File No: LTD/1759

July 2014

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Chemical in Irgazin Orange EH 1287

This Assessment has been compiled in accordance with the provisions of the *Industrial Chemicals (Notification and Assessment) Act 1989* (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 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.

For the purposes of subsection 78(1) of the Act, this Public Report may be inspected at our NICNAS office by appointment only at Level 7, 260 Elizabeth Street, Surry Hills NSW 2010.

This 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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SUMMARY

The following details will be published in the NICNAS *Chemical Gazette:*

ASSESSMENT REFERENCE	APPLICANT(S)	CHEMICAL OR TRADE NAME	HAZARDOUS CHEMICAL	INTRODUCTION VOLUME	USE
LTD/1759	BASF Australia Ltd	Chemical in Irgazin Orange EH 1287	ND*	≤ 1 tonne per annum	Colourant for industrial and decorative paints

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
Based on the available data provided for toxicity, the notified chemical cannot be classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

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

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

Environmental risk assessment
On the basis of the PEC/PNEC ratio and the assessed use pattern, the notified chemical is not considered to pose an unreasonable risk to the environment.

Recommendations

CONTROL MEASURES

Occupational Health and Safety

- A person conducting a business or undertaking at a workplace should implement the following isolation and engineering controls to minimise occupational exposure to the notified chemical as introduced:
  - Enclosed mixing processes during reformulation where possible.
  - Local exhaust ventilation when the chemical is handled in powder form.

- 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 notified chemical as introduced:
  - Avoid inhalation of aerosols.

- 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 notified chemical as introduced:
  - Glasses
  - Gloves
  - Dust mask
  - Coveralls

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

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

- If products and mixtures containing the notified chemical are classified as hazardous to health in accordance with the *Globally Harmonised System for the 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.

Disposal

- The notified chemical should be disposed of to landfill.

Emergency procedures

- Spills or accidental release of the notified chemical should be handled by physical 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 chemical 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 chemical, have post-assessment regulatory obligations to notify NICNAS when any of these circumstances change. These obligations apply even when the notified chemical 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 importation volume exceeds one tonne per annum notified chemical;

or

(2) Under Section 64(2) of the Act; if
  - the function or use of the chemical has changed from colourant for industrial and decorative paints, or is likely to change significantly;
  - the amount of chemical being introduced has increased, or is likely to increase, significantly;
  - the chemical has begun to be manufactured in Australia;
  - additional information has become available to the person as to an adverse effect of the chemical 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 (M)SDS of the product containing the notified chemical provided by the notifier was reviewed by NICNAS. The accuracy of the information on the (M)SDS remains the responsibility of the applicant.

ASSESSMENT DETAILS

1. APPLICANT AND NOTIFICATION DETAILS

APPLICANT
BASF Australia Ltd (ABN: 62 008 437 867)
Level 12, 28 Freshwater Place
SOUTHBANK VIC 3006

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

EXEMPT INFORMATION (SECTION 75 OF THE ACT)
Data items and details claimed exempt from publication: chemical name, other names, CAS number, molecular and structural formulae, molecular weight, analytical data, degree of purity, impurities, additives/adjuvants, and import volume.

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
No variation to the schedule of data requirements is claimed.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
EU

2. IDENTITY OF CHEMICAL

MARKETING NAME(S)
Irgazin Orange EH 1287 (product containing the notified chemical)

MOLECULAR WEIGHT
< 500 Da

ANALYTICAL DATA
Reference NMR and IR spectra were provided.

3. COMPOSITION

DEGREE OF PURITY
> 94%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Odourless orange powder

Property	Value	Data Source/Justification
Melting Point	> 235 °C	Measured (product)
Boiling Point	Not determined	Solid
Density	1200 kg/m^3 at 20 °C	(M)SDS (product)
Vapour Pressure	< 1.10^{-7} kPa at 25 °C (or 20 °C)	Measured
Water Solubility	3.8 × 10^{-5} g/L at 20 °C (mean value)	Measured
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities. However, the notified chemical is not expected to significantly hydrolyse under environmental conditions (pH 4 – 9).
Partition Coefficient (n-octanol/water)	log Pow = 2	Measured
Adsorption/Desorption	Not determined.	Expected to associate to soil, sediment

		and sludge based on its potential cationicity
Dissociation Constant	Not determined	The notified chemical has potential to be ionised under normal environmental pH range of 4 to 9
Particle Size	Inhalable fraction (< 100 μm): 100% Respirable fraction (< 10 μm): 15.7%	Measured (product)
Flash Point	Not determined	Solid (with very low vapour pressure)
Flammability	Not flammable	(M)SDS (product)
Autoignition Temperature	377 °C	(M)SDS (product)
Explosive Properties	Not expected to be explosive	The structural formula contains no functional groups that would imply explosive properties
Oxidising Properties	Not expected to have oxidising properties	The structural formula contains no functional groups that would imply oxidising properties

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

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

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

5. INTRODUCTION AND USE INFORMATION

MODE OF INTRODUCTION OF NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified chemical will not be manufactured in Australia. The notified chemical will be imported by sea into Australia as a component (< 5%) of the product Irgazin Orange EH 1287.

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

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

PORT OF ENTRY
Melbourne

IDENTITY OF MANUFACTURER/RECIPIENTS
BASF Australia Ltd

TRANSPORTATION AND PACKAGING
The notified chemical (at < 5% concentration) will be imported in 20 kg UN approved fibreboard cartons with two inner PE-lined paper bags. The imported product will be transported by road from the wharf to the contracted warehouse for storage then dispatched to customers.

USE
The notified chemical will be used in the manufacture of industrial and decorative paints.

OPERATION DESCRIPTION
Paint formulation
At the formulation sites, the imported product containing the notified chemical at < 5% will be weighed on mechanical scales or load cells. The weighed product will be added to the pre-mix vessel containing other raw materials. Local exhaust ventilation will be used as possible aerosol generation could occur. The pigment is

added in stages over 30 minutes and mixed to ensure a thorough wetting of all particles. Mixing and blending of paint components takes place in closed mixing vessels. After dispersion on bead mills, attritors or ball mills, the milled material is sampled and checked and adjusted if necessary. Further blending processes may occur prior to packaging. Automated filling of the final paint formulation into drums will be used. The final formulated product will contain < 1% of the notified chemical.

Trials are performed for new paint formulations (once a year) in the laboratories using small amount of the notified chemical (< 1 kg).

Paint Application/End-users
Formulated paints containing the notified chemical at < 1% will be applied by workers and the public to various substrates using rollers and brushes.

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)*
Transportation and storage	1-2	10-20
Formulation operators	4	50-100
Laboratory Technicians	2-4	50-100

EXPOSURE DETAILS
Transport and warehouse workers
Workers are not expected to be exposed to the notified chemical except in the case of accident. Dermal and ocular exposure may occur in the event of a leak or spill.

Paint formulation
Dermal, ocular and inhalation exposure to the notified chemical at < 5% may occur during weighing and adding the notified chemical to the mixing vessel. The process operators will be wearing appropriate personal protective Equipment (PPE) such as glasses, gloves, dust mask and coveralls. Local exhaust ventilation will be used as possible aerosol generation could occur. Mixing and blending of paint components takes place in closed mixing vessels.

Laboratory technicians may be exposed through dermal, ocular and inhalation routes to the notified chemical at < 5% concentration when sampling, testing and spray trialling for quality control (QC) of the paint formulations. These processes will be typically undertaken under local exhaust ventilation or in spray booths where appropriate extraction is available. Workers will wear appropriate personal protective equipment (PPE) (glasses, gloves, dust mask and coveralls).

Paint Application/End-users
Dermal, ocular and inhalation exposure to the notified chemical at < 1% concentration could occur during painting and cleaning up painting equipment. Workers will usually be wearing appropriate protective clothing.

6.1.2. Public Exposure
Public incidental dermal or ocular contact may occur during application of the decorative paints by brush or roller. It is not expected that the public would apply the paints by spray methods.

Public may have contact with the substrates coated with or containing the notified chemical. Once incorporated into the decorative paints, the notified chemical will be encapsulated in the dried paint films and will not be bioavailable.

6.2. Human Health Effects Assessment

The results from toxicological investigations conducted on the notified chemical are summarised in the

following table. For full details of the studies, refer to Appendix B.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 >2000 mg/kg bw; low toxicity
Skin irritation, EpiDerm	non-irritating
BCOP test, eye irritation	not corrosive or severely irritating
Mouse, skin sensitisation – Local lymph node assay (up to 25%)	no evidence of sensitisation
Mutagenicity – bacterial reverse mutation	non mutagenic
Genotoxicity – in vitro Chromosome Aberration, in Chinese Hamster V79 cells	non genotoxic

Toxicokinetics, metabolism and distribution.
No information is available on the toxicokinetics of the notified chemical. However, based on the low molecular weight <500 Da) and partition coefficient (log Pow = 2), absorption may occur; however, this may be limited by the low water solubility.

Acute toxicity.
The notified chemical was found to be of low acute oral (LD_{50} >2000 mg/kg) toxicity in the rat. Data on acute dermal and inhalation toxicity were not provided.

Irritation and sensitisation.
The notified chemical was predicted to be non-irritating to skin in an EpiDerm Reconstructed Three Dimensional Human Epidermis model test. It was considered not corrosive or severely irritating to eyes in a Bovine Corneal Opacity and Permeability (BCOP) test, in which the low scores suggested low potential for irritation. It is noted however that this *in vitro* method does not cover conjunctival effects. There was no evidence of skin sensitisation when the notified chemical was tested up to 25% in a modified LLNA study.

Repeated dose toxicity.
No data on repeated dose toxicity was provided.

Mutagenicity/Genotoxicity.
The notified chemical was not mutagenic in a bacterial reverse mutation study and was not clastogenic in an *in vitro* mammalian chromosome aberration test. In the latter test, an equivocal result for one of the test conditions was not seen when that part of the test was repeated.

Health hazard classification
Based on the data provided, the notified chemical is not classified according to the *Globally Harmonised System for the Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia, or the *Approved Criteria for Classifying Hazardous Substances* (NOHSC, 2004).

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The limited toxicological data provided for the notified chemical indicated that it is not acutely toxic or highly irritating, and is not a skin sensitiser. Dermal, ocular and inhalation exposure of workers to the notified chemical at < 5% may occur during formulation processes, particularly during emptying/weighing, transferring and quality control operations. The use of engineering controls such as local exhaust ventilation and personal protective equipment (PPE) such as glasses, gloves, dust mask and coveralls will minimise exposure. In addition, mixing processes are normally performed in closed vessels.

Workers applying paints may also have dermal and ocular exposure to the notified chemical at < 1%.

Therefore, provided that adequate control measures are in place to minimise worker exposure, the risk to workers from the use of paints containing the notified chemical (< 5% concentration) is not considered to be unreasonable.

6.3.2. Public Health

The public may come into contact with the notified chemical during application of the decorative paints. However, the low concentration of the notified chemical (<1%) in such paints is not considered to pose a risk to the public health.

The public may also come into contact with surfaces that have been coated with paints containing the notified chemical. However, once the notified chemical is incorporated into the decorative paints it will be encapsulated in the resin/polymer of paint films and will not be bioavailable.

Therefore, the risk to public health from exposure to paints containing the notified chemical (< 1% concentration) 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 notified chemical will not be manufactured in Australia; therefore, there will be no release from this activity. Environmental release during importation, transport and distribution may occur as a result of accidental spills. In the event of a spill, the notified chemical is expected to be contained and collected with a damp absorbent material (to lower dust levels). The solid waste is expected to be sent to a licensed off site waste disposal centre which is most likely to be disposed of to landfill.

During reformulation activities, solvent waste containing residues of the notified chemical (up to 0.5% of the total volume) from cleaning of the mixing vessel is expected to be sent to an onsite solvent recovery tank. The solid waste generated from the solvent recovery tank is expected to be disposed of to an approved landfill through a licensed waste contractor.

RELEASE OF CHEMICAL FROM USE

The notified chemical will be used as a tint in high quality decorative paints. The formulated products containing the notified chemical will be applied to substrates such as interior walls using brushes and rollers by professional or Do-It-Yourself (DIY) users.

The major release of the notified chemical to the aquatic environment is likely to be from the cleaning of application equipment, especially the brushes or rollers used by DIY users. It is expected that up to 5% (a commonly used assumption) of the imported quantity of notified chemical may be disposed of to sewers during the clean-up of paint application equipment. Notified chemical released to sewers is expected to be treated at the wastewater treatment facility during the waste water treatment processes. Empty containers are expected to be disposed of to landfill.

RELEASE OF CHEMICAL FROM DISPOSAL

The residual notified chemical remaining in empty containers is expected to be up to 2% of the total import volume, which is expected to be disposed of to landfill with the discarded containers. Paint drums containing the notified chemical (up to 4% of the total import volume) are expected to be sent to a drum recycler where the notified chemical is likely to be thermally decomposed during container reclamation processes. The disposal of the major fraction of the notified chemical will be linked to the ultimate disposal of the dried paint on painted articles. It is expected that the majority of the notified chemical will ultimately be disposed of to landfill in the form of discarded paint chips or as coated articles.

7.1.2. Environmental Fate

The notified chemical is not readily biodegradable based on the environmental fate study provided. For the details of the environmental fate study please refer to Appendix C. The notified chemical has a tendency to sorb to soil or sludge sediment based on its potential cationicity. Hence, the notified chemical that may be released to the sewer is expected to mainly partition to sludge during the sewage treatment processes in sewage treatment plants (STPs). The sludge containing notified chemical may be sent to landfill or applied to soils for land remediation. Notified chemical released to surface waters is expected to associate to suspended solids and

organic matter in water. Consequently, the notified chemical is not expected be significantly bioavailable to aquatic species. The notified chemical has potential cationicity. Therefore, it is unlikely to cross the lipid cell membrane and therefore, is not expected to bioaccumulate.

The majority of the notified chemical is expected to be sent to landfill with the associated articles. In landfill, the notified chemical is not expected to leach due to the expected adsorption to soil due to its potential cationicity. Ultimately, the notified chemical is expected to eventually degrade via biotic and abiotic processes in landfill or aquatic environment, or by thermal decomposition during the associated substrates' reclamation processes, to form water and oxides of carbon and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

No significant release of the notified chemical is expected from professional uses. However, the notified chemical may be released to sewers during its use in paint by Do-It-Yourself users. Therefore, as a worst case scenario, it is assumed that 5% of the entire volume will be discharged into sewers over 365 days per year. Assuming no removal of the notified chemical in STPs, the resultant Predicted Environmental Concentration (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	1,000	kg/year
Proportion expected to be released to sewer	5%	
Annual quantity of chemical released to sewer	50	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)	22.613	million
Removal within STP	0%	
Daily effluent production:	4,523	ML
Dilution Factor - River	1.0	
Dilution Factor - Ocean	10.0	
PEC - River:	0.03	µg/L
PEC - Ocean:	0.003	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 notified 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 0.2 µg/kg. Assuming accumulation of the notified chemical in soil for 5 and 10 years under repeated irrigation, the concentration of notified chemical in the applied soil in 5 and 10 years may be approximately 1.0 µg/kg and 2.0 µg/kg, respectively.

7.2. Environmental Effects Assessment

Environmental effect endpoints for the notified chemical are presented in the table below. Details of the studies can be found in Appendix C.

Endpoint	*Result*	*Assessment Conclusion*
Fish Toxicity (96 h)	LL50 > 100 mg/L (filtered WAF)	Not harmful to fish
Daphnia Toxicity (48 h)	EL50 > 100 mg/L (filtered WAF)	Not harmful to aquatic invertebrates
Algal Toxicity (72 h)	E_rL50 = > 100 mg/L (filtered WAF)	Not harmful to algae

WAF: Water Accommodated Fraction

Based on the above reported endpoints for the notified chemical, it is not considered to be harmful to fish, daphnia and algae. Therefore, the notified chemical is not harmful to aquatic organisms. Consequently, Under the Globally Harmonised System of Classification and Labelling of Chemicals (GHS; United Nations, 2009), the notified chemical has not been formally classified for acute and chronic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effect concentration (PNEC) for the notified chemical has been calculated and is presented in the table below. The PNEC is calculated based on the common endpoint for all the test species (fish, daphnia, and algae). Since acute ecotoxicity endpoints for aquatic species from three trophic levels are available, an assessment factor of 100 has been used.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
EC50 (Fish).	> 100	mg/L
Assessment Factor	100	
PNEC:	> 1,000	µg/L

7.3. Environmental Risk Assessment

Based on the above PEC and PNEC values, the following Risk Quotient (Q) has been calculated:

Risk Assessment	***PEC µg/L***	***PNEC µg/L***	***Q***
Q - River:	0.03	> 1000	< 0.00003
Q - Ocean:	0.003	> 1000	< 0.000003

The Risk Quotients (Q = PEC/PNEC) for a conservative discharge scenario have been calculated to be << 1 for the river and ocean compartments. The notified chemical is not rapidly biodegradable in the environment. However, it is not likely to be significantly bioavailable based on its expected low potential to bioaccumulate. On the basis of the assessed use pattern, it is unlikely to result in ecotoxicologically significant concentrations in aquatic environment. Therefore, the notified chemical is not expected to pose an unreasonable risk to the environment.

APPENDIX A: PHYSICAL AND CHEMICAL PROPERTIES

Vapour Pressure $< 1.10^{-7}$ kPa at 25 °C (or 20 °C)

Method OECD TG 104 Vapour Pressure.
Remarks The vapour pressure was determined for the notified chemical (solid) by the effusion method and weight loss.
Test Facility BASF (2012)

Water Solubility 3.8×10^{-5} g/L at 20 °C (mean value)

Method OECD TG 105 Water Solubility.
EC Council Regulation No 440/2008 A.6 Water Solubility.
Remarks Flask Method. The water solubility of the notified chemical was in a range of 0.039 mg/L to 0.034 mg/L (measured after 72, 96, 264, 360 and 384 hours). The mean water solubility of the test substance was determined to be 3.8×10^{-5} g/L at approximately at 20 °C. The solubility of the test substance after the 48 hours test period was 0.099 mg/L approximately at 20 °C, which was considered as an outlier and was not included in determination of the mean value.
Test Facility BMG (2013a)

Partition Coefficient (n-octanol/water) log Pow = 2

Method OECD TG 117 Partition Coefficient (n-octanol/water).
EC Council Regulation No 440/2008 A.8 Partition Coefficient.
Remarks HPLC method. Log Pow value of the notified chemical was determined to be 2 at a column temperature of 23 °C and pH 10 (pH of the buffer used for the preparation of the eluent).

The octanol solubility of the test substance was <11.24 mg/L. Whereas, the water solubility of the test substance was about 0.038 mg/L. Hence, the log Pow value was estimated from the single solubilities as less than 2.5. This value corresponds to the value determined with HPLC method (log Pow = 2.0).
Test Facility BASF (2013)

APPENDIX B: TOXICOLOGICAL INVESTIGATIONS

B.1. Acute toxicity – oral

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 423 Acute Oral Toxicity – Acute Toxic Class Method.
Species/Strain	Rat/Wistar/Crl:WI (Han)
Vehicle	Olive oil
Remarks - Method	No protocol deviation occurred during the study. Two test groups of three fasted Wistar rats were administered with a single oral dose of 2000 mg/kg bw of the notified chemical by gavage.

RESULTS

Group	*Number and Sex of Animals*	*Dose mg/kg bw*	*Mortality*
1	3 F	2000	0
2	3 F	2000	0

LD50	>2000 mg/kg bw
Signs of Toxicity	No mortality has occurred in both administered groups. No clinical signs were observed during clinical examination, and no macroscopic pathological findings at necropsy.
Effects in Organs	None. The mean body weights of the test groups increased throughout the study period within the normal range.
Remarks - Results	No treatment related changes were observed.
CONCLUSION	The notified chemical is of low toxicity via the oral route.
TEST FACILITY	Bioassay Labor fur biologische Analytik GmbH (2012)

B.2. Irritation – skin (in vitro)

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 439 In vitro Skin Irritation: Reconstructed Human *Epidermis* Test Method EpiDerm™ Reconstructed Three Dimensional Human Epidermis Model
Vehicle	DMEM
Remarks - Method	Skin irritation determination method following OECD Guideline for testing of chemicals No. 404. Tissue destruction was determined by measuring the metabolic activity (mitochondrial dehydrogenase activity) of the tissue after exposure/post incubation using colorimetric test. The reduction of the metabolic activity is measured by reduced formazan production after incubation with MTT (tetrazolium salt). The formazan production of the test substance treated epidermal tissues was compared to the negative control tissues. The quotient of both values shows the relative tissue viability. Two tests were performed. Three EpiDerm tissue samples per test were incubated with the test substance for one hour followed by a 42 hours post incubation period. In the second test, an additional MTT-reduction control (killed tissue control, KC) was introduced. - Negative control (NC): PBS, sterile. - Positive control (PC): 5% sodium dodecyl sulfate in deionised water, sterile. - MTT-reduction control (KC): PBS, sterile or test substance.

RESULTS

Test 1

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	1.995	100	12.49
Test substance	1.940	97	14.59
Positive control	0.060	3	0.15

OD = optical density; SD = standard deviation

Test 2

Test material	*Mean OD_{570} of triplicate tissues*	*Relative mean Viability (%)*	*SD of relative mean viability*
Negative control	2.275	100	4.83
Test substance	1.602	70	9.68
Positive control	0.052	2	0.06

Remarks - Results

The test substance was able to reduce MTT directly. Therefore as test substance residue remained after rinsing in the first test run a second test run was performed including an additional MTT reduction control (KC). However, the result of the KC did not indicate an increased MTT reduction; therefore the KC was not used for viability calculation.

CONCLUSION

The notified chemical was non-irritating to the skin under the conditions of the test.

TEST FACILITY

BASF SE (2012)

B.3. Irritation – eye (in vitro)

TEST SUBSTANCE

Notified Chemical

METHOD

OECD TG 437 Bovine Corneal Opacity and Permeability Test Method for Identifying Ocular Corrosives and Severe Irritants

Vehicle

Deionised water

Remarks - Method

No significant protocol deviations.
Negative control (NC): Deionised water
Positive control (PC): Imidazole at 20% in deionised water

RESULTS

Test material	*Mean opacities of triplicate tissues (SD)*	*Mean permeabilities of triplicate tissues (SD)*	*IVIS (SD)*
Vehicle control	5.4 (2.5)	-0.004 (0.003)	5.3 (2.5)
*Test substance**	1.8 (4.4)	0.006 (0.003)	1.9 (4.4)
*Positive control**	69.4 (13.1)	3.644 (0.322)	124.0 (13.6)

SD = Standard deviation; IVIS = in vitro irritancy score
*Corrected for background values

Remarks - Results

CONCLUSION

The notified chemical was not corrosive or a severe eye irritant under the conditions of the test.

TEST FACILITY

BASF SE (2012)

B.4. Skin sensitisation – mouse local lymph node assay (LLNA)

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 442B Local Lymph Node Assay: BrdU-ELISA
Species/Strain	Mouse/ CBA/CaOlaHsd
Vehicle	Acetone:Olive oil (4:1 v/v)
Remarks - Method	The highest concentration tested was noted by the study authors to be the highest concentration that could be technically used, whilst avoiding systemic toxicity and excessive local irritation as determined based on preliminary experiments. The criterion for consideration as a sensitiser was a 1.6 fold or greater increase in the stimulation index (SI). Positive control: 25% α-Hexyl cinnamaldehyde in acetone:olive oil (4:1).

RESULTS

Concentration (% w/w)	*Proliferative response (Mean lymph node cell count x10^6)*	*Stimulation Index (Test/Control Ratio)*
Test Substance		
0 (vehicle control)	17.8	1.0
5%	20.5	1.2
10%	17.1	1.0
25%	13.8	0.8
Positive Control		
25%	37.4*	2.1

*Statistically significant increase versus control group ($p < 0.05$)

Remarks - Results	No mortality was observed. The animals did not show any sign of systemic toxicity or local skin irritation during the course of the study. An EC1.6 value could not be determined as all test article SIs were below the threshold 1.6. Ear weights in the test item groups were not increased, compared to the vehicle control. A deviation of 11.8% in one test item preparation was reported as an amendment of the analytical measurement values in the study. The author indicated that the impact of the deviation is considered minimal as it did not influence the results of the study. The positive control showed an increase in SI >1.6, confirming the validity of the test system.
CONCLUSION	There was no evidence of induction of a lymphocyte proliferative response indicative of skin sensitisation to the notified chemical under the conditions of the test.
TEST FACILITY	Bioassay Labor fur biologische Analytik GmbH (2012)

B.5. Genotoxicity – bacteria

TEST SUBSTANCE	Notified Chemical
METHOD	OECD TG 471 Bacterial Reverse Mutation Test. EC Directive 2000/32/EC B.13/14 Mutagenicity – Reverse Mutation Test using Bacteria. Plate incorporation procedure – Test 1 Pre incubation procedure – Test 2
Species/Strain	*S. typhimurium*: TA1535, TA1537, TA98, TA100 *E. coli*: WP2uvrA
Metabolic Activation System	S9-mix from phenobarbital / β-naphthaoflavone induced rat (SD) liver

Concentration Range in Main Test	a) With metabolic activation: 33-5600 µg/plate (33, 100, 333, 1000, 2800 and 5600 µg/plate). b) Without metabolic activation: 33-5600 µg/plate (33, 100, 333, 1000, 2800 and 5600 µg/plate).
Vehicle	DMF (dimethylformamide)
Remarks - Method	There were no deviations from the study protocol. Negative controls: Additional plates treated with soft agar, S9 mix and buffer were used as sterility control for vehicle or test substance. Vehicle control: with and without S9 mix contains the vehicle used for the test substance at the same concentration and volume for all tester strains. Positive controls in DMSO: With S9 mix: 2-aminoanthracene (2-AA) dissolved in DMSO for all tester strains. Without S9 mix: Strains TA 1535 and TA 100: N-methyl-N'-nitro-N-nitrosoguanidine (MNNG) Strain TA 98: 4-nitro-o-phenylenediamine (NOPD) Strain TA 1537: 9-aminoacridine (AAC) Strain *E. coli*: WP2uvrA : 4-nitroquinoline-N-oxide (4-NQO)

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/plate) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		>5600	>333	negative
Test 2		>5600	>333	negative
Present				
Test 1		>5600	>333	negative
Test 2		>5600	>333	negative

Remarks - Results	No bacteriotoxicity effect was observed under all test conditions. Precipitation of the test substance was found from 333 µg/plate. Significant increases in revertants were seen in the positive controls, confirming the validity of the test system.

CONCLUSION The notified chemical was not mutagenic to bacteria under the conditions of the test.

TEST FACILITY BASF SE (2012)

B.6. Genotoxicity – in vitro

TEST SUBSTANCE Notified Chemical

METHOD OECD TG 473 In vitro Mammalian Chromosome Aberration Test.

Species/Strain	Chinese Hamster
Cell Type/Cell Line	V79 cells
Metabolic Activation System	S9 fraction from phenobarbital/β-naphthoflavone induced rat liver
Vehicle	Suspension in deionised water
Remarks - Method	No significant protocol deviations. Solvent controls: Deionised water Positive controls: Without metabolic activation: EMS (ethylmethane sulfonate) and with metabolic activation: CPA (cyclophosphamide). Three independent experiments were performed. The highest applied concentration was 1400 µg//mL equivalent to approximately 3 mM). Dose selection was based on the toxicity data and the occurrence of test item precipitation.

Metabolic Activation	*Test Substance Concentration (µg/mL)*	*Exposure Period*	*Harvest Time*
Absent			
Test 1	0.9, 2.3*, 5.7*, 14.3*, 35.8, 89.6, 224.0*, 1400.0*	4 h	18 h
Test 2	0.9, 2.3, 5.7, 14.3*, 35.8*, 89.6, 224.0, 560.0*, 1400.0*	18 h	18 h
Test 3	0.9, 2.3, 5.7, 14.3*, 35.8*, 89.6, 224.0, 560.0*, 1400.0*	28 h	28 h
Present			
Test 1	0.9, 2.3, 5.7*, 14.3*, 35.8*, 89.6, 224.0, 560.0, 1400.0	4 h	18 h
Test 2	5.0, 7.5, 10.0*, 12.5*, 15.0*, 17.5*, 20.0*, 30.0*, 40.0*	4 h	18 h
Test 3	0.9, 2.3, 5.7, 14.3*, 35.8*, 89.6, 224.0*, 560.0*, 1400.0	4 h	28 h

*Cultures selected for metaphase analysis.

RESULTS

Metabolic Activation	*Test Substance Concentration (µg/mL) Resulting in:*			
	Cytotoxicity in Preliminary Test	*Cytotoxicity in Main Test*	*Precipitation*	*Genotoxic Effect*
Absent				
Test 1		>1400.0	≥89.6	Negative
Test 2		>1400.0	≥35.8	Negative
Test 3		>1400.0	≥35.8	Negative
Present				
Test 1		>35.8	≥35.8	Equivocal
Test 2		>40.0	≥20.0	Negative
Test 3		>560	≥35.8	Negative

Remarks - Results

Doses were chosen on the basis of toxicity and precipitation. In the absence and presence of S9 mix for the three experiments no clear cytotoxicity up to the highest dose was observed except in the experiment 2 in the presence of S9 mix a clear cytotoxicity was observed at the highest evaluated concentration (evaluation was limited by severe test item precipitation on the slides).
In Test 1 with metabolic activation, there were increases in aberrant cells that were above the historical solvent controls, and the results were statistically significant at one concentration. However a repeat with the same test conditions (Test 2) did not show these increases, nor were the structural aberrations in the other test groups higher than the historical solvent controls. The occurrence of polyploidy and endomitotic metaphases was within the rates of solvent controls. Significant increases in aberrant cells were seen in all the positive controls, confirming the validity of the test system.

CONCLUSION

The notified chemical was not considered clastogenic to Chinese Hamster V79 cells treated in vitro under the conditions of the test.

TEST FACILITY

Harlan Cytotest Cell Research GmbH (2013)

APPENDIX C: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

C.1. Environmental Fate

C.1.1. Ready biodegradability

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sludge
Exposure Period	28 days
Auxiliary Solvent	Not reported
Analytical Monitoring	The total organic carbon (TOC) was analysed using a TOC-analyser (Shimadzu TOC-5000A)
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported.

RESULTS

Test substance		*Aniline (Reference substance)*	
Day	*% Degradation*	*Day*	*% Degradation*
2	1	2	2
14	-2	14	84
28	-2	28	88

Remarks - Results	All validity criteria for the test were satisfied. The toxicity control exceeded 25% biodegradation (required by guideline) showing that the toxicity to micro-organisms was not a factor resulting the low biodegradability of the test substance. The degree of degradation of the test substance after the cultivation period was -2%. Therefore, the test substance cannot be classified as readily biodegradable according to the OECD 301 B guideline
CONCLUSION	The notified chemical is not readily biodegradable
TEST FACILITY	BASF (2012)

C.2. Ecotoxicological Investigations

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 203 Fish, Acute Toxicity Test – Static Test
Species	*Danio rerio* (Zebrafish)
Exposure Period	96 hours
Auxiliary Solvent	Not reported
Water Hardness	(146 – 188) mg $CaCO_3$/L
Analytical Monitoring	HPLC Analysis
Remarks – Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The fish ecotoxicity test was conducted in Water Accommodated Fractions (WAF) of the notified chemical as it has low water solubility. WAF of a nominal loading rate of 100 mg/L was prepared by moderately stirring the test substance in natural water for 72 hours. The WAF was then filtered prior to use in the test.

RESULTS

Nominal Concentration (WAF;mg/L)	*Number of Fish*	*Cumulative mortality (%)*				
		2 h	*24 h*	*48 h*	*72 h*	*96 h*
Control	7	0	0	0	0	0
100	7	0	0	0	0	0

LL50	> 100 mg/L at 96 hours (Filtered WAF)
NOEL	100 mg/L at 96 hours (Filtered WAF)
Remarks – Results	All validity criteria for the test were satisfied. The actual concentrations of the test substance in WAFs were measured periodically at 0, 24, 48, and 96 hours within the 96-h test period. The analysis confirmed the low solubility of the test substance. All measurements were below the quantification limit of the analytical method (LOQ = 0.1 mg/L). Therefore, the median lethal loading rate (LL50) and no observed effect loading rate (NOEL) values were determined based on the nominal loading rate.
CONCLUSION	The notified chemical is not harmful to fish
TEST FACILITY	BMG (2013b)

C.2.1. Acute toxicity to aquatic invertebrates

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 202 *Daphnia* sp. Acute Immobilisation Test – Static Test
Species	*Daphnia magna*
Exposure Period	48 hours
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	HPLC Analysis
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The daphnia ecotoxicity test was conducted in Water Accommodated Fractions (WAF) of the notified chemical as it has low water solubility. WAF of a nominal loading rate of 100 mg/L was prepared by moderately stirring the test substance in natural water for a minimum period of 96 hours. The WAF was then filtered prior to use in the test.

RESULTS

Nominal Concentration (WAF;mg/L)	*Number of D. magna*	*Cumulative % Immobilised*	
		24 h	*48 h*
Control	60	0	0
100	40	0	5

EL50	> 100 mg/L at 96 hours (Filtered WAF)
NOEL	≥ 100 mg/L at 96 hours (Filtered WAF)
Remarks - Results	All validity criteria for the test were satisfied. The actual concentrations of the test substance in WAFs were measured periodically at 0, 24 and 48 hours within the 48-h test period. The analysis confirmed the low solubility of the test substance. All measurements were below the quantification limit of the analytical method (LOQ = 0.1 mg/L). Therefore, the median lethal loading rate (LL50) and no observed effect loading rate (NOEL) values were determined based on the nominal loading rate.
CONCLUSION	The notified chemical is not harmful to aquatic invertebrates
TEST FACILITY	BMG (2013c)

C.2.2. Algal growth inhibition test

TEST SUBSTANCE	Notified chemical
METHOD	OECD TG 201 Alga, Growth Inhibition Test
Species	*Desmodesmus subspicatus*
Exposure Period	72 hours
Concentration Range	Nominal: 100 mg/L
Auxiliary Solvent	Not reported
Water Hardness	Not reported
Analytical Monitoring	HPLC Analysis
Remarks - Method	The test was conducted according to the guidelines above and good laboratory practice (GLP) principles. No significant deviations from the test guidelines were reported. The algal ecotoxicity test was conducted in Water Accommodated Fractions (WAF) of the notified chemical as it has low water solubility. WAF of a nominal loading rate of 100 mg/L was prepared by moderately stirring the test substance in natural water for a minimum period of 96 hours. The WAF was then filtered prior to use in the test. The resulting water soluble fraction (WSF) was used in the test.

RESULTS

Biomass (72 h) (Filtered WAF)		*Growth (72 h) (Filtered WAF)*	
E_yL50 (mg/L)	*NOE_yL (mg/L)*	*E_rL50 (mg/L)*	*NOE_rL (mg/L)*
> 100	100	> 100	100

Remarks - Results	All validity criteria for the test were satisfied. The actual concentrations of the test substance in WAFs were measured periodically at 0, 24, 48 and 72 hours within the 72-h test period. The analysis confirmed the low solubility of the test substance. All measurements were below the quantification limit of the analytical method (LOQ = 0.1 mg/L). Therefore, the endpoints were determined based on the nominal loading rate.
CONCLUSION	The notified chemical is not harmful to algae
TEST FACILITY	BMG (2013d)

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