File No: LTD/1943

December 2016

NATIONAL INDUSTRIAL CHEMICALS NOTIFICATION AND ASSESSMENT SCHEME (NICNAS)

PUBLIC REPORT

Poly(oxy-1,2-ethanediyl), α-sulfo-ω-(isotridecyloxy)-, sodium salt (1:1)

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 and Energy.

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

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Director
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/1943	BASF Australia Ltd	Poly(oxy-1,2-ethanediyl), α-sulfo-ω-(isotridecyloxy)-, sodium salt (1:1)	ND*	≤ 1 tonne per annum	Component of construction products

*ND = not determined

CONCLUSIONS AND REGULATORY OBLIGATIONS

Hazard classification
As only limited toxicity information was provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

The environmental hazard classification according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS) is presented below. Environmental classification under the GHS is not mandated in Australia and carries no legal status but is presented for information purposes.

Hazard classification	*Hazard statement*
Acute (Category 3)	H402 - Harmful to aquatic life

Human health risk assessment
Provided that the recommended controls are being adhered to, under the conditions of the occupational settings described, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

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

Environmental risk assessment
On the basis of the reported use pattern and limited expected aquatic release, the notified polymer 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 engineering controls to minimise occupational exposure to the notified polymer during reformulation:
  - Automated/enclosed systems where possible

- A person conducting a business or undertaking at a workplace should implement the following safe work practices to minimise occupational exposure to the notified polymer during reformulation:
  - 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 notified polymer during reformulation and end-use:
  - Protective clothing
  - Gloves

- Goggles

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 polymer 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.

Disposal

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

Emergency procedures

- Spills or accidental release of the notified polymer should be handled by containment, physical 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 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 importation volume exceeds one tonne per annum notified polymer;

or

(2) Under Section 64(2) of the Act; if
- the function or use of the polymer has changed from a component of construction products, or is likely to change significantly;
- the amount of polymer being introduced has increased, or is likely to increase, significantly;
- the polymer has begun to be manufactured in Australia;
- additional information has become available to the person as to an adverse effect of the polymer on occupational health and safety, public health, or the environment.

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

(Material) Safety Data Sheet
The (M)SDS of a product containing the notified polymer 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: Synthetic polymer with Mn < 1,000 Da (1 tonne or less per year)

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

VARIATION OF DATA REQUIREMENTS (SECTION 24 OF THE ACT)
Variation to the schedule of data requirements is claimed for all physico-chemical endpoints.

PREVIOUS NOTIFICATION IN AUSTRALIA BY APPLICANT(S)
None

NOTIFICATION IN OTHER COUNTRIES
None

2. IDENTITY OF CHEMICAL

MARKETING NAME
Disponil® BES 20 (product containing the notified polymer at < 40% concentration)

CAS NUMBER
150413-26-6

CHEMICAL NAME
Poly(oxy-1,2-ethanediyl), α-sulfo-ω-(isotridecyloxy)-, sodium salt (1:1)

MOLECULAR WEIGHT
Mn < 1,000 Da

ANALYTICAL DATA
Reference GPC data provided

3. COMPOSITION

DEGREE OF PURITY
> 85%

4. PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AT 20 °C AND 101.3 kPa: Colourless to yellow liquid*

Property	Value	Data Source/Justification
Pouring Point	Not determined	Introduced in aqueous solution
Boiling Point	Not determined	Introduced in aqueous solution
Density*	1,060 kg/m^3 at 20 °C	(M)SDS
Vapour Pressure	Not determined	Expected to be low based on molecular weight
Water Solubility	Soluble	(M)SDS
Hydrolysis as a Function of pH	Not determined	Contains hydrolysable functionalities

Property	Value	Data Source/Justification
Partition Coefficient (n-octanol/water)	Not determined	Expected to partition to phase boundaries based on surfactant properties
Adsorption/Desorption	Not determined	Expected to adsorb strongly to soil and sediment based on surfactant properties
Dissociation Constant	Not determined	The notified polymer is a salt and expected to be ionised under environmental conditions.
Flash Point	Not determined	Introduced in aqueous solution
Flammability	Not determined	Introduced in aqueous solution
Autoignition Temperature	Not determined	Introduced in aqueous solution
Explosive Properties	Not determined	Contains no functional groups that would imply explosive properties
Oxidising Properties	Not determined	Contains no functional groups that would imply oxidative properties

* Properties of the product containing the notified polymer at < 40% concentration in aqueous solution

DISCUSSION OF PROPERTIES

Reactivity
The notified polymer 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 polymer 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 NOTIFIED CHEMICAL (100%) OVER NEXT 5 YEARS
The notified polymer will not be manufactured in Australia. It will be imported at < 40% concentration in aqueous solution. In the future, finished construction products containing the notified polymer at < 2% concentration will also be imported.

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

TRANSPORTATION AND PACKAGING
The product containing the notified polymer at < 40% concentration will be imported in 25 kg open head plastic drums or 1,000 L intermediate bulk containers (IBC). In the future, finished construction products containing the notified polymer at < 2% concentration will be imported in 1,000 L IBCs. All imported products containing the notified polymer will be transported by road for distribution to warehouses around the country.

USE
The notified polymer will be used as an anionic surfactant for construction products, including flexible adhesives, waterproofing membranes and concrete/cement admixtures. Typical final use concentrations for the notified polymer will be < 0.1% in concrete or cement and < 2% in flexible adhesives or waterproofing membranes. The finished products containing the notified polymer will be used by the construction industry only and will not be sold to the public.

OPERATION DESCRIPTION

Reformulation
The imported product containing the notified polymer at < 40% concentration will be reformulated at customer sites of the notifier. The product containing the notified polymer will be pumped or poured from the containers into a blending tank and blended with other components to produce finished construction products, such as

flexible adhesives, waterproofing membranes and concrete admixtures. The concrete admixture products containing the notified polymer at < 2% concentration will be packed into 1,000 L bulk containers, 200 L drums or 20 L cubes and sold to concrete manufacturers. The flexible adhesives and waterproofing membranes containing the notified polymer at < 2% concentration will be packed in 20 L pails for supply to the construction industry. The reformulation and packaging processes are expected to be mainly automated with minor manual handling.

After reformulation, empty containers, pipelines and hoses will be rinsed with water, and the waste water will be collected for recycling.

End use
At construction sites, the flexible adhesives and waterproofing membranes containing the notified polymer at < 2% concentration will directly be used by professional workers for various applications.

At concrete production sites, the concrete admixtures containing the notified polymer at < 2% concentration will be automatically pumped and dosed from the packaging containers into a mixing tank together with other ingredients. After blending, the final concrete will contain < 0.1% concentration of the notified polymer which will be fed into pre-cast concrete moulds, or into ready-mix concrete trucks for transport to construction sites.

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	2	5 – 10
Bulk loading/unloading	2 – 3	90 – 100
Reformulation	8	220
End users	< 1	90 – 100

EXPOSURE DETAILS

Transport and storage
Exposure of transport and storage workers to the notified polymer is not expected except in the event of accidental spill or breach of packaging.

Reformulation
During reformulation, dermal and incidental ocular exposure to the notified polymer at < 40% concentration may occur during transfer, blending and equipment cleaning processes. Inhalation of the notified polymer for workers is not expected unless aerosol and mist formation occurs. Exposure of workers to the notified polymer will be limited as the reformulation processes will take place in industrial settings and workers are expected to wear personal protective equipment (PPE) including protective clothing, gloves and goggles.

End use
During construction processes involving end use of finished products containing the notified polymer, workers may be exposed to the notified polymer at < 2% concentration. The main exposure route is expected to be dermal, while incidental ocular exposure is possible. Exposure to the notified polymer is expected to be limited due to its low use concentration and the use of PPE by workers.

Construction workers may come into contact with solidified concrete/cement or flexible adhesives/membranes containing the notified polymer; however, in this state the notified polymer will be bound within the hardened matrix and is not expected to be available for exposure.

6.1.2. Public Exposure
The products containing the notified polymer will only be used by industry and will not be sold to the public. Members of the public may come into contact with solidified concrete/cement and flexible adhesives/membranes

containing the notified polymer. However, the notified polymer will be bound within the hardened matrix and is not expected to be bioavailable for exposure.

6.2. Human Health Effects Assessment

No toxicology study reports on the notified polymer were submitted. The results from toxicological investigations conducted on an acceptable analogue of the notified polymer are summarised in the following table. Detailed study reports of the investigations were not provided.

Endpoint	*Result and Assessment Conclusion*
Rat, acute oral toxicity	LD50 > 5,000 mg/kg bw; low toxicity
Rat, acute dermal toxicity	LD50 > 5,000 mg/kg bw; low toxicity
Rat, acute inhalation toxicity	LC50 > 3 mg/L/4 hour
Rabbit, skin irritation	irritating
Rabbit, eye irritation	slightly irritating
Rat, repeat dose oral toxicity – 28 days	NOEL = 1,000 mg/kg bw/day
Rat, repeat dose oral toxicity – 90 days	NOEL = 480 mg/kg bw/day

Toxicokinetics

No toxicokinetic data on the notified polymer were submitted. Based on the low molecular weight (< 1,000 Da) with large proportion (> 75%) of low molecular weight species (< 500 Da), absorption across biological membranes may occur. However this may be limited by the high water solubility and ionic character of the notified polymer.

Acute toxicity

The acute oral toxicity of the analogue was investigated in rats, rabbits and dogs. Rats given 10,000 µl/kg bw and 6,810 µl/kg bw of the test substance showed diarrhoea and dyspnoea after 4 hours, whereas on the second day all test rats behaved normally. No mortalities, clinical signs of toxicity or pathological findings were observed in rabbits dosed at up to 10,000 µl/kg bw. Beagle dogs given 10,000 µl/kg bw vomited whereas doses of 6,810 and 3,830 µl/kg bw were well tolerated, with the exception of slight diarrhoea.

Acute dermal toxicity studies on the analogue were conducted in rats and rabbits. Rats exposed to 5,000 µl/kg bw on a clipped skin area of 50 cm^2 for 24 hours developed slight erythema and oedema that resolved in 8 days. Rabbits exposed to 4,000 µl/kg bw on a clipped skin area of 267 cm^2 for 24 hours developed severe erythema and oedema that resolved after 8 and 14 days, respectively. Pathological examination showed bile-coccidiosis gangs in 2 of the 6 test rabbits.

The acute inhalation toxicity of the analogue was investigated in rats. Rats were exposed to an aerosol of the test substance at 3.0 mg/L (actual) for 4 h with head nose only technique. Observed immediate clinical signs were staggered breathing, bloody eyes/nose and shaggy fur which resolved after 3 days. There were no mortalities.

Based on the available information, the notified polymer is likely to be of low acute toxicity.

Irritation and sensitisation

The skin and eye irritation potential of the analogue was studied in rabbits.

For skin irritation, six test rabbits received an occlusive test patch of (2.5 × 2.5 cm^2) soaked with the test substance (0.5 mL) to the clipped back skin for 24 hours. Moderate to severe erythema and slight to severe oedema were observed during the course of the study with mean values (average of 6 animals and 24 h/72 h measurements) for erythema and oedema of 2.9 and 1.7, respectively. After 8 days all effects disappeared to scaling. Based on the findings, the analogue was classified as a Category 2 skin irritant (H315 – Causes skin irritation) under the GHS.

For eye irritation, six test rabbits received 0.1 mL test substance applied to the conjunctival sac. No effects on the cornea or iris were reported. Conjunctive redness and chemosis were observed during the course of the study with mean values (average of 6 animals and 24 h/72 h measurements) for redness and chemosis of 0.8 and 0.2, respectively. The analogue was slightly irritating to eyes; however the findings observed did not warrant hazard classification under the GHS.

Based on the available information, the notified polymer is likely to have the potential for skin irritation and may also be slightly irritating to eyes.

No information on skin sensitisation potential of the notified polymer or the analogue was provided.

Repeated dose toxicity
Repeated dose oral toxicity of the analogue was investigated in two rat studies.

In a 28-day feeding study, rats were fed with the test substance in the diet at doses up to 50,000 ppm. A 2-week recovery period was included in the study. An influence on body weight gain was observed for males treated at 50,000 ppm. Variations in clinical chemistry (urea, inorganic phosphate, calcium and triglycerides) were observed in males treated at 25,000 and 50,000 ppm but these were not considered to be related to the test substance. Biochemistry showed increased activity in serum glutamic pyruvate transaminase levels within males treated at 12,500 to 50,000 ppm, as well as a decrease of alkaline phosphatase activity. Slight liver necrosis was found in some test animals correlating with the biochemistry variation. Increase of relative liver weights within males treated at 12,500 to 50,000 ppm was also seen in connection with the biochemistry variation and the histopathological findings. Slight increase in liver fat deposition was found in some test animals treated at 25,000 and 50,000 ppm. After the recovery period, this increase in liver fat deposition remained. The No Observed Effect Level (NOEL) was determined to be 10,000 ppm (approximately 1000 mg/kg bw/day).

In a 90-day feeding study, rats were fed the test substance in the diet at doses up to 20,000 ppm. A 6-week recovery period was included in the study. A moderate influence on body weight gain was observed for males treated at 20,000 ppm. One male at 20,000 ppm and one male at 4,800 ppm died with no correlation to the treatment. Slight variations in haematology and clinical chemistry were also observed with no correlation to the treatment. At the end of the treatment the relative liver weights of the test animals treated at 20,000 ppm was increased, with fat disposition observed. A slight fat disposition was also observed in the liver of the control animals. Within the recovery period, the relative liver weight increases became normal. The NOEL was determined to be 4,800 ppm (approximately 480 mg/kg bw/day).

Based on the available information, the notified polymer is likely to have similar repeated dose toxicity as observed in the analogue.

Health hazard classification
As only limited toxicity information on an analogue was provided, the notified polymer cannot be classified according to the *Globally Harmonised System of Classification and Labelling of Chemicals* (GHS), as adopted for industrial chemicals in Australia.

Although not considered in this risk assessment, NICNAS notes that the notified polymer contains impurities that are classified as hazardous according to the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS),* as adopted for industrial chemicals in Australia. These are not present in the notified polymer as introduced above the cut off concentrations for classification.

6.3. Human Health Risk Characterisation

6.3.1. Occupational Health and Safety
The notified polymer may have potential to cause skin and eye irritation. At the reformulation sites, workers may have potential to come into contact with the notified polymer at < 40% concentration. However, the reformulation and packaging processes are expected to be mainly automated with minor manual handling. Exposure to workers should be limited by the use of control measures in the industrial settings. For construction applications, involving the use of products containing the notified polymer, significant irritation effects caused by the notified polymer are not expected at the final use concentration of < 2%. The risk to the health of workers is expected to be further migrated by the proposed use of PPE including protective clothing, gloves and goggles.

Given the relatively low end-use concentration of < 2% and stated protective measures in place to minimise exposure, the notified polymer is not considered to pose an unreasonable risk to the health of workers.

6.3.2. Public Health
The products containing the notified polymer are intended for industrial use only and will not be available to the public. Members of the public may come into contact with solidified concrete/cement and flexible adhesives or membranes containing the notified polymer. At that stage, the notified polymer is expected to be bound within the hardened matrix and will not be bioavailable for exposure.

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

7. ENVIRONMENTAL IMPLICATIONS

7.1. Environmental Exposure & Fate Assessment

7.1.1. Environmental Exposure

RELEASE OF CHEMICAL AT SITE

The notified polymer will be imported into Australia in solution for reformulation to produce finished construction products for industrial applications only. No significant release of the notified polymer is expected from transportation and storage, except in the unlikely event of accidental spills or leaks. In the event of spills, the products containing the notified polymer are expected to be collected with adsorbents, and disposed of to landfill in accordance with local government regulations.

Local blending and repackaging of the formulation containing the notified polymer into industrial construction products is expected to occur within enclosed automated systems. Wastes containing the notified polymer generated during reformulation include equipment wash water, empty import containers, and spilt materials. It is estimated by the notifier that a maximum of 0.1% of the import volume (or up to 1 kg) of the notified polymer may be released from reformulation processes. Wastes may be collected and released to sewers in a worst case scenario, or disposed of to landfill in accordance with local government regulations.

RELEASE OF CHEMICAL FROM USE

The notified polymer will be used in construction products including flexible adhesives, waterproofing membranes and concrete/cement admixtures. Release to the environment is expected to be minimal at construction sites and concrete production sites. The notified polymer will be bound within the construction matrix and is not expected to be bioavailable.

RELEASE OF CHEMICAL FROM DISPOSAL

The notified polymer is expected to share the fate of the construction materials and is expected to be disposed of to landfill at the end of its useful life.

Wastes containing the notified polymer include equipment wash water, empty packaging, container residues, and spilt materials. Residues on application equipment are expected to be rinsed, and the wash water collected and allowed to cure before disposal as solid wastes to landfill. As a worst case scenario, a minor amount of the notified polymer may be disposed of to the sewer from washing of application equipment. Empty packaging, residues, and spilt materials will be disposed of in accordance with local government regulations, most likely to landfill.

7.1.2. Environmental Fate

Based on the results of the ready biodegradability study, the notified polymer is considered readily biodegradable (80 – 90 % in 28 days). For details of the environmental fate study, please refer to Appendix A.

The majority of the notified polymer is expected to be cured within an inert construction matrix and is expected to share the fate of the construction materials, which will involve eventual disposal to landfill. The notified polymer is also expected to enter landfill as collected wastes and residues. Once cured, the notified polymer is not expected to be mobile, bioavailable or bioaccumulative. In surface waters and in landfill, the notified polymer is expected to eventually degrade via biotic and abiotic processes to form water and oxides of carbon, sulphur and nitrogen.

7.1.3. Predicted Environmental Concentration (PEC)

The predicted environmental concentration (PEC) has not been calculated, since significant release of the notified polymer to the aquatic environment is not expected from the reported use pattern.

7.2. Environmental Effects Assessment

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

Endpoint	*Result*	*Assessment Conclusion*
Algal Toxicity	72 h E_rC50 = 68.4 mg/L	Harmful to algae
	72 h NOE_rC = 22 mg/L	Not harmful to algae with long lasting effects

Based on the above acute ecotoxicological endpoint, the notified polymer is expected to be harmful to algae. Therefore, under the *Globally Harmonised System of Classification and Labelling of Chemicals (GHS)* (United Nations, 2009), the notified polymer is formally classified as "Acute Category 3; Harmful to aquatic life". Based on its low chronic toxicity endpoint and ready biodegradability, the notified polymer is not formally classified under the GHS for chronic toxicity.

7.2.1. Predicted No-Effect Concentration

The predicted no-effects concentration (PNEC) has been calculated from the most sensitive endpoint for algae. A safety factor of 50 was used given acute and chronic endpoints for algae are available.

Predicted No-Effect Concentration (PNEC) for the Aquatic Compartment		
E_rC (Algae, 72 h)	68.4	mg/L
Assessment Factor	50	
Mitigation Factor	1.00	
PNEC:	1,368	µg/L

7.3. Environmental Risk Assessment

The risk quotient (Q = PEC/PNEC) of the notified polymer has not been calculated, since the PEC was not calculated due to its low potential for release to the aquatic compartment. When used in construction products, the notified polymer will be irreversibly bound within the inert construction matrix, and is not likely to be released into the aquatic environment in a bioavailable form. The notified polymer is readily biodegradable, and is expected to have a low potential for bioaccumulation based on the high water solubility. Therefore, on the basis of its limited aquatic exposure, low predicted toxicity to aquatic organisms, and assessed use pattern, the notified polymer is not expected to pose an unreasonable risk to the environment.

APPENDIX A: ENVIRONMENTAL FATE AND ECOTOXICOLOGICAL INVESTIGATIONS

A.1. Environmental Fate

A.1.1. Ready biodegradability

TEST SUBSTANCE	Disponil BES 20 (product containing the notified polymer at < 40% concentration)
METHOD	OECD TG 301 B Ready Biodegradability: CO_2 Evolution Test.
Inoculum	Activated sewage sludge
Exposure Period	28 days
Auxiliary Solvent	None
Analytical Monitoring	Theoretical Carbon Dioxide ($ThCO_2$)
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles.

RESULTS

Test substance		*Aniline*	
Day	*% Degradation*	*Day*	*% Degradation*
6	10-13	6	14
14	19-28	14	68
22	47-60	22	89
28	84-92	28	101

Remarks - Results	All validity criteria for the test were satisfied. The percentage degradation of the reference compound surpassed the threshold level of 60% by 14 days (68%). Therefore, the tests indicate the suitability of the inoculum. The percentage degradation of the toxicity control surpassed the threshold level of 25% by 10 days (25%; 72% in 28 days), showing that toxicity was not a factor inhibiting the biodegradability of the test substance. The test material attained 80 – 90% degradation after 28 days. As the test substance is surface active, the 10-day window is not applicable. Therefore, the test substance is considered to be readily biodegradable according to the OECD Guideline 301 B.
CONCLUSION	The notified polymer is readily biodegradable.
TEST FACILITY	BASF (2015)

A.2. Ecotoxicological Investigations

A.2.1. Algal growth inhibition test

TEST SUBSTANCE	Disponil BES 20 (product containing the notified polymer at < 40% concentration)
METHOD	OECD TG 201 Fresh Water Algal, Growth Inhibition Test - Static
Species	*Pseudokirchneriella subcapitata* (green algae)
Exposure Period	72 hours
Concentration Range	Nominal: 0 – 748.3 mg/L (test substance) Actual: 0 – 228 mg/L (active ingredient)
Auxiliary Solvent	None
Water Hardness	Not reported
Analytical Monitoring	Total organic carbon (TOC)
Remarks - Method	Conducted in accordance with the test guidelines above, and in compliance with GLP standards and principles.

The stock solutions was prepared by adding the test substance directly to the test medium followed by stirring for approximately 10 min until visibly dissolved. The stock test solutions were prepared at 111% of the nominal concentration to compensate for the dilution by the addition of algal inoculum.

RESULTS

Biomass		*Growth*	
EC50	*NOEC*	*EC50*	*NOEC*
mg/L at 72 h	*mg/L*	*mg/L at 72 h*	*mg/L*
37.5	22	68.4 (95% CI 60.4-77.3)	22

Remarks - Results

All validity criteria of the test guideline were satisfied.

The measured concentrations of the test substance in the test medium were in a range of 81 – 105% of the nominal concentration (based on test substance mass) at the start of exposure and at the end of exposure, in a range of 97 – 109% of the nominal concentrations (based on test substance mass). All measured concentrations were within a range of ± 20% of the geometric mean measured concentration over the whole exposure period. Results were based on nominal concentrations of the 'active ingredient' of the test substance.

CONCLUSION

The notified polymer is considered to be harmful to algae.

TEST FACILITY

BASF (2016)

BIBLIOGRAPHY

BASF (2015) Disponil BES 20 – Determination of the Ready Biodegradability in the CO_2-Evolution Test (Study No. 22G0547/14G250, July, 2015). Ludwigshafen, Germany, BASF SE (Unpublished report submitted by the notifier).

BASF (2016) Disponil BES 20 – Growth inhibition study in unicellular green algae *Pseudokirchneriella subcapitata* KORSHIKOV (Study No. 60E0547/14E052, April, 2016). Ludwigshafen, Germany, BASF SE (Unpublished report submitted by the notifier).

United Nations (2009) Globally Harmonised System of Classification and Labelling of Chemicals (GHS), 3rd revised edition. United Nations Economic Commission for Europe (UN/ECE), <http://www.unece.org/trans/danger/publi/ghs/ghs_rev03/03files_e.html>.