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NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

FULL PUBLIC REPORT

Polyquaternium-72

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (Cwlth) (the Act) and Regulations. This legislation is an Act of the Commonwealth of Australia. The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) is administered by the Department of Health and Ageing, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of the Environment, Water, Heritage and the Arts.

For the purposes of subsection 78(1) of the Act, this Full Public Report may be inspected at our NICNAS office by appointment only at 334-336 Illawarra Road, Marrickville NSW 2204.

This Full Public Report is also 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
NICNAS

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1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Croda Singapore Pty Ltd (Trading as Croda Australia) (ABN: 34 088 345 457)
Ground Floor, Suite A1,
44-46 Mandarin Street,
Villawood, NSW 2163

NOTIFICATION CATEGORY
Limited: Synthetic polymer with Mn ≥ 1000 Da.

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, molecular formula, structural formula, molecular weight, spectral data, methods of detection and determination, residual monomers, additives/adjuvants, introduction volumes, details of use and polymer composition.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed as follows: melting point/boiling point, density, vapour pressure, hydrolysis as a function of pH, partition co-efficient, adsorption/desorption, dissociation constant, particle size, flash point, flammability limits and autoignition temperature.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
Unknown

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Polymer in MiruStyle CP (contains < 30% notified polymer)

CAS NUMBER
Not assigned

OTHER NAME(S)
INCI name: Polyquaternium-72

MOLECULAR WEIGHT
NAMW > 10,000 Da

ANALYTICAL DATA
Reference IR and GPC spectra were provided.

3. COMPOSITION

DEGREE OF PURITY > 90%

HAZARDOUS IMPURITIES/RESIDUAL MONOMERS None

NON HAZARDOUS IMPURITIES/RESIDUAL MONOMERS (>1% by weight) None

LOSS OF MONOMERS, OTHER REACTANTS, ADDITIVES, IMPURITIES
Stable under normal conditions of use.

DEGRADATION PRODUCTS
Combustion may lead to the production of carbon oxides, nitrogen oxides, water and hydrogen chloride gas.

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20°C AND 101.3 kPa: The notified polymer will be introduced as a component of MiruStyle CP, which is a yellow to amber coloured aqueous solution

Property	Value	Data Source/Justification
Melting Point/Freezing Point	Not determined	Will only be introduced as a component of an aqueous solution, from which it will not be separated.
Boiling Point	Not determined	Will only be introduced as a component of an aqueous solution, from which it will not be separated.
Density	Not determined	Will only be introduced as a component of an aqueous solution, from which it will not be separated.
Vapour Pressure	Not determined	Estimated to be low based on the high molecular weight
Water Solubility	> 1 g/L at 20°C	Estimated. Ready water solubility is implied in the MSDS and by the use pattern.
Hydrolysis as a Function of pH	Expected to be stable.	Contains no readily hydrolysable groups. Hydrolytic stability is a functional requirement.
Partition Coefficient (n-octanol/water)	log P_{ow} < 2 at 20°C	Estimated based on water solubility. A test would be inapplicable because the notified polymer is likely to be surface active.
Adsorption/Desorption	log K_{oc} > 1.5	Estimated. As a polyquaternium compound, the notified polymer is likely to adsorb to organic matter.
Dissociation Constant	Not determined.	The notified polymer will be cationic in the environmental pH range of 4–9.
Particle Size	Not determined	Will only be introduced as a component of an aqueous solution, from which it will not be separated.
Flash Point	Not determined	The notified polymer is a high molecular weight solid.
Flammability	Not determined	Will only be introduced as a component of an aqueous solution, from which it will not be separated.
Autoignition Temperature	Not determined.	Will only be introduced as a component of an aqueous solution, from which it will not be separated.
Explosive Properties	Not expected to be explosive	The structural formula contains no explosophores

DISCUSSION OF PROPERTIES
For full details of tests on physical and chemical properties, please refer to Appendix A.

Reactivity
Stable under normal conditions of use. Avoid strong oxidising agents.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. The notified polymer will either be imported as a component of MiruStyle CP (< 30%) or as a component in hair care products (< 4.5%).

MAXIMUM INTRODUCTION VOLUME OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	1-3	1-3	1-3	1-3	1-3

PORT OF ENTRY
Throughout Australia

TRANSPORTATION AND PACKAGING
The notified polymer will be imported in 25 kg plastic pails when imported as MiruStyle CP. The notified polymer and products containing the notified polymer will be transported by road or rail for distribution. Following reformulation the final products containing the notified polymer will be packaged into different sized containers, including 150 mL tubes, 200 g cans and 170 mL spray cans.

USE
The notified polymer is a hair fixative polymer that is designed to enhance the hold of curls. The notified polymer is used as a component of aqueous cosmetic hair styling products (< 4.5%) and conditioners (< 1.5%) and may be used daily by hairdressers or the general public.

OPERATION DESCRIPTION
The notified polymer will not be manufactured within Australia. Products containing the notified polymer, which are imported as finished products, will not be reformulated or repackaged in Australia. Such products will be warehoused before distribution to customers.

Reformulation
The notified polymer will be reformulated into a finished cosmetic product only when imported as MiruStyle CP (< 30% notified polymer in an aqueous solution). MiruStyle CP will be transported by road or rail in plastic pails to the site where it will be reformulated into hair care products.
During reformulation, workers will weigh and dispense the required amount of the MiruStyle CP into a blending tank. Other components of the hair care products are added and the mixture is blended in a closed vessel. Sampling and quality control testing of the formulated product is conducted prior to packaging. The finished formulation is then transferred via pipes to a storage tank, equipped with a filler machine and mechanically pumped into the product containers. The product containers are then sealed and packaged for distribution to customer sites.
The blending tanks and other blending equipment will be cleaned when required. This will involve removal of the residual product and washing down with an appropriate solvent.

End use
The finished products containing the notified polymer will be used occupationally by hairdressers. Depending on the nature of the product these could be applied a number of ways such as by hand, using an applicator or sprayed.

6. HUMAN HEALTH IMPLICATIONS

6.1 Exposure assessment

6.1.1 Occupational exposure

NUMBER AND CATEGORY OF WORKERS

Category of Worker	*Number*	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and warehouse	2	2	30
Laboratory/quality control	2	7	60
Plant operators: Weighing and compounding	4	8	60
Plant operators: Filling and packaging	2	2	30
Hairdressers	> 1000	1-2	220

EXPOSURE DETAILS

Transport and warehousing of the notified polymer

It is expected that transport and warehouse workers handling the imported aqueous solution containing up to 30% notified polymer will only be exposed to the notified polymer in the event of spills due to an accident or as result of leaking drum. Following reformulation into final hair products, transport, warehouse and retail workers handling products will be exposed to concentrations of < 4.5% notified polymer in the case of an accident when packaging is breached. The main route of exposure in these situations will be dermal. Workers may wear protective coveralls, hard hats, gloves and safety glasses.

Reformulation

During reformulation, dermal and ocular exposure to the notified polymer (at < 30%) may occur when connecting and disconnecting transfer lines and pumps.

The concentration of the notified polymer in the finished bulk product will be < 4.5%. During the quality control sampling and filling processes, workers may be exposed to the notified polymer as result of drips and spills, this will primarily be dermal. Worker exposure will be minimised by the use of the use of protective gloves, coverall or laboratory coats in the case of workers involved in quality control testing, safety glasses and safety boots.

End use

Hairdressers will be exposed to the hair products containing the notified polymer (< 4.5%) during final application of the products to their clients. The main route of exposure is expected to be dermal, although ocular exposure to splashes is possible and inhalation exposure could occur during spray application. PPE is not expected to be worn, however good hygiene practices are expected to be in place.

6.1.2. Public exposure

The general public will be repeatedly exposed to the notified polymer via a number of different consumer products (< 4.5%).

Exposure to the notified polymer will vary depending on individual use patterns. Small quantities of the finished product (approximately 14g for conditioners and 5 g for hair styling products) are applied to hair. It is predicted that 1% of the applied conditioner and 10% of the applied hair styling product will be retained on the skin. Thus, a maximum of 0.0006 g/day of the notified polymer will remain on the skin after use with conditioner (based on 0.28 applications per day and a maximum concentration of 1.5% in hair conditioners) and 0.045 g/day after use with hair styling products (based on two applications per day at maximum concentration in product of 4.5%) (SCCP, 2006).

Inhalation exposure could occur during use of spray applied products.

Public exposure from transport, storage, reformulation or disposal is considered to be negligible.

Since products containing the notified polymer are stored and used in a domestic environment, there is the possibility of accidental ingestion by a child.

6.2. Human health effects assessment

The results from toxicological investigations conducted on the notified polymer are summarised in the table below. Details of these studies can be found in Appendix A.

Endpoint	*Result and Assessment Conclusion*
Skin irritation – *in vitro* MatTek EpidDerm skin model (< 30% notified polymer)	mildly to moderately irritating
Skin irritation – *in vitro* MatTek EpidDerm skin model (< 1.5, 3 and 4.5% notified polymer)	non-irritating
Eye irritation - HET-CAM study (< 1.5, 3 and 4.5% notified polymer)	practically non-irritating up to 9%
Skin sensitisation – Human repeat insult patch test.	no evidence of sensitisation and irritation

Toxicokinetics, metabolism and distribution.
Absorption of the notified polymer is likely to be low based on the high molecular weight of the notified polymer. Any notified polymer that is inhaled is expected to be rapidly cleared from the respiratory tract.

Irritation and Sensitisation.
The notified polymer was found to be non-irritating in an *in vitro* MatTek EpidDerm skin model at concentrations up to 4.5%, but mildly to moderately irritating at a concentration of 30%. However, there was no irritation caused by the notified polymer at a 30% concentration during the human repeat insult patch test (HRIPT). The notified polymer was found to be practically non-irritating at concentrations up to 4.5% in a HET-CAM test, which is equivalent to a concentration of 9% in a Draize scored test. Based on the available information the notified polymer may be irritating to eyes and to a lesser extent skin as introduced. The potential for irritation will be reduced at lower concentrations.

The notified polymer (at < 30%) showed no evidence of sensitisation by skin contact based on the results seen in the human repeat insult patch test with 57 test subjects.

Observations on Human Exposure.
The notified polymer is currently being used overseas in hair care products. The notifier has indicated that they are not aware of any adverse reactions from this use.

Health hazard classification
Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human health risk characterisation

6.3.1. Occupational health and safety
The highest occupational exposure to the notified polymer (at 30%) is expected to be to workers during reformulation. Significant dermal exposure may also occur for hairdressers using the finished products (< 4.5% notified polymer). Inhalation exposure could occur during the use of certain products.

Local effects
Exposure to the notified polymer is expected to be minimised due to the use of personal protective equipment in the case of reformulation workers, and the lower concentrations (< 4.5%) and good hygiene practices in the case of hairdressers/beauticians. Therefore the risk of local effects after exposure to the notified polymer is not considered to be unacceptable.

Systemic effects
No toxicological data for repeated exposure to the notified polymer is available. However, based on the expected low absorption of the notified polymer the risk to workers from exposure would not be considered unacceptable.

6.3.2. Public health
The general public will be repeatedly exposed to the notified polymer via a number of different consumer products.

Local effects
The notified polymer is considered to have low potential for skin or eye irritation at the proposed use concentrations (< 4.5%), therefore, the risk of irritancy in consumers is not considered to be unacceptable.

Systemic effects
No toxicological data for repeated exposure to the notified polymer is available. However, based on the expected low absorption of the notified polymer the risk to the public from exposure would not be considered unacceptable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1 Environmental Exposure

RELEASE OF CHEMICAL AT SITE
There will be three main routes of release to the environment. The first route of exposure may arise as a result of accidental spills. In these cases the spill containing the notified polymer will be first contained physically, collected on absorbent material and disposed to landfill. The second route of environmental release is likely to arise from disposal of import containers containing the notified polymer. It is expected that the pails will be disposed of to landfill by licensed waste management companies. The third and final route of environmental release will be from wastewater produced from cleaning the equipment used in the reformulation processes. The wastewater is disposed to trade waste systems and biological processing treatment plants prior to being released to sewer.

It estimated that less than 1% of the annual introduction volume will be released to the environment from spills and wastewater from cleaning and maintenance activities. Three percent will be released to the environment through product containers.

RELEASE OF CHEMICAL FROM USE
The end use products containing the notified polymer are designed to be applied to hair. Due to the high water solubility of the notified polymer, it is expected to be washed off and enter the sewer. Environmental exposure can therefore be expected to be widespread but diffuse. A small quantity of the notified polymer (< 1%) is expected to stay within the end use packaging. These packagings will be disposed of to landfill via domestic wastes. The majority of the notified polymer is expected to be released to the sewer during the washing of hair. The notified polymer is expected to be largely removed by adsorption to sludge at the STP before treated effluent is released to surface water.

RELEASE OF CHEMICAL FROM DISPOSAL
The residual notified polymer remaining in the import containers will be immobilised in landfill by adsorption to soil and organic matter. Waste water containing notified polymer produced at the site of formulation will be disposed of to trade waste systems and then biological processing treatment plants. From here the wastewater will then be appropriately disposed of to sewers. The end use containers which will contain small amounts of residual notified polymer will be disposed to landfill as domestic waste.

7.1.2 Environmental fate

No environmental fate data were submitted. Polyquaternium compounds tend to be resistant to biodegradation. However, polyquaternium-72 is a new generation plant-derived polymer (Myers and Ryan, 2006). As such, the notified polymer would be expected to biodegrade during sewage treatment and if released to surface waters. The MSDS for MiruStyle CP states that biodegradability is to be expected, but only at low concentrations or where its germicidal action has been neutralised. Removal by adsorption to sludge during sewage treatment would also be expected, as such behaviour is typical of polyquaternium compounds because of the presence of quaternary ammonium functionality. If released to surface water, the notified polymer would not be expected to bioaccumulate because of its water solubility.

7.1.3 Predicted Environmental Concentration (PEC)

The following PEC is determined based on the unlikely assumption that no removal occurs during sewage treatment.

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	3000	kg/year
Proportion expected to be released to sewer	97%	
Annual quantity of polymer released to sewer	2910	kg/year
Days per year where release occurs	365	days/year
Daily polymer release:	8.0	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	21.161	million
Removal within STP	0%	
Daily effluent production:	4,232	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	1.9	µg/L
PEC - Ocean:	0.19	µg/L

7.2. Environmental effects assessment

No ecotoxicity data were submitted.

7.2.1 Predicted No-Effect Concentration

A PNEC cannot be calculated as no ecotoxicity data were submitted.

7.3. Environmental risk assessment

A risk quotient cannot be calculated as the ecotoxicity data required to determine the PNEC are not available.

The notified polymer is not expected to pose a risk to the environment, based on its likely biodegradability and the reported use pattern.

8. CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data the notified polymer is not classified as hazardous under the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)].

Human health risk assessment
Under the conditions of the occupational settings described, the notified polymer is not considered to pose an unacceptable risk to the health of workers.

When used in the proposed manner, the notified polymer is not considered to pose an unacceptable risk to public health.

Environmental risk assessment
On the basis of the likely biodegradability and the reported use pattern, the notified polymer is not considered to pose a risk to the environment.

Recommendations

CONTROL MEASURES
Occupational Health and Safety

- Employers should implement the following safe work practices to minimise occupational exposure during handling of the notified polymer:
  - Good hygiene practices

- Employers should ensure that the following personal protective equipment is used by reformulation workers to minimise occupational exposure to the notified polymer:
  - Safety glasses
  - Gloves
  - Protective clothing

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

- A copy of the MSDS should be easily accessible to employees.

- If products and mixtures containing the notified polymer are classified as hazardous to health in accordance with the *Approved Criteria for Classifying Hazardous Substances* [NOHSC:1008(2004)] workplace practices and control procedures consistent with provisions of State and Territory hazardous substances legislation must be in operation.

Disposal

- The notified polymer should be disposed of by landfill.

Emergency procedures

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

Regulatory Obligations

Secondary Notification
This risk assessment is based on the information available at the time of notification. The Director may call for the reassessment of the polymer under secondary notification provisions based on changes in certain circumstances. Under Section 64 of the *Industrial Chemicals (Notification and Assessment) Act (1989)* the notifier, as well as any other importer or manufacturer of the notified polymer, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified polymer is listed on the Australian Inventory of Chemical Substances (AICS).

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

(1) Under Section 64(1) of the Act; if
  - the polymer has a number-average molecular weight of less than 1000; or

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the polymer has changed from a component of hair care products at concentrations of < 4.5%, or is likely to change significantly;
  - the amount of polymer being introduced has increased from 3 tonnes, or is likely to increase, significantly;
  - if 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.

Material Safety Data Sheet

The MSDS of the notified polymer provided by the notifier was reviewed by NICNAS. The accuracy of the information on the MSDS remains the responsibility of the applicant.

APPENDIX A: TOXICOLOGICAL INVESTIGATIONS

A.1. Irritation – skin Irritancy Potential by In vitro MatTek EpiDerm skin model

TEST SUBSTANCE: Mirustyle CP, Batch number: 149533 (containing < 30% notified polymer).

METHOD: The MatTek Corporation EpiDerm™ Skin Model *In vitro* Toxicity Testing System.

Remarks – Method: Normal human epidermal keratinocytes cultured to form a multilayered, highly differentiated model of the human epidermis. Cell viability is determined by the activity of mitochondrial succinate dehydrogenase, which reduces a yellow, water soluble, tetrazolium salt to a purple, insoluble formazan derivative. The amount of reduction is determined by spectrophotometry.

The cell layer is incubated at 37ºC, 5% carbon dioxide and ≥ 90% humidity with 100µL of the test substance and controls in microplates, extracted and the absorbance read at 570 nm. The absorbance of the negative control was defined as 100%.

RESULTS

Test substance concentration & Exposure time	*Percent Viability*	*Percent Inhibition*
(100% - 1 hr)	88	12
(100% - 4.5 hr)	77	23
(100% - 20 hr)	15	85

Remarks – Results: The ET-50 is a measure of 50% cell viability. The ET-50 was estimated to be approximately 8.7 hours. The irritation guidelines were according to the MatTek Corporation.

CONCLUSION: Under the conditions of this test, Mirustyle CP containing the notified polymer at < 30% has an expected *in vivo* dermal irritancy potential in the mildly to moderately irritating range.

TEST FACILITY: Consumer Product Testing (2006a)

A.2. Irritation – skin Irritancy Potential by In vitro MatTek EpiDerm skin model

TEST SUBSTANCE: Mirustyle CP, Batch number: 149533 (containing < 30% notified polymer) tested at 5, 10 and 15% in aqueous solution (< 1.5, 3 and 4.5% of the notified polymer).

METHOD: The MatTek Corporation EpiDerm™ Skin Model *In vitro* Toxicity Testing System.

Remarks – Method: Normal human epidermal keratinocytes cultured to form a multilayered, highly differentiated model of the human epidermis. Cell viability is determined by the activity of mitochondrial succinate dehydrogenase, which reduces a yellow, water soluble, tetrazolium salt to a purple, insoluble formazan derivative. The amount of reduction is determined by spectrophotometry.

The cell layer is incubated at 37ºC, 5% carbon dioxide and ≥ 90% humidity with 100µL of the test substance and controls in microplates, extracted and the absorbance read at 570 nm. The absorbance of the negative control was defined as 100%.

Mirustyle CP was tested at 5, 10 and 15% by dilution with distilled

water, which corresponds to < 1.5, 3 and 4.5% of the notified polymer.

RESULTS

Test substance concentration & Exposure time	*Notified polymer concentration*	*Percent Viability*	*Percent Inhibition*
(15% - 1 hr)	4.5%	104	-4
(15% - 4.5 hr)	4.5%	105	-5
(15% - 20 hr)	4.5%	83	17
(10% - 1 hr)	3%	93	7
(10% - 4.5 hr)	3%	104	-4
(10% - 20 hr)	3%	89	11
(5% - 1 hr)	1.5%	94	6
(5% - 4.5 hr)	1.5%	96	4
(5% - 20 hr)	1.5%	93	7

Remarks – Results

The ET-50 is a measure of 50% cell viability. The ET-50 was estimated to be > 24 hours for all three concentrations tested. The irritation guidelines were according to the MatTek Corporation.

CONCLUSION

Under the conditions of this test, the notified polymer at < 4.5% has an expected *in vivo* dermal irritancy potential in the non-irritating range.

TEST FACILITY

Consumer Product Testing (2006b)

A.3. Irritation – eye **The Hen's Egg Test – Utilizing the Chorioallantoic Membrane (HET-CAM)**

TEST SUBSTANCE

Mirustyle CP, Batch Number: 149533 (containing the notified polymer at < 30%) at 5%, 10%, 15% in aqueous solution (< 1.5, 3 and 4.5% of the notified polymer).

METHOD

Hen's Egg Test (HET) - Chorioallantoic Membrane (CAM) Test. Modification of that described by Kemper and Luepke (1986).

Species: White Leghorn chicken eggs

Number of eggs: 4 for each test concentration and control

Observation period: Readings taken at 0.5, 2 and 5 minutes

Treatment: After a 10-day incubation at 37°C, the shell over the air section of each egg was removed and following hydration, the inner membrane was removed to reveal the CAM. The test solution (0.3 mL) was added to each CAM for a period of twenty seconds and effects of hyperemia, haemorrhage (including minimal haemorrhage) and coagulation were observed over a period of 5 minutes.

The reactions of the CAM, blood vessels, including the capillaries, and the albumin were examined and scored for irritant effects.

Effect	*Scores at time (min):*		
	0.5	2	5
Hyperemia	5	3	1
Minimal Hemorrhage ("Feathering")	7	5	3
Hemorrhage (Obvious leakage)	9	7	5
Coagulation and/or Thrombosis	11	9	7

The numerical, time dependent scores were totalled for each CAM. Each reaction type can be recorded only once for each CAM, therefore the maximum score per CAM is 32. The mean score was determined for all CAM's similarly tested.

Remarks - Method

No details of test substance preparation was included. Distilled water was the only control substance included in the study.

RESULTS

Test Solution	*Notified polymer concentration*	*Average Irritation score*
Negative control – Distilled Water (100 %)	0%	1.75
Mirustyle CP(5%)	1.5%	1.25
Mirustyle CP (10%)	3%	1.25
Mirustyle CP (15%)	4.5%	2.50

Remarks - Results: Previous studies were stated by the study authors to have shown that the CAM of the hen's egg is more sensitive to liquid irritants than is the rabbit eye. They state that, the CAM results for the test article at a specific concentration equate to the Draize results for the test article at two times that concentration.

CONCLUSION: The notified polymer is predicted to be practically non-irritating to the eye at a concentration of up to 9% based on no irritation observed at concentration up to < 4.5% under the conditions of the HET-CAM test.

TEST FACILITY: Consumer Product Testing Co. (2006c)

A.4. Skin sensitisation – human volunteers

TEST SUBSTANCE: Mirustyle CP, Batch number: 149533 (containing < 30% notified polymer)

METHOD: Human Repeat Insult Patch Test (HRIPT)
Tests conducted in accordance with ICH Guideline E6 for Good Clinical Practice and requirements provided for in 21 CFR parts 50 & 56.

Study Design: Induction Procedure: Nine repeat, 24-hour applications of approximately 0.2 ml of the test substance under semi-occluded patch at three applications per week, to the same skin area between the scapulae. Inspection of the site for irritation was performed prior to re-application. Rest periods consisted of 24 hours or 48 hours when the application occurred on a Friday.

Rest Period: 14 days.

Challenge Procedure: A single application following the induction procedure was applied to a new test site adjacent to the original Induction test site approximately 2 weeks after the final patch application. The site was inspected for irritation 24 and 72 hours post-application.

Study Group: 57 qualified males and females, ranging in age from 16 to 76 years completed the study.

Vehicle: Test substance administered as supplied.

Remarks - Method: 5 subjects discontinued during the study for reasons unrelated to administration of the test substance.
The number of test subjects used is too low to reliably detect sensitisation rates < 1% (McNamee et al., 2008).

RESULTS

Remarks - Results: No adverse skin reactions indicative of irritation or sensitisation were observed throughout the study.

CONCLUSION: The notified polymer (at < 30%) was non-irritating and non-sensitising under the conditions of the test.

TEST FACILITY: Consumer Product Testing (2006d)

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