of the spectrum provided |

## 2.2 Composition

| | |
|---|---|
| **Degree of purity (of the notified polymer alone):** | >97% |
| **Toxic or hazardous impurities:** | none |
| **Non-hazardous impurity/impurities (≥1% by weight):** | none |
| **Maximum content of residual monomers/reactants:** | 0.3% |

**Additives:**

| *Grade* | *Chemical name* | *CAS number* | *Weight percentage* |
|---|---|---|---|
| ABIL Quat 3270<br>ABIL Quat 3272 | 1,2-propanediol | 57-55-6 | ~50% |
| ABIL Quat 3474 | 1,2-propanediol | 57-55-6 | ~2.5% |
| ABIL Quat 3676 | Dipropylene glycol | 25265-71-8 | ~20% |

## 2.3 Physical and chemical properties

The physical and chemical data of the notified polymer are shown in the table below.

**Summary of the notified polymer's physical and chemical properties**

| Property | Value/Result |
|---|---|
| **Appearance at 20°C and 101.3 kPa** | Highly viscous "liquid salt" (pure chemical); amber liquids (trade products). |
| **Melting/boiling point** | Methods to estimate melting and boiling point are inapplicable as the notified polymer is a highly viscous liquid. |
| **Density** | ~1014 kg/m$^3$ (ABIL Quat 3270); ~1008 kg/m$^3$ (ABIL Quat 3272); ~1000 kg/m$^3$ (ABIL Quat 3474); ~986 kg/m$^3$ (ABIL Quat 3676) |
| **Vapour pressure** | 0.07 mmHg @ 20°C (product) |
| **Water solubility** | ABIL Quat 3270 is soluble in water; solubility decreasing with increasing degree of polymerisation of the dimethylpolysiloxane moiety g/L at 20°C.<br>ABIL Quat 3474 and ABIL Quat 3676 are insoluble in water. |
| **Hydrolysis as a function of pH** | No hydrolysis expected at pH 4-9<br>At pH <2 and >11, and at >90°C, cleavage of Si-O-Si bonds of dimethylpolysiloxane is expected. |
| **Partition coefficient (n-octanol/water)** | The notified polymer is expected to accumulate at the phase boundaries based on its surface activity. |
| **Surface tension** | ~31.5 g/cm$^3$ (ABIL Quat 3270); ~44 g/cm$^3$ (ABIL Quat 3272)<br>Cannot be measured for ABIL Quat 3474 and ABIL Quat 3676 as they are insoluble in water. |

| | |
|---|---|
| **Dissociation constant** | Expected to dissociate completely. |
| **Flash point** | 87 °C (ABIL Quat 3270); 93 °C (ABIL Quat 3272); >100 °C (ABIL Quat 3474, ABIL Quat 3676) |
| **Flammability** | Not measured. |
| **Autoignition temperature** | Not measured. |
| **Explosive properties** | Not measured. |
| **Oxidising products** | At high temperatures the trade products oxidise giving rise to propionaldehyde, lactic acid, pyruvic acid and acetic acid. |
| **Reactivity/Stability** | There is no specific reactivity. |

# 3. Importation and use

## Importation

The notified polymer is not manufactured in Australia, and will continue to be imported in products containing 50% of the polymer for reformulation and in finished products. Whereas the polymer was originally notified for the new chemical assessment in 1993 as being imported in two grades, ABIL Quat 3270 and ABIL Quat 3272, currently the polymer is reported as being imported in the two grades, ABIL Quat 3272 and ABIL Quat 3474. In addition, information submitted indicates that ABIL Quat 3676 (NAMW ~7000), another polymer grade, is expected to replace ABIL Quat 3474 in the near future but is currently not imported into Australia.

No applicants for this secondary notification assessment have indicated importation of the shortest polymer length, ABIL Quat 3270 (50% notified polymer in propylene glycol). The formulation ABIL Quat 3270 is no longer manufactured by Evonik Germany and sales have stopped since January 2016. Therefore, importation of the polymer has shifted to grades containing longer average chain lengths since the original assessment as a new chemical.

The maximum import volume of the polymer is up to 4.667 tonnes per annum, compared to an initial annual introduction of 2 tonnes as originally assessed. Most of the import volume (up to 4 tonnes) is of ABIL Quat 3272 (50% notified polymer in propylene glycol) for reformulation. The remaining volume is of ABIL Quat 3272 or ABIL Quat 3474 as a component of finished products.

## Existing use

The polymer in grades ABIL Quat 3272 and ABIL Quat 3474 is used as a conditioning agent in leave-on and rinse-off hair care products at a concentration of up to 2.5%.

## New use

The new chemical assessment (NICNAS, 1993) also identified that the polymer may be an ingredient (final concentration up to 2%) for:

- fabric softeners
- corrosion inhibitors
- antistatic additives for plastics
- pigment dispersants
- fibre lubricants.

For the secondary notification assessment, the polymer in grade ABIL Quat 3272 will be used as a component of fabric softeners for domestic washing machines at a concentration of up to 5%.

# 4. Exposure

No significant change in the use of the notified polymer or in operational procedures for handling and formulation were notified for the secondary notification assessment. Therefore, the public and occupational exposure sections have been reproduced from the new chemical assessment report (NICNAS, 1993), with further discussion where relevant.

## 4.1 Occupational exposure

### 4.1.1 Operational description

The polymer is imported in 50 kg drums in the formulation ABIL Quat 3272. These drums are transported by road to reformulation sites. Workers at these sites weigh and add ABIL Quat 3272 from the drum through a hatch at the top of the mixing tank to produce shampoo or conditioner formulations (up to 2.5% notified polymer). They then pack final products for shipment to end users (wholesalers, hair salons).

### 4.1.2 Estimates of occupational exposure

The new chemical assessment (NICNAS, 1993) identified multiple reformulation sites, which may differ to current sites. Worker exposure and the time spent on each task vary at each site, making it difficult to measure exposure accurately.

Special guidelines and precautions are used during manufacture of formulated products, such as use of enclosed systems when splashing or spillage is anticipated and the use of appropriate PPE (long trousers, enclosed shoes, gloves and safety glasses). The number of workers handling the polymer is not anticipated to be large, and worker contact with the notified polymer is expected to be low under normal use situations.

Professional hair salon workers may also be exposed to the polymer; however, the concentration of the notified polymer in these workplaces is at $\leq$ 2.5%.

## 4.2 Public exposure

There will be widespread and repeated exposure of the public to the polymer (at $\leq$ 2.5% concentration) through the use of hair care products.

Dermal and accidental ocular exposure of consumers may occur during application of shampoo products to the scalp and hair using the hands, and to other parts of the body during rinsing off of the product. A small quantity of the notified polymer may be retained on the scalp after rinsing.

Accidental short term exposures of the public via the dermal route may also occur from use in fabric softeners for domestic washing machines (at $\leq$ 5% concentration).

## 4.3 Environmental exposure

### 4.3.1 Releases

*Release of chemical at site*

The polymer is not manufactured in Australia and, therefore, no release to the environment is expected from this activity. Reformulation of the polymer to finished products is undertaken

by professional operators following standard procedures. No changes in the reformulation processes and disposal of wastes were notified for the secondary notification assessment.

In the new chemical assessment (NICNAS, 1993), the notifier, International Sales and Marketing Pty Ltd/Salkat Australia Pty Ltd, stated that one of its customers reformulating the polymer follows procedures aimed at reducing the level of waste in all areas of operations. The company's factory was reported to be equipped with a modern waste water treatment plant (dissolved air flotation with chemical pretreatment and biological oxidation). Discharge from the plant to sewer is monitored on a regular basis by the company, following the local regulator's requirements in regard to the company's discharge specifications. The procedures discussed in the new chemical assessment for reducing waste still apply to current operations and are relevant to this secondary notification assessment. It is estimated by the notifier in the original new chemical assessment that up to 1% of the total import volume of the polymer (< 40 kg) is likely to be released to sewer as shampoo wastes at reformulating sites.

Release of the polymer to the environment from transport and storage is unlikely, except in the case of accidental spills and leaks. In the event of spills, the polymer is expected to be collected with adsorbents and be disposed of to landfill in accordance with local government regulations.

*Release of chemical from use*

The polymer is used in leave-on or rinse off hair care products or in laundry products. Most of the notified polymer is expected to be released to sewer at the end of its useful life.

*Release of chemical from disposal*

It is expected that some of the products containing the polymer will remain in end-use containers. These containers are expected to be disposed of through domestic garbage disposal and will enter landfill or be recycled. The residues of the polymer remaining in the empty containers are expected to be rinsed with water and to enter the sewer system when these containers are sent for recycling.

### 4.3.2 Environmental fate

Biodegradability studies were not provided for the polymer assessed as a new chemical in 1993 or in this secondary notification assessment. Polydimethylsiloxanes are considered unstable in terrestrial environments, where clays can catalyse cleavage of the siloxane linkage. However, they are probably more permanent in aquatic sediment as the catalytic action of clays is inversely related to their degree of hydration (Hamelink, 1992). The polymer also contains two amide linkages that may be susceptible to hydrolysis, particularly through clay-mediated catalysis in a terrestrial environment. However, hydrolysis of the notified substance is unlikely under typical environmental conditions due to its hydrolytic stability and expected adsorption to surfaces.

Following its use, the majority of the polymer is expected to enter sewer systems before potential release to surface waters on a nationwide basis. Based on its surface activity and cationic properties, most of the polymer is expected to adsorb to suspended matter or sludge at wastewater treatment plants when it enters sewer systems. Any polymer that remains in treated wastewater and then enters receiving waters is likely to photodegrade to silicates (Anderson et al, 1987). Sludge containing the polymer may be applied to agricultural soils or be disposed of to landfill as waste. In soil or land, the polymer is not expected to be mobile based on its cationic properties and surface activity.

The polymer is not expected to have high potential to bioaccumulate based on its large molecular weight and surface activity. In the aquatic and soil compartments, the polymer is expected to degrade through biotic and abiotic processes to form water and oxides of carbon, nitrogen and silicon.

### 4.3.3 Predicted environmental concentration (PEC)

The calculation for the Predicted Environmental Concentration (PEC) is summarised in the following table. It is assumed that 100% of the total import volume of the polymer is released to the sewer based on its use in cosmetic and laundry products. The release is assumed to be nationwide over 365 days per year, i.e. any polymer expected to be released at site following reformulation activities is accounted for by assuming it is released at end use. This is appropriate given the small amount expected to be released at site and such release will be to sewer. The notified polymer is a cationic polymer with NAMW > 1000 Da. Therefore, more than 90% of the polymer is expected to be removed from the sewage influent during sewage treatment processes by partitioning to sludge or sediment (Boethling and Nabholz, 1997).

| Predicted Environmental Concentration (PEC) for the Aquatic Compartment | | |
|---|---|---|
| Total Annual Import/Manufactured Volume | 4,667 | kg/year |
| Proportion expected to be released to sewer | 100% | |
| Annual quantity of chemical released to sewer | 4,667 | kg/year |
| Days per year where release occurs | 365 | days/year |
| Daily chemical release: | 12.79 | kg/day |
| Water use | 200.0 | L/person/day |
| Population of Australia (Millions) | 22.613 | million |
| Removal within STP | 90% | |
| Daily effluent production: | 4,523 | ML |
| Dilution Factor - River | 1.0 | |
| Dilution Factor - Ocean | 10.0 | |
| PEC - River: | 0.28 | µg/L |
| PEC - Ocean: | 0.028 | µg/L |

STP effluent re-use for irrigation occurs throughout Australia. The agricultural irrigation application rate is assumed to be 1000 L/m$^2$/year (10 ML/ha/year). The polymer in this volume is assumed to infiltrate and accumulate in the top 10 cm of soil (density 1500 kg/m$^3$). Using these assumptions, irrigation with a concentration of 0.283µg/L for one year may potentially result in a soil concentration of approximately 1.88 µg/kg. Assuming accumulation of the polymer in soil for 5 and 10 years under repeated irrigation, the concentration of the polymer in the applied soil in 5 and 10 years may be approximately 9.42 µg/kg and 18.85 µg/kg, respectively.

# 5. Hazard assessment

## 5.1 Physico-chemical and human health hazard assessment

This section contains a summary of all the data relevant to the physico-chemical and human health hazard assessment of the notified polymer, with a focus on new data. The robust summaries of the toxicological data available for the assessment of the polymer as a new chemical are reproduced from the new chemical assessment report (NICNAS, 1993) in Appendix A.2 of this report. The robust summaries of the new human health studies on the polymer submitted for the secondary notification assessment are analysed in this section and designated as **ND**. The robust summaries of the new studies are provided in Appendix A.1 of this report.

### 5.1.1 Physico-chemical effects assessment

No new physico-chemical data were submitted for the secondary notification assessment.

### 5.1.2 Human health effects assessment

**Summary of toxicity data**

| Endpoint | New chemical assessment (NICNAS, 1993) | Secondary notification assessment (ND) |
|---|---|---|
| **ABIL Quat 3270** | | |
| Rat, acute oral | LD50 > 5091 mg/kg bw | LD50 > 5000 mg/kg bw |
| Rabbit, skin irritation | Non-irritating | Slightly irritating |
| Rabbit, eye irritation | Slightly irritating | Not provided |
| Guinea pig, skin sensitisation (GPMT) | Not provided | Sensitising |
| Genotoxicity – bacterial reverse mutation | Not provided | Non-mutagenic |
| **ABIL Quat 3272** | | |
| Rat, acute oral | Not provided | LD50 > 5000 mg/kg bw |
| Rabbit, skin irritation | Not provided | Slightly irritating |
| Rabbit, eye irritation | Not provided | Slightly irritating |
| Guinea pig, skin sensitisation (Buehler) | Not provided | No evidence of sensitisation (at 5% induction concentration) |
| Genotoxicity – bacterial reverse mutation | Not provided | Non-mutagenic |
| **ABIL Quat 3474** | | |
| Rat, acute oral | Not provided | LD50 > 5000 mg/kg bw |
| Rabbit, skin irritation | Not provided | Slightly irritating |
| Rabbit, eye irritation | Not provided | Slightly irritating |

*Acute toxicity*

Acute oral toxicity studies using ABIL Quat 3270 (Product Safety Labs, 1987a; **ND**), ABIL Quat 3272 (Product Safety Labs, 1987b; **ND**) and ABIL Quat 3474 (Product Safety Labs, 1995; **ND**) were submitted for the secondary notification assessment. The studies concluded that the polymer was of low acute oral toxicity (LD50 > 5000 mg/kg bw). The data provided for the new chemical assessment (NICNAS, 1993) also confirmed that the polymer was of low toxicity via the oral route.

No data are available to assess the acute dermal or inhalation hazard of the polymer. However, as it is a high molecular weight polymer, dermal absorption is anticipated to be low. Therefore, dermal toxicity is expected to be low. Given the low volatility of the notified polymer and that it is not introduced in solid form, it is also not expected to pose a significant inhalation hazard.

*Irritation*

The new chemical assessment (NICNAS, 1993) considered a skin irritation study using ABIL Quat 3270 and concluded the polymer was not an irritant. However, new skin irritation studies using ABIL Quat 3270 (Product Safety Labs, 1988a; **ND**), ABIL Quat 3272 (Product Safety Labs, 1988b; **ND**) and ABIL Quat 3474 (Product Safety Labs, 1995b; **ND**) submitted for the secondary notification assessment concluded that the polymer is slightly irritating to skin. It is noted that, in the submitted studies, the test animals were exposed to the test substance for a 24 hour period rather than the 4 hours recommended under current OECD test guidelines (OECD TG 404). Additionally, the three submitted studies did not measure skin irritation in the test animals for longer than 72 hours, and irritant effects (erythema and oedema) were still present at this time. Therefore, these studies could not be used to determine the reversibility of the irritant effects seen. Based on the studies provided, it is considered that the polymer has the potential to be slightly irritating to skin.

The new chemical assessment (NICNAS, 1993) considered eye irritation studies using ABIL Quat 3270. No corneal opacity or iritis were observed during the test period, while all treated eyes exhibited slight to mild conjunctival irritation under test conditions. However, the scores were not high enough to classify the test substance as an irritant. Similar findings were reported in the eye irritation studies using ABIL Quat 3272 (Product Safety Labs, 1988c; **ND**) and ABIL Quat 3474 (Product Safety Labs, 1995c; **ND**) submitted for the secondary notification assessment. The studies concluded that the polymer is slightly irritating to eyes but is not classified as an eye irritant.

*Sensitisation*

Data for skin sensitisation were not available at the time of the new chemical assessment and the endpoint was not evaluated. Skin sensitisation studies using ABIL Quat 3270 (MK, 1996; **ND**) and ABIL Quat 3272 (Product Safety Labs, 1992; **ND**) were submitted for the secondary notification assessment.

In a guinea pig maximisation test with ABIL Quat 3270, erythma and/or oedema were observed in 65% of the animals after 48 h following induction exposure (0.5% (intradermal) and 10% (dermal) concentration) and challenge exposure (1% (dermal) concentration). Thus, ABIL Quat 3270 is a strong skin sensitiser under the test conditions.

The potential skin sensitising properties of ABIL Quat 3272 were assessed in a Buehler study, and it was not considered to be a skin sensitiser under the test conditions. It is noted that this study was not performed under current OECD TG 406. For induction, the highest dose that causes mild irritation was not identified since the study used a test sample with a maximum concentration of 5% ABIL Quat 3272. Only one animal exhibited very slight erythema after initial topical exposure to 5% ABIL Quat 3272, and no further irritation was noted following

subsequent induction and challenge by topical exposure to 5% ABIL Quat 3272. Mild irritation was noted in a skin irritation study of ABIL Quat 3272 using 10% concentration (see Appendix A.1.5). However, this concentration was not used in the sensitisation study. While the study concluded that ABIL Quat 3272 is not sensitising at ≤5% concentration, the potential skin sensitising properties of ABIL Quat 3272 following exposure to optimal doses for induction (>5% concentration) is unknown. No sensitisation data are available for the longer chain length ABIL Quat 3474.

The polymer contains quaternary ammonium groups, which is a structural alert for skin sensitisation (Barrett et al., 1994). Therefore, the possibility of sensitisation effects cannot be ruled out for the grades ABIL Quat 3272 and ABIL Quat 3474 despite its longer polymer chain length compared to ABIL Quat 3270. However, with the quaternary ammonium groups situated at each end of the polymer, a longer neutral polymer backbone will result in a lower charge density and, thus, impart lower toxicity. Having a low charge density is one characteristic that defines a polymer of low concern (Section 5 of the Act), and is therefore a factor that implies a polymer is unlikely to be hazardous. To establish a cut-off, it must be noted that according to Regulation 4C(c) of the Act, a polymer is considered for regulatory purposes to have a low charge density if the total combined functional group equivalent weight (FGEW) of any cationic group is at least 5,000. The FGEW of a polymer is defined as the ratio of the NAMW to the number of functional groups in the polymer. Hence, with the polymer containing 2 cationic quaternary ammonium groups, it may be regarded as a low charge density polymer if the NAMW ≥ 10,000, and so would be unlikely to be a skin sensitiser. All reported polymer grades in this secondary notification assessment have NAMW less than 10,000 and, thus, are likely to be skin sensitisers.

Furthermore, the sensitising properties of ABIL Quat 3270 may also be due to the presence of low MW species (<1000 Da), estimated to be 30-50% of the trade product. Considering that ABIL Quat 3272 was reported to contain 6.64% of low MW species <1000 Da and 3.33% of low MW species <500 Da, the skin sensitisation potential of ABIL Quat 3272 cannot be ruled out but it may be less than that of ABIL Quat 3270. No data on low MW species are available for the longer chain length ABIL Quat 3474.

Based on the skin sensitisation data for the shortest chain polymer grade, ABIL Quat 3270, and the presence of high concern quaternary ammonium groups in all polymer grades, it is conservatively concluded that all grades of the polymer with NAMW < 10,000 are, or are likely to be, skin sensitisers if present at a high enough concentration.

*Repeated dose toxicity*

There are no available repeated dose toxicity data on the polymer. However, due to the high molecular weight of the polymer, it is unlikely to cross biological membranes and cause systemic effects.

*Genotoxicity*

Data for genotoxicity were not available at the time of the new chemical assessment and so this endpoint was not evaluated.

Genotoxicity studies using ABIL Quat 3270 (Labor L+S AG, 1996; **ND**) and ABIL Quat 3272 (SITEK Research Laboratories, 1995; **ND**) were submitted for the secondary notification assessment. The studies found that ABIL Quat 3270 and ABIL Quat 3272 were not mutagenic to bacteria under the test conditions.

### 5.1.3 Hazard classification

Based on the available information, the polymer is recommended for hazard classification according to the GHS (United Nations, 2009), as adopted for industrial chemicals in Australia.

The recommended hazard classification is presented in the following table.

| Hazard classification | Hazard statement |
|---|---|
| Skin Sensitisation (Category 1A) | H317 - May cause an allergic skin reaction |

It is recommended that this entry be accompanied by a note that the classification only applies to polymer grades with NAMW < 10,000.

## 5.2 Environmental hazard assessment

This section contains a short summary of the new data submitted for secondary notification assessment of the polymer. Ecotoxicological data were not available at the time of the new chemical assessment.

### 5.2.1 Environmental effects assessment

Ecotoxicological data were not available at the time of the new chemical assessment. The new ecotoxicological studies on ABIL Quat 3272 and ABIL Quat 3474, and the summary data for ABIL Quat 3270 submitted for the secondary notification assessment are summarised in the table below and designated as **ND**. The robust summaries of the new studies are provided in Appendix B of this report.

**Summary of ecotoxicity data**

| Endpoint | New data **(ND)** | Assessment Conclusion |
|---|---|---|
| **ABIL Quat 3270*** | | |
| Fish toxicity | 96 h LC50 = 0.65 mg/L | Very toxic to fish |
| Daphnia toxicity | 48 h LC50 = 0.16 mg/L | Very toxic to aquatic invertebrates |
| Algal toxicity | EC50 = 32 mg/L | Harmful to algae |
| **ABIL Quat 3272** | | |
| Algal toxicity | 72 h EC10 = 0.29 mg/L | Very toxic to algae |
| | 72 h EC50 = 0.49 mg/L | Very toxic to algae |
| **ABIL Quat 3474** | | |
| Fish toxicity | 96 h LC50 = 30.8 mg/L | Harmful to fish |
| Daphnia toxicity | **48 h EC50 = 248.3 mg/L (WAF***) | Harmful to aquatic invertebrates |
| Algal toxicity | 72 h EL10 = 2.2 mg/L (WAF) | Toxic to algae |
| | 72 h EL50 = 7.2 mg/L (WAF) | Toxic to algae |
| Algal toxicity | 72 h EC10 = 7.3 mg/L (WAF) | Toxic to algae |
| | 72 h EC50 = 17.2 mg/L (WAF) | Harmful to algae |

* Only a summary of the ecotoxicity data was submitted for the secondary notification assessment.
** The endpoint 48h EC50 = 248.3 mg/L reported in the original study report is not considered to be reliable as it did not match the raw data (See Appendix B.2).
*** WAF: Water Accommodated Fraction

Based on the acute ecotoxicological endpoints for ABIL Quat 3270, the most toxic grade of the polymer, it is conservatively concluded that the notified polymer is very toxic to aquatic

life. A biodegradability study for the polymer is not available. Thus, based on its acute ecotoxicity and unknown biodegradability, the notified polymer is considered very toxic to aquatic life with long lasting effects.

The established cut-off, where the polymer may be regarded as a low charge density polymer (a characteristic that defines a polymer of low concern) if the NAMW ≥ 10,000 (see section 5.1.2), can also be applied to aquatic toxicity. Hence, polymer grades with NAMW ≥ 10,000 are unlikely to be hazardous to aquatic life.

### 5.2.2 Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) has been calculated from the acute ecotoxicological endpoint data available for ABIL Quat 3270 (summary data) for the most sensitive aquatic species, daphnia, and an assessment factor of 100. The assessment factor 100 is applied as the measured acute endpoints are available for aquatic species across three trophic levels.

| **PNEC for the Aquatic Compartment** | | |
|---|---|---|
| EL50 (daphnia , 48 h) | 0.16 | mg/L |
| Assessment Factor | 100 | |
| PNEC: | 1.6 | µg/L |

### 5.2.3 Hazard classification

The environmental hazard classification according to the GHS (United Nations, 2009) is presented in the following table. This classification differs from the conclusion in the new chemical assessment (NICNAS, 1993) where no ecotoxicity data for the polymer were available. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

| **Hazard classification** | **Hazard statement** |
|---|---|
| Acute (Category 1) | H400 – Very toxic to aquatic life |
| Chronic (Category 1) | H410 – Very toxic to aquatic life with long lasting effects |

It is recommended that these entries be accompanied by a note that the classification only applies to polymer grades with NAMW < 10,000.

# 6. Risk characterisation

## 6.1 Occupational health risk characterisation

*Reformulation*

The notified polymer is a charged polymer with high molecular weight (>1000 Da). It is, therefore, not likely to cross biological membranes and cause any systemic effects. The trade products containing the polymer are stable at ambient temperature, and have no known explosive or reactivity properties.

Dermal and ocular exposure of workers to the polymer at concentrations of up to 50% may occur during handling of the products containing it. At such high concentrations, there may be an unacceptable risk of skin irritation, eye irritation and skin sensitisation for workers involved in these operations. However, provided that control measures are in place to minimise worker exposure to the polymer, including the use of enclosed systems and PPE, the risk to the health of workers from the use of the polymer is not considered to be unreasonable.

*End-use*

The polymer is used in consumer products such as shampoos and conditioners that are also available for professional use. Hairdressers applying products containing 2.5% of the polymer to clients will be exposed to it. The risk to these workers is expected to be similar to the risk to consumers using products containing the polymer (for details of the public health risk assessment, see Section 6.2).

## 6.2 Public health risk characterisation

As the polymer is used in consumer products such as shampoos and conditioners, there is likely to be widespread public exposure. Inadvertent exposures may also occur from use in fabric softeners. The principal route of exposure will be dermal with some potential for accidental ocular exposure.

While the polymer has the potential to cause sensitisation and irritation, such effects are expected to be concentration-dependent and unlikely at the proposed use concentrations (up to 5%) for ABIL Quat 3272 and 3474. Therefore, the risk of skin irritation, eye irritation or skin sensitisation in consumers with use of products containing ABIL Quat 3272 and ABIL Quat 3474 at proposed use concentrations (up to 5%) is expected to be low.

There are no specific restrictions for the use of the polymer in cosmetic products internationally. In Australia, however, restrictions are in place for consumer products containing the polymer. The polymer is covered by the entry for 'Quaternary ammonium compounds' listed in the Poisons Standard (SUSMP, 2017). Quaternary ammonium compounds are listed in Schedules 5 and 6 requiring substances to be labelled with the signal word "Caution" for ≤ 20% concentration or "Poison" for concentration greater than 20%, respectively. Preparations containing ≤ 5% concentration of quaternary ammonium compounds do not require labelling.

As a component of hair care products, there is repeated dermal contact with the polymer. However, due to the high molecular weight of the polymer, dermal absorption is anticipated to be low. No toxicological data for repeated exposure to the polymer are available. Nonetheless, based on the expected low absorption of the polymer and that systemic effects are therefore unlikely, the risk to the public from repeated exposure would not be considered unreasonable.

## 6.3 Environmental risk characterisation

| Risk Assessment | PEC µg/L | PNEC µg/L | PEC/PNEC |
|---|---|---|---|
| River: | 0.28 | 1.6 | 0.18 |
| Ocean: | 0.028 | 1.6 | 0.018 |

The risk quotient (RQ = PEC/PNEC) is calculated based on its maximum use volume and assessed use pattern, indicating that the polymer is unlikely to reach ecotoxicologically significant concentrations in surface waters. On the basis of the RQ ratio, maximum annual importation volume and assessed use pattern in cosmetic formulations and household products, the polymer is not expected to pose an unreasonable risk to the environment.

# Appendix A: Toxicological Investigations

## A.1 Secondary notification assessment

The robust summaries of the toxicological studies analysed for the secondary notification assessment of the notified polymer are presented here.

### A.1.1 Acute toxicity – oral

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3270 |
| METHOD | Similar to OECD TG 401 Acute Oral Toxicity – Limited Test |
| Species/Strain | Rat/Wistar albino |
| Vehicle | None |
| Remarks – Method | No significant protocol deviations |

RESULTS

| Group | *Number and sex of animals* | *Dose (mg/kg bw)* | *Mortality* |
|---|---|---|---|
| 1 | 5 males, 5 females | 5000 | 0 |

| | |
|---|---|
| LD50 | >5000 mg/kg bw |
| Remarks – Signs of toxicity | One animal had a swollen left eye on days 4 and 5. |
| CONCLUSION | ABIL Quat 3270 is of low toxicity via the oral route. |
| TEST FACILITY | Product Safety Labs (1987a) |

### A.1.2 Acute toxicity – oral

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3272 |
| METHOD | Similar to OECD TG 401 Acute Oral Toxicity – Limited Test |
| Species/Strain | Rat/Wistar albino |
| Vehicle | None |
| Remarks – Method | No significant protocol deviations |

RESULTS

| Group | *Number and sex of animals* | *Dose (mg/kg bw)* | *Mortality* |
|---|---|---|---|
| 1 | 5 males, 5 females | 5000 | 0 |

| | |
|---|---|
| LD50 | >5000 mg/kg bw |
| Remarks – Signs of toxicity | None |
| CONCLUSION | ABIL Quat 3272 is of low toxicity via the oral route |
| TEST FACILITY | Product Safety Labs (1987b) |

### A.1.3 Acute toxicity – oral

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3474 |
| METHOD | Similar to OECD TG 401 Acute Oral Toxicity – Limited Test |
| Species/Strain | Rat/Sprague Dawley (albino) |
| Vehicle | None |
| Remarks – Method | No significant protocol deviations |

RESULTS

| Group | *Number and sex of animals* | *Dose (mg/kg bw)* | *Mortality* |
|---|---|---|---|
| 1 | 5 males, 5 females | 5000 | 0 |

| | |
|---|---|
| LD50 | >5000 mg/kg bw |
| Remarks – Signs of toxicity | None |
| CONCLUSION | ABIL Quat 3272 is of low toxicity via the oral route |
| TEST FACILITY | Product Safety Labs (1995a) |

### A.1.4 Irritation – skin

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3270 |
| METHOD | Primary Dermal Irritation Test<br>US Federal Guidelines 16 CFR 1500.41 PSL Protocol 002/P201 |
| Species/Strain | Rabbit/New Zealand White (albino) |
| Number of animals | 6 males |
| Vehicle | Distilled water |
| Observation period | 3 days |
| Type of dressing | Semi-occlusive |
| Remarks – Method | Abraded skin and intact skin sites on each animal were tested with the test substance as a 10% w/w solution for a 24 hour exposure period. Observations were recorded at 24 and 72 hours after patch removal only. The FHSA Primary Skin Irritation Scoring system was used to grade the skin reaction observations. Original data tables were not provided. |

RESULTS

| | |
|---|---|
| Remarks – Results | At 24 hour post-dosing, moderate to well-defined erythema was observed at all abraded and intact sites. Oedema ranging from very slight to slight was observed at all but one abraded site and at all intact sites. By 72 hours, erythema in four rabbits increased from well-defined to severe. Thickening of the skin was noted at all sites. The remaining two rabbits had eschar at the abraded site, with erythema being stable at the intact sites. Oedema cleared in one rabbit and remained stable |

| | |
|---|---|
| | or decreased slightly in the other five. |
| CONCLUSION | ABIL Quat 3270 is slightly irritating to the skin under the conditions of the test |
| TEST FACILITY | Product Safety Labs (1988a) |

### A.1.5 Irritation – skin

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3272 |
| METHOD | Primary Dermal Irritation Test |
| | US Federal Guidelines 16 CFR 1500.41 PSL Protocol 002/P201 |
| Species/Strain | Rabbit/New Zealand White (albino) |
| Number of animals | 6 males |
| Vehicle | Distilled water |
| Observation period | 3 days |
| Type of dressing | Occlusive |
| Remarks – Method | Abraded skin and intact skin sites in each animal were tested with the test substance as a 10% w/w solution for a 24 hour exposure period. Observations were recorded at 24 and 72 hours after patch removal only. The FHSA Primary Skin Irritation Scoring system was used to grade the skin reaction observations. |

RESULTS

| *Lesion* | *Mean Score** | | *Maximum Duration of Any Effect* |
|---|---|---|---|
| | *24 h* | *72 h* | |
| **Intact sites** | | | |
| Erythema/Eschar | 1.33 | 0.33 | > 72 hours |
| Oedema | 0 | 0 | - |
| **Abraded sites** | | | |
| Erythema/Eschar | 1.5 | 0.67 | > 72 hours |
| Oedema | 0 | 0 | - |

*Calculated on the basis of the scores at 24 and 72 hours for ALL animals.

| | |
|---|---|
| Remarks – Results | At 24 hour post-dosing, very slight to well-defined erythema was observed at all abraded and intact sites. By 72 hours, erythema decreased on 3 rabbits and 3 rabbits had no erythema. In the remaining animal the effects were essentially the same as at 24 hours except for blanching noted in the abrasions. No oedema was present in any of the animals. |
| CONCLUSION | ABIL Quat 3272 is slightly irritating to the skin under the conditions of the test. |
| TEST FACILITY | Product Safety Labs (1988b) |

### A.1.6 Irritation – skin

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3474 |
| METHOD | Primary Dermal Irritation Test |
| | US Federal Guidelines 16 CFR 1500.41 PSL Protocol 002/P201 |
| Species/Strain | Rabbit/New Zealand White (albino) |
| Number of animals | 3 males, 3 females |
| Vehicle | Distilled water |
| Observation period | 3 days |
| Type of dressing | Occlusive |
| Remarks - Method | Abraded and intact skin sites in each animal were tested with the test substance as a 10% w/w solution for a 24 hour exposure period. Observations were recorded at 25 and 72 hours after patch removal only. The FHSA Primary Skin Irritation Scoring system was used to grade the skin reaction observations. |

RESULTS

| *Lesion* | *Mean Score** | | *Maximum Value*** | *Maximum Duration of Any Effect* | *Maximum Value at End of Observation Period* |
|---|---|---|---|---|---|
| | *25 h* | *72 h* | | | |
| **Intact sites** | | | | | |
| Erythema/Eschar | 2.2 | 2.3 | 3 | > 72 hours | 3 |
| Oedema | 2.2 | 1.8 | 3 | > 72 hours | 3 |
| **Abraded sites** | | | | | |
| Erythema/Eschar | 2.2 | 2.5 | 3 | > 72 hours | 3 |
| Oedema | 1.8 | 2.2 | 3 | > 72 hours | 3 |

*Calculated on the basis of the scores at 25 and 72 hours for ALL animals.
** Observations recorded at 25 and 72 hours only

| | |
|---|---|
| Remarks – Results | At 25 hour post-dosing, very slight to moderate erythema and oedema were observed at all abraded and intact sites. Irritation persisted at all sites through 72 hours. |
| CONCLUSION | ABIL Quat 3474 is slightly irritating to the skin under the conditions of the test. |
| TEST FACILITY | Product Safety Labs (1995b) |

### A.1.7 Irritation – eye

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3272 |
| METHOD | Primary Eye Irritation |
| | US Federal Guidelines 16 CFR 1500.42 PSL Protocol 003/P202 |
| Species/Strain | Rabbit/New Zealand White (albino) |
| Number of animals | 4 males, 2 females |

| | |
|---|---|
| Vehicle | Distilled water |
| Observation period | 72 hours |
| Remarks – Method | 0.1 mL of test substance was instilled as a 10% w/w solution into the right eyes of the test animals. The eyes of 3 animals were irrigated. Observations were taken at 24, 48 and 72 hours post-dosing. The Draize Scoring system was used to grade the eye reaction observations. |

RESULTS

| *Lesion* | *Mean score* Animal No.* | | | | | | *Maximum value* | *Maximum duration of any effect* | *Maximum value at end of observation period* |
|---|---|---|---|---|---|---|---|---|---|
| | *Unwashed* | | | *Washed* | | | | | |
| | *1* | *2* | *3* | *4* | *5* | *6* | | | |
| Conjunctiva: redness | 1.7 | 1.3 | 1 | 1 | 0.3 | 1 | 2 | 72 hours | 1 |
| Conjunctiva: chemosis | 0.7 | 0.7 | 0.7 | 0.3 | 0.3 | 0.3 | 2 | 48 hours | 0 |
| Corneal opacity | 0 | 0 | 0 | 0 | 0 | 0 | 0 | N/A | 0 |
| Iridial inflammation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | N/A | 0 |

*Calculated on the basis of the scores at 24, 48, and 72 hours for each animal.

| | |
|---|---|
| Remarks – Results | No corneal opacity or iridial damage was observed in any treated unwashed or washed eye during the test period. At 24 hours after dosing, all treated eyes, unwashed and washed, exhibited slight to mild hyperaemia, chemosis and/or ocular discharge. At 48 hours, all unwashed eyes still exhibited slight conjunctival irritation while 1 of 3 washed eyes was free of all irritation. By 72 hours, all remaining unwashed and washed eyes were free of all irritation. |
| CONCLUSION | ABIL Quat 3272 is slightly irritating to the eye under the conditions of the test. |
| TEST FACILITY | Product Safety Labs (1988c) |

### A.1.8 Irritation – eye

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3474 |
| METHOD | Primary Eye Irritation<br>US Federal Guidelines 16 CFR 1500.42 PSL Protocol 003/P202 |
| Species/Strain | Rabbit/New Zealand White (albino) |
| Number of animals | 3 males, 3 females |
| Vehicle | Distilled water |

| | |
|---|---|
| Observation period | 72 hours |
| Remarks – Method | 0.1 mL of test substance was instilled as a 10% w/w solution into the right eyes of the test animals. Observations were taken at 24, 48 and 72 hours post-dosing. The Draize scoring system was used to grade the eye reaction observations. |

RESULTS

| *Lesion* | *Mean score* Animal No.* | | | | | | *Maximum value* | *Maximum duration of any effect* | *Maximum value at end of observation period* |
|---|---|---|---|---|---|---|---|---|---|
| | *1* | *2* | *3* | *4* | *5* | *6* | | | |
| Conjunctiva: redness | 2 | 2 | 1 | 2 | 1.7 | 1.3 | 2 | >72 hours | 2 |
| Conjunctiva: chemosis | 1.7 | 0.7 | 1.7 | 1 | 1 | 1 | 2 | >72 hours | 1 |
| Corneal opacity | 0 | 0 | 0 | 0 | 0 | 0 | 0 | N/A | 0 |
| Iridial inflammation | 0 | 0 | 0 | 0 | 0 | 0 | 0 | N/A | 0 |

*Calculated on the basis of the scores at 24, 48, and 72 hours for each animal.

| | |
|---|---|
| Remarks - Results | No corneal opacity or iritis were observed during the test period. At 24 hours after dosing, all treated eyes exhibited slight to mild hyperaemia, chemosis and ocular discharge. A slight increase in the severity of the irritation from 24 to 48 hours was observed, and although there was a slight decrease in irritation thereafter, irritation persisted in all rabbits through 72 hours. |
| CONCLUSION | ABIL Quat 3474 is slightly irritating to the eye under the conditions of the test. |
| TEST FACILITY | Product Safety Labs (1995c) |

### A.1.9 Skin Sensitisation – GPMT

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3270 |
| METHOD | OECD TG 406 Skin Sensitisation – GPMT |
| Species/Strain | Guinea pig/Pirbright White |
| Vehicle | Water |
| PRELIMINARY STUDY | Maximum Non-irritating Concentration:<br>intradermal: 0.5%<br>topical: 1% |
| MAIN STUDY | |
| Number of Animals | Test Group: 20 Control Group: 10 |
| INDUCTION PHASE | Induction Concentration:<br>intradermal: 0.5%<br>topical: 10% |
| Signs of Irritation | Not reported |
| CHALLENGE PHASE | Challenge Concentration:<br>topical: 1% |

Remarks – Method No significant protocol deviations.

RESULTS

| *Animal* | *Challenge Concentration* | *Number of Animals Showing Skin Reactions after:* | |
|---|---|---|---|
| | | *24 h* | *48 h* |
| *Treated Group* | 1% | 0 | 13/20 |
| *Control Group* | 1% | 0 | 0 |

Remarks – Results No erythema or oedema were observed at 24 hours in the treated group. At 48 hours very slight to slight oedema were observed in 25% of animals in the treated group, and very slight to well-defined erythema in 65% of animals. The positive control (ethyl 4-aminobenzoate) confirmed the sensitivity of the test system.

CONCLUSION ABIL Quat 3270 is a strong skin sensitiser under the conditions of the test.

TEST FACILITY MK (1996)

### A.1.10 Skin Sensitisation – Buehler

TEST SUBSTANCE ABIL Quat 3272

METHOD Similar to OECD TG 406 Skin Sensitisation – Buehler
PSL Protocol P251, Modified

Species/Strain Guinea pig/Hartley
Vehicle Water
PRELIMINARY STUDY Maximum Non-irritating Concentration:
topical: 5%
MAIN STUDY
Number of Animals Test Group: 10 males Control Group: 5 males
INDUCTION PHASE Induction Concentration:
topical: 5%
Signs of Irritation Slight erythema was observed in one animal after the initial application.
CHALLENGE PHASE Challenge Concentration:
topical: 5%
Remarks – Method No significant protocol deviations. However, the highest dose causing mild irritation was not identified for use as an induction dose.

RESULTS

| *Animal* | *Challenge Concentration* | *Number of Animals Showing Skin Reactions after:* | |
|---|---|---|---|
| | | 24 h | 48 h |
| *Test Group* | 5% | 0 | 0 |
| *Control Group* | 5% | 0 | 0 |

Remarks - Results No erythema or oedema were observed at 24 or 48 hours in the treated group. The positive control

(dinitrochlorbenzene) confirmed the sensitivity of the test system.

CONCLUSION ABIL Quat 3272 is not a skin sensitiser under the conditions of the test.

TEST FACILITY Product Safety Labs (1992)

### A.1.11 Genotoxicity - bacteria

TEST SUBSTANCE ABIL Quat 3270

METHOD OECD TG 471 Bacterial Reverse Mutation Test.
EC Directive 92/69/EEC B.14
Plate incorporation procedure

| | |
|---|---|
| Species/Strain | *S. typhimurium*: TA1535, TA1537, TA98, TA100 |
| Metabolic Activation System | Post-mitochondrial fraction (S9 fraction) from rats treated with Aroclor 1254. |
| Concentration Range in Main Test | a) With metabolic activation: 0.32 - 200 µg/plate<br>b) Without metabolic activation: 0.32 - 200 µg/plate |
| Vehicle | Distilled water |
| Remarks - Method | In the preliminary test, the test substance at a concentration of 156.25 µg/plate reduced survival to 3.4% of the control value. Therefore, the highest concentration selected was 200 µg/plate. |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/plate) Resulting in:* | | |
|---|---|---|---|
| | *Cytotoxicity in Main Test* | *Precipitation** | *Genotoxic Effect* |
| *Absent* | | | |
| Test 1 | ≥ 200 | Not measured | Negative |
| *Present* | | | |
| Test 1 | > 200 | Not measured | Negative |
| Test 2 | ≥ 200 | Not measured | Negative |

*No comments regarding precipitation were made in the test report.

Remarks - Results The test substance was tested up to the maximum recommended dose level of 200 µg/plate. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.

All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains.

CONCLUSION ABIL Quat 3270 is not mutagenic under the conditions of the test.

TEST FACILITY Labor L+S AG (1996)

### A.1.12 Genotoxicity - bacteria

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3272 |
| METHOD | Similar to OECD TG 471 Bacterial Reverse Mutation Test<br>Plate incorporation procedure |
| Species/Strain | *S. typhimurium*: TA1535, TA1537, TA98, TA100<br>*E. coli*: WP2uvrA$^-$ |
| Metabolic Activation System | Post-mitochondrial fraction (S9 fraction) from rats treated with Aroclor 1254. |
| Concentration Range in Main Test | a) With metabolic activation: 50 - 1000 µg/plate<br>b) Without metabolic activation: 100 - 5000 µg/plate |
| Vehicle | Distilled water |
| Remarks – Method | No significant protocol deviations. |

RESULTS

| *Metabolic Activation* | *Test Substance Concentration (µg/plate) Resulting in:* | | | |
|---|---|---|---|---|
| | *Cytotoxicity in Preliminary Test* | *Cytotoxicity in Main Test* | *Precipitation* | *Genotoxic Effect* |
| *Absent* | | | | |
| Test 1 | > 1,000 | > 1,000 | > 1,000 | Negative |
| Test 2 | | > 1,000 | > 1,000 | Negative |
| Test 3 | | > 1,000 | > 1,000 | Negative |
| Test 4 | | > 1,000 | > 1,000 | Negative |
| *Present* | | | | |
| Test 1 | > 5,000 | > 5,000 | > 5,000 | Negative |
| Test 2 | | > 5,000 | > 5,000 | Negative |
| Test 3 | | > 5,000 | > 5,000 | Negative |
| Test 4 | | > 5,000 | > 5,000 | Negative |

| | |
|---|---|
| Remarks – Results | The test substance was tested up to the maximum recommended dose level of 5000 µg/plate. No toxicologically significant increases in the frequency of revertant colonies were recorded for any of the bacterial strains, with any dose of the test material, either with or without metabolic activation.<br><br>All the positive control chemicals used in the test induced marked increases in the frequency of revertant colonies thus confirming the activity of the S9-mix and the sensitivity of the bacterial strains. |
| CONCLUSION | ABIL Quat 3272 is not mutagenic under the conditions of the test. |
| TEST FACILITY | SITEK Research Laboratories (1995) |

## A.2 New chemical assessment

The robust summaries of the toxicological studies analysed for the assessment of the notified polymer as a new chemical (NICNAS, 1993) are presented here.

### A.2.1 Acute toxicity – oral

| | |
|---|---|
| Test Substance | ABIL Quat 3270 |
| Method | OECD TG 401 Acute Oral Toxicity |
| | EC guidelines 84/449/EWG |
| Species/Strain | Rat/Wistar (Crl:(WI)BR) |
| Vehicle | None |
| Remarks - Method | No significant protocol deviations |

Results

| Group | *Number and sex of animals* | *Dose (mg/kg bw)* | *Mortality* |
|---|---|---|---|
| 1 | 2 females | 5091 | 0 |
| 2 | 5 males, 5 females | 5091 | 0 |

| | |
|---|---|
| LD50 | >5091 mg/kg bw |
| Signs of toxicity | None – all rats showed no clinical or toxicological symptoms over the entire observation period. |
| | Bodyweight gains were unaffected by treatment. |
| Effects in organs | None – upon necropsy at the end of the 14 day observation period, no macroscopic lesions were reported in the cranial, thoracic and abdominal cavity. |
| Remarks – Results | No deaths occurred. |
| Conclusion | ABIL Quat 3270 is of low toxicity via the oral route. |
| Test Facility | IBR Forschungs (1988a) |

### A.2.2 Irritation - skin

| | |
|---|---|
| Test Substance | ABIL Quat 3270 |
| Method | OECD TG 404 Acute Dermal Irritation/Corrosion |
| | ECC guidelines 84/499/EC |
| Species/Strain | Rabbit/New Zealand White (albino) |
| Number of animals | 6 |
| Vehicle | Distilled water |
| Observation period | 3 days |
| Type of dressing | Occlusive |
| Remarks – Method | No significant protocol deviations |

Results

| *Lesion* | *Mean score* Animal No.* | | | | | | *Maximum value* | *Maximum duration of any effect* | *Maximum value at end of observation period* |
|---|---|---|---|---|---|---|---|---|---|
| | 1 | 2 | 3 | 4 | 5 | 6 | | | |
| *Erythema/Eschar* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | N/A | 0 |
| *Oedema* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | N/A | 0 |

*Calculated on the basis of the scores at 24, 48, and 72 hours for each animal.

| | |
|---|---|
| Remarks – Results | A single dose of 0.5 mL diluted ABIL Quat 3270 (10% w/w in distilled water) was applied occlusively to the abraded and intact skin of 6 New Zealand White rabbits. No erythema or oedema was observed at 24, 48 or 72 hours. All rabbits appeared healthy and active during the test period. |
| Conclusion | ABIL Quat 3270 is not a skin irritant. |
| Test Facility | IBR Forschungs (1988b) |

### A.2.3 Irritation - eye

| | |
|---|---|
| Test Substance | ABIL Quat 3270 |
| Method | OECD TG 405 Acute Eye Irritation/Corrosion<br>ECC guidelines 84/449/EC |
| Species/Strain | Rabbit/New Zealand White (albino) |
| Number of animals | 6 |
| Vehicle | Distilled water |
| Observation period | 72 hours |
| Remarks - Method | No significant protocol deviations. |

Results

| *Lesion* | *Mean score* Animal No.* | | | | | | *Maximum value* | *Maximum duration of any effect* | *Maximum value at end of observation period* |
|---|---|---|---|---|---|---|---|---|---|
| | *1* | *2* | *3* | *4* | *5* | *6* | | | |
| *Conjunctiva: redness* | 2 | 1 | 2 | 1.25 | 1.25 | 1 | 2 | 72 hours | 2 |
| *Conjunctiva: chemosis* | 1 | 1 | 1.75 | 1.25 | 1.25 | 1.75 | 2 | 72 hours | 1 |
| *Corneal opacity* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | N/A | 0 |
| *Iridial inflammation* | 0 | 0 | 0 | 0 | 0 | 0 | 0 | N/A | 0 |

*Calculated on the basis of the scores at 24, 48, and 72 hours for each animal.

| | |
|---|---|
| Remarks - Results | A single dose of 0.1 mL ABIL Quat 3270 (3% in distilled water) was instilled in the conjuctival sac of the left eye of each of 6 New Zealand White rabbits. There was no evidence of corneal opacity or uveitis in any of the animals over the entire observation period. Erythema of the conjuctivae was observed in all rabbits, and these reactions persisted for the entire observation period in four of the animals (including 1 rabbit with rinsed eye). However the scores were not high enough to classify the test substance as an irritant. Chemosis was also present in all animals with obvious conjuctival swelling persisting for at least 24 hours in 5 of the animals. |
| Conclusion | ABIL Quat 3270 slightly irritating to eyes but is not classified as an eye irritant. |
| Test Facility | IBR Forschungs (1988c) |

# Appendix B: Ecotoxicological investigations

The robust summaries of the ecotoxicological studies analysed for the secondary notification assessment of the notified polymer are presented here.

## B.1 Acute toxicity – Algae

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3272 |
| METHOD | OECD TG 201 Freshwater Alga and, Growth Inhibition Test - Static |
| Species/Strain | *Pseudokirchneriella subcapitata* |
| Exposure period | 72 hours |
| Concentration Range | Nominal: Control, 0.0781, 0.156, 0.313, 0.625, 1.25, 2.5 mg/L<br>Actual: Not determined |
| Auxiliary Solvent | None |
| Analytical monitoring | Total organic carbon (TOC) |
| Remarks - Method | 100 mg test item/L was freshly prepared with test medium and gently agitated at room temperature until the solution was homogenous. This solution was diluted to get a stock solution with a concentration of 10 mg/L.<br>The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. |

RESULTS

| *Yield* | | | *Growth* | | |
|---|---|---|---|---|---|
| *EC10 mg/L at 72 h* | *EC50 mg/L at 72 h* | *NOEC mg/L at 72 h* | *EC10 mg/L at 72h* | *EC50 mg/L at 72h* | *NOEC mg/L at 72h* |
| 0.223 | 0.316 | 0.156 | 0.293 | 0.49 | 0.313 |

| | |
|---|---|
| Remarks – Results | All validity criteria for the test were satisfied. The test results were based on nominal concentrations. The test results are considered to be acceptable as TOC recovery results indicated that there was no significant loss of test substance at the end of the test. |
| CONCLUSION | ABIL Quat 3272 is toxic to algae. |
| TEST FACILITY | Noack (2016a) |

## B. 2 Acute toxicity – fish

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3474 |
| METHOD | OECD TG 203 Fish Acute toxicity test - Static |
| Species/Strain | Zebra fish (*Danio rerio*) |
| Exposure period | 96 hours |
| Auxiliary Solvent | None |

| | |
|---|---|
| Analytical monitoring | Dissolved organic carbon analysis (DOC) |
| Remarks - Method | The test substance is poorly soluble in water. Therefore, a stock solution of 100 mg/L was prepared by stirring the test substance in water for 24 hours. Undissolved material was removed by paper filtration. The test solutions were prepared by direct dilution of stock solution. Therefore, the substance concentrations are based on nominal values.<br><br>The test was conducted in accordance with the test guideline above, with no significant deviation in the protocol reported. |

RESULTS

| *Concentration mg/L* | | *Number of fish* | *Mortality* | | | |
|---|---|---|---|---|---|---|
| *Nominal* | *Actual* | | *24 h* | *48 h* | *72 h* | *96 h* |
| Control | - | 10 | 0 | 0 | 0 | 0 |
| 6.25 | ND* | 10 | 0 | 0 | 0 | 0 |
| 12.5 | ND | 10 | 0 | 0 | 0 | 0 |
| 25 | ND | 10 | 0 | 0 | 1 | 3 |
| 50 | ND | 10 | 0 | 8 | 9 | 9 |
| 100 | ND | 10 | 10 | 10 | 10 | 10 |

* ND: not determined

| | |
|---|---|
| LC50 | 30.8 mg/L at 96 hours (95% confident limit: 24.4-38.9 mg/L) |
| NOEC | Not reported |
| Remarks – Results | All validity criteria for the test were satisfied. DOC recovery results indicated that there was no significant loss of test substance at the end of the test. Therefore, the test results are based on nominal concentrations. |
| CONCLUSION | ABIL Quat 3474 is harmful to fish. |
| TEST FACILITY | Evonik (2009) |

## B.3 Acute toxicity – Invertebrates

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3474 |
| METHOD | OECD TG 202 Daphnia toxicity *Daphnia sp.*, Acute immobilisation test – static |
| Species/Strain | *Daphnia magna* |
| Exposure period | 48 hours |
| Auxiliary Solvent | None |
| Analytical monitoring | Dissolved organic carbon (DOC) |
| Remarks – Method | The test substance is poorly soluble in water. Therefore, the water accommodation fractions (WAFs) of the test substance were prepared by adding weighed amount of test substance in test medium and stirring for 24 hours. Any undissolved material was removed by paper filtration. Therefore, the |

substance concentrations were based on nominal values.

The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

| *Concentration mg/L* | | *Number of daphnia* | *Number of immobilised daphnia* | |
|---|---|---|---|---|
| *Nominal* | *Actual* | | *24 h* | *48 h* |
| Control | - | 25 | 0 | 0 |
| 6.25 | ND* | 25 | 0 | 0 |
| 12.5 | ND | 25 | 0 | 0 |
| 25 | ND | 25 | 0 | 0 |
| 50 | ND | 25 | 0 | 1 |
| 100 | ND | 25 | 1 | 13 |

* ND: not determined

| | |
|---|---|
| EC50 | 248.3 WAF mg/L at 48 hours |
| NOEC | 50 WAF mg/L at 48 hours |
| Remarks – Results | Based on the data in the table, 13 daphnia were immobilised when exposed to the test concentration of 100 mg/L for 48 hours which corresponds to 52% immobilisation. This is inconsistent with the calculated EC50 value of 248.3 mg/L at 48 hours in the original report. Therefore, the EC50 and NOEC values reported for daphnia in the original report are not used for the purpose of risk assessment in this secondary notification. |
| CONCLUSION | ABIL Quat 3474 is considered to be harmful to aquatic invertebrates. |
| TEST FACILITY | Evonik (2008a) |

### B.4 Acute toxicity – Algae

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3474 |
| METHOD | OECD TG 201 Freshwater Alga, Growth Inhibition Test – Static |
| Species/Strain | *Pseudokirchneriella subcapitata* |
| Exposure period | 72 hours |
| Concentration Range | Nominal: Control, 1.00, 3.16, 10.0, 31.6, 100 mg/L<br>Actual: Not determined |
| Auxiliary Solvent | None |
| Analytical monitoring | Total organic carbon (TOC) |
| Remarks – Method | Water accommodation fractions (WAFs) was used in the test as the test substance is poorly soluble in water. WAFs were prepared by dissolving weighed amounts of test substance in water within individual containers, stirring for 24 hours. The |

aqueous phase WAFs were removed by siphoning after phase separation for 48 hours. Therefore, the substance concentrations were based on nominal values.

Natural river water was used as the test medium in the test. The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported.

RESULTS

| *Yield* | | | *Growth* | | |
|---|---|---|---|---|---|
| *EL10 mg/L at 72 h* | *EL50 mg/L at 72 h* | *NOEL mg/L at 72h* | *EL10 mg/L at 72h* | *EL50 mg/L at 72h* | *NOEL mg/L at 72h* |
| 1.58 | 2.73 | 1.0 | 2.2 | 7.2 | 1.0 |

| | |
|---|---|
| Remarks – Results | All validity criteria for the test were satisfied. The test results were based on nominal concentrations. The test results are considered to be acceptable as TOC recovery results indicated that there was no significant loss of test substance at the end of the test. |
| CONCLUSION | ABIL Quat 3474 is toxic to algae. |
| TEST FACILITY | Noack (2016b) |

### B.5 Acute toxicity – Algae

| | |
|---|---|
| TEST SUBSTANCE | ABIL Quat 3474 |
| METHOD | OECD TG 201 Freshwater Alga and, Growth Inhibition Test - Static |
| Species/Strain | *Desmodesmus subspicatus* |
| Exposure period | 72 hours |
| Concentration Range | Nominal: Control, 1, 3, 9, 27, 81 mg/L<br>Actual: Not determined |
| Auxiliary Solvent | None |
| Analytical monitoring | Dissolved organic carbon (DOC) |
| Remarks - Method | The test substance is poorly soluble in water. Therefore, the water accommodation fractions (WAFs) of the test substance were used in the test. WAFs were prepared by adding weighed amounts of test substance in culture medium within the individual bottles. The mixtures were stirred for 24 hours. Any undissolved material was removed by paper filtration. Therefore, the substance concentrations were based on nominal values.<br>The test was conducted in accordance with the test guideline above, with no significant deviation in protocol reported. |

RESULTS

| *Yield* | | | *Growth* | | |
|---|---|---|---|---|---|
| *EC10 mg/L at 72 h* | *EC50 mg/L at 72 h* | *NOEC mg/L at 72 h* | *EC10 mg/L at 72h* | *EC50 mg/L at 72h* | *NOEC mg/L at 72h* |
| 3.8 | 8.5 | 3.0 | 7.3 | 17.2 | 3.0 |

| | |
|---|---|
| Remarks – Results | All validity criteria for the test were satisfied. The test results were based on nominal concentrations. The test results are considered to be acceptable as DOC recovery results indicated that there was no significant loss of test substance at the end of the test. |
| CONCLUSION | ABIL Quat 3474 is harmful to algae. |
| TEST FACILITY | Evonik (2008b) |

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