File No.: LTD/2148

September 2020

AUSTRALIAN INDUSTRIAL CHEMICALS INTRODUCTION SCHEME (AICIS)

PUBLIC REPORT

2,1-Benzisothiazole-5-sulfonamide, 3-[(1*E*)-2-(3-chloro-4-hydroxyphenyl)diazenyl]- (INCI name: HC Blue 18)

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals Act 2019 (the IC Act) and Industrial Chemicals (General) Rules 2019 (the IC Rules) by following the Industrial Chemicals (Consequential Amendments and Transitional Provisions) Act 2019 (the Transitional Act) and Industrial Chemicals (Consequential Amendments and Transitional Provisions) Rules 2019 (the Transitional Rules)*. The legislations are Acts of the Commonwealth of Australia. The Australian Industrial Chemicals Introduction Scheme (AICIS) is administered by the Department of Health, and conducts the risk assessment for public health and occupational health and safety. The assessment of environmental risk is conducted by the Department of Agriculture, Water and the Environment.

This Public Report is available for viewing and downloading from the AICIS website. For enquiries please contact AICIS at:

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Executive Director
AICIS

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SUMMARY

The following details will be published on our website:

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/2148	Kao Australia Pty Ltd	2,1-Benzisothiazole-5-sulfonamide, 3-[(1*E*)-2-(3-chloro-4-hydroxyphenyl)diazenyl]- (INCI name: HC Blue 18)	Yes	≤ 0.05 tonne per annum	Oxidative hair dye ingredient for professional use only

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard Classification
Based on the information available in the SCCS Opinion (2015), the assessed chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the assessed chemical is presented in the following table.

Hazard Classification	*Hazard Statement*
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

Human Health Risk Assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the assessed chemical is not considered to pose an unreasonable risk to the health of workers.

When used in the proposed manner, the assessed chemical is not considered to pose an unreasonable risk to public health.

Environmental Risk Assessment
On the basis of the reported use pattern and import volume of less than one tonne, the assessed chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

REGULATORY CONTROLS

Hazard Classification and Labelling

- The assessed chemical should be classified as follows:
  – Skin sensitisation (Category 1): H317 – May cause an allergic skin reaction

  The above should be used for products/mixtures containing the assessed chemical, if applicable, based on the concentration of the assessed chemical present.

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure during handling of the assessed chemical as introduced in hair dye products:
  – Avoid contact with skin and eyes

- A person conducting a business or undertaking at a workplace should ensure that the following personal protective equipment is used by workers to minimise occupational exposure to the assessed chemical as introduced in hair dye products:
  - Impervious gloves

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

- Due to skin sensitising potential of the assessed chemical, employers should carry out health surveillance for any worker who has been identified in the workplace risk assessment as having a significant risk of sensitisation.

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

- If products and mixtures containing the assessed chemical are classified as hazardous to health in accordance with the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* 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.

Storage

- The handling and storage of the assessed chemical should be in accordance with the Safe Work Australia Code of Practice for *Managing Risks of Hazardous Chemicals in the Workplace* (SWA, 2012) or relevant State or Territory Code of Practice.

Emergency procedures

- Spills or accidental release of the assessed chemical should be handled by physical containment, collection and subsequent safe disposal.

Disposal

- Where reuse or recycling are not appropriate, dispose of the assessed chemical in an environmentally sound manner in accordance with relevant Commonwealth, state, territory and local government legislation.

Regulatory Obligations

Specific Requirements to Provide Information
This risk assessment is based on the information available at the time of the application. The Executive Director may initiate an evaluation of the chemical based on changes in certain circumstances. Under Section 101 of the IC Act the applicant of the assessed chemical has post-assessment regulatory obligations to provide information to AICIS when any of these circumstances change. These obligations apply even when the assessed chemical is listed on the Australian Inventory of Industrial Chemicals (the Inventory).

Therefore, the Executive Director of AICIS must be notified in writing within 20 working days by the applicant or other introducers if:

- the function or use of the chemical has changed from hair dye for professional use only, or is likely to change significantly;
- the importation volume exceeds one tonne per annum assessed chemical;
- the chemical has begun to be manufactured in Australia;
- the assessed chemical is imported for reformulation in Australia;
- the assessed chemical is imported in solid form;
- the on-head concentration of the assessed chemical has increased from 0.35%;
- additional information has become available to the person as to an adverse effect of the chemical on human health, or the environment.

The Executive Director will then decide whether an evaluation of the introduction is required.

Safety Data Sheet
The SDSs of products containing the assessed chemical provided by the applicant were reviewed by AICIS. The accuracy of the information on the SDSs remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT(S)
Kao Australia Pty Ltd (ABN: 59 054 708 299)
Level 2, 293 Camberwell Road
CAMBERWELL VIC 3124

NOTIFICATION CATEGORY
Limited-small volume: Chemical other than polymer (1 tonne or less per year)

PROTECTED INFORMATION (SECTION 38 OF THE TRANSITIONAL ACT)
Data items and details taken to be protected information include: specific other names, analytical data, degree of purity, introduction and use concentrations and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 6 OF THE TRANSITIONAL RULES)
Schedule data requirements are varied for all physical and chemical properties except melting point and dissociation constant.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU (2018)

2. IDENTITY OF CHEMICAL

MARKETING NAME
HC Blue 18 (INCI Name)

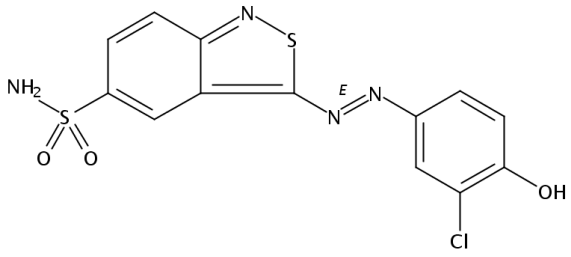
CAS NUMBER
1166834-57-6

CHEMICAL NAME
2,1-Benzisothiazole-5-sulfonamide, 3-[(1*E*)-2-(3-chloro-4-hydroxyphenyl)diazenyl]-

OTHER NAME(S)
FPK-145
Colipa No. B112

MOLECULAR FORMULA
$C_{13}H_9ClN_4O_3S_2$

STRUCTURAL FORMULA



MOLECULAR WEIGHT
368.82 g/mol

ANALYTICAL DATA
Reference NMR, IR and UV spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 99%

IMPURITIES

Chemical Name	3 unknown impurities		
CAS No.	N/A	*Weight %*	< 0.75 (total)

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: red powder (SCCS 2015)

Property	***Value***	***Data Source/Justification***
Melting Point	273-279 °C	Measured*
Boiling Point	549.21 °C at 101.3 kPa	Calculated (US EPA MPBVP (v1.43))
Density	~1,100-1,200 kg/m^3	Estimated by applicant
Vapour Pressure	1.11 x 10^{-13} kPa at 25 °C	Calculated (US EPA MPBVP (v1.43))
Water Solubility	25.71 mg/L at 25 °C	Calculated (US EPA (2012) WSKOW (v1.42))
Hydrolysis as a Function of pH	Not determined	Contains no functionality susceptible to hydrolysis. Found to be stable in alkaline peroxide for 45 min (EU 2015).
Partition Coefficient (n-octanol/water)	log Pow = 2.83 at 25 °C	Calculated for an unionised state (US EPA (2012) KOWWIN (v1.68))
Adsorption/Desorption	log K_{oc} = 4.21 at 25 °C	Calculated (US EPA (2012) KOCWIN (v2.0))
Dissociation Constant	pKa = 6.31	Measured*
Flash Point	Not determined	Not expected to form flammable vapours (information provided by the applicant)
Flammability	Not determined	Not expected to be flammable
Autoignition Temperature	Not determined	Not expected to autoignite
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply explosive properties

* Study report was not provided.

DISCUSSION OF PROPERTIES

Reactivity
The assessed chemical is expected to be stable under normal conditions of use.

Physical Hazard Classification
Based on the information depicted in the above table, the assessed chemical is not recommended for hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia.

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF ASSESSED CHEMICAL (100%) OVER NEXT 5 YEARS
The assessed chemical will not be manufactured in Australia. It will be imported into Australia as a component of oxidative hair dye products at ≤ 0.35% concentration.

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

Year	*1*	*2*	*3*	*4*	*5*
Tonnes	0.01-0.05	0.01-0.05	0.01-0.05	0.01-0.05	0.01-0.05

PORT OF ENTRY
Major ports in Australia

IDENTITY OF MANUFACTURER/RECIPIENTS
Kao Australia Pty Ltd

TRANSPORTATION AND PACKAGING
The assessed chemical will be imported as a component of finished hair dying products (at ≤ 0.35% concentration) in containers, such as tubes (50-120 g) or tubs (500 g), for professional use only.

USE
The assessed chemical will be used as an oxidative dye in hair dye formulations. The assessed chemical will be introduced in finished oxidative hair dye products at ≤ 0.35% concentration. The hair dye product will be mixed with a developer to give a maximum on-head concentration of 0.12% for the assessed chemical. The hair dye products will be available for use by professionals only (e.g. hairdressers or hair salon workers).

OPERATION DESCRIPTION
The assessed chemical will not be reformulated or repacked in Australia. Hair dye products containing the assessed chemical at ≤ 0.35% concentration will be used by professionals only (such as hairdressers and hair salon workers). Professional hairdressers and hair salon workers will mix the hair dye products with a developer and then apply the dye mixture containing the assessed chemical at ≤ 0.12% concentration to the customer's hair by brush.

6. HUMAN HEALTH IMPLICATIONS

6.1. Exposure Assessment

6.1.1. Occupational Exposure

CATEGORY OF WORKERS

Category of Worker	*Exposure Duration (hours/day)*	*Exposure Frequency (days/year)*
Transport and warehouse	2	12
Retail Workers	0.5	100
Professional salon workers	4	220

EXPOSURE DETAILS
Transport, warehousing and retail workers are not expected to be exposed to the assessed chemical except in the unlikely event of an accident.

Dermal exposure to the assessed chemical at ≤ 0.35% concentration in hair dying products may occur in professionals (e.g. hairdressers or hair salon workers) where the services provided involve the application of the products to clients. Such professionals may use personal protective equipment (PPE), such as impervious gloves, to minimise dermal exposure, and good hygiene practices are expected to be in place.

6.1.2. Public Exposure
Hair dye products containing the assessed chemical will not be made available for home use. The public will be exposed to hair dye products containing the assessed chemical during hair dye treatments in hair salons. The main route of exposure will be dermal, with some potential for accidental ocular exposure. The maximum on-head concentration of the assessed chemical will be 0.12%.

6.2. Human Health Effects Assessment
The results from toxicological investigations conducted on the assessed chemical are summarised in the table and study descriptions below, taken from a report by the Scientific Community on Consumer Safety (SCCS, 2015). Study dossiers were not provided by the applicant.

Endpoint	***Result and Assessment Conclusion***
Dermal percutaneous absorption - *in vitro* dermatomed porcine skin (0.7% mixture)	85.8 ± 49.8 ng/cm² (oxidative conditions)
Bioavailability after oral gavage	63.99%
Skin irritation – rabbit	non-irritating

Endpoint	*Result and Assessment Conclusion*
Eye irritation – rabbit	slightly irritating
Skin sensitisation – mouse local lymph node assay	moderate sensitiser (SCCS opinion) (study 1: tested up to 15%, EC3 < 5%; study 2: tested up to 10%, EC3 = 10.5%)
Repeat dose oral toxicity – rat, 14 days	NOAEL < 250 mg/kg bw/day; non genotoxic
Repeat dose oral toxicity – rat, 90 days	NOAEL = 25 mg/kg bw/day
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – *in vitro* mammalian cell gene mutation test	non genotoxic
Genotoxicity – i*n vitro* micronucleus test using V79 cells	non genotoxic
Genotoxicity – i*n vitro* micronucleus test using human lymphocytes	non genotoxic
Genotoxicity – *in vivo* mammalian erythrocyte micronucleus test	non genotoxic
Prenatal developmental toxicity – rat	NOAEL = 300 mg/kg bw/day (maternal and developmental toxicity) No teratogenic potential up to 1000 mg/kg bw/day

The SCCS Opinion (2015) indicated that there are discrepancies and uncertainties related to the purity of test substance used in the toxicological studies.

Dermal / percutaneous absorption
The dermal penetration of assessed chemical under oxidative conditions from a formulation containing the assessed chemical at 0.7% concentration (on-head concentration of 0.35%) was investigated in dermatomed pig ear skin according to OECD TG 428. Under the reported conditions, the dermal delivery of the assessed chemical was 85.8 ± 49.8 ng/cm² (0.14 ± 0.085 % of applied dose).

Toxicokinetics
The oral bioavailability of the assessed chemical after oral gavage is expected to be 65%, based on the results of a study on ^{14}C radioactive isomer of the assessed chemical according to OECD TG 417.

Acute Toxicity
No data were submitted for acute oral, dermal and inhalation toxicity.

It was inferred that the assessed chemical is of low acute oral toxicity as there were no deaths following a single oral administration of the assessed chemical up to the limit dose level of 1000 mg/kg/day in rats (n = 10).

Irritation
The assessed chemical caused no skin reactions in rabbits when tested according to OECD TG 404. Slight red staining of the skin occurred and it was not noted whether this hindered scoring.

The assessed chemical caused slight and reversible irritation to rabbit eyes, when tested according to OECD TG 405. The observed irritation scores (≤ 1) do not warrant hazard classification.

Skin sensitisation
The possible allergic potential of the assessed chemical was investigated by two local lymph node assays (LLNA) according to OECD TG 429.

In the first assay, the test substance induced stimulation index (SI) values of 5.9, 4.7 and 6.4 at concentrations of 5, 10 and 15%, respectively and the estimated concentration that elicits a three-fold increase in lymphocyte proliferation (EC3) could not be calculated (SCCS, 2015). These results imply the assessed chemical to be a skin sensitiser with an EC3 value below 5%.

To further clarify the skin sensitisation potency of the assessed chemical, a second LLNA was conducted with different concentrations of the assessed chemical (1, 2.5, 5 and 10% in DMSO) and with a different batch of the assessed chemical. No mortalities or clinical signs were observed and the lymphoproliferative response evidenced by stimulation indices above the threshold value of 3 was not achieved. The EC3 was calculated as 10.5%.

SCCS (2015) commented that the LLNA results were highly dependent on the batch of the assessed chemical used. The first test batch which contained several impurities induced SI values above 3 at all concentrations tested and the second batch which contained no such impurities did not induce SI values equal to or higher than 3. Since the second test substance was borderline positive at the highest concentration tested (10%) and induced a dose-dependent response, the SCCS Opinion (2015) considered the assessed chemical as a moderate skin sensitiser.

Repeated Dose Toxicity
In a 14-day dose range finding study, the assessed chemical was administered by oral gavage to rats (5/sex/group) at dose levels of 0, 250, 500 and 1000 mg/kg/day once daily for 14 days according to OECD TG 407.

The following test substance-related changes were noted:
- In animals treated at 1000 mg/kg bw/day: decrease in food consumption in males and females on day 3, statistically significant increases in relative seminal vesicles weight in males and relative adrenals weight in females (they were not considered by the study director to be treatment-related because there were no changes in their absolute organ weights and no changes in these organs in histopathological examination).
- In animals treated at 500 mg/kg bw/day or more: inflammatory cell infiltration in the lamina propria in the caecum in males and females.
- In animals treated at 250 mg/kg bw/day and above chromaturia (orange urine) in males and females, minimal hyperplasia of the mucosal epithelium in the urinary bladder in males and females (in 1 male and 2 females treated at 250 mg/kg bw/d, in 2 males and 2 females treated at 500 mg/kg bw/day and in 4 males and 3 females treated at 1000 mg/kg bw/day), statistically significant increase in haemoglobin concentration in males treated at 250 and 1000 mg/kg bw/day.

No treatment-related changes were noted in the bodyweights, ophthalmological observations, urinalysis, haematology and blood chemistry parameters, organ weights, or at necropsy.

The no-observed-adverse-effect-level (NOAEL) of the test substance was considered to be lower than 250 mg/kg bw/day in males and females under the conditions of this study.

On the basis of the results obtained in the 14-day dose range finding study the following dose levels for the 90 day sub-chronic study were proposed: 0, 2.5, 25 and 250 mg/kg bw/day.

In a 90-day repeated dose toxicity study, rats (10/sex/group) were treated by the assessed chemical via oral gavage once daily for 91 days at dose levels of 0, 2.5, 25 and 250 mg/kg bw/day according to OECD TG 408, with 5 animals per sex of the control group and high dose group were allowed a 4-week treatment-free recovery period.

No treatment-related abnormalities were noted in function tests, motor activity, bodyweight, food consumption, ophthalmological observations, urinalysis, haematology, blood chemistry, or organ weight, except chromaturia was observed in males and females treated at 25 mg/kg bw /day or more and considered to be due to the colouration of the test substance.

Histopathological examination showed a minimal simple hyperplasia of the mucosal epithelium in the urinary bladder in males and females treated at 250 mg/kg bw/day.

The effect of the test substance was considered to be reversible as no treatment-related abnormalities were observed in any high dose animals after a 4-week recovery period.

The NOAEL was considered to be 25 mg/kg bw/day in males and females based on the simple hyperplasia of the mucosal epithelium in the urinary bladder observed at 250 mg/kg bw/day under the condition of this study.

Mutagenicity/Genotoxicity
The assessed chemical was tested negative for the induction of gene mutations in in strains of *Salmonella typhimurium* and *Escherichia coli* according to OECD TG 471.

The assessed chemical was negative for gene mutations at the *hpr*t locus of Chinese hamster V79 cells both in the absence and presence of metabolic activation according to OECD TG 476.

The assessed chemical was tested negative in the absence and presence of metabolic activation for the induction of micronuclei in human lymphocytes according to OECD TG 487.

The assessed chemical was found to be negative for induction of micronuclei in the bone marrow cells of mice treated by a single oral dose of 0, 500, 1000 and 2000 mg/kg bw/day according to OECD TG 474.

In a micronucleus test integrated into a 14-day dose range finding study in rats, no increase in bone marrow cells with micronuclei was observed after the repeated treatments.

Developmental Toxicity
In a dose range finding study for prenatal developmental toxicity, the assessed chemical (purity: 99.34%) was administered by oral gavage to mated female rats (5-6 females/group) at dose levels of 0, 125, 250, 500 and 1000 mg/kg bw/day from gestation day 6 to 19.

The following results were reported:
- Chromaturia that was considered attributable to test substance colour was observed in all treated groups.
- Decreased bodyweight and food consumption were observed in animals treated at 1000 mg/kg bw/day.
- No effects on gravid uterus weights or necropsy findings for dams were observed in any group.
- No effects on embryo-foetal development (post-implantation loss index, number of live foetuses, sex ratio or bodyweights of the live foetuses) were observed in any group.
- No placental anomalies were observed.
- No test substance-related foetal anomalies were observed in external, visceral or skeletal examination in any live foetus.
- No effects were observed in the progress of ossification of sternebrae and sacrocaudal vertebrae.

Based on the results, dose levels of 100, 300 and 1000 mg/kg bw/day were proposed for the main developmental study.

In the main study for prenatal developmental toxicity, the assessed chemical was administered by oral gavage to mated female rats (20 females/group) at dose levels of 0, 100, 300 and 1000 mg/kg bw/day from gestation day 6 to 19 according to OECD TG 414.

The following results were reported:
- No death occurred in any dams.
- Chromaturia that was considered to be attributable to the test substance colour was observed in treated groups.
- Decreased body weight and food consumption were observed in animals treated at 1000 mg/kg bw/day.
- No adverse effects on gravid uterus weights or necropsy findings for dams were observed.
- No effects on embryo-foetal development (post-implantation loss index, number of live foetuses, sex ratio or bodyweights of the live foetuses) were observed.
- Decreased bodyweight of live foetuses was observed in animals treated at 1000 mg/kg bw/day.
- No placental anomalies were observed.
- No test substances–related foetal anomalies were observed in external, visceral or skeletal examination in any treatment group.
- No effects in the progress of ossification of the sternebrae and sacrocaudal vertebrae.

The NOAEL was considered to be 300 mg/kg bw/day for maternal toxicity and embryo-foetal development. The assessed chemical did not reveal any teratogenic potential up to 1000 mg/kg bw/day.

Health Hazard Classification
Based on the information available in the SCCS Opinion (2015), the assessed chemical is a hazardous chemical according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. The hazard classification applicable to the assessed chemical is presented in the following table.

Hazard Classification	***Hazard Statement***
Skin sensitisation (Category 1)	H317 – May cause an allergic skin reaction

6.3. Human Health Risk Characterisation
Based on the toxicity data evaluated by the SCCS (2016), the assessed chemical is considered to be a skin sensitiser and a mild eye irritant. However, eye irritation and skin sensitisation effects are not expected at the low end-use concentrations in hair dye products (≤ 0.35%).

6.3.1. Occupational Health and Safety

Workers involved in professions where the services provided involve the application of hair dye products containing the assessed chemical to clients (*e.g.*, hairdressers and hair salon workers) may be exposed to the assessed chemical at concentrations up to 0.35%. The greatest potential for exposure is during hair dyeing processes, mainly via skin contact, although ocular exposure may also occur.

Given that the product is a dye, skin contact is expected to be avoided by workers. Workers will use PPE (such as disposable gloves) to minimise repeated exposure, and good hygiene practices are expected to be in place.

Overall, based on the low concentration of the assessed chemical in hair dye products and PPE (gloves) are worn, the risk to workers from exposure to the assessed chemical is not considered to be unreasonable.

6.3.2. Public Health

Hair dye products containing the assessed chemical will be supplied to hairdressing salons only. Therefore, members of the public may potentially be exposed to the assessed chemical when having the product applied to their scalp (at ≤ 0.12% concentration). The degree and type of exposure may vary depending on the frequency of application, the care taken when applying the dye and amount of dye applied.

Irritation and sensitisation

Irritation or sensitisation effects are not expected from the application of products containing the assessed chemical at the proposed low use concentrations (up to 0.12%) in hair dyes.

Systemic effects from repeated use

The assessed chemical was the subject of a SCCS Opinion (SCCS, 2015) which calculated the margin of safety (MOS) for the assessed chemical (at oxidative conditions, 0.7% in the formulation, on-head concentration of 0.35%) as follows:

Absorption through the skin	A	0.136 μg/cm^2
Skin area surface	SAS	580 cm^2
Dermal absorption per treatment	SAS × A × 0.001	0.079 mg
Typical body weight of human		60 kg
Systemic exposure dosage (SED)	SAS × A × 0.001/60	0.0013 mg/kg bw/day
No Observed Adverse Effect Level	NOAEL	25 mg/kg bw/day (derived from sub-chronic toxicity study, oral, rat)
65% bioavailable*		16 mg/kg bw/day
MOS	adjusted NOAEL/SED	12,300

* based on the toxicokinetic study

The SCCS (2015) concluded that the use of the assessed chemical at a maximum on-head concentration of 0.35% in oxidative hair dye formulations does not pose a risk to the health of the consumer.

The proposed Australian use of the assessed chemical in oxidative hair dye products (at a maximum on-head concentration of 0.12%) is lower than the concentration assessed by the SCCS (2015). Therefore, systemic repeated dose risks from use of the assessed chemical by members of the general public at ≤ 0.12% on-head concentration in oxidative hair dyes is not considered to be unreasonable.

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The assessed chemical will not be manufactured, reformulated or repacked in Australia. It will be imported as a component of finished hair dye products. Some release of the assessed chemical may be from spills during the transport and storage of the finished products containing the assessed chemical. Accidental spills will be collected for disposal, in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE
The majority of the assessed chemical will be rinsed into the sewer system as a result of its use in hair dye products.

RELEASE OF CHEMICAL FROM DISPOSAL
Residues of the assessed chemical in empty product containers are likely to either share the fate of the containers and be disposed of to landfill or be released to the sewer system when containers are rinsed before recycling through an approved waste management facility.

7.1.2. Environmental Fate
The majority of the assessed chemical is expected to enter the sewer system before potential release to surface waters on a nationwide basis.

A proportion of the assessed chemical may be applied to land when effluent is used for irrigation or when sewage sludge is used for soil remediation, or disposed of to landfill as a waste (see Predicted Environmental Concentration). Minor amounts of the assessed chemical may also be disposed of to landfill as collected spills and empty container residues. The assessed chemical residues in landfill and soils are expected to have low mobility based on its estimated soil adsorption coefficient (log Koc = 4.21). The assessed chemical is not expected to bioaccumulate based on the estimated moderate partition coefficient (log Pow = 2.83). In the aquatic and soil compartments, the assessed chemical is expected to degrade through biotic and abiotic processes to form water and oxides of carbon, nitrogen, sulphur and chlorine.

7.1.3. Predicted Environmental Concentration (PEC)
The use pattern will result in most of the assessed chemical being washed into the sewer. The predicted environmental concentration (PEC) has been calculated assuming the realistic worst-case scenario with 100% release of the assessed chemical into sewer systems nationwide over 365 days per annum. The extent to which the assessed chemical is removed from the effluent in STP processes based on the properties of the assessed chemical has not been considered for this scenario, and therefore no removal of the assessed chemical during sewage treatment processes, is assumed. The PEC in sewage effluent on a nationwide basis is estimated as follows:

Predicted Environmental Concentration (PEC) for the Aquatic Compartment		
Total Annual Import/Manufactured Volume	50	kg/year
Proportion expected to be released to sewer	100%	
Annual quantity of chemical released to sewer	50.000	kg/year
Days per year where release occurs	365	days/year
Daily chemical release:	0.14	kg/day
Water use	200.0	L/person/day
Population of Australia (Millions)	24.386	million
Removal within STP	0%	
Daily effluent production:	4,877	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.03	µg/L
PEC - Ocean:	0.00	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 assessed chemical 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 0.03 µg/L may potentially result in a soil concentration of approximately 0.00018 mg/kg. Assuming accumulation of the assessed chemical in soil for 5 and 10 years under repeated irrigation, the concentration of assessed chemical in the applied soil in 5 and 10 years may be approximately 0.0009 mg/kg and 0.0018 mg/kg, respectively.

7.2. Environmental Effects Assessment
No ecotoxicity studies on the assessed chemical were submitted.

7.2.1. Predicted No-Effect Concentration
The Predicted No-Effect Concentration (PNEC) has not been calculated as no ecotoxicity studies were available.

7.3 Environmental Risk Assessment

A risk quotient (PEC/PNEC) for the assessed chemical was not calculated, as no ecotoxicity studies were available. The assessed chemical is unlikely to reach ecotoxicologically significant concentrations in the environment based on its annual importation quantity. On the basis of the low import volume, the assessed chemical is not considered to pose an unreasonable risk to the environment.

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